JCR Pharmaceuticals

変革

REVOLUTION

into the Future

JCR Report 2020

JCR Pharmaceuticals Co.,Ltd.

Year Ended March 31, 2020

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 has drawn up its new 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 2020," we have prepared an integrated report that outlines JCR's business activities, 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:** FY2019 (From April 1, 2019 to March 31, 2020)
  * This report also contains some information from FY2020.
- **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 2020" 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.

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, production 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 take a unique approach in advancing our research and development and provide high-quality products and information with confidence in the aim of providing world-class pharmaceuticals.

Belief

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

We have embarked on a “REVOLUTION” to fully globalize our businesses.

FY2019 was the final year of the Midterm Business Plan for FY2015-FY2019 “HIYAKU” (Leap into the Future). I’m pleased to see solid achievements delivered, with all of us ready to move on to a next stage. Notably, we launched Darbepoetin Alfa BS Inj. [JCR], a long-acting erythropoiesis-stimulating agent, while we are accelerating global development of JR-141, a therapeutic for lysosomal storage disorders (LSDs) that applies J-Brain Cargo®, JCR’s proprietary technology platform.

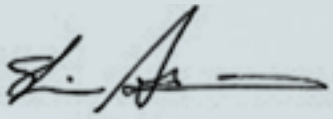
JCR aspires to be a “Research-oriented specialty pharma with global exposure.” To realize this objective, the Mid- to Long-Term Management Vision “Toward 2030” and the Midterm Business Plan for FY2020-FY2022 “REVOLUTION” have been issued, which will give a roadmap to drive further growth in the years to come.

With new strategies for the future in place, JCR revolutionizes its business and transforms itself into a global specialty pharma in the rare disease arena. We will marshal Team JCR’s entire capabilities to generate “one step beyond” technologies—technologies that go one step ahead of our competitors—while striving to create new values through R&D and Manufacturing.

August 2020

Shin Ashida

Representative Director, Chairman, President, CEO and COO



FY2019 Business Overview

Net sales has reached an all-time high following eight straight years of sales growth. We are moving faster with research and development (R&D) leveraging JCR's proprietary technologies.

In FY2019, JCR reported its highest-ever net sales of 24,781 million yen (7.0% increase from the previous fiscal year), following eight straight years of sales growth. Operating income was 3,244 million yen (34.7% decrease year on year), of which profit attributable to owners of parent was 2,678 million yen (27.9% decrease year on year). Revenues from licensing, initially expected in FY2019, have been postponed to FY2020. For this reason, financial results fell short of numerical targets for the Midterm Business Plan. However, product sales were firm. Net sales of GROWJECT®, a recombinant human growth hormone product, increased to 12,650 million yen (5.6% increase year on year) in addition to steady market penetrations by renal anemia treatments and TEMCELL® HS Inj., a regenerative medical product.

I'm also pleased to report on the achievements from research and development. In November 2019, we launched Darbepoetin Alfa BS Inj. [JCR], a long-acting erythropoiesis-stimulating biosimilar agent that has significantly expanded treatment options for renal anemia.

JCR aims to develop novel therapeutics for 16 types of rare diseases (LSDs) by applying J-Brain Cargo® technology. We have completed a Phase III clinical trial in Japan for JR-141, a therapeutic enzyme for Hunter syndrome, along with completing the drug administration in the last patient for a Phase II clinical trial in Brazil. We are also planning to initiate global clinical trials of JR-141 and JR-171, a therapeutic enzyme for Hurler syndrome, within 2020. Further clinical trials of several therapeutic enzymes will be initiated within the next three years: JR-162 for Pompe disease; JR-441 for Sanfilippo syndrome type A; JR-443 for Sly syndrome; and JR-446 for Sanfilippo syndrome type B.

Our patient-centric development efforts also cover fields such as human growth hormone products, cell therapy, regenerative medicine, and gene therapy. We will be committed to delivering more added values in all these areas.

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Midterm Business Plan for FY2020-FY2022 "REVOLUTION"

We will implement growth strategies, guided by the Mid- to Long-Term Management Vision "Toward 2030."

With our 50th anniversary coming in 2025, we will strive to fully globalize our businesses from FY2020. This task will require JCR to revolutionize all aspects of its business. It will also require every employee to transform themselves. Hence our new Midterm Business Plan for FY2020-FY2022 "REVOLUTION," with a new slogan "REVOLUTION into the Future."

In proposing this plan, we thoroughly examined our history, values and business characteristics in order to develop a strategy that would fully realize our growth potential over the next ten years. These reflections resulted in our Mid- to Long-Term Management Vision "Toward 2030." We are determined to take the following steps in order to be a "Research-oriented specialty pharma with global exposure."

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

I strongly believe that "Team JCR" is the wellspring of the value we offer, with which all of our employees share the entrepreneurial spirit JCR has fostered since its foundation. Every employee in our highly diverse workforce has a vital part to play in contributing to the rare disease arena by refining JCR's unique corporate culture, focusing on R&D and Manufacturing to accelerate innovation.

FY2020 marks the beginning of our new Midterm Business Plan that will commit us to the pursuit of a "REVOLUTION" —a qualitative and quantitative transformation of our business activities—that will marshal all of Team JCR's capabilities. It will also put us on a path to realize our Mid- to Long-Term Management Vision "Toward 2030." In order to transform JCR into a truly global enterprise in the rare disease arena, six important business challenges have been identified as below:

1. **Qualitative and quantitative reorganization of the quality assurance system**
2. **Actions for sustainable growth in the sales of our products**
3. **Expansion of basic and applied research activities**
4. **Evaluation and implementation of further capital investment for manufacturing and research**
5. **Product strategy planning including evidence generation**
6. **Transformation of operations and organizations along with talent development**

In FY2022, the plan's final year, we assume net sales of 32.0 to 36.0 billion yen, based on expectations for steady growth through higher year-on-year sales. We plan sufficient R&D investments required to expedite R&D activities, including those for LSDs. R&D expenditures are estimated to be around 20% of sales, or more when required. Operating income of 7.0 to 10.0 billion yen in FY2022 is targeted, thereby absorbing R&D expenditures.

Furthermore, JCR is committed to advancing its "REVOLUTION" in its sustainability. This will be done by driving a qualitative and quantitative transformation and by addressing challenges through its business activities, with our focus on Rare Diseases (RD) and Environment, Society and Corporate Governance (ESG).

JCR's R&D and production have not been affected by the COVID-19 pandemic. However, JCR concluded commitment line agreements with financial institutions in April 2020 for the purpose of securing operating funds as a backup line. Should any events arise to affect our financial results, its details will be announced as soon as possible.

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Return to Shareholders

We will provide continuous and stable dividends to shareholders.

Returning profits to shareholders is an important management policy for JCR. In FY2019, we increased the term-end dividend by 2 yen per share from the previous fiscal year, with an annual dividend of 32 yen, resulting in a dividend payout ratio of 36.8%.

The new Midterm Business Plan expects a dividend payout ratio of 30% based on our basic policy to provide stable dividends as we focus on balancing returns shareholders expect and our financial soundness.

Management Team with New Directors

JCR will vigorously promote the "REVOLUTION" process, led by a management team with new directors. The team will focus on globalization of JCR's businesses.

JCR reshaped its management team by appointing two new directors at the Ordinary General Shareholders Meeting held in June 2020.

Hiroyuki Sonoda, Ph.D., one of the new directors, invented J-Brain Cargo®, JCR's original technology platform. After joining JCR, Dr. Sonoda has been contributing to the Research Institute by his excellent research abilities. He is also an inspiring leader to bring people together, and is thus expected to assert leadership in R&D for bringing first-in-class innovative biopharmaceuticals into the world from Japan. The other new director is Mathias Schmidt, PD, Ph.D., CEO of ArmaGen, Inc. of the U.S. which has joined the JCR Group in April 2020. His outstanding research achievements in academia and extensive experience in research and clinical development at major global pharmaceutical companies will be instrumental in accelerating future R&D at JCR and contribute to enhancing our corporate values. I'm confident that our new management team, including these new directors, will actively drive JCR's "REVOLUTION" and strong growth into the future.

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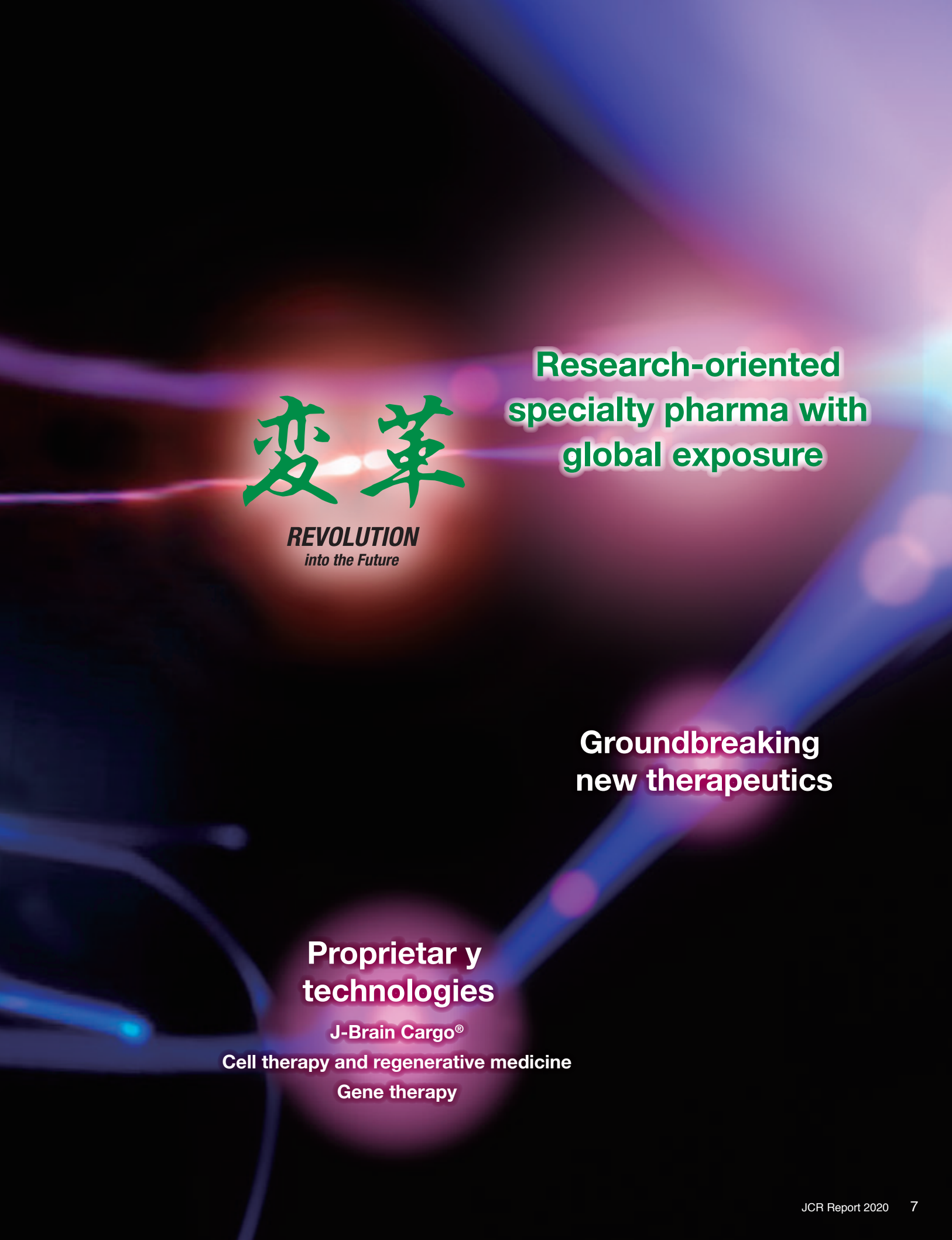
JCR will achieve sustained value creation by working to develop proprietary technologies and innovative products in anticipation of the needs of the times.

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.


Research-oriented specialty pharma with global exposure
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REVOLUTION
into the Future
Groundbreaking new therapeutics
Proprietar y 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 proprietary "one step beyond" technologies and products. This has led to steady growth and the Company's recognition as "JCR, the biopharma company," culminating in its successful listing on the First Section of the Tokyo Stock Exchange in 2013. In 2015, which marked the 40th anniversary of JCR, we received marketing approval for TEMCELL® HS Inj., the first allogeneic regenerative medical product in Japan. In these and other ways, we will continue to make ambitious development efforts in the fields of cell therapy and regenerative medicine.

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

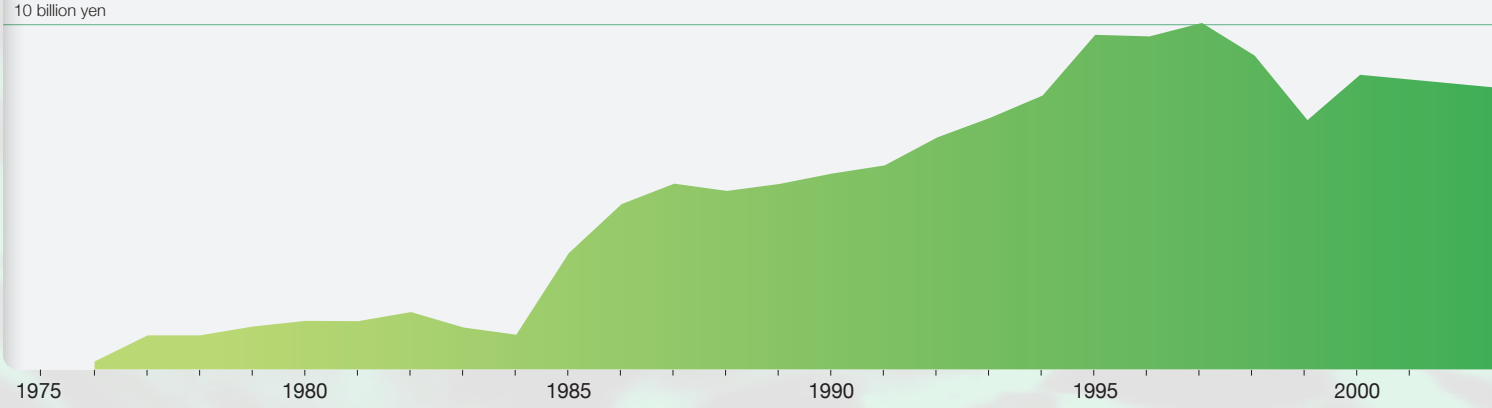
2003
Concluded license agreement for mesenchymal stem cells (MSCs) with Osiris Therapeutics, Inc. (U.S.)*

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



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

2017
Launched new liquid formulation of GROWJECT®, a recombinant hGH product

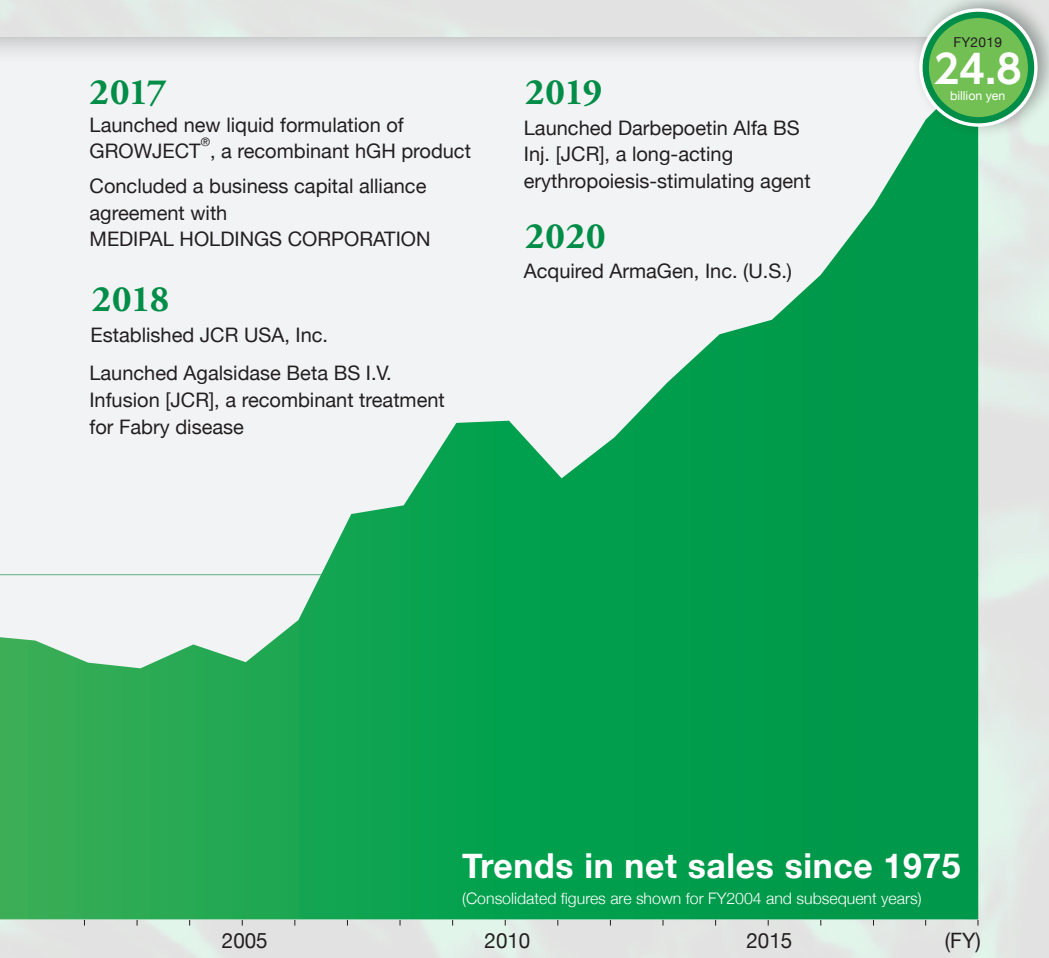
Concluded a business capital alliance agreement with MEDIPAL HOLDINGS CORPORATION

2018
Established JCR USA, Inc.

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

2019
Launched Darbepoetin Alfa BS Inj. [JCR], a long-acting erythropoiesis-stimulating agent

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

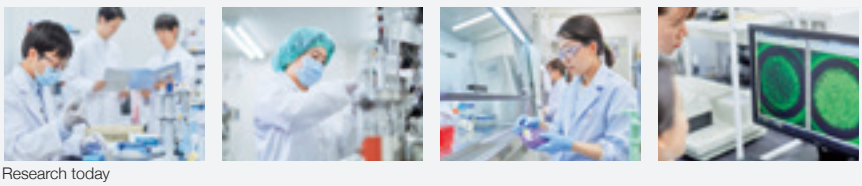


Trends in net sales since 1975
(Consolidated figures are shown for FY2004 and subsequent years)

* 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



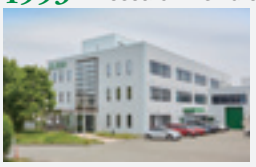
Research today

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

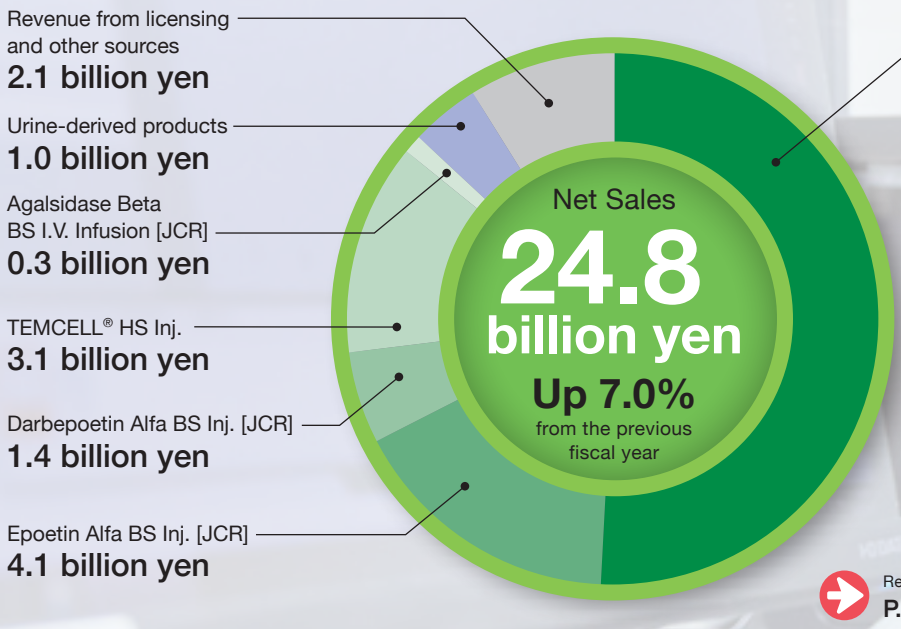
2013 Kobe API Plant

2016
Clinical Trial Material Manufacturing Center (CTMC)

Cell Processing Center (CPC)

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

Net Sales in FY2019



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Key Topics for FY2019

May 2019

Joint Research Collaboration Between PeptiDream and JCR Achieves Successful Development of Blood-Brain Barrier (BBB) Carrier Peptides Capable of Targeting Therapeutic Payloads to the Brain

JCR and PeptiDream Inc. had initiated a joint research collaboration utilizing JCR's knowledge of J-Brain Cargo®, its proprietary BBB technology, and PeptiDream's constrained peptide development technology based on its proprietary Peptide Discovery Platform System. This collaboration resulted in the successful development of constrained peptides capable of carrying various therapeutic payloads across the BBB for delivery/targeting to the brain.

May 2019

JCR Initiates Phase I Clinical Trial of JR-142, a Long-Acting Growth Hormone

Growth hormone replacement therapy normally requires six to seven self-injections a week, which is inconvenient and can be painful for patients. To address these issues, JCR has been advancing research and development of a long-acting growth hormone product that can achieve sustained effects.

June 2019

JCR Initiates Phase I/II Clinical Trial of TEMCELL® HS Inj. Allogeneic Bone Marrow-Derived Mesenchymal Stem Cells for the Expanded Indication of Neonatal Hypoxic Ischemic Encephalopathy (HIE)

Business Process

Research and Development (R&D)

We leverage our platform technologies 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 carry out marketing activities focused on target domains at eight 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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June 2019

JCR Expands Research-Related Facilities

JCR acquired real estate in Nishi-ku, Kobe to upgrade its drug discovery capabilities in the gene therapy field and accommodate an increase in research personnel.

September 2019

JCR Receives Marketing Approval in Japan for Darbepoetin Alfa BS Inj. [JCR] (JR-131), a Long-Acting Erythropoiesis-Stimulating Agent

JCR and Kissei Pharmaceutical Co., Ltd. have been developing a treatment for renal anemia since the two companies entered into a collaborative research and development agreement for JR-131 in September 2013. Darbepoetin Alfa BS Inj. [JCR] is manufactured by JCR, while delivery of medical information to healthcare providers and marketing activities are undertaken by Kissei.

March 2020

Achievement of Milestone in Research Stage under License Agreement on BBB Penetration Technology J-Brain Cargo® with Sumitomo Dainippon Pharma for Creation of a Therapeutic Agent for Central Nervous System Diseases

This is JCR’s first license agreement on a candidate drug using J-Brain Cargo®.

March 2020

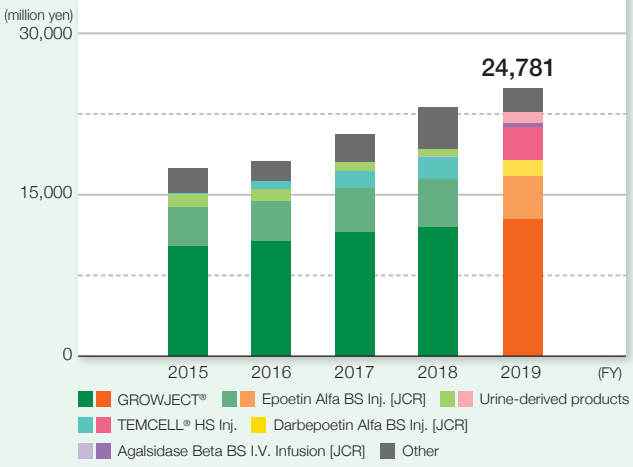
JCR Reaches Agreement to Acquire ArmaGen, Inc. (U.S.)

JCR is currently focused on the research and development of innovative drugs for lysosomal storage diseases for the global market. JCR decided to acquire ArmaGen’s technology portfolio, including intellectual property rights for its proprietary BBB penetration technology, based on the determination that this acquisition will ensure JCR’s technological lead and competitive edge with respect to the introduction of BBB-penetrating products onto the global market.

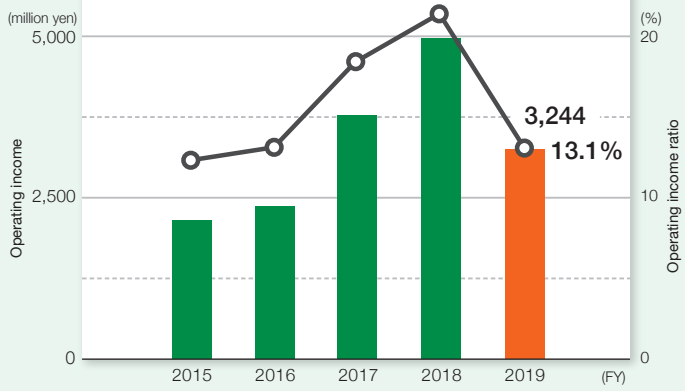
Consolidated Financial and Non-Financial Highlights

JCR Pharmaceuticals Co., Ltd. and Subsidiaries

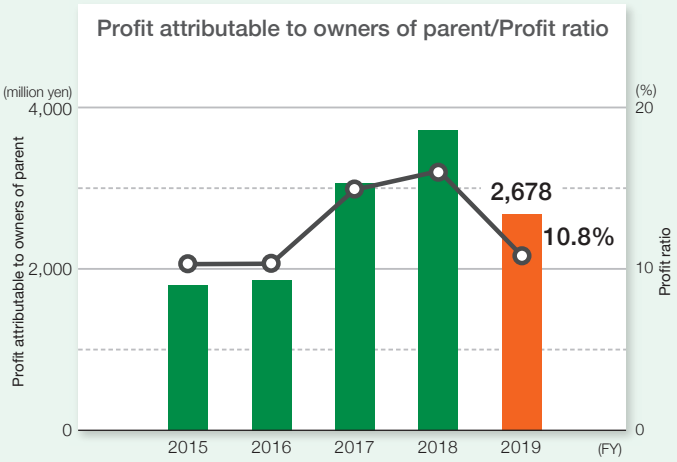
Net sales by product



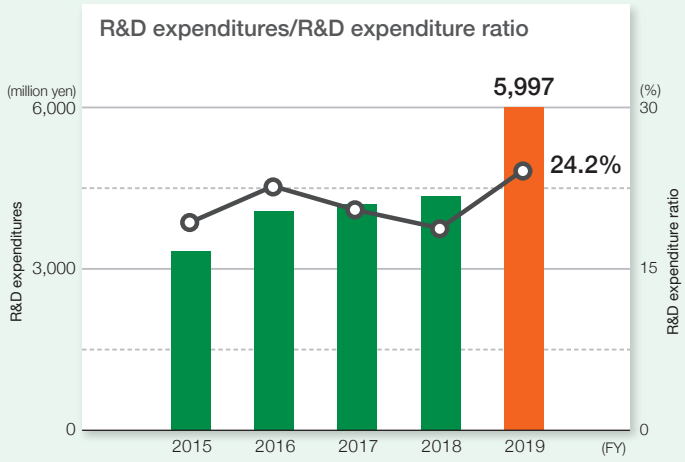
Operating income/Operating income ratio



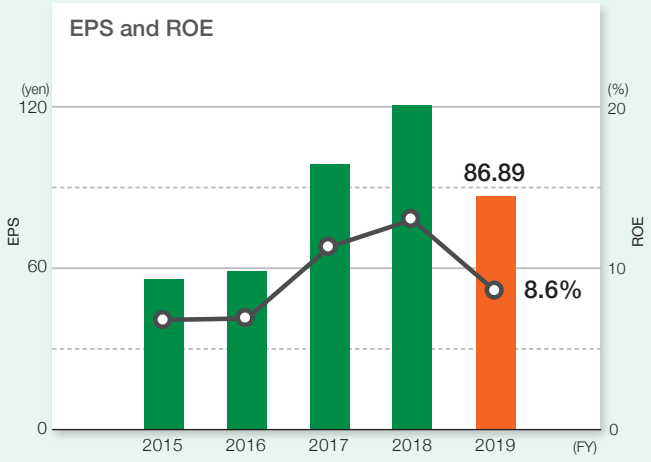
Profit attributable to owners of parent/Profit ratio



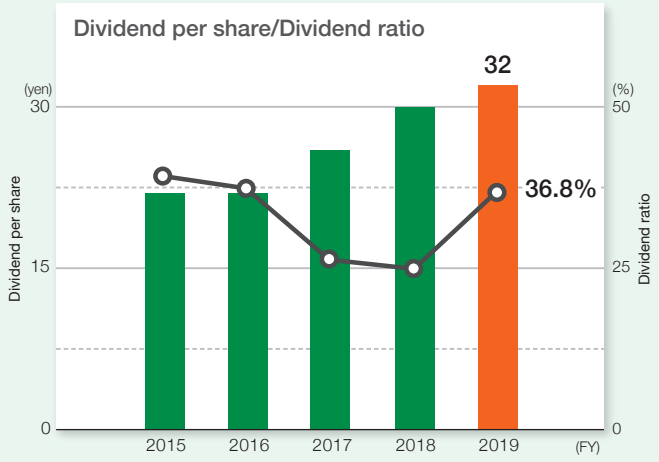
R&D expenditures/R&D expenditure ratio



EPS and ROE



Dividend per share/Dividend ratio



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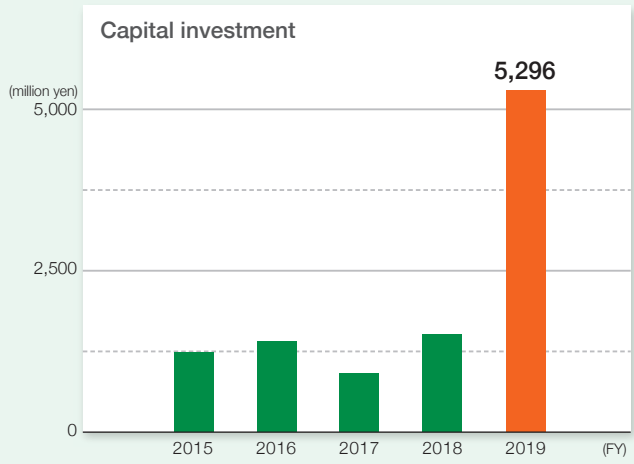
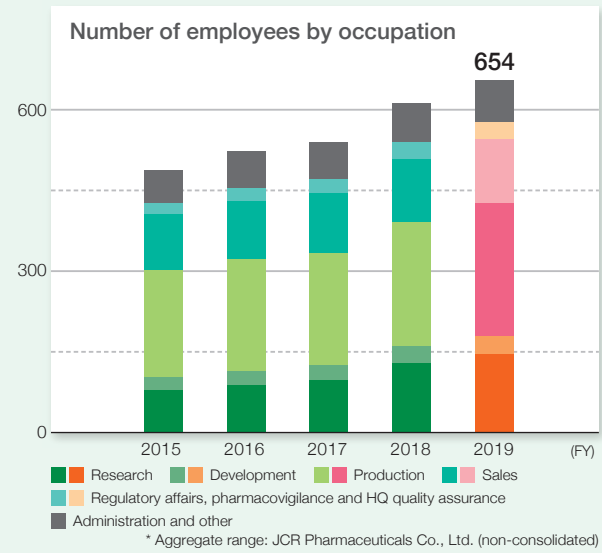
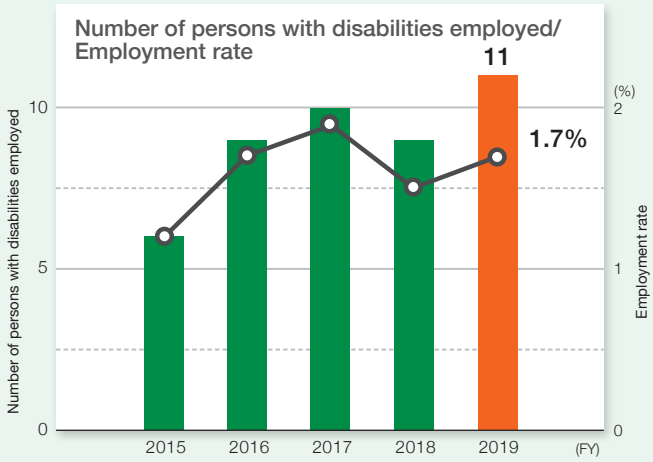




* Aggregate range: JCR Pharmaceuticals Co., Ltd. (non-consolidated)



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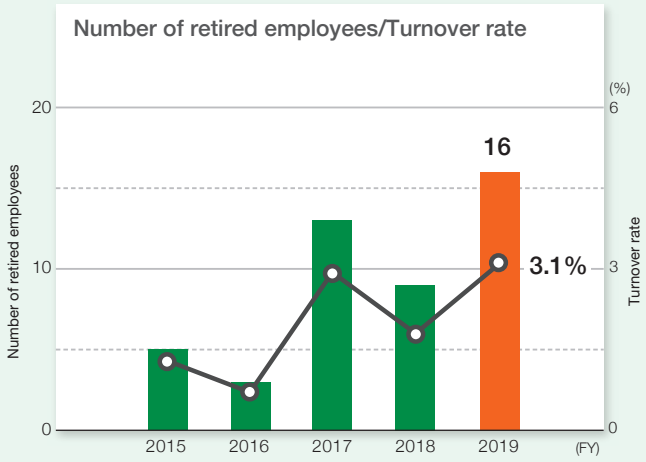

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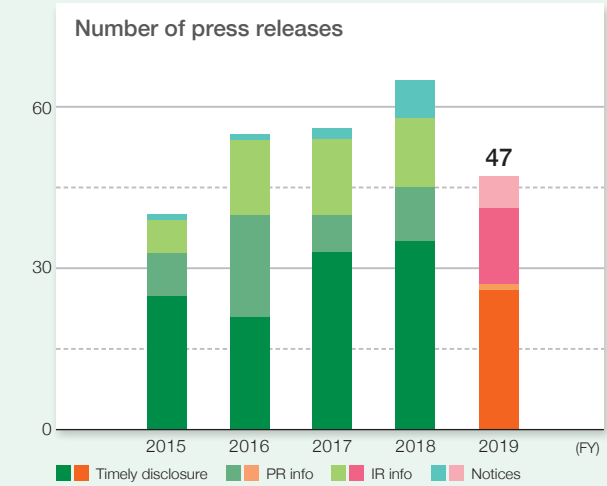
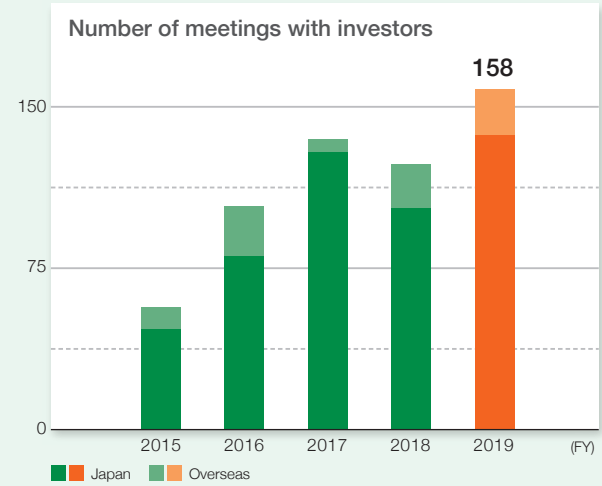
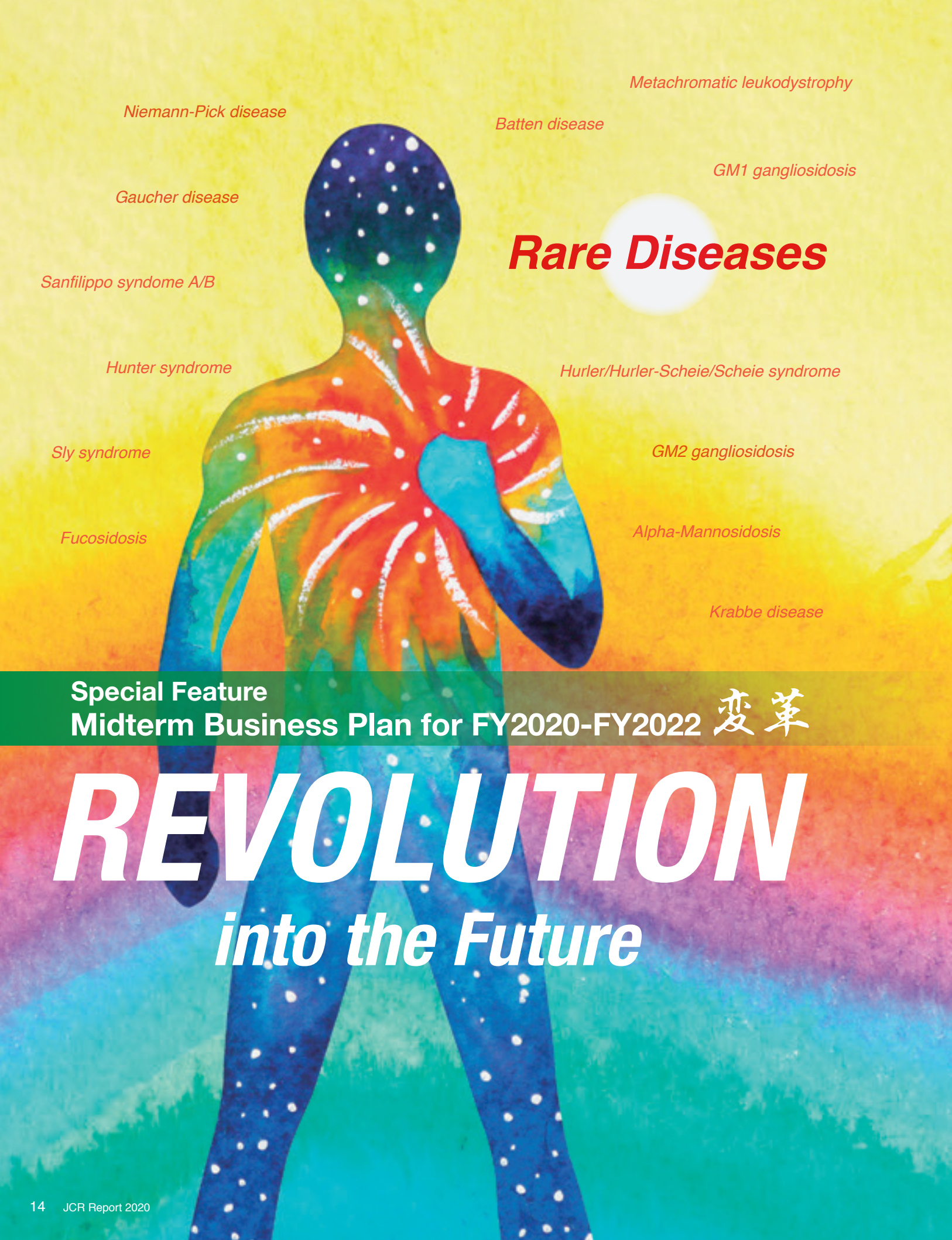






Special Feature
Midterm Business Plan for FY2020-FY2022 変革

REVOLUTION
into the Future

Foreseeing 2030, we will steadily implement medium- to long-term strategies that will make JCR a global specialty pharma in the rare disease arena.

The Midterm Business Plan for FY2015-FY2019 “HIYAKU” (Leap into the Future) has guided JCR’s efforts over the past five years, in which JCR has swiftly taken on a range of challenges, driven by the strengths fostered since its foundation, e.g. advancement of R&D activities ahead of our competitors, resulting in immense achievements as a springboard for next generations. The Mid- to Long-Term Management Vision “Toward 2030” and the Midterm Business Plan for FY2020-FY2022 “REVOLUTION” will expedite global business evolution from FY2020.

JCR’s entrepreneurial spirit has remained the bedrock of the Company since its foundation. R&D and Manufacturing have nurtured JCR’s corporate culture, embraced by every employee keen to contribute to the rare disease arena. Development of original technologies including J-Brain Cargo® has established solid business foundations with which to go on the global stage.

With “Team JCR” as the wellspring of our corporate values, we will marshal the capabilities of every employee in our highly diverse workforce and continue striving to be a “Research-oriented specialty pharma with global exposure.” To realize this goal, our concrete corporate vision calls on JCR to be “a global specialty pharma in the rare disease arena.” We will focus on R&D and Manufacturing driven by a dedicated small group of specialists par excellence and refine JCR’s original corporate culture in order to accelerate innovation.

In the face of increasing uncertainty for the pharmaceutical industry, JCR will swiftly make audacious and apt decisions to achieve steady and sustained growth that meets the expectations of all stakeholders.

Toru Ashida
Vice President
In charge of Corporate Strategy and Head of Sales Division,
Executive Director, Sales Division

Performance under the Midterm Business Plan for FY2015-FY2019

Net sales reached an all-time high after eight straight years of sales growth, with expedited R&D activities and human resource development fundamental to create sustainable values.

The Midterm Business Plan for FY2015-FY2019 “HIYAKU” (Leap into the Future) covered the past five years, during which JCR has swiftly developed its business, delivering numerous achievements that pave the way for future growth.

Four new products have been successfully launched as our new growth drivers, including TEMCELL® HS Inj., the first allogeneic regenerative medical product in Japan. Substantial investments have been made in production and research, highlighted by the completion of the Clinical Trial Material Manufacturing Center and the Cell Processing Center in FY2016.

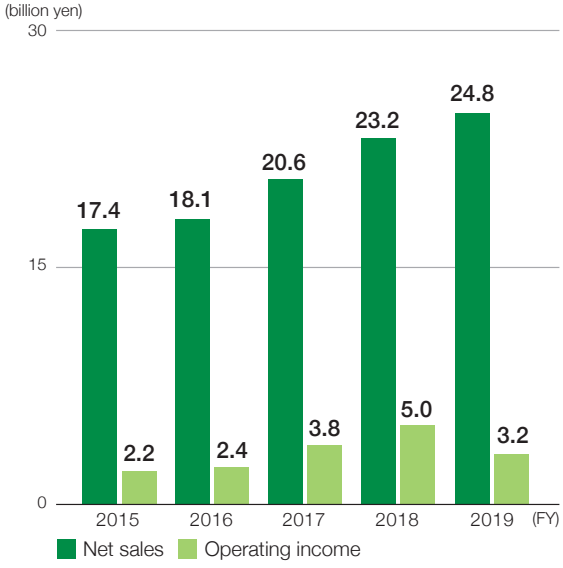
In R&D, JCR has been focusing on therapeutic agents for lysosomal storage disorders (LSDs) that apply J-Brain Cargo®, its proprietary technology platform. Notably, clinical trials of JR-141 have been successfully conducted in Brazil as our first experience in global clinical development. The acquisition of ArmaGen, Inc. in the U.S. has resolved potential intellectual property risks pertaining to the development of therapeutic agents for LSDs. We also embark on regenerative medicine and gene therapy to deal with their challenges for the next generation.

In sustainability, JCR recognizes its core duty of “Realizing medical care for those living with rare diseases” and has been carrying out initiatives in Rare Diseases and Environment, Safety and Corporate Governance (ESG).

Our human resource management concentrates on training and development of talents essential to sustain our growth, in addition to a wide range of initiatives to create workplaces comfortable and conducive for employees, e.g. provision of an in-house day care center.

Net sales have increased from 17.4 billion yen to 24.8 billion yen, and operating income from 2.2 billion yen to 3.2 billion yen. Notwithstanding these figures that fell below our targets for net sales of 25.0 billion yen and operating income of 5.0 billion yen, solid business results have been achieved, despite a licensing agreement initially expected in FY2019 being postponed to FY2020.

Net Sales and Operating Income



Launch of New Products

2016
Human somatic stem cell-processed products
Human (allogeneic) bone marrow-derived mesenchymal stem cells
TEMCELL® HS Inj.

2017
Recombinant human growth hormone product
GROWJECT® (liquid formulation)

2018
Recombinant treatment for Fabry disease
Agalsidase Beta BS I.V. Infusion [JCR]

2019
Long-acting erythropoiesis-stimulating agent
Darbepoetin Alfa BS Inj. [JCR]

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

We strive to create “one step beyond” technologies ahead of our competitors. With “Team JCR” as the wellspring of our values, we aim to be a “Research-oriented specialty pharma with global exposure.”

In formulating our new Midterm Business Plan, JCR’s history of growth, values and business characteristics are herewith summarized to examine our growth potentials over the next ten years.

During the first 25 years since its foundation in 1975, JCR established its purification technology through R&D in biological substances derived from urine and blood. In the early 2000s, JCR’s R&D activities focused more on biotechnology and regenerative medical products, resulting in launches of biopharmaceuticals, e.g. Epoetin Alfa BS Inj. [JCR], and regenerative medical products (TEMCELL® HS Inj.) that have been contributing to steady growth.

One of our most important characteristics in research is innumerable rigorous formulations and validations of hypotheses with scientific integrity in order to develop original technologies and innovative products one step beyond our competitors. It is this scientific outlook that has enabled creation of various platform technologies including J-Brain Cargo®.

JCR’s unswerving objective has been to become a “research-oriented specialty pharma with global exposure.” To realize this, we thoroughly reexamined our core corporate values through dialogues in all internal divisions and business meetings amongst senior management, and have reached a common understanding that the wellspring of JCR’s values lies in the notion of “Team JCR,” based on which the Mid- to Long-Term Management Vision “Toward 2030” has been finalized as below, which articulates our basic strategies and a concrete corporate vision.

JCR will continue concentrating its business resources on R&D and Manufacturing, without developing its own overseas sales sites in principle, so that the corporate culture can be shared by every member of “Team JCR.” We will seek collaborations with other companies whose corporate culture resonates with ours, while we will move forward further to be “a global specialty pharma in the rare disease arena,” fully globalizing our businesses in the near future.

Our Goal

Research-oriented specialty pharma with global exposure

Concrete Corporate Vision

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

Basic Strategies

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

Midterm Business Plan for FY2020-FY2022 “REVOLUTION”

We will strive to realize our Mid- to Long-Term Management Vision “Toward 2030” by pursuing a “REVOLUTION”—qualitative and quantitative transformations of our business activities by marshaling all capabilities of “Team JCR.”

JCR will celebrate its 50th anniversary in 2025, while the latter half of the 2020s will see its full globalization that requires transformations in all aspects of our business activities and ourselves, without indulging in our past successes, hence “REVOLUTION” as the key theme in 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.

With the coming full globalization of our businesses in the rare disease arena, the new Midterm Business Plan for FY2020-FY2022 “REVOLUTION” lists six important business challenges as shown in the table below.

JCR believes that the most important duty of pharmaceutical companies lies in the 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” is designated as the top priority amongst business challenges.

Furthermore, in order to prepare for rapid business expansions from the latter half of the 2020s, JCR stipulates five important business challenges.

Key Theme

変革

REVOLUTION
into the Future

Important Business Challenges

Top-priority business challenge

1 In anticipation of the growing presence of JCR in the rare disease arena
Qualitative and quantitative reorganization of the quality assurance system

2 For strengthening our foundations for profits over the next several years
Actions for sustainable growth in the sales of our products

3 Exploring new therapeutic targets succeeding LSDs
Expansion of basic and applied research activities

4 For full-fledged globalization of businesses
Evaluation and implementation of further capital investment for manufacturing and research

5 For maximizing business values of future therapeutic drugs for LSDs
Product strategy planning including evidence generation

6 In anticipation of business expansion after full-fledged globalization of businesses
Transformation of operations and organizations along with talent development

Until LSD therapeutics fully contribute to JCR's business performance, "the sustainable growth of the sales of our products" will uphold our business, while "expansion of basic and applied research activities" will be expedited to explore new therapeutic targets succeeding LSDs.

To fully globalize our businesses, we will proactively evaluate and implement "capital investment for manufacturing and research." As mid- and long-term clinical evidence is indispensable in rare diseases, "product strategy planning including evidence generation" will be undertaken.

Finally, in order to successfully address the aforementioned business challenges, we will implement "transformation of operations and organizations along with talent development," so that future expansions in our business operations can be met effectively.

In terms of the business performance, steady year-on-year growth in key metrics is assumed. The table below lists our targets for net sales, operating income, R&D expenditures and the dividend payout ratio.

Sustainability Initiatives

JCR is committed to transforming its sustainability initiatives in terms of both quality and quantity, in order to become a global specialty pharma in the rare disease arena.

As "Realizing medical care for those living with rare diseases," is fundamental to JCR's value creation, JCR focuses on the key areas of "Rare Diseases," "Environment," "Society," and "Corporate Governance," in each of which challenges will be addressed through our business activities, the achievements thereof to be shared with a wide range of stakeholders.

We are committed to realizing sustainability with the spirit of "No one will be left behind," as set forth in the Sustainable Development Goals (SDGs).

Related page
P.34 Sustainability

Guidance

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

“Team JCR” is determined to realize the Mid- to Long-Term Management Vision “Toward 2030” and fulfill its duty as

a global specialty pharma in the rare disease arena.

What kind of a “REVOLUTION” is needed to make this happen, and what must we do to tackle various challenges?

In this section, individual members of “Team JCR” discuss their ambitions and passions for the future.

Our





Message from “Team JCR”

Passion


Research and Development

Discussion

We will not only accelerate global development of therapeutic agents for lysosomal storage disorders (LSDs), but we will also take steps to reach the next stage.

Eiji Yoden, Yuri Koshimura, Jun Tsushima
Research Division

Minako Kobayashi
Development Division

JCR's Strengths and Essential Changes

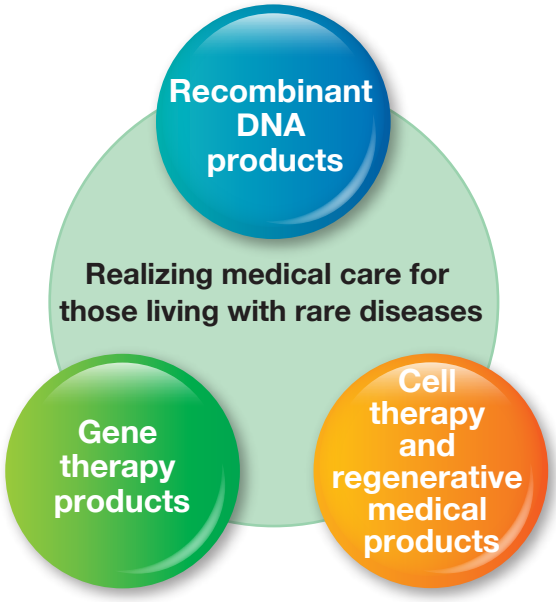
Yoden: We earnestly wish to deliver new medicines to patients suffering from rare diseases. Keeping this aspiration close to heart, JCR has tackled various challenges and guided those efforts to success. We would like to remain a company that moves quickly to tackle new challenges. One thing we should change is how we foster cooperation between divisions. I feel that there are many areas where we have not shared enough information with one another.

Koshimura: JCR offers a high degree of freedom to employees. Individual employees have used this freedom to come up with a steady stream of new ideas. As a result, JCR has continued to achieve rapid growth. This is certainly one of JCR's strengths. On the other hand, some projects have gathered momentum before the necessary equipment and personnel could be put in place. Consequently, there have been instances where relatively excessive pressure has been put on staff, particularly young employees. I believe that this problem needs to be addressed.

Tsushima: I also believe that JCR's speed and agility are its key strengths. For example, we submitted a clinical trial application in Brazil in only around six months after a specialist doctor from Brazil came to JCR. Employees are given work with a lot of responsibility from a relatively young age. Therefore, one of JCR's strengths is that it allows employees to change their environment by themselves. Without losing sight of such qualities, JCR will need to raise the level of its work to a world-class standard. That is clearly one of the challenges facing the Company, in my view.

Kobayashi: I would describe JCR as a company that makes decisions quickly, and allows employees to work on things that other companies are not doing. And I feel that JCR is a compassionate company that cares about patients. One of the challenges facing the Development Division is that staff are so busy with current projects that

R&D Platform



they don't have enough time to think about the future. Looking ahead, I would like the Development Division to have the ability to study issues from a broad perspective, such as considering where the pharmaceutical industry will go in the future.

Challenges in Each R&D Organization

Yoden: I'm a member of the Pharmacology & Toxicology Unit. In our unit, we need to conduct activities such as acquiring efficacy and pharmacokinetics data for compounds in the research stage, in addition to acquiring pre-clinical data on compounds for projects that have advanced to the pre-clinical stage. Personnel shortages relative to the increase in the amount of work are putting a strain on our unit. We need to strive to raise operational efficiency by stepping up information sharing and coordination even more than before.

Koshimura: I feel that an awareness of the "Team JCR" spirit has not fully permeated the Research Institute. I sometimes hear staff members say things like, "That is not the job of our group" or "That's something that other groups should do." It may be JCR's open corporate culture that allows such statements to be easily heard in the first place. In any case, I'm extremely concerned about this situation.

Tsushima: I'm a member of the Project Coordination Unit. From the perspective of our unit, we need to pay particularly close attention to collaborations between departments and projects. In addition, although those who are involved in a project know what is best for the project, there are a lot of members who simply wait for instructions to come down from the Company or their supervisor. I feel that the eagerness to "change things by yourself" has diminished. It could be that JCR is on the verge of succumbing to the so-called curse of bigness.

Kobayashi: In the Development Division, we have also shifted to a project manager system, and this has perhaps led to a culture where people tend to consider only their own assigned work. All members of the Development Division work on the same floor. I would like to make the most of this advantage and actively work to share information and jointly consider problems. I would also like to foster teamwork and solidarity not only within the Development Division, but also with other departments.

Importance of Basic Research for the Future

Tsushima: Customized healthcare is a trend facing the pharmaceutical industry as a whole. In the future, I believe it will be more important to make improvements that fit patient needs, based on targeting of therapeutic areas.

Koshimura: It will be crucial to carefully assess which and to what extent we should focus our efforts on the three options of gene therapy, regenerative medicine including cell therapy, and recombinant DNA products. I also think we should set our sights on collaborations with external organizations and academia in the future.

Yoden: I believe that the time has come for JCR to consider applying J-Brain Cargo® to therapeutic agents for rare diseases other than LSDs. Whenever you start something new, you will need creativity, the ability to gather information and the agility to respond flexibly to circumstances. Basic research serves as the foundation for the development of new drugs. Therefore, the deeper and broader we can make the foundation, the better it will be for drug development.

Kobayashi: It would be fine for all stakeholders that JCR develops any kind of drug as long as the needs of patients and JCR's technology mesh well together. I believe that the most important thing is to develop new drugs with a focus on the needs of patients.

Vision for JCR Ten Years from Now

Yoden: Ten years from now, I would like JCR to remain a company that puts a premium on speed and a "challenge spirit." By fostering close collaboration between departments, I would like JCR to deliver new medicines to patients at the earliest opportunity.

Koshimura: Through my experience working on JR-141, I realized just how encouraging and uplifting it is to hear the satisfied voices of patients who have benefited from drugs that I have been involved in. I envision the next ten years filled with hope for us that the patients JCR serves can enjoy happier lives.

Tsushima: JCR needs to strengthen its management capabilities further. As the organization grows even larger, some people may find themselves left behind. In practice, it is people who move projects forward. That is why I believe that measures that put the focus on each and every individual employee will be crucial.

Kobayashi: Besides steadily delivering new drugs as a matter of course, I would like to work to support patients in areas other than treatment. With a strong sense of purpose, JCR should remain a company that contributes to health improvements with better treatment options for people around the world.

Production System

Discussion

Our mission is to ensure a steady supply of high-quality medicines. We will strive to enhance our production and quality assurance systems by deploying cutting-edge technology.

Naoki Imagawa, Takanori Maeda
Quality Assurance Dept., Production Division

Hiroshi Ohashi
Manufacturing Section, Production Division

JCR's Strengths and Essential Changes

Imagawa: Looking back, GROWJECT® was the main product at the time when I joined JCR. It was a time when we had started to work on the additional indication of Adult Growth Hormone Deficiency (AGHD)/Small for Gestational Age (SGA). Things progressed rapidly from 2005, when we began developing Epoetin Alfa BS Inj. [JCR]. JCR's strength lies in developing businesses with flexibility and speed. In my opinion, that's something that should be kept unchanged in the future. Meanwhile, I believe that it is crucial to enhance our ability to correct course and adapt when we encounter problems, along with emphasizing speed.

Maeda: Above all, I believe that it is important to keep the entrepreneurial spirit we have had since our founding. When I was a university student, I studied therapeutic agents for rare diseases, including LSDs, as a research theme. JCR specializes in the rare disease arena. That is its reason for existence. I believe that there is great social significance in doing what nobody else is doing, and giving children the power to live.

Ohashi: When I joined JCR, the Company was pushing ahead with development activities to obtain approval for Agalsidase Beta BS I.V. Infusion [JCR]. In a good sense, my first impression of JCR was that there were many interesting and "eccentric" persons in the Company at the time. People came up with ideas freely and expressed their opinions from unexpected perspectives, and had the freedom and initiative to act on and realize their ideas. However, if there is a major problem, we must have "the courage to take pause and reassess the situation." In my opinion, this is something we must change.

Challenges Faced by the Production Division's Plants and Departments

Imagawa: Going forward, the Kobe API Plant, where I'm stationed, will produce JR-141 for the global market. Clinical trials in Brazil and a global clinical study are currently under way. In ten years from now, I believe that we will have submitted applications for approval of JR-141 in many countries and regions. To pass the review process of overseas health authorities, it will be imperative to gain knowledge of matters such as the regulations of foreign countries and interact with local consultants. In terms of production activity, we will have a duty to provide a stable supply of pharmaceuticals on a global scale. In this regard, our ability to communicate effectively with JCR's overseas counterparts will be critical. For this reason, I believe that now is the time when we must strengthen the recruitment and training of human resources.

Maeda: Good Manufacturing Practices (GMP) for pharmaceuticals are standardized worldwide, so we are able to communicate effectively with our counterparts abroad without having to use highly polished English. However, failure to pay close attention to the details of how we communicate can lead to misunderstandings. In areas other than communication in English, we need to carefully assess how many more years our cultivation technology will remain competitive and viable. I believe that the Production Division and the Research Division must work closely together and think through the mass production of gene therapy drugs, which will provide a new platform. Additionally, in terms of operating efficiency, I feel that we should abolish paper-based work processes and speed up the development of an electronic document management system.

Ohashi: The most urgent challenge for our manufacturing sites is that under our current production system, supply could fall behind demand as JCR expands its business globally. In response, digitalization and automation of equipment will be a key priority for enhancing the production capacity of each plant. We will collect and analyze data through the adoption of IT and IoT, and improve our processes further. By doing so, I'm confident that we will enhance our production capacity dramatically.

Seeking to Achieve Qualitative and Quantitative Reorganization of the Quality Assurance System

Imagawa: In quality assurance, I believe that our quality assurance system falls short quantitatively in terms of auditing and control processes over raw material suppliers and contract testing organizations. Looking at the qualitative enhancement of quality assurance, I believe that while information about problems that occur at each plant and observations by the health authorities are shared among plants, we do not share enough of this information. I believe that sharing the agenda of quality meetings held at each plant with the other plants will lead to a stronger quality assurance system.

Maeda: I believe that there is not enough intense debate on quality between employees on the manufacturing floor and the Quality Assurance Dept. Recently, we have developed the tools to learn more about how the entire company stands, through news releases and other means. Learning more about other departments gives us an opportunity to re-examine our own operations and to consider quality in more depth. In addition, JCR is currently focusing on active pharmaceutical ingredients (API). In the future, I believe that JCR should also turn its attention to formulations and expand its formulation plant further.

Ohashi: From the perspective of manufacturing sites, I believe that every employee needs to ask themselves "What kind of work affects quality?" and to foster a stronger awareness of this work. In addition, I would like the Quality Assurance Dept. to inspect JCR's manufacturing sites more often, and to share with us their specific observations and advice. Conducting in-depth internal checks will enable us to effectively address audits and reviews by overseas health authorities, such as the U.S. Food and Drug Administration (FDA).

The Kobe API Plant has established a world-class production and quality assurance system. The plant mainly carries out the manufacturing of APIs for therapeutic agents for LSDs. The quality assurance departments of the Kobe API Plant and the Kobe Plant conduct quality assurance work such as deciding whether or not APIs (Kobe API Plant) and formulations (Kobe Plant) can be shipped.

The Pharmacovigilance Dept. reports directly to the president of JCR. It collects information on the safety and effectiveness of JCR's products, evaluates the collected information, and provides reporting to public institutions and conveys information to medical institutions. The Pharmacovigilance Dept. evaluates information consistently from the development to the post-marketing stages and conveys the information to medical professionals and related parties. These efforts help to ensure the proper use of JCR's products.

Safety Control

We will collect and properly assess safety information in order to grow and develop what JCR offers into higher-value products.

Mayumi Ikai
Safety Information Office, Pharmacovigilance Dept.

I joined JCR ten years ago and have been engaged in work on post-marketing safety control. With every new product that JCR has delivered to the market, the Company has steadily grown little by little and has assumed greater social responsibilities. In the course of fulfilling my daily duties and interacting with many people, I have found that JCR's employees have a strong sense of responsibility and show kindness to others. I believe that these qualities have shaped this company and have been the engine behind its development.

At JCR, we are now attempting a new transformation.

JCR has a long list of priorities ahead, including first-ever medicines, its first global expansion initiatives, and new technologies such as J-Brain Cargo®. The path ahead is fraught with many unknown obstacles. Even if medicines are developed with new technologies and they seem likely to be effective, pharmaceuticals may not be sold unless their safety is verified. Therefore, we must draw up a risk management plan (RMP) for pharmaceuticals and monitor their safety from the pre-clinical stage to the clinical trial and the post-marketing stages.

As with existing products, we must collect information on the effectiveness of new medicines and any adverse events that may have happened to patients, properly evaluate the risk-benefit profile of pharmaceuticals, and implement measures as necessary. To do so, the knowledge and experience we have gained to date are immensely helpful, but more is needed to get the job done. I believe that we have several urgent tasks for the future. First, every member of our department must think and act by oneself, obtain new knowledge, and share that knowledge with our team members. To avoid falling prey to self-righteous decisions, it is crucial that everyone works closely not only with our department, but also with the HQ Quality Assurance Dept., which assures the quality of products, and the Regulatory Affairs Dept., which interacts with the regulatory authorities of each country. Recently, our department has seen an increase in young employees and mid-career professionals joining the Company. This has given JCR the ability to see things from many different angles as a team. I firmly believe that we can find solutions to problems by respecting the opinions of all of our staff, regardless of age, title and job category. Additionally, in order to understand risks from the pre-clinical stage to the clinical trial and post-marketing stages, I would like to share information and cooperate with each department even more closely than before.

We will foster our growth more than ever and harness the capabilities of the new members that have joined "Team JCR." In doing so, I'm confident that we can achieve the transformation that lies before us.

The HQ Quality Assurance Dept. reports directly to the president of JCR. It is responsible for conducting activities in accordance with Good Quality Practices (GQP) for pharmaceuticals and other medical products and Quality Management Systems (QMS) for medical devices and related products. Its main duty is the management of JCR's manufacturing sites in Japan and abroad. The department conducts activities such as regular audits and quality evaluations related to changes in manufacturing methods.

Quality Control

We strictly monitor manufacturing of pharmaceuticals and other medical products after approval, thereby ensuring the delivery of quality-assured products to the markets.

Masahiro Taguchi
GQP/QMS Office, HQ Quality Assurance Dept.

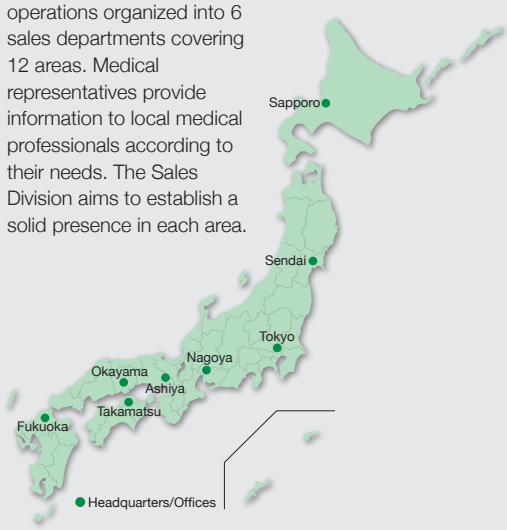
The HQ Quality Assurance Dept., where I work, conducts a wide range of quality assurance duties based on JCR's quality policy. Until now, JCR has carried only products marketed in Japan. For this reason, the HQ Quality Assurance Dept. has conducted operations in accordance with the GQP Ministerial Ordinance*, and our internal systems had been structured to address only Japanese regulations. However, as we roll out JCR's products globally, it will be essential to build a global quality assurance system that can function effectively in any country JCR may enter.

We have had a quality assurance system that has so far performed quality assurance work fairly well. In order to meet the aforementioned goals, we are now establishing JCR's quality policy and a Pharmaceutical Quality System (PQS) for the Company as a whole. In the course of implementing the new PQS, we can expect to face a variety of issues. I believe it will be crucial to make improvements every time there is an issue by conducting repeated PDCA cycles.

Around ten years have passed since I joined JCR. I have a real sense that our tireless ambitions to enter new fields such as biosimilar products and regenerative medical products have fueled JCR's incredible advance forward. I believe that these ambitious initiatives have produced results because the course set by the management team and our frontline capabilities for executing this course have meshed together effectively. In general, as the numbers of departments and employees in a company grow, it is said to become more difficult to instill company policies and foster cooperation within the organization using conventional methods. The same tendency can be thought to apply to quality assurance work as well. We will work to foster close cooperation between the management team and the front lines under the new quality assurance system that will be built. By doing so, we have every expectation that we can make a success of our ambitious initiatives in the rare disease arena and the LSD field going forward.

*GQP Ministerial Ordinance: Quality assurance standards for pharmaceuticals and other medical products in Japan set forth in the Pharmaceuticals and Medical Devices Act.

The Sales Division has approximately 80 medical representatives stationed at 8 offices across Japan, with operations organized into 6 sales departments covering 12 areas. Medical representatives provide information to local medical professionals according to their needs. The Sales Division aims to establish a solid presence in each area.



Marketing – Sales Promotion

We will conduct information delivery and collection that will allow JCR to help build even stronger relationships of trust between patients and medical professionals.

Hiroaki Sakusa
Kinki/Hokuriku Sales Dept., Sales Division

I believe that our theme of “developing the LSD business while preserving and building out the growth hormone business” will remain the bedrock of our activities ten years from now, as it is today.

One source of JCR’s strength is its extensive pipeline in the field of LSDs, based on the foundation of stable sales in the growth hormone business. Currently, JCR maintains a balance by allowing these fields to coexist. In my view, JCR will need to determine how to best maintain the growth hormone business alongside the LSD business. This will be a key challenge for our division.

In the future, we will need to consider forming a specialized team focused on LSDs and it will be essential to clearly define the challenges JCR faces by considering such possibilities. We are working to simultaneously provide information for GROWJECT® and Agalsidase Beta BS I.V. Infusion [JCR]. In the process, if the market response to GROWJECT® matures, we should be able to focus even more on the field of LSDs, such as Agalsidase Beta BS I.V. Infusion [JCR].

The key to our success with GROWJECT® will hinge on our efforts to enhance the brand power of GROWJECTOR® L, JCR’s unique electronically controlled injector. By accelerating information delivery activities further, GROWJECT® will garner a solid market reputation and enter a period of maturity. Meanwhile, we will need to address risks. For example, the emergence of long-acting formulations by other companies is expected to erode JCR’s market share. To mitigate such risks, I believe it will be imperative to deliver information more efficiently in the growth hormone business going forward.

Our first product in the LSD field is Agalsidase Beta BS I.V. Infusion [JCR]. This product faces many hurdles, and the path to success is unclear. First, we must urgently foster a broader understanding of this product’s value on the clinical front lines by meeting needs at the forefront of clinical care. As with other fields, I’m convinced that the most direct path to success for products for LSDs will be for “Team JCR” to join forces and work as one.

The sales planning function works to align various departments in the same direction and achieve overall optimization across the Company based on business strategies, from the standpoint of the Corporate Planning Division. It conducts medium- to long-term life cycle management, and devises marketing promotion strategies that maximize the strengths of each product and product strategies that consider factors such as the intensive allocation of business resources.

Marketing – Planning

We will formulate a strategy for maximizing product value for patients eagerly awaiting therapeutic drugs for LSDs.

Hidemasa Umezawa
In Charge of Sales Strategy Planning, Corporate Planning Division

My first impression of JCR upon joining the Company was that its corporate culture allows employees to ambitiously tackle initiatives they have proposed. They are free to do so without being constrained by the barriers of departments or their position within the Company. I also felt that management was strongly determined to affirm those initiatives. Having very few boundaries has made JCR very quick on its feet, and its positive, "challenge spirit" has become an integral part of JCR's approach to work. I believe it is one factor that has shaped JCR's corporate culture and the "Team JCR" spirit. On the other hand, there has also been a stronger tendency toward "sectionalism" as business has expanded and the numbers of departments and employees have increased. I sense that there have been changes in how operations are carried out and how employees approach their work. Every employee must do more than merely fulfill their assigned duties. I believe that one key challenge for JCR is to ensure that employees can maintain ties across departments so that they can understand how their duties affect other areas, and have clear visibility of the full range of JCR's operations, from basic research to the delivery of medicines to patients.

Since the Midterm Business Plan for FY2015-FY2019 "HIYAKU" (Leap into the Future), JCR has accelerated its ambitious initiatives in the field of LSDs. JCR has mainly sold growth hormone products in Japan. From now on, we plan to successively launch therapeutic agents related to LSDs. Being in charge of sales planning in the Corporate Planning Division, I will need to devise sales strategies that consider several development lineups and business strategies over the medium to long term, as JCR seeks to enter new fields. In addition, JCR will also begin offering post-launch support services in the global market, so we have begun considering initiatives such as tie-ups with partner companies. Under these conditions, I would like to meet the task at hand by seeking to build partnerships that deliver value not only by supplying products, but also by conveying JCR's ambitions as a company.

I believe that the next step is for all members of "Team JCR" to take action not only based on urgent tasks at hand, but also based on consideration of where the Company will be ten years from now and their vision for their individual careers. "Team JCR" members will need to grow faster than the Company does. In doing so, they should also anticipate JCR's full-fledged global business expansion and additional business growth in the years to come. We will continue to tackle challenges and transform ourselves so that we can, as much as possible, contribute to healthcare in ways that are truly unique to JCR.

The Medical Affairs Dept. reports directly to the president. It is responsible for drafting clinical research proposals, and executing and supporting clinical research activities. The Medical Affairs Dept. builds evidence from clinical research and supplies useful information concerning efficacy and safety to clinical sites, with the aim of enhancing the value of JCR's products and realizing patient-centric healthcare.

Medical Affairs

In anticipation of the globalization of JCR's business in the near future, we will establish useful evidence for clinical practitioners involved in LSDs worldwide.

Minoru Ioroi
Medical Affairs Dept.

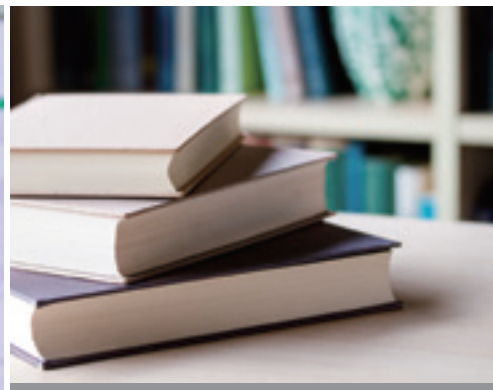
JCR has a corporate culture that allows employees to undertake ambitious initiatives. I believe that it is the culture that is the main driver of JCR's growth and it will be essential to accomplishing our transformation in the future. To date, our ambitious initiatives have come to fruition by producing breakthroughs such as the first cell therapy products and biosimilar products in Japan. Moreover, the Medical Affairs Dept. was created in 2018 as part of those ambitious initiatives. At the time, many corporate medical affairs departments could be strongly characterized as support departments for medical representatives. In contrast, JCR's Medical Affairs Dept. was created from an early stage as a department specialized mainly in conducting clinical research, without appointing an MSL*.

Clinical research has been used by many pharmaceutical companies as a means of marketing. As a result, marketing pressures had started to overpower scientific integrity, leading to consequences such as the withdrawal of some scientific research papers and the enactment of laws governing clinical research. This has raised the bar for conducting clinical research itself. In this environment, JCR formed a new department specialized in clinical research because many of the pharmaceuticals it handles are therapeutic agents for rare diseases for which, unlike ordinary pharmaceuticals, very little clinical data can be obtained in the period leading up to sales. JCR will conduct clinical research and supply additional clinical data to doctors and patients in order to deliver the greatest possible satisfaction with treatment options.

In the course of providing new treatment options in the LSD field, JCR believes that it is crucial to cooperate with not only doctors, but also all other people who are fighting those diseases, such as patient groups. The Medical Affairs Dept. will acquire the information needed by patients in Japan and overseas through clinical research, in order to maximize the value of JCR's products.

Looking ahead, JCR will likely experience major changes, beginning with the globalization of its businesses. To ensure that all employees, including myself, can stay on top of those changes, I would like to adopt the position of constantly making improvements based on an accurate reading of the conditions facing JCR.

* MSL (Medical Science Liaison): a job category for professionals responsible for liaising on medical and scientific affairs with external experts in medical science.



The Legal Affairs Dept. is part of the Corporate Planning Division. It is responsible for duties such as review and preparation of contracts to be concluded with business partners worldwide, and providing legal advice on contract negotiations. In other pertinent areas, the Legal Affairs Dept. works to ensure that all employees are familiar with laws and regulations applicable to each division, conducts surveys on legal systems, and carries out promotional activities for compliance.

Corporate Planning – Legal Affairs

We aim to contribute further to patients' lives in Japan and abroad in accordance with compliance with laws and regulations as a matter of course, as well as the highest ethical standards.

Kaede Shimizu
Legal Affairs Dept., Corporate Planning Division

JCR has continued to vigorously take innovative approaches in developing new technologies and fields while nurturing its foundational businesses. In doing so, JCR has leveraged technologies developed in each stage of its history in the areas of purification technology, growth hormone business, recombinant DNA products, and regenerative medical products. These measures have shaped today's JCR, and have led to its achievements during the previous midterm business plan.

The field of LSDs will drive remarkable growth at JCR in the years ahead. In this field, we are making progress on preparations to expand business in overseas markets. In the Legal Affairs Dept., we have seen a rapid increase in the volume of overseas projects we are handling, including transactions with foreign companies and individuals. Every day, I feel that JCR is evolving at a breakneck pace.

In the Legal Affairs Dept., we review contractual documents and provide supportive service for negotiations on contract terms and conditions in connection with overseas business expansion, along with developing an environment that ensures our integrity and strict compliance. I believe that the role of the Legal Affairs Dept. is to prevent situations that could put the brakes on JCR's entire cycle of business operations, from research and development to production and sale of proprietary products, and provide extensive support to each internal organization so that business can be carried out efficiently. Notably, our main responsibility in the area of compliance has been to build and operate a compliance system that addresses laws, ordinances and regulations in Japan. Going forward, our key priority will be to build and operate a system required by a business enterprise with global operations. For example, it will be essential to take specific measures to respond to anti-bribery laws for foreign government officers and privacy protection laws for individuals in various countries.

Our activities in the area of compliance with overseas laws and regulations mainly consists of initial responses at this time. Looking ahead, we will build and operate monitoring systems and conduct necessary activities in cooperation with experts and other internal departments. We will also take steps such as requiring compliance with important regulations to be expressly incorporated into the terms and conditions of contracts. Since the number of employees is expected to increase further, we would like to implement regular activities to ensure that all employees can obtain the necessary information concerning laws and regulations and internal rules.

The Human Resources Dept. is part of the Administration Division. It is responsible for duties involving workplaces and people, such as recruitment activities, improvements in workplace environments and mental health, and the development of various systems. The Human Resources Dept. listens carefully to people in various positions to ensure that all employees can work comfortably, and strives to carry out personnel affairs focused on employees.

Human Resources

We are developing workplaces where every employee can work in good health and remain highly motivated.

Ayako Watari
Human Resources Dept., Administration Division

I joined JCR in 2001 and marked my 20th year with the Company in 2020. Looking at conditions 10 years ago, I had assumed that it would take a lot longer before we would see new drugs come out of JCR's Research Institute, let alone see JCR aim to become a global business enterprise. However, over the past 10 years, JCR has produced a steady stream of innovative new drugs. I'm excited about JCR's excellent R&D capabilities. At the same time, I draw motivation every day from thinking about what I can do to deliver medicines to patients.

During this time, the number of employees has roughly tripled, JCR has listed its shares on the First Section of the Tokyo Stock Exchange, and net sales and the stock price have performed firmly. Looking from the outside, I think that it would appear that JCR has achieved solid growth over this period. I feel that JCR's growth today is supported by several factors not so easily visible from the outside. These factors include the hard work of employees who have striven tirelessly to surmount numerous obstacles over the past 10 years, and our unwavering corporate culture, which has always promoted an "at-home" atmosphere and valued people since the founding of JCR. Other factors include our flat organization with very close ties between employees and management, and rapid decision-making.

JCR is now working to accomplish a profound transformation to expand its business globally. Companies usually experience teething pains in their growth phases. The Human Resources Dept. faces immense challenges that it must address, such as an increase in exhausted employees due to burgeoning work volumes, and the emergence of new problems concerning people and the organization due to diversifying values. However, I believe that the driving forces behind JCR are its wealth of ideas made possible by its open and free corporate culture, its fast-moving R&D system, and its strong ambitions in rare diseases. Going forward, I'm confident that JCR will remain a company that works tirelessly to accomplish its mission.

To this end, the Human Resources Dept. should address the following key challenges over the next ten years: (1) develop workplaces that adapt to the times, allowing employees to work comfortably; (2) recruit and develop human resources who can perform effectively on the global stage; and (3) build a dynamic organization. I believe that valuing our human resources even more than before, and empowering every employee to grow while giving each of them a great place to work, will lead to the development of the Company. We will listen carefully to employees and heed their views, as we aim to build a strong organization for "Team JCR."

The HR Development & Compliance Dept. is part of the Administration Division. It plans and implements human resource development programs (such as new employee training and tier-specific training) covering all employees. In addition, the HR Development & Compliance Dept. implements compliance activities throughout the Company, and rigorously enforces and monitors fair competition codes and promotion codes in marketing activities.

Talent Development and Compliance

We are working to enhance the skills of employees and improve compliance awareness, in order to achieve lasting growth.

Yukako Onishi
HR Development & Compliance Dept., Administration Division

Heading toward the landmark year of its 50th founding anniversary, JCR expects the Company to grow even larger in the future, as it accelerates R&D and increases the number of employees to expand business globally. Considering the changes JCR will face in its operating environment in the years ahead, I strongly believe that it will be essential to enhance JCR's organizational capabilities even further. With an awareness of the importance of strategic and effective compliance activities and human resource development, I am carrying out the three main duties listed in the diagram below.

If a company becomes widely known for a compliance violation, the resulting harm to its reputation can inflict a fatal wound on the Company. To deliver JCR's medicines to patients around the world, it is imperative that JCR remains a sustainable company. I am assigned to an operation that does not contribute directly to an improvement in business performance. However, I believe that my work provides "road signs" that indicate the relevant laws and regulations, and the voluntary industry standards and internal rules, that JCR should follow, in a simple and straightforward manner. I see my role as making sure everybody can do the right things in the right ways.

I will continue to be driven by a "challenge spirit" and will be guided by JCR's belief of "Think by oneself, act by oneself." Whatever may happen at any time, I would like to assess business operations from a perspective above the fray and consider what is being required of JCR by all of its stakeholders, as I go about fulfilling my duties.

Strengthen compliance awareness ⊗ **Develop human resources who are resilient to change and will serve as the next generation of JCR's leaders**

- Impart an understanding of the need for compliance among all employees and create an environment that encourages habitual conduct based on this understanding
- Support business development to achieve global expansion through such means as gathering the latest information on voluntary industry regulations worldwide and related matters and sharing this information with the relevant departments
- Establish tier-specific training and enhance training systems in accordance with future midterm business plans

Sustainability

Message

JCR believes that “realizing medical care for those living with rare diseases” is the basis for value creation. Based on this belief, JCR seeks to realize sustainability in keeping with the spirit of “No one will be left behind,” as set forth in the Sustainable Development Goals (SDGs). In parallel, JCR will work to solve issues in the key areas of “Rare Diseases,” “Environment,” “Society” and “Corporate Governance,” and share and return the achievements of those efforts to a wide range of stakeholders within and outside the Company.

JCR aims to be a “research-oriented specialty pharma with global exposure.” All members of “Team JCR” will also make a concerted effort to realize a sustainable society. We look forward to your continued understanding and support as we work to achieve our sustainability goals.

Yutaka Honda
Senior Corporate Officer, Head of Corporate Planning Division

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 diseases 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.

Going forward, 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 the achievements of these efforts to a wide range of stakeholders.

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	3
E	**Environment** • Activities rooted in the community to reduce environmental burden through business operations	6, 7, 13, 14, 15
S	**Society** • Improvement of work environments and human resource development for "Team JCR" • Stronger support and new initiatives for rare pediatric diseases and public health	3, 4, 5, 8, 10
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	16
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"	3, 9, 12

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” 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.

At JCR, we promote awareness within the Company by conducting fundraising activities and encouraging employees to wear official badges for Rare Disease Day (RDD), distributing reports on participation by employees in events organized by patient groups and organizations that support patients with rare diseases, and arranging internal lectures for our employees. For each lecture, we invite rare disease specialists and members of patient groups to talk about disease mechanisms and their experiences.

In January 2019, we held our first public seminar titled “Learning More about Rare Diseases” in Ashiya, Hyogo Prefecture, where JCR is headquartered. In addition, we worked closely with the RDD Japan secretariat office to play host to the RDD Internship for Senior High School Students. For this event, we welcomed the participation of students from Kobe Kaisei Girls’ School (September 2019) and Osaka Meisei Gakuen (November 2019). In December 2019, JCR held the first RDD Charity Golf Competition. Japanese professional golfer Masahiro Kawamura, who has been appointed as an RDD Japan ambassador, was invited to the event as a special guest.

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. Funds raised are currently donated on behalf of all employees to The Support Network for NANBYO Children of Japan. From 2020, as a new undertaking, glass film bearing the official RDD logo has been created in-house, and applied to and displayed on the doors and windows of each office. In addition, magnetic sign sheets for vehicles have been applied to company cars and other places as part of our efforts to raise awareness.

Message Yukiko Nishimura President and Founder, NPO ASrid

Therapeutic drugs truly provide the “Hope to Live” to those with rare and intractable diseases and their family members. In the rare and intractable disease arena, companies, patients and researchers can be thought of as the stakeholders of this field. Each of these stakeholders holds high hopes for “getting better” and “finding a cure.” They are making every effort to realize these hopes.

The NPO ASrid sees itself as an intermediary organization independent of stakeholders. From this position, ASrid strives to understand the roles of each stakeholder and conducts patient advocacy activities that harness patients’ voices. Its activities cover a broad range of fields, spanning not only support for basic, applied and clinical research and development, but also public awareness activities and the preparation of basic reports for policy recommendations. None of our activities would be possible without the support of stakeholders in the rare and intractable diseases arena. The rare disease community is an invaluable asset, and JCR is a member of this community. ASrid holds high expectations for its collaboration and partnership with JCR. By working closely together, we are confident that ASrid and JCR can make the “Hope to Live” come true in the broadest possible sense.

NPO ASrid

ASrid stands for “Advocacy Service for Rare and Intractable Diseases’ multi-stakeholders in Japan.” It aims to serve all stakeholders in the rare and intractable disease arena. The RDD Japan secretariat office is located inside ASrid, and ASrid supports official RDD activities in Japan.

Message Masahiro Kawamura Professional golfer and RDD Japan Ambassador

Overseas, professional athletes, as with other prominent members of society, are eager to contribute to society. As a professional golfer, I was looking for a way to give back to society. That was when I crossed paths with JCR’s RARE DISEASE Project and had the opportunity to learn about rare and intractable diseases.

I often compete in professional golf tours in Northern Europe, where RDD activities are popular. My participation in these golf tours is suitable for raising public awareness, and I wanted to let more people know that there is a rising tide of support for RDD activities in Japan. From the summer of 2019, I have displayed the RDD logo on my caddy golf bag, and I have handed out lapel pins and postcards at tournament venues and other sites. I believe that delivering solid results in the tournaments I attend will also help to make RDD known to as many people as possible.

In December 2019, I was appointed as an RDD Japan ambassador. Going forward, I would like to keep on coming up with unique ways to contribute to RDD, while continuing to raise public awareness.

Contributing to Unmet Medical Needs

S Society

Related SDGs

©Nicolas Cleuet

Support for the Swiss Nonprofit Foundation "Global Foundation for Life Sciences"

As part of its efforts to contribute to global health, JCR has continued to support the "Global Foundation for Life Sciences," a nonprofit foundation, since it was 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 this 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.

Support for the "Award for Promotion of Maternal Child Health"

Since 2004, JCR has supported 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, the screening committee selects 15 award recipients from among candidates working in the field of maternal and child health and the awards are presented to the recipients. 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. After the awards presentation ceremony, the recipients are granted the honor of visiting the Akasaka East Residence. There, they receive gracious words of congratulations and encouragement from Her Imperial Highness Crown Princess Akishino.

Photo courtesy of the Mothers' and Children's Health and Welfare Association

Momiji House, a Short-Stay Medical Care Facility

JCR supports Momiji House, Japan's first short-stay medical care facility for children requiring constant medical care. 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 those living with rare and intractable diseases and their family members, JCR has continued to provide seamless 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 2020, JCR gave oral and poster presentations on two candidate treatments for lysosomal storage disorders (LSDs), JR-141 and JR-162, which it is developing with its proprietary J-Brain Cargo® technology, at the 16th Annual WORLD*Symposium*™ 2020 held in Orlando, Florida, in the U.S. This international symposium covers themes ranging from basic research to clinical applications for LSDs. JCR also opened a booth at the event, where it exchanged information with medical professionals, researchers, and patient groups from various countries. JCR is conducting a Phase III trial in Japan and Phase II trial in Brazil for JR-141, a therapeutic enzyme for Hunter syndrome. During 2020, JCR aims to file an application for marketing approval of JR-141 in Japan. We are also making preparations to initiate clinical trials of JR-162, a therapeutic enzyme for Pompe disease, within three years.

JCR's booth at the 16th Annual WORLD*Symposium*™ 2020

Human Resource Management

S Society

Related SDGs

Introducing Flexible Working Systems to Realize Workstyle Reforms

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

Creating an Ideal Workplace Environment Where Employees Can Work Comfortably

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. Separately, in order to explore the possibilities of working from home in each job category, we have been introducing telework on a trial basis in some divisions and job categories, and we have been studying the future introduction of telework on a full scale. JCR aims to introduce a variety of systems in order to provide a workplace environment where employees can work comfortably.

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

Supporting Employees Raising Children

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

In-house childcare center JCR Kids Land

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 9.1% in FY2017), 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.

Introducing Automated External Defibrillators (AEDs)

We have installed AEDs* at each office, plant, and the Research Institute, in order to ensure the safety of employees.

* AED: A medical device that restores normal heart function by delivering an electrical shock to a heart that has undergone ventricular fibrillation (a state in which the heart quivers and cannot pump blood to the entire body).

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 for each employee level. 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

Initiatives to Foster a Sense of Belonging within the Company

As a company that values people, JCR commends employees through a long-service award ceremony held on its founding anniversary in September every year, and gives commemorative gifts to all employees. We also hold a founding anniversary golf tournament, in which many employees participate. In other initiatives, we observe Valentine's Day by presenting sweets made by a local confectioner in Hyogo Prefecture to all employees.

Enhancing Health and Welfare

In preparation for its global development, JCR conducts its annual Study Tour in Europe for employees who have been working at JCR for more than three years. In FY2019, 32 participants visited Luxembourg and Rome. JCR also strives to enhance employee benefits, signing contracts with several outsourcing companies that allow employees and their family members to receive support for leisure pursuits or assistance with efforts to gain qualifications, as well as receive services such as parenting support.

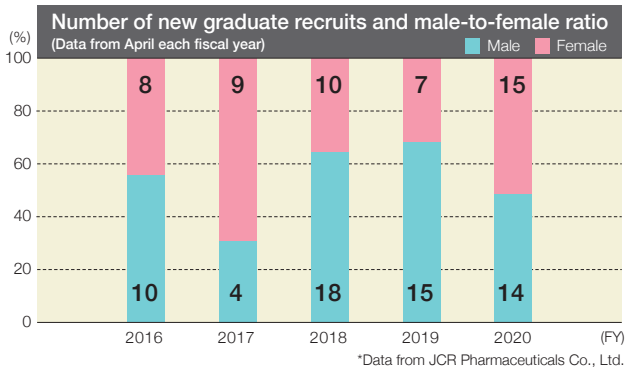
Message

Toshiaki Ikeda Clinical Intelligence Dept., Development Division

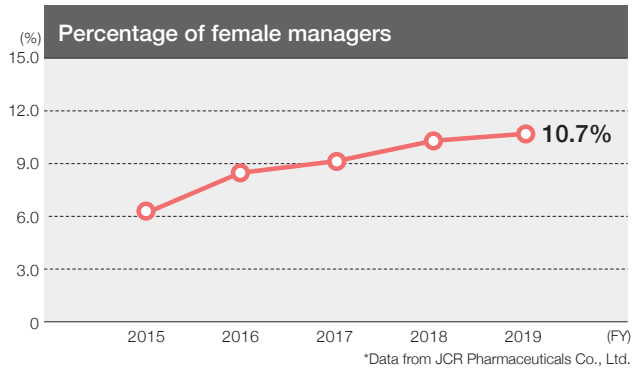
With tier-specific training, we offer a variety of training programs according to job level. These programs range from basic business skills to human resource development. The programs cover a lot of topics that can be put into practice immediately to solve problems and advance projects efficiently. They also provide an opportunity for employees to identify subtle problems in their daily work and fix them. One major selling point of these training programs is that they bring employees together from various departments. This gives employees the chance to swap thoughts and ideas with counterparts in operations where they may have little involvement.

Partnerships with many more people will be needed as the globalization of projects moves forward. In response, I hope to keep on putting these partnerships to work in effective ways, in order to lay a solid foundation for teamwork and build even more attractive teams.

Human Resource Management



*Data from JCR Pharmaceuticals Co., Ltd.



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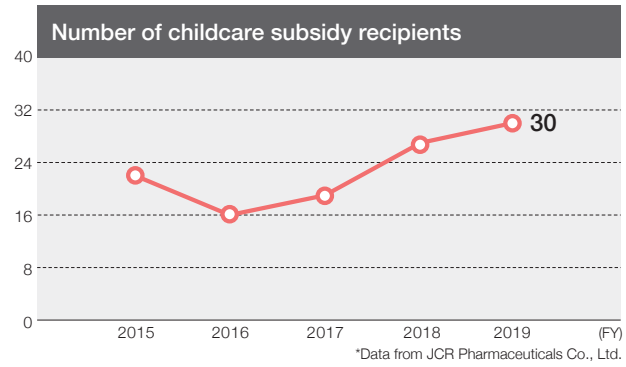

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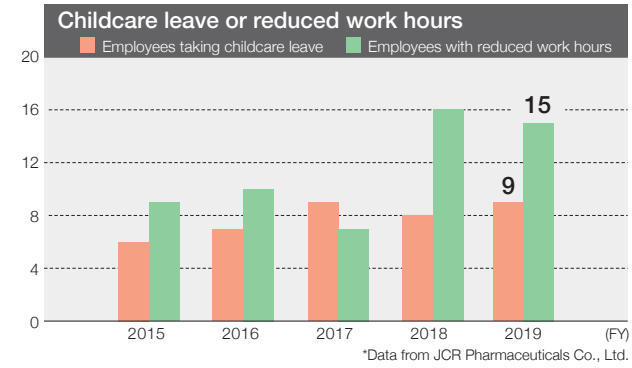


*Data from JCR Pharmaceuticals Co., Ltd.

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 compound pharmaceuticals. Moreover, pharmaceuticals for rare diseases require detailed manufacturing plans because a large number of items are produced in small quantities. At its production sites, JCR sets quality targets to continuously manufacture products with a consistent level of quality, and evaluates the status of achievement of those targets every year. As we pursue future global expansion, we have started operating a new 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

JCR's products require a longer period of time to manufacture than small molecule pharmaceuticals because they involve more time-consuming and complicated manufacturing processes. Meanwhile, biopharmaceuticals and regenerative medical products have a short shelf life, so it would be impractical to build up inventories. Additionally, since many JCR products are administered to patients over the long term, an unstable supply can be directly detrimental to the interests of patients. For this reason, JCR conducts manufacturing at its in-house manufacturing sites in Japan to allow for flexible manufacturing schedules for important processes. 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 our in-house facilities 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. The information collected is evaluated immediately and the need for any safety measures is confirmed. Concurrently, JCR compares the information it collects with accumulated safety data and verifies whether there are any changes in trends. Regular safety evaluations are also conducted. If safety measures are necessary, JCR will convey information swiftly and reliably to all users that require it, such as medical professionals, in accordance with its procedures. These activities are implemented and records are kept based on a clear assignment of responsibility.

In order to implement these measures appropriately, JCR has prepared safety management operating procedures and regularly communicates the importance of collecting information to all employees, as well as management. Notably, JCR provides regular training to medical representatives (MRs), who directly interface with medical professionals, as part of its efforts to improve the safety awareness vital to undertaking its corporate business activities.

System of Cooperation among Three Executives

In accordance with the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, 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 shipment, recall and safety measures, which are critical decisions for JCR. Through this independent governance system, JCR assures the safety and effectiveness 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 product transportation, 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” with an internally developed logistics system, along with implementing logistics measures in compliance with Good Distribution Practice (GDP) guidelines.

Due to their physical properties, the products handled by JCR require strict temperature control at all times, including during delivery. Pharmaceuticals such as GROWJECT® are delivered using Eco Thermostat Shuttle (ETS) boxes designed and developed in-house. ETS boxes maintain a constant internal temperature regardless of the outside air temperature. In addition, security tags are attached to ETS boxes to ensure theft prevention measures and the prevention of contamination with counterfeit medicines, in line with the priority of ensuring the “Integrity of Pharmaceuticals” as set forth by the GDP guidelines. Moreover, JCR has enabled the delivery and storage of TEMCELL® HS Inj. under a constant extremely low temperature of less than −150°C for more than 10 days by utilizing an ultra-low cold chain system developed jointly with MEDIPAL HOLDINGS CORPORATION.

In recent years, in order to address an increasingly serious shortage of truck drivers, the “White Logistics Movement” has been advanced in Japan for the purpose of ensuring the stable logistics activities necessary for daily life and industrial activity, and to support economic growth. JCR believes that this crisis in the transportation industry could lead to a situation where it would be unable to ship products, which could impact its supply obligations. Based on this belief, JCR endorsed the “White Logistics Movement” at an early stage. JCR cooperates closely with carriers by providing advance notice of arrival and shipment information and through other means. By doing so, JCR strives to reduce the waiting time for truck drivers during the loading or unloading of shipments.

Going forward, JCR will continue to build relationships of trust with carriers and to actively study how to secure delivery routes during disasters as a business continuity planning (BCP) measure. One particularly urgent task is to secure delivery routes under unpredictable conditions when there are earthquakes.

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.

Environmental Awareness

E Environment

Related SDGs

Initiatives for Environmental Conservation

JCR has been taking a wide range of steps to mitigate its environmental impact, including reducing CO_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.

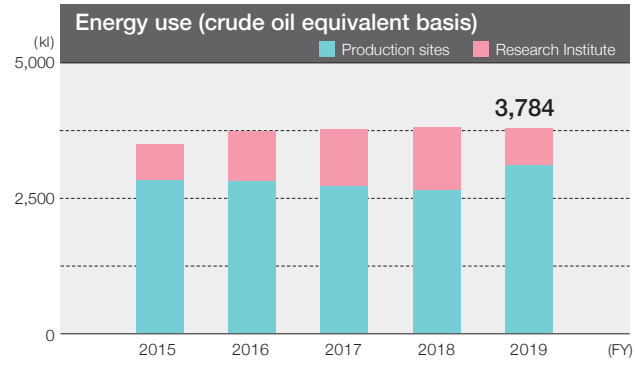
In 2015, we introduced electric vehicles as a means of transportation between sites, in conjunction with installing power feed systems at our headquarters as well as at plants and the Research Institute. Currently, hybrid cars account for around half of the vehicles used in JCR's business activities. Going forward, we will gradually phase in electric vehicles as public charging stations become more widely available. In 2016, we installed a solar power generation system at our Research Institute (in Nishi-ku, Kobe). Moreover, we have taken steps to improve energy consumption in production activities in cooperation with The Kansai Electric Power Company, Incorporated.

Electric vehicle

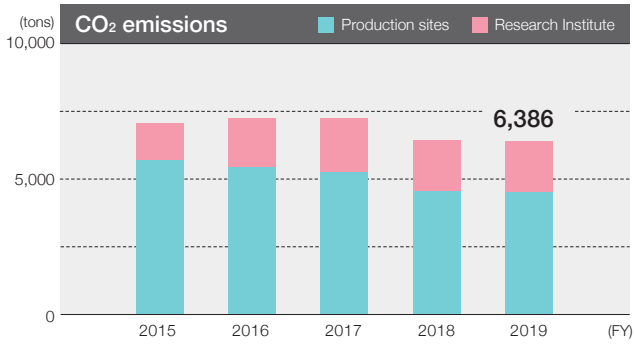
Energy Use

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.

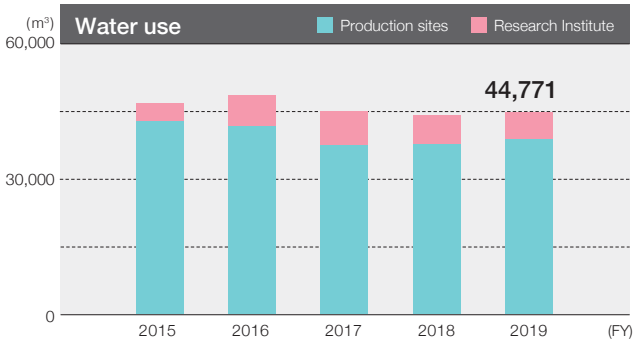
CO_2 emissions from business activities in FY2019 were 426 tons.



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



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



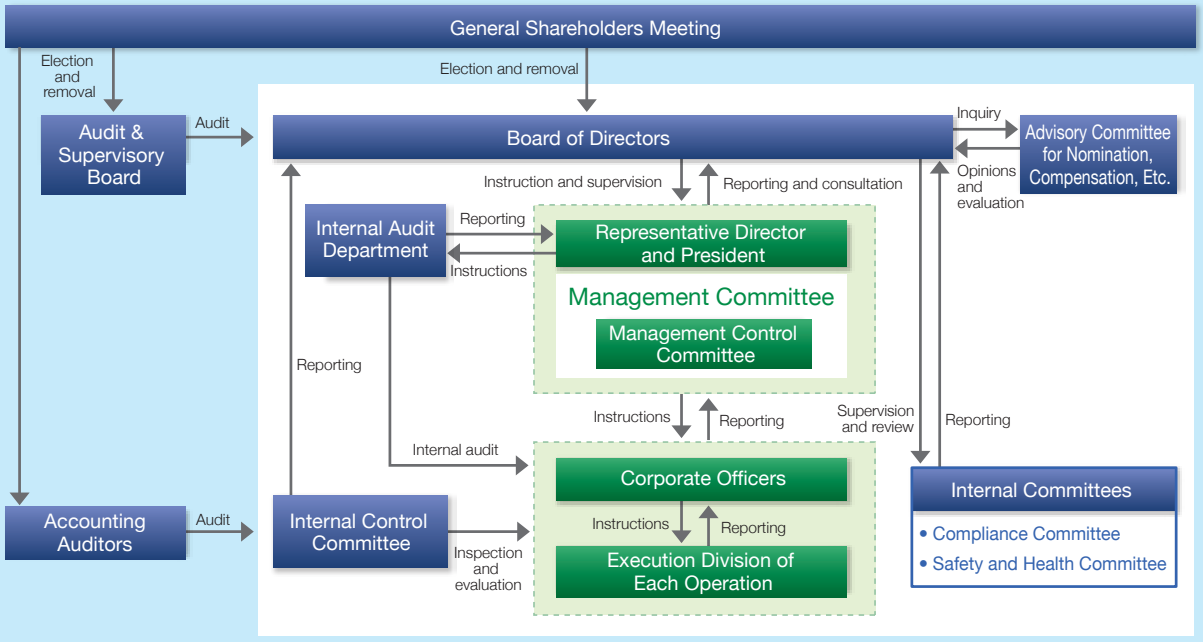
*Data from production sites and the Research Institute of JCR Pharmaceuticals Co., Ltd.

Water Resources

We have managed to either reduce or maintain 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. All water used in research and production activities has been treated appropriately.

Corporate Governance

Corporate Governance System (As of June 24, 2020)



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, and Safety and Health Committee. 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, two Senior Corporate Officers and two 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. Two Senior Corporate Officers and two 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 three 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., Human Resources 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.

Composition, Number of Meetings Held, and Attendance Rate for Organs of the Company in FY2019

(As of end of FY2019)

Board of Directors	Composition	9 members (5 Internal Directors, 3 Independent Outside Directors, 1 Outside Director)
	Number of meetings held	13 (including 1 extraordinary Board of Directors' meeting)
	Attendance rate	99.15% (Absence: 1 Outside Director, 1 time)
Management Committee	Composition	18 members (5 Internal Directors, 1 Independent Outside Director, 2 Independent Outside Audit & Supervisory Board Members, 1 Director of a subsidiary, 6 Corporate Officers, 1 Executive Director of Development Div., 1 Adviser, 1 Consultant)
	Number of meetings held	20
	Attendance rate	88.14% (Absence: 1 Internal Director, two times; 1 Independent Outside Director, 15 times; 1 Independent Outside Audit & Supervisory Board Member, 1 time; 1 Director of a subsidiary, 3 times; 1 Adviser, 3 times; and several Corporate Officers, several times)
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	90.24% (Absence: 2 Independent Outside Directors, several times)
Audit & Supervisory Board	Composition	5 members (5 Independent Outside Audit & Supervisory Board Members)
	Number of meetings held	13 (including 1 extraordinary Audit & Supervisory Board meeting)
	Attendance rate	100%
Internal Control Committee	Composition	10 members (1 Executive Director of Administration Div., 2 from Legal Affairs Dept., 3 from Internal Audit Dept., 1 from Accounting Dept., 2 from Human Resources & General Affairs Dept., and 1 from Production Management Dept.)
	Number of meetings held	7
	Attendance rate	80.00% (Absence: Several members, several times)

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 22.46% 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.

Reasons for Appointment of Outside Directors and Outside Audit & Supervisory Board Members

Category	Name	Independent Directors	Reason for Appointment
Outside Directors	Toshihiro Ishikiriyama	○	Appointed as an Outside Director because we would like him to make use of his experience and knowledge as a leader of a pharmaceutical company in JCR's management.
	Takashi Suetsuna	○	Appointed as an Outside Director because of his wealth of experience in administrative agencies; we would like him to apply this experience, as well as his global perspective as a diplomat, to JCR's management.
	Toshihide Yoda	—	Appointed as an Outside Director because of his extensive knowledge as a pharmaceutical sector analyst in the financial industry; we would like him to apply his experience as a leader of many new businesses over the years to JCR's management.
	Yuko Hayashi, Ph.D.	○	Appointed as an Outside Director because of her professional knowledge on the practical application of innovation and extensive experience in areas such as research activities related to advanced medicines and promoting diversity and women's participation and advancement in the workplace. We would like her to apply this experience to JCR's management.
Outside Audit & Supervisory Board Members	Kazumasa Oizumi	○	Appointed as an Outside Audit & Supervisory Board Member to leverage his experience in the financial industry as well as experience as a company board member; we would like him to perform audits based on his abundant knowledge and insights.
	Kazuhiko Yamada	○	Appointed as an Outside Audit & Supervisory Board Member due to his professional experience and expertise as a certified tax accountant; we would like him to perform audits from a taxation and financial perspective.
	Kenjiro Miyatake	○	Appointed as an Outside Audit & Supervisory Board Member to utilize his experience as a leader of a pharmaceutical company; we would like him to perform audits from an experienced and well-informed standpoint.
	Takeshi Komura	○	Appointed as an Outside Audit & Supervisory Board Member because of his wealth of experience in administrative agencies and broad insights into monetary and financial affairs; we would like him to perform audits of JCR using the aforementioned experience and insights, as well as his experience and knowledge as an Outside Director for other companies.
	Shuichi Tani	○	Appointed as an Outside Audit & Supervisory Board Member because of his wealth of experience related to public health, deep insights into medical welfare, and profound perspectives on educational institutions; we would like him to perform audits of the Company based on his experience, insights and perspectives.

Compliance

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, Director 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 Manual, along with making compliance matters more widely known and raising awareness through a compliance newsletter.

Occupational Safety and Health

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.

Risk Management

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 Business Continuity Plan (BCP) priorities. The BCP is reviewed each fiscal year and revised if needed.

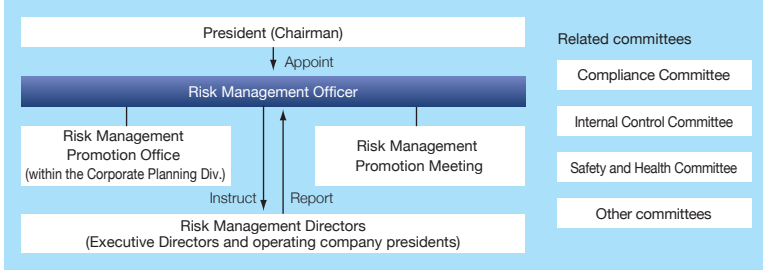
1. Response measures in the event of a disruption in the supply of GROWJECT®
2. Company-wide response measures in the event of a large-scale disaster
3. Response measures in the event of a major compliance violation

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 in FY2019

(As of end of FY2019)

Compliance Committee	Compliance Control Committee	Composition	16 members (2 attorneys, 5 Internal Directors, 1 Independent Outside Audit & Supervisory Board Member, 7 Corporate Officers, 1 from Legal Affairs Dept.)
		Number of meetings held	1
		Attendance rate	93.75% (Absence: 1 Internal Director, 1 time)
	Compliance Promotion Committee	Composition	16 members (1 from Legal Affairs Dept., 3 from HR Development & Compliance Dept., 2 from Human Resources & General Affairs Dept., 1 from Sales Div., 1 from Development Div., 1 from Research Div., 6 from Production Div., 1 from Quality Assurance Div.)
		Number of meetings held	2
		Attendance rate	100%
Safety and Health Committee		Composition	18 members (1 licensed social insurance labor consultant, 3 industrial physicians, 6 from Human Resources & General Affairs Dept., 1 from Sales Div., 2 from Corporate Planning Div., 1 from Quality Assurance Div., 1 from Tokyo Office, 1 from Development Div., 2 from consolidated subsidiaries)
		Number of meetings held	12
		Attendance rate	91.20% (Absence details omitted)

Board of Directors and Corporate Officers

(As of July 1, 2020)

Directors

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)

Hiroshi Yoshimoto

Representative Director
Senior Vice President
In charge of Production Division
Executive Director, Production Division

1972 Entered Taito Pfizer Co., Ltd. (currently Pfizer Japan Inc.)
1999 Plant Manager, Basic Production Plant
Nagoya Plant of the same
2003 Executive Officer, Pharmaceutical Bulk Manufacturing, Nagoya Plant of the same
2011 Entered JCR Pharmaceuticals
Executive Director, Production Division (current post)
Appointed Corporate Officer
2012 Appointed Director
2014 Appointed Managing Director
2016 Appointed Senior Vice President (current post)
2018 Appointed Representative Director (current post)
Head of Production Division
2020 In charge of Production Division (current post)

Toru Ashida

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

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

Hiroyuki Sonoda, Ph.D.

Senior Executive Director
Head of Research and Development Division
Executive Director, Research Division
Director, Drug Discovery Research, 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 (current post)
Head of Research and Development Division (current post)
Executive Director, Research Division (current post)
Director, Drug Discovery Research, Research Division (current post)

Mathias Schmidt, PD, Ph.D.

Senior Executive Director
In charge of Global Strategy
ArmaGen, Inc. President and 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 (current post)
2010 Principal and Head of Biologics Department, Nycomed GmbH, Germany (currently, Takeda GmbH)
2012 Vice President of Biological Sciences, Takeda California, Inc.
2016 President and Chief Executive Officer, ArmaGen, Inc. (current post)
2019 Executive Vice President, Head of Research and Development, Triphase Accelerator Corporation (current post)
2020 Appointed Director, JCR Pharmaceuticals (current post)
In charge of Global Strategy (current post)

Outside Directors

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. (current post)
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
2008 Entered Barclays Capital Securities Japan Limited
Managing Director of the same
2010 Director, MEDIPAL HOLDINGS CORPORATION
2012 Director and Managing Director of the same
In charge of IR and General Manager, Business Development Department CMA® of the same (current post)
2016 Director, SPLine Corporation
Director, MEDIE Co., Ltd. (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)

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

Akihiro Haguchi
Senior Corporate Officer
Head of Administration Division
Executive Director,
Administration Division

Yutaka Honda
Senior Corporate Officer
Head of Corporate Planning Division
Director, Office of the President
Executive Director,
Corporate Planning Division

Takayo Egawa
Corporate Officer
Director,
International Affairs Office

Kazunori Tanizawa
Corporate Officer
Executive Director,
Development Division

Audit & Supervisory Board Members/Messages from an Outside Director and an Outside Audit & Supervisory Board Member

(As of July 1, 2020)

Audit & Supervisory Board Members

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)

Further Advancement of JCR's Female Employees

Yuko Hayashi, Ph.D.
Outside Director

In the World Economic Forum's Gender Gap Index, Japan posted a low reading of 0.652 (Iceland placed first, at 0.887. Perfect gender equality is set at index value of 1). Japan has had to accept a ranking of 121st out of 153 countries. Japan's low index is due partly to very few women in decision-making positions. JCR is no exception. JCR has relatively low ratios of women in positions of Director or Audit & Supervisory Board Member (6.7%), manager (10.9%), and assistant manager (22.2%). Clearly, this is a pressing issue that the Company needs to work on going forward.

As the COVID-19 pandemic runs rampant, one common feature of countries that have managed the outbreak effectively are that they have female leaders. This has attracted a lot of interest. Forbes magazine has listed the leadership characteristics of female leaders behind this feat as "acceptance of the truth," "decisiveness," "the use of technology," and "empathy and care." For example, Prime Minister Sanna Marin of Finland, the world's youngest head of state, mobilized social media influencers to provide fact-based information on managing the pandemic to those in age groups that seldom read the press. Prime Minister Erna Solberg of Norway, Prime Minister Mette Frederiksen of Denmark, and Prime Minister Jacinda Ardern of New Zealand captured the hearts of many of their citizens by communicating directly with them. Notably, Norway's Prime Minister held a dedicated press conference for her country's children, using television to talk directly to them. This kind of leadership, which differs from conventional leadership styles, can be learned by first gaining experience as a leader of a small group, and then broadening your sphere of influence to larger groups. I have every expectation that from the moment they take their first steps forward, JCR's female employees will grow into new leaders in the post-pandemic era.

JCR's Governance Priorities from the Perspective of a Full-Time Outside Audit & Supervisory Board Member

Kazumasa Oizumi
Full-Time Outside Audit & Supervisory Board Member

Guided by its corporate philosophy of "Contributing towards people's healthcare through pharmaceutical products," JCR has initiated a revolution to expand business not only in Japan but also globally, with concerted efforts led by "Team JCR." Against this backdrop, as a full-time Outside Audit & Supervisory Board Member, I'm determined to contribute to JCR's sound and sustainable growth and improvement in corporate value. I'm particularly focused on the Environment, Society and Governance (ESG) fields.

The relevant topics include the priorities listed below:

- Increase the appointment of Independent Outside Directors among the members of the Board of Directors (3 Independent Outside Directors (including one woman) and 5 Independent Outside Audit & Supervisory Board Members among a total of 15 Directors and Audit & Supervisory Board Members, for a total of 8 independent outside members; as of April 2020)
- Foster in-depth constructive discussion in forums such as the Board of Directors, Audit & Supervisory Board, Advisory Committee for Nomination, Compensation, Etc., and business meetings (discussion sessions with specific themes among members of the Board of Directors and Audit & Supervisory Board).
- Analysis and assessment of the effectiveness of the Board of Directors and responses to identified issues
- Ensure management transparency and dialogue with market participants through timely and accurate disclosure of information
- Strive to contribute to unmet medical needs through business activities focused on pediatric diseases, along with enhancing activities related to Rare Diseases (RD).

Looking ahead, we can expect various issues to occur as JCR expands the scale of its business, such as issues in the Rare Diseases (RD) domain, including in overseas markets. In response, we will listen closely to those on the front lines, and perform effective audit activities as Audit & Supervisory Board Members. By doing so, I would like to facilitate the creation of new value by "Team JCR" and achieve strong corporate governance and sustainability.

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 commenced sales of 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.

【Indications】 • 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 sales of 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.

【Indications】 • 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 sales of 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.

【Indications】 • Fabry disease

Production Sites

Seishin Plant
Regenerative medical products and 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] and Darbepoetin Alfa BS Inj. [JCR]
- APIs for investigational products such as JR-141

Development pipeline and progress (As of July 1, 2020)

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)	Japan	Phase III	Enzyme Replacement Therapy (ERT) J-Brain Cargo®*1
			Brazil	Phase II	
JR-162	J-Brain Cargo®-applied acid α-glucosidase (rDNA origin)	Pompe disease	Japan	Preclinical	ERT J-Brain Cargo®
JR-171	BBB-penetrating α-L-iduronidase (rDNA origin)	Mucopolysaccharidosis I (Hurler syndrome, etc.)	Japan	Preclinical	ERT J-Brain Cargo® J-MIG System®*2
JR-441	BBB-penetrating heparan N-sulfatase (rDNA origin)	Mucopolysaccharidosis III-A (Sanfilippo syndrome type A)	Japan	Preclinical	ERT J-Brain Cargo®
JR-443	BBB-penetrating β-glucuronidase (rDNA origin)	Mucopolysaccharidosis VII (Sly syndrome)	Japan	Preclinical	ERT J-Brain Cargo®
JR-446	BBB-Penetrating α-N-acetylglucosaminidase (rDNA origin)	Mucopolysaccharidosis III-B (Sanfilippo syndrome type B)	Japan	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 I	J-MIG System®
JR-041	Follicle-stimulating hormone (rDNA origin)	Infertility	Japan	Phase I/II	Out-licensed to ASKA Pharmaceutical Co., Ltd.
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.

*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 and were higher than initially anticipated, as a steady sales trend outweighed the negative impact of NHI price revisions. Sales of TEMCELL® HS Inj. (regenerative medical product) also trended steadily, with sales much higher than initially anticipated and up sharply on the previous fiscal year's result. Moreover, in November 2019, we commenced sales of Darbepoetin Alfa BS Inj. [JCR], a long-acting erythropoiesis-stimulating agent. Together with Epoetin Alfa BS Inj. [JCR], sales of JCR's therapeutic products for renal anemia increased from the previous fiscal year. On the other hand, revenue from licensing decreased year on year. Overall, the JCR Group's net sales for FY2019 amounted to 24,781 million yen (7.0% increase from the previous fiscal year), marking the eighth straight year of sales growth.

Sales Breakdown (Millions of yen)

	FY2018	FY2019
GROWJECT®	11,978	**12,650**
Epoetin Alfa BS Inj. [JCR]	4,511	**4,097**
Darbepoetin Alfa BS Inj. [JCR]	—	**1,412**
TEMCELL® HS Inj.	2,041	**3,126**
Agalsidase Beta BS I.V. Infusion [JCR]	74	**317**
Urine-derived products	690	**1,041**
Revenue from licensing	3,560	**2,050**
Others	303	**84**
Total	23,160	**24,781**

Gross Profit

Due to the increase in net sales, gross profit increased 1.7% from the previous fiscal year to 16,880 million yen. As a result of the decrease in revenue from licensing, the cost of sales ratio increased 3.5 percentage points from FY2018 to 31.9%.

Operating Income

R&D expenditures increased 37.7% from FY2018, and selling, general and administrative expenses, including R&D expenditures, were 13,635 million yen, up 17.3% from the previous fiscal year. As a result, operating income decreased 34.7% year on year to 3,244 million yen.

Ordinary Income

JCR recorded non-operating income, primarily interest income and dividends income. Nonetheless, ordinary income decreased 35.0% year on year to 3,293 million yen.

Profit Attributable to Owners of Parent

Extraordinary income was 131 million yen, an increase of 49 million yen year on year, due to the recording of reversal of provision for loss on guarantees. As a result of the foregoing, income before income taxes was 3,422 million yen, down 30.6% year on year. Profit attributable to owners of parent declined 27.9% year on year to 2,678 million yen.

Financial Position

Assets

Total assets as of March 31, 2020 stood at 47,775 million yen, an increase of 5,259 million yen from March 31, 2019.

Current assets rose 973 million yen from a year earlier to 28,342 million yen. This increase was mainly due to an increase in cash and deposits, which offset decreases in notes and accounts receivable-trade and securities. Non-current assets increased 4,285 million yen from a year ago to 19,433 million yen. This increase was mainly due to an increase in property, plant and equipment, primarily reflecting the expansion of research facilities.

Liabilities

Total liabilities as of March 31, 2020 stood at 15,195 million yen, an increase of 3,553 million yen from March 31, 2019.

Current liabilities rose 1,749 million yen from a year earlier to 10,434 million yen. This increase was mainly due to increases in short-term loans payable and accounts payable-other. Non-current liabilities increased 1,803 million yen from March 31, 2019 to 4,761 million yen. This increase was mainly due to an increase in long-term loans payable.

Net Assets

Net assets rose 1,705 million yen from March 31, 2019 to 32,579 million yen. This increase was mainly due to the recording of profit attributable to owners of parent.

As a result, the equity ratio as of March 31, 2020 was 66.6%, down 4.5 percentage points from March 31, 2019.

Cash Flow

Net cash provided by operating activities in FY2019 amounted to 4,927 million yen, an increase of 1,022 million yen from the previous fiscal year. The main components were income before income taxes of 3,422 million yen, depreciation and amortization of 1,434 million yen, and a decrease in notes and accounts receivable-trade of 857 million yen.

Net cash used in investing activities amounted to 4,161 million yen (a change of 4,401 million yen from net cash provided in the previous fiscal year). Cash was used mainly for the purchase of property, plant, and equipment of 4,838 million yen, while there were proceeds from sales and redemption of securities of 698 million yen.

Net cash provided by financing activities amounted to 2,048 million yen (a change of 2,965 million yen from cash used in the previous fiscal year). Cash was provided mainly by proceeds from long-term loans payable of 3,050 million yen, while there were cash dividends paid of 989 million yen.

Forecast for FY2020

In terms of sales, we anticipate net sales growth on top of steady increases in sales volume for mainstay products such as GROWJECT®, and our therapeutic products for renal anemia, specifically Epoetin Alfa BS Inj. [JCR] and Darbepoetin Alfa BS Inj. [JCR]. In addition, we will continue our proactive efforts in the licensing business. Based on these factors, the JCR Group's overall sales are forecast at 27,200 million yen, an increase of 9.8% 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 6,000 million yen, up 84.9% from the current fiscal year. Ordinary income is forecast to increase 82.2% year on year to 6,000 million yen. Profit attributable to owners of parent is forecast at 4,800 million yen, an increase of 79.2% 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.

Under our basic policy to provide continuous and stable dividends, we will pay out a term-end dividend for FY2019 of 17 yen per share. Together with the interim dividend of 15 yen per share, the total annual dividend is 32 yen per share.

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 FY2020 (the term ending March 2021) of 36 yen per share, comprising an interim dividend and term-end dividend of 18 yen each.

11-Year Financial Data

Consolidated fiscal years ended March 31

	FY2009	FY2010	FY2011	FY2012
Fiscal year				
Net sales	14,387	14,457	12,845	14,099
Operating income	2,007	1,407	1,089	1,150
Profit attributable to owners of parent	1,302	926	633	730
Comprehensive income	—	783	664	1,161
R&D expenditures	2,325	2,017	1,841	1,991
Capital investment	2,369	2,417	487	1,494
Depreciation and amortization	743	975	1,101	979
Cash flows from operating activities	2,357	(18)	(421)	1,661
Cash flows from investing activities	(3,396)	(2,211)	1,539	(178)
Cash flows from financing activities	1,756	(1,276)	(1,065)	(238)
End of fiscal year				
Total assets	29,148	29,817	28,967	31,286
Net assets	20,483	22,832	22,633	23,496
Shareholders' equity	20,462	22,762	22,535	23,368
Information per share				
Earnings per share (EPS)	50.77	28.93	19.75	23.03
Net assets	700.80	704.96	710.82	735.86
Dividends	15.00	12.00	12.00	12.00
Financial indicators				
Equity ratio (%)	70.2	76.3	77.8	74.7
Return on equity (ROE) (%)	7.0	4.3	2.8	3.2
Dividend payout ratio (%)	29.5	41.5	60.8	52.1
Numbers of employees	311	399	424	437

(Millions of yen)

FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	**FY2019**
15,705	16,855	17,438	18,085	20,594	23,160	**24,781**
1,545	2,014	2,152	2,362	3,784	4,967	**3,244**
1,296	1,682	1,789	1,863	3,070	3,715	**2,678**
1,544	1,936	1,557	1,831	3,016	4,008	**2,504**
2,202	3,334	3,348	4,071	4,211	4,354	**5,997**
2,260	1,522	1,237	1,409	908	1,517	**5,296**
1,111	1,352	1,407	1,447	1,382	1,343	**1,434**
4,565	499	2,201	2,651	3,133	3,905	**4,927**
(2,668)	(1,419)	(980)	(841)	(1,587)	240	**(4,161)**
(369)	(1,261)	(1,314)	146	(2,175)	(917)	**2,048**
33,464	34,086	35,346	36,385	38,398	42,516	**47,775**
24,580	26,264	27,062	27,585	27,528	30,874	**32,579**
24,417	26,101	26,819	27,305	26,999	30,249	**31,806**

(Yen)

40.79	52.85	56.12	58.95	98.73	120.68	**86.89**
768.13	818.64	843.34	864.66	877.86	982.14	**1,031.69**
17.00	18.50	22.00	22.00	26.00	30.00	**32.00**
73.0	76.6	75.9	75.0	70.3	71.1	**66.6**
5.4	6.6	6.8	6.9	11.3	13.0	**8.6**
41.7	35.0	39.2	37.3	26.3	24.9	**36.8**
472	501	526	566	568	632	**667**

(Millions of yen)

Consolidated Balance Sheets

	As of March 31, 2019	**As of March 31, 2020**
Assets		
Current assets		
Cash and deposit	7,836	10,973
Notes and accounts receivable-trade	8,835	7,977
Securities	661	220
Merchandise and finished goods	2,281	880
Work in process	1,473	2,929
Raw materials and supplies	5,363	5,046
Other	917	315
Total current assets	27,368	28,342
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	4,475	5,115
Machinery, equipment and vehicles, net	830	867
Land	3,882	5,664
Lease assets, net	239	74
Construction in progress	851	2,283
Other, net	782	869
Total property, plant and equipment	11,061	14,875
Intangible assets	110	263
Investments and other assets		
Investment securities	2,941	2,408
Deferred tax assets	378	721
Net defined benefit assets	297	243
Other	383	943
Allowance for doubtful accounts	(24)	(23)
Total investments and other assets	3,975	4,294
Total non-current assets	15,147	19,433
Total assets	42,516	47,775

(Millions of yen)

	As of March 31, 2019	**As of March 31, 2020**
Liabilities		
Current liabilities		
Notes and accounts payable-trade	586	679
Short-term loans payable	3,630	4,880
Lease obligations	178	46
Accounts payable-other	1,104	2,854
Income taxes payable	801	534
Provision for bonuses	666	713
Provision for directors' bonuses	77	77
Other	1,639	648
Total current liabilities	8,684	10,434
Non-current liabilities		
Long-term loans payable	1,850	3,800
Lease obligations	73	31
Provision for loss on guarantees	240	108
Allowance for employee stock ownership benefits	36	47
Net defined benefit liability	710	730
Other	46	44
Total non-current liabilities	2,957	4,761
Total liabilities	11,642	15,195
Net assets		
Shareholders' equity		
Capital stock	9,061	9,061
Capital surplus	10,922	10,891
Retained earnings	13,350	15,039
Treasury stock	(3,937)	(3,865)
Total shareholders' equity	29,397	31,127
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	773	583
Foreign currency translation adjustments	149	134
Remeasurements of defined benefit plans	(71)	(39)
Total accumulated other comprehensive income	851	679
Subscription rights to shares	435	584
Non-controlling interests	189	189
Total net assets	30,874	32,579
Total liabilities and net assets	42,516	47,775

(Millions of yen)

Consolidated Statements of Income

	FY2018 (From April 1, 2018 to March 31, 2019)	**FY2019** (From April 1, 2019 to March 31, 2020)
Net sales	23,160	24,781
Cost of sales	6,567	7,901
Gross profit	16,592	16,880
Selling, general and administrative expenses	11,625	13,635
Operating profit	4,967	3,244
Non-operating income		
Interest income	20	19
Dividend income	25	25
Foreign exchange gains	39	8
Insurance income	39	—
Dividend income from insurance	13	14
Other	10	13
Total non-operating income	148	81
Non-operating expenses		
Interest expenses	21	22
Loss on redemption of securities	19	—
Other	7	9
Total non-operating expenses	47	32
Ordinary income	5,068	3,293
Extraordinary income		
Reversal of provision for loss on guarantees	75	131
Other	6	—
Total extraordinary income	82	131
Extraordinary losses		
Loss on disposal of non-current assets	37	2
Loss related to voluntary recalling of products	181	—
Other	2	—
Total extraordinary losses	221	2
Profit before income taxes	4,928	3,422
Income taxes – current	1,169	1,017
Income taxes – deferred	48	(274)
Total income taxes	1,217	742
Profit	3,710	2,679
Profit (loss) attributable to non-controlling interests	(4)	1
Profit attributable to owners of parent	3,715	2,678

Consolidated Statements of Comprehensive Income

Profit	3,710	2,679
Other comprehensive income		
Valuation difference on available-for-sale securities	311	(189)
Foreign currency translation adjustment	(10)	(18)
Remeasurements of defined benefit plans, net of tax	(3)	32
Total other comprehensive income	297	(175)
Comprehensive income	4,008	2,504
(Comprehensive income attributable to)		
Comprehensive income attributable to owners of parent	4,003	2,505
Comprehensive income attributable to non-controlling interests	4	(0)

Consolidated Statements of Changes in Net Assets

From April 1, 2018 to March 31, 2019

(Millions of yen)

	Shareholders' equity				
	Capital stock	Capital surplus	Retained earnings	Treasury stock	Total shareholders' equity
Beginning balance	9,061	10,947	10,469	(4,042)	26,435
Changes during the year					
Dividends paid			(833)		(833)
Profit attributable to owners of the parent			3,715		3,715
Purchase of treasury shares				(0)	(0)
Disposal of treasury shares		(25)		105	80
Changes of items other than shareholders' equity (net)					
Total changes for the year	—	(25)	2,881	105	2,961
Ending balance	9,061	10,922	13,350	(3,937)	29,397

	Accumulated other comprehensive income						
	Valuation difference on available-for-sale securities	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	462	169	(67)	563	344	185	27,528
Changes during the year							
Dividends paid							(833)
Profit attributable to owners of the parent							3,715
Purchase of treasury shares							(0)
Disposal of treasury shares							80
Changes of items other than shareholders' equity (net)	311	(19)	(3)	288	90	4	384
Total changes for the year	311	(19)	(3)	288	90	4	3,345
Ending balance	773	149	(71)	851	435	189	30,874

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 the parent			2,678		2,678
Purchase of treasury shares				(1)	(1)
Disposal of treasury shares		(29)		73	43
Purchase 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	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 the parent							2,678
Purchase of treasury shares							(1)
Disposal of treasury shares							43
Purchase 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

(Millions of yen)

Consolidated Statements of Cash Flows	FY2018 (From April 1, 2018 to March 31, 2019)	**FY2019** (From April 1, 2019 to March 31, 2020)
Net cash provided by (used in) operating activities		
Income before income taxes	4,928	3,422
Depreciation and amortization	1,343	1,434
Increase (decrease) in provision for loss on guarantees	(75)	(131)
Increase (decrease) in net defined benefit liability	69	37
Increase (decrease) in provision for bonuses	105	46
Share-based compensation expenses	144	175
Interest and dividends income	(45)	(44)
Interest expenses	21	22
Foreign exchange losses (gains)	(23)	(11)
Decrease (increase) in notes and accounts receivable-trade	(1,732)	857
Decrease (increase) in accounts receivable-other	93	35
Decrease (increase) in inventories	(157)	258
Increase (decrease) in accounts payable-trade	0	92
Increase (decrease) in accounts payable-other	57	357
Increase (decrease) in accrued consumption taxes	138	(164)
Increase (decrease) in advanced received	(83)	11
Other, net	364	(233)
Subtotal	5,150	6,167
Interest and dividends income received	49	44
Interest expenses paid	(21)	(22)
Income taxes (paid) refund	(1,272)	(1,262)
Net cash provided by (used in) operating activities	3,905	4,927
Net cash provided by (used in) investing activities		
Expenditures on time deposits	(100)	—
Purchase of securities	—	100
Proceeds from sales and redemption of securities	1,257	698
Purchase of property, plant and equipment	(895)	(4,838)
Purchase of investment securities	(0)	(30)
Other, net	(20)	(91)
Net cash provided by (used in) investing activities	240	(4,161)
Net cash provided by (used in) financing activities		
Increase (decrease) in short-term loans payable	300	1,000
Proceeds from long-term loans payable	200	3,050
Repayment of long-term loans payable	(413)	(850)
Repayments of lease obligations	(196)	(176)
Net decrease (increase) in treasury stock	26	15
Cash dividends paid	(834)	(989)
Other, net	—	(1)
Net cash provided by (used in) financing activities	(917)	2,048
Effect of exchange rate change on cash and cash equivalents	12	20
Net increase (decrease) in cash and cash equivalents	3,241	2,836
Cash and cash equivalents at beginning of period	4,850	8,091
Cash and cash equivalents at end of period	8,091	10,928

Corporate Information

As of March 31, 2020

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
667 (Consolidated) 654 (Non-Consolidated)

Subsidiaries

Family Health Rental Co., Ltd. (Japan)*1
Chromatech Co., Ltd. (Japan)
JCR Engineering Co., Ltd. (Japan)
He Bei Jie Xi Bio-products Co., Ltd.*2
JCR INTERNATIONAL SA (Switzerland)
JCR USA, Inc. (U.S.)

*1 Absorbed by JCR through a merger on April 1, 2020.
*2 In liquidation.
Note: JCR reached an agreement to acquire ArmaGen, Inc. (U.S.) on March 26, 2020. The acquisition was completed on April 10, 2020, and ArmaGen became a wholly owned subsidiary of JCR.

Stock Information

Listed on
Tokyo Stock Exchange First Section

Securities Code
4552

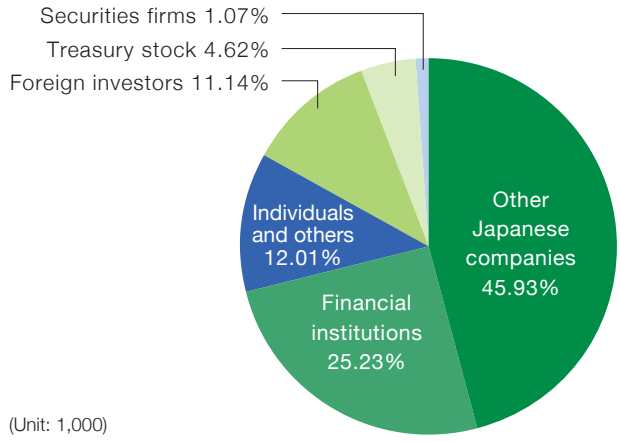
Total Number of Outstanding Shares
32,421,577

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
3,734

Composition of Shareholders



Principal Shareholders

(Unit: 1,000)

Name of shareholder	Number of shares held
MEDIPAL HOLDINGS CORPORATION	7,282
Kissei Pharmaceutical Co., Ltd.	3,800
Future Brain Co., Ltd.	2,177
The Master Trust Bank of Japan, Ltd. (Trust account)	2,072
Japan Trustee Services Bank, Ltd. (Trust account)	1,783
The Nomura Trust and Banking Co., Ltd. (Trust account: A)	1,630
Sumitomo Dainippon Pharma Co., Ltd.	850
Mochida Pharmaceutical Co., Ltd.	550
Japan Trustee Services Bank, Ltd. (Trust account: 5)	287
Employee Shareholding Association of JCR Pharmaceuticals Co., Ltd.	275

* The Company holds 1,497,959 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)797-32-8591

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

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