JCR Pharmaceuticals

JCR Report 2021

JCR Pharmaceuticals Co.,Ltd.

Together
We Soar.

Year Ended March 31, 2021

We aspire to be a global specialty pharma in the rare disease arena. To this end, we are fully committed to tackling ambitious initiatives in service of our patients worldwide.

Basic Philosophy

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

Reliability

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

Confidence

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

Belief

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

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

JCR Pharmaceuticals Co., Ltd. (JCR) has the important missions of tackling rare and intractable diseases with its advanced biotechnologies, and researching, developing and creating innovative medicines in the areas of cell therapy, regenerative medicine, and gene therapy. Mindful of those missions, JCR is implementing its Midterm Business Plan for FY2020-FY2022 "REVOLUTION." Guided by this plan, JCR is working as one "Team JCR" to continuously meet the challenge of staying one step ahead of its competitors. In editing "JCR Report 2021," we have prepared an integrated report that outlines JCR's business activities and progress on 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 JCR's business activities among a wide range of stakeholders.

Contents

- **Period covered:** FY2020 (From April 1, 2020 to March 31, 2021)
  * This report also contains some information from FY2021.
- **Organizations covered:** JCR Group
  (JCR Pharmaceuticals Co., Ltd. and six consolidated subsidiaries)
  * See explanatory notes for exceptions.
- **Presentation of currency units:** Numerical values are rounded down to the nearest whole number in the specific unit, in principle. However, numerical values presented in units of hundred millions of yen are rounded up or down to the nearest hundred million yen.

Forward-Looking Statements

"JCR Report 2021" 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.

With a strong determination to achieve our second foundation, we will continue to tackle even more ambitious challenges and to accelerate our “REVOLUTION.”

In FY2020, the first year of the Midterm Business Plan for FY2020-FY2022 “REVOLUTION,” JCR achieved record-high results with significantly higher net sales and profit than our forecasts. In March 2021, JCR obtained marketing approval in Japan for IZCARGO® I.V. infusion 10mg for the treatment of mucopolysaccharidosis II (MPS II), which is a critical milestone for JCR.

In addition, JCR is contracted by AstraZeneca K.K. (AstraZeneca) to carry out the domestic production of its COVID-19 vaccine bulk solution, and we are making every effort to help end the pandemic as early as possible by leveraging the sophisticated biotechnologies we have developed since our foundation. As it enters a new phase that could be described as its second foundation, JCR is making powerful strides toward realizing its growth strategy to become a global specialty pharma in the rare disease arena.

Looking ahead, we will continue to focus on R&D and Manufacturing driven by a dedicated small group of specialists par excellence, marshal all capabilities of “Team JCR,” and tackle even more ambitious challenges.

September 2021

Shin Ashida

Representative Director, Chairman,
President, CEO and COO

FY2020 Business Overview

Both net sales and profits significantly surpassed initial forecasts, reaching record highs.

In FY2020, JCR reported its highest-ever net sales of 30,085 million yen (21.4% increase year on year), with nine consecutive years of growth. Operating income was 8,269 million yen (154.9% increase year on year) and profit attributable to owners of parent was 6,892 million yen (157.4% increase year on year). Net sales of GROWJECT®, a mainstay recombinant human growth hormone product, increased to 13,256 million yen (4.8% increase year on year) due to an increase in sales volume, despite an NHI price revision in April 2020. Furthermore, total net sales for renal anemia treatments and revenue from licensing rose year on year, leading to record-high business performance.

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Achievements of Innovative Product Development and Acceleration of Global Businesses

The launch of IZCARGO® in Japan marked a critical milestone. With this step, we will continue to tackle even more ambitious challenges.

In research and development, we are accelerating efforts to supply novel therapeutics for 16 types of lysosomal storage disorders (LSDs) by applying our proprietary blood-brain barrier (BBB) penetration technology, J-Brain Cargo®.

In March 2021, JCR received marketing approval of JR-141, a therapeutic enzyme for mucopolysaccharidosis II (MPS II), in Japan, and in May 2021, JR-141 was launched as IZCARGO®. In December 2020, JCR filed an application with the Brazilian Health Regulatory Agency (Agência Nacional de Vigilância Sanitária [ANVISA]) for marketing approval of JR-141 with a Phase II clinical trial conducted in Brazil. Now, JCR is preparing to initiate a global Phase III clinical trial of JR-141 in the U.S., Brazil and Europe (Germany, France and the U.K.).

Regarding JR-171, a therapeutic enzyme for MPS I, JCR has been conducting Phase I/II clinical trials of JR-171 in Japan, Brazil, and the U.S since October 2020, as JCR's first global clinical trials. JR-171 was granted orphan drug designation (a designation for promoting new drug development for rare diseases) by the U.S. Food and Drug Administration (FDA) in February 2021 and the European Commission (EC) in March 2021. We are also steadily advancing efforts to conduct global clinical trials of other treatments at the earliest opportunity. These treatments include the therapeutic enzymes JR-162 for Pompe disease; JR-441 for MPS III-A; JR-443 for MPS VII; and JR-446 for MPS III-B.

We are committed to delivering more added value in all these areas with our patient-centric research and development efforts in various fields such as human growth hormone products, cell therapy, regenerative medicine, and gene therapy, including a Phase II clinical trial of JR-142, a long-acting growth hormone.

Guided by the Mid- to Long-Term Management Vision "Toward 2030" and Midterm Business Plan for FY2020-FY2022 "REVOLUTION," JCR is steadily implementing strategies to become a global specialty pharma in the rare disease arena.

In August 2020, JCR officially decided to expand its business in Brazil and commenced business activities at JCR DO BRASIL FARMACÊUTICOS IMPORTAÇÃO E EXPORTAÇÃO LTDA. (JCR DO BRASIL), which will serve as our local business site. Exploring ways to expand business in Europe and the U.S. also remains a key priority. We are considering approaches on two different fronts. For treatments of LSDs using J-Brain Cargo® that are currently under development, we are advancing negotiations toward the conclusion of licensing agreements with companies that have global sales capabilities. For diseases that have small global patient populations, such as MPS VII and MPS III, we are considering plans that include independent global sales activities by JCR.

One of the important business challenges of Midterm Business Plan for FY2020-FY2022 "REVOLUTION" is "Exploring new therapeutic targets in addition to LSDs: Expansion of basic research activities." To address this challenge, we are working to develop and strengthen our research framework. In January 2021, we newly opened the Bioresearch Center, which is a new research facility, in order to expand the capacity of research projects and research staff, and to strengthen our capabilities for new drug development. JCR will further accelerate R&D activities with a focus on three modalities: recombinant protein therapeutics, cell therapy/regenerative medicine, and gene therapies. Furthermore, JCR will strengthen collaboration with academia and other partners as part of its promotion of translational research.

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Our Mission to Fight COVID-19

JCR will fulfill its mission as a pharmaceutical company through the production of the COVID-19 vaccine bulk solution under contract from AstraZeneca.

In December 2020, JCR was contracted to produce in Japan AstraZeneca's COVID-19 vaccine bulk solution known as AZD1222. In assuming this task, JCR has positioned it as one of the top priorities for the whole company. We have reassigned personnel, conducted mid-career recruitment and secured a production line at an existing plant. Currently a young team centered on personnel in their 30s is leading efforts at the production site. We are moving forward with the production and shipment of the vaccine bulk solution.

In March 2021, JCR decided to construct a new plant for producing the COVID-19 vaccine bulk solution. AstraZeneca, which is the outsourcer of production, was selected by the Ministry of Health, Labour and Welfare (MHLW) in 2020 to manufacture the vaccine as part of an urgent improvement project for vaccine manufacturing systems. The project's public solicitation requirements state that the company which has been selected must secure a system to manufacture vaccines, etc. at least until the end of March 2030. JCR will construct a new plant in Kobe Science Park (Nishi-ku, Kobe), so that it can satisfy these requirements as a subcontractor for the manufacture of the vaccine bulk solution.

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P.36 Actions for COVID-19

Return to Shareholders

We will provide continuous and stable dividends to shareholders.

Returning profits to shareholders is an important management policy for JCR. In FY2020, JCR achieved record-high operating results. Therefore, we decided to pay a term-end dividend of 7.5 yen per share (including a commemorative dividend of 0.5 yen per share to mark our 45th founding anniversary). On October 1, 2020, JCR conducted a 4-for-1 stock split of its common shares. Excluding the impact of this stock split, the annual dividend was 48 yen per share, an increase of 16 yen per share from the previous fiscal year. As a result, the dividend payout ratio was 21.5%.

Sustainability

Based on the belief that "realizing medical care for those living with rare diseases" is fundamental to its value creation, JCR will contribute to the development of a sustainable society.

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

JCR believes that partnership and cooperation with the international community are the most important priorities for realizing sustainability. JCR will link its activities to the 17 goals laid out in the SDGs, in keeping with the spirit of "No one will be left behind." It will share with and return to a wide range of stakeholders the achievements of these efforts.

In corporate governance, I have a real sense that our new management team, which includes young directors, is leading the way to new growth. JCR is working to drive its "REVOLUTION" in every facet of its business activities at a rapid pace, with a focus on promoting the globalization of its businesses in earnest. I invite you to share in my excitement for JCR's future.

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JCR aims to become a global specialty pharma in the rare disease arena. Under the Midterm Business Plan for FY2020-FY2022 “REVOLUTION,” we are driving transformations on many different fronts, such as strengthening our organizational capabilities, so that we can meet the expectations of all our stakeholders, including shareholders. I believe that reaffirming the spirit of “Team JCR” will be increasingly crucial to JCR’s sustainable growth. In other words, we must continue to preserve and develop our corporate culture, particularly our emphasis on originality (the ability to think things through independently without easily falling back on like instances), rapid decision-making (maintaining a flat organization), and an open and free culture (ensuring an organization with inner stability and emotional wellbeing). By remaining committed to preserving and developing such a corporate culture, we will continue to contribute to the health and wellbeing of patients who are suffering from rare diseases.

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

The approval of IZCARGO® is a milestone for JCR and will catalyze the globalization of JCR as we plan to bring this innovation to MPS II patients worldwide. The production of AstraZeneca’s AZD1222 vaccine bulk solution is a major contribution to a society that is suffering from the global COVID-19 pandemic and a testament to JCR’s capabilities in biopharmaceutical manufacturing. As JCR globalizes, we will have to adapt our processes, comply with global standards, and reinvent ourselves every day. While globalization requires us to be flexible and adaptive, two things must remain constant: Our values and our culture. Global partnerships and novel commercialization models will allow JCR to remain nimble and to globalize without overbuilding our infrastructure.

Mathias Schmidt, PD, Ph.D.
Vice President
Clinical Development, Global Business Strategy and Business Development
ArmaGen, Inc. CEO
JCR USA, Inc. President and CEO

JCR conducts research and development focused on rare diseases, particularly lysosomal storage disorders (LSDs). We will continue to develop life-changing and truly meaningful therapeutic agents for patients by using proprietary biotechnologies including J-Brain Cargo®, our blood-brain barrier (BBB) penetration technology. Created in our laboratories, J-Brain Cargo® is the world's first technology platform of its kind. In addition, we will expand our research and development efforts to rare diseases other than LSDs and other disorders using J-Brain Cargo®, which has been verified to be effective in human subjects. Concurrently, we will strengthen our efforts in basic research to establish new platform technologies in the fields of protein engineering, gene therapy, and regenerative medicine including cell therapy. In these ways, we will actively invest in research and development.

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

Looking ahead, JCR will supply and market innovative new medicines using J-Brain Cargo® technology globally, along with steadily supplying in Japan the core products that have underpinned JCR over many years, such as growth hormone products. Additionally, JCR may need to supply vaccines, including one against COVID-19, upon request from the Japanese government until the end of FY2030. To put JCR's comprehensive strengths in service of public health around the world, it will be imperative to build platforms for the global manufacture and supply of products, while strengthening our quality and safety assurance system to ensure the proper use of products worldwide, and to remain in strict compliance with laws and regulations. There are many issues to address, and they will not be easy to solve. With the spirit of "Team JCR," I'd like to bring together our collective wisdom and knowledge to materialize our commitments one by one.

Yoshio Hiyama, Ph.D.
Senior Executive Director
Production and Quality & Safety Management
Head of Production Division


JCR will achieve sustained value creation by working to develop proprietary technologies and innovative products in anticipation of the needs of the times.
Since our inception, we have embraced the spirit of challenge under a corporate culture with a high degree of freedom. Inspired by this approach, every employee will embrace continuing challenges with stalwart faith to contribute to rare diseases, pursuing the creation of new value as we seek to realize our corporate philosophy.
Sustainability
Team JCR
Rare diseases
Together We Soar
Contributing towards people's healthcare through pharmaceutical products


Research-oriented specialty pharma with global exposure
変革
REVOLUTION
into the Future
Groundbreaking new therapeutics
Proprietary technologies
J-Brain Cargo®
Cell therapy and regenerative medicine
Gene therapy

An entrepreneurial spirit has run in JCR's corporate DNA since its foundation. Guided by this DNA, we have nurtured JCR's unique strengths and achieved sustained growth over the years.

Since its inception in 1975, JCR has been working on the development and creation of "one step beyond" technologies and products. This has led to continued steady growth and the Company's recognition as "JCR, the biopharma company." In May 2021, JCR launched sales of IZCARGO®, the world's first-ever approved enzyme replacement treatment to apply JCR's proprietary J-Brain Cargo® blood-brain barrier penetration technology. Going forward, JCR, as a specialty pharma in the rare disease arena, will continue to proactively engage in research and development of transformative treatment options for patients with rare diseases.

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.)*

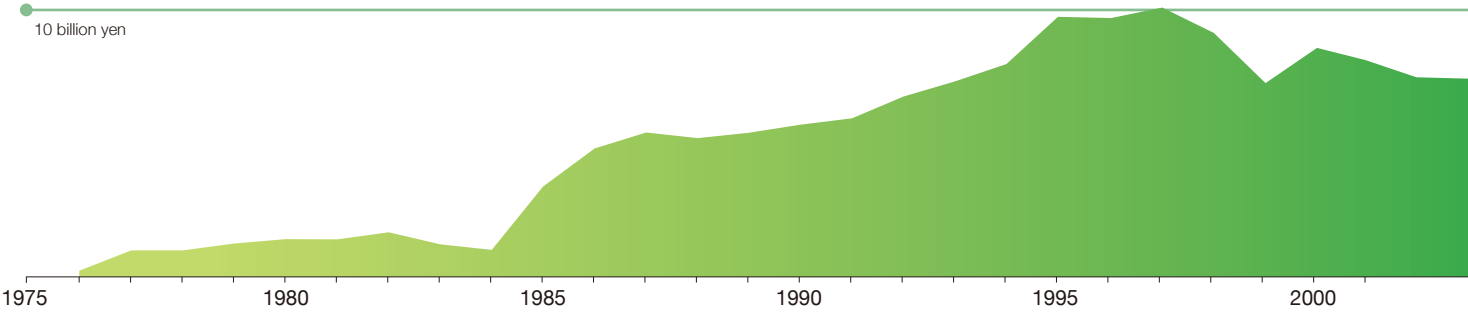
2010
Launched Epoetin Alfa BS Inj. [JCR] for treatment of renal anemia, the first domestically produced biosimilar

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



Established purification technology

Building on its foundation of accumulated technologies, JCR will meet the challenges of a "REVOLUTION" to reach the next stage.

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


☐ Production at the time of foundation


☐ Production today

FY2020
30.1
billion yen

2017
Concluded a business capital alliance agreement with MEDIPAL HOLDINGS CORPORATION

2018
Established JCR USA, Inc.

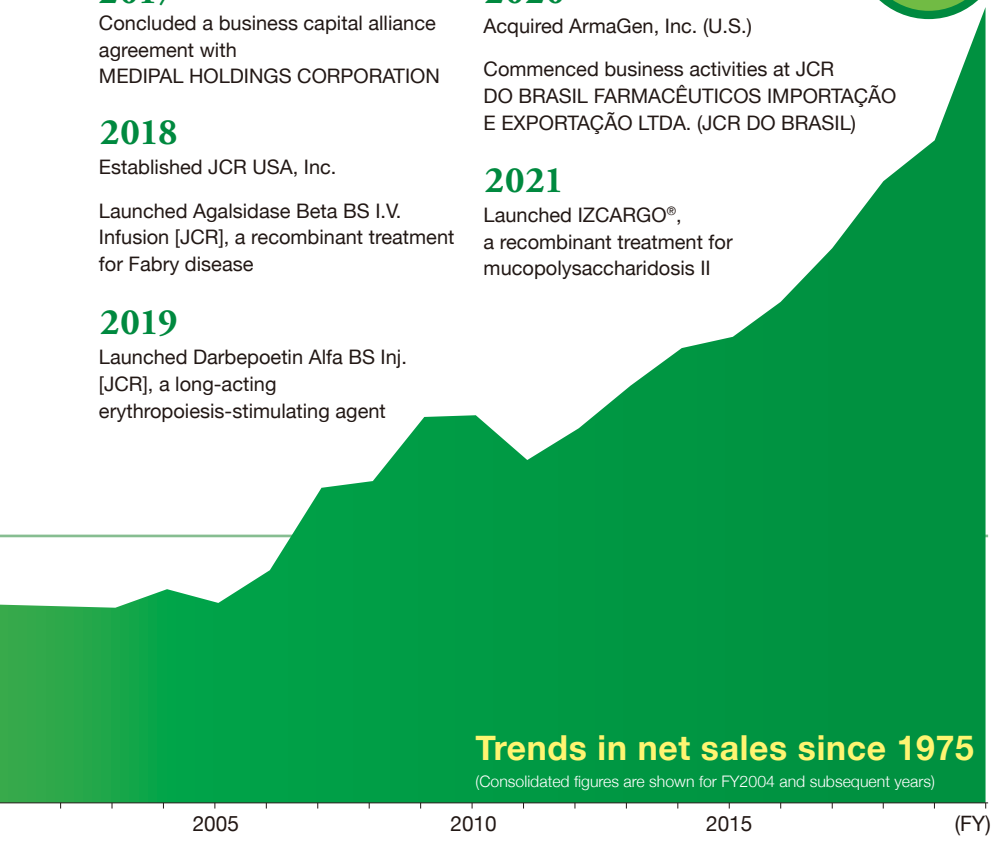
Launched Agalsidase Beta BS I.V. Infusion [JCR], a recombinant treatment for Fabry disease

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



Trends in net sales since 1975

(Consolidated figures are shown for FY2004 and subsequent years)

* 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 technologies ranging from cell development to culture technologies

Entered the regenerative medical product field

☐ Research today

Expansion of research and production facilities

JCR has built production and quality assurance systems that meet global standards. We continue to make capital investments in these systems from a medium- to long-term perspective.

1986 Seishin Plant

1993 Research Institute

2000 Kobe Plant

2008 Murotani Plant

2013 Kobe API Plant

2016

Clinical Trial Material Manufacturing Center (CTMC)

Cell Processing Center (CPC)

2021 Bioresearch Center

Foreseeing 2030, we will strive to realize medium- to long-term qualitative and quantitative transformations of our business activities.

JCR’s objective is to become a “research-oriented specialty pharma with global exposure.” To realize this objective, we have reached a common understanding that the wellspring of JCR’s values lies in the notion of “Team JCR,” and based on this notion, we have formulated the Mid- to Long-Term Management Vision “Toward 2030” in anticipation of 2030. JCR seeks to realize full globalization from the latter half of the 2020s. This will require transformations in all aspects of our business activities and ourselves. That is why “REVOLUTION” has been adopted as the key theme of the Midterm Business Plan for FY2020-FY2022. The plan’s slogan is elaborated as “REVOLUTION into the future,” reflecting our determination to implement transformations come what may.

Mid- to Long-Term Management Vision “Toward 2030”

Our Goal

Research-oriented specialty pharma with global exposure

Concrete Corporate Vision

- Global specialty pharma in the rare disease arena
- Continuing challenges to create “one step beyond” technologies based on our original technology platforms such as J-Brain Cargo®
- Continuing challenges to keep on creating new values with “R&D” and “Manufacturing”
- Continuing challenges with stalwart faith to contribute to rare diseases

Key Theme and Guidance in the Midterm Business Plan for FY2020-FY2022

变革

REVOLUTION
into the Future

Financial metric	FY2022 target
Net sales	**¥32 to ¥36 billion** Based on steady year-on-year sales growth
Operating income	**¥7 to ¥10 billion**
R&D expenditures	**R&D expenditures of around 20% of net sales** A greater allocation of funds is permitted when required

Dividend payout ratio of 30%, under a basic policy of providing stable dividends with a focus on balancing returns shareholders expect and our financial soundness

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

Top priority business challenge

Qualitative and quantitative reorganization of the quality assurance system

JCR believes that the most important duty of a pharmaceutical company lies in providing a stable supply of high-quality pharmaceuticals. Mindful of this duty as well as the growing presence of JCR in the rare disease arena, “qualitative and quantitative reorganization of the quality assurance system” has been identified as our top priority business challenge. JCR’s treatments for lysosomal storage diseases (LSDs) including IZCARGO®, which is a recombinant treatment of mucopolysaccharidosis II launched in May 2021, and subsequent drug candidates applying its blood-brain barrier (BBB) penetration technology J-Brain Cargo® that are currently under development have the potential to become the first-ever therapies for LSDs that manifest central nervous system symptoms. Based on this, JCR’s supply chain is expected to expand further. Keeping this issue in mind, we will work to implement qualitative and quantitative reorganization of the quality assurance system.

Actions for sustainable growth of the sales of our products

Sales of existing products constitute the source of funding for all of our research and development activities, including research and development of treatments of LSDs. For this reason, we continue to identify the sustainable growth of sales of our products as an important business challenge. Notably, we believe that it is of utmost importance to strengthen the sales base of GROWJECT®, a recombinant human growth hormone product that accounts for around half of our net sales. By adapting appropriately to changes in the business environment, while providing information effectively and efficiently, we will work to preserve and drive growth in net sales of existing products.

Expansion of basic and applied research activities

In research and development, we will strengthen measures to address basic research in order to create new platform technologies in anticipation of the period after we have developed treatments for LSDs. We will advance basic research to develop technologies that can efficiently deliver small molecules, nucleic acids and other molecular compounds to the brain. By doing so, JCR will seek to establish stable earnings drivers through the creation of platform technologies that can be licensed out to other companies.

Evaluation and implementation of further capital investment for manufacturing and research

To achieve globalization in earnest, we will actively consider and make capital investments in production and research. In January 2021, we newly opened the Bioresearch Center, which serves as a new research facility, in order to expand the capacity of research projects and research staff, and to strengthen our capabilities for new drug development.

Product strategy planning including evidence generation

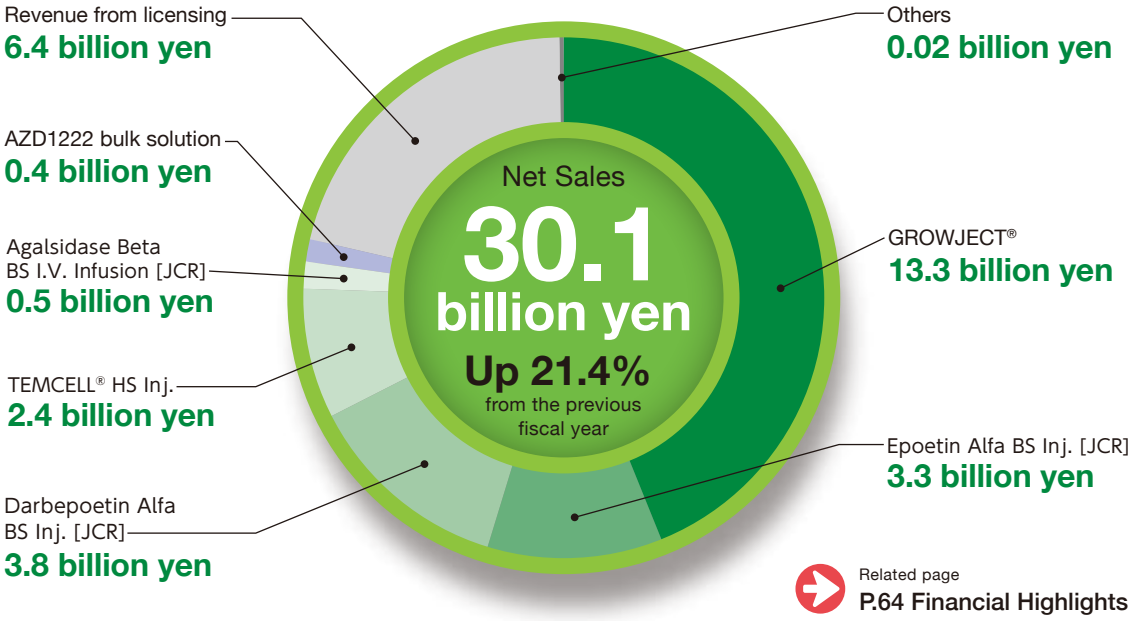
JCR has an important duty to provide useful information to clinical sites worldwide that are engaged in the treatment of LSDs. We believe that fulfilling this duty will help to increase our corporate value. Based on this belief, we will advance product strategy planning including evidence generation.

Transformation of operations and organizations along with human resource development

In order to successfully implement measures to tackle the business challenges described above, we will push ahead with the transformation of operations and organizations along with human resource development. These efforts will facilitate future business expansion and support further growth of each member of “Team JCR.”

We deliver high-quality pharmaceutical products through our full range of integrated capabilities from R&D to production and marketing.

Net Sales in FY2020



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Business Process

Research and Development

We leverage our biotechnologies as well as technologies for cell therapy and regenerative medicine to accelerate R&D of therapeutic candidates for rare diseases.

Production

We have a world-class production/quality assurance system in place, with cutting-edge production technologies deployed at four sites.

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 and 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.

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Key Topics for FY2020

April 2020

JCR Acquires ArmaGen, Inc. (U.S.) (ArmaGen Becomes a Subsidiary)

As a result of this acquisition, ArmaGen has provided JCR with full access to its portfolio of intellectual property rights applicable to a broad disease spectrum, including lysosomal storage disorders (LSDs), in several key markets, that ArmaGen owns.

April 2020

JCR Initiates Development of New Drug Candidates JR-443 for MPS VII and JR-446 for MPS III-B, Both of Which Use J-Brain Cargo®

August 2020

JCR Officially Decides to Expand Its Business in Brazil

JCR commenced business activities at JCR DO BRASIL FARMACÊUTICOS IMPORTAÇÃO E EXPORTAÇÃO LTDA. (JCR DO BRASIL), a local subsidiary.

September 2020

JR-141 for MPS II Granted Orphan Drug Designation by the Ministry of Health, Labour and Welfare

October 2020

Launches Growth Hormone Therapy Medication Management App Melon Nikki™

JCR and PHC Corporation jointly developed Melon Nikki™, which is a dedicated smartphone app for GROWJECTOR® L, a motorized growth hormone delivery device that is designed to help improve medication adherence among patients using injectable growth hormone therapy in Japan.

October 2020

JCR Announces First Patient Dosed in Phase I/II Global Clinical Trial of JR-171 for MPS I

This announcement marks JCR's first global clinical trial, and it will be conducted in Japan, Brazil and the U.S.

December 2020

JCR Signs Provisional Production Master Service Agreement with AstraZeneca Regarding Domestic Production of COVID-19 Vaccine Bulk Solution

January 2021

JCR Initiates Operation of Bioresearch Center, Its New Research Facility

February 2021

JCR Receives FDA IND Clearance to Initiate Global Phase III Clinical Trial of JR-141

This global Phase III clinical trial will be conducted in the U.S., Brazil and Europe (U.K., Germany and France).

February 2021

JR-141 Granted Fast Track Designation by the U.S. Food and Drug Administration

February 2021

JR-171 Granted Orphan Drug Designation by the U.S. Food and Drug Administration

March 2021

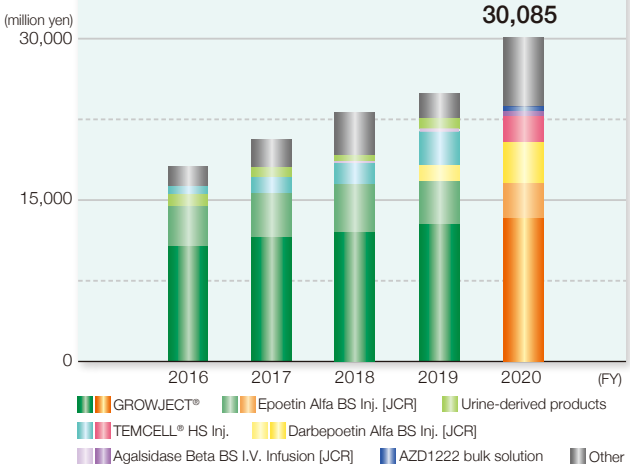
JCR Receives Marketing Approval in Japan for JR-141 (Product Name: IZCARGO® I.V. Infusion 10mg)

IZCARGO®, a pharmaceutical product that applies J-Brain Cargo®, was approved in Japan under SAKIGAKE designation.

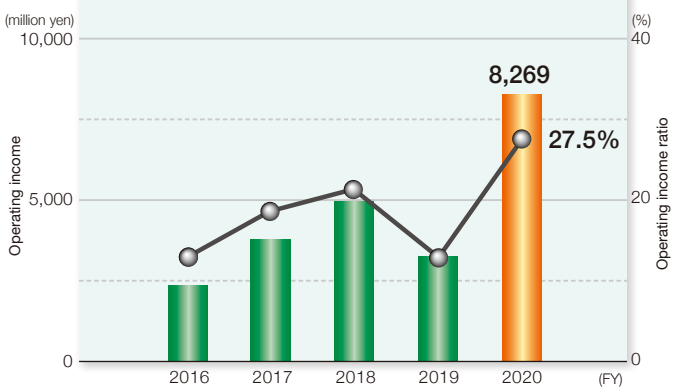
March 2021

JR-171 Granted Orphan Drug Designation by the European Commission

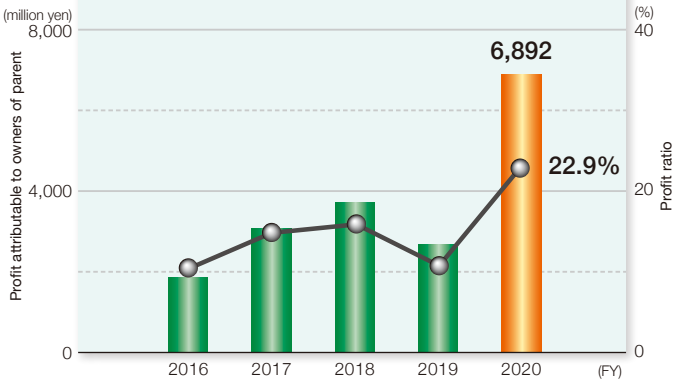
Net sales by product



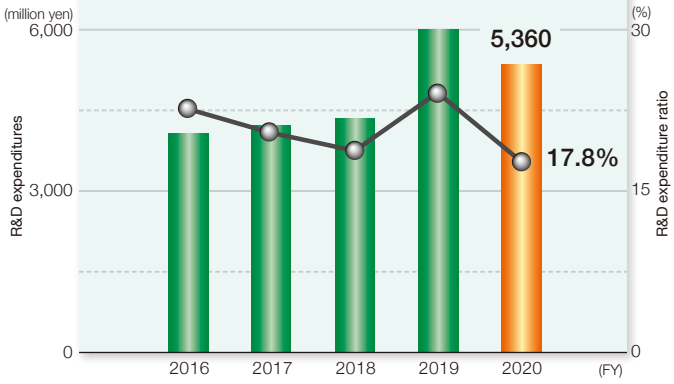
Operating income/Operating income ratio



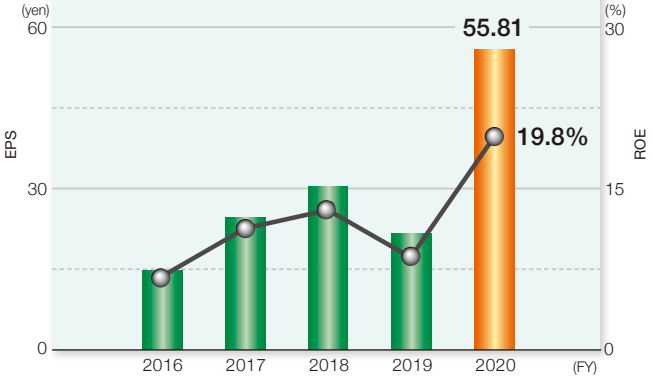
Profit attributable to owners of parent/Profit ratio



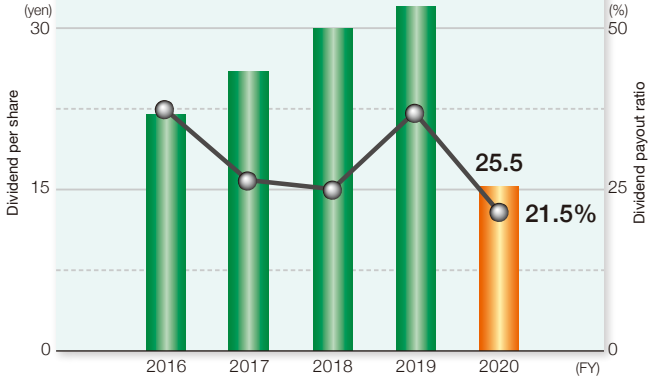
R&D expenditures/R&D expenditure ratio



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 66.

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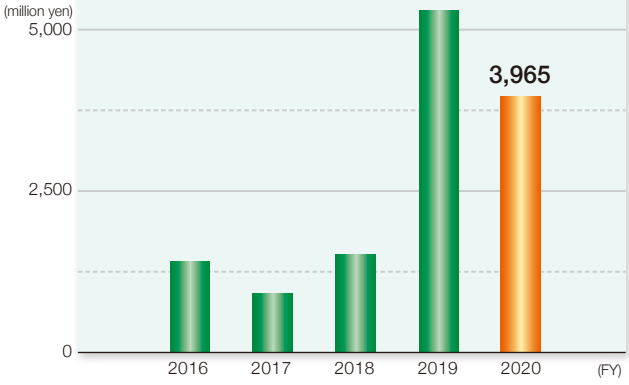
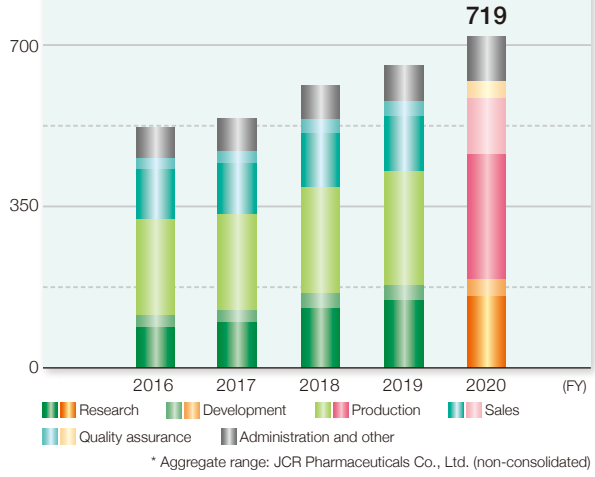
Capital investment

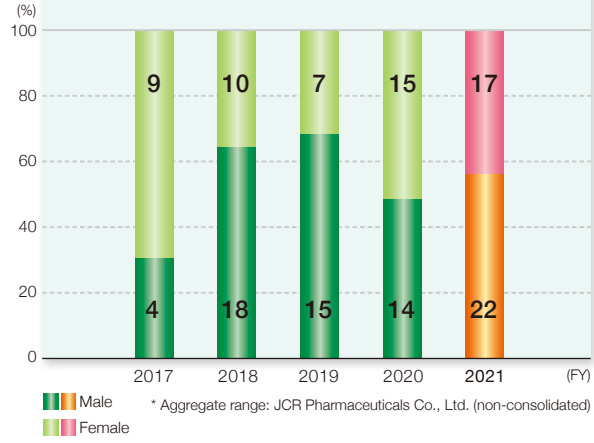


Number of employees by occupation



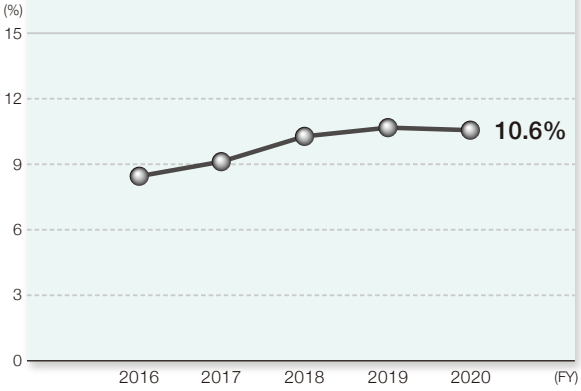
* Aggregate range: JCR Pharmaceuticals Co., Ltd. (non-consolidated)

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



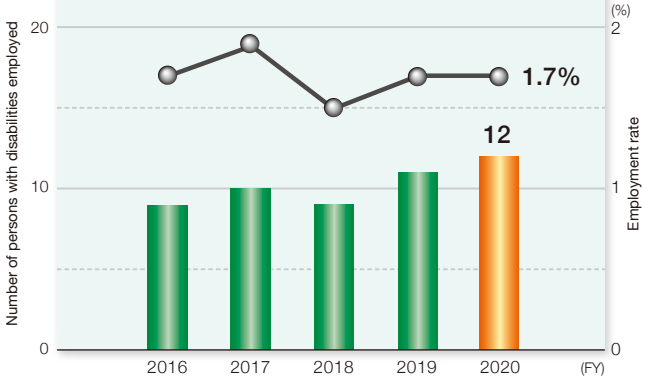
* Aggregate range: JCR Pharmaceuticals Co., Ltd. (non-consolidated)

Percentage of female managers



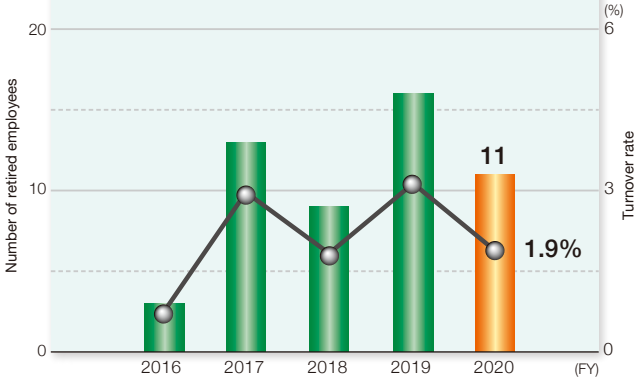
* Aggregate range: JCR Pharmaceuticals Co., Ltd. (non-consolidated)

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)

Changing the world of rare diseases — “Team JCR”

JCR is focused on R&D and Manufacturing driven by a dedicated small group of specialists par excellence. With this focus in mind, “Team JCR” is working as one to implement strategies that will make JCR a global specialty pharma in the rare disease arena. This section explains the present and future of these bold and ambitious efforts.

Special Feature

Together

We Soar

Global Business Expansion

Mathias Schmidt, PD, Ph.D.

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

We are accelerating global business expansion in earnest in the rare disease arena.

The approval of IZCARGO® in March 2021 by the Japanese MHLW for the treatment of MPS II marked a milestone for the entire biopharmaceutical industry and starts a new chapter in the history of JCR. IZCARGO® is the first ever approved protein therapeutic designed to cross the blood-brain barrier and address a severe CNS pathology of an incurable, progressive disease.

The approval of IZCARGO® is a major catalyst for the globalization of JCR. Through the acquisition of ArmaGen, Inc. in April 2020, JCR significantly broadened its IP portfolio for BBB technologies in several key international markets, allowing JCR to market its J-Brain Cargo® assets more broadly. The initiation of the global JR-141 Phase III clinical trial in 2021 is a testament of JCR's commitment to bring this innovation to MPS II patients across the globe. This commitment will not stop with IZCARGO®. Early biomarker data in patients with MPS I treated with our second clinical J-Brain Cargo® asset, JR-171, give us confidence that this technology is more broadly applicable. Like in many other lysosomal storage diseases, the CNS manifestations of MPS II are progressive and irreversible. It is our responsibility to act fast and execute with excellence to help young patients with MPS II fulfill some of their hopes and dreams.

As we progress towards becoming an international biopharmaceutical company, this new chapter brings its own challenges: We need to learn to adopt and comply with international standards in the manufacturing of our biotherapeutics, quality assurance and control, and meet different regulatory requirements, just to name a few. New business

Number of Patients and Size of Market for Six LSDs

Indication (abbreviation/name of enzyme)	Number of patients*1		Market size*2	
	Japan	Worldwide	Japan (2018)	Worldwide (2018)
MPS II: Hunter syndrome (IDS/iduronate-2-sulfatase)	Approx. 250	Approx. 7,800	Approx. 7.6 billion yen	Approx. 87.0 billion yen
Pompe disease (GAA/acid α-glucosidase)	Approx. 80	Approx. 10,600	Approx. 3.0 billion yen	Approx. 111.0 billion yen
MPS I: Hurler syndrome (IDUA/iduronidase)	Approx. 60	Approx. 3,600	Approx. 1.6 billion yen	Approx. 28.0 billion yen
MPS III-A: Sanfilippo syndrome type A (SGSH/heparan N-sulfatase)	Approx. 30 (AB total)	Type A: Approx. 4,000 Type B: Approx. 1,900	—	—
MPS III-B: Sanfilippo syndrome type B (NAGLU/α-N-acetylglucosaminidase)				
MPS VII: Sly syndrome (β-glucuronidase)	Several	Approx. 200	—	Approx. 1.7 billion yen

Source: JCR analysis *1 Number of patients: Calculated by JCR based on information published in the Ministry of Health, Labour and Welfare's research and others
*2 Market size: From data published by companies carrying existing therapeutics

processes will likely need to be implemented as well. We need to acquire new skill sets and interact cross-functionally at a level we have not done before.

Among JCR's biggest assets is its talent pool. We need to foster and grow our next generation of young leaders. With all these challenges ahead of us and the imperative to remain flexible and nimble, we want to preserve what made JCR strong: Our values, our culture and our inventive spirit.

When we find our personal values reflected in JCR's corporate values, it gives us a greater sense of purpose and unites us in our common goal to create a better tomorrow for the patients we serve. For many of us, it is a privilege to work together and develop solutions for the most pressing unmet medical needs in rare diseases. Program failures in rare diseases often are like cutting the lifeline for patients who hope for these innovations to come to market. Fulfilling these hopes is a big responsibility, but also one of our highest motivating factors.

Our culture is best described as one "Team JCR" – A corporate culture that fosters collaboration and values the power of the team, a mindset to let the better be the enemy of the good, the diversity in skill sets and knowledge, the appreciation of different opinions and the strength of a solid scientific dialog, creativity and the awareness that we are not perfect and are allowed to make mistakes.

JCR's pillars of strength are the discovery, development and manufacturing of innovative biotherapeutics and we have a strong marketing presence in Japan. As we take the next steps towards becoming an international biopharmaceutical company, we want to ensure that we do not leave this basis of strength. Two aspects will be key to a successful internationalization: The successful global development of IZCARGO® and remaining lean and nimble in our commercialization strategy and infrastructure outside Japan. Partnerships will be key for both aspects. They will allow us to remain flexible and not build a large international organization with burdensome overhead at the expense of losing flexibility.

For the global development of IZCARGO® we have partnered with a world-renowned clinical research organization company with a strong track record of developing therapeutics to approval in the U.S., Europe, and in other geographies. We will benefit from their knowledge and experience in the execution of the JR-141 global clinical trial. Moreover, we have started to reach out early to the global clinical leaders in the field to help us in the design of the clinical trial and definition of endpoints.

Our marketing strategy will similarly aim on a blend of partnerships with global pharmaceutical companies and the use of local partners for certain products or in regions in which JCR sees value in commercializing them by ourselves.

Partnerships with global pharmaceutical companies are of particular value in indications where the J-Brain Cargo® technology brings incremental benefit over an existing standard of care. Such partnerships may also be invaluable in our path to learn the uniqueness of commercializing drugs internationally and adopt global standards. Conversely, in indications with no established treatment standard where JCR would be the first to offer a treatment option, JCR may want to retain commercialization rights for certain international territories.

In contrast to therapeutics in general medicine, the marketing of orphan disease drugs generally does not require the establishment of a large sales force. In the U.S., rare disease companies often partner with specialty pharmacies to utilize their established infrastructure in the distribution of orphan drug products to patients, hospitals, nurses, or physicians. These specialty pharmacies offer a comprehensive range of services beyond mere drug distribution, which would be amenable to JCR as well. We believe that such partnerships with specialty pharmacies can offer an efficient way to commercialize certain J-Brain Cargo® products in a lean and efficient manner, with minimal infrastructure and without shifting JCR away from our basis of strength.

The development of further portfolio assets will be necessary to solidify JCR's position as an international company. JCR's portfolio in lysosomal storage disorders, cell therapies, and growth deficiencies holds significant promise. We are in a unique situation that we currently have more promising portfolio assets than internal capacity to progress all of them with the urgency the patients deserve. We will proactively address existing bottlenecks that slow the progression of our portfolio. The manufacturing of AstraZeneca's COVID-19 vaccine bulk solution, which started in 2020, is an immense contribution to society to bring relief from the COVID-19 pandemic, which almost brought the world to a standstill. The income from the vaccine bulk solution manufacturing strengthens JCR's financial position. It gives us opportunities to reinvest some of these proceeds so that we can address constraints in the advancement of our portfolio or accelerate the development of the next breakthrough innovation. Development partnerships with other pharma companies are a viable option whenever our capacities are not sufficient to advance assets expeditiously enough by ourselves. Our strategy will focus on finding partners that bring in the right competencies and resources to perfectly complement JCR's needs.

The innovation brought to patients through the J-Brain Cargo® technology brings JCR's corporate philosophy to contribute towards people's healthcare through pharmaceutical products to a new dimension. The approval of IZCARGO® shifts JCR's role from being a contributor towards being a driver. We are cognizant of this responsibility towards the patients we aspire to serve to not disappoint their expectations or give promises we cannot fulfill. JCR's reputation is built on a trustful relationship with the patients and patient communities. Building and maintaining our relationships with them is a constant commitment and a deep source of motivation for us. We see them as true partners in the development of new treatment approaches. Their input is invaluable for the design of trials that are least burdensome or for the definition of endpoints that are meaningful to patients or their caregivers. The most relevant promise we can give to the community is a sense of urgency: Patients with an irreversible disease progression cannot wait.

Business Expansion in Brazil

We will make steady strides in Brazil while supporting the needs of patients with mucopolysaccharidosis.

Vanessa Tubel

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

I remember as if it was yesterday when I was in the plane returning from Brasilia to São Paulo, when I read JCR's release on PI/II trials for MPS II in Japan. I forwarded it immediately to Mr. Daher, President of Casa Hunter, since he was desperate to find a new treatment for his son, whose disease (MPS II) was evolving at a very fast pace. He called me astonished after reading the release, especially because he had never heard of JCR before. He also contacted MD Giugliani to understand if he was aware of these facts and they both went positively surprised again. Fully motivated by the above, they reached out to JCR, managing to schedule an urgent visit in Japan to introduce themselves and to convince the Company to start the business in Brazil by offering the best treatment option for Brazilian MPS II patients.

I commenced this journey at JCR DO BRASIL (JCRB) in September 2020, and even though not a full year has yet gone by at JCRB, I can share that many things have been done, truly accomplished, along with many others that are still under development.

My management decisions were often driven since day one by how fast I could positively impact patients' lives, and with this in mind my first new hire was the head of regulatory affairs who successfully managed to prepare and submit JR-141's registration dossier in 30 days.

And by keeping up the same pace, the heads of medical affairs and commercial were also onboarded in less than 90 days after headcount approval, enabling us as one JCRB Team to make one of our main deliveries in this start up momentum, the five-year business plan, already addressing not only MPS II, but MPS I, MPS III-A and Fabry disease figures as well.

On top of that JCRB also managed to achieve a major change in Brazilian legislation which will enable, from now on, physicians to perform a newborn screening test that will cover more than 50 rare diseases, compared to the previous 7 available. We are also hiring a more structured warehouse, and to make all of this happen in the most appropriate way, the main policies have already been developed and put in place.

And I can finally say that working for a company that can bring to market innovative therapies that can change people's lives is rather motivating, and I am certainly thrilled by the many possibilities that are still to come.

Research and Development

Breakthroughs that will change the world of rare diseases. IZCARGO® embodies JCR's spirit of challenge.

R&D of new drugs ordinarily takes much longer than 10 years. While new possibilities can be found after extensive trial and error, sometimes newly obtained data can force us to reverse the progress that we have made over time. We also face numerous issues in clinical trials. Not only does research and development require substantial amounts of investment, but sometimes development plans can be revised or withdrawn due to a variety of reasons.

IZCARGO®, a therapeutic enzyme for mucopolysaccharidosis II (MPS II), was approved and launched in Japan as the world's first enzyme replacement therapy that applies JCR's proprietary blood-brain barrier (BBB) penetration technology, J-Brain Cargo®. Throughout this process, we remained confident in the potential of BBB penetration technology without shrinking away from numerous difficulties. We brought together JCR's wisdom to achieve our goals, solving the issues we faced one by one.
In 2005, this journey began with an ambitious endeavor by one young researcher. Following 12 years of research, it finally reached the clinical stage in 2017. In the clinical stage, we continued to tackle bold challenges, such as initiating JCR's first-ever global development program in Brazil.
We are currently conducting a global clinical Phase III trial so that we can deliver this medicine, which was launched in Japan in May 2021 as IZCARGO®, to patients with Hunter syndrome (MPS II) around the world. In addition, we are working to develop medicines for other lysosomal storage disorders (LSDs) that apply J-Brain Cargo® and to realize additional technological possibilities.

In this section, two key research and development personnel explain the stories behind the creation of J-Brain Cargo® and research and development of IZCARGO®.

Kenichi Takahashi, Ph.D.

Scientific Expert Fellow, Research Division and Director, Innovative Technology Research Institute

IZCARGO®* Research and Development History

* Code: JR-141

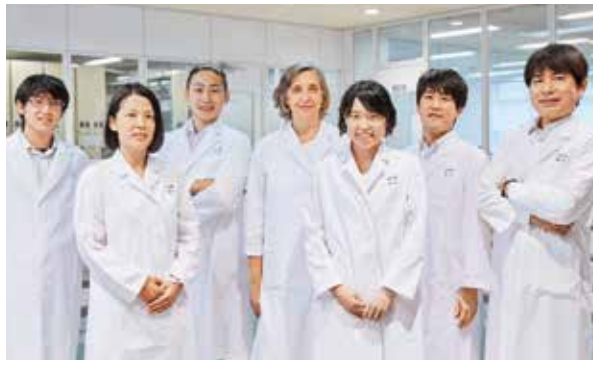
Here, we will retrace the steps of our drug discovery journey, beginning with how JCR came up with the concept of J-Brain Cargo®, JCR's proprietary BBB penetration technology.

In 2005, Hiroyuki Sonoda, Ph.D. (currently Vice President, Research and Corporate Strategy, Executive Director, Research Division) was in his third year since joining JCR. That year, Dr. Sonoda attended a meeting with a patient group for LSDs, where he listened attentively to the earnest wishes of patients' family members. This opportunity to hear the pleas of the family members reinforced his belief that a therapeutic enzyme that could migrate to the brain was essential to patients with LSDs who have central nervous system (CNS) symptoms. Dr. Sonoda enlisted the cooperation of research members of the former Pharmacology Group (currently Pharmacology Group, Drug Discovery Research Institute) and embarked on the challenge of developing a BBB penetration technology. Sometime around 2011, as part of these efforts, the researchers decided to prepare a fusion enzyme consisting of an anti-mouse transferrin receptor (TfR) antibody and iduronate-2-sulfatase (IDS) and to evaluate its efficacy. The results were startling. Following intravenous administration of the fusion enzyme into a mouse model for Hunter syndrome (MPS II), the researchers observed a marked decrease in substrate accumulation in the brain, and a behavioral evaluation clearly showed that long-term administration could suppress the deterioration of cognitive functions.

In the past, many reports had been published on BBB penetration technology using antibodies against mouse and rat TfR. However, this was the world's first study that clearly showed efficacy in the CNS. Based on these results, Dr. Sonoda decided to start working on obtaining an anti-human TfR antibody to advance the project to clinical development. At the time, no clinically applicable anti-human TfR antibodies had been reported anywhere in the world. ArmaGen, Inc., which was leading the scientific community in research on BBB penetration technology using anti-mouse TfR antibodies, had shifted to the use of anti-insulin receptor antibodies in clinical development. Therefore, Dr. Sonoda's decision to pursue an anti-human TfR antibody was extremely ambitious. Around the end of 2012, I joined the project. Together with members of the current Drug Discovery Research Institute, we first clearly identified the epitope*1 of the anti-mouse TfR antibody that has BBB penetration capability. We then adopted a strategy of seeking to obtain an antibody that would bind to the site of the human TfR that corresponds to the epitope we had identified.

In the process of obtaining antibodies, I newly developed the J-Mab System®*2, a high-performance antibody discovery technology. Working together with other research members, our group established enzyme-linked immunosorbent assay (ELISA) using baculovirus and cell capture immunoassay as antibody screening techniques. Using these techniques, we conducted screening to identify antibodies that would bind with the site described above. This strategy proved effective, and we succeeded in obtaining several candidate clones.

*1 The specific site of an antigen to which an antibody binds
*2 A technology for discovering antibodies that have an extremely strong affinity and specificity relative to membrane protein antigens with complex structures

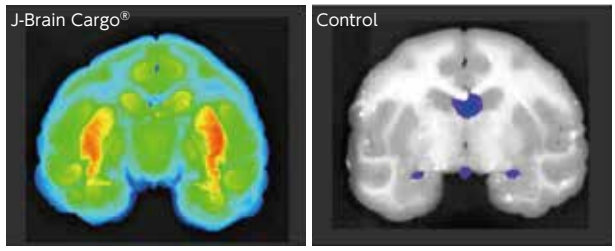


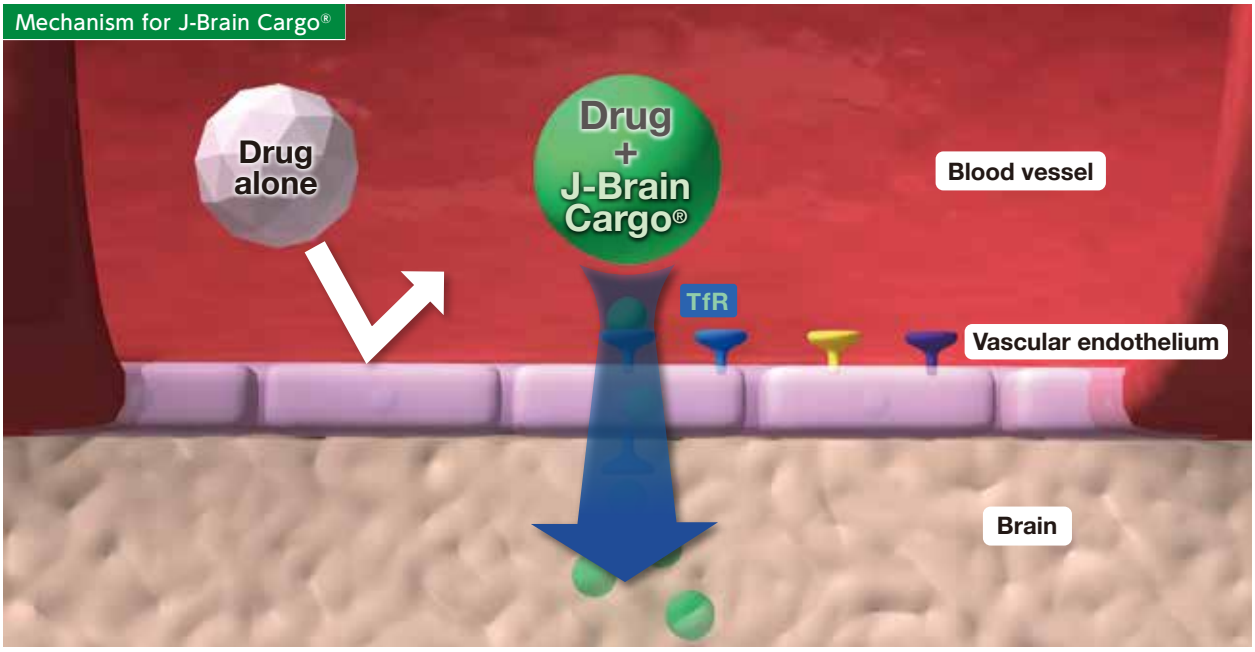
Following these developments, in 2014 Dr. Sonoda et al. evaluated the ability of the individual candidate clones to migrate to the brain using TfR knock-in (hTfR KI) in mice and cynomolgus monkeys and identified antibodies that have the highest ability to migrate to the brain. Thereafter, Dr. Sonoda et al. advanced the humanization of this antibody and obtained a humanized antibody that possesses a high brain migration capability. Next, the group produced on a trial basis a fusion enzyme of this humanized antibody and IDS as a development candidate compound and verified its functionality*1. Finally, efficacy was confirmed in the hTfR KI mouse model for Hunter syndrome and a production cell line was established. Following these steps, JCR decided to develop the compound as JR-141*2*3.

That was how the BBB penetration technology named J-Brain Cargo® and JR-141, the first drug candidate substance to apply this technology, were born. While Dr. Sonoda created the opportunity for the birth of these innovations, he did not produce any major results in the first few years and seems to have occasionally considered giving up on the project during that time. However, researchers with many different qualities joined what had begun as a small movement with Dr. Sonoda's idea. Each researcher thought carefully about the issues in their respective areas of responsibility and shared ideas. These activities eventually created a large, unified movement within JCR's Research Institute. The birth of J-Brain Cargo® and JR-141 was a feat that was made possible by JCR's research team, which always faces science with the utmost integrity. This achievement embodies the spirit of challenge of "Team JCR."

*1 A Blood-Brain-Barrier-Penetrating Anti-human Transferrin Receptor Antibody Fusion Protein for Neuronopathic Mucopolysaccharidosis II: Sonoda et al., Mol Ther. 2018; 26: 1366-1374
*2 Evaluation of cerebrospinal fluid heparan sulfate as a biomarker of neuropathology in a murine model of mucopolysaccharidosis type II using high-sensitivity LC/MS/MS: Tanaka et al., Mol Genet Metab. 2018; 125: 53-58
*3 Clearance of heparan sulfate in the brain prevents neurodegeneration and neurocognitive impairment in MPS II mice: Hideto Morimoto et al., Mor Ther. 2021; 29(5): 1853-1861

Study in monkeys
(cross-sectional brain IVIS imaging analysis)





Various types of antibody-based, tissue-targeting technology have been under development to **adapt to multiple receptors**

J-Brain Cargo® is applicable to a variety of substances, **from small to large molecules** (e.g. enzymes and antibodies)

Drugs can effectively be transported not only across **BBB**, but also into **skeletal muscles**

IZCARGO®* Research and Development History

* Code: JR-141

We have brought together the collective strength of "Team JCR" and accelerated development, in order to fulfill the aspirations of patients with LSDs.

Sairei So, Ph.D.

Director, Planning Dept., Development Division

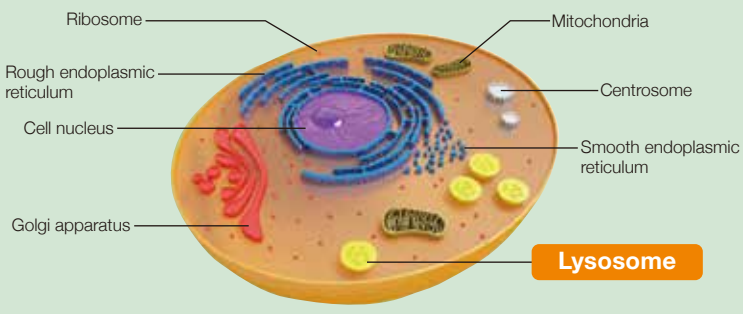
A kick-off meeting in August 2015 initiated clinical development of JR-141 in earnest. The development of a new drug using J-Brain Cargo®, JCR's proprietary BBB penetration technology, signified a new challenge for the Development Division, and an opportunity to take an immense leap forward.

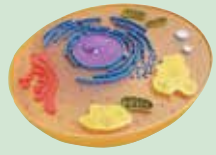
Our first major hurdle was to confirm whether JR-141 could generate safety and efficacy results as expected in clinical trials where patients were dosed for the first time. Given that the drug reaches the CNS, we did not know what kinds of side effects might occur. For this reason, we administered the drug carefully starting with low dosages, and confirmed that there were no safety problems*4. Moreover, we confirmed that dosing with JR-141 resulted in a decrease in heparan sulfate concentrations in cerebrospinal fluid. This confirmation marked a critical milestone for JCR that determined the destiny of J-Brain Cargo® thereafter.

Clinical trials in Brazil are essential to any discussion of JR-141. One of the most frequently asked questions we receive is why we decided to implement clinical trials in Brazil. It all started when we heard directly of the urgent need to develop JR-141 in Brazil from a Brazilian key opinion leader and a representative of a patient group, both of whom had learned of the development of JR-141 in Japan. Thereafter, we conducted a survey of conditions in Brazil such as the situation faced by patients with mucopolysaccharidosis, the regulatory requirements, and the feasibility of implementing clinical trials in the country. As a result, we judged that we could rapidly initiate clinical trials in Brazil, and that is how we came to implementing the clinical trials.

*4 Iduronate-2-Sulfatase with Anti-human Transferrin Receptor Antibody for Neuropathic Mucopolysaccharidosis II: A Phase 1/2 Trial: Okuyama T, et al. Mol Ther. 2019; 27(2): 456-64.

Cell Structure and Mechanism of Mucopolysaccharidosis





A deficiency or decreased activity of the enzymes (iduronate-2-sulfatase in the case of MPS II) needed to break down waste substances in the body can result in a failure to break down mucopolysaccharides (glycosaminoglycans (GAGs)), which accumulate in lysosomes and cause a variety of symptoms.

The clinical trial in Brazil unexpectedly became JCR's first step in a global development. The trial in Brazil produced results as expected and provided critical insights into determining the optimal dosage for JR-141*5.

A confirmatory trial was also initiated in Japan at the same time as the trial in Brazil*6. Over a short registration period of 6 months, 28 patients were enrolled in this trial, which was far more than our target of 20 patients. There are very few patients with rare diseases, particularly LSDs, even on a nationwide level, so it is often difficult to conduct these kinds of trials on schedule. However, I saw the enrollment levels in this trial as a strong indication of the high expectations patients had toward JR-141.

With the completion of patient enrollment in the trial, we now finally had a clear roadmap to obtaining approval in Japan. To deliver JR-141 to patients as a new drug as soon as possible, we shortened the examination period using the SAKIGAKE Designation System in Japan. While this designation drastically increased the work load for this application, JCR worked as one to surmount difficulties and accelerated efforts to apply for approval in Japan.

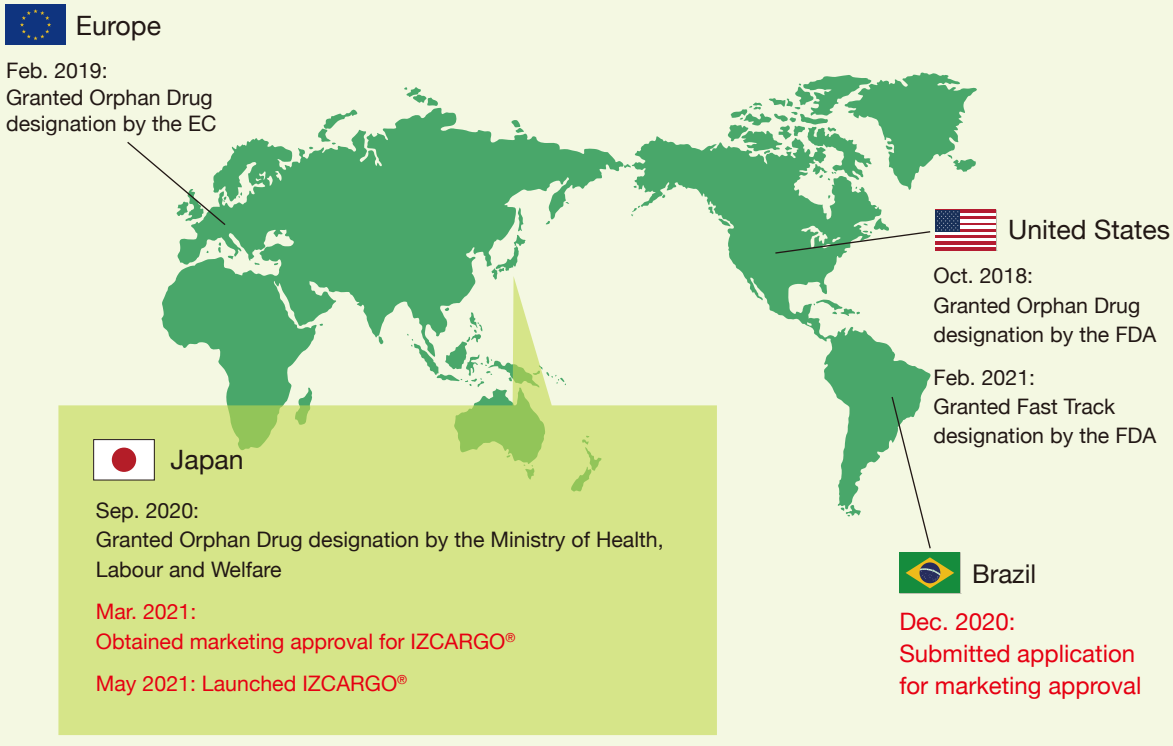
One main matter for discussion in the review process was the adoption of concentrations of the biomarker heparin sulfate in cerebrospinal fluid as the primary endpoint. The Pharmaceuticals and Medical Devices Agency (PMDA) evaluated the effectiveness of JR-141 and it fulfilled the needs of the front lines of healthcare. I believe that these factors led to the approval of JR-141 in Japan.

Going forward, the JR-141 project will continue for much longer as we seek to reach our higher goal of obtaining global approval in Brazil, the U.S. and Europe. Achieving our goal of obtaining approval in Japan was one major milestone along the way. We are confident that it will serve as a crucial first step for JR-141 to take to the skies around the world.

*5 Iduronate-2-sulfatase fused with anti-human transferrin receptor antibody, pabinafusp alfa, for treatment of neuronopathic and non-neuronopathic mucopolysaccharidosis II: Report of a phase 2 trial in Brazil: Roberto Giugliani, et al. Mot Ther. 2021; 29(7): 2378-2386

*6 A Phase 2/3 Trial of Pabinafusp Alfa, IDS Fused with Anti-Human Transferrin Receptor Antibody, Targeting Neurodegeneration in MPS-II: Okuyama T, et al. Mol Ther. 2021; 29(2): 671-679.

Progress on global development of JR-141



Global Phase III clinical trial planned to start in FY2021

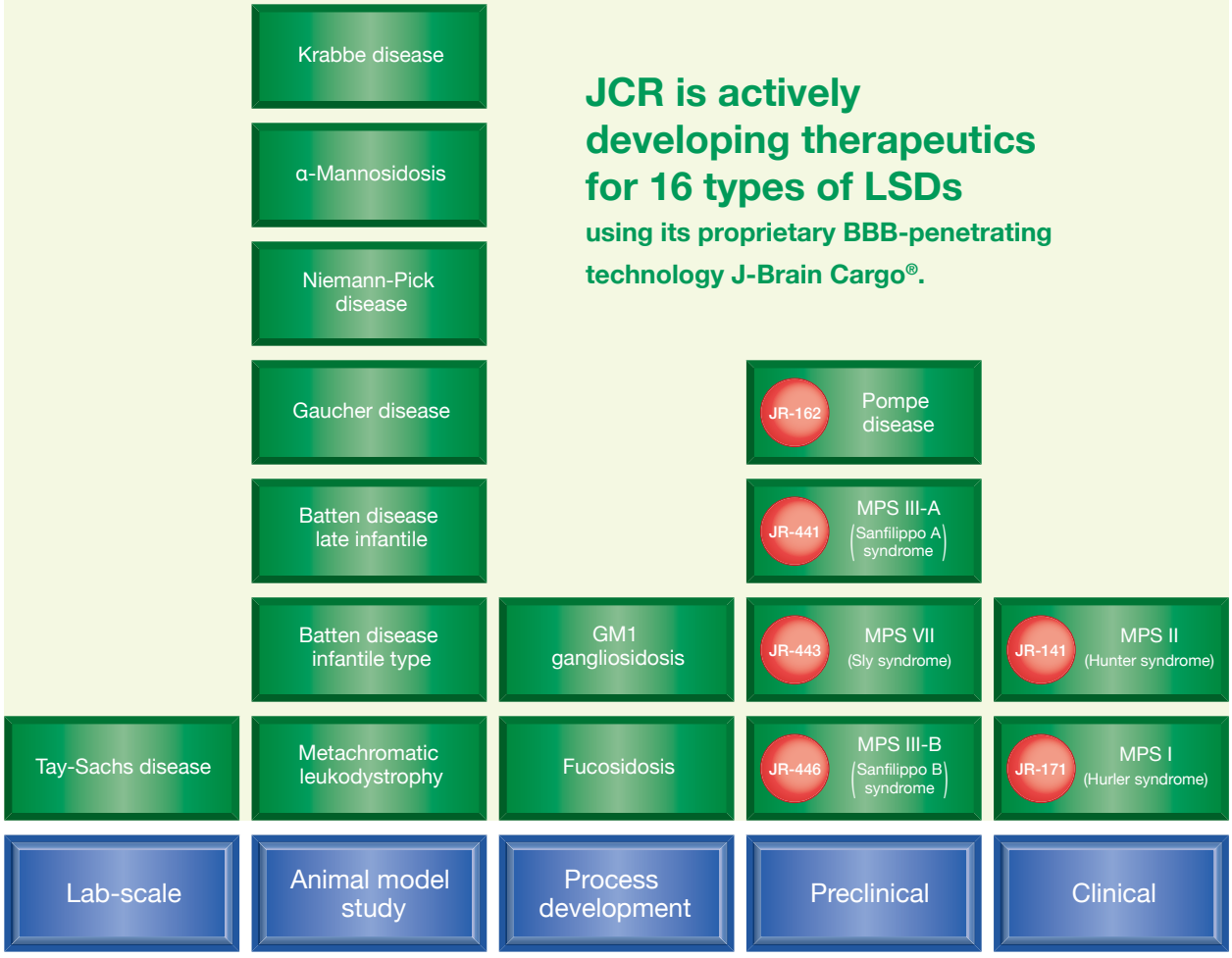
Initiatives Ahead

JCR's research and development activities have harnessed biotechnologies to deliver a wide range of pharmaceutical products to society. Beginning with urine-derived products, JCR rolled out GROWJECT®, a human growth hormone product using recombinant DNA technology, and the renal anemia treatment Epoetin Alfa BS Inj. [JCR], which was the first domestically produced biosimilar, followed by the renal anemia treatment Darbepoetin Alfa BS Inj. [JCR]. JCR has also launched TEMCELL® HS Inj., the first allogeneic mesenchymal stem cells product in Japan, and Agalsidase Beta BS I.V. Infusion [JCR], the first domestic enzyme replacement therapy for LSDs. Furthermore, in March 2021, JCR obtained approval for IZCARGO®, the world's first treatment of MPS II using J-Brain Cargo®, a BBB penetration technology. This achievement signifies the completion of a new platform technology for creating new drugs, in addition to JCR's biopharmaceutical production technology, which it has developed over many years. Beginning with IZCARGO®, we will develop therapeutic enzymes that are effective in the CNS in the LSD field, while actively expanding our drug development to rare diseases other than LSDs and CNS disorders in other areas.

In addition, we will strengthen our efforts in platform technology development and basic research. These efforts will seek to establish new platform technologies by skillfully integrating the expertise and technologies we have developed in the fields of recombinant DNA technology, protein engineering, gene therapy and regenerative medicine.

JCR will strive to create its next proprietary drug discovery platform technology in tandem with the active use of J-Brain Cargo®. Through these efforts, JCR will continuously tackle the challenge of developing truly meaningful treatments that can change the lives of patients for the better.

Our initiatives for LSD drug development



Production System

Our mission is to provide a stable supply of high-quality pharmaceuticals, including IZCARGO®.

JCR's quality policy is "provision of high-quality products worldwide to fulfill our mission in contributing to people's health." Quality is the top priority in each phase of development, manufacturing and delivery of products. Guided by this policy, we strive to ensure a stable supply of high-quality products.

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

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

In finished product manufacturing, the Kobe Plant manufactures finished products for all JCR pharmaceuticals delivered in Japan, such as Epoetin Alfa BS Inj. [JCR], Agalsidase Beta BS I.V. Infusion [JCR], and IZCARGO®, as well as our core product GROWJECT®. In the course of developing and launching IZCARGO®, the Kobe Plant has assumed responsibility for all processes employing the active pharmaceutical ingredients (APIs) supplied by JCR's API plant. These processes range from manufacturing the experimental drug for obtaining stability testing data used in submitting applications for drug approval to manufacturing investigational products and final products on the market.

In this manner, we have been engaged in production from the initial stage of pharmaceutical development, and we have carefully crafted finished products with our own hands. We have been able to conduct stable manufacturing as we maintain high levels of quality under the best possible conditions.

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

In March 2021, JCR completed work to expand production capacity at the Seishin Plant for TEMCELL® HS Inj., an allogeneic regenerative medical product launched in 2016. With the completion of this work, we have established a production system capable of supplying TEMCELL® HS Inj. to medical facilities throughout Japan.

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

Production Sites

Seishin Plant
Regenerative medical products, medical devices

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

Kobe Plant
Finished products

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

Murotani Plant
Active pharmaceutical ingredients (APIs)

Main manufactured items
- APIs for Epoetin Alfa BS Inj. [JCR]

Kobe API Plant
APIs

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

Message

At the Kobe Plant, we manufacture all final products marketed by JCR. We also manufacture investigational products for new pipeline products. IZCARGO®, which was launched in May 2021, began with the manufacture of investigational products at the Kobe Plant and has now become one of the plant's important manufactured items. When manufacturing pipeline products, new manufacturing methods must be established. The thoughts and ideas of the employees actually working on the manufacturing front lines are critical when considering factors such as procedures and the operating condition of equipment. We propose methods that will facilitate more efficient and accurate manufacturing work from each of our perspectives, and exchange views with staff from research and development departments as we decide on those methods. Therefore, this process enables all personnel, even young staff, to freely express their thoughts and ideas and proactively get involved in the project. In this manner, we strive to fulfill our daily duties as members of "Team JCR" so that all personnel, from young to experienced staff, can work closely in unison across organizational boundaries to provide a stable supply of high-quality pharmaceuticals.

Hiromu Tanaka
1st Formulation Section, Kobe 2nd Formulation Unit, Production Division

Quality Assurance

JCR has established a new quality assurance system. The system is led by the Quality Assurance Division, which comprises the Quality Assurance Dept., Pharmacovigilance Dept. and Regulatory Affairs Dept.

Quality Assurance Dept.

The roles of the Quality Assurance Dept. are to assure the effectiveness and safety of pharmaceuticals and regenerative medical products by confirming the entire process related to products, from the raw materials used to manufacturing, packaging, examination and testing, storage and distribution management.

In June 2021, JCR integrated the HQ Quality Assurance Dept., which is responsible for corporate functions, and the Production Division's Quality Assurance Dept. to newly establish the Quality Assurance Dept. as one department. Through this measure, JCR will strive to unify the quality system, build a quality assurance system with tightly integrated corporate and production functions, and make qualitative improvements. We have laid the groundwork for fostering solid teamwork and solidarity as "Team JCR."

In the Quality Assurance Dept., the section responsible for corporate functions will ensure compliance with GQP*1 as a holder of marketing authorization, while the quality assurance sections assigned to each plant will ensure compliance with GMP and GCTP*2 to assure product quality at all times. Both functions will appropriately manage the quality system while promoting close cooperation under a shared quality system, with a view to ensuring the high quality of JCR's proprietary products. In addition, they are working to build an even better quality system that complies with overseas laws and regulations, guidelines and other rules, with the aim of promoting future global business expansion.

Through this new quality assurance system, the Quality Assurance Dept. will adopt "Quality First" as a shared principle, assure the high quality of JCR's products, and provide peace of mind and safety to all patients.

*1 Good Quality Practice (GQP): Quality assurance standards for pharmaceuticals, quasi-drugs, cosmetics, and regenerative medical products
*2 Good Manufacturing Practice (GMP) and Good Gene, Cellular, and Tissue-based Products Manufacturing Practice (GCTP): Standards for manufacturing management and quality assurance for pharmaceuticals and quasi-pharmaceutical products (regenerative medical products)

Pharmacovigilance Dept.

The Pharmacovigilance Dept. is a department that manages safety information about investigational products and marketed items. By centrally managing safety information from the time of clinical trials to the post-marketing period, the department can identify product risks from an early stage and evaluates the information it gathers while constantly considering the balance between benefits and risks. As a result, the department can provide information about

the appropriate use of products to the medical front lines in a timely manner. We believe that these efforts can lead to products that contribute to more appropriate treatment. In other words, in our view these efforts will pave the way for drug fostering and evolution in the post-marketing phase.

Whenever JCR has expanded into new fields, such as combination products or regenerative medical products, the Pharmacovigilance Dept. has worked to gather the safety information required by medical front lines from a wide range of sources and supply that information in a timely and appropriate manner, without letting down its guard against unknown risks. The Pharmacovigilance Dept. will conduct post-marketing safety control of IZCARGO®, a new pharmaceutical, in Japan and global risk management of this product in the future. In the process, the department will strengthen its understanding of the laws and regulations of various countries, and enhance collaboration with partners in Japan and abroad. Through a concerted effort by "Team JCR," the department will strive to conduct evaluations based on consistent global standards.

Regulatory Affairs Dept.

The Regulatory Affairs Dept. is involved in almost all processes from the development stage of pharmaceuticals and regenerative medical products to submission of applications for approval, placement on the National Health Insurance (NHI) reimbursement price list, subsequent stable supply and cancellation of approval at the final stage of the lifecycle.

In the development stage, the Regulatory Affairs Dept. conducts various duties in cooperation mainly with the Research Division and Development Division. Based on data obtained from quality tests and non-clinical and clinical trials, the Regulatory Affairs Dept. prepares materials for applications together with each department, along with addressing post-submission reviews and duties related to the NHI reimbursement price, among other duties. GCP*3 audits of clinical trials are a duty essential to improving the quality of data and ensuring reliability. After approval, the Regulatory Affairs Dept. maintains and manages regulatory approvals and manufacturing and marketing business, along with providing the necessary support to provide a stable supply of products.

Looking at activities in FY2020, in September the Regulatory Affairs Dept. submitted an application for approval of JR-141 (IZCARGO®), which is JCR's first-ever finished product to apply J-Brain Cargo®, and obtained approval in March 2021. A premium for usefulness (I) has been applied to the NHI reimbursement price for JR-141. We believe this premium was added in recognition of the high value of this product. In addition, in December, JCR DO BRASIL submitted an application for approval of JR-141 in Brazil. Working closely with the Regulatory Affairs Dept., JCR DO BRASIL is taking steps to address the requirements of the Brazilian authorities.

Going forward, the Regulatory Affairs Dept. is planning to expand JR-141 to Europe and the U.S. and to conduct global clinical trials and submit applications for regulatory approval of additional finished products that apply J-Brain Cargo®. In anticipation of these developments, the Regulatory Affairs Dept. will strive to deliver as early as possible pharmaceuticals that are eagerly awaited by patients around the world.

*3 Good Clinical Practice (GCP): Ministerial orders concerning implementation standards for clinical trials of pharmaceuticals

Message

In my group within the Regulatory Affairs Dept., our main duties are to submit applications for approval of new drugs, maintain the approval status of existing approved drugs, and manage various business licenses. Our most recent task was to apply for and obtain approval of IZCARGO® in Japan. To this end, we focused on fostering cooperation among departments within JCR and building a good relationship with the Pharmaceuticals and Medical Devices Agency (PMDA). In the work of the Regulatory Affairs Dept., we have the opportunity to coordinate with almost all of JCR's departments in areas such as research, development, production, quality assurance, and marketing. In this process, I believe that our corporate culture of going beyond inter-departmental boundaries and working together to achieve challenging goals has strongly taken root within JCR. This culture has enabled us to carry out operations rapidly. We will continue to make every effort to understand and utilize the regulatory frameworks of various countries and collaborate with departments within JCR, so that we can deliver effective, safe and high-quality products to patients suffering from rare diseases around the world.

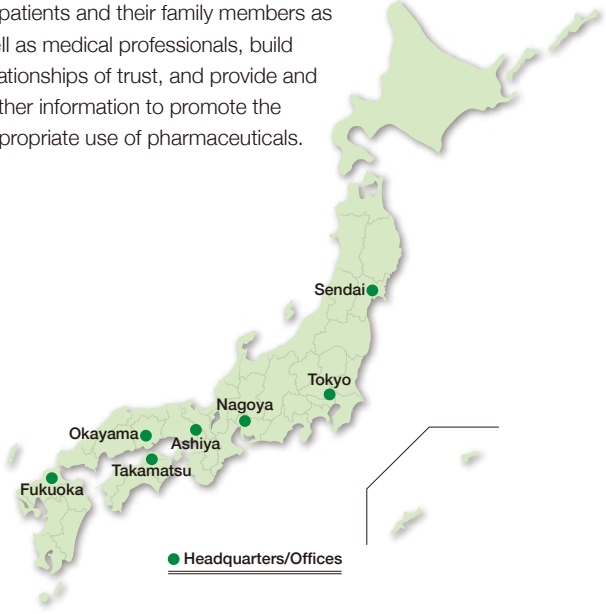
Yoshihiro Wake
Regulatory Affairs Dept., Quality Assurance Division

Marketing

We will accelerate measures to maximize the value of IZCARGO® and drive the sustained growth of existing products.

In May 2021, IZCARGO® was placed on the National Health Insurance (NHI) reimbursement price list and sales of this product were launched, marking a crucial milestone for JCR. This product is JCR's first-ever pharmaceutical to apply J-Brain Cargo®, JCR's proprietary technology. Going forward, JCR plans to successively launch new medicines that apply this technology in the field of lysosomal storage disorders (LSDs).

Previously, one major issue for treating the central nervous system symptoms that occur in many LSDs was that the therapeutic enzymes used for treatment could not penetrate the blood-brain barrier (BBB). IZCARGO® is a pharmaceutical product that addresses such unmet medical needs. It will be used by patients with various backgrounds on the actual medical front lines. IZCARGO® has a mechanism of action that is being employed for the first time in the world. For this reason, JCR will need to demonstrate a high degree of professional expertise to provide and gather information that will ensure the appropriate use of this product. In anticipation of future pipeline products, JCR has set up a marketing framework at an early stage by newly establishing the Lysosomal Storage Disease Group within the Marketing Dept. The Lysosomal Storage Disease Group is made up of full-time LSD staff and functions as an organization that can carry out even more highly specialized personnel development and activities. Along with this specialized group, every member of the Sales Division will support the needs of patients and their family members as well as medical professionals, build relationships of trust, and provide and gather information to promote the appropriate use of pharmaceuticals.



JCR's core product GROWJECT® obtained marketing approval in 1993. GROWJECT® continued to post growth in net sales and market share, despite being impacted by a price reduction due to NHI price revisions. One of the strengths of this product is GROWJECTOR® L, the only electronically controlled injector available on the growth hormone product market. GROWJECTOR® L supports the injections of patients almost every day while reducing their burden.

In 2020, JCR released Melon Nikki™, a dedicated smartphone app that links GROWJECTOR® L and smartphones. Melon Nikki™ hosts events that encourage patients to continue their treatment and allows patients to support one another's treatment by facilitating interactions between them. In these ways, JCR will strive to improve added value in step with the times by developing apps and providing information that help patients to continue their treatment. Through these efforts, JCR will seek to increase its market share further and achieve sustained, stable growth, with a view to establishing a solid management platform.

Marketing Activities Amid the COVID-19 Pandemic

COVID-19 has led to restrictions on social activity. In response, JCR has been actively working to use digital tools. We conduct meetings with medical professionals over the internet and provide them with information via e-mail, so that we can provide and gather essential information even under conditions where it is difficult to visit medical institutions in person. In addition, recipients of various materials sometimes prefer to read the materials on paper. In these cases, JCR sends physical copies of the materials by postal mail.

Rare diseases are defined as one of JCR's core areas. The number of medical professionals engaged in the treatment and care of patients with rare diseases is limited because only a few patients have such diseases. In fact, we are often unable to obtain sufficient information from many patients on their diseases. JCR believes that the efficient supply and exchange of information among specialist doctors and from specialist to non-specialist doctors are crucial to ensuring that the interests of patients with rare diseases are not harmed. JCR has been using digital tools to conduct web seminars and related activities, with the goal of creating opportunities for doctors to communicate in a safe environment even during the COVID-19 crisis. Looking ahead to the post-pandemic era, JCR is advancing plans to implement marketing strategies that will increase productivity through a hybrid approach that combines digital and in-person marketing activities.

Message

The Lysosomal Storage Disease Group was established concurrently with the launch of IZCARGO®. With this step, I was transferred from Medical Representatives (MRs) to the Lysosomal Storage Disease Group, where I was assigned to marketing. Based on JCR's corporate culture of embracing the spirit of challenge, I'm involved in a wide range of operations with support from my colleagues, as I collaborate with various departments within JCR and exchange information with our overseas partners. JCR is preparing to expand IZCARGO® overseas, and I would like to do my utmost to address any opportunity I might have to push ahead with those efforts. When IZCARGO® was launched, I received many inquiries from doctors who said they wanted to use IZCARGO®. This gave me a true appreciation of their high expectations for this product. I'm convinced that IZCARGO®, which penetrates the BBB, will provide significant hope to patients with mucopolysaccharidosis II and their family members. I would like to make it our mission to deliver this medicine to as many patients as possible.

Shohei Harada
Marketing Dept., Sales Division

Actions for COVID-19

We will accomplish our mission as a pioneering biopharmaceuticals company through the production of a COVID-19 vaccine bulk solution.

In spring 2020, JCR was approached by management of AstraZeneca K.K. with an informal request to outsource the manufacturing of its COVID-19 vaccine bulk solution to JCR. At the time, AstraZeneca was developing the adenovirus vector-based vaccine known as AZD1222 (product name: Vaxzevria intramuscular injection) worldwide and it was looking for a manufacturing site so that it could supply the vaccine in Japan. AZD1222 was developed by AstraZeneca and Oxford University. We believe that JCR was approached because it had just completed construction of an API plant, and it was expected to possess surplus manufacturing capacity. Another factor was that JCR had a track record of manufacturing biopharmaceuticals with single-use technology. Although we understood the significance of this request, our first impression was that it would be difficult for JCR to manufacture the vaccine, because we did not have expertise in the vaccine field. In addition, although it would be possible to manufacture the vaccine using facilities at the new plant, the plant would need to be modified. Moreover, if the new plant were unable to manufacture JCR's products due to the manufacturing of the vaccine bulk solution, the development of therapies for rare diseases could be impacted. For these reasons, we initially turned down the request. However, given that AstraZeneca continued to face difficulties in finding another candidate to manufacture the vaccine in Japan, the management teams of JCR and AstraZeneca continued to hold negotiations on this matter.

We faced a dilemma. Although we understood the importance of manufacturing the vaccine bulk solution, we could not afford to delay the development of therapeutic drugs for rare diseases that are eagerly awaited by patients. In these circumstances, our discussions dramatically shifted course in June 2020. The Ministry of Health, Labour and Welfare (MHLW) announced details of its urgent improvement project for vaccine manufacturing systems. Participating in this project would allow JCR to manufacture the vaccine bulk solution at the plant it had completed in February, while opening the possibility of newly constructing a separate API plant, where it could manufacture both the vaccine and therapeutic drugs for rare diseases. JCR continued to exchange thoughts and ideas with AstraZeneca and MHLW. Considering the social significance of supplying the vaccine, among other factors, JCR's management team made a firm decision to participate in the vaccine project in July 2020.

We needed to overcome a wide range of issues to start manufacturing the vaccine. These issues ranged from modifying

facilities to securing raw materials, recruiting personnel, transferring technologies, and addressing regulatory affairs. Ordinarily, it would take more than one year to deal with those issues, but we had to complete the entire process in around four months to satisfy the project's public solicitation requirements. Within JCR, some people raised concerns about this abnormal schedule. However, JCR judged that it could overcome these challenges by harnessing the strong skills and motivation of its employees, its experience in handling vector-based pharmaceuticals under development, and its track record in manufacturing with single-use technology over many years.

Message

My Involvement in the Manufacturing of AZD1222 Vaccine Bulk Solution

When I heard that JCR was approached with a request to manufacture a vaccine bulk solution, my honest impression was that it would be impossible to start manufacturing the vaccine in a short period of time because we do not have any expertise in vaccine manufacturing. Even so, JCR was able to successfully start manufacturing in a short period of time because it had a range of key factors in place, including human resources comprising a small group of specialists par excellence with a strong sense of agency, rapid decision-making, teamwork across departments, and the spirit of challenge needed to tackle new initiatives in uncharted territory. I believe that these factors are inseparable from the strengths of "Team JCR" itself. Additionally, I believe that JCR's high degree of flexibility, which is made possible using one of Japan's leading single-use manufacturing facilities, also contributed to the success of the project. It has been extremely worthwhile to participate in a project that is making such an immense contribution to society, and it has reaffirmed my belief in the possibilities of "Team JCR."

J.I.*
Vaccine Manufacturing Team (Manufacturing), Production Division
* For security reasons, only the writer's initials are disclosed.

When we started preparing to manufacture the vaccine, we encountered a steady stream of unexpected developments. The project members faced an enormous workload. For example, they found that around three times more personnel would be needed compared with JCR's products. The schedule was extremely tight, so the time available to review manufacturing and quality tests was limited. The manufacturing process was not established, so parameters needed to be changed frequently. However, with the cooperation of AstraZeneca, JCR solved all the issues through the hard work and ingenuity of the project members. JCR was able to commence production in 2021 as initially planned. We have been steadily manufacturing the vaccine without any major problems to date.

Vaccines and therapeutics for COVID-19 are currently being developed around the world. These development activities have caused shortages in materials that are used in cultivation processes. Foreseeing this situation, JCR ordered one year's worth of materials and supplies immediately after the project was initiated. Those materials and supplies were many and varied, meaning that a vast space was needed to store them. To address this problem, JCR obtained considerable support from a partner company, and this support was one key factor behind the success of this project.

JCR will continue to do its best to accomplish its mission of contributing to society through its proprietary technological capabilities not only in COVID-19 vaccines but in other areas as well.

Message

My Involvement in the Manufacturing of AZD1222 Vaccine Bulk Solution

I joined JCR in January 2021 because I was interested in the manufacturing of a COVID-19 vaccine bulk solution. I believed that I could gain invaluable experience since the manufacturing of this vaccine bulk solution would be undertaken on an unprecedented, global scale and would also require speed. Although I joined the project a little late, I was deeply impressed with how the team made up for the lack of knowledge that comes from being entrusted with outsourced manufacturing through in-depth meetings with AstraZeneca and responded to the demands of manufacturing at a rapid pace. From the standpoint of a member of the quality assurance section, I was also involved in processes ranging from manufacturing to shipments and applying for approval. In a short period of time, I'm convinced that I've gained an unimaginably broad range of experience. In the future, I will continue to make every effort to ensure that I can apply this experience to vaccine manufacturing and other businesses as well.

Y.H.*
Vaccine Manufacturing Team (Manufacturing), Production Division
* For security reasons, only the writer's initials are disclosed.

We are pushing ahead with the construction of a new plant that will enable the stable supply of a COVID-19 vaccine bulk solution.

Makoto Ashida
President and CEO, JCR Engineering Co., Ltd.

AstraZeneca's COVID-19 vaccine was selected for MHLW's urgent improvement project for vaccine manufacturing systems in 2020. JCR is contracted by AstraZeneca to produce the vaccine bulk solution. The project's public solicitation requirements state that vaccine manufacturing, including that of AstraZeneca's vaccine, must be supported according to the government's requests, at least until the end of March 2030. For this reason, JCR has been constructing a new plant to meet these requirements.

Base Concept

JCR plans to construct a plant based on an innovative new concept that will take into consideration future global expansion, workstyle reforms for employees, and the environment. The new plant will shift away from the traditional model of plants focused on manufacturing.

Manufacturing Facility

- JCR plans to install independent manufacturing areas that can address manufacturing of both vaccine bulk solutions and biopharmaceutical APIs. We will use a facility layout and equipment configuration premised on the adoption of single-use systems.
- JCR anticipates the need to ensure compliance with global GMP including Japan, Europe and the U.S. Accordingly, JCR will design the facility so that it can support Biosafety Level 2 (BSL2) / Cartagena Category 1 (Type 2 Use in Industry) / Virus Management When Working on the Open Bench and ISO 14644-1 Class Management (including recommended airborne microorganism levels).
- JCR will show consideration for the environment by deploying energy-efficient equipment and inactivation treatment systems for viruses. Consideration for the local community will also be shown given that the plant is located next to a residential area. Equipment will be configured within the plant to reflect consideration for noise levels and other impacts on the local community.

Administration Building

- JCR will create an employee-friendly work environment within the administration building. Office spaces will be designed based on a cutting-edge office concept with a focus on transparency through the adoption of glass partitions and other such features. The design will also anticipate future increases in the number of personnel working in the office.
- The building will be divided into the MC (Manufacturing), QA (Quality Assurance), and QC (Quality Control) areas. The layout will reflect how people move around as they work and facilitate easy communication. The building will adopt an external design based on a design philosophy of bringing natural light into the building, and an interior layout with a unified look.
- JCR will promote the use of renewable energy, including solar power.

Scheduled Manufactured Items

- COVID-19 vaccine bulk solution
- JCR's biopharmaceutical APIs and other items

Artist's rendering of the new COVID-19 vaccine bulk solution plant

Sustainability

Message

When reflecting on the purpose of pharmaceutical companies in today's environment, our attention at JCR is directed towards the why (our sense of purpose), the what (what JCR can do for unmet medical needs) and the how (how we can address those needs, identify any issues, find optimal solutions and act in the best interest of our stakeholders – patient communities, healthcare professionals, shareholders, our society more generally as well as our employees who all follow the same sense of purpose as one "Team JCR").

JCR's commitment to sustainability starts from this recognition of our purpose that leads to our proactive approach of saying "Yes" to advance research and development of treatment options for rare diseases, focusing on patient centricity "Yes" to enhance our workplace, nurturing the creativity of each of our employees, particularly with gender equality but also through diversity more generally; and "Yes" to conserve natural resources, designing environmentally friendly and energy-efficient manufacturing plants.

JCR aims to be a "Research-oriented specialty pharma with global exposure." As we work to attain this goal, we will endeavor to realize a sustainable global society that seeks an even better tomorrow with pioneering contributions from Japan that advance sustainable global health.

I ask for the continued support and understanding of you as our stakeholder as we strive to make this a reality, so that "Together We Soar."

Takayo Egawa
Corporate Officer
Director, International Affairs Office

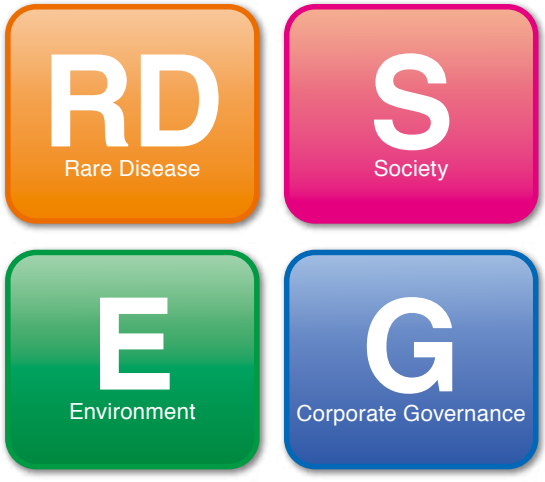
JCR will contribute to the development of a sustainable society through business activities based on its corporate philosophy of "Contributing towards people's healthcare through pharmaceutical products."

Basic Approach to Sustainability

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

The global environment and conditions and issues facing society have been changing year by year. With this in mind, JCR believes that it is crucial to create sustained corporate value through its business activities, while contributing to the development of a sustainable society.

As a reliable pharmaceutical company contributing to the welfare of society, we will proactively implement activities in the core areas of Rare Diseases (RD), Environment (E), Society (S), and Corporate Governance (G).



Addressing the SDGs

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

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

Direction of Sustainability Initiatives and Related SDGs

RD	**Rare Diseases** • Expansion of basic research for the treatment of rare diseases • Activities to improve awareness and understanding of rare diseases • Continuous implementation of internal awareness-raising and Company-wide activities for rare diseases	
E	**Environment** • Activities rooted in the community to reduce environmental burden through business operations	
S	**Society** • Creation of work environments and human resource development for the success of every member of "Team JCR" • Stronger support and new initiatives for rare pediatric diseases and public health	
G	**Corporate Governance** • Reinforcement of a stable product supply system in anticipation of globalization • Establishment of a management system with bold, appropriate and rapid decision-making processes • Implementation of stricter risk management	
Contribution through our business	**"Realizing medical care for those living with rare diseases"** at the earliest opportunity by transforming every aspect of our business through "Team JCR"	

Contributing to Unmet Medical Needs

RD Rare Diseases

Related SDGs

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 fight rare diseases.

Action for RD Rare Disease

What JCR can do for rare diseases

As awareness-raising activities within the Company, we conduct such activities as encouraging employees to wear official badges for Rare Disease Day (RDD), fundraising activities, distributing reports on participation by employees in events organized by patient groups and organizations that support patients with rare diseases, and holding in-house lectures. In FY2020, the COVID-19 pandemic compelled us to conduct activities centered on participation in events held online, such as webinars organized by patient groups, and distribution of reports on those events. In December, we held the RDD Internship online. For this event, we welcomed the participation of students from Kobe Kaisei Girls' School. JCR will continue to carry out not only research and development focused on pharmaceuticals for rare diseases, but also activities that lead to broad-based support for patients on a global basis.

MPS Awareness Day

In FY2021, the RARE DISEASE Project was kicked off with its first global awareness-raising activity. In collaboration with JCR USA, Inc. and JCR DO BRASIL, we exchanged ideas for initiatives that could be implemented under the circumstances of the COVID-19 pandemic in each country, and jointly conducted some awareness-raising activities that incorporated the color purple, the theme color of MPS awareness, for MPS Awareness Day on May 15, organized by the MPS Society, a support group for MPS patients in the U.S., with details as follows:

- Screenshots including the theme color purple and the message of MPS awareness were solicited Company-wide, and posters were created based on the collected images and displayed internally. In addition, we donated funds to the MPS Society in proportion to the number of screenshots collected.
- We produced handmade purple ribbon badges, which were worn by all Company staff in each country.
- Video letters from leaders of patient groups, researchers and others in each country were shared in-house.

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

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 and Japanese professional tennis player Masamichi Imamura have been lending their support to awareness-raising activities worldwide by serving as RDD Japan Ambassadors. JCR signed a sponsor agreement with Mr. Kawamura in October 2019 and newly signed a sponsor agreement with Mr. Imamura in April 2021.

Message

Professional Golfer and RDD Japan Ambassador

Masahiro Kawamura

I've been participating in awareness-raising activities as an RDD Japan Ambassador since December 2019.

As a professional golfer mainly active in the European Tour, I compete in tournaments worldwide in locations including Europe, the Middle East, and Africa. Overseas, I've found that professional athletes are highly eager to contribute to society.

Since the summer of 2019, I've put the RDD logo on my caddy bag. I've also handed out postcards and pin badges at tournament venues to raise awareness of RDD. Following my signing of the sponsor agreement with JCR, I've learned about rare and intractable diseases through the RARE DISEASE Project. And now, I feel proud to have played a pivotal role in these awareness-raising activities as I carry out my activities as a professional golfer.

Looking ahead, I'd like to work hard and expand my activities further afield, so that I can spread the word about RDD to even more people around the world.

Message

Professional Tennis Player and RDD Japan Ambassador

Masamichi Imamura

I'm honored to have been chosen as an RDD Japan Ambassador since FY2021.

Speaking frankly, I've so far had very few opportunities to learn about rare and intractable diseases, and I previously didn't have a detailed understanding of these diseases. With my appointment as an RDD Japan Ambassador, I have started to learn about rare and intractable diseases. This appointment has given me the opportunity to study the matter more closely. I think it is important for me to become an influential player in order to let a wide range of people know about the activities of RDD. Therefore, I will work in earnest to deliver strong results at tournaments.

Professional tennis players often travel to different countries to compete in tournaments. For this reason, it is an occupation where we meet many people of different nationalities and racial backgrounds. Making the most of these characteristics, I would like to focus on what I can do now to the best of my ability, such as handing out postcards and other materials related to awareness-raising activities, playing in matches with the RDD logo mark on my tennis match wear and providing information on social media. I will work hard so that people like me, who might be initially unfamiliar with rare and intractable diseases, can develop an interest in these diseases.

Contributing to Unmet Medical Needs

S Society

Related SDGs

Support for the International Medical Research Foundation

JCR supports the activities of the International Medical Research Foundation, which aims to foster young medical researchers who can succeed internationally through programs such as study abroad grants. The International Medical Research Foundation was established in April 2019. In its first year, the foundation commenced its study abroad grant program for young medical researchers. Since then, it has provided grants to five researchers every year for a period of up to two years. Since its second year, the foundation has also provided grants to international symposiums on medical research that are held in Japan.

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

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

The Award for Promotion of Maternal Child Health was created to commemorate the International Year of the Child in 1979. The award seeks to encourage the good work of individuals who have made great contributions to society and the field of community-based maternal and child health, in areas such as research on motherhood and children’s health, raising widespread awareness of public health principles, providing practical education and instruction, and upgrading and expanding the development of public health facilities. By recognizing these accomplishments, the award program seeks to further promote the development of maternal and child health. Every year, 15 award recipients are selected from among candidates working in the field of maternal and child health. The recipients include public health nurses, midwives, nurses, doctors, dentists, nutritionists, dental hygienists, nursery school teachers, and maternal and child health support workers, who are chosen for the award based on recommendations from the head of prefectures, ordinance-designated cities, core cities and special wards.

Momiji House, a Short-Stay Medical Care Facility

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

もみじの家

Providing 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 2021, JCR gave poster presentations at the 17th Annual WORLD*Symposium*™ 2021 on JR-141, JR-171, JR-162, JR-441 and JR-446, which are candidate treatments for lysosomal storage disorders (LSDs) using J-Brain Cargo®, JCR’s proprietary technology. This international symposium covers themes ranging from basic research to clinical applications for LSDs. Concurrently, JCR opened a virtual booth at the event so that it could exchange information with event participants.

Human Resource Management

S Society

Related SDGs

Introducing Worker Friendly Systems

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

Since 2019, we have introduced a “savable paid leave system”* as a new program. Previously, employees working while raising children, providing nursing care and fulfilling other responsibilities would sometimes run out of their remaining hourly paid leave at the fiscal year-end, and would have no choice but to use their annual leave in daily increments. This “savable paid leave system” can be used by employees whenever they need to provide childcare or nursing care to family members, or whenever they need to see a doctor regularly for the treatment or screening of a personal injury, illness, or chronic disease, among other situations. From 2021, the scope of eligibility for nursing care, which had previously been limited to parents in terms of its scope of use, has been expanded to family members. JCR aims to introduce a variety of systems in order to provide a workplace environment where employees can work comfortably.

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

Creating an Ideal Workplace Environment Where Employees Can Work Comfortably

As an initiative to create an ideal workplace environment where employees can work healthily and comfortably, 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.

Initiatives to Prevent the Spread of COVID-19

Since 2020, the COVID-19 pandemic has wreaked havoc around the world. As a measure to prevent the spread of COVID-19, JCR has formed the COVID-19 Action Team to carry out a broad spectrum of initiatives to protect employees from infections. The team also encourages employees, as members of a pharmaceutical company, to adhere to behavior that will prevent infections.

Description of Initiatives

- Work from home is actively implemented by employees in job categories where work from home is possible.
- The JCR Model, which is tailored to the status of COVID-19 infections in each prefecture, is established and measures to prevent COVID-19 infections are implemented.
- The Action Team provides various types of information on COVID-19 every Monday.
- Masks are regularly handed out to all employees. Portable alcohol sprays are also handed out.
- Facial recognition and body temperature measurement systems and automatic hand sanitizer devices are installed at major business sites.
- All employees receive antigen tests once every two weeks (Personnel involved in the manufacturing of AstraZeneca’s COVID-19 vaccine bulk solution receive PCR tests every week.)

Creating Workplaces Where Women Can Participate Actively

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 10.6% in FY2020), 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.

Supporting Employees Raising Children

We have provided an in-house daycare center at the Research Institute for employees who are raising children. In addition, we provide a monthly childcare subsidy to support employees who are unable to use the in-house childcare center due to their work location. In recognition of these and other efforts, we received the Kurumin certification from the Ministry of Health, Labour and Welfare in July 2018. Currently, we are implementing measures to receive our second Kurumin certification.

In-house childcare center JCR Kids Land

Measures to Improve the Childcare Leave Acquisition Rate among Men

Achieving gender equality and workstyle reforms have become urgent priorities for solving social problems. Even so, childcare leave by men has not permeated society sufficiently, and no real progress on the acquisition of childcare leave by men has been made. At JCR too, the childcare leave acquisition rate among men (80%* in FY2020, *Includes leave taken for childcare purposes) is lower than the childcare leave acquisition rate among women (100% in FY2020).

We believe that fostering workplace understanding and instilling awareness among male employees are essential to improving the childcare acquisition rate among men. Based on this belief, the Child-Raising Support Café (37 voluntary participants in FY2020) and Ikuboss training (7 voluntary participants in FY2020) (Ikuboss: a boss supportive of child-raising) were held as in-house seminars. In these seminars, outside instructors discussed, among other topics, the benefits that men could enjoy by participating in child-raising. From within JCR, male employees and managers who have acquired childcare leave in the past shared their experiences as part of efforts to encourage understanding and cooperation toward the acquisition of childcare leave by male employees. Moreover, staff from human resources departments explained various programs that enable male employees to actively acquire childcare leave. As a first step, JCR is working to foster awareness of the acquisition of childcare leave by men within the Company.

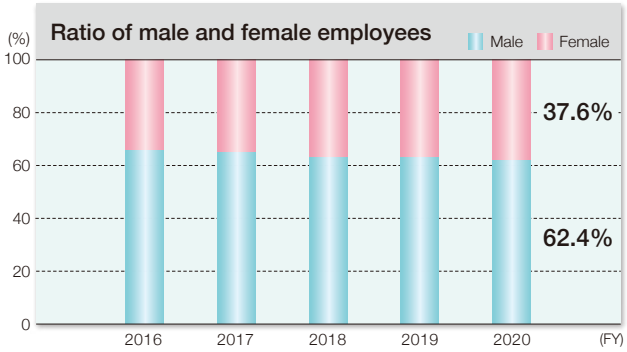
Through these measures, the childcare acquisition rate among men has been increasing every year.

Enhanced Training Programs

JCR is pouring energy into employee training, because it believes that improving employee skills will help it to grow. In their first month after joining JCR, new graduate recruits attend group training. This program covers business etiquette, communication skills, presentations from each business division, on-site training at plants and the Research Institute, and fieldwork training with medical representatives. We also regularly conduct tier-specific training where participation is mandatory for each level. We also seek to support the self-development and growth of employees. To this end, voluntary training, where employees can voluntarily express their intent to participate in planned training seminars, and e-learning programs were incorporated into training from FY2020, alongside English language training. This training takes a variety of forms, such as group training sessions led by external guest instructors and participation in open public lectures held outside the Company. English language training also features a broad range of training options and formats, such as group training sessions and web-based e-learning programs.

Career advancement seminar for women (At a group training session in FY2019)

Human Resource Management

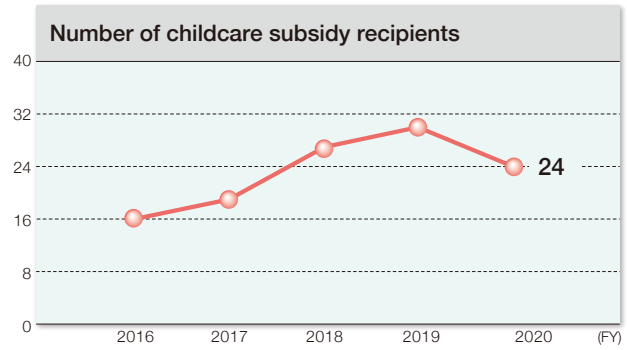


*Data from JCR Pharmaceuticals Co., Ltd.

Training track record

FY		2016	2017	2018	2019	2020
Group training	Number of sessions	2	10	15	15	**8**
Tier-specific training	Hours	15	90	135	126	**60**
Voluntary training	Amount (Millions of yen)	0.6	4.6	6.6	9.0	**5.1**
English language training	Amount (Millions of yen)	1.2	2.0	5.7	7.2	**17.0**

*Data from JCR Pharmaceuticals Co., Ltd.



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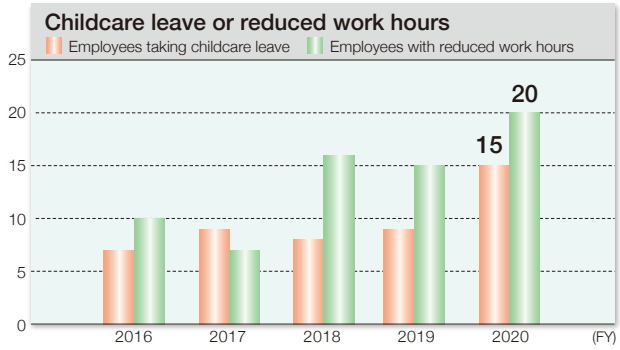


*Data from JCR Pharmaceuticals Co., Ltd.

Quality Assurance and Stable Supply

S Society

Related SDGs

Stable Supply of High-Quality Pharmaceuticals

Quality Assurance Based on Global Standards

All of JCR's production sites implement consistent management practices encompassing the purchase of raw materials, manufacturing and product distribution, in compliance with PIC/S GMP, an international standard. JCR utilizes single-use equipment and supplies in the manufacturing of its biopharmaceutical products, with a wide range of culture medium and diagnostic agent suppliers in Japan and overseas. Because it also utilizes custom-made items, JCR enters into multiple-year contracts with suppliers worldwide and ensures quality by conducting regular on-site visits according to the level of risk.

Consistent Quality

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

Ensuring a Stable Supply

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

Ensuring Product Safety

Safety Monitoring System

Given that the safety evaluation carried out when a new product is approved is based on limited clinical trials, JCR prepares a risk management plan (RMP) and continues to collect and evaluate safety information on products after they are approved. All the information collected is evaluated immediately and the need for implementing any safety measures is considered. Concurrently, JCR compares the collected information with accumulated safety data and verifies whether there are any changes in trends. Regular safety evaluations are conducted. If safety measures are necessary, JCR will convey information swiftly and reliably to all users that require it, such as medical professionals.

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

System of Cooperation among Three Executives

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

Quality Assurance and Stable Supply

Logistics Measures

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

JCR works to grasp the conditions surrounding pharmaceutical logistics and to make daily improvements. In the process, JCR strives to achieve "seamless logistics" by establishing internally developed logistics standards, along with implementing logistics measures in compliance with Good Distribution Practice (GDP) guidelines.

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

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

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

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

Voluntary Pledge on Actions to Realize Sustainable Logistics

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

Action Policy	JCR recognizes that securing the sustainable and stable logistics essential to business activities is a key management priority. Accordingly, JCR will work to improve logistics by fostering mutual understanding and cooperation with business partners, logistics service providers and other related parties, with a view to achieving highly productive logistics and workstyle reforms.
Considerations for Compliance	JCR will make the necessary considerations to ensure that the logistics service providers of its business partners are able to comply with laws and regulations related to labor matters and the motor truck transportation business. For example, JCR will respond appropriately to revise the content of contracts and transportation services in cases where there is a risk of a violation of laws and regulations.
Clarification and Compliance with the Content of Contracts	JCR will strive to clarify the content of contracts related to transportation services and non-transportation services such as loading/unloading and inspection. Concurrently, JCR will strive to ensure compliance with the content of contracts by obtaining the cooperation of business partners, logistics service providers and other related parties.

Environment

Related SDGs

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, including those used at plants and the Research Institute, to hybrid cars and electric vehicles. In addition, we have promoted measures such as reducing water use at manufacturing sites, along with adopting single-use bioreactors to ensure the efficient use of manufacturing facilities.

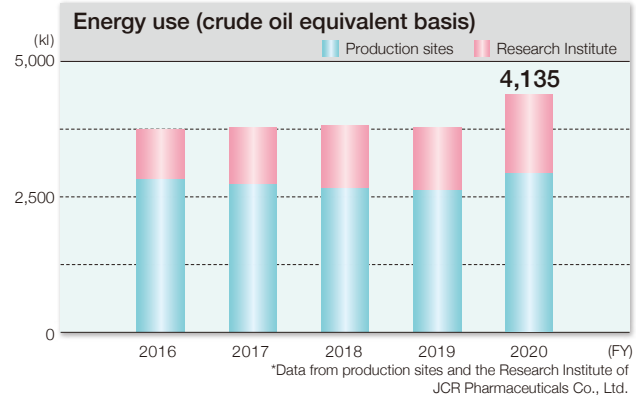
JCR plans to make active use of renewable energy sources, such as solar power generation, at new manufacturing sites that it will begin constructing from FY2021. Additionally, environmentally friendly investments will be made as part of our efforts to further upgrade and expand production sites, which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

Eyeing global business expansion in the future, JCR will consider matters such as developing more specific environmental targets and setting targets that are ideal for the Company.

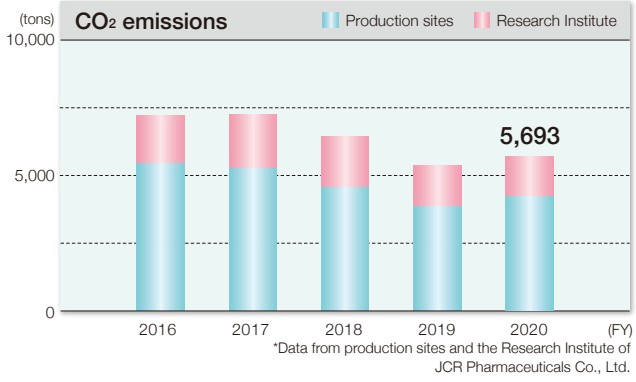
Electric vehicle

Energy Use

JCR has seen an uptrend in total energy use (electricity, gas) as its business results have grown. In the Research Division, total energy use has increased with the opening of the Clinical Trial Material Manufacturing Center (CTMC) and Cell Processing Center (CPC) in 2016. In the Production Division, total energy use has remained mostly flat, mainly owing to the installation of highly energy-efficient equipment and changes in how we use energy. CO_2 emissions from business activities in FY2020 were 244 tons, decreasing by almost half compared with 430 tons in FY2019. This decrease was mainly because we restrained our business activities amid the COVID-19 pandemic.



*Data from production sites and the Research Institute of JCR Pharmaceuticals Co., Ltd.



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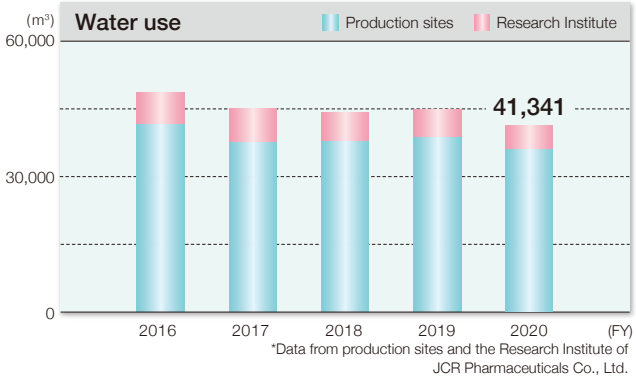


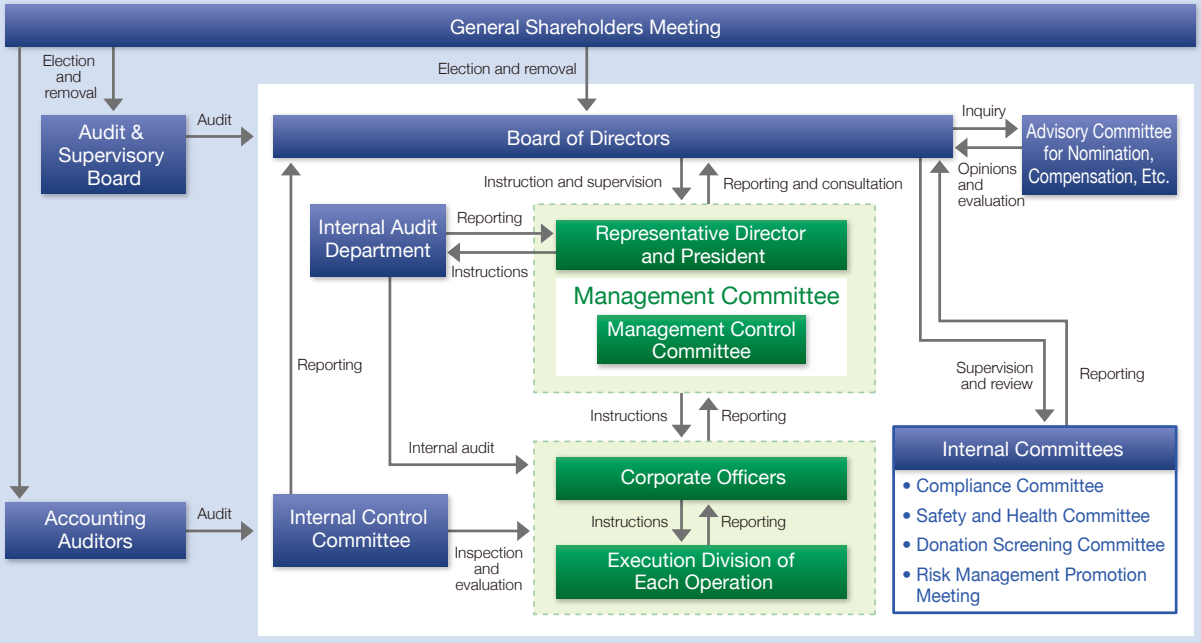
*Data from production sites and the Research Institute of JCR Pharmaceuticals Co., Ltd.

Water Resources

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

Corporate Governance

Corporate Governance System (As of June 23, 2021)



Related SDGs

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.

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 nine Directors, including four 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., Management Committee, Internal Audit Department, Internal Control Committee, Compliance Committee, Safety and Health Committee, Donation Screening Committee and Risk Management Promotion Meeting. As for the composition of the corporate governance system we believe the corporate governance system covers an appropriate scope in line with our current condition, and that it enables efficient management of business operations. Also, we have judged that the current governance system, which includes four 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 nine Directors, and in principle, an ordinary Board of Directors' meeting is held once per month, and an extraordinary Board of Directors' meeting is held as necessary. The Board of Directors decides important matters concerning the management of the Company in addition to matters specified by laws and regulations.

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

Management Control Committee

The Management Control Committee consists of Representative Directors and Internal Directors. The Management Committee deliberates and decides important management matters related to management policy, management strategy and other priorities, in principle. However, the Management Control Committee operates as a meeting body when expeditious responses are needed depending on the matter in question.

Advisory Committee for Nomination, Compensation, Etc.

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

Management Committee

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

Corporate Officer System

We have introduced the corporate officer system for the purpose of ensuring the efficiency of management of the Company and to accelerate the execution of operations. Four Corporate Officers execute operations based on the management policy decided by the Board of Directors.

Audit & Supervisory Board

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

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

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

Internal Audit Department

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

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

Internal Control Committee

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

Compliance Committee

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

Safety and Health Committee

JCR has set up the Safety and Health Committee for the purposes of securing the safety and health of employees at our workplaces, and establishing and promoting a comfortable work environment. The Committee consists of employees selected from each division of JCR, along with a licensed social insurance labor consultant, and industrial physicians, all of whom serve as outside committee members. The Committee holds meetings every month to report on the status of each workplace and exchange opinions, as it works to secure and improve occupational safety and health.

Donation Screening Committee

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

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

Risk Management Promotion Meeting

JCR has established the Risk Management Promotion Meeting, which is led by the Risk Management Officer (Director) appointed by President Shin Ashida, and includes division general managers (or department general managers 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 procedures for risk control in each of its divisions along with ascertaining risk in business activities. It also determines basic risk management guidelines and develops its risk management system based on those guidelines. Furthermore, JCR is creating systems to address risk prevention, risk management, and risk contingencies through collaboration with related committees such as the Risk Management Promotion Office, Internal Control Committee and Compliance Committee.

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

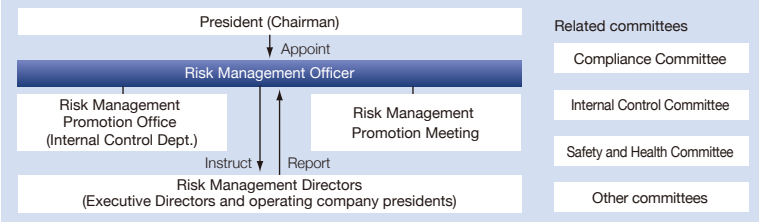
1. Response measures in the event of a disruption in the supply of GROWJECT®
2. Company-wide response measures in the event of a large-scale disaster
3. Response measures in the event of a major compliance violation

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

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

Risk Management System

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



Composition, Number of Meetings Held, and Attendance Rate for Internal Committees and Other Organs of the Company in FY2020 (As of end of FY2020)

Advisory Committee for Nomination, Compensation, Etc.		Composition	6 members (1 Internal Director, 3 Independent Outside Directors, 2 Independent Outside Audit & Supervisory Board Members)
		Number of meetings held	7
		Attendance rate	100.00%
Internal Control Committee		Composition	9 members (1 Executive Director of Administration Div., 1 from Legal Affairs Dept., 4 from Internal Audit Dept., 1 from Accounting Dept., 1 from General Affairs Dept., and 1 from Production Management Dept.)
		Number of meetings held	6
		Attendance rate	92.31%
Compliance Committee	Compliance Control Committee	Composition	13 members (2 attorneys, 5 Internal Directors, 1 Independent Outside Audit & Supervisory Board Member, 4 Corporate Officers, 1 from Legal Affairs Dept.)
		Number of meetings held	2
		Attendance rate	100.00%
	Compliance Promotion Committee	Composition	18 members (1 from Legal Affairs Dept., 3 from HR Development & Compliance Dept., 1 from General Affairs Dept., 1 from Sales Div., 2 from Development Div., 2 from Research Div., 6 from Production Div., 1 from Pharmacovigilance Dept., 1 from Tokyo Office)
		Number of meetings held	3
		Attendance rate	100.00%
Safety and Health Committee		Composition	14 members (1 licensed social insurance labor consultant, 2 industrial physicians, 2 from Human Resources Dept., 2 from General Affairs Dept., 1 from Sales Div., 1 from Corporate Planning Div., 1 from HQ Quality Assurance Dept., 1 from Tokyo Office, 1 from Development Div., 2 from Safety and Health Committee)
		Number of meetings held	12
		Attendance rate	91.48%
Donation Screening Committee		Composition	8 members (1 Adviser, 1 Executive Director of Administration Division, 1 from Legal Affairs Dept., 1 from Accounting Dept., 1 from General Affairs Dept., and 3 from HR Development & Compliance Dept.)
		Number of meetings held	7
		Attendance rate	91.07%
Risk Management Promotion Meeting		Composition	18 members (4 Internal Directors, 1 Independent Outside Audit & Supervisory Board Member, 4 Corporate Officers, 1 from Quality Assurance Dept., 1 from Regulatory Affairs Dept., 1 from Pharmacovigilance Dept., 2 from Medical Affairs Dept., 1 from Internal Audit Dept., 3 from subsidiaries)
		Number of meetings held	2
		Attendance rate	100.00%

Outside Directors and Outside Audit & Supervisory Board Members

Functions and Roles of Outside Directors

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

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

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

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

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

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

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

Skill Matrix of Directors and Audit & Supervisory Board Members and Attendance Rate at Board of Directors and Audit & Supervisory Board Meetings in FY2020

			Advisory Committee for Nomination, Compensation, Etc.	Skill											Attendance Rate of the Board Meetings (FY2020)
				Overall Management	Industry Knowledge	Global Experience	R&D	Production	Sales	ICT	Administrative Experience	Legal Affairs	Tax, Finance and Accounting	Other	
Board of Directors	Shin Ashida	Representative Director CEO & COO	●	●											100%
	Toru Ashida	Senior Vice President		●	●				●				●		100%
	Mathias Schmidt	Vice President			●	●	●								100%
	Hiroyuki Sonoda	Vice President			●		●								100%
	Yoshio Hiyama	Senior Executive Director			●	●		●				●		Quality and safety	—
	Toshihiro Ishikiriyama	Director (Independent/Outside)	●	●	●	●	●	●	●				●		100%
	Takashi Suetsuna	Director (Independent/Outside)	●			●					●	●	●		100%
	Toshihide Yoda	Director (Outside)		●	●	●							●		93%
	Yuko Hayashi	Director (Independent/Outside)	●	●		●	●			●					100%
Audit & Supervisory Board	Kazumasa Oizumi	Audit & SBM* (Independent/Outside)	●	●					●					Audit experience	100%
	Kazuhiko Yamada	Audit & SBM* (Independent/Outside)									●		●		100%
	Kenjiro Miyatake	Audit & SBM* (Independent/Outside)		●	●				●		●				100%
	Takeshi Komura	Audit & SBM* (Independent/Outside)	●	●							●	●	●		100%
	Shuichi Tani	Audit & SBM* (Independent/Outside)			●						●				100%

* Audit & Supervisory Board Member

Board of Directors and Corporate Officers

(As of July 1, 2021)

Directors (From left) Hiroyuki Sonoda, Toru Ashida, Shin Ashida, Mathias Schmidt, Yoshio Hiyama

Shin Ashida

Representative Director
Chairman, President, CEO and COO

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

Hiroyuki Sonoda, Ph.D.

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

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

Toru Ashida

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

1992 Entered Nippon Life Insurance Company
2006 Appointed Representative Director and President at the establishment of JBS Co., Ltd.
2014 Entered JCR Pharmaceuticals
Appointed Corporate Officer
Executive Director, Corporate Business Support Division and Director, Corporate Strategy Department
2016 General Manager, Office of the President
2018 Appointed Director
Head of Quality Assurance Division, Corporate Planning Division, Medical Affairs Department and Office of the President
2019 In charge of Corporate Strategy
Head of Quality Assurance Division, Administration Division, Medical Affairs Department and Office of the President
2020 Executive Director, Sales Division (current post)
Appointed Vice President
In charge of Corporate Strategy and Head of Sales Division
2021 Appointed Senior Vice President (current post)
In charge of Sales and Administration (current post)

Yoshio Hiyama, Ph.D.

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

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

Mathias Schmidt, PD, Ph.D.

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

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

Outside Director

(From left) Toshihide Yoda, Toshihiro Ishikiriyama, Takashi Suetsuna, Yuko Hayashi

Toshihiro Ishikiriyama
Outside Director

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

Takashi Suetsuna
Outside Director

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

Toshihide Yoda
Outside Director

1985 Entered Nippon Kangyo Kakumaru Securities
1989 Entered UBS Securities Japan Co., Ltd.
1996 Entered ING Bearing Securities
2000 Entered Lehman Brothers Securities
2009 Entered Barclays Capital Securities Japan Limited
Managing Director of the same
2010 Director, MEDIPAL HOLDINGS CORPORATION
2012 Director and Managing Director of the same
In charge of IR and General Manager, Business Development Department CMA® of the same (current post)
2016 Director, SPLine Corporation
Director, MEDIE Co., Ltd. (current post)
Director, MEDICEO CORPORATION (current post)
2018 Director, JCR USA, Inc. (current post)
Senior Managing Director, MEDIPAL HOLDINGS CORPORATION (current post)
Appointed Director, JCR Pharmaceuticals (current post)
2020 Manager, Business Investment Department, Business Development Division, MEDIPAL HOLDINGS CORPORATION (current post)
2021 Director, PharField Corporation (current post)

Yuko Hayashi, Ph.D.
Outside Director

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

Corporate Officers

Yutaka Honda
Corporate Officer
Executive Director,
Administration Division
(reporting to the president)

Takayo Egawa
Corporate Officer
Director, International Affairs Office

Kazunori Tanizawa
Corporate Officer
Executive Director,
Development Division

Junichi Ando
Corporate Officer
Executive Director,
Quality Assurance Division

Audit & Supervisory Board Members/Messages from Outside Directors and Outside Audit & Supervisory Board Members

(As of July 1, 2021)

Audit & Supervisory Board Members

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

Kazumasa Oizumi
Full-Time Outside Audit & Supervisory Board Member

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

Kazuhiko Yamada
Outside Audit & Supervisory Board Member

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

Kenjiro Miyatake
Outside Audit & Supervisory Board Member

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

Takeshi Komura
Outside Audit & Supervisory Board Member

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

Shuichi Tani, M.D., M.P.H.
Outside Audit & Supervisory Board Member

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

Targeting Global Business Expansion

Toshihiro Ishikiriyama
Outside Director

With the launch of the groundbreaking drug IZCARGO®, JCR is about to start implementing globalization in earnest in the rare disease arena. Global business expansion and growth in the size of the Company will spur a dramatic transformation in JCR's corporate culture. Under the Midterm Business Plan for FY2020-FY2022 "REVOLUTION," JCR has set out to develop "Team JCR," the source of its value, within a corporate culture that has an abundance of diversity. JCR will clearly define what it means by "Team JCR," foster a shared understanding of "Team JCR" among all team members and strive to develop "Team JCR" into an integral part of its corporate culture. Establishing the "Team JCR" concept will involve a wide range of stakeholders reflecting a diverse mix of people and will enable JCR to evolve without losing sight of its core values.

Aiming for Future Global Business Expansion

Currently, JCR is implementing Midterm Business Plan for FY2020-FY2022 "REVOLUTION," a 3-year plan that began in FY2020. Besides this plan, JCR has drawn up the Mid- to Long-Term Management Vision "Toward 2030." This outstanding and promising vision foresees growth in JCR's business scale through FY2030. Notably, JCR has developed treatments for lysosomal storage diseases (LSDs) such as IZCARGO®, which was launched in 2021. The development of these pharmaceutical products is highly anticipated to drive global business expansion beyond JCR's existing activities in the rare disease arena. In these ways, given that business expansion is almost inevitable, I believe that JCR's greatest priority is to nurture and recruit versatile human resources who can fully support this globalization. Indeed, I'm convinced that now is the time when every member of "Team JCR," the cornerstone of JCR's proud corporate culture, must urgently strive to increase JCR's corporate value through self-improvement and hard work.

Takashi Suetsuna
Outside Director

Human Resource Development

Toshihide Yoda
Outside Director

Human resource development is a key priority at every company. For companies large or small, the growth of their business models is driven by human resources who can work proactively with strong ownership. At companies like JCR that are rapidly expanding their business scale, human resources often fall behind the growth of these companies. Human resource development requires improvement in skills as well as diversity. When companies like JCR that have only carried out business in Japan shift to expanding their business overseas, they will need to not only improve their workforce's foreign language skills, but also recruit human resources who are well versed in overseas systems. There is a need not only to develop people internally, but also to appoint human resources from the outside. Building a flexible corporate culture will surely be necessary.

SDG Initiatives

Yuko Hayashi, Ph.D.
Outside Director

Technology and innovation are expected to contribute to a sustainable society. This initiative has been described as Science, Technology and Innovation for the Sustainable Development Goals (SDGs). One example of this initiative is JCR's swift manufacturing of a COVID-19 vaccine bulk solution, which was outsourced from AstraZeneca K.K. The manufacturing of this vaccine bulk solution through a sophisticated technology transfer will help to save many people's lives. Meanwhile, there are now clear differences in vaccination rates between advanced and developing countries. The emergence of such healthcare disparity is a serious concern. From the standpoint of the SDGs, the international community is being called upon to ensure equitable vaccine distribution through the COVAX initiative and government-level talks. It will be crucial for JCR to contribute through technology as a global enterprise, along with focusing on building a sustainable society.

SDGs and JCR

Audit & Supervisory Board Members have a duty as an independent body to ensure JCR's sound and sustained growth and improvement in corporate value by conducting effective audits through a process of consolidating the results of their audit activities and the activities of the Accounting Auditors and the Internal Audit Department. JCR's market capitalization has increased from 81.0 billion yen in early 2013, when I was appointed as an Audit & Supervisory Board Member, to 464.9 billion yen in early 2021, marking a 5.7-fold increase. During this time, JCR has advanced not only its business domains in Japan, but it has also pushed ahead with the globalization of its business domains by leveraging the world's first pharmaceutical products of their kind. JCR has dramatically transformed its research and manufacturing facilities, products, intellectual property, human resources, organizations and other aspects. Looking ahead, one urgent management priority for JCR will be to meet the expectations of stakeholders by increasing JCR's economic value along with its social value and sustainability. Doing so will entail measures to address, among other matters, the Task Force on Climate-Related Financial Disclosures (TCFD), in addition to Japan's Corporate Governance Code.

Kazumasa Oizumi
Full-Time Outside Audit & Supervisory Board Member

Improving Tax Governance

Kazuhiko Yamada
Outside Audit & Supervisory Board Member

JCR will need to implement appropriate measures to address tax and accounting, particularly international tax matters, such as transfer price information and valuation of intangible assets. JCR has decided to outsource these duties because of the complexity of national tax systems in other countries, among other factors. Apart from this, it will also be important for JCR to review and consider how it coordinates its Group information and how it assigns personnel to specialist positions.
JCR should consider the following measures:
(1) Share effective overseas information in collaboration and partnership with audit firms and other partners;
(2) Confirm appropriate decision-making through tax corporate governance (national tax) and prior consultation systems; and
(3) Strengthen systems by developing in-house subject-matter experts and forming specialist teams.
Through these and other measures, I believe that it is crucial for JCR to address the issue of enhancing the overall level of its business processes.

Priorities for JCR to Develop Further

Kenjiro Miyatake
Outside Audit & Supervisory Board Member

Generally, the mission of a company is to sustain and develop its business, thereby contributing to society. The mission of a research-oriented specialty pharma is to contribute to better health and treatment options for people. JCR's corporate philosophy is "Contributing towards people's healthcare through pharmaceutical products." This corporate philosophy acknowledges that illnesses have no national borders, and that JCR can improve the lives of all people suffering from illnesses by delivering pharmaceutical products to the farthest reaches of the world. However, most pharmaceutical companies in the modern world have repeatedly conducted mergers and acquisitions, as part of efforts to enlarge their business scale. Meanwhile, the current reality is that the number of people suffering from rare diseases has only continued to increase around the world, and almost no progress has been made on research and development in the rare disease arena because there are relatively few patients with such rare diseases. I believe that the most important priority for pharmaceutical companies whose mission is research and development is not expansion in scale, but growth and evolution in quality. Human resources are the foundation of such pharmaceutical companies. The key to their future development lies in developing their human resource capabilities.

Seeking Authentic Management

Companies in a growth phase that are not clinging to past successes are resilient in periods of rapid change and can adequately absorb the demands of the new era. Therein lies JCR's strength. In recent times, many issues have come to the fore in corporate management, such as ESG and SDGs, compliance, gender, and digital transformation (DX). Business magazines and other media sources have provided information about these issues to stakeholders, including investors, by announcing company rankings and so forth. Clearly, external stakeholders are looking at companies much more strictly than they did before. Meanwhile, companies that are dependent on past traditions and strengths may be unable to respond immediately when confronted with issues concerning what they should preserve and what they should change. For the time being, these companies are likely to go along with current trends, take great pains to implement outward-facing measures, conduct skillful PR campaigns, and put on appearances. I often see examples of this happening at prestigious major companies. JCR, which is still in a growth phase, should not get caught up in these trends. In my view, rather than putting on outward appearances, JCR should steadfastly implement authentic management appropriate to current conditions.

Takeshi Komura
Outside Audit & Supervisory Board Member

Priorities for Strengthening Governance

Shuichi Tani, M.D., M.P.H.
Outside Audit & Supervisory Board Member

First, I believe that JCR needs to work to enhance functions related to internal control of the Board of Directors, which received low marks in the assessment of the effectiveness of the Board of Directors carried out in March 2021, and to improve the implementation status, reporting of activities and certain other aspects of the Advisory Committee for Nomination, Compensation, Etc. Moreover, JCR is making progress on research and development focused on ten-odd treatments of lysosomal storage disorders (LSDs), following on from IZCARGO®, which is at the vanguard of LSD treatments. This progress offers prospects for obtaining approval overseas. JCR is now in the stage where it should prepare at the earliest opportunity to build a framework for global business expansion. I will fulfill my duties so that JCR can address its future advancement and transformation, with the aim of enhancing its corporate value.

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, along with the dedicated electronically controlled injector, GROWJECTOR® L. Sales of the liquid formulation and injector have grown steadily.

【Indications】• Growth hormone deficiency • Adult growth hormone deficiency
• Turner syndrome • Small for gestational age

Therapeutic Products for Renal Anemia

Recombinant erythropoietin product

Epoetin Alfa BS Inj. [JCR]*

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

【Indications】• Renal anemia in dialysis patients • Anemia of prematurity

Long-acting erythropoiesis-stimulating agent

Darbepoetin Alfa BS Inj. [JCR]*

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

【Indication】• Renal anemia

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

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

Recombinant treatment for Fabry disease

Agalsidase Beta BS I.V. Infusion [JCR]

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

【Indication】• Fabry disease

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

Development Pipeline and Progress (As of August 2021)

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)	Brazil	Filed	Enzyme replacement therapy (ERT) J-Brain Cargo®*1
			Global	Phase III	
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-162	J-Brain Cargo®-applied acid α-glucosidase (rDNA origin)	Pompe disease	—	Preclinical	ERT J-Brain Cargo®
JR-441	BBB-penetrating heparan N-sulfatase (rDNA origin)	Mucopolysaccharidosis III-A (Sanfilippo syndrome type A)	—	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-401X	Somatropin (rDNA origin)	SHOX deficiency	Japan	Phase III	Expanded indication of GROWJECT®
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	Expanded indication of TEMCELL® HS Inj.
JTR-161/ JR-161	Dental pulp stem cells (DPCs)	Acute cerebral infarction	Japan	Phase I/II	Co-developed with Teijin Ltd. Regenerative medical product

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

Operating Results

Net Sales

Sales of our core product, GROWJECT® (human growth hormone product), increased year on year, as a steady sales trend outweighed the negative impact of National Health Insurance price revisions. In therapeutic products for renal anemia, total sales of JCR's therapeutic products for renal anemia increased year on year, supported by an increase in sales of Darbepoetin Alfa BS Inj. [JCR], a long-acting erythropoiesis-stimulating agent, while there was a decrease in sales of Epoetin Alfa BS Inj. [JCR]. Sales of TEMCELL® HS Inj. (regenerative medical product) decreased year on year because of the impact of implementing supply restrictions from April to August 2020, for the purpose of stockpiling additional inventories in response to greater-than-anticipated demand. Moreover, in March 2021, JCR commenced shipments of AZD1222 bulk solution, which was outsourced from AstraZeneca K.K. Furthermore, revenue from licensing increased year on year. As a result, the JCR Group's net sales for FY2020 amounted to 30,085 million yen (21.4% increase from the previous fiscal year), marking the ninth straight year of sales growth and record-high sales.

Trend of Sales by Product (Unit: Million yen)

	FY2019	FY2020
GROWJECT®	12,650	**13,256**
Epoetin Alfa BS Inj. JCR	4,097	**3,278**
Darbepoetin Alfa BS Inj. [JCR]	1,412	**3,809**
TEMCELL® HS Inj.	3,126	**2,441**
Agalsidase Beta BS I.V. Infusion [JCR]	317	**470**
Urine-derived products	1,041	—
AZD1222 bulk solution	—	**404**
Revenue from licensing	2,050	**6,406**
Others	84	**19**
Total	24,781	**30,085**

Gross Profit

Due to the increase in net sales, gross profit increased 31.9% from the previous fiscal year to 22,272 million yen. As a result of the increase in revenue from licensing, the cost of sales ratio improved 5.9 percentage points from FY2019 to 26.0%.

Operating Income

JCR conducted efficient R&D activities, resulting in a decrease in R&D expenditures of 10.6% from FY2019, and selling, general and administrative expenses, including R&D expenditures, were 14,003 million yen, up 2.7% from the previous fiscal year. As a result, operating income increased 154.9% year on year to 8,269 million yen.

Ordinary Income

JCR recorded non-operating income, primarily foreign exchange gains. As a result, ordinary income increased 157.7% year on year to 8,488 million yen.

Profit Attributable to Owners of Parent

Extraordinary income was 170 million yen, an increase of 38 million yen year on year, mainly due to factors such as the recording of reversal of provision for loss on guarantees. As a result of the foregoing, income before income taxes was 8,653 million yen, up 152.8% year on year. Profit attributable to owners of parent rose 157.4% year on year to 6,892 million yen.

Financial Position

Assets

Total assets as of March 31, 2021 stood at 73,784 million yen, an increase of 26,008 million yen from March 31, 2020.

Current assets rose 20,203 million yen from a year earlier to 48,545 million yen. This increase was mainly due to an increase in cash and deposits and inventories. Non-current assets increased 5,805 million yen from a year ago to 25,238 million yen. This increase was mainly due to the recording of patent rights following the acquisition of ArmaGen, Inc. in the U.S. and the acquisition of land for the construction of a new COVID-19 bulk solution plant.

Liabilities

Total liabilities as of March 31, 2021 stood at 35,227 million yen, an increase of 20,031 million yen from March 31, 2020.

Current liabilities rose 18,594 million yen from a year earlier to 29,028 million yen. This increase was mainly due to an increase in short-term loans payable. Non-current liabilities increased 1,437 million yen from March 31, 2020 to 6,199 million yen. This increase was mainly due to increases in bonds payable and long-term loans payable.

Net Assets

Net assets rose 5,977 million yen from March 31, 2020 to 38,557 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, 2021 was 51.3%, down 15.3 percentage points from March 31, 2020.

Cash Flow

Net cash provided by operating activities in FY2020 amounted to 10,341 million yen, an increase of 5,413 million yen from the previous fiscal year. The main components were income before income taxes of 8,653 million yen, depreciation and amortization of 1,892 million yen, and an increase in inventories of 4,699 million yen.

Net cash used in investing activities amounted to 3,290 million yen (a decrease of 870 million yen from net cash used in the previous fiscal year). Cash was used mainly for the purchase of property, plant, and equipment of 4,780 million yen and the purchase of patent rights of 2,747 million yen, while there were subsidies received of 3,892 million yen.

Net cash provided by financing activities amounted to 8,304 million yen (an increase of 6,255 million yen from cash provided in the previous fiscal year). Cash was provided by a net increase in short-term loans payable of 8,320 million yen, while there were cash dividends paid of 1,083 million yen.

Forecast for FY2021

In terms of sales, we anticipate an increase in sales of our mainstay product GROWJECT® on top of a steady increase in sales volume. In addition, we started sales of IZCARGO®, a treatment of mucopolysaccharidosis II, in May 2021, and we will continue our proactive efforts in manufacturing AstraZeneca K.K.'s COVID-19 vaccine bulk solution and the licensing business. Based on these factors, the JCR Group's overall sales are forecast at 49,000 million yen, an increase of 62.9% from the current fiscal year.

Although we are planning to pursue research and development activities even more proactively, we are forecasting increases in profits based on an increase in gross profit associated with sales growth. We anticipate operating income of 18,700 million yen, up 126.1% from the current fiscal year. Ordinary income is forecast to increase 120.3% year on year to 18,700 million yen. Profit attributable to owners of parent is forecast at 13,300 million yen, an increase of 92.9% from the current fiscal year.

Dividends Policy

Basic Policy on Profit Distribution and Dividends

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

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

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

JCR marked its 45th founding anniversary on September 13, 2020. Therefore, to express our gratitude to our shareholders, we decided to pay a commemorative dividend of 0.5 yen per share as part of the term-end dividend for FY2020.

Given that we achieved record-high operating results, under the above basic policy, we will pay out a term-end dividend for FY2020 of 7.5 yen per share (including the commemorative dividend of 0.5 yen per share). Excluding the impact of a stock split, the term-end dividend for FY2020 would be 30 yen per share. Together with the interim dividend of 18 yen per share, the total annual dividend would be 48 yen per share, an increase of 16 yen from the previous fiscal year.

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

We expect to pay out a full-year dividend for FY2021 (the term ending March 2022) of 16 yen per share, comprising an interim dividend and term-end dividend of 8 yen each.

11-Year Financial Data

Consolidated fiscal years ended March 31

	FY2010	FY2011	FY2012	FY2013
Fiscal year				
Net sales	14,457	12,845	14,099	15,705
Operating income	1,407	1,089	1,150	1,545
Profit attributable to owners of parent	926	633	730	1,296
Comprehensive income	783	664	1,161	1,544
R&D expenditures	2,017	1,841	1,991	2,202
Capital investment	2,417	487	1,494	2,260
Depreciation and amortization	975	1,101	979	1,111
Cash flows from operating activities	(18)	(421)	1,661	4,565
Cash flows from investing activities	(2,211)	1,539	(178)	(2,668)
Cash flows from financing activities	(1,276)	(1,065)	(238)	(369)
End of fiscal year				
Total assets	29,817	28,967	31,286	33,464
Net assets	22,832	22,633	23,496	24,580
Shareholders' equity	22,762	22,535	23,368	24,417
Information per share				
Earnings per share (EPS)	7.23	4.94	5.76	10.20
Net assets	176.24	177.70	183.97	192.03
Dividends	12.00	12.00	12.00	17.00
Financial indicators				
Equity ratio (%)	76.3	77.8	74.7	73.0
Return on equity (ROE) (%)	4.3	2.8	3.2	5.4
Dividend payout ratio (%)	41.5	60.8	52.1	41.7
Numbers of employees	399	424	437	472

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 FY2010. Dividends under information per share represent the actual 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. This amount is equivalent to an annual dividend per share of 48.00 yen that would be calculated if the impact of the stock split had been excluded.

(Millions of yen)

FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	**FY2020**
16,855	17,438	18,085	20,594	23,160	24,781	**30,085**
2,014	2,152	2,362	3,784	4,967	3,244	**8,269**
1,682	1,789	1,863	3,070	3,715	2,678	**6,892**
1,936	1,557	1,831	3,016	4,008	2,504	**6,841**
3,334	3,348	4,071	4,211	4,354	5,997	**5,360**
1,522	1,237	1,409	908	1,517	5,296	**3,965**
1,352	1,407	1,447	1,382	1,343	1,434	**1,892**
499	2,201	2,651	3,133	3,905	4,927	**10,341**
(1,419)	(980)	(841)	(1,587)	240	(4,161)	**(3,290)**
(1,261)	(1,314)	146	(2,175)	(917)	2,048	**8,304**
34,086	35,346	36,385	38,398	42,516	47,775	**73,784**
26,264	27,062	27,585	27,528	30,874	32,579	**38,557**
26,101	26,819	27,305	26,999	30,249	31,806	**37,864**

(Yen)

13.21	14.03	14.74	24.68	30.17	21.72	**55.81**
204.66	210.84	216.17	219.46	245.54	257.92	**306.31**
18.50	22.00	22.00	26.00	30.00	32.00	**25.50**
76.6	75.9	75.0	70.3	71.1	66.6	**51.3**
6.6	6.8	6.9	11.3	13.0	8.6	**19.8**
35.0	39.2	37.3	26.3	24.9	36.8	**21.5**
501	526	566	568	632	667	**732**

(Millions of yen)

Consolidated Balance Sheets

	As of March 31, 2020	**As of March 31, 2021**
Assets		
Current assets		
Cash and deposits	10,973	**26,260**
Notes and accounts receivable-trade	7,977	**8,183**
Securities	220	**—**
Merchandise and finished goods	880	**1,367**
Work in process	2,929	**3,538**
Raw materials and supplies	5,046	**8,649**
Other	315	**546**
Total current assets	28,342	**48,545**
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	5,115	**6,295**
Machinery, equipment and vehicles, net	867	**1,282**
Land	5,664	**7,663**
Construction in progress	2,283	**841**
Other, net	944	**1,088**
Total property, plant and equipment	14,875	**17,172**
Intangible assets		
Patent rights	—	**2,988**
Other	263	**244**
Total intangible assets	263	**3,232**
Investments and other assets		
Investment securities	2,408	**2,572**
Net defined benefit asset	243	**225**
Deferred tax assets	721	**1,739**
Other	943	**300**
Allowance for doubtful accounts	(23)	**(4)**
Total investments and other assets	4,294	**4,833**
Total non-current assets	19,433	**25,238**
Total assets	47,775	**73,784**

(Millions of yen)

	As of March 31, 2020	**As of March 31, 2021**
Liabilities		
Current liabilities		
Notes and accounts payable-trade	679	**2,932**
Short-term loans payable	4,880	**12,850**
Income taxes payable	534	**2,646**
Special suspense account for tax purpose reduction entry	—	**3,828**
Provision for bonuses	713	**850**
Provision for directors' bonuses	77	**63**
Other	3,549	**5,855**
Total current liabilities	10,434	**29,028**
Non-current liabilities		
Bonds payable	—	**500**
Long-term loans payable	3,800	**4,750**
Provision for loss on guarantees	108	**—**
Allowance for employee stock ownership benefits	47	**62**
Net defined benefit liability	730	**798**
Other	75	**88**
Total non-current liabilities	4,761	**6,199**
Total liabilities	15,195	**35,227**
Net assets		
Shareholders' equity		
Capital stock	9,061	**9,061**
Capital surplus	10,891	**10,941**
Retained earnings	15,039	**20,904**
Treasury stock	(3,865)	**(3,685)**
Total shareholders' equity	31,127	**37,222**
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	583	**691**
Deferred gains or losses on hedges	—	**0**
Foreign currency translation adjustment	134	**(18)**
Remeasurements of defined benefit plans	(39)	**(31)**
Total accumulated other comprehensive income	679	**641**
Stock acquisition rights	584	**517**
Non-controlling interests	189	**174**
Total net assets	32,579	**38,557**
Total liabilities and net assets	47,775	**73,784**

(Millions of yen)

Consolidated Statements of Income

	FY2019 (From April 1, 2019 to March 31, 2020)	**FY2020 (From April 1, 2020 to March 31, 2021)**
Net sales	24,781	**30,085**
Cost of sales	7,901	**7,812**
Gross profit	16,880	**22,272**
Selling, general and administrative expenses	13,635	**14,003**
Operating income	3,244	**8,269**
Non-operating income		
Interest income	19	**7**
Dividend income	25	**25**
Foreign exchange gains	8	**206**
Other	28	**65**
Total non-operating income	81	**305**
Non-operating expenses		
Interest expenses	22	**42**
Commission expenses	—	**11**
Other	9	**31**
Total non-operating expenses	32	**85**
Ordinary income	3,293	**8,488**
Extraordinary income		
Gain on liquidation of subsidiaries and associates	—	**22**
Reversal of provision for loss on guarantees	131	**108**
Reversal of allowance for doubtful accounts	—	**19**
Reversal of losses related to voluntary recall	—	**19**
Total extraordinary income	131	**170**
Extraordinary losses		
Loss on disposal of non-current assets	2	**5**
Total extraordinary losses	2	**5**
Income before income taxes	3,422	**8,653**
Income taxes – current	1,017	**2,836**
Income taxes – deferred	(274)	**(1,072)**
Total income taxes	742	**1,764**
Profit	2,679	**6,888**
Profit (loss) attributable to non-controlling interests	1	**(4)**
Profit attributable to owners of parent	2,678	**6,892**

Consolidated Statements of Comprehensive Income

Profit	2,679	**6,888**
Other comprehensive income		
Valuation difference on available-for-sale securities	(189)	**107**
Deferred gains or losses on hedges	—	**0**
Foreign currency translation adjustment	(18)	**(162)**
Remeasurements of defined benefit plans, net of tax	32	**7**
Total other comprehensive income	(175)	**(47)**
Comprehensive income	2,504	**6,841**
(Comprehensive income attributable to)		
Comprehensive income attributable to owners of parent	2,505	**6,855**
Comprehensive income attributable to non-controlling interests	(0)	**(14)**

Consolidated Statements of Changes in Net Assets

From April 1, 2019 to March 31, 2020

(Millions of yen)

	Shareholders' equity				
	Capital stock	Capital surplus	Retained earnings	Treasury stock	Total shareholders' equity
Beginning balance	9,061	10,922	13,350	(3,937)	29,397
Changes during the year					
Dividends paid			(989)		(989)
Profit attributable to owners of parent			2,678		2,678
Purchase of treasury shares				(1)	(1)
Disposal of treasury shares		(29)		73	43
Changes of shares of consolidated subsidiaries		(1)			(1)
Changes of items other than shareholders' equity (net)					
Total changes for the year	—	(31)	1,689	71	1,729
Ending balance	9,061	10,891	15,039	(3,865)	31,127

	Accumulated other comprehensive income							
	Valuation difference on available-for-sale securities	Deferred gains or losses on hedges	Foreign currency translation adjustment	Remeasurements of defined benefit plans, net of tax	Total accumulated other comprehensive income	Stock acquisition rights	Non-controlling interests	Total net assets
Beginning balance	773	—	149	(71)	851	435	189	30,874
Changes during the year								
Dividends paid								(989)
Profit attributable to owners of parent								2,678
Purchase of treasury shares								(1)
Disposal of treasury shares								43
Changes of shares of consolidated subsidiaries								(1)
Changes of items other than shareholders' equity (net)	(189)	—	(15)	32	(172)	149	(0)	(24)
Total changes for the year	(189)	—	(15)	32	(172)	149	(0)	1,705
Ending balance	583	—	134	(39)	679	584	189	32,579

From April 1, 2020 to March 31, 2021

(Millions of yen)

	Shareholders' equity				
	Capital stock	Capital surplus	Retained earnings	Treasury stock	Total shareholders' equity
Beginning balance	**9,061**	**10,891**	**15,039**	**(3,865)**	**31,127**
Changes during the year					
Dividends paid			**(1,083)**		**(1,083)**
Profit attributable to owners of parent			**6,892**		**6,892**
Purchase of treasury shares				**(0)**	**(0)**
Disposal of treasury shares		**49**		**181**	**230**
Changes of shares of consolidated subsidiaries		**1**	**55**		**56**
Changes of items other than shareholders' equity (net)					
Total changes for the year	**—**	**50**	**5,865**	**180**	**6,095**
Ending balance	**9,061**	**10,941**	**20,904**	**(3,685)**	**37,222**

	Accumulated other comprehensive income							
	Valuation difference on available-for-sale securities	Deferred gains or losses on hedges	Foreign currency translation adjustment	Remeasurements of defined benefit plans, net of tax	Total accumulated other comprehensive income	Stock acquisition rights	Non-controlling interests	Total net assets
Beginning balance	**583**	**—**	**134**	**(39)**	**679**	**584**	**189**	**32,579**
Changes during the year								
Dividends paid								**(1,083)**
Profit attributable to owners of parent								**6,892**
Purchase of treasury shares								**(0)**
Disposal of treasury shares								**230**
Changes of shares of consolidated subsidiaries								**56**
Changes of items other than shareholders' equity (net)	**107**	**0**	**(152)**	**7**	**(37)**	**(66)**	**(14)**	**(118)**
Total changes for the year	**107**	**0**	**(152)**	**7**	**(37)**	**(66)**	**(14)**	**5,977**
Ending balance	**691**	**0**	**(18)**	**(31)**	**641**	**517**	**174**	**38,557**

(Millions of yen)

Consolidated Statements of Cash Flows	FY2019 (From April 1, 2019 to March 31, 2020)	**FY2020 (From April 1, 2020 to March 31, 2021)**
Net cash provided by (used in) operating activities		
Income before income taxes	3,422	**8,653**
Depreciation and amortization	1,434	**1,892**
Increase (decrease) in provision for loss on guarantees	(131)	**(108)**
Increase (decrease) in net defined benefit liability	37	**74**
Increase (decrease) in provision for bonuses	46	**137**
Share-based compensation expenses	175	**149**
Interest and dividends income	(44)	**(33)**
Interest expenses	22	**42**
Foreign exchange losses (gains)	(11)	**(140)**
Decrease (increase) in notes and accounts receivable-trade	857	**(205)**
Decrease (increase) in accounts receivable-other	35	**1**
Decrease (increase) in inventories	258	**(4,699)**
Increase (decrease) in accounts payable-trade	92	**2,253**
Increase (decrease) in accounts payable-other	357	**202**
Increase (decrease) in accrued consumption taxes	(164)	**175**
Increase (decrease) in advances received	11	**2,493**
Other, net	(233)	**265**
Subtotal	6,167	**11,156**
Interest and dividends income received	44	**39**
Interest expenses paid	(22)	**(46)**
Income taxes (paid) refund	(1,262)	**(807)**
Net cash provided by (used in) operating activities	4,927	**10,341**
Net cash provided by (used in) investing activities		
Expenditures on time deposits	—	**(300)**
Purchase of securities	100	**345**
Proceeds from sales and redemption of securities	698	**239**
Purchase of property, plant and equipment	(4,838)	**(4,780)**
Subsidies received	—	**3,892**
Purchase of patent rights	—	**(2,747)**
Purchase of investment securities	(30)	**(91)**
Other, net	(91)	**152**
Net cash provided by (used in) investing activities	(4,161)	**(3,290)**
Net cash provided by (used in) financing activities		
Increase (decrease) in short-term loans payable	1,000	**8,320**
Proceeds from long-term loans payable	3,050	**1,250**
Repayment of long-term loans payable	(850)	**(650)**
Proceeds from issuance of bonds	—	**500**
Repayments of lease obligations	(176)	**(47)**
Net decrease (increase) in treasury stock	15	**13**
Cash dividends paid	(989)	**(1,083)**
Other, net	(1)	**1**
Net cash provided by (used in) financing activities	2,048	**8,304**
Effect of exchange rate change on cash and cash equivalents	20	**(22)**
Net increase (decrease) in cash and cash equivalents	2,836	**15,332**
Cash and cash equivalents at beginning of period	8,091	**10,928**
Cash and cash equivalents at end of period	10,928	**26,260**

As of March 31, 2021

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
732 (Consolidated) 719 (Non-Consolidated)

Subsidiaries

Chromatech Co., Ltd. (Japan)
JCR Engineering Co., Ltd. (Japan)
JCR INTERNATIONAL SA (Switzerland)
JCR USA, Inc. (U.S.)
JCR DO BRASIL FARMACÊUTICOS IMPORTAÇÃO E EXPORTAÇÃO LTDA. (Brazil)
ArmaGen, Inc. (U.S.)

Stock Information

Listed on
Tokyo Stock Exchange First Section

Securities Code
4552

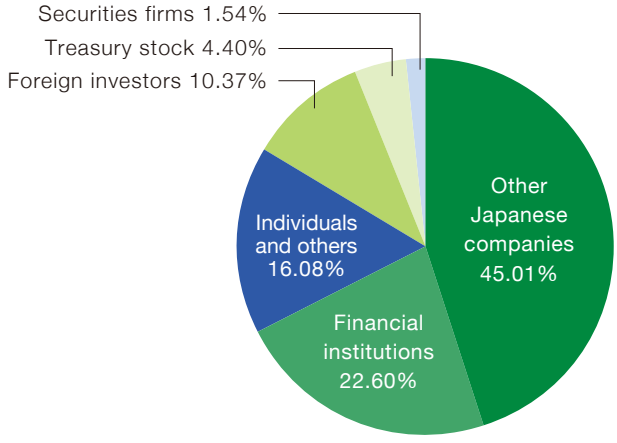
Total Number of Outstanding Shares
129,686,308

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
20,953

Composition of Shareholders



Principal Shareholders

(Unit: 1,000)

Name of shareholder	Number of shares held
MEDIPAL HOLDINGS CORPORATION	29,131
Kissei Pharmaceutical Co., Ltd.	13,920
Future Brain Co., Ltd.	8,711
The Master Trust Bank of Japan, Ltd. (Trust account)	6,889
The Nomura Trust and Banking Co., Ltd. (Trust account: A)	6,518
Custody Bank of Japan, Ltd. (Trust account)	5,778
Sumitomo Dainippon Pharma Co., Ltd.	3,400
Mochida Pharmaceutical Co., Ltd.	2,200
JPMBL RE BARCLAYS CAPITAL SECURITIES LIMITED COLL EQUITY	1,101
Employee Shareholding Association of JCR Pharmaceuticals Co., Ltd.	1,075

* The Company holds 5,707,744 shares of treasury stock, which are not included in the above table.

JCR Pharmaceuticals Co.,Ltd.

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

www.jcrpharm.co.jp/en/site/en/

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