# Annual Report 2019

"HIYAKU" Leap into the Future 飛躍

JCR Pharmaceuticals Co.,Ltd.

Year Ended March 31, 2019

# We continue to take on challenges as a specialty pharma to create innovative pharmaceutical products as value-added treatment options for the under-served patient community.

## 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.

## Compilation Policy

# In accordance with its corporate philosophy, JCR seeks to be a company which "takes one step beyond" at all times. 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 engaging in rare and intractable diseases with our advanced biotechnologies, and further developing and creating regenerative medical products. To fulfill those missions, JCR has continuously taken on challenges one step ahead of its competitors in a unified manner as "Team JCR."

In "Annual Report 2019," we explain the broad outlines of JCR's business activities, with a focus on business management and financial information. The report also covers non-financial information including sustainability activities. Through this report, we seek to foster a full understanding of JCR's business activities among a wide range of stakeholders.

## Contents







- **Period covered:** FY2018 (From April 1, 2018 to March 31, 2019)
  * This report contains some contents of FY2019.
- **Organizations covered:** JCR Group (JCR Pharmaceuticals Co., Ltd. and other six consolidated subsidiaries)
  * See explanatory notes for exceptions.
- **Unit in financial information:** In principle, numerical values are rounded down to the nearest whole number in the specific unit. However, when a unit is in hundred millions, values are rounded up or down to the nearest hundred million yen.

### Forward-Looking Statements

This Annual Report 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. Factors or events that could cause our actual results to be materially different from those expressed in our forward-looking statements include, but not limited to, 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.

# 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 proprietary technology development and creation of products in a manner keeping one step ahead of competitors at all times. This has led to steady growth and recognition as "JCR, the biopharma," and the successful listing on the First Section of the Tokyo Stock Exchange in 2013. In 2015, which marked the 40th anniversary of JCR, we received the marketing approval for TEMCELL® HS Inj., the first allogeneic regenerative medical product in Japan. We will continue to actively take on challenges for development also in the field of cell therapy and regenerative medicine.

**1975**
JCR Pharmaceuticals Co., Ltd. founded

**1978**
Sales of Urokinase drug solution (intermediate) started

**1985**
Import and sales of Grorm® started
Urokinase product launched

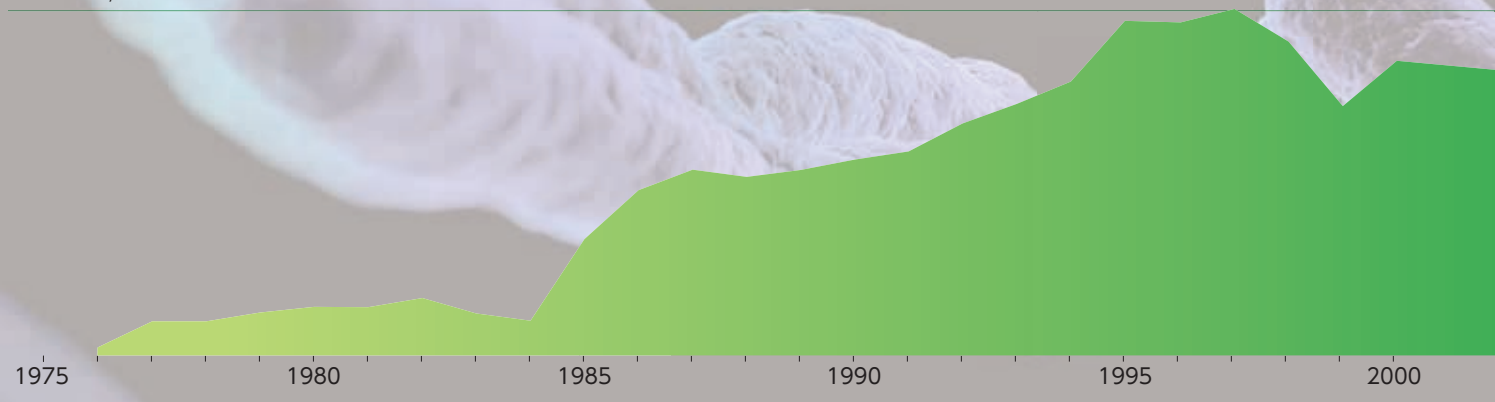
**1993**
GROWJECT® Inj. 4IU, a recombinant hGH product, launched

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

**2010**
Epoetin Alfa BS Inj. [JCR] for treatment of renal anemia, the first biosimilar in Japan, launched

**2013**
Listing on the First Section of the Tokyo Stock Exchange (TSE)

**2014**
Japanese corporate name changed to JCRファーマ 株式会社




## With "Accumulated Technologies" as the Foundation, Moving to the Stage of Further "HIYAKU" (Leap into the Future)

JCR's history started from the production of "Urokinase," a urine-derived protein-degrading enzyme. JCR aims to achieve further "HIYAKU" as a specialty pharma company that keeps taking on challenges in drug development for rare diseases, which has been our target since our inception, with our proprietary biotechnologies, technologies for cell therapy and regenerative medicine, and gene therapy technologies.


Production at the time of foundation


Production today

- Challenge to New Technologies
- Tissue Targeting Technologies
- Technologies for Cell Therapy and Regenerative Medicine
- Technologies for Developing Recombinant DNA Product
  - High-level Protein Purification Technology

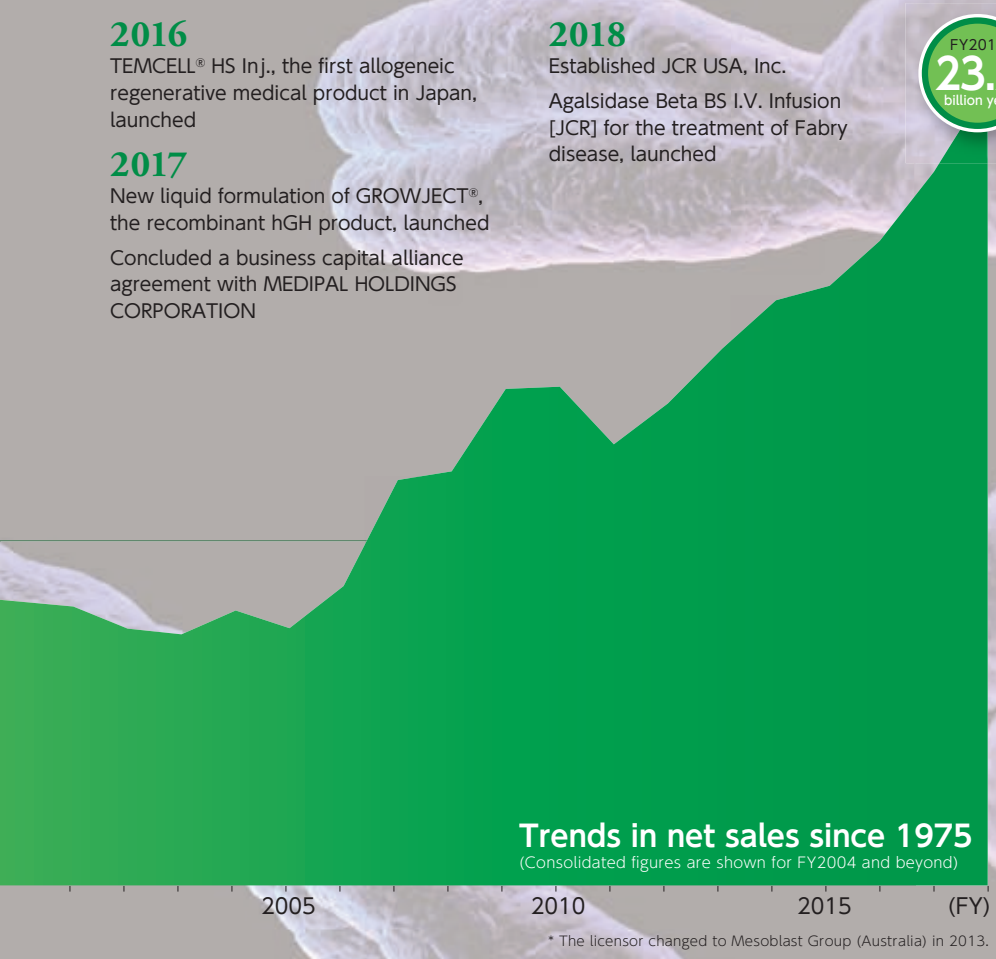
## 2016
TEMCELL® HS Inj., the first allogeneic regenerative medical product in Japan, launched

## 2017
New liquid formulation of GROWJECT®, the recombinant hGH product, launched

Concluded a business capital alliance agreement with MEDIPAL HOLDINGS CORPORATION

## 2018
Established JCR USA, Inc.

Agalsidase Beta BS I.V. Infusion [JCR] for the treatment of Fabry disease, launched




**Trends in net sales since 1975**
(Consolidated figures are shown for FY2004 and beyond)

* The licensor changed to Mesoblast Group (Australia) in 2013.

- Gene Therapy
- Blood-Brain Barrier Penetration Technology, J-Brain Cargo®
- Cell Therapy and Regenerative Medicine Technology
- Recombinant DNA Technology
- Cell Culture Technology
- Scale up Cultivation Technology

## JCR's Strengths

**1 Proprietary Biotechnologies**
– at the forefront of innovation

**2 Cell Therapy and Regenerative Medicine Technologies**
– achievement of our challenges

**3 Development Capabilities**
– full-fledged from research to commercialization

**4 Production System**
– adapted to global standards

**5 Business Structure**
– focused on target domains

**6 Management Structure**
– capable of speedy decision making

**7 Proactive Team of Multi-Talented Human Resources**

# In FY2018, JCR delivered a wide range of achievements that will further accelerate its growth.

### July 2018

**JCR Initiates Phase III Clinical Trial for the Expanded Indication of GROWJECT® (Recombinant Human Growth Hormone) for Short Stature Homeobox-containing Gene (SHOX) Deficiency (JR-401X)**

SHOX deficiency will be the fifth indication for GROWJECT®.

### August 2018

**JCR Initiates Phase III Clinical Trial of JR-141, a Blood-Brain Barrier-Penetrating Therapeutic Enzyme for the Treatment of Hunter Syndrome**

JR-141 has been designed under the SAKIGAKE Designation System in Japan by the Ministry of Health, Labour and Welfare in March 2018. During 2020, JCR plans to file an application for marketing approval for JR-141 in Japan.

### September 2018

**JCR to Initiate Development of a New Drug Candidate for Sanfilippo Syndrome Type A Using J-Brain Cargo® (JR-441)**

Sanfilippo syndrome type A (mucopolysaccharidosis type IIIA) belongs to mucopolysaccharidosis, of which Hunter syndrome and Hurler syndrome are well-known subtypes. It is characterized by the deficiency of a specific enzyme called heparan N-sulfatase, which is responsible for the degradation of heparan sulfate. This deficiency results in accumulation of heparan sulfate, leading to various symptoms including central nervous system (CNS) disorders, sleep disorders, hepatosplenomegaly and seizures.

### September 2018

**JCR Files for Marketing Approval for JR-131, a Long-Acting Erythropoiesis-Stimulating Agent**

JCR and Kissei Pharmaceutical Co., Ltd. have been conducting development of JR-131, a proposed biosimilar to darbepoetin alfa, since the two companies entered into a collaborative research and development agreement for JR-131 in September 2013.

### October 2018

**Orphan Drug Designation by the US Food Drug Administration for JR-141 for Hunter Syndrome**

### November 2018

**Launch of Agalsidase Beta BS I.V. Infusion [JCR] for Fabry Disease**

This product is not only JCR's first enzyme replacement therapy (ERT) product for lysosomal storage disorders (LSDs), but also the first domestically-produced therapeutic enzyme for LSDs.

2018.4 | 5 | 6 | 7 | 8 | 9 | 10

### August 2018

**JCR Receives "Kurumin" Certification to Support the Development of the Next Generation**

JCR has received the "Kurumin" Certification from the Minister of Health, Labour and Welfare, in compliance with certification criteria based on Japan's Act on Advancement of Measures to Support Raising Next-Generation Children.

### October 2018

**JCR Receives Recognition in the 2018 (Third Annual) Hyogo Women's Active Participation Awards**

JCR has received recognition in the 2018 (Third Annual) Hyogo Women's Active Participation Awards as a company that promotes active roles for working women in Hyogo Prefecture.

## December 2018

### JCR Completes Patient Enrollment in Phase III Clinical Trial of JR-141 in Japan for Hunter Syndrome

This clinical trial will evaluate the effect of JR-141 on the changes in the systemic and central nervous system (CNS) symptoms over a 12-month period in patients with Hunter syndrome. The primary endpoint is changes of biomarkers in the cerebrospinal fluid.

## February 2019

### Administration of JTR-161/JR-161 Dental Pulp Cells Product Starts in Clinical Trial in Japan, Aiming to Provide a New Treatment Option for Acute Cerebral Infarction

In July 2017, Teijin and JCR signed a co-development and license agreement for JTR-161/JR-161 in Japan. JTR161/JR-161 is a regenerative medical product composed of dental pulp stem cells (DPCs) for the indication of acute cerebral infarction (stroke). Since signing the agreement, the two companies have been conducting research and development on JTR-161/JR-161.

## February 2019

### JCR Receives EMA Orphan Designation for JR-141 in Hunter Syndrome

## February 2019

### JCR Completes Patient Enrollment in Phase II Clinical Trial of JR-141 for Hunter Syndrome in Brazil

JCR is pursuing clinical trials of JR-141 for Hunter syndrome in Brazil with the full participation of leading specialists in this area and their contribution to the study. Brazil has been selected as our first step toward global development because of its substantial number of patients diagnosed with Hunter syndrome, many of whom are concentrated in specialist hospitals for treatment by leading specialists in this area.

## March 2019

### JCR Files for Additional Marketing Approval of TEMCELL® HS Inj. (JR-031EB) (Allogeneic Bone Marrow-Derived Mesenchymal Stem Cells) for the Indication of Epidermolysis Bullosa

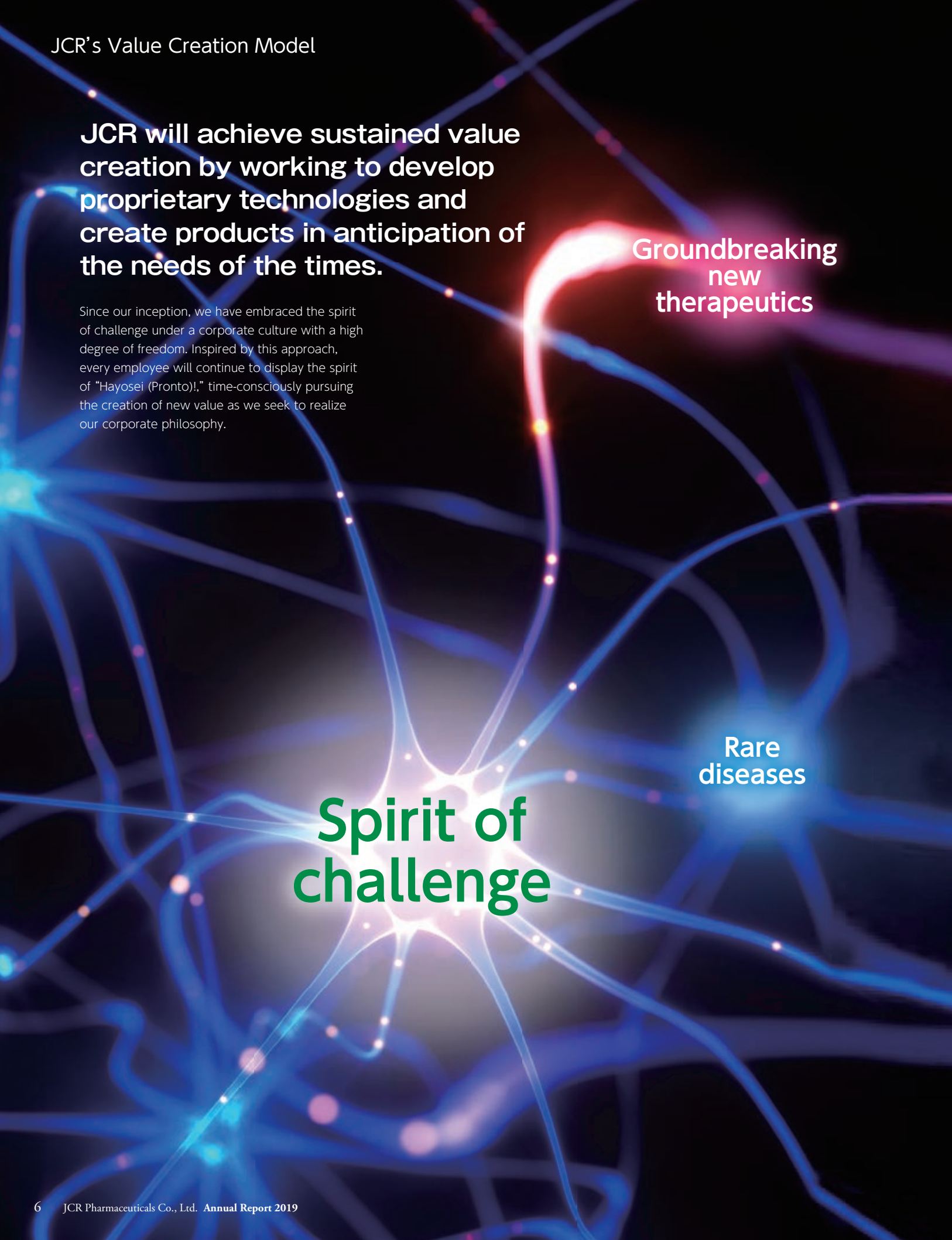
Epidermolysis Bullosa is a serious and rare genetic disease in which the extremities and joints can become covered in blisters and sores from slight external force, and developments in new treatment methods are greatly desired.



## January 2019

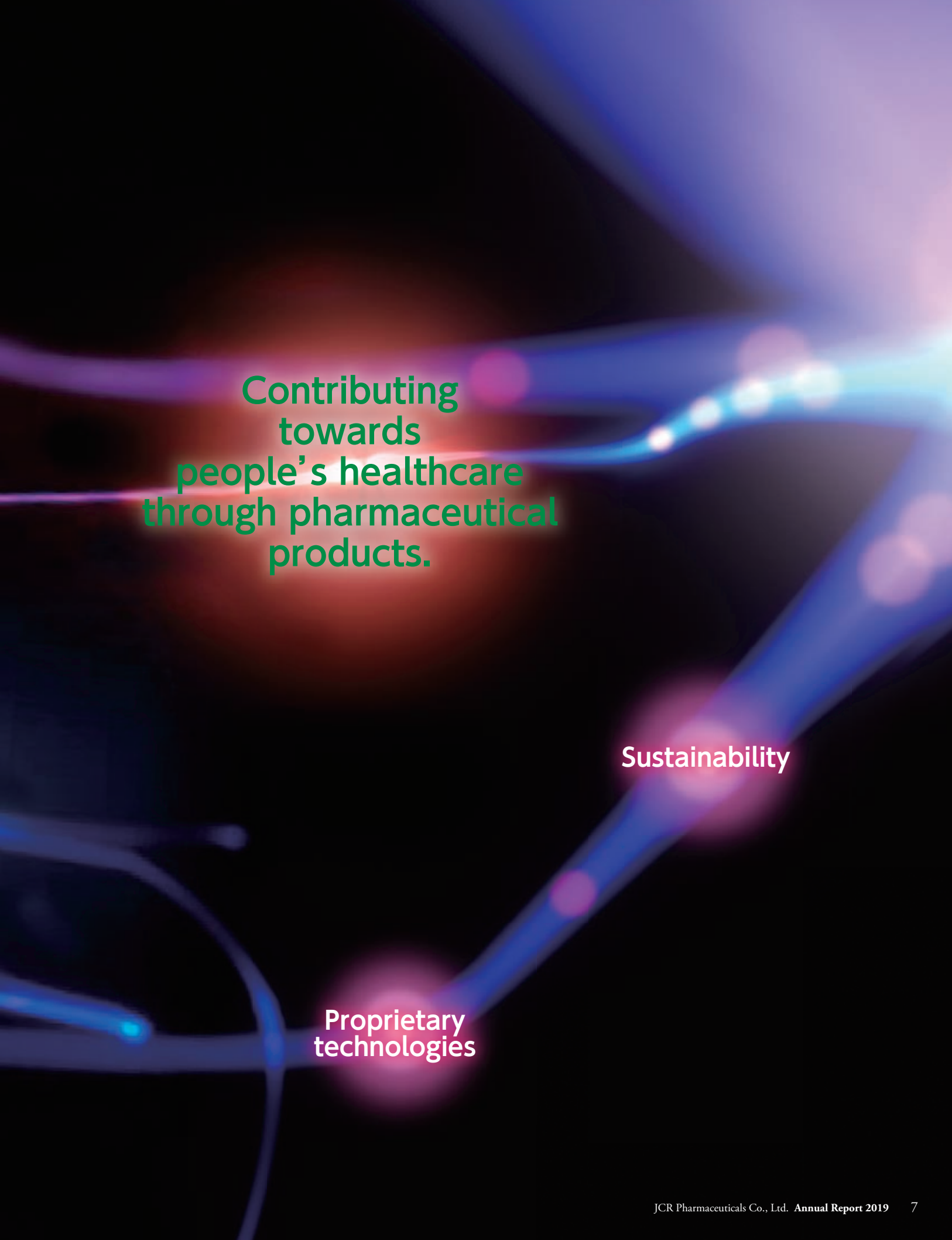
### JCR Acquires “Eruboshi” Certification Based on the Act on Promotion of Women’s Participation and Advancement in the Workplace

The “Eruboshi” certification system requires a company to compile and report to the Ministry of Health, Labour and Welfare (MHLW) an action plan based on the Act on Promotion of Women’s Participation and Advancement in the Workplace. The Minister of Health, Labour and Welfare certifies companies that demonstrate outstanding performance in the promotion of women’s advancement. JCR satisfied four of the five criteria and was awarded “Eruboshi” (Grade 2) certification.



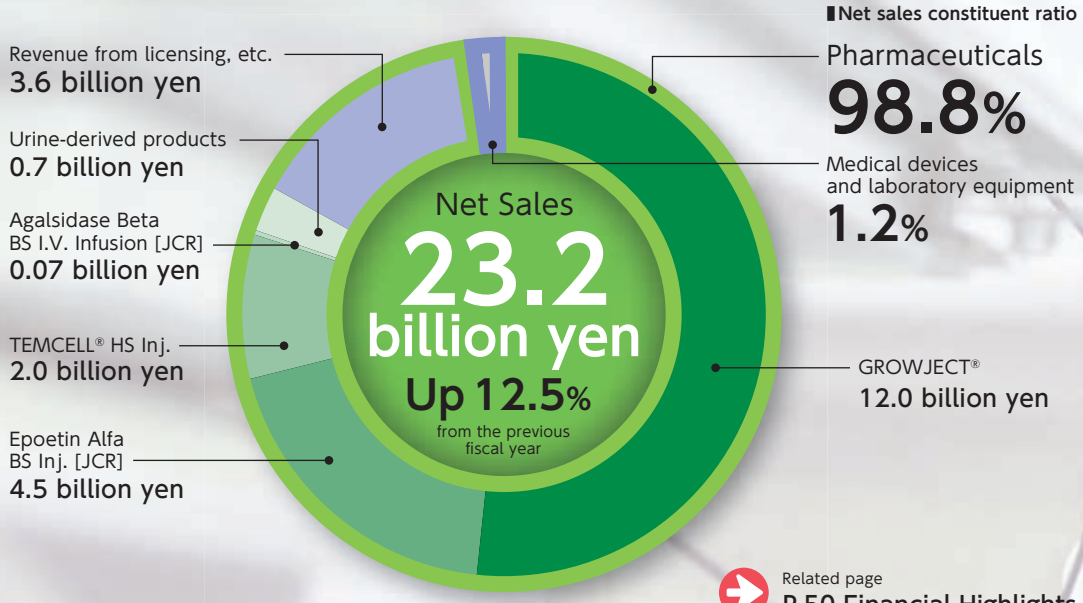

## JCR will achieve sustained value creation by working to develop proprietary technologies and create products in anticipation of the needs of the times.

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 continue to display the spirit of "Hayosei (Pronto)!," time-consciously pursuing the creation of new value as we seek to realize our corporate philosophy.


Contributing towards people's healthcare through pharmaceutical products.
Sustainability
Proprietary technologies

# We deliver high-quality biopharmaceuticals and regenerative medical products through our full-fledged capabilities from R&D to production and commercialization.

## Net Sales in FY2018

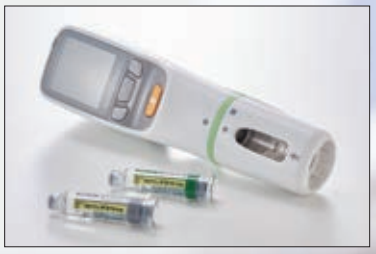



Related page
P.50 Financial Highlights

## Core Products

Recombinant human growth hormone product

GROWJECT®



Recombinant erythropoietin product

Epoetin Alfa BS Inj. [JCR]

## Business Process

### Research and Development

We leverage our proprietary biotechnologies, cell therapy and regenerative medicine technologies to accelerate the research and development of therapeutic candidates for rare diseases.

Related pages
P.22 Special Topic: Challenges in Cell Therapy and Regenerative Medicine
P.26 Research and Development

### Production

A world-class production/quality assurance system has been established, with cutting edge production technologies introduced to four sites.

Related page
P.32 Production System

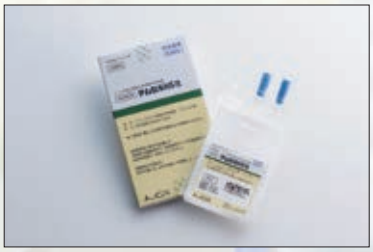
### Marketing

We carry out sales promotion activities focused on the target domain at eight business bases across Japan and address the needs of medical professionals of each region.

Related page
P.34 Marketing Strategies

Human somatic stem cell-processed products
Human (allogenic) bone marrow-derived mesenchymal stem cells

### TEMCELL® HS Inj.



Recombinant product for Fabry disease

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

# Accepting the challenge of creating the world's first innovative biopharmaceuticals originating from Japan, JCR will leap into a new stage.

The key concept of the "Mid-Term Management Plan for FY2015 to FY2019" is "HIYAKU (leap into the future)" towards a new stage. Under this plan, we are advancing initiatives to become a "research-oriented specialty pharma with global exposure," driven by strengths cultivated since JCR's inception.

Related page
P.14 Top Message

## Key Concept of Mid-Term Management Plan for FY2015 to FY2019

飛躍 HIYAKU

**Now is the time to leap into the future**

## What JCR Is Today

### R&D oriented pharmaceutical company with leading technologies

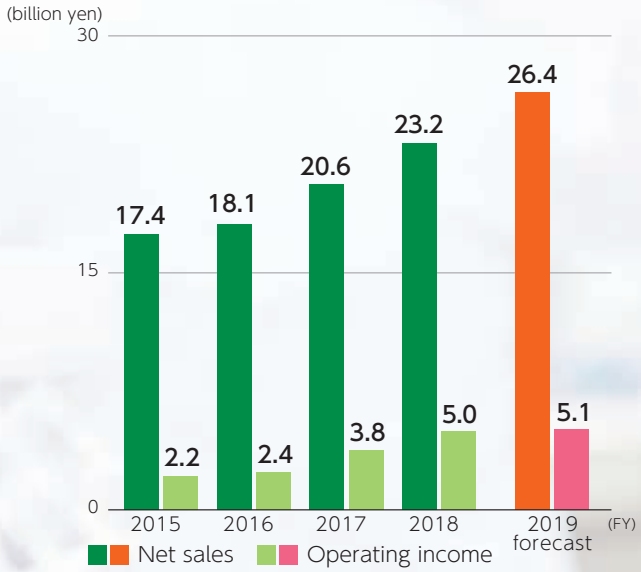
Proprietary biotechnologies,
cell therapy and regenerative medicine technologies,
and gene therapy technologies

## Points of Focus to Achieve Our Goals

1. Advancing R&D activities one step beyond
2. Reinforcing our capabilities via new businesses development
3. Further enhancing "Business Structure" and "Product Strategy"
4. Reinforcing "Management Platform"

## Fiscal 2015-2018 Results

### Net Sales/Operating Income




### Launch of New Products

TEMCELL® HS Inj.

GROWJECT® (liquid formulation)

Agalsidase Beta BS I.V. Infusion [JCR]

[JCR's Vision]

# Research oriented specialty pharma with global exposure

### Initiation of Drug Development

- JR-162 (Therapeutic enzyme for the treatment of Pompe disease)
- JR-171 (Therapeutic enzyme for the treatment of Hurler syndrome)
- JR-441 (Therapeutic enzyme for the treatment of Sanfilippo syndrome type A)
- JR-401X (Expanded indication of GROWJECT® for short stature homeobox-containing gene (SHOX) deficiency)
- JR-031EB (Expanded indication of TEMCELL® HS Inj. for epidermolysis bullosa through subcutaneous administration)
- JR-031HIE (Expanded indication of TEMCELL® HS Inj. for neonatal hypoxic ischemic encephalopathy)
- JTR-161/JR-161 (Regenerative medical product for the indication of acute cerebral infarction (stroke))

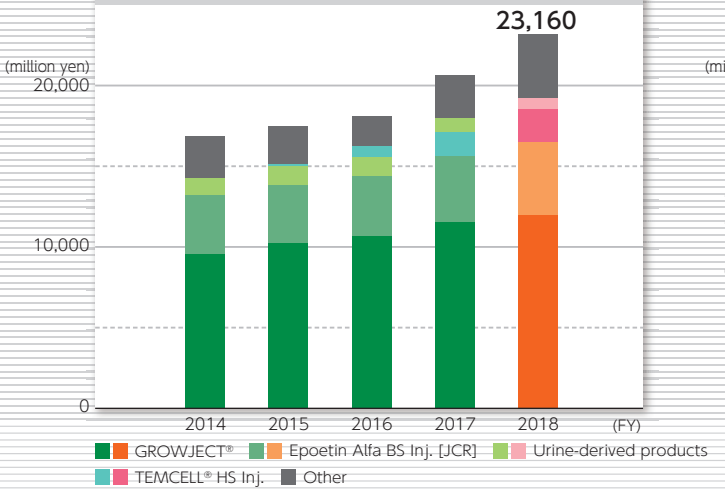
### Business Expansion

- Opened the Clinical Trial Material Manufacturing Center (CTMC) and Cell Processing Center (CPC)
- Signed a business and capital alliance agreement with MEDIPAL HOLDINGS CORPORATION
- Signed a memorandum of understanding (MoU) with the Grand Duchy of Luxembourg on the leasing of an industrial site
- Established JCR USA, Inc. as a joint venture company in the United States
- Initiated JCR's first clinical trial in Brazil as a step towards global development (JR-141)
- Started construction of the Second Clinical Trial Material Manufacturing Center

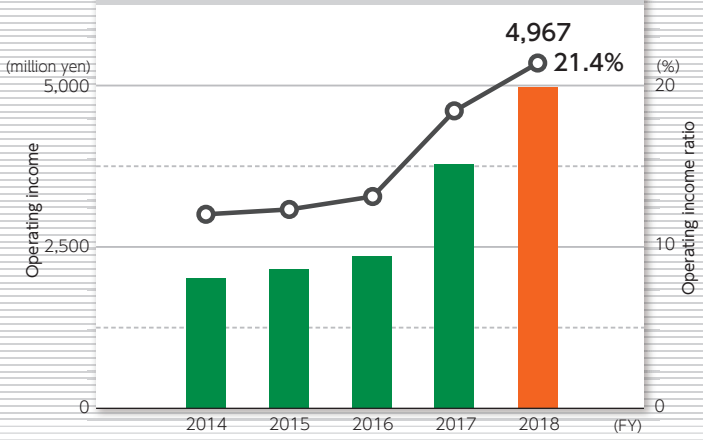
# Consolidated Financial and Non-Financial Highlights

JCR Pharmaceuticals Co., Ltd. and Subsidiaries

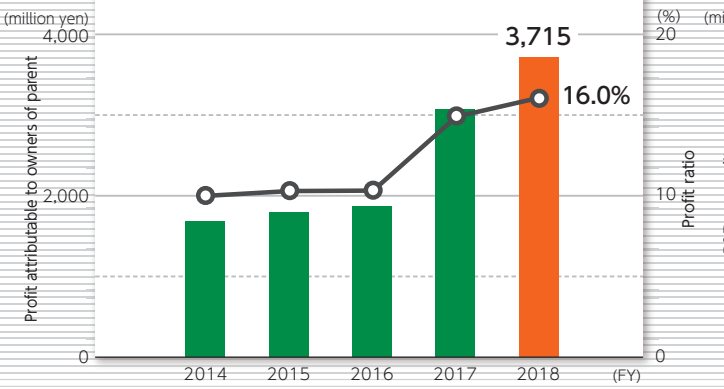
## Net sales by product



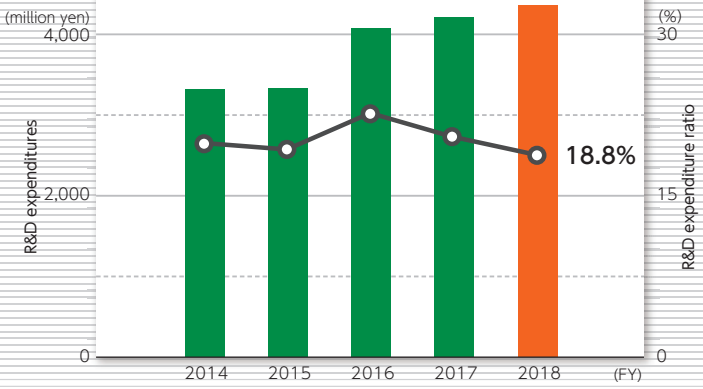

## Operating income/Operating income ratio



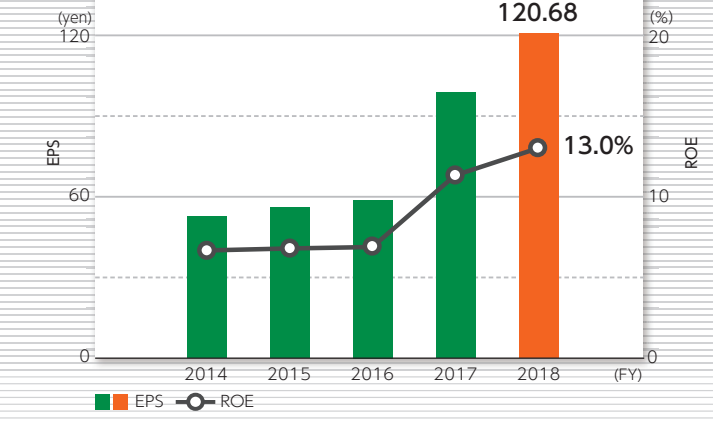

## Profit attributable to owners of parent/Profit ratio



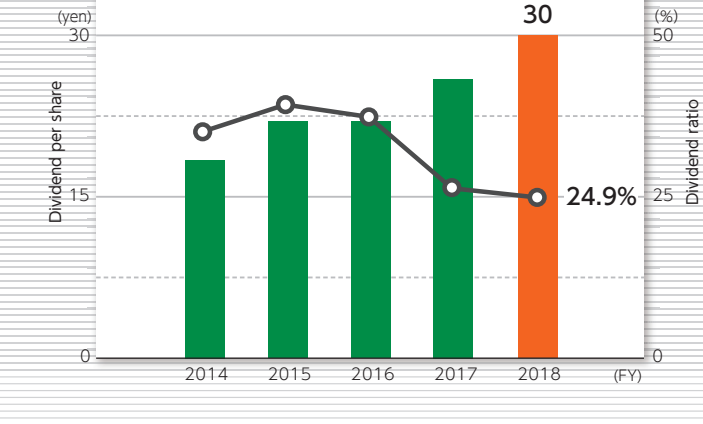

## R&D expenditures/R&D expenditure ratio




## EPS and ROE




## Dividend per share/Dividend ratio





Related pages

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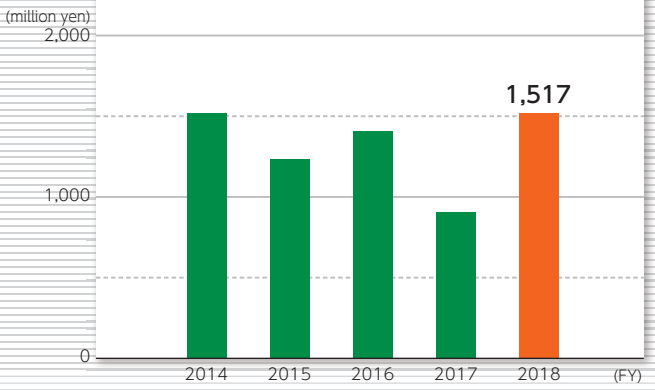
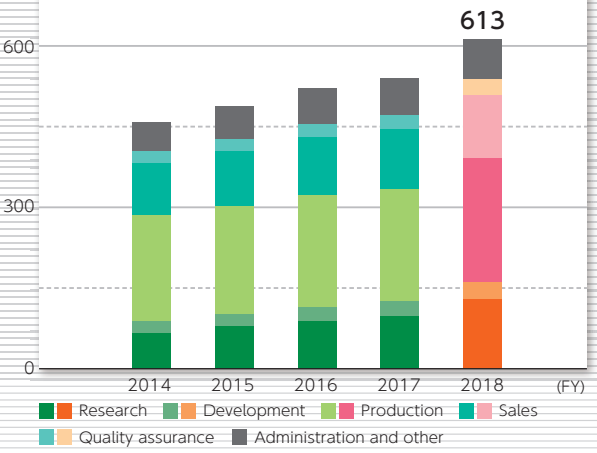
## Capital investment

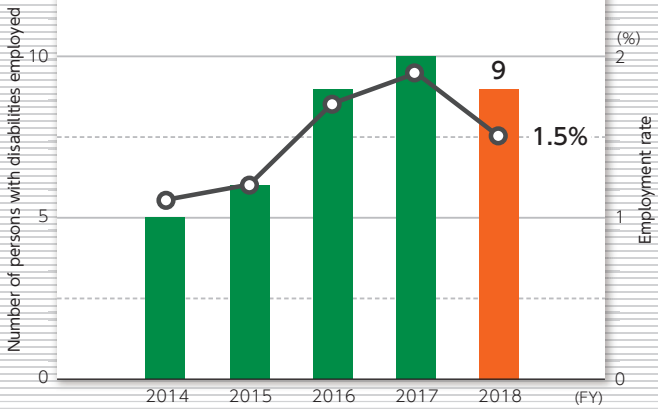



## Number of employees by occupation



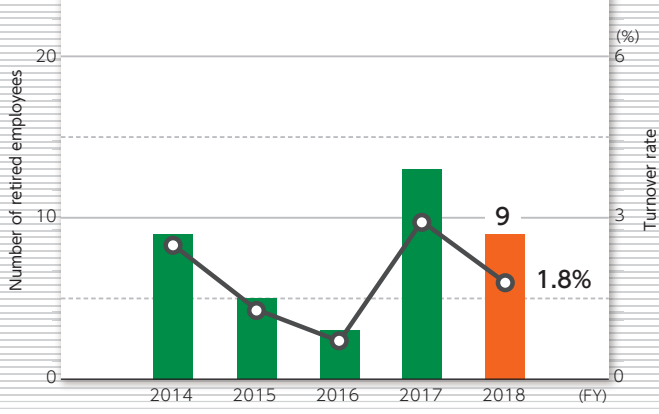

* Aggregate range: JCR Pharmaceuticals Co., Ltd. (non-consolidated)

## Number of persons with disabilities employed/ Employment rate



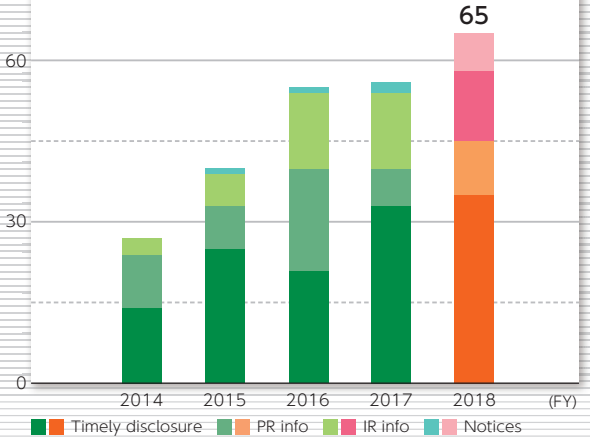

* Aggregate range: JCR Pharmaceuticals Co., Ltd. (non-consolidated)

## Number of retired employees/Turnover rate

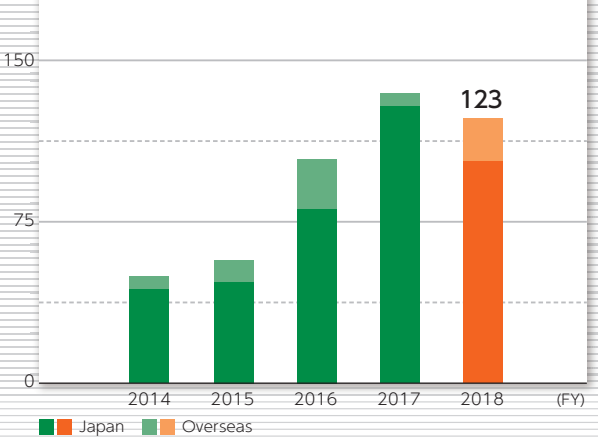



* Aggregate range: JCR Pharmaceuticals Co., Ltd. (non-consolidated)

## Number of press releases




## Number of meetings with investors



# Thorough the advancement to a new stage “HIYAKU” (leap into the future), we will realize sustained value creation.

Ever since the foundation of JCR, we have always maintained an entrepreneurial spirit and continuously taken on bold challenges. In FY2018, we achieved a wide range of achievements focused on our HIYAKU towards a "Research-oriented specialty pharma with global exposure" – JCR's vision set forth in the "Mid-Term Management Plan for FY2015 to FY2019." These achievements included the launch of Agalsidase Beta BS I.V. Infusion [JCR], the first domestically-produced therapeutic enzyme for lysosomal storage disorders (LSDs) based on the serum-free culture technology. In addition, we worked to further enhance our sustainability initiatives from an ESG perspective, in order to contribute to the development of a sustainable society. Looking ahead, we will continue to operate as a specialty pharma working to create groundbreaking new therapeutics, particularly in the rare diseases field. To this end, we will continue to create value with our proprietary technologies, "J-Brain Cargo®" as our breakthrough technology, "Cell therapy and regenerative medicine" technology as a pioneer and newly-founded "Manufacturing technology for Gene therapy."

August 2019
**Shin Ashida**
Representative Director, Chairman, President, CEO and COO

## Outline of business results in FY2018

### With a steady growth of the sales of core products, we achieved a record performance for the fifth consecutive year.

Net sales achieved in FY2018 were 23,160 million yen (up 12.5% from the previous fiscal year). Operating income was 4,967 million yen (up 31.3% from the previous fiscal year), and profit attributable to owners of parent was 3,715 million yen (up 21.0% from the previous fiscal year). We achieved new record high results for both sales and profits for five consecutive terms, owing to further growth in sales of core products and a significant increase in revenue from licensing in connection with progress on research and development. Sales of GROWJECT®, a recombinant human growth hormone, increased to 11,978 million yen (up 4.2% from the previous fiscal year). Sales of both Epoetin Alfa BS Inj. [JCR], a recombinant erythropoietin product, and TEMCELL® HS Inj., a regenerative medical product, performed steadily and both products increased their revenues.

## Return to shareholders

### We will successively and stably provide dividends to shareholders.

JCR regards the distribution of profits to our shareholders as an important management policy. In FY2018, since both net sales and profits surpassed record highs, we increased the term-end dividend by 4 yen per share from the most recent forecast and provided an annual dividend of 30 yen. As a result, the dividend payout ratio was 24.9%. As for the dividend for FY2019, we plan to provide an annual dividend of 30 yen, maintaining the same amount from FY2018. We will successively and stably provide dividends to shareholders as we execute research and development investments that will pave the way for future growth.

## Advancing our research and development

### We will accelerate research and development (R&D) using JCR's original technology, while exploring new ways to capture synergies with partners.

In the Mid-Term Management Plan for FY2015 to FY2019, JCR has positioned "Advancing R&D activities one step beyond" as one focal point. Accordingly, we are focused on various programs for the development of biopharmaceuticals and regenerative medical products that will address unmet medical needs.

In November 2018, we launched Agalsidase Beta BS I.V. Infusion [JCR], a recombinant treatment for Fabry disease, as the first domestically-produced therapeutic enzyme for LSDs based on the serum-free culture technology. Also, in September 2018, we filed for marketing approval of JR-131, a biosimilar for the long-acting erythropoiesis-stimulating agent darbepoetin alfa. In March 2019, we filed for additional marketing approval of the regenerative medical product TEMCELL® HS Inj. (JR-031EB) for the indication of epidermolysis bullosa.

JCR aims to apply J-Brain Cargo® technology to create novel therapies for 15 types of LSD. JCR is conducting a Phase III clinical trial in Japan and a Phase II clinical 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. In addition, we are implementing R&D activities with the aim of initiating clinical trials of JR-171, a therapeutic enzyme for Hurler syndrome, during FY2019; and JR-441, a therapeutic enzyme for Sanfilippo syndrome type A, during FY2020. We are also pushing ahead with R&D activities to initiate clinical trials of JR-162, a therapeutic enzyme for Pompe disease, at an early stage. In May 2019, collaborative research between JCR and PeptiDream Inc. resulted in the successful development of constrained peptides capable of carrying various therapeutic payloads across the blood-brain barrier (BBB). This achievement will enable J-Brain Cargo® to be applied to a wide range of drugs. It is expected to sharply accelerate the development of pharmaceuticals for a variety of central nervous system disorders in addition to LSDs.

Furthermore, in FY2018, we established proprietary manufacturing technologies for gene therapies. Gene therapies may be applicable to a broad range of disorders that could not be treated effectively with conventional therapies. We are currently working towards the goal of initiating clinical trials in FY2021.

In the fields of cell therapy and regenerative medicine, JCR and Teijin Limited have been developing JTR-161/JR-161, a regenerative medical product composed of dental pulp stem cells (DPCs) for the indication of acute cerebral infarction (stroke). The two companies initiated Phase I/II clinical trial in February 2019. Moreover, JCR is conducting Phase I/II clinical trial for JR-031HIE, TEMCELL® HS Inj. for the indication of neonatal hypoxic ischemic encephalopathy.

In the growth hormone business, JCR has started a Phase III clinical trial of JR-401X, an expanded indication of its core product, GROWJECT®, for Short Stature Homeobox-containing Gene (SHOX) deficiency. In addition, JCR has initiated a Phase I clinical trial of JR-142, a long-acting growth hormone. Going forward, we will continue to conduct development activities from the standpoint of patients and strive to improve the added value of the Company.

## Reinforcing our capabilities and management platform

### JCR will advance business activities overseas with the aim of expanding its reach in the global markets.

JCR's vision is to become a "research-oriented specialty pharma with global exposure." To realize this vision, we have been implementing a broad range of measures from a long-term perspective.

In January 2018, JCR USA, Inc. was established as a U.S. joint venture. JCR USA serves as a site for achieving early drug approval in the U.S. It oversees and manages clinical development of enzyme replacement therapies that JCR is developing currently for LSDs based on the application of J-Brain Cargo®, notably JR-141.

JR-141 is a groundbreaking pharmaceutical that is expected to prove effective against central nervous system (CNS) symptoms. As such, JR-141 was granted orphan drug designation by the US Food and Drug Administration (FDA) in October 2018 and the European Medicines Agency (EMA) in February 2019. At this time, JCR has commenced discussions with both the FDA and EMA on the initiation of clinical trials in the U.S. and Europe, following on from clinical trials that have already begun in Japan and Brazil. JCR has been considering various options for its overseas sales structure for JR-141 after the launch of this product, including forming cooperative arrangements with partners.

Since 2017, JCR has also been exploring the development of a global production structure in Luxembourg.

**Progress on global development of JR-141**

**Europe**
Orphan drug designation granted by the EMA in February 2019

**United States**
Orphan drug designation granted by the FDA in October 2018

**Japan**
Designated under the SAKIGAKE Designation System in Japan by the Ministry of Health, Labour and Welfare in March 2018
Phase III clinical trial under way

**Brazil**
Phase II clinical trial under way

## Sustainability Initiatives

### JCR has been working to enhance its sustainability initiatives from an ESG perspective, with the view to driving sustained value creation.

Since its foundation in 1975, JCR has achieved sustained growth by seeking to create groundbreaking new 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. Looking ahead, we believe that JCR's mission is to continue to address rare and intractable diseases, and to develop and create the world's first innovative biopharmaceuticals originating from Japan.

Meanwhile, in light of the global environment and conditions and issues facing society, we believe it is crucial to contribute to the sustainable development of society. JCR has identified Rare Diseases, Environment, Society and Corporate Governance as its core areas, and will work to solve issues in each of those areas through its business activities. The benefits of these activities will be returned to and shared with a broad range of stakeholders both within and outside the Company. At the same time, we aim to achieve sustainability from an ESG perspective.

JCR will continue to embrace challenges as a company that constantly generates innovation. We look forward to your continued understanding and support as we endeavor to reach our goals.

# Board of Directors and Corporate Officers

(As of July 1, 2019)

## 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
Head 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 (current post)

### Yuji Sato, M.D., Ph.D.

Vice President
Head of Research and Development

2003 Entered Banyu Pharmaceutical Co., Ltd. (currently, MSD K.K., Japan)
Director, Clinical Development Institute of the same
2005 Director, CNS Development of the same
2007 Professor, Center for Clinical Research of Keio University School of Medicine
2009 Director, Center for Clinical Research of the same
2015 Entered Sanofi K.K., Japan
Corporate Officer and Head of Japan of Research and Development of the same
2017 Entered JCR Pharmaceuticals
Appointed Corporate Officer
2018 Executive Director, Development Division
Head of Research and Development (current post)
Appointed Vice President (current post)

### Mamoru Morita

Director
Head of Sales Division

1990 Entered JCR Pharmaceuticals
2006 Sales Manager, West Japan Sales Dept, Sales Division and Manager, Kyushu Area
2014 Executive Director, Sales Division
Appointed Corporate Officer
2016 Head of Sales
Appointed Director (current post)
2018 Head of Sales Division (current post) and Administration Division

### Toru Ashida

Director
In Charge of Corporate Strategy
Head of Quality Assurance Division, Corporate Planning Division, Administration Division and Medical Affairs Department

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 Head of Quality Assurance Division, Corporate Planning Division, Medical Affairs Department and Office of the President (current post)
Appointed Director (current post)
2019 In charge of Corporate Strategy (current post)
Head of Administration Division (current post)

(From left) Toshihide Yoda, Takashi Suetsuna, Toru Ashida, Mamoru Morita, Shin Ashida, Hiroshi Yoshimoto, Yuji Sato, M.D., Ph.D., Yuko Hayashi, Ph.D., Toshihiro Ishikiriyama

## 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)

### 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 HOLDING CORPORATION
2012 Director and Managing Director of the same
In charge of IR and General Manager of 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 HOLDING CORPORATION (current post)
Appointed Director, JCR Pharmaceuticals (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)

### 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
2012 Associate Professor, Graduate School of Innovation and Technology Management of the same
2015 Professor, Graduate School of Innovation and Technology Management of the same (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
Corporate Officer
Executive Director,
Administration Division

### Takayo Egawa
Corporate Officer
Director,
Overseas Business Promotion

### Tohru Hirato, D.V.M
Corporate Officer
Executive Director,
Research Division

### Yoshihiko Ohnishi
Corporate Officer
Executive Director,
Sales Division

### Yutaka Honda
Corporate Officer
Executive Director,
Corporate Planning Division

### Hiroyuki Sonoda, Ph.D.
Corporate Officer
Executive Director,
Research Planning Division

### Atsuko Sato
Corporate Officer
Executive Director,
Quality Assurance Division

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

(As of July 1, 2019)

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

## 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
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)

### 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)

# Message

## Yuko Hayashi, Ph.D.

Outside Director

One year has passed since I was appointed as an Outside Director. I have attended meetings of the Board of Directors from an objective and independent perspective, based on an awareness of my supervisory role over business execution. JCR currently finds itself in a crucial period. It must accelerate the development of treatments for lysosomal storage disorders and J-Brain Cargo®, a technology to deliver medicine into the brain, launching the world's first technology of its kind. In this crucial period, JCR must also lay the groundwork for global business expansion in Europe, the U.S., Brazil and other countries. JCR has an R&D expenditure ratio to sales – an indicator of JCR's expenditures to promote product innovation – of about 20%, which is at the highest level in the industry. In addition, JCR has integrated process innovation for enhancing the productivity and safety of drugs, such as employing single-use technology and adopting ICT, into its existing assets and is proactively pushing ahead with these initiatives. In response to the growing complexity and globalization of its business operations, JCR has established its vision for the future as a "research-oriented specialty pharma engaged in rare and intractable diseases." As an Outside Director, I will closely monitor conditions to ensure that JCR strategically allocates resources into key areas in order to realize its vision. In addition, I will put an even stronger emphasis on active discussions based on accurate evidence in order to facilitate rapid decision-making. Moreover, as you can see from recent ESG investment trends, companies are now being assessed in terms of their contribution to the environment and to society, and investments undertaken from medium- and long-term perspectives have been on the rise. It will be important to foster an internal awareness of ESG indicators related to factors such as reducing the environmental impact, appointing diverse human resources and developing responsible work environments, along with the disclosure of such information. With these factors in mind, I will continue working as a member of JCR to increase its corporate value further.

## Kazuhiko Yamada

Outside Audit & Supervisory Board Member

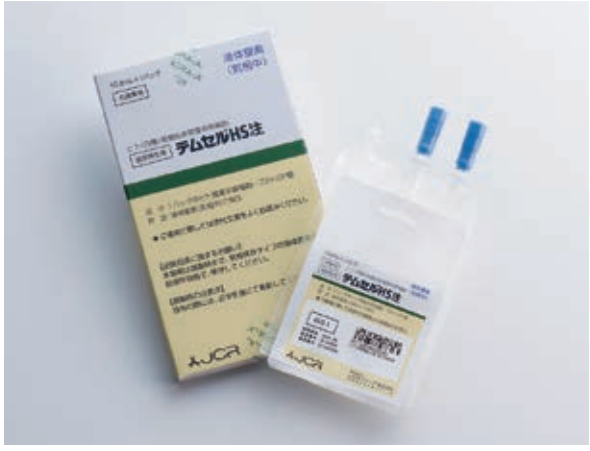
In FY2018, the fourth year of the Mid-Term Management Plan for FY2015 to FY2019, JCR delivered record-high business results. This performance was achieved through the sustained growth brought about by JCR's proactive efforts to create new drugs. Indeed, these efforts have helped tremendously to strengthen governance and increase corporate value. In response to changes in the past few years, Audit & Supervisory Board Members have been called upon to enhance their credibility, transparency and the value of the information they provide. Under the leadership of Chairman Ashida, frank exchanges of opinions have been carried out in various meetings, including the Board of Directors' meetings, which are implemented in accordance with their respective purposes. Management has fostered relationships of trust and an awareness of checks and balances in every direction across the organization – vertically, horizontally and diagonally – based on discussions, the sharing of information and other interactions within the organization. This approach has helped to drive overall innovation and ensure legal compliance, risk management, transparency and other key matters. Looking ahead, JCR has 11 new drug candidates in its pipeline (R&D), centered on therapeutics for rare diseases employing proprietary technologies. Based on this pipeline, JCR is expected to experience accelerated growth. JCR is also undergoing globalization more rapidly than ever before, owing to growth in international transactions through its overseas subsidiaries and affiliates, supported by factors such as clinical trials in Brazil and the orphan designation of drugs in Europe and the U.S. Due to the faster pace of R&D and related activities plus globalization through business expansion, JCR will need to build an even stronger management platform encompassing factors such as new facilities, recruitment and retention of personnel, human resources development, and information gathering. Forums for decision-making based on the corporate philosophy carry a vital importance. I'm determined to fulfill my duties while remaining strongly aware of my responsibilities, so that I may play a part in increasing public trust in JCR.

Special Topic

# Challenges in Cell Therapy and Regenerative Medicine

Although research and development are being actively promoted in regenerative medicine using iPS cells and human mesenchymal stem cells (MSCs) nowadays, JCR has long been committed in regenerative medicine using MSCs since early 2000s when few pharmaceutical companies had recognized the potential of cell therapy. JCR successfully launched TEMCELL® HS Inj. as the first allogeneic regenerative medical product in Japan, which is by now an established important therapeutic option for steroid-refractory acute graft-versus-host disease (GVHD).

As a pioneer in cell therapy and regenerative medicine, JCR is advancing development of regenerative medical products as its additional focus therapeutic area along with its recombinant DNA products and gene therapies.




## Cell Therapy and Regenerative Medicine: A Developmental History

**The history of JCR's R&D in cell therapy and regenerative medicine is presented by Kiwamu Imagawa Ph.D., Director of Regenerative Medicine, Research Div., who has been engaging in this research since its inception in the early 2000s.**

### How I came to Initiate Research in Cell Therapy and Regenerative Medicine

When I joined in 1998, JCR had long been engaging in the R&D for drug manufacturing from urine and blood, whose limitations were being recognized by then, as exemplified by an aborted development of a urine-derived product. Cell therapy was one of the new projects JCR initiated at the time in order to break this impasse.

The R&D project on TEMCELL® HS Inj. started with an agreement in 2003 with U.S.-based Osiris Therapeutics, Inc. to license its MSC cultivation technology. I was highly motivated to contribute to this project, which gave me an opportunity to work on a new initiative to pursue R&D in cell therapy with an American counterpart. In the latter half of 2003, I spent three months in the U.S., worked on technology transfer to JCR, and learned a variety of things, ranging from the MSC manufacturing technology and quality assurance to new insights into how people think and work in a company overseas.

# Special Topic
## Challenges in Cell Therapy and Regenerative Medicine

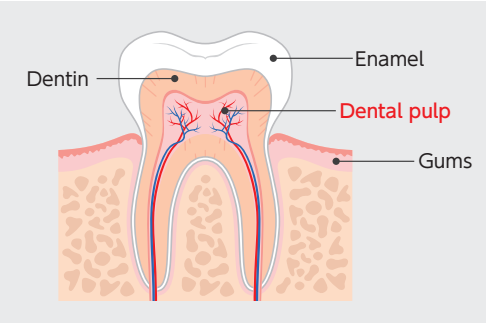
On returning to Japan I began manufacturing MSCs, but we had not yet had a full understanding of these cells. Besides, there were no regulations or guidelines for manufacturing and quality assessment for these products in Japan. Many days were spent, with lots of trials and errors, to establish methods of manufacturing MSCs with the same quality as the licensor; we had to overcome numerous difficulties along the way. For example, dealing with the "confirmation application system" in force at the time; failure of a Phase III clinical trial conducted by the licensor in the U.S.; implementation of Phase I/II and Phase III clinical trials in Japan; negotiations with the regulatory authorities on the interpretation of the the Phase III data. After surmounting many hurdles, we finally obtained marketing approval: a success that significantly boosted confidence of JCR as a whole as well as of all the project members.

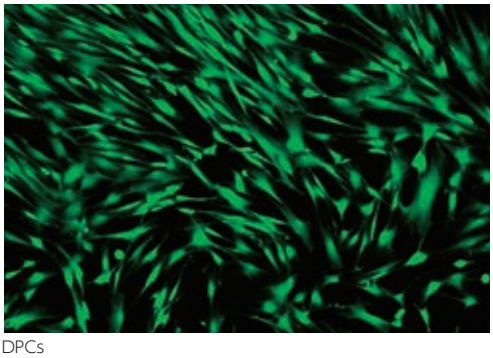
### On JTR-161/JR-161 (Dental Pulp Stem Cells (DPCs))

This project started with the research that I initiated on my own around 2010. At the time, many articles had reported on successful isolation of MSCs from various tissues (fat, umbilical cords, umbilical cord blood, and dental pulp). With that in mind, I was aware of the difficulties in collecting bone marrow aspirate, a source of MSCs, in Japan, so I thought to myself: "Why not obtain MSCs from a tissue easily collected locally then?" This idea led to isolation of MSCs from various tissues other than bone marrow, which in reality turned out to be hard. Among the tissues we tried, dental pulp seemed most promising. Exploring ways to isolate cells from extracted teeth didn't go well at first with many setbacks. Having worked out many different ways of dental pulp collection from extracted teeth and of cellular cultivation, I saw the cells increase for the first time from the dental pulp collected from the 51st extracted tooth. I cannot forget how moved I was then; I remember I kept on cellular cultivation with utmost caution, which since then went on stably.
Subsequently, the project has progressed significantly, e.g. co-development of JTR-161/JR-161 with Teijin for acute cerebral infarction in 2017. It is immensely gratifying that the work that I had begun in a corner of our lab has over 10 years evolved into a cell therapy that is clinically applicable today.

There is no significant difference between the basic properties expected of DPCs and of TEMCELL® HS Inj. However, DPCs outperform TEMCELL® HS Inj. in terms of differentiation and proliferation potentials, as well as the types and the secretion volumes of expressed neurotrophic factors. Meanwhile, we have advanced the development of DPCs while dealing with various issues that we have come across in dealing with

JCR × TEIJIN



DPCs

TEMCELL® HS Inj. The major advantages of DPCs are that their sources can be secured stably in Japan; cell cultivation is carried out by an efficient mass cultivation method; and their manufacturing can be completed entirely in Japan. In addition, DPCs are our proprietary product that allows us further development at our own discretion, including new indication acquisition and global development.

### Further Challenges for Cell Therapy and Regenerative Medicine

Since 2003, JCR has been developing regenerative medical products ahead of other companies. In 2016, TEMCELL® HS Inj. was successfully launched as the first allogeneic regenerative medical product in Japan. It also remains to date the only MSC product successfully commercialized in the world. This achievement results from collaborative efforts by "The Team JCR," encompassing not just the Research Institute but also Development, Manufacturing, Quality Assurance, Sales and Post Marketing Surveillance. This has been only possible thanks to JCR's corporate culture of proactively taking on new challenges. In moving forward, we believe it crucial to develop regenerative medical products as a core driver for JCR's pharmaceutical business by leveraging the experience, insight and success that we have gained through this project.

## Future Initiatives in Cell Therapy and Regenerative Medicine

JCR will pursue value maximization of TEMCELL® HS Inj. and JTR-161/JR-161.

Regarding TEMCELL® HS Inj., JCR finds it essential to establish its clinical significance as a new treatment option for acute GVHD. This will be achieved by conscientious maintenance of its stable supply as a therapeutic for acute GVHD, and by its wide and continuous prescription.

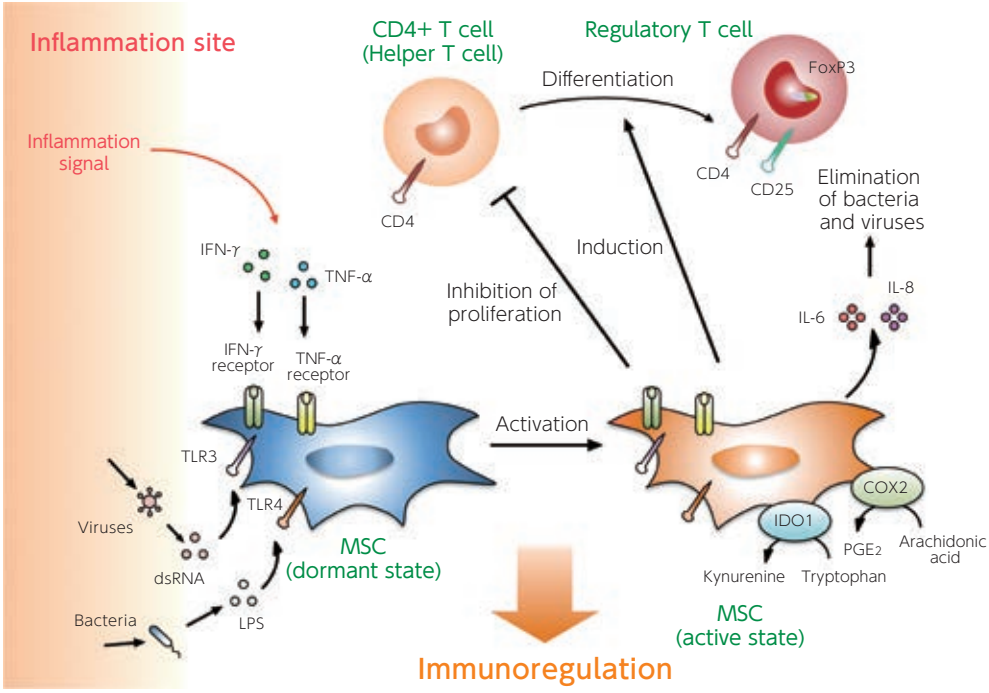
JCR has also been working on additional indications for new diseases based on the characteristics of TEMCELL® HS Inj. and JTR-161/JR-161. One achievement was the filing in March 2019 of an application for additional marketing approval of TEMCELL® HS Inj. for the indication of epidermolysis bullosa. JCR and Teijin Limited are jointly pursuing clinical development of JTR-161/JR-161 for the indication of acute cerebral infarction. As has been the case with TEMCELL® HS Inj., we will explore additional indications of JTR-161/JR-161 for other conditions. Potential overseas developmental opportunities for JTR-161 are also being discussed conjointly.

JCR aims at swift development of new drugs primarily targeting rare diseases, in particular paediatric intractable ones, which long for new therapies.

As a pioneer in cell therapy and regenerative medicine, JCR will continue its challenge in exploring various possibilities in cell therapy and regenerative medicine.

### Immunoregulatory action of MSCs

MSCs gather at inflammation sites in the body, where they are activated by pro-inflammatory cytokines and other substances, so that anti-inflammatory effects ensue. Conversely, MSCs can promote inflammation to eliminate bacterial or viral infections, thereby regulate excessive immunological responses.



# RESEARCH & DEVELOPMENT

## JCR is committed to establish the three treatment strategies of "J-Brain Cargo®," "cell therapy and regenerative medicine," and "gene therapy" through proactive research and development (R&D).

Since its foundation in 1975, JCR has steadily advanced R&D through applications of physiologically active substances derived from urine and blood, recombinant DNA technology, and regenerative medicine technology. These activities have produced solid achievements. JCR has launched products such as GROWJECT® (our core recombinant human growth hormone product); Epoetin Alfa BS Inj. JCR (a recombinant erythropoietin product and the first biosimilar product made in Japan); TEMCELL® HS Inj.(the world's first regenerative medical product using mesenchymal stem cells (MSCs)); and Agalsidase Beta BS I.V. Infusion [JCR] (a recombinant product for Fabry disease and JCR's first biosimilar product in the rare diseases field).

## Overview of Our Development Pipeline

Currently, JCR is advancing R&D into protein compounds utilizing J-Brain Cargo®, JCR's proprietary blood-brain barrier (BBB)- penetrating technology. We are also promoting R&D in regenerative medicine and gene therapy.

For JR-141, our blood-brain barrier-penetrating therapeutic enzyme for Hunter syndrome, JCR has obtained promising results in a Phase I/II clinical trial conducted in Japan, succeeded by a Phase III trial in Japan and a Phase II trial in Brazil in 2018, in both of which patient enrollment has been completed and the test drug administration started. Moreover, aiming for development in the U.S. and Europe in the near future, JCR received orphan drug designation for JR-141 in the U.S. and Europe in October 2018 and February 2019, respectively. JCR is consolidating development plans along with negotiations with the overseas regulatory authorities.

In the field of lysosomal storage diseases (LSDs), R&D activities for therapeutic enzymes are in progress regarding JR-171 for Hurler syndrome, JR-441 for Sanfilippo syndrome type A, and JR-162 for Pompe disease, in addition to the aforementioned JR-141. JCR is successively moving forward with R&D into therapies also for other LSDs with central nervous system (CNS)

symptoms. A global clinical study, including Japan, of JR-171 is in preparation to be initiated within FY2019.

In other therapeutic areas, JCR has filed for marketing approval for JR-131, a biosimilar to darbepoetin alfa, in September 2018 as well as for an additional marketing approval of TEMCELL® HS Inj. in March 2019 for the indication of epidermolysis bullosa. Both products are expected to receive marketing approval and commence sales within FY2019.

Furthermore, JCR has initiated a Phase I/II clinical trial of JTR-161/JR-161, an allogeneic regenerative medical product from dental pulp stem cells (DPCs) in co-development with Teijin Limited. JTR-161/JR-161 was administered to the first patient in February 2019.

JCR is currently conducting a Phase III clinical trial for Short Stature Homeobox-containing Gene (SHOX) deficiency as an expanded indication for its core product GROWJECT®. A Phase I clinical trial of JR-142, a recombinant long-acting growth hormone with modified albumin, has also started in May 2019.

Research Institute (Kobe, Hyogo)

## Development pipeline and progress (As of July 2019)

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) | Hunter syndrome (LSD) | 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 (LSD) | Japan | Preclinical | ERT J-Brain Cargo® J-MIG System®*2 |
| **JR-171** | BBB-penetrating acid α-L iduronidase (rDNA origin) | Hurler syndrome (LSD) | Japan | Preclinical | ERT J-Brain Cargo® J-MIG System® |
| **JR-441** | BBB-penetrating heparan N-sulfatase (rDNA origin) | Sanfilippo syndrome type A (LSD) | Japan | Preclinical | ERT J-Brain Cargo® J-MIG System® |
| **JR-131** | Darbepoetin Alfa (rDNA origin) | Renal anemia | Japan | Filed | Co-developed with Kissei Pharmaceutical Co., Ltd. Biosimilar |
| **JR-401X** | Somatropin (rDNA origin) | SHOX deficiency | Japan | Phase III | Expanded Indication of GROWJECT® |
| **JR-041** | Follicle stimulating hormone (rDNA origin) | Infertility | Japan | Phase I/II | Out-licensed to ASKA Pharmaceutical Co., Ltd. |
| **JR-142** | Long-acting growth hormone (rDNA origin) | Growth disorders | Japan | Phase I | J-MIG System® |
| **JR-031EB** | Mesenchymal stem cells | Epidermolysis bullosa | Japan | Filed | Expanded Indication of TEMCELL® HS Inj. |
| **JR-031HIE** | Mesenchymal stem cells | Neonatal hypoxic ischemic encephalopathy | Japan | Phase I/II | Expanded Indication of TEMCELL® HS Inj. |
| **JTR-161/ JR-161** | Dental pulp stem cells | Acute cerebral infarction | Japan | Phase I/II | Co-developed with Teijin Ltd. Regenerative medical product |

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

## Future Prospects of JCR's R&D

Through the R&D capabilities developed over the past 44 years since its foundation, JCR has established three treatment strategies, i.e. J-Brain Cargo®, cell therapy and regenerative medicine, and gene therapy, in addition to other proprietary technologies, such as J-mAb System®, J-MIG System®, J-GlycoM®/J-GlycoS®, and long-acting protein technology with modified albumin. Leveraging these achievements, JCR specializes in the field of rare diseases, where new drug development has been considered difficult, and contributes to the development of groundbreaking new therapies.

This section will explain, among the platform technologies above, J-Brain Cargo®, focusing on its innovativeness and clinical significance, along with its potential business values. JCR's rationales for undertaking research into gene therapy, as well as our related proprietary technologies and future prospects, will be illustrated.

## J-Brain Cargo®

### Mechanism of J-Brain Cargo®

Capillary blood vessels constitute a dense network throughout the brain. Vascular endothelial cells of these vessels are closely interconnected and form tight junctions that selectively limit the exchange of substances between the vessels and the brain. This structure allows active uptake of substances needed to support and sustain life, e.g. sugars and iron, into the brain, while removing toxic substances and wastes, hence it is named BBB. However, the very existence of the BBB prevents many therapeutic compounds, such as large molecules, from reaching the brain. This has been regarded as one of the reasons for difficulties of developing therapeutics for CNS disorders.

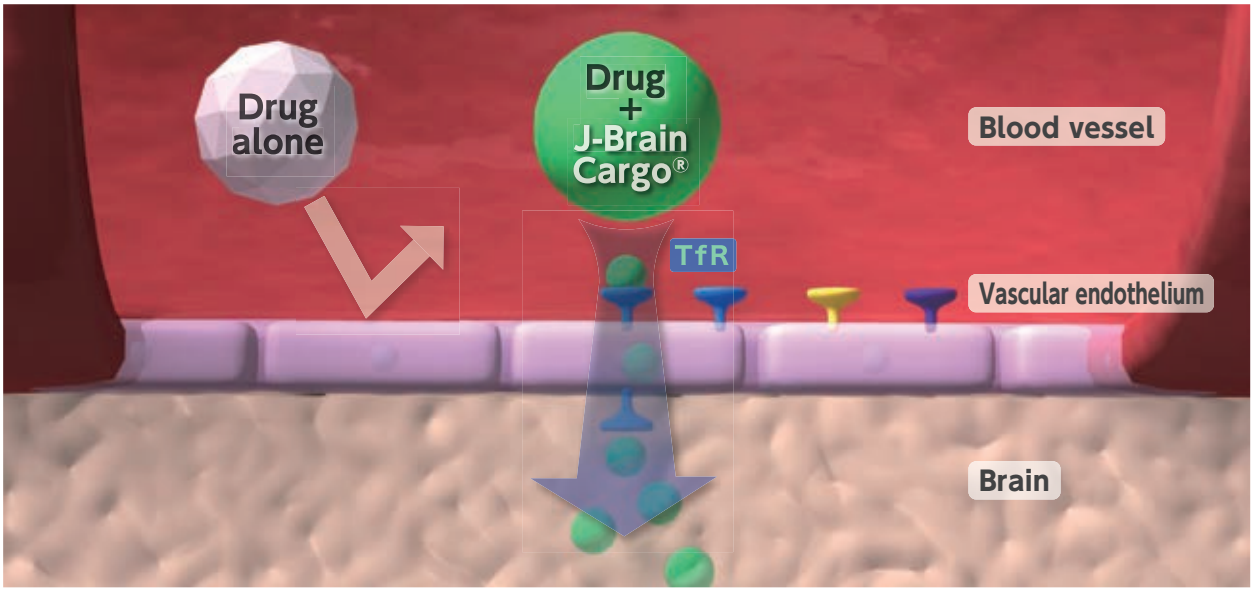
JCR has successfully developed "J-Brain Cargo®" with the aim of developing therapeutics for the CNS symptoms of LSDs that do not improve by conventional enzyme replacement therapy (ERT). This achievement was made possible by the passionate commitment and ingenuity of JCR's researchers over many years. J-Brain Cargo® is a platform technology that utilizes the transferrin receptors on the cerebral capillary endothelial cells to deliver the intravenously administered substances into the brain.

### Our initiatives at JCR

JCR has been conducting R&D focusing on the application of J-Brain Cargo® to 15 types of LSDs, which are rare diseases with CNS symptoms.

Above all, the greatest progress has been made of JR-141 for Hunter syndrome at the moment, followed by JR-171, with its clinical trial being planned during

Mechanism for J-Brain Cargo®




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

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

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

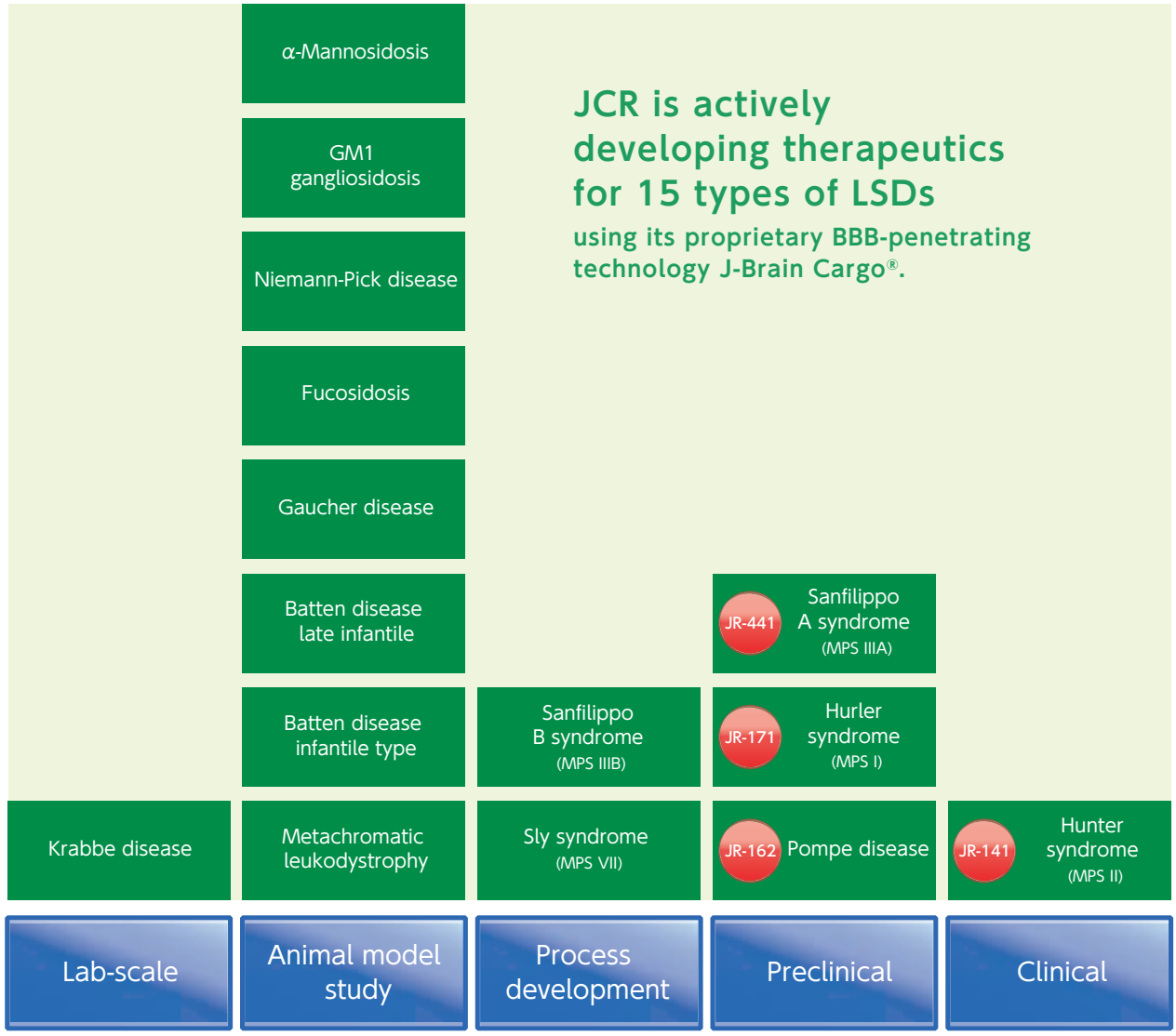
FY2019, along with passionate commitment to other compounds. JCR's mission lies in the delivery of new medicines for these currently untreatable rare diseases as swiftly as possible.

Non-clinical evaluation of JR-141 indicated its efficacy by successful penetration of an enzyme using J-Brain Cargo® through the blood-brain barrier (BBB) into CNS, where neurotoxic substances are dissolved*1. Based on these results, JCR conducted a Phase I/II clinical trial in Japan in 2017 to evaluate safety and efficacy of JR-141 in 14 patients with Hunter syndrome, stable on the ERT with conventional therapeutics. The trial did not identify safety concerns. The endpoint substances reflecting systemic symptoms were stable in both blood and urine, showing efficacy equivalent to the conventional therapeutics. Moreover, the substance levels in the cerebrospinal fluid suggestive of CNS symptoms decreased in all patients. These data suggest clinical significance of J-Brain Cargo®. Additionally, despite the administration for only four weeks, two patients were reported to show signs suggesting stabilization of the brain, such as "expression has become brighter," "smile resumed," "mood has stabilized with better sleep."*2

These results led to initiation of a Phase III clinical trial in Japan and a Phase II trial in Brazil in 2018, both of which are proceeding steadily. The results of the Phase I/II clinical trial has enabled the designation of JR-141 in March 2018 under the SAKIGAKE Designation System by the Japanese Ministry of Health, Labour and Welfare. JR-141 has also received orphan drug designation in Europe and the U.S. Its market approval is expected in 2020 in Japan. Global development also proceeds in Europe and the U.S in parallel.

*1 Mol. Ther. 26, 1366–1374, 2018.
*2 Mol. Ther. 27, 456–464, 2019.

Our initiatives for LSDs drug development



### The Significance of Enzyme Replacement in LSDs and Related Clinical Challenges

ERT has already been approved for several LSDs. Before the advent of ERT, there were no effective therapies for any LSDs, including those with CNS symptoms. LSDs have been with extremely poor prognosis; the patients with infantile-onset Pompe disease, a severe type of this disease, would not survive beyond the first year of age. The emergence of ERT has made long-term survival possible for LSD patients, even those with severe types of Pompe disease. The development of treatment for the CNS symptoms of LSDs still remains a major clinical challenge, although some time has passed since ERT became available.

### Values of J-Brain Cargo®

Potential business values of J-Brain Cargo® can be illustrated by the number of patients with LSDs and the market size. Of the LSDs listed in the table below, Hunter syndrome, Pompe disease and Hurler syndrome already have their therapeutics, all of which have been launched since more than 10 years ago. However, no other new therapeutics have been launched since.

Therapeutics for LSDs using J-Brain Cargo® have potential efficacy for both systemic and CNS symptoms, a significant advantage over the existing ERTs. Therefore, they will not only establish new treatment methods with immense clinical significance for LSDs, but also contribute to enhance JCR's corporate values.

### Alliances with Other Companies

As J-Brain Cargo® is expected to contribute to new treatments for a wider range of diseases beyond LSDs, JCR has been pursuing joint research with several companies on the CNS therapeutic area outside JCR's focus so far.

In 2015, JCR and Sumitomo Dainippon Pharma Co., Ltd. concluded an agreement for a feasibility study. The achievement of the criteria set forth therein led to a license agreement in February 2018. Aiming to expand the technological potnetial of J-Brain Cargo®, JCR entered into collaborative research agreements with PeptiDream Inc. in 2016 and with NanoCarrier Co., Ltd. in 2017, respectively. The joint research with PeptiDream Inc. has successfully developed constrained peptides capable of carrying various therapeutic payloads across the BBB, which is expected to significantly accelerate drug development for CNS disorders and other conditions.

PeptiDream

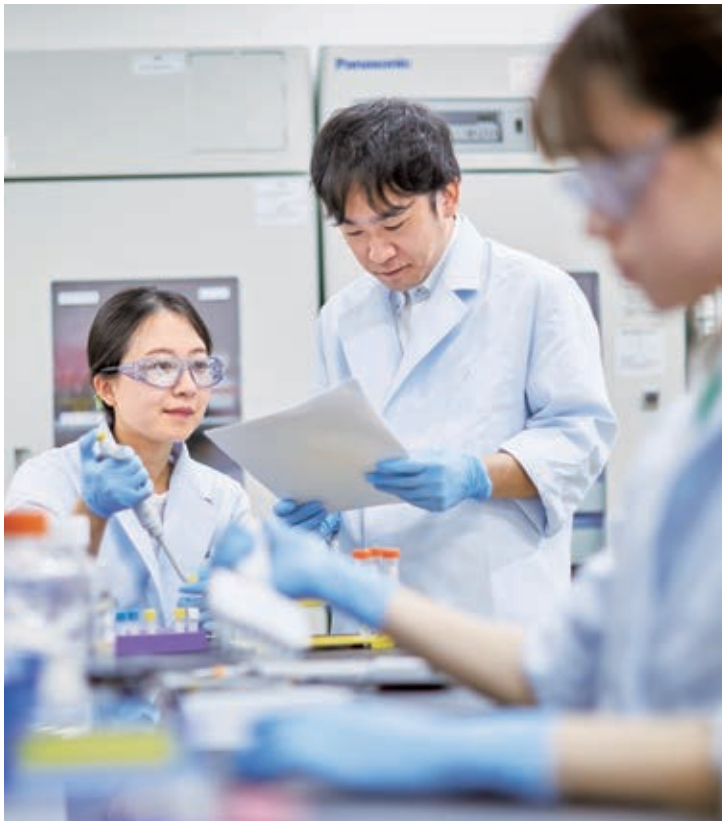
Sumitomo Dainippon Pharma

NanoCarrier®

Number of Patients and Size of Market for Five LSDs

| Indication (abbreviation/name of enzyme) | Number of patients*1 | | Market size*2 | |
|---|---|---|---|---|
| | Japan | Worldwide | Japan (2018) | Worldwide (2018) |
| Hunter syndrome (IDS/iduronate-2-sulfatase) | Approx. 250 | Approx. 7,800 | Approx. 8.0 billion yen | Approx. 81.0 billion yen |
| Pompe disease (GAA/acid α-glucosidase) | Approx. 80 | Approx. 10,600 | Approx. 3.0 billion yen | Approx. 99.0 billion yen |
| Hurler syndrome (IDUA/iduronidase) | Approx. 60 | Approx. 3,600 | Approx. 1.5 billion yen | Approx. 24.0 billion yen |
| Sanfilippo A syndrome (SGSH/N-sulfoglucosamine sulfohydrolase) | Approx. 60 (AB total) | Approx. 6,890 (AB total) | — | — |
| Sanfilippo B syndrome (NAGLU/α-N-acetylglucosaminidase) | | | | |

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



## Gene Therapy

JCR has been advancing R&D activities based on the belief that its path to growth lies in the rare disease therapeutic area, resulting in the successful creation of the J-Brain Cargo® platform technology. JCR has also been undertaking research in gene therapy technology in order to create novel therapeutic strategies for rare diseases that cannot be treated with the existing ERT.

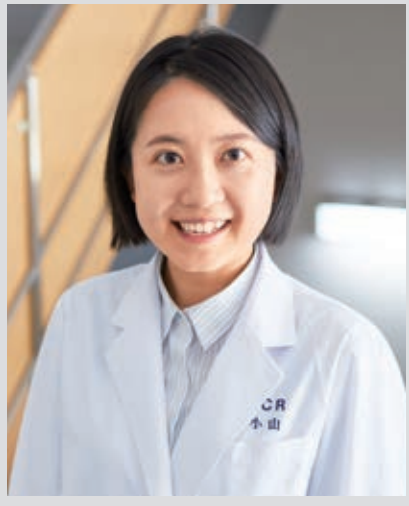
R&D of various gene therapy technologies are ongoing around the world now, one of which is gene therapy using adeno-associated virus (AAV). AAV needs to be produced as the carrier (virus vector) for the targeted gene. The current manufacuturing standard reqires a large-scale production system in order to secure adequate amounts of virus vector into which the targeted gene is correctly introduced, whereas JCR has established an efficient mass production method for virus vectors based on its hitherto fostered in-house technology. JCR will move forward to further apply its gene therapy technology to rare diseases, including investment in virus vector manufacturing facilities.

Development of therapeutics for rare diseases is known to be difficult due to the limited number of patients. However, successful completion of R&D of a groundbreaking new therapeutic will put its company in a long-term exclusive position in the market. Many rare diseases still lack any available treatments and thus this therapeutic area befits JCR, a relatively small pharmaceutical company, to carry out its social responsibility through R&D activities by making full use of its innovative technologies. Our efforts in the rare disease area will also enhance our corporate values. JCR seeks to deliver new treatment options for intractable rare diseases by further refining its proprietary platform technologies by its continuous transformation.

# Message

The Department of Regenerative Medicine is in charge of the development of JTR-161/JR-161, a regenerative medical product that is derived from the stem cells extracted from unneeded wisdom teeth. I'm responsible for its quality tests and characterization. JCR launched TEMCELL® HS Inj. as the first allogeneic regenerative medical product in Japan. Few companies in the world have launched such products, thus the expertise gained from its development is one of JCR's major strengths. While absorbing such expertise every day, I take part in the quality testing of JTR-161/JR-161 that has been manufactured as an investigational new drug. Meanwhile, I also conduct characterization analysis of JTR-161/JR-161. At present, the differences between the characteristics of TEMCELL® HS Inj. and JTR-161/JR-161, both stem cells, are not clear. Clarifying the different characteristics of both substances will be crucial in expanding the indications of both therapeutics. My work allows me to conduct research into areas that have not yet been clearly understood, therefore my findings may prove to be useful to patients. This is what makes my work very worthwhile.

Riko Koyama
Regenerative Medicine,
Research Institute, Research Division



# PRODUCTION SYSTEM

## Our mission is the stable supply of high-quality pharmaceuticals.

JCR handles a wide range of products, from urine-derived drug substances early in its history, to biopharmaceuticals and regenerative medical products today. In addition to existing products, we continue the development of new products with cutting-edge technologies, backed by our production/quality assurance system.

## Our Activities for the Production System

Our quality policy is "provision of high-quality products worldwide to fulfill our mission in contributing to people's health." Quality is the top priority in each phase of development, manufacturing and delivery of products. JCR currently has four production sites, Seishin Plant, Kobe Plant, Murotani Plant and Kobe API Plant, all located in Nishi-ku, Kobe. Each plant carries out the full-fledged manufacturing of pharmaceuticals from drug substances to finished products. We perform manufacturing under the appropriate manufacturing and quality control in compliance with applicable laws and regulations, along with Good Manufacturing Practice (GMP) and Good Gene, Cellular, and Tissue-based Products Manufacturing Practice (GCTP). We are currently building the Second Clinical Trial Material Manufacturing Center. This center will have the same scale of manufacturing facilities as the Kobe API Plant. The Second Clinical Trial Material Manufacturing Center is designed not only to manufacture research and investigational drugs. It is also designed so that JCR can use the facility as a production site in the future. Moreover, we are pushing ahead with plans to build a new plant in Luxembourg that will serve as JCR's first overseas production site.

For drug substance manufacturing, we utilize cutting-edge technologies including single-use technology (use of

disposable culture vessels or single-use bioreactors, etc.). Single-use technology eliminates significant amounts of cleaning and sterilizing between product change-over and enables the efficient production of many different small volume drug substances. Our unique production platform incorporates Serum-Free Cultivation Technology focused on the non-use of animal origin components.

We have established a production system for TEMCELL® HS Inj., an allogeneic regenerative medical product launched in 2016. This production system is capable of supplying TEMCELL® HS Inj. to medical facilities throughout Japan. We are committed to maintaining and improving our production systems with advanced technologies and information to ensure stable and timely supply of high-quality and useful pharmaceuticals.

## Production Sites

### Seishin Plant
**(urine-derived drug substances, a regenerative medical product, medical devices)**

Urokinase and Ulinastatin, drug substances derived from urine, are manufactured by purifying crude raw materials imported from our subsidiary in China. TEMCELL® HS Inj., a regenerative medical product, is manufactured by expanding human mesenchymal cells (MSCs) isolated from bone marrow aspirate. This process is carried out through strictly aseptic operations using one of the largest cell culture facilities in Japan. In medical devices, Seishin Plant conducts testing and packaging of TWIN-JECTOR® EZ II, a needle-free injector for GROWJECT®.

### Kobe Plant (finished products)

Pharmaceuticals marketed by JCR are formulated, fill-finished and final packaged at Kobe Plant. Kobe Plant has two buildings on the same premise, where products in vials, lyophilized products, liquid products and pre-filled syringe products are manufactured. Lyophilized products are manufactured in vials and also in double-chamber cartridges that house a lyophilized active ingredient and a solvent in separate chambers of the cartridge. In FY2019, we plan to launch JR-131 (darbepoetin alfa), a new biosimilar, as a syringe product.

### Murotani Plant
**(active pharmaceutical ingredient)**

In this plant, CHO cells developed by JCR are cultured under serum-free conditions to manufacture the active pharmaceutical ingredient (API) or drug substance of erythropoietin utilizing high-level protein purifying technology. Murotani Plant is JCR's first plant that manufactures API for biopharmaceuticals. Since Epoetin Alfa BS Inj. [JCR] sales are growing steadily, we installed additional bioreactors in 2015 to ensure the stable supply of the product.

### Kobe API Plant
**(active pharmaceutical ingredients)**

This plant, established in June 2013, was designed in preparation for the global development of JCR products. It is a cutting-edge biopharmaceutical API plant equipped with a global standard manufacturing/quality assurance system and single-use equipment (single-use bioreactors). In this plant, we manufacture the API for Agalsidase Beta I.V. Infusion [JCR] (a therapeutic enzyme product for Fabry disease) and JR-131, as well as APIs for investigational products such as JR-141 (blood-brain barrier penetrating therapeutic for Hunter syndrome).

# Message

At Kobe Plant, we formulate finished sterile products. The manufacturing work at Kobe Plant requires an understanding of various properties of active ingredients and formulations, as well as knowledge of chemistry and biology, which is needed to confirm the effects of cleaning, decontamination, and sterilization of equipment, and mechanical and electrical knowledge, which is needed to solve equipment problems. For that reason, every day I work hard to increase my knowledge and apply what I learn. JCR has a corporate culture that encourages even young employees to speak up and express their ideas without holding back. It is a culture that allows me to tackle tasks that I'm interested in and make improvements that I would like to address. I'm able to communicate immediately with members of my own department, as well as those of other departments. The manufacturing departments can work closely with the inspection and packaging departments and quality assurance departments, exchanging opinions to ensure a stable supply of products. We are responsible for manufacturing the finished products that will be used directly by patients. Recognizing this responsibility, we will work as one to make daily improvements so that we can ensure a stable supply of high-quality pharmaceuticals.

Shogo Tsuge
Formulation,
Kobe Plant, Production Division

# MARKETING

## Enhancing the marketing system and product strategy for our core products.


We have established a solid marketing system for the promotion of the proper use of medical products and the marketing of core products. We will continue to provide and collect information to support good relationships between patients and medical professionals, while coping with shifting economic trends in the medical field.

### Marketing Activities at Eight Business Bases across Japan

JCR's marketing organization consists of approximately 80 medical representatives deployed at eight business bases across Japan.

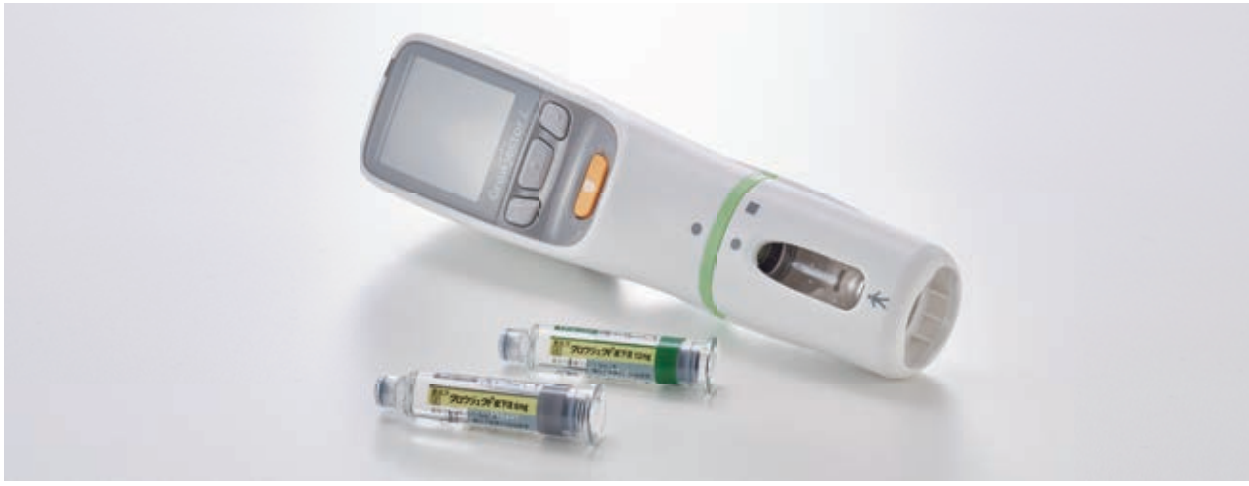
Marketing is conducted by five business units covering thirteen areas. We formulate marketing strategies tailored to each area, provide information that satisfies the needs of local medical professionals, and establish the presence of JCR in each area.

**Sales Div.**

- East Japan Sales
- Tokyo Metropolitan Area Sales
- Central Japan Sales
- West Japan Sales
- Cell Regeneration Medical Sales
- Logistics Management
- Sales Operations
- Marketing

# GROWJECT®

Recombinant human growth hormone product



GROWJECT® is one of our core products, approved for manufacture and marketing in 1993. It improves symptoms such as short stature, caused by the deficiency of growth hormone that stimulates the body's growth and development. Growth hormone is indicated for both diseases of childhood and adulthood, and requires self-injection by patients at home. Many of the patients are children who, if too young, might need help from their parents or guardians to receive the injection if they cannot perform it themselves. We consider that it is important not only to provide high-quality and reliable pharmaceuticals but also to supply user-friendly injectors to all patients. In January 2017, we launched the new liquid formulation of GROWJECT® along with the dedicated electronically-controlled injector, GROWJECTOR® L, which was jointly developed by JCR and PHC Holdings Corporation*. This injector is the third generation model of GROWJECTOR®, which was launched as the world's first electronically-controlled injector in 2006. GROWJECTOR® L offers enhanced usability by featuring a more compact design as well as providing the highly rated functions of the previous model. It has thus evolved into an even more user-friendly injector.

In February 2018, the two companies began to jointly develop dedicated smartphone application software for GROWJECTOR® L. In other areas, for patients who will start growth hormone therapy using GROWJECTOR® L for the first time, JCR prepares support materials to ease their concerns about self-injections. We also regularly publish "Child Nursing," a nursing support book on growth hormone therapy for healthcare professionals. Since the launch of GROWJECT®, we have constantly worked to ensure a stable supply of high-quality products. Concurrently, we have advanced the development of a treatment for Short Stature Homeobox-containing Gene (SHOX) deficiency as an expanded indication of GROWJECT®, along with the development of a long-acting growth hormone. We will constantly strive to add value to our product portfolio through developing new devices such as patient-friendly injectors and supplying information on diseases. Along with these efforts, we aim to further increase our market share by proactively performing strategic and systematic sales activities.

Indications:
- Growth Hormone Deficiency
- Turner Syndrome
- Adult Growth Hormone Deficiency
- Small for Gestational Age

* PHC Holdings Corporation
PHC Holdings Corporation, established in 1969, is a healthcare company engaged in development, manufacturing, sales and service activities in the business fields of diabetes care, diagnosis, life sciences, and healthcare IT.


Child Nursing

Support materials for patients

Sales in FY2018

**11,978 million yen**

Compared to the previous fiscal year

**↑4.2%**

## Epoetin Alfa BS Inj. [JCR]

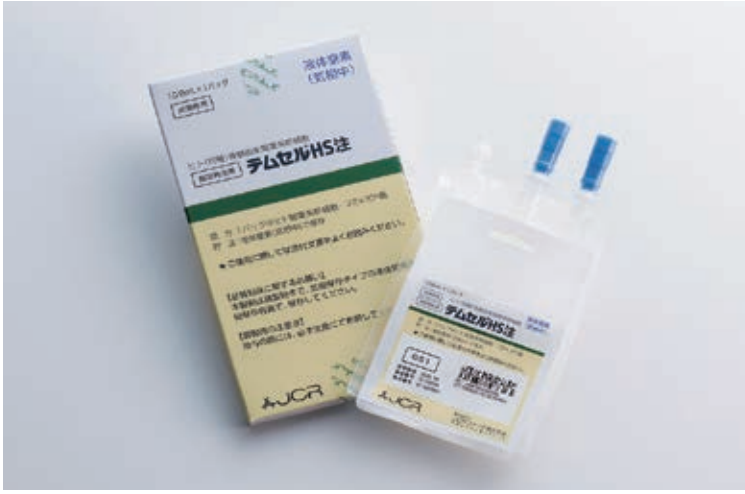
Recombinant erythropoietin product

Epoetin Alfa BS Inj. [JCR], a therapeutic product for renal anemia launched in May 2010, was developed utilizing our serum-free technology and proprietary biotechnologies. The product improves anemic symptoms of patients with chronic renal failure on dialysis treatment. Epoetin Alfa BS Inj. [JCR] was jointly developed by JCR and Kissei Pharmaceutical Co., Ltd. (Kissei Pharmaceutical) and was approved as the first biosimilar in Japan based on the robust clinical data that demonstrated equivalence and similarity to the originator drug.

Sales have steadily increased and it is now one of our core products thanks to the increasing awareness of the equivalence of this biosimilar to the originator drug in terms of efficacy and

## TEMCELL® HS Inj.

World's first Human somatic stem cell-processed products
Human (allogenic) bone marrow-derived mesenchymal stem cells




TEMCELL® HS Inj. is a regenerative medical product using human mesenchymal stem cells (MSCs) for the treatment of acute graft-versus-host disease (GVHD)*, a severe complication arising from hematopoietic stem cell transplantation. We obtained manufacturing and marketing approval for TEMCELL® HS Inj. in September 2015, and launched sales of this product, the world's first of its kind, in February 2016. TEMCELL® HS Inj. is a product manufactured by isolating and expanding mesenchymal stem cells derived from the bone marrow aspirate of a healthy adult donor. It utilizes the function of mesenchymal stem cells.

Since the launch of TEMCELL® HS Inj., the number of medical institutions taking delivery of this product and the number of cases have

# Topics

New

### Launch of Agalsidase Beta BS I.V. Infusion [JCR], a Recombinant Treatment for Fabry Disease

JCR has developed Agalsidase Beta BS I.V. Infusion [JCR] as a biosimilar for agalsidase beta for the treatment of Fabry disease, a type of lysosomal storage disorder (LSD). Pharmacokinetic studies initiated in February 2015 have shown that Agalsidase Beta BS I.V. Infusion [JCR] has biological equivalence to the innovator product agalsidase beta (genetic recombination). Phase II/III clinical trial in patients with Fabry disease initiated in May 2015 have shown that Agalsidase Beta BS I.V. Infusion [JCR] has the same efficacy and safety profiles as the innovator product. Agalsidase Beta BS I.V. Infusion [JCR] is not only JCR's first enzyme replacement therapy (ERT) for

quality and growing needs for cost effective biosimilars for dialysis treatment, where the cost is controlled by the flat sum reimbursement system. To further strengthen our presence in this market, we are jointly developing with Kissei Pharmaceutical "JR-131," a biosimilar of darbepoetin alfa, a long-acting erythropoiesis-stimulating agent. We filed an application for marketing authorization in September 2018.

Indications: • Renal anemia in dialysis patients
• Anemia of prematurity

Sales in FY2018

**4,511 million yen**

Compared to the previous fiscal year

**↑9.6%**

steadily increased. Currently, activities to provide information on its proper use are carried out by the Cell Regeneration Medical Sales Department. Going forward, we will continue to carry out activities to provide information on proper use in an effort to further increase market penetration.

* Acute GVHD is a life-threatening transplant-associated complication that arises following hematopoietic stem cell transplants. It is a disease in which immunocompetent cells (e.g. lymphocytes) present in the transplanted hematopoietic stem cells regard the recipient's body as foreign and attack the recipient's cells.

Indications: • Acute GVHD following hematopoietic stem cell transplantation

Sales in FY2018

**2,041 million yen**

Compared to the previous fiscal year

**↑32.2%**

LSDs, but also the first domestically-produced ERT product for LSDs. As JCR has realized high-quality manufacturing through its serum-free culture technology, Agalsidase Beta BS I.V. Infusion [JCR] is expected to become a new treatment option for Fabry disease. JCR will strive to increase market penetration of this product by promoting the aforementioned product characteristics, as well as factors such as JCR's track record and reliability as a manufacturer that has launched the first biosimilar product in Japan, and the ability of this product to help curtail national medical expenditures based on the National Health Insurance Drug Price Standard (priced at 70% of the price of the innovator product).

Indications: • Fabry disease

# Message

JCR is focused on the development of pharmaceuticals for rare diseases using biotechnologies, as well as cell therapy and regenerative medicine technologies. In 2018, we launched JCR's first enzyme replacement therapy (ERT) for lysosomal storage disorders (LSDs). Through such new innovations, JCR is expected to contribute positively to the broader patient population. Healthcare professionals and patients alike have high expectations for JCR, particularly in specialized fields, and I strongly appreciate the need for our products. As medical representatives, we work on a daily basis to deliver such JCR products to the frontlines of healthcare. We provide information that contributes to the daily treatment of rare diseases and increased public awareness of these conditions. We feel very happy when we hear positive comments on these activities from patients. As members of "Team JCR," we will continue to work as one to support the needs of as many patients and healthcare professionals as possible.

Masatada Mori
West Japan Sales, Sales Division

# SUSTAINABILITY

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

## Basic Approach to Sustainability

Since its inception in 1975, JCR has sought to create groundbreaking therapeutics that respond to unmet medical needs, particularly in the rare 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, environment, society, and corporate governance.

# Message

Since its inception, JCR has developed unique strengths and achieved sustained growth as a company which takes “one step ahead” of competitors at all times. We believe that our core mission is to focus in rare and intractable diseases and develop and create the world’s first innovative biopharmaceuticals originating from Japan.

JCR has defined rare diseases, environment, society, and corporate governance as its priority areas, and is determined to solve issues in each through its business activities. The benefits derived from these activities will be returned to and shared with a broad range of stakeholders within and outside the Company. In the process, we aim to achieve sustainability from an ESG perspective.

JCR seeks to be a “Research oriented specialty pharma with global exposure.” Concurrently, we will make a concerted effort to engage in sustainability and steadily realize our corporate philosophy of “Contributing towards people’s healthcare through pharmaceutical products.” We look forward to your continued understanding and support as we endeavor to reach our goals.

**Toru Ashida** Senior Executive Director, In charge of Corporate Strategy

As a company that has been engaged in the research and development of pharmaceuticals for rare diseases since its inception, JCR is involved in awareness-raising activities to support patients.

Action for RD Rare Disease

What JCR can do for rare diseases

## Rare Diseases

### RARE DISEASE Project

JCR started the activities of the RARE DISEASE Project to contribute as much as possible to the cause of the patients suffering from rare and intractable diseases. The project's activities will further increase JCR's understanding of such diseases. We started this project with a sense of responsibility and pride as members of a company committed to fighting these diseases. 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, 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. At the event, lectures were given by a rare disease specialist, a leader of a patient support group, and the manager of Momiji House, a facility for seriously ill children and their families operated by the National Center for Child Health and Development. Through this seminar, we strove to increase knowledge of rare and intractable diseases primarily among Ashiya residents.

RARE DISEASE Project team

In addition to our commitment to the research and development of pharmaceuticals for rare diseases, JCR will also continue wide-ranging activities that will lead to the support of the patient community.


Poster for public seminar

## Rare Disease Day

From FY2015, JCR has been a supporter of Rare Disease Day (celebrated globally). 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. Rare Disease Day 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.



## Fundraising Activities

To commemorate Rare Disease Day, JCR encourages employees to wear official Rare Disease Day badges and raises funds within the Company in February every year. Funds raised are donated to organizations working to provide information to patients with rare diseases, encourage cooperation with healthcare professionals, promote research to develop therapies, and raise awareness in society.

Donations from fundraising activities

| | |
|---|---|
| FY2014 | 205,159 yen |
| FY2015 | 164,570 yen |
| FY2016 | 145,969 yen |
| FY2017 | 192,990 yen |
| FY2018 | 261,634 yen |

# Message

"Momiji House" is a short-stay medical care facility set up by the National Center for Child Health and Development. Children who require medical care and their families can stay at Momiji House for several days. Even after children leave the hospital, family members are often very busy providing various forms of medical care at home, with tasks such as artificial ventilation management. Momiji House allows such family members to feel secure and comfortable during their stay, as if the facility were their second home. To do so, "Momiji House" has a staff of specialists in medicine, welfare and rehabilitation, and nursing care who continuously take very good care of the children on a daily basis.

Meanwhile, donations from the private sector are essential to keeping Momiji House open. This is because under the current public healthcare system, there are not enough funds to fully cover all of the necessary personnel costs needed to provide 24-hour-a-day care and services that will promote the growth and development of children in need of constant medical care.

I'm sincerely grateful to JCR for continuously making large donations to assist with the care of the children and their families before and after the facility was opened. I look forward to JCR's continuing support as we seek to realize the happiness and wellbeing of children in need of constant medical care and their families.

**Katsuyasu Uchida** House Manager (former NHK TV presenter), Momiji House, National Center for Child Health and Development


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

Momiji House provides 24-hour-a-day care for children who require medical care at home. Those with serious illness or disability and their families can stay several days at Momiji House, feeling secure and comfortable as if they were at home. JCR supports the important mission and activities of Momiji House.

## Society

### Initiatives for the Workplace Environment

#### Introducing Flexible Working Systems to Realize Workstyle Reforms

We believe that work and private life are both important, and 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

As an initiative to create an ideal workplace environment where employees can work healthily and comfortably, we are encouraging the use of annual paid leave. We also provide Group administration of influenza vaccinations and support employees aged 35 and over who wish to receive a comprehensive health check. To improve the workplace environment, we hold a monthly Safety and Health Committee meeting and assist one another to implement any necessary improvements. We also have a team of three selected corporate physicians, including one who provides mental healthcare as a designated mental healthcare physician. Furthermore, inside the Research Institute, we have created a space called "JCR Oasis" where employees can get a massage and refresh themselves during work.

#### 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 initiatives, we received the Kurumin certification from the Ministry of Health, Labour and Welfare in July 2018.

In-house childcare center JCR Kids Land

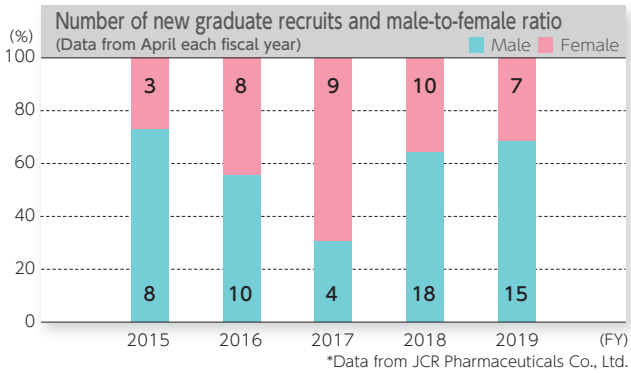
# Message

The times are rapidly changing as the new imperial era of Reiwa dawns in Japan. Notably, the new Work Style Reform Act has entered force. In this environment, JCR will need to move faster than ever to tackle the challenges of unmet medical needs. To do so, I believe it will be crucial for JCR to continue to flexibly address changes as it improves the workplace environment so that each of its employees can fully demonstrate their abilities.

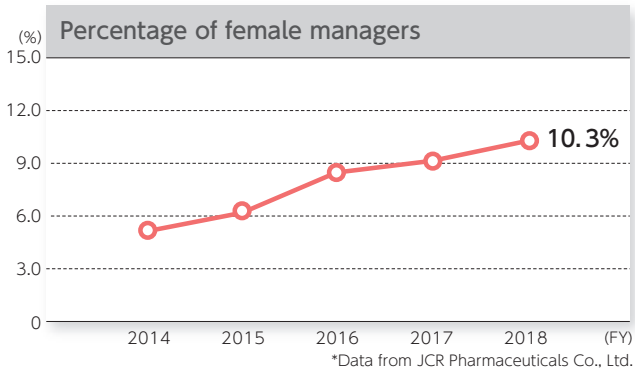
Many rare and intractable diseases are serious illnesses that progress rapidly. Accordingly, JCR has a very important role to fulfill in society, especially for patients eagerly awaiting new medicines.

The ability of every employee to take pride in their work, and feel happy as they work, will ultimately lead to the happiness of patients. Guided by the management team's aspirations to value each and every employee, I will strive to develop various environments and systems so that all employees can work in good health and with a high level of motivation. By doing so, I would like to make JCR one of the world's most fulfilling places to work.

**Ayako Watari** Section Manager, Human Resources & General Affairs Dept., Administration Division



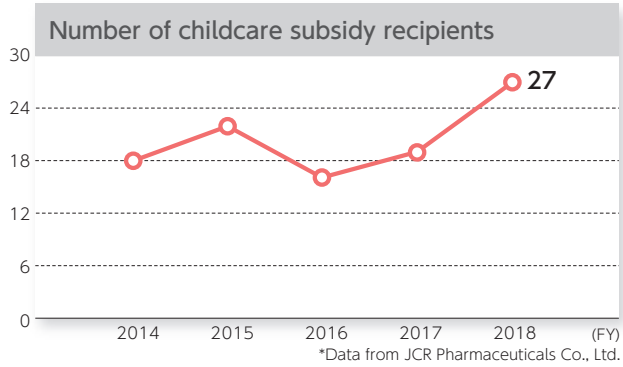
*Data from JCR Pharmaceuticals Co., Ltd.



*Data from JCR Pharmaceuticals Co., Ltd.

## Enhanced Training Programs

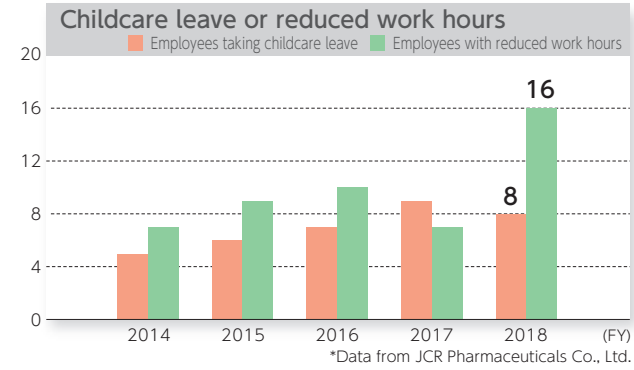
JCR focuses its efforts on employee training, considering that improving employee skills leads to growth for the Company. In their first month after joining JCR, new graduate recruits attend group training, which includes business etiquette, communication skills, presentations from each business division, practical training at plants and the Research Institute, and accompanying medical representatives in the field. We also conduct specific training for each employee rank regularly, as well as English language training.



*Data from JCR Pharmaceuticals Co., Ltd.

## Creating Workplaces Where Women Can Participate Actively

In October 2018, JCR was recognized in the Third Annual Hyogo Women's Active Participation Awards 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. We also received Eruboshi certification (Grade 2) from the Minister of Health, Labour and Welfare as an outstanding company with regard to promoting active participation of women based on the Act on Promotion of Women's Participation and Advancement in the Workplace.



*Data from JCR Pharmaceuticals Co., Ltd.

I was able to take full childcare leave without reducing the period of leave, because I was able to leave my child in the care of JCR Kids Land, an in-house day-care center. After returning to work from childcare leave, I sometimes needed to take time off work, such as when my child was feeling unwell. Whenever this happened, my supervisor would repeatedly assure me that "We will follow-up on your work, so there is no need to worry!" Those words put my mind at ease. While I was pregnant, I found that commuting to the office sometimes required a lot of effort. In the future, I have high hopes for JCR to introduce new work styles such as working from home.

**Naoko Takasao** Clinical Intelligence, Development Division

I took childcare leave for three months on the recommendation of the Human Resources & General Affairs Department of the Research Institute. While I was on leave, I truly appreciated how difficult it is to look after children. After I returned to work, JCR continued to show an understanding of my situation, allowing me to work reduced hours while leaving my child in the care of JCR Kids Land. Recently, there has been a steady string of male employees who have acquired childcare leave. I feel that the office has steadily become an easier place for employees to continue working while raising children.

**Makoto Yamagami** Biomanufacturing Technology, Research Institute, Research Division

# Initiatives for Society

## Support for Better Learning Opportunities

### Support for the Swiss Nonprofit Foundation GLOBAL FOUNDATION FOR LIFE SCIENCES

In the field of medicine, the foundation provides humanitarian assistance in various medically underprivileged countries, and supports the development of young researchers.

### Support for the Job Yearbook

We sponsor the Job Yearbook, which is a career education tool published by The Asahi Shimbun Company and distributed to elementary and middle schools throughout Japan. Under the title "Why Do We Grow Taller?," we provided a simple explanation of the mechanism for growth.


## Initiatives for Contributing to Society

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

We support the Award for Promotion of Maternal Child Health, which aims to further the development of maternal and child health by encouraging the good work of individuals who have made great contributions to society in the field of community-based maternal and child health.


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

### Donation to Child Chemo House

JCR supports Child Chemo House (Chuo-ku, Kobe), Japan's first special treatment facility designed for improving the QOL (Quality of Life) of children with pediatric cancer undergoing medical treatments and also their families. At Child Chemo House, children can receive advanced treatments while having a normal life, spending time with their families in an environment similar to their own home.

NPO法人
チャイルド・ケモ・ハウス
child chemo house

### Support for the Home Prefecture of Hyogo

We support our home prefecture through the following initiatives.

- Research Institute observations and internships for local high school students
- Sponsorship for the Kobe Festival
- Sponsorship for Kobe Luminarie
- Sponsorship for Relay for Life Japan in Ashiya
- Donation to the Uchideten Shrine

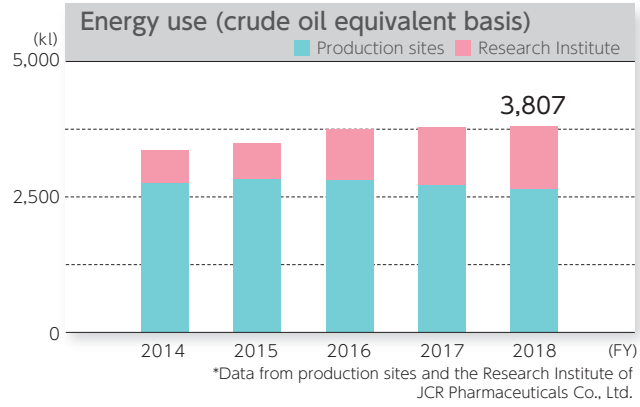
# Environment

## Initiatives for Environmental Conservation

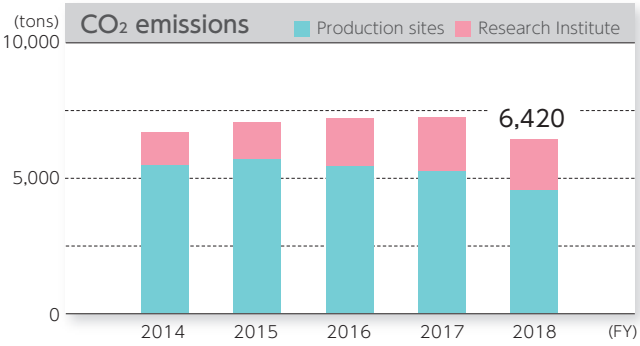
JCR has been implementing a wide range of measures to mitigate its environmental impact, including reducing $CO_2$ emissions and effectively using water resources. For example, we have worked to transition to LED lighting at all company facilities and shift all our commercial vehicles, including those 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 business activities. Going forward, we will sequentially switch over to electric vehicles as public charging stations become more widely available. In 2016, we installed a solar power generating 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



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



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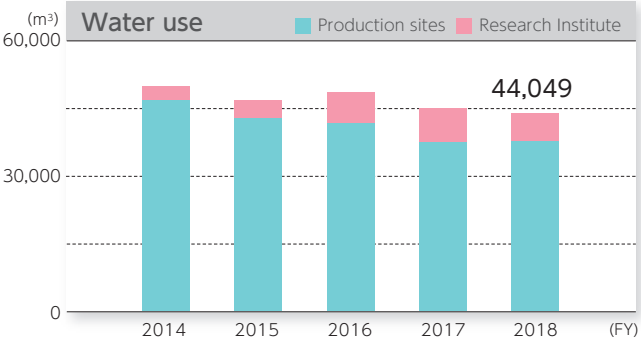


*Data from production sites and the Research Institute of JCR Pharmaceuticals Co., Ltd.

### Energy Use

JCR has seen an increase in total energy use (electricity, gas) as its business results have grown. In the Research Division, total energy use has increased due to the start of operation 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 revisions to how we use energy. We expect to obtain data on energy use in business activities (mainly gasoline) from FY2019.

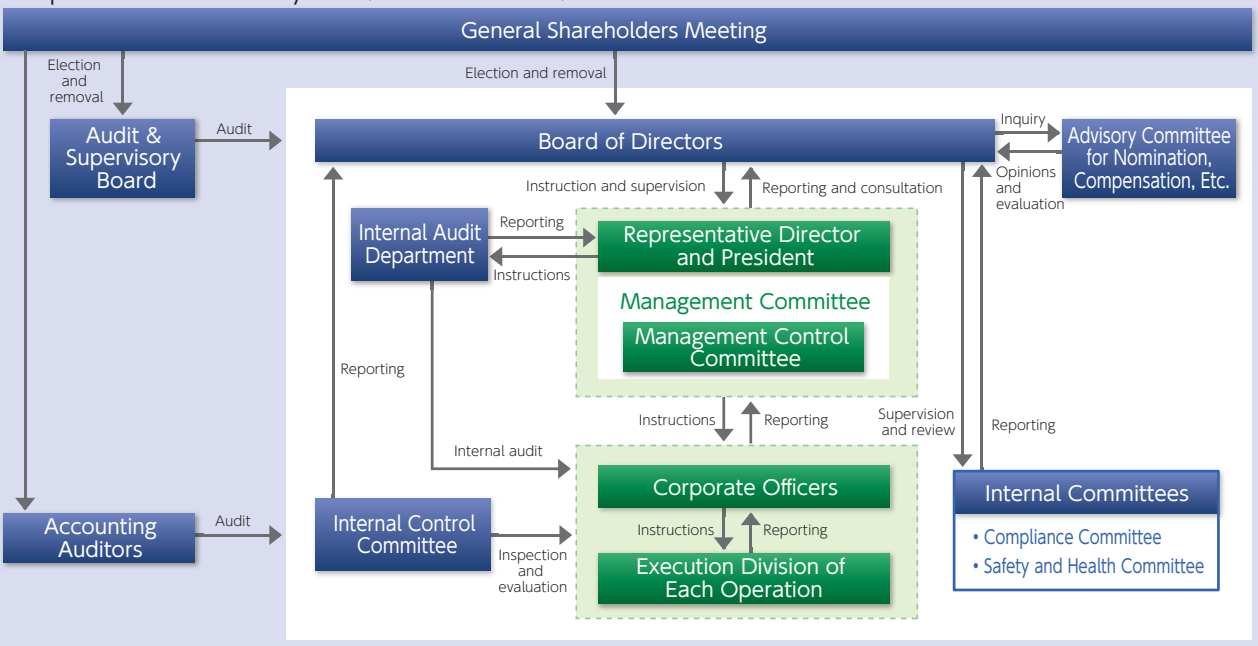
### Water Resources

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

For other information, please refer to the Sustainability page of our website. http://www.jcrpharm.co.jp/en/site/en/sustainability/index.html

# CORPORATE GOVERNANCE

Corporate Governance System (As of June 27, 2019)




## Basic Concept

JCR Group considers 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 the Company's management, to heighten our corporate value further, and at the same time to build a system to ensure the protection of the interests of shareholders. For this purpose, we are putting forth effort to secure implementation and operation of effective internal control systems, to evaluate the effectiveness of such systems on our own, and to fulfill social responsibilities as a corporation.

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 a heightened sense of ethics in the course of day-to-day corporate activities.

## Overview of Corporate Governance System

JCR as a company with the Audit & Supervisory Board, has 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 it covers an appropriate scope in line with the Company's current condition, and that it is possible to conduct efficient management operations. Also, we judge 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 independence of supervision over management.

## Details 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, and it decides important matters concerning the management of the Company in addition to matters specified by laws and regulations.

It is defined in our articles of incorporation that our Company must 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. Although important management matters related to management policy, management strategy, etc., are in principle deliberated and decided by Management Committee, it operates as a meeting body for expeditious response 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), and it deliberates on important matters concerning nomination and compensation for Directors and Corporate Officers and Audit & Supervisory Board Members. It also makes suggestions regarding the evaluation of the Board of Directors as necessary and provides opinions to the Board of Directors.

## Management Committee

The Management Committee consists of five Internal Directors and seven Corporate Officers, and a meeting is held in principle twice per month. The purpose of the Committee is to make deliberations and decisions necessary for management judgment 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. Seven Corporate Officers execute operations based on the management policy decided by the Board of Directors.

## Audit & Supervisory Board

The Company is a company with the Audit & Supervisory Board, and 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 Board also serves as a system that can demonstrate supervising functions for company management, and ascertain the status of the Company through consultations with top management members including General Managers in charge.

## Internal Audit Department

The Internal Audit Department directly under the control of the Director and President performs audits on 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, and the results of internal audits are submitted to Audit & Supervisory Board Members, in addition to the Director and President.

## Internal Control Committee

The Internal Control Committee consists of members of the Legal Affairs Department, Accounting Department, Human Resources & General Affairs Department, Internal Audit Department, and Production Management Department, etc. It exchanges opinions with and makes reports to Audit & Supervisory Board Members, etc., as necessary and further secures appropriate financial reporting by Accounting Auditors with respect to the effectiveness of the reporting of internal controls through self-inspection processes.

### Organs of the Company, Number of Meetings Held, and Attendance Rate in FY2018

(As of end of FY2018)

| | | |
|---|---|---|
| Board of Directors | Composition | 9 members (5 Internal Directors, 3 Independent Outside Directors, 1 Outside Director) |
| | Number of meetings held | 14 (including 2 resolutions in writing) |
| | Attendance rate | 98.39% (Absence: 1 Independent Outside Director, 1 time; and 1 Outside Director, 1 time) |
| Management Committee | Composition | 17 members (5 Internal Directors, 1 Independent Outside Director, 2 Independent Outside Audit & Supervisory Board Members, 1 Director of a subsidiary, 7 Corporate Officers, 1 Adviser) |
| | Number of meetings held | 22 |
| | Attendance rate | 91.44% (Absence: 1 Independent Outside Director, 16 times; 1 Director of a subsidiary, 1 time; 1 Adviser, 5 times; and several Corporate Officers, several times) |
| Advisory Committee for Nomination, Compensation, etc. | Composition | 5 members (1 Internal Director, 3 Independent Outside Directors, 1 Independent Outside Audit & Supervisory Board Member) |
| | Number of meetings held | 4 |
| | Attendance rate | 95.00% (Absence: 1 Independent Outside Director, 1 time) |
| 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 | 98.46% (Absence: 1 Independent Outside Audit & Supervisory Board Member, 1 time) |
| Internal Control Committee | Composition | 10 members (2 from Legal Affairs Dept., 3 from Internal Audit Dept., 2 from Accounting Dept., 2 from Human Resources & General Affairs Dept., and 1 from Production Management Dept.) |
| | Number of meetings held | 5 |
| | Attendance rate | 91.67% (Absence: 1 from Legal Affairs Dept., 3 times; and 1 from Accounting Dept., 1 time) |

## 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, and five Outside Audit & Supervisory Board Members who are also Independent Outside Audit & Supervisory Board Members.

Outside Directors supervise the 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 the Board of Directors' meeting. Outside Directors strengthen cooperation with the Audit & Supervisory Board, exchange information, share recognition, and appropriately reflect these aspects to the Board of Directors with 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 Department, and monitor the execution of Directors' duties through operational and accounting audits. As they are expected to present objective opinions for audits, Outside Audit & Supervisory Board Members make unreserved questions and 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 Outside Directors

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 into development. MEDIPAL HOLDINGS also retains 22.46% of JCR's shares.

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

JCR designates eight members - 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 - as independent directors as stipulated in the listing regulations for the Tokyo Stock Exchange.

### Reasons for appointment of Outside Directors and 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 pharmaceutical company manager in the Company's management. |
| | Takashi Suetsuna | ○ | Appointed as an Outside Director because he has a wealth of experience in administrative agencies; we would like him to apply this experience, as well as his global perspective as a diplomat to the Company's management. |
| | Toshihide Yoda | — | Appointed as an Outside Director because he has extensive knowledge as a pharmaceutical sector analyst in the financial industry; we would like him to apply his experience in serving as a leading force in many new businesses over the years to the Company's management. |
| | Yuko Hayashi, Ph.D. | ○ | Appointed as an Outside Director because she has professional knowledge on the practical application of innovation and we would like her to apply her wide-ranging wealth of experience in areas such as research activities related to advanced medicines and promoting diversity and promotion of women's participation and advancement in the workplace, to the Company'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 from an experienced and well-informed standpoint. |
| | 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 manager 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 he has a wealth of experience in administrative agencies and broad insights into monetary and financial affairs; we would like him to perform audits of the Company 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 he has a 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 established a Compliance Committee as an organization 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 the Company's compliance action plans and policies, and provides employee training and education in accordance with the Compliance Code of Conduct and the Compliance Handbook, along with making compliance matters more widely known and raising awareness through a compliance newsletter.

# 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 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 corporate activities. It also determines basic risk management guidelines and develops its risk management system based on those guidelines. Furthermore, the Company is creating systems that can respond to 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) items. The BCP is reviewed each fiscal year and revised if needed.

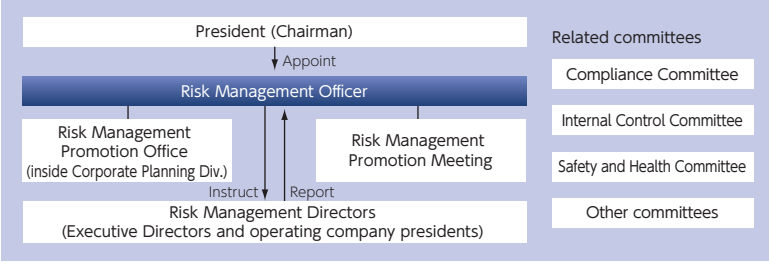
1. Response measures for GROWJECT® supply in the event of disruption
2. Company-wide response measures in the event of a large-scale disaster
3. Response measures in the event of a major compliance violation

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 global-standard drug quality system and pursue an even higher level of safety.

### Risk Management System

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




### Members, Number of Meetings, and Attendance Rate at Internal Committee Meetings in FY2018

| | | | |
|---|---|---|---|
| Compliance Committee | Compliance Control Committee | Composition | 14 members (2 attorneys, 4 Directors, 8 Corporate Officers) |
| | | Number of meetings held | 2 |
| | | Attendance rate | 96.67% (Absence: 1 Corporate Officer, 1 time) |
| | Compliance Promotion Committee | Composition | 17 members (1 from Corporate Planning Div., 3 from HR Development & Compliance Dept., 2 from Human Resources & General Affairs Dept., 1 from Sales Div., 1 from Development Div., 2 from Research Div., 6 from Production Div., 1 from Quality Assurance Div.) |
| | | Number of meetings held | 2 |
| | | Attendance rate | 97.06% (Absence: 1 from Development Div., 1 time) |
| Safety and Health Committee | | Composition | 19 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 Overseas Business Promotion Office, 1 from Quality Assurance Div., 1 from Tokyo Office, 1 from Development Div., 2 from consolidated subsidiaries) |
| | | Number of meetings held | 12 |
| | | Attendance rate | 93.84% (Absence details omitted) |

# Operating Results

## Net Sales

Sales of our core product, GROWJECT®, (human growth hormone product), Epoetin Alfa BS Inj. [JCR] (renal anemia treatment) and TEMCELL® HS Inj. (regenerative medical product) trended steadily and were all higher than in the previous fiscal year. Sales of these products were higher than initially anticipated, offsetting the negative impact of NHI price revisions. Moreover, in November 2018 we launched Agalsidase Beta BS I.V. Infusion [JCR], a treatment for Fabry disease that is the first lysosomal storage disease (LSD) therapy to be produced in Japan. There was also an increase in revenue from licensing. As a result, sales amounted to 23,160 million yen (up 12.5% from the previous fiscal year) in FY2018. Sales from pharmaceuticals, JCR's main business sector, amounted to 22,887 million yen (up 13.4% from the previous fiscal year) and accounted for 98.8% of total sales.

Trend of Sales in Each Business Segment (unit: million yen)

| | | FY2017 | FY2018 |
|---|---|---|---|
| Pharmaceuticals | GROWJECT® | 11,495 | 11,978 |
| | Epoetin Alfa BS Inj. [JCR] | 4,115 | 4,511 |
| | TEMCELL® HS Inj. | 1,544 | 2,041 |
| | Agalsidase Beta BS I.V. Infusion [JCR] | — | 74 |
| | Urine-derived products | 834 | 690 |
| | Revenue from licensing | 2,137 | 3,560 |
| | Others | 50 | 30 |
| | Total | 20,177 | 22,887 |
| Medical devices and laboratory equipment | | 417 | 272 |
| Total | | 20,594 | **23,160** |

## Gross Profit

Due to the increase in net sales, gross profit increased 14.7% from the previous fiscal year to 16,592 million yen. Mainly due to the increase in revenue from licensing and the reduction of product cost, the ratio of cost of sales to net sales improved 1.4 percentage points from FY2017 to 28.4%.

## Operating Income

R&D expenditures increased 3.4% from FY2017, and selling, general and administrative expenses, including R&D expenditures, were 11,625 million yen (up 8.8% from the previous fiscal year). As a result, operating income was 4,967 million yen (up 31.3% from the previous fiscal year).

## Ordinary Income

Non-operating income increased 43 million yen compared with FY2017, mainly due to the recording of foreign exchange gains. As a result, ordinary income amounted to 5,068 million yen (up 31.9% from the previous fiscal year).

## Profit Attributable to Owners of Parent

Extraordinary income was 82 million yen (up 4 million yen from the previous fiscal year) due to the reasons such as the recording of reversal of provision for loss on guarantees. Furthermore, extraordinary losses came to 221 million yen (up 195 million yen from the previous fiscal year), mainly due to the recording of loss related to voluntary recall of products. As a result, income before income taxes was 4,928 million yen (up 26.5% from the previous fiscal year), and profit attributable to owners of parent amounted to 3,715 million yen (up 21.0% from the previous fiscal year).

# Financial Position

## Assets

Total assets at the end of FY2018 stood at 42,516 million yen (up 4,117 million yen from the previous fiscal year-end).

Current assets stood at 27,368 million yen (up 4,537 million yen from the previous fiscal year-end) due to increases in cash and deposits and notes and accounts receivable-trade, which offset a decrease in securities. Noncurrent assets stood at 15,147 million yen (down 419 million yen from the previous fiscal year-end), mainly due to the decrease in investment securities.

## Liabilities

Total liabilities at the end of FY2018 stood at 11,642 million yen (up 772 million yen from the previous fiscal year-end).

Current liabilities stood at 8,684 million yen (up 1,579 million yen from the previous fiscal year-end), mainly due to increases in short-term loans payable and provision for bonuses. Noncurrent liabilities stood at 2,957 million yen (down 806 million yen from the previous fiscal year-end), mainly due to decreases in long-term loans payable and lease obligations.

## Net Assets

Net assets stood at 30,874 million yen (up 3,345 million yen from the previous fiscal year-end) mainly due to a decrease in capital surplus, despite recording profit attributable to owners of parent.

As a result, the equity ratio at the end of the fiscal year under review was 71.1% (up 0.8 percentage point from the previous fiscal year-end).

## Cash Flow

Net cash provided by operating activities in FY2018 amounted to 3,905 million yen (up 771 million yen from the previous fiscal year). The main factors were income before income taxes of 4,928 million yen and depreciation and amortization of 1,343 million yen, partially offset by an increase in notes and accounts receivable-trade of 1,732 million and an increase in inventories of 157 million yen.

Net cash provided by investing activities amounted to 240 million yen (a change of 1,827 million yen from net cash used in the previous fiscal year). The main factor was proceeds from sales and redemption of investment securities of 1,257 million yen, which was partially offset by purchase of property, plant, and equipment of 895 million yen.

Net cash used in financing activities amounted to 917 million yen (down 1,258 million yen from the previous fiscal year). The main factor was cash dividends paid of 834 million yen.

# Forecast for FY2019

In terms of sales, we anticipate net sales growth on top of steady increases in sales volume for mainstay products such as GROWJECT®, erythropoiesis-stimulating agent (ESA) products, TEMCELL® HS Inj., and Agalsidase Beta BS I.V. Infusion [JCR]. In addition, we will continue our proactive efforts in the licensing business. Based on these factors, the overall sales forecast of the JCR Group is for 26,400 million yen (up 14.0% from the current fiscal year).

In terms of profits, although we are planning to pursue research and development activities even more proactively, we anticipate operating income of 5,140 million yen (up 3.5% from the current fiscal year), ordinary income of 5,150 million yen (up 1.6% from the current fiscal year) and profit attributable to owners of parent of 4,080 million yen (up 9.8% from the current fiscal year) due to an increase in gross profit associated with sales growth.

# Dividends Policy

## Basic Policy on Profit Distribution and Dividends

JCR regards the distribution of its profits to shareholders as an important management policy.

Our basic policy in regard to the declaration of cash dividends and so forth is to provide continuous and stable dividends by taking into account factors such as the business performance and cash flow while securing sufficient internal reserves for the development of new drug products and the strengthening of our management structure, which will be a source of future profits.

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

For the term-end dividend for FY2018, under our basic policy to provide continuous and stable dividends, we will provide a term-end dividend of 17 yen per share. Together with the interim dividend of 13 yen per share, the total annual dividend is 30 yen per share.

Internal reserves will be effectively used as a resource to contribute to strengthening our management, increasing revenue, and returning of profits in the future.

For the dividend of FY2019 (the term ending in March 2020), we expect to distribute a full-year dividend of 30 yen per share (interim dividend of 15 yen and term-end dividend of 15 yen).

# Summary of Financial Data for Eleven Years

Consolidated fiscal years ended March 31

| | FY2008 | FY2009 | FY2010 | FY2011 |
|---|---|---|---|---|
| **Fiscal year** | | | | |
| Net sales | 12,082 | 14,387 | 14,457 | 12,845 |
| Operating income | 546 | 2,007 | 1,407 | 1,089 |
| Profit attributable to owners of parent | 539 | 1,302 | 926 | 633 |
| Comprehensive income | — | — | 783 | 664 |
| R&D expenditures | 2,804 | 2,325 | 2,017 | 1,841 |
| Capital investment | 876 | 2,369 | 2,417 | 487 |
| Depreciation and amortization | 694 | 743 | 975 | 1,101 |
| Cash flows from operating activities | 1,825 | 2,357 | (18) | (421) |
| Cash flows from investing activities | 121 | (3,396) | (2,211) | 1,539 |
| Cash flows from financing activities | (1,276) | 1,756 | (1,276) | (1,065) |
| **End of fiscal year** | | | | |
| Total assets | 24,767 | 29,148 | 29,817 | 28,967 |
| Net assets | 16,984 | 20,483 | 22,832 | 22,633 |
| Shareholders' equity | 16,879 | 20,462 | 22,762 | 22,535 |
| **Information per share** | | | | |
| Earnings per share (EPS) | 20.09 | 50.77 | 28.93 | 19.75 |
| Net assets | 635.20 | 700.80 | 704.96 | 710.82 |
| Dividends | 10.00 | 15.00 | 12.00 | 12.00 |
| **Financial indicators** | | | | |
| Equity ratio (%) | 68.2 | 70.2 | 76.3 | 77.8 |
| Return on equity (ROE) (%) | 3.2 | 7.0 | 4.3 | 2.8 |
| Dividend payout ratio (%) | 49.8 | 29.5 | 41.5 | 60.8 |
| Numbers of employees | 280 | 311 | 399 | 424 |

Unit: million yen

| FY2012 | FY2013 | FY2014 | FY2015 | FY2016 | FY2017 | **FY2018** |
|---|---|---|---|---|---|---|
| 14,099 | 15,705 | 16,855 | 17,438 | 18,085 | 20,594 | **23,160** |
| 1,150 | 1,545 | 2,014 | 2,152 | 2,362 | 3,784 | **4,967** |
| 730 | 1,296 | 1,682 | 1,789 | 1,863 | 3,070 | **3,715** |
| 1,161 | 1,544 | 1,936 | 1,557 | 1,831 | 3,016 | **4,008** |
| 1,991 | 2,202 | 3,334 | 3,348 | 4,071 | 4,211 | **4,354** |
| 1,494 | 2,260 | 1,522 | 1,237 | 1,409 | 908 | **1,517** |
| 979 | 1,111 | 1,352 | 1,407 | 1,447 | 1,382 | **1,343** |
| 1,661 | 4,565 | 499 | 2,201 | 2,651 | 3,133 | **3,905** |
| (178) | (2,668) | (1,419) | (980) | (841) | (1,587) | **240** |
| (238) | (369) | (1,261) | (1,314) | 146 | (2,175) | **(917)** |
| 31,286 | 33,464 | 34,086 | 35,346 | 36,385 | 38,398 | **42,516** |
| 23,496 | 24,580 | 26,264 | 27,062 | 27,585 | 27,528 | **30,874** |
| 23,368 | 24,417 | 26,101 | 26,819 | 27,305 | 26,999 | **30,249** |

Unit: yen

| | | | | | | |
|---|---|---|---|---|---|---|
| 23.03 | 40.79 | 52.85 | 56.12 | 58.95 | 98.73 | **120.68** |
| 735.86 | 768.13 | 818.64 | 843.34 | 864.66 | 877.86 | **982.14** |
| 12.00 | 17.00 | 18.50 | 22.00 | 22.00 | 26.00 | **30.00** |
| 74.7 | 73.0 | 76.6 | 75.9 | 75.0 | 70.3 | **71.1** |
| 3.2 | 5.4 | 6.6 | 6.8 | 6.9 | 11.3 | **13.0** |
| 52.1 | 41.7 | 35.0 | 39.2 | 37.3 | 26.3 | **24.9** |
| 437 | 472 | 501 | 526 | 566 | 568 | **632** |

## Consolidated Balance Sheets

Unit: million yen

| | As of March 31, 2018 | As of March 31, 2019 |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash and deposit | 4,895 | 7,836 |
| Notes and accounts receivable-trade | 7,103 | 8,835 |
| Securities | 1,217 | 661 |
| Merchandise and finished goods | 1,759 | 2,281 |
| Work in process | 1,790 | 1,473 |
| Raw materials and supplies | 5,474 | 5,363 |
| Other | 592 | 917 |
| Total current assets | 22,831 | 27,368 |
| Non-current assets | | |
| Property, plant and equipment | | |
| Buildings and structures, net | 4,755 | 4,475 |
| Machinery, equipment and vehicles, net | 1,044 | 830 |
| Land | 3,882 | 3,882 |
| Lease assets, net | 392 | 239 |
| Construction in progress | — | 851 |
| Other, net | 778 | 782 |
| Total property, plant and equipment | 10,853 | 11,061 |
| Intangible assets | 112 | 110 |
| Investments and other assets | | |
| Investment securities | 3,194 | 2,941 |
| Deferred tax assets | 562 | 378 |
| Net defined benefit assets | 268 | 297 |
| Other | 599 | 383 |
| Allowance for doubtful accounts | (22) | (24) |
| Total investments and other assets | 4,600 | 3,975 |
| Total non-current assets | 15,567 | 15,147 |
| Total assets | 38,398 | 42,516 |

Unit: million yen

| | As of March 31, 2018 | As of March 31, 2019 |
|---|---|---|
| **Liabilities** | | |
| Current liabilities | | |
| Notes and accounts payable-trade | 585 | 586 |
| Short-term loans payable | 2,893 | 3,630 |
| Lease obligations | 193 | 178 |
| Income taxes payable | 887 | 801 |
| Provision for bonuses | 560 | 666 |
| Provision for directors' bonuses | 80 | 77 |
| Other | 1,904 | 2,744 |
| Total current liabilities | 7,105 | 8,684 |
| Non-current liabilities | | |
| Long-term loans payable | 2,500 | 1,850 |
| Lease obligations | 218 | 73 |
| Provision for loss on guarantees | 315 | 240 |
| Allowance for employee stock ownership benefits | 19 | 36 |
| Net defined benefit liability | 641 | 710 |
| Other | 69 | 46 |
| Total non-current liabilities | 3,764 | 2,957 |
| Total liabilities | 10,870 | 11,642 |
| **Net assets** | | |
| Shareholders' equity | | |
| Capital stock | 9,061 | 9,061 |
| Capital surplus | 10,947 | 10,922 |
| Retained earnings | 10,469 | 13,350 |
| Treasury stock | (4,042) | (3,937) |
| Total shareholders' equity | 26,435 | 29,397 |
| Accumulated other comprehensive income | | |
| Valuation difference on available-for-sale securities | 462 | 773 |
| Foreign currency translation adjustments | 169 | 149 |
| Remeasurements of defined benefit plans | (67) | (71) |
| Total accumulated other comprehensive income | 563 | 851 |
| Subscription rights to shares | 344 | 435 |
| Non-controlling interests | 185 | 189 |
| Total net assets | 27,528 | 30,874 |
| Total liabilities and net assets | 38,398 | 42,516 |

# Consolidated Financial Statements

Unit: million yen

## Consolidated Statements of Income

| | FY2017 (From Apr. 1, 2017 to March 31, 2018) | FY2018 (From Apr. 1, 2018 to March 31, 2019) |
|---|---|---|
| Net sales | 20,594 | 23,160 |
| Cost of sales | 6,128 | 6,567 |
| Gross profit | 14,465 | 16,592 |
| Selling, general and administrative expenses | 10,681 | 11,625 |
| Operating income | 3,784 | 4,967 |
| Non-operating income | | |
| Interest income | 20 | 20 |
| Dividends income | 25 | 25 |
| Foreign exchange gains | — | 39 |
| Gain on sale of investment securities | 26 | — |
| Insurance income | 11 | 39 |
| Other | 21 | 23 |
| Total non-operating income | 105 | 148 |
| Non-operating expenses | | |
| Interest expenses | 27 | 21 |
| Foreign exchange losses | 7 | — |
| Loss on redemption of securities | — | 19 |
| Other | 11 | 7 |
| Total non-operating expenses | 46 | 47 |
| Ordinary income | 3,843 | 5,068 |
| Extraordinary income | | |
| Gain on sale of non-current assets | 54 | — |
| Reversal of provision for loss on guarantees | 22 | 75 |
| Other | 0 | 6 |
| Total extraordinary income | 77 | 82 |
| Extraordinary losses | | |
| Loss on disposal of non-current assets | 25 | 37 |
| Loss related to voluntary recalling of products | — | 181 |
| Other | — | 2 |
| Total extraordinary losses | 25 | 221 |
| Profit before income taxes | 3,895 | 4,928 |
| Income taxes-current | 964 | 1,169 |
| Income taxes-deferred | (139) | 48 |
| Total income taxes | 825 | 1,217 |
| Profit | 3,069 | 3,710 |
| Profit (loss) attributable to non-controlling interests | (0) | (4) |
| Profit attributable to owners of parent | 3,070 | 3,715 |

## Consolidated Statements of Comprehensive Income

| | | |
|---|---|---|
| Profit | 3,069 | 3,710 |
| Other comprehensive income | | |
| Valuation difference on available-for-sale securities | (107) | 311 |
| Foreign currency translation adjustment | 19 | (10) |
| Remeasurements of defined benefit plans, net of tax | 35 | (3) |
| Total other comprehensive income | (53) | 297 |
| Comprehensive income | 3,016 | 4,008 |
| (Comprehensive income attributable to) | | |
| Comprehensive income attributable to owners of parent | 3,016 | 4,003 |
| Comprehensive income attributable to non-controlling interests | (0) | 4 |

## Consolidated Statements of Changes in Net Assets

From April 1, 2017 to March 31, 2018

Unit: million yen

| | Shareholders' equity | | | | |
|---|---|---|---|---|---|
| | Capital stock | Capital surplus | Retained earnings | Treasury stock | Total shareholders' equity |
| Beginning balance | 9,061 | 10,964 | 8,149 | (1,486) | 26,689 |
| Changes during the year | | | | | |
| Dividends paid | | | (750) | | (750) |
| Profit attributable to owners of the parent | | | 3,070 | | 3,070 |
| Purchase of treasury shares | | | | (2,622) | (2,622) |
| Disposal of treasury shares | | (16) | | 66 | 49 |
| Changes of items other than shareholders' equity (net) | | | | | |
| Total changes for the year | — | (16) | 2,319 | (2,556) | (253) |
| Ending balance | 9,061 | 10,947 | 10,469 | (4,042) | 26,435 |

| | Accumulated other comprehensive income | | | | | | |
|---|---|---|---|---|---|---|---|
| | Valuation difference on available-for-sale securities | Foreign currency translation adjustments | Remeasurements of defined benefit plans, net of tax | Total accumulated other comprehensive income | Stock acquisition rights | Non-controlling interests | Total net assets |
| Beginning balance | 569 | 149 | (103) | 616 | 279 | 0 | 27,585 |
| Changes during the year | | | | | | | |
| Dividends paid | | | | | | | (750) |
| Profit attributable to owners of the parent | | | | | | | 3,070 |
| Purchase of treasury shares | | | | | | | (2,622) |
| Disposal of treasury shares | | | | | | | 49 |
| Changes of items other than shareholders' equity (net) | (107) | 19 | 35 | (53) | 64 | 184 | 195 |
| Total changes for the year | (107) | 19 | 35 | (53) | 64 | 184 | (57) |
| Ending balance | 462 | 169 | (67) | 563 | 344 | 185 | 27,528 |

From April 1, 2018 to March 31, 2019

Unit: million 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 adjustments | 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 |

## Consolidated Statements of Cash Flows

Unit: million yen

| | FY2017 (From Apr. 1, 2017 to March 31, 2018) | FY2018 (From Apr. 1, 2018 to March 31, 2019) |
|---|---|---|
| **Net cash provided by (used in) operating activities** | | |
| Income before income taxes | 3,895 | 4,928 |
| Depreciation and amortization | 1,382 | 1,343 |
| Increase (decrease) in provision for loss on guarantees | (22) | (75) |
| Increase (decrease) in net defined benefit liability | 75 | 69 |
| Increase (decrease) in provision for bonuses | 35 | 105 |
| Share-based compensation expenses | 77 | 144 |
| Interest and dividends income | (46) | (45) |
| Interest expenses | 27 | 21 |
| Foreign exchange losses (gains) | 13 | (23) |
| Decrease (increase) in notes and accounts receivable-trade | (1,668) | (1,732) |
| Decrease (increase) in accounts receivable-other | 290 | 93 |
| Decrease (increase) in inventories | (1,314) | (157) |
| Increase (decrease) in accounts payable-trade | (114) | 0 |
| Increase (decrease) in accounts payable-other | (14) | 57 |
| Increase (decrease) in accrued consumption taxes | 258 | 138 |
| Increase (decrease) in advanced received | 83 | (83) |
| Other, net | 288 | 364 |
| Subtotal | 3,246 | 5,150 |
| Interest and dividends income received | 48 | 49 |
| Interest expenses paid | (27) | (21) |
| Income taxes (paid) refund | (133) | (1,272) |
| Net cash provided by (used in) operating activities | 3,133 | 3,905 |
| **Net cash provided by (used in) investing activities** | | |
| Expenditures on time deposits | — | (100) |
| Purchase of securities | (611) | — |
| Proceeds from sales and redemption of securities | 300 | 1,257 |
| Purchase of property, plant and equipment | (922) | (895) |
| Purchase of investment securities | (494) | (0) |
| Proceeds from sales and redemption of investment securities | 150 | — |
| Other, net | (10) | (20) |
| Net cash provided by (used in) investing activities | (1,587) | 240 |
| **Net cash provided by (used in) financing activities** | | |
| Increase (decrease) in short-term loans payable | 1,220 | 300 |
| Proceeds from long-term loans payable | 200 | 200 |
| Repayment of long-term loans payable | (233) | (413) |
| Proceeds from payment from non-controlling interests | 184 | — |
| Repayments of lease obligations | (212) | (196) |
| Net decrease (increase) in treasury stock | (2,585) | 26 |
| Cash dividends paid | (748) | (834) |
| Net cash provided by (used in) financing activities | (2,175) | (917) |
| Effect of exchange rate change on cash and cash equivalents | 14 | 12 |
| Net increase (decrease) in cash and cash equivalents | (614) | 3,241 |
| Cash and cash equivalents at beginning of period | 5,464 | 4,850 |
| Cash and cash equivalents at end of period | 4,850 | 8,091 |

# Corporate Information

As of March 31, 2019

## 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**
632 (Consolidated) 613 (Non-Consolidated)

## Subsidiaries

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

*In liquidation.

## Stock Information

**Listed on**
Tokyo Stock Exchange First Section

**Securities Code**
4552

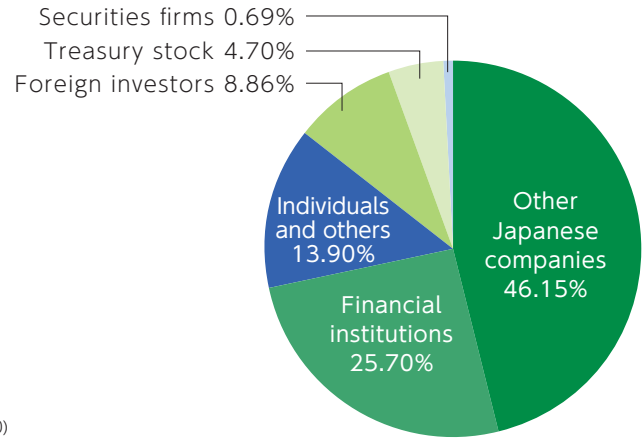
**Total Number of Outstanding Shares**
32,421,577

**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**
3,815

**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 |
| Japan Trustee Services Bank, Ltd. (Trust Account) | 2,108 |
| The Master Trust Bank of Japan, Ltd. (Trust Account) | 1,858 |
| The Nomura Trust and Banking Co., Ltd. (Trust A Account) | 1,634 |
| Sumitomo Dainippon Pharma Co., Ltd. | 850 |
| Mochida Pharmaceutical Co., Ltd. | 550 |
| Trust & Custody Services Bank, Ltd. (Securities Investment Trust Account) | 283 |
| Employee Shareholding Association of JCR Pharmaceuticals Co., Ltd. | 276 |

* The Company holds 1,525,779 shares of treasury stock, which is 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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