JCR Pharmaceuticals

# Annual Report 2018

## "HIYAKU"

Leap into the Future

飛 躍

JCR Pharmaceuticals Co.,Ltd.

Year Ended March 31, 2018

# A company which “takes one

Engaging in rare and intractable diseases, including inborn metabolic disorders, with our advanced biotechnologies and further developing and creating regenerative medical products are important missions of JCR Pharmaceuticals Co., Ltd. (JCR). Since our inception, we have held the spirit of challenge under a corporate culture with a high degree of freedom and that has made us what we are today. Every employee continues to display the spirit of “Hayosei (Pronto)!,” time-consciously taking on challenges one step ahead of our competitors in a unified manner as “Team JCR.”

## *Rare Diseases*

## *Biotechnologies*

## *Cell Therapy & Regenerative Medicine Technologies*

# step beyond” at all times

# Since our foundation, we have realized sustainable growth by nurturing JCR's unique strengths as a company that "takes one step beyond."

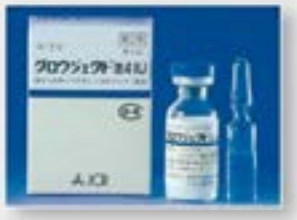
Since its inception in 1975, JCR has been working on proprietary technology development and creation of products in a manner keeping one step ahead of competitors at all times. This has led to a steady growth and recognition as "JCR, the biopharma," and the successful listing on the First Section of 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

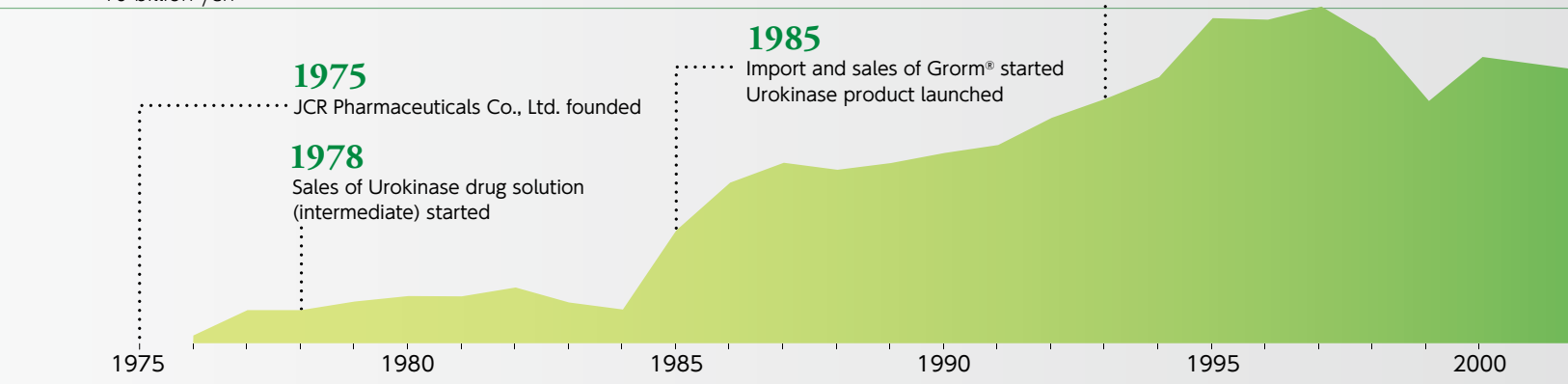
**1985**
Import and sales of Grorm® started
Urokinase product launched

**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




## 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 the "Urokinase," a urine-derived protein-degrading enzyme. In 1983, we obtained an approval for production of Urokinase product and drug solution, which brought us into the limelight.
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 and technologies for cell therapy and regenerative medicine.


Production at the time of foundation


Production today

**Technologies for Cell Therapy and Regenerative Medicine**

**Technologies for Developing Recombinant DNA Product**

- High-level Protein Purification Technology (Urokinase)
- Recombinant DNA Technology (Epoetin Alfa BS Inj. JCR)

# History

**2018**
**Established JCR USA, Inc.**

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

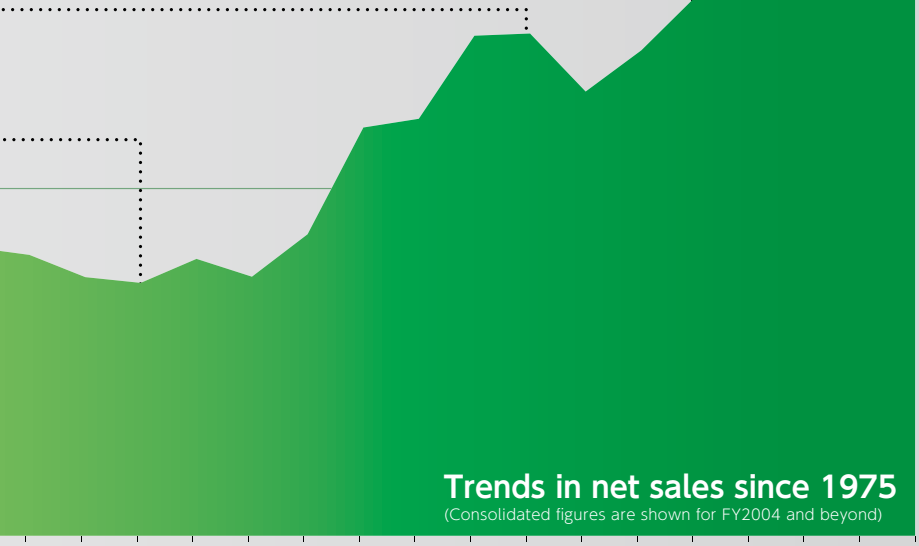
Concluded a business capital alliance agreement with MEDIPAL HOLDINGS CORPORATION

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

FY2017 20.6 billion yen

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

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




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

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

**Challenge to New Technologies**
- Gene Therapy
- iPS Cells

**Tissue Targeting Technologies**
- Blood-Brain Barrier Penetration Technology, J-Brain Cargo®

- Cell Therapy and Regenerative Medicine Technology (TEMCELL® HS Inj.)
- 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**

# JCR is striving to maximize its strengths by encouraging every employee to demonstrate a venture spirit under a free-spirited corporate culture.

R&D expenditure ratio to sales **20.5%**

Number of drugs under development **11**

## 1 Proprietary Biotechnologies

– at the forefront of innovation

Biopharmaceuticals have an extremely complex physical structure compared with conventional small molecule pharmaceuticals, and require highly advanced technologies. Leveraging the proprietary biotechnologies it has developed since its founding in 1975, JCR will accelerate the evolution of biopharmaceuticals.

## 2 Cell Therapy and Regenerative Medicine Technologies

– achievement of our challenges

For a long time, JCR has accumulated expertise in cell therapy and regenerative medicine technology, and has successfully developed and launched TEMCELL® HS Inj., the first allogeneic regenerative medical product in Japan. At present, JCR continues to ambitiously push ahead with research and development focused on new regenerative medical products to follow the aforementioned product.

## 3 Development Capabilities

– full-fledged from research to commercialization

JCR focuses on rare diseases, intractable diseases, and the pediatrics and neonatology fields. JCR is pursuing activities under an integrated system ranging from basic studies to create innovative technologies and pharmaceutical seeds, to the development of production technology for biopharmaceuticals with various properties.

Related page
P.22 Special Topic: Seeking to Improve the Central Nervous System Manifestations of Lysosomal Storage Diseases
P.26 Research and Development

Number of production sites **4**

Number of Medical Representatives **Approx. 80**

## 4 Production System

### – adapted to global standards

JCR delivers high-quality pharmaceuticals from its four domestic production sites equipped with cutting-edge facilities. In 2013, JCR established a manufacturing/quality assurance system meeting global standards in anticipation of future global business expansion.

Related page
P.32 Production System

## 5 Business Structure

### – focused on target domains

JCR's marketing organization consists of approximately 80 medical representatives deployed at eight business bases across Japan. Through marketing activities focused on target domains, JCR continues to provide and collect information to support good relationships between patients and medical professionals.

Related page
P.34 Marketing Strategies

# Strengths

## 6 Management Structure

### – capable of speedy decision making

JCR is working to continuously strengthen corporate governance by enhancing the legal compliance, transparency and objectivity of management. By doing so, JCR seeks to supply high-quality and even more effective pharmaceuticals and medical devices to society, thereby further enhancing its corporate value.

Related page
P.44 Corporate Governance

## 7 Proactive Team of Multi-Talented Human Resources

JCR is focused on developing human resources who will support its sustainable growth. Guided by the management team's aspirations to value each and every employee, JCR is working to improve its workplace environment in order to allow employees to fully demonstrate their capabilities and adopt a diverse range of work styles.

Related page
P.38 CSR Activities

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

## Business Process

### Research and Development

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

### Production

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

### 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.

## Core Products

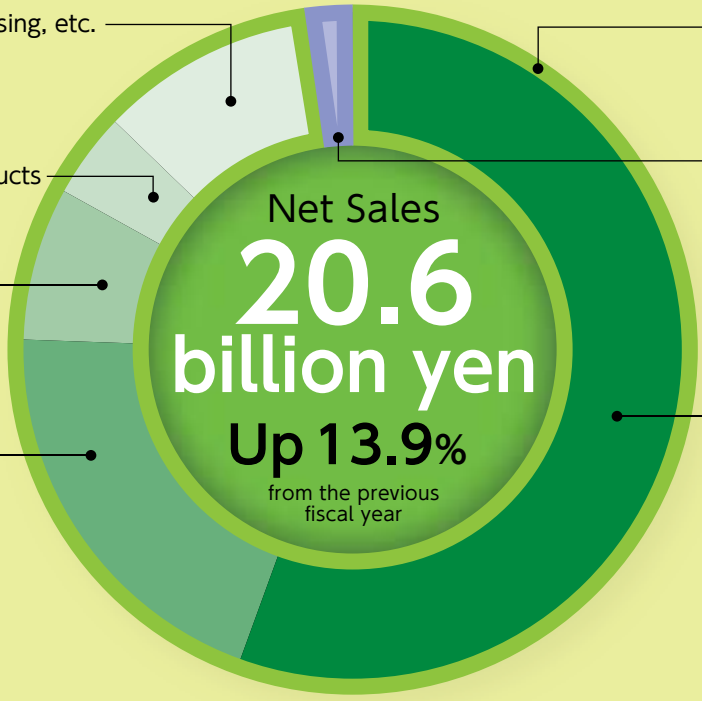
Recombinant human growth hormone product

GROWJECT®

GROWJECT® was approved for production and marketing in 1993 for the treatment of short stature primarily caused by growth hormone deficiency in children. We offer an array of injectors to satisfy patients' needs. Furthermore, the liquid formulation of GROWJECT® along with its dedicated electrically-controlled injector was launched in January 2017.

# At a Glance

## Net Sales in FY2017




Revenue from licensing, etc.
**2.2 billion yen**

Urine-derived products
**0.8 billion yen**

TEMCELL® HS Inj.
**1.5 billion yen**

Epoetin Alfa
BS Inj. JCR
**4.1 billion yen**

GROWJECT®
**11.5 billion yen**

**Net sales constituent ratio**

Pharmaceuticals
**98.0%**

Medical devices
and laboratory equipment
**2.0%**

Related page
P.14 Top Message
P.48 Financial Highlights

Recombinant erythropoietin product

### Epoetin Alfa BS Inj. JCR

Epoetin Alfa BS Inj. JCR is for the treatment of anemia, a common indication in dialysis patients. It was launched in May 2010 as the first made-in-Japan biosimilar.

Mesenchymal stem cell-based product
for acute graft-versus-host disease

### TEMCELL® HS Inj.

TEMCELL® HS Inj., launched in 2016, is the world's first human mesenchymal stem cell-based product for the treatment of acute graft-versus-host disease.*

* A severe complication following hematopoietic stem cell transplant

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

JCR formulated the "Mid-Term Management Plan for FY2015 to FY2019" with "HIYAKU (leap into the future)" towards a new stage as the key concept in June 2015. We are advancing a variety of measures, aiming to become a "research-oriented specialty pharma with global exposure" leveraging our strengths cultivated since the inception as drivers of HIYAKU.

Related page
P.14 Top Message

[What JCR Is Today]

## R&D oriented pharmaceutical company with leading technologies

Proprietary biotechnologies and cell therapy and regenerative medicine technologies

[JCR's Strengths (Drivers to Achieve "HIYAKU")]

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**

[JCR's Vision]

## Research oriented specialty pharma with global exposure

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

# 飛躍 HIYAKU

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

2015 2016 2017 2018 2019

### 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"

### Numerical Goals

| | Achievements in FY2017 | Goals for FY2019 |
|---|---|---|
| Net sales | 20.6 billion yen | **25.0 billion yen** |
| Operating income | 3.8 billion yen | **5.0 billion yen** |

# Strategy

# 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.

# Contents



## Compilation Policy

In this "Annual Report 2018," we mainly focus on the business management and financial information and also provide non-financial information including CSR activities to readers to explain our business activities in a comprehensive manner.

- Period covered: FY2017 (From April 1, 2017 to March 31, 2018)
  * This report contains some contents of FY2018.
- Organizations covered: JCR Group (JCR Pharmaceuticals Co., Ltd. and other five 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.

## Details Concerning Financial Information

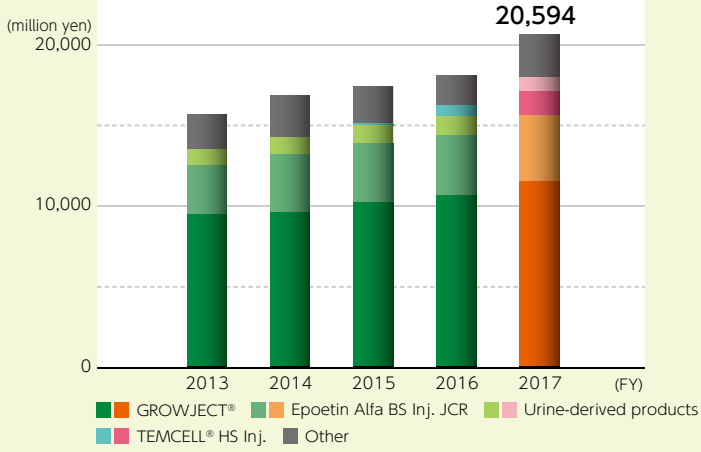
For details of financial information concerning FY2017, please refer to the "Financial Report."

http://www.jcrpharm.co.jp/en/site/en/ir/financial.html

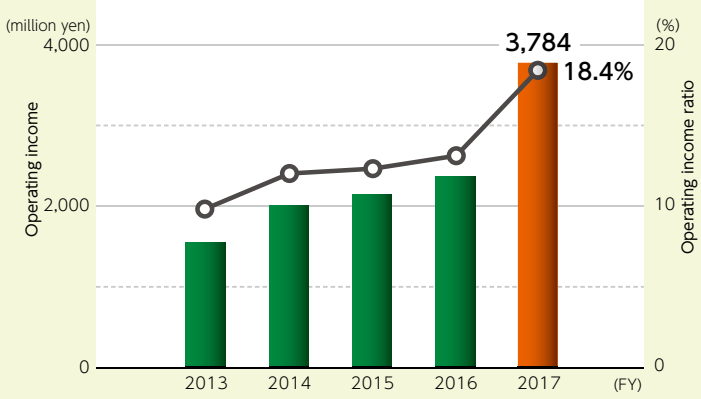
# Consolidated Financial and Non-Financial Highlights

JCR Pharmaceuticals Co., Ltd. and Subsidiaries

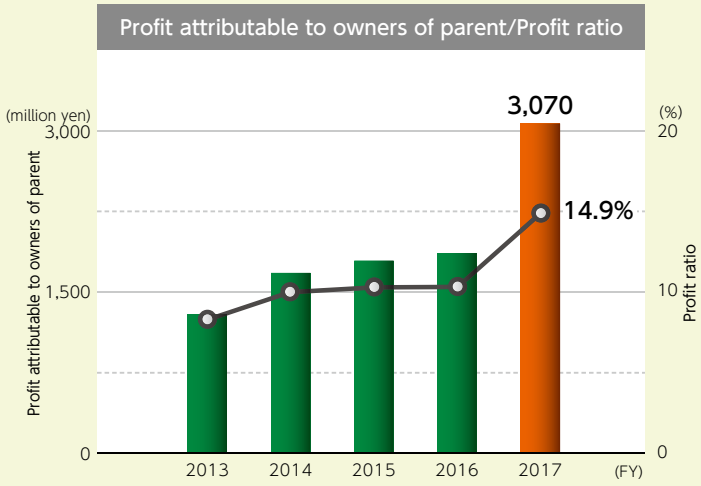
## Net sales by product



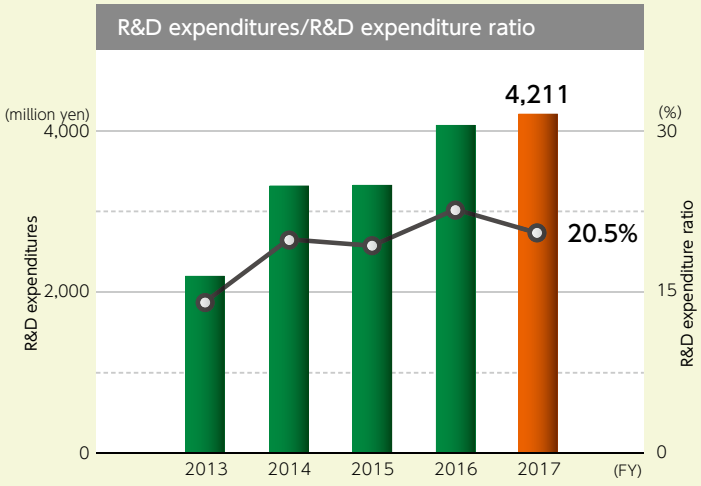

## Operating income/Operating income ratio



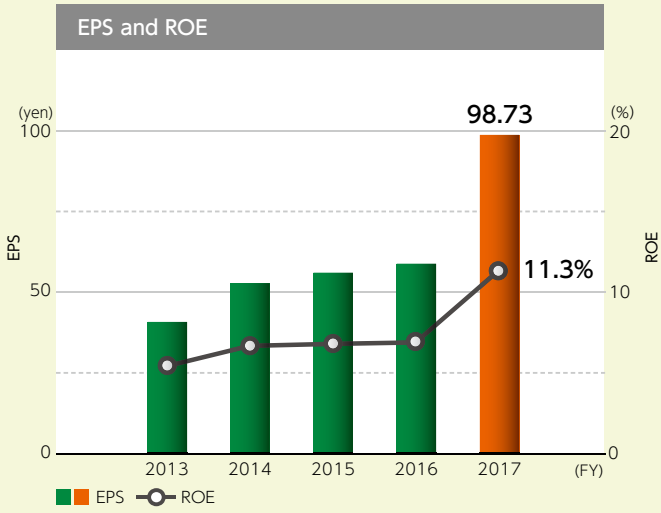

## Profit attributable to owners of parent/Profit ratio



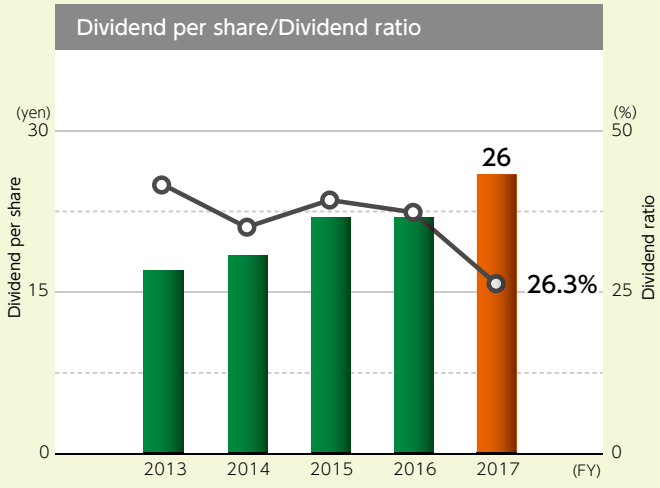

## R&D expenditures/R&D expenditure ratio




## EPS and ROE




## Dividend per share/Dividend ratio




Related page
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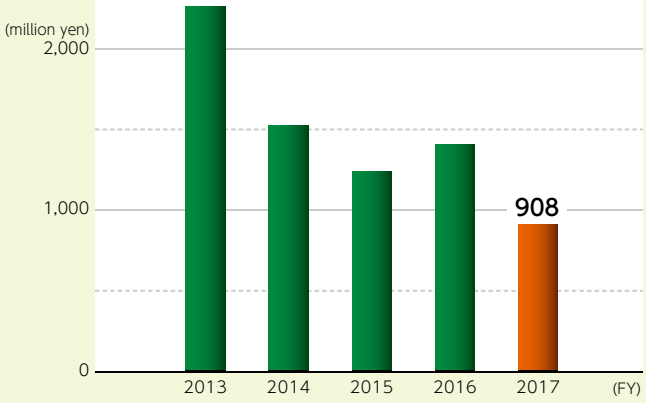
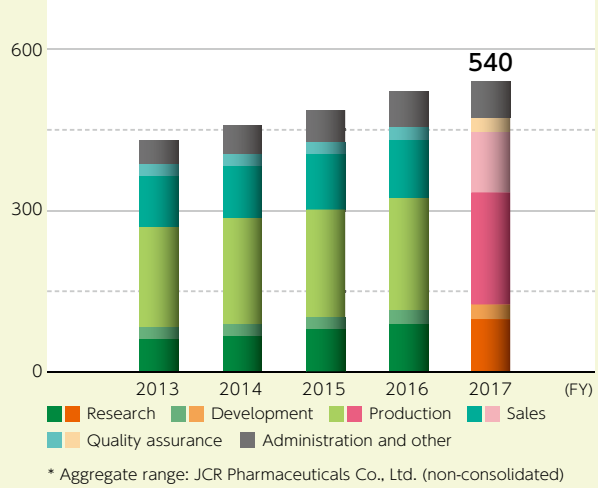
## Capital investment

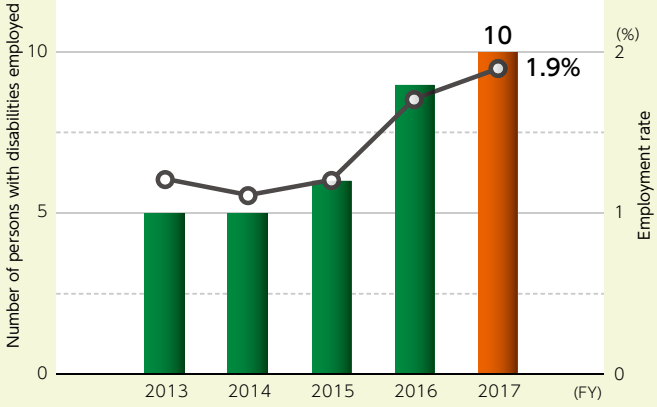



## Number of employees by occupation



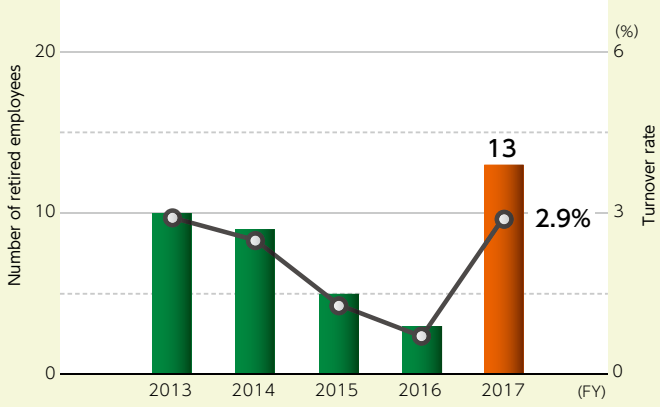

* Aggregate range: JCR Pharmaceuticals Co., Ltd. (non-consolidated)

## Number of persons with disabilities employed/ Employment rate



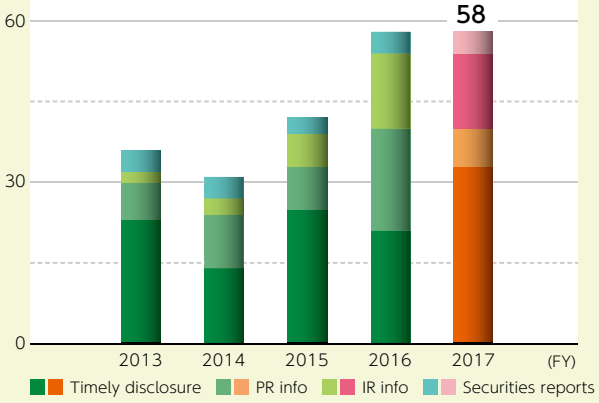

* Aggregate range: JCR Pharmaceuticals Co., Ltd. (non-consolidated)

## Number of retired employees/Turnover rate

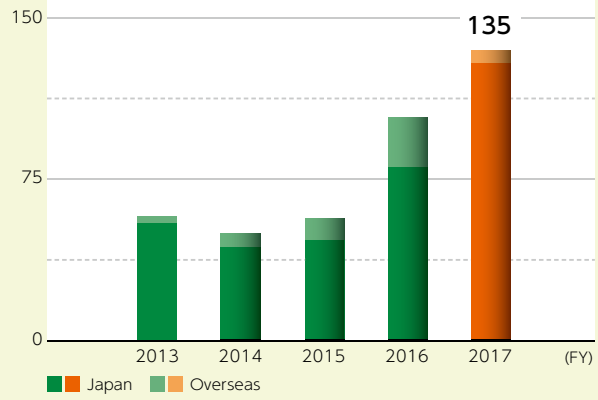



* Aggregate range: JCR Pharmaceuticals Co., Ltd. (non-consolidated)

## Number of press releases




## Number of meetings with investors



We have been accelerating our initiatives aimed at making "HIYAKU" (leap into the future) towards "Research oriented specialty pharma with global exposure."

Ever since the foundation of JCR, we have always maintained the spirit of venture and continuously taken on bold challenges. During the FY2017 the third year of the "Mid-Term Management Plan for FY2015 to FY2019," we more vigorously geared up our HIYAKU towards "Research oriented specialty pharma with global exposure," including by working to expand our development pipeline and by advancing the creation of a clinical development base in the U.S. Looking ahead, we will continue to leverage our proprietary biotechnologies and technologies for cell therapy and regenerative medicine to operate as a specialty pharma working to create ground breaking new therapeutics that respond to unmet medical needs, particularly in the rare diseases field. In doing so, we will realize sustainable growth.

August 2018

**Shin Ashida**

Representative Director, Chairman, President, CEO and COO

## Outline of business results in FY2017

### Sales of core products grew steadily and we achieved a record performance for the fourth consecutive year.

Net sales achieved in FY2017 were 20,594 million yen (up 13.9% from the previous fiscal year). The operating income was 3,784 million yen (up 60.2% from the previous fiscal year), and the profit attributable to owners of parent was 3,070 million yen (up 64.8% from the previous fiscal year). Having achieved new record high results for both sales and profits for four consecutive terms, we have significantly propelled the company forward to HIYAKU towards JCR's desirable status, "Research oriented specialty pharma with global exposure."

This growth is attributed to our growth driver, which is the existence of our core products. The sales of GROWJECT®, the recombinant human growth hormone, continuously increased to 11,495 million yen (up 7.6% from the previous fiscal year), partly due to the contribution of a new liquid formulation of GROWJECT® launched in January 2017. The 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.

| Outline of consolidated financial results in FY2017 | Compared to the previous fiscal year |
|---|---|
| Net sales<br>20,594 million yen | ↑ 13.9% |
| Operating income<br>3,784 million yen | ↑ 60.2% |
| Profit attributable to owners of parent<br>3,070 million yen | ↑ 64.8% |

## Return to shareholders

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

JCR regards the distribution of our profits to our shareholders is an important management policy. In FY2017, since the both net sales and profits broke the record highs, we increased the term-end dividend by 2 yen per share from the most recent forecast and provided an annual dividend of 26 yen. As a result, the dividend payout ratio was 26.3%. As for the dividend for the FY2018, we plan to provide 26 yen, maintaining the same amount from the FY2017 to achieve successive and stable provision of the dividends to shareholders.

## Advancing our research and development

### We are accelerating research and development (R&D) using JCR's original technology while reinforcing our collaborative efforts with partners.

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

In September 2017, we applied for marketing approval of JR-051, a biosimilar of agalsidase beta, an enzyme replacement therapy for Fabry disease. JR-131, a biosimilar for the long-acting erythropoiesis-stimulating agent darbepoetin alfa, has made solid progress in Phase 3 clinical trials. We have also obtained good results in the clinical Phase 1/2 studies on the enzyme replacement therapy JR-141 for treating Hunter syndrome in patients where our proprietary blood-brain barrier technology J-Brain Cargo® has been applied. The Ministry of Health, Labour and Welfare announced the designation of JR-141 under the SAKIGAKE system in March 2018, and we plan to initiate a Phase 3 clinical trial in Japan in August 2018. As part of the global development program, a Phase 2 clinical study of JR-141 in Brazil also started in June 2018.

We aim to apply J-Brain Cargo® technology to create novel therapies for 15 types of lysosomal storage disease (LSD), all of which are rare conditions. Our current development pipeline contains enzyme replacement therapies JR-162 for the treatment of Pompe disease and JR-171 for the treatment of Hurler syndrome. Besides LSDs, we are looking to use this technology in a range of central nervous system (CNS) diseases. We concluded a licensing agreement with Sumitomo Dainippon Pharma Co., Ltd. in February 2018 relating to the development of therapeutic agents using J-Brain Cargo® technology from the joint research program that we have been conducting since 2015.

In the field of cell therapy and regenerative medicine, in July 2017 we announced that we had concluded a co-development and licensing agreement with Teijin Ltd. for JTR-161/JR-161, a regenerative medical product that uses dental pulp stem cells (DPCs) in the indication of acute cerebral infarction (stroke). We are preparing to initiate clinical trials by the end of March 2019.

In the growth hormone business, in July 2018 we started a Phase 3 clinical trial of JR-401X, targeting short stature patients with a SHOX (short stature homeobox containing gene) deficiency, as part of the expansion of the indication of GROWJECT®, a recombinant human growth hormone. We will continue our efforts in the development from the standpoint of patients and strive to improve the added value of the Company.

## Reinforcing our capabilities and management platform

### We are looking to grow corporate value from a long-term perspective through our business and capital alliance with MEDIPAL HOLDINGS CORPORATION.

In September 2017, we concluded an agreement for a business and capital alliance with MEDIPAL HOLDINGS CORPORATION (MEDIPAL HOLDINGS). Separately, MEDIPAL HOLDINGS agreed to acquire shares in JCR from GLAXO GROUP LIMITED, in the process becoming our largest shareholder.

Founded in 1898, MEDIPAL HOLDINGS' business tradition extends over more than a century. In April 2000, the distribution group gained scale in pursuit of growth through innovation via the merger of three pharmaceutical wholesalers. It operates in the fields of pharmaceuticals, health and beauty, with over 300 operating bases in Japan. It conducts business development in the three segments of prescription pharmaceuticals wholesaling; cosmetics, daily necessities and OTC pharmaceuticals wholesaling; and also animal


### US joint venture (JCR USA, Inc.)

JCR USA, Inc. is overseeing and managing the early-stage US clinical development of enzyme replacement therapies that we are developing currently for LSDs based on the application of J-Brain Cargo® technology, notably JR-141 for the treatment of Hunter syndrome (already in clinical development in Japan). We also plan to conduct global development for other products.

health products and food processing raw materials wholesaling.

Our collaboration with MEDIPAL HOLDINGS began in July 2011 with a joint development project. We built mutual trust over the years by signing multiple development investment agreements. These efforts have helped us accelerate our R&D activities. We jointly developed an ultra-low cold chain distribution system based on liquid nitrogen to support the introduction in February 2016 of TEMCELL® HS Inj., Japan's first allogeneic regenerative medical product. This product has made a substantial contribution to the lives of many patients.

We established the joint venture JCR USA, Inc. in January 2018 as a global development base. In June 2018, Mr. Toshihide Yoda, a Managing Director of MEDIPAL HOLDINGS, was appointed as an Outside Director of JCR. We will continue to target further growth in the corporate value of both companies from a long-term perspective by aiming to make effective use of our respective strengths for sustained business development.

## Promoting CSR activities

### We fulfill our social responsibility toward the achievement of sustainable growth.

JCR proactively promotes CSR activities under its corporate philosophy, "Contributing towards people's healthcare through pharmaceutical products" as a reliable pharmaceutical company which contributes to society. We do this through four frameworks: "work environment," "environment," "society," and "rare diseases," the pillars of our CSR activities.

In 2016, we began the "RARE DISEASE Project" as an internal cross-divisional educational initiative to deepen understanding of rare diseases based on the collection and dissemination of relevant information. This project involves collaborating with and assisting patient groups and various organizations that support patients with rare conditions. Going forward, in addition to R&D into drug treatments for rare diseases. JCR will continue to promote a range of initiatives to help provide support to such patients.

# Board of Directors and Corporate Officers

(As of July 1, 2018)

(Front row, from left) Shin Ashida, Hiroshi Yoshimoto (Back row, from left) Toru Ashida, Mamoru Morita, Yuji Sato, M.D., Ph.D.

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

Yuko Hayashi, Ph.D.

## 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
General Manager, 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)

### Yuji Sato, M.D., Ph.D.
Vice President
Head of Research and Development
(Executive Director, Development Division)

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 General Manager, Development Division (current post)
Head of Research and Development (Executive Director, Development Division) (current post)
Appointed Vice President (current post)

### Mamoru Morita
Director
Head of Sales Division and Administration Division

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

### Toru Ashida
Director
Head of Quality Assurance Division, Corporate Planning Division, Medical Affairs Department and Office of the President

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

## Outside Director

### 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
2009 Entered Barclays Capital Securities Japan Limited
Managing Director of the same
2010 Director, MEDIPAL HOLDING CORPORATION
2012 Director and Managing Director of the same (current post)
In charge of IR and General Manager of Business Development Department CMA® (current post)
2016 Director, SPLine Corporation (current post)
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

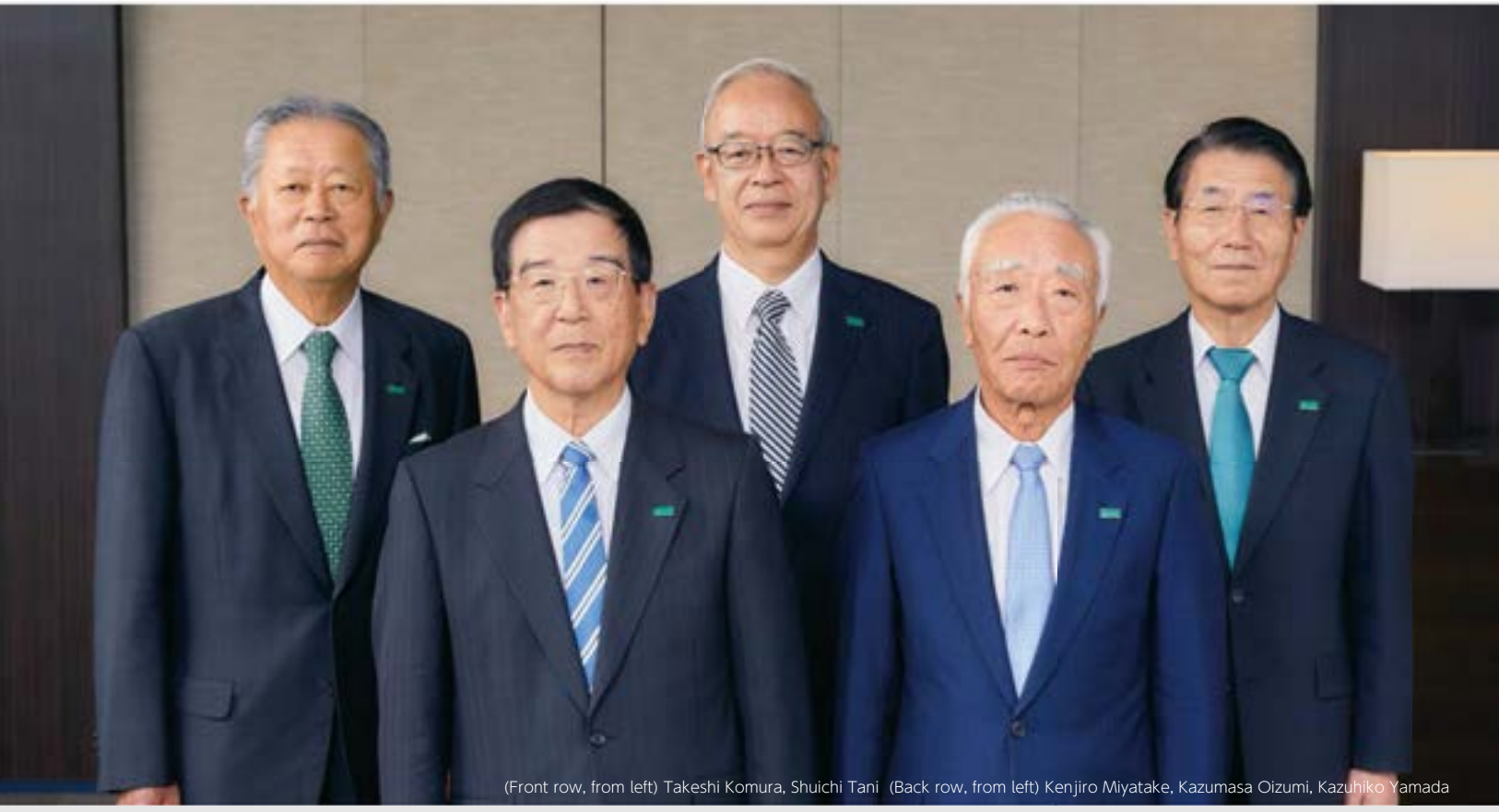
### Yoshihiko Ohnishi
Corporate Officer
Executive Director,
Sales Division

### 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

(As of July 1, 2018)



(Front row, from left) Takeshi Komura, Shuichi Tani (Back row, from left) Kenjiro Miyatake, Kazumasa Oizumi, Kazuhiko Yamada

# Message

## Takashi Suetsuna

Outside Director

In the past few years, the boards of directors and related bodies of publicly listed companies on the First Section of the Tokyo Stock Exchange have undergone a dramatic transformation in character. Notably, the adoption of Japan's Corporate Governance Code in 2015 has reshaped the workings of corporate management. Consequently, boards of directors have become much more transparent and have embraced a much stronger sense of urgency based on a greater awareness of stakeholders.

Two years ago, I joined the fast-growing research-oriented specialty pharma that is JCR as an Outside Director. In the past two years alone, JCR's management has boldly undertaken several proactive initiatives, including the development of new products leveraging proprietary technologies such as JR-141, the strengthening of the management platform through a business alliance with MEDIPAL HOLDINGS CORPORATION, overseas business expansion through the establishment of JCR USA, Inc. and related actions, and the promotion of globalization measures. As a result, JCR has achieved remarkable development and growth, and JCR's corporate value, as measured by its share price and market capitalization, has nearly doubled.

That said, I believe that JCR will enter its most crucial and challenging period in the next few years. Under the leadership of Mr. Ashida, the Chairman of JCR, the most urgent issues are to strengthen the business management system to enable faster decision-making by "Team JCR" as a whole, and to secure and nurture multi-talented human resources who will drive further growth in research and development in the years to come. I feel delighted and satisfied to be able to work together with the employees of JCR, a company filled with bright prospects for the future. I would like to continue striving together with JCR's employees to advance the company to a new stage of growth.

## Audit & Supervisory Board Members

### 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
2013 Appointed Audit & Supervisory Board Member, JCR Pharmaceuticals (current post)
2015 Chairman of the Board, Kobe Pharmaceutical University (current post)

### 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)

### 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, CREATE CORPORATION (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

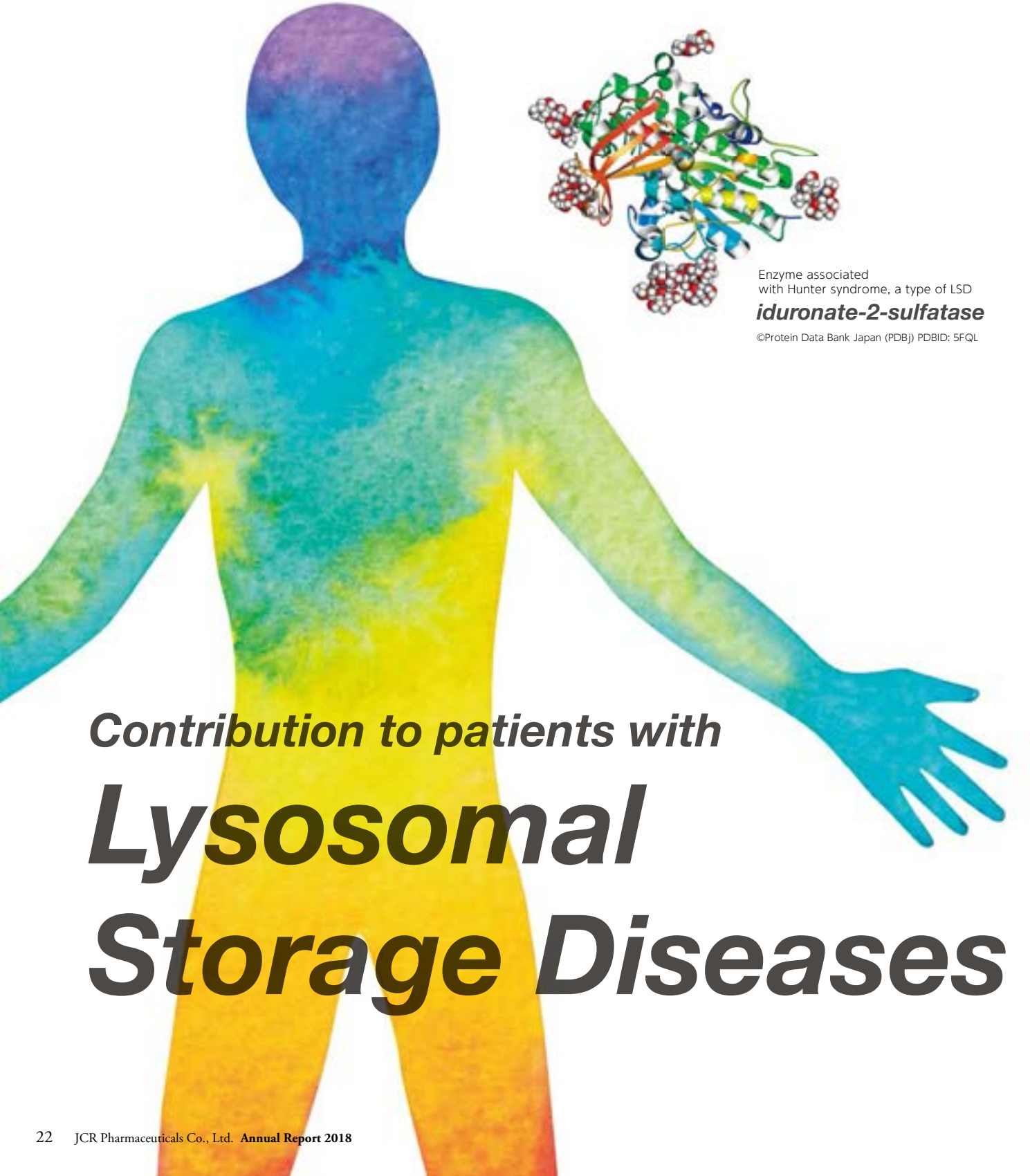
1964 Entered Ichihara Public Health Center, Chiba Prefecture
1969 Entered Ministry of Health and Welfare
1988 Director, Health Science Division, Minister's Secretariat, Ministry of Health and Welfare
1990 Minister's Secretariat Councilor (Science and Technology), Ministry of Health and Welfare
1992 Director-General 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)

## Toshihide Yoda
Outside Director

At MEDIPAL HOLDINGS CORPORATION, where I serve as a Director, I have the opportunity to receive opinions from many different angles from the Outside Directors during discussions in the Board of Directors. In particular, the Outside Directors sometimes point out risks in the new businesses that I am responsible for. On other occasions, they often provide advice on strengthening business models. Sometimes, resolutions are put on hold based on opinions received from the Outside Directors. From the perspective of ensuring a management structure that facilitates rapid decision-making, there will inevitably be situations when decision-making must be slowed down. However, I'm convinced that the process of incorporating the opinions of Outside Directors into management decisions leads to stronger corporate governance, and a wide range of opinions serves to strengthen business models.

Strong leadership by top management is undoubtedly essential to rapid decision-making. However, I believe that we can increase the potential of projects by embracing the diverse views of Outside Directors, and that this will ultimately lead to an increase in corporate value. In my view, the role of Outside Directors is not just to apply the brakes on projects, so to speak, but to judge how far to push down the accelerator. By keeping this in mind, I believe that Outside Directors can both enhance the quality of projects and facilitate rapid decision-making. As an Outside Director of JCR, I will constantly endeavor to increase its corporate value.

JCR is aiming to improve the central nervous system (CNS) symptoms of lysosomal storage diseases (LSDs) using the groundbreaking world-first drug delivery system J-Brain Cargo®, to address the challenges conventional therapies have been failing to solve.





Enzyme associated
with Hunter syndrome, a type of LSD
***iduronate-2-sulfatase***



## *Contribution to patients with*

# *Lysosomal Storage Diseases*

## Lysosomal Storage Diseases (LSDs)

**LSDs are a group of rare inherited disorders caused by the accumulation of metabolic wastes which fail to dissolve. It is designated by MHLW as an intractable disease as well as a specific pediatric chronic disease.**

LSDs belong to hereditary metabolic disorders, along with other disorders related to amino acid or organic acid metabolisms (Fig. 1). One of the many organelles within a cell, a lysosome is a small vesicle, bound to the cell membrane, containing large quantities of hydrolase enzymes in an acidic environment. A lack of, or a mutation in, a gene coding for a hydrolase enzyme or a related membrane transporter protein, results in an LSD. The substrates that cannot be dissolved accumulate in the lysosomes, damaging the cell and its surrounding tissues. Since specific enzymes have evolved to metabolize different sugars and fats, the precise form of the LSD and its symptoms vary depending on the affected enzymes and the accumulating substrates. Over 50 LSD types are classified according to the substrates, including lipidosis, mucopolysaccharidosis, and glycogen storage disease. Symptoms vary, including problems with the heart or kidneys, bone deformation, and respiratory disorders. Nearly all reported LSDs also involve CNS symptoms. Worldwide, there are some 10,000 LSD patients in total. In Japan, patient numbers per LSD vary from a few to several hundred.

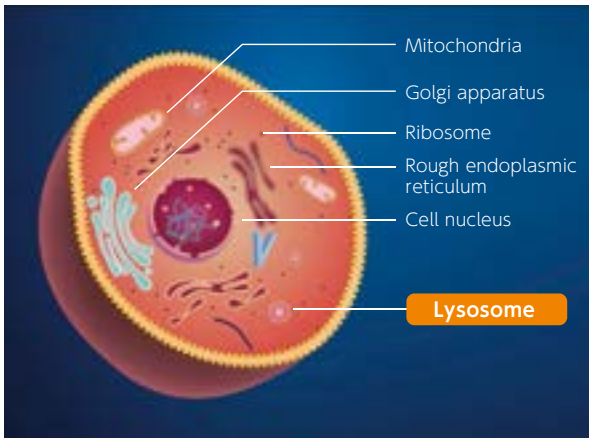
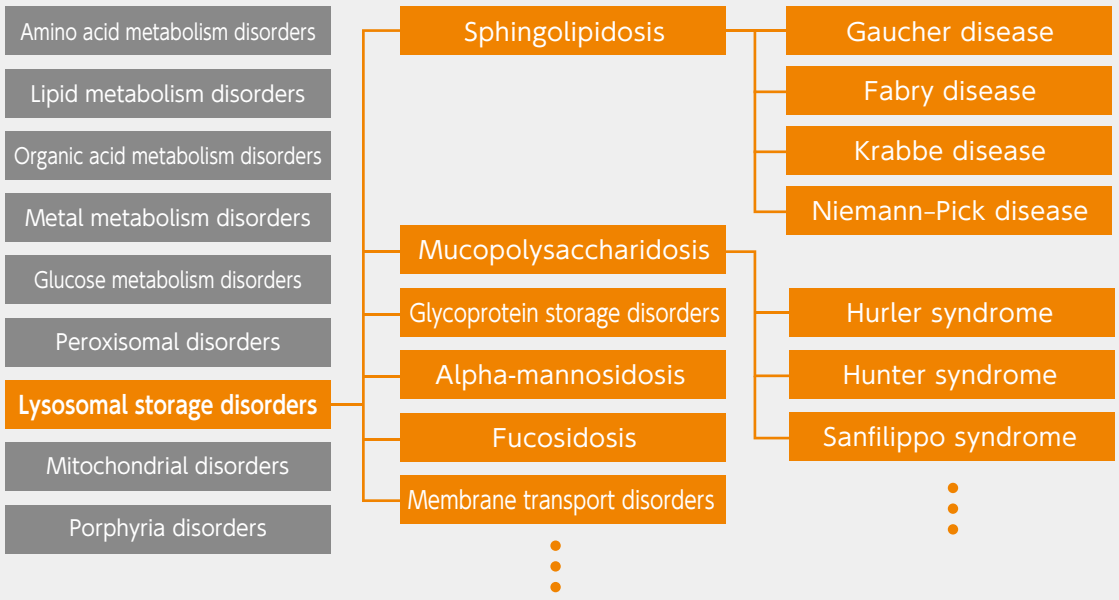



Fig. 1 Hereditary metabolic disorders



## Therapeutic Approaches to Lysosomal Storage Diseases (LSDs)

**Enzyme replacement therapy can supplement the enzymal shortages that cause an LSD, but there is still no effective therapy for the associated central nervous system (CNS) symptoms.**

### Enzyme Replacement Therapy (ERT)

This approach involves providing the patient with an external replacement of the relevant enzyme with a deficiency that causes an LSD. The recombinant form of the lysosomal enzyme is administered intravenously and taken up into cells through the mannose-6-phosphate (M6P) receptor before localization in the lysosome (Fig. 2). ERT is now a recognized approach for many LSDs, notably Gaucher disease, Fabry disease, Pompe disease, and mucopolysaccharidosis. It is the usual treatment option since the risks are low compared with bone marrow transplantation. However, ERT is ineffective in treating the CNS symptoms because the enzyme cannot cross the blood-brain barrier.

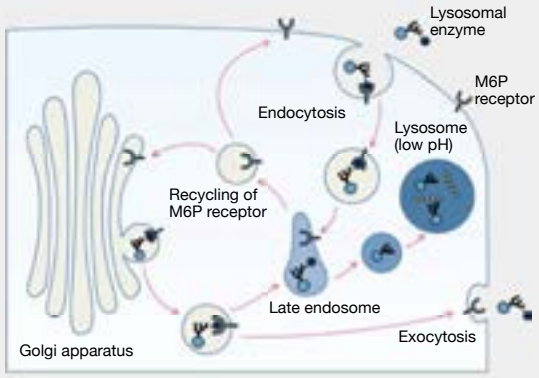
### Bone Marrow Transplantation

Bone marrow transplantation is mainly used in mucopolysaccharidosis, a disease for which it is as effective as ERT. Despite its advantage being that it needs only be performed once in a lifetime, there is a risk of graft failure or potentially life-threatening complications. In addition, the need to find an HLA-compatible donor limits it as a therapeutic option.

### Substrate Reduction Therapy (SRT)

This approach reduces the amount of substrate accumulation by inhibiting its synthetic pathway. SRT has been approved for Gaucher disease and Niemann–Pick disease Type C.

Fig. 2 Enzyme transport pathway




### Chemical Chaperone Therapy

Patients with certain mutations may have structurally unstable enzymes, resulting in their degradation prior to their transportation into the lysosome. In this approach, a small molecule is used to chaperone the unstable enzyme in the cell by structural stabilization, thus boosting the proportion of the enzyme transported into lysosomes to enhance substrate decomposition.

### Gene Therapy

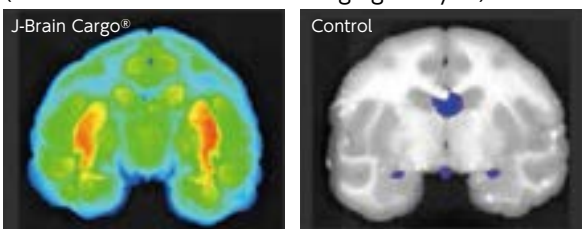
Currently, there are no established gene therapies for LSDs. Clinical trials have examined the use of adeno-associated virus (AAV) vectors for delivering DNA to brain cells in the patients with mucopolysaccharidosis, while gene therapy has also been studied in long-term lysosomal enzyme expression in the liver. In theory, gene therapy should have a long-term effect merely in a single treatment. It has attracted attention as a potential therapeutic option for LSDs, since in most cases the hereditary abnormalities involve a single genetic mutation.

## Potential of J-Brain Cargo® (Blood-Brain Barrier Penetration Technology)

**JCR is developing new therapeutic approaches based on its proprietary technology for delivering enzymes across the structural barrier protecting the brain.**

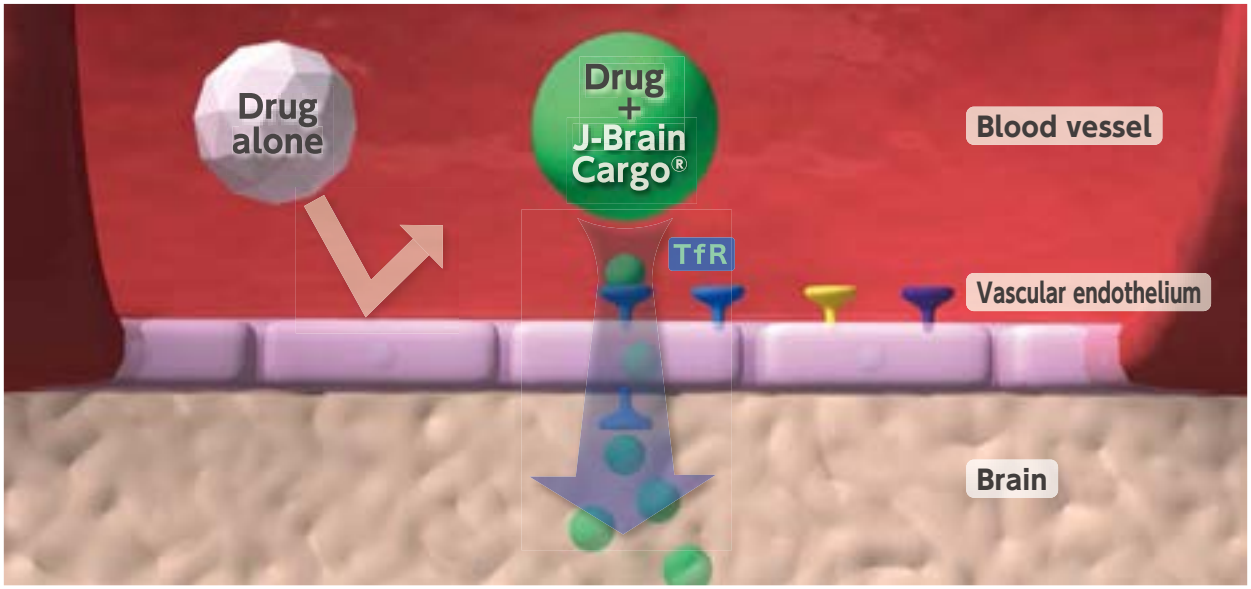
The brain has a highly complex structural barrier called the "blood-brain barrier" (BBB). This is formed by intercellular connections (tight junctions) that selectively limit the passage of substances from the blood into the brain. The BBB not only prevents the passage of harmful substances into the brain, but it also prevents therapeutic compounds, such as lysosomal enzymes, from crossing the BBB. For this reason, currently available ERT has no effect on the CNS. J-Brain Cargo® is our platform technology that enables the delivery of substances, administered intravenously, to cross the BBB through certain receptors expressed on the surface of capillary endothelial cells of the brain (Fig. 3). It is potentially applicable to a wide range of compounds, from small molecules to proteins such as enzymes or antibodies. By using JCR's BBB-penetrating technology J-Brain Cargo®, JCR aims to provide new therapeutic drugs to ameliorate CNS symptoms seen in the 15 types of LSD, all of which are rare diseases.

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




Images clearly show that J-Brain Cargo® delivers medicine into the brain in contrast to control.

Fig. 3 Mechanism for J-Brain Cargo®




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

Can be applied to a variety of substances, from small molecules to large ones including enzymes and antibodies

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

# R&D RESEARCH & DEVELOPMENT

## Swift and smooth global research and development of J-Brain Cargo®.

The researchers at JCR with innovative ideas have contributed to groundbreaking technologies including the proprietary blood-brain barrier penetration technology J-Brain Cargo®. In March 2018, JR-141, our therapeutic enzyme for Hunter syndrome to which J-Brain Cargo® has been applied, was designated by the Ministry of Health, Labour and Welfare as a first-in-class innovation in Japan, under the SAKIGAKE (medical pioneers) system. The Phase I/II clinical trial conducted in Japan has demonstrated its positive effects on the central nervous system (CNS) symptoms, leading to preparations for a Phase III clinical trial in Japan. A Phase II clinical trial of JR-141 in Brazil also started in June 2018 as a part of the global development program.

In the field of cell therapy, a new pillar for JCR's enterprise, we are making progress toward an expanded indication of epidermolysis bullosa for TEMCELL® HS Inj. Further potential indications in pediatric and neonatal patients are also under consideration.

### Research and Development (R&D) Organization

JCR is committed to developing new drugs based on its proprietary technology, focusing on the rare or intractable diseases as well as pediatric and neonatal conditions. As these drugs can contribute significantly to the society and the patients at large, we will continue to focus on lysosomal storage disease (LSD) enzymes, to which J-Brain Cargo® technology can be applied, as well as regenerative medical products by applying TEMCELL® HS Inj. and Human Dental Pulp Stem Cells (DPCs) technology. Following the positive results from the Phase I/II clinical trials with JR-141 that demonstrated the effects of J-Brain Cargo® in penetrating the blood-brain barrier, we are conducting research into recombinant enzyme delivery using J-Brain Cargo® technology to address CNS symptoms in 15 types of LSD. We are fortifying our R&D organization in order to implement global development of multiple compounds simultaneously.

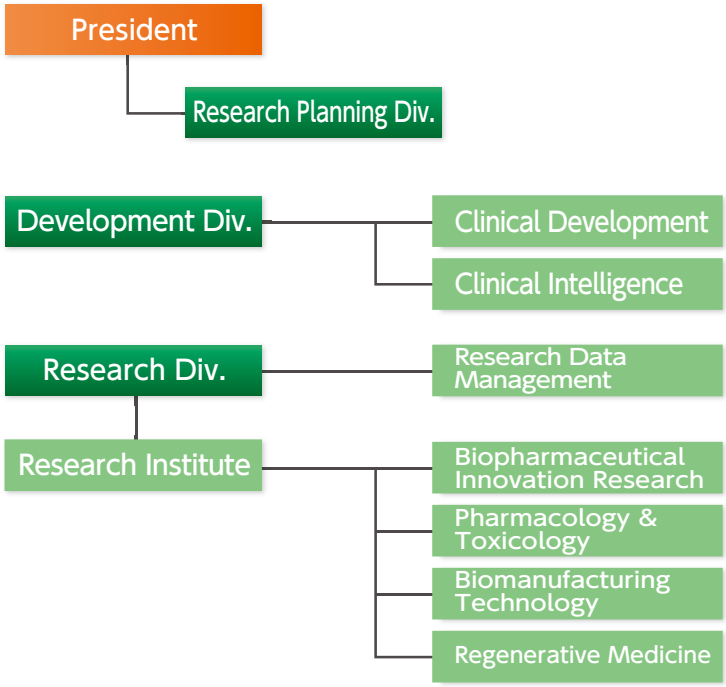
In April 2018, as part of reinforcing our R&D organization, the Research Planning Division has been newly separated from the Research Division to expedite decision-making and research conduct. Under the direct command of the President, the new division will guide our efforts to create new platform technologies to

Research Institute (Kobe, Hyogo)

maximize the potential of J-Brain Cargo®. We have also increased the headcount in the Bioprocess Development Group to facilitate the evaluation of manufacturing processes for multiple sets of drug production for clinical trials. Moreover, we have decided to construct the Second Clinical Trial Material Manufacturing Center to ensure prompt supply of test drugs.

The Development Division is recruiting qualified professionals for the global development of enzyme therapies for LSDs in Brazil and the United States. By delegating authority to improve efficiency and allowing individuals more accountability for their projects, we aim to achieve an organizational milieu that enables simultaneous development of multiple compounds.

By strengthening the R&D organization as listed above, we will be promoting steady yet swift global R&D, while ensuring the internal capabilities in the development of all necessary production technology from early-stage research to GMP-compliant pharmaceutical manufacturing.




# Message

One of my major responsibilities is the development of the cultivation processes for biopharmaceutical manufacturing. More specifically, we develop high-grade, high-yield cultivation processes that are scalable up to 2,000 L, while establishing the management criteria for all the process control parameters. At the moment, the Research Institute has multiple compounds in development, and we are all striving as "Team JCR" in order to achieve their early approvals. Given the time-consuming nature of the cultivation process, any mistake can affect the overall development schedule. Caution and speed are our watchwords; we check for possible mistakes mutually within the group. This is my second year at JCR. We are making steady progress toward submitting and gaining approval for our products, and I am motivated to contribute to that progress on a daily basis.

**Takuya Miura**
Biomanufacturing Technology, Research Division

## R&D Pipeline

We submitted in September 2017 for marketing approval of JR-051, a biosimilar of Fabrazyme (agalsidase beta), a therapeutic enzyme for Fabry disease. Regulatory approval is expected within 2018. This product is important as our first medicinal product for lysosomal storage disease (LSD), a new therapeutic area for JCR.

For our blood-brain barrier-penetrating therapeutic enzyme for Hunter syndrome JR-141, a clinical Phase I/II trial has been successfully completed, to be followed by a Phase III trial now in preparation. Within our global development program, working with JCR USA, Inc., our US-based subsidiary established in January 2018, we plan to discuss with the regulatory authorities in the United States and Europe based on the Japanese trial data and the coming results of a Phase II dose-finding trial that has started in Brazil in June 2018. Collaborations with patient advocacy groups and specialist physicians in Japan and abroad are essential in enabling the global development of this product amid high expectations. We are also preparing for global development programs (including Brazil) with our two other therapeutic enzymes utilizing the J-Brain Cargo® technology, namely JR-162 for Pompe disease and JR-171 for Hurler syndrome.

Another product to which our biopharmaceutical R&D technology has been applied is JR-131, a biosimilar for Nesp (darbepoetin alfa). Its development is progressing well, with a Phase III clinical trial demonstrating bioequivalence with the original drug. We expect to submit its approval application in Japan in September 2018.

In our core business, human growth hormones, we have started application of a long-acting protein technology to the development of JR-142, a long-acting recombinant human growth hormone product, since 2015. Its dose-finding relationships and other aspects have been examined to accelerate the initiation of

## Development pipeline and progress

(As of August 2018)

Lysosomal storage disease (LSD)
Other biopharmaceuticals
Regenerative medical product

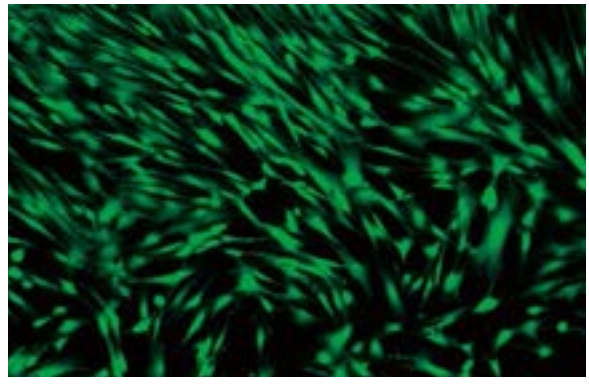
| Code | Nonproprietary Name | Indication | Region | Preclinical / Clinical trials / Filed / Approved | Remarks |
|---|---|---|---|---|---|
| **JR-051** | Alpha-galactosidase A (rDNA origin) | Fabry disease (LSD) | Japan | Filed | Enzyme Replacement Therapy (ERT) Biosimilar |
| **JR-141** | BBB-penetrating Iduronate-2-sulfatase (rDNA origin) | Hunter syndrome (LSD) | Japan | Phase III | ERT J-Brain Cargo®*1 |
| | | | Brazil | Phase II | |
| **JR-032** | Iduronate-2-sulfatase (rDNA origin) | Hunter syndrome (LSD) | Japan | Clinical trials in preparation | ERT Biosimilar |
| **JR-101** | Glucocerebrosidase (rDNA origin) | Gaucher disease (LSD) | Japan | Clinical trials in preparation | ERT J-GlycoM®*2 Biosimilar |
| **JR-162** | J-Brain Cargo® applied acid alpha-glucosidase (rDNA origin) | Pompe disease (LSD) | Japan | Preclinical | ERT J-Brain Cargo® J-MIG System® |
| **JR-171** | BBB-penetrating acid alpha-L Iduronidase (rDNA origin) | Hurler syndrome (LSD) | Japan | Preclinical | ERT J-Brain Cargo® |
| **JR-131** | Darbepoetin (rDNA origin) | Renal anemia | Japan | Filed in preparation | 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 | Preclinical | Long-acting human growth hormone product J-MIG System®*3 |
| **JTR-161/ JR-161** | Dental pulp stem cells | Acute cerebral infarction | Japan | Phase I/II in preparation | Co-developed with Teijin Ltd. Regenerative medical product |

*1 Blood-brain barrier penetration technology *2 Glycoengineering technology *3 CHO cell high-level expression technology

clinical development. We have also started a Phase III clinical trial with JR-401X to expand the indication for GROWJECT® as a treatment for short stature homeobox-containing gene (SHOX) deficiency.

Successfully developed and launched by JCR as the first allogeneic regenerative medical product in Japan, TEMCELL® HS Inj. is now being established as an important therapeutic for steroid-refractory acute graft-versus-host disease (GVHD). As a pioneer in cell therapy and regenerative medicine, we are advancing development in this field as an additional focus therapeutic area in addition to the recombinant DNA products. TEMCELL® HS Inj., the stem cells derived from bone marrow, demonstrates diverse pharmacological effects. We are exploring these characteristics to seek for new indications in the JCR's target therapeutic areas of rare diseases as well as pediatric and neonatal conditions. Following positive results from an investigator-initiated trial in epidermolysis bullosa, a rare but serious disease, we will prepare NDA submission to expand indication.

To succeed TEMCELL® HS Inj. in cell therapy and regenerative medicine, we are developing human dental pulp stem cells (DPCs) as a new product. An agreement for co-development and licensing has been announced in July 2017 with Teijin Ltd. for JTR-161/JR-161, a regenerative medical product for an indication of acute cerebral infarction (stroke). We are preparing to initiate its clinical trial by the end of March 2019.



Human dental pulp stem cells (DPCs)

JCR × TEIJIN

## Application of Our Core Technologies to Various Therapeutic Fields

### Recombinant DNA Products

#### Human Growth Hormone Business

GROWJECT®

**JR-142**
Long-acting human growth hormone product

#### ESA*4 Business

Epoetin Alfa BS Inj. JCR

**JR-131**
Darbepoetin biosimilar

#### Rare Diseases

**JR-051** Fabry disease therapeutic product
**JR-141** Hunter syndrome therapeutic product
**JR-162** Pompe disease therapeutic product
**JR-171** Hurler syndrome therapeutic product
Other lysosomal storage disease therapeutic products (at research stage)

### Regenerative Medical Products

**TEMCELL® HS Inj.**
Epidermolysis bullosa*5
(expanded indication)

Dental Pulp Stem Cells
**JTR-161/JR-161**
Acute cerebral infarction

*4 ESA: Erythropoiesis-stimulating agent

*5 Investigator-initiated trial by Osaka University Hospital is ongoing

## Partnering

J-Brain Cargo® has potentials to generate new therapeutic products for not only LSDs but for a wide range of diseases. At present, we are promoting research collaborations with multiple partner companies including Sumitomo Dainippon Pharma Co., Ltd. and Eisai Co., Ltd. in the development of therapeutics for the treatment of CNS disorders. Furthermore, we are collaborating on the development of new types of J-Brain Cargo® using the macrocyclic peptides with PeptiDream Inc. In January 2018, a license agreement was signed between Sumitomo Dainippon Pharma Co., Ltd and JCR, so that the former can select several candidate compounds, with J-Brain Cargo® being applied thereto, for the two companies to share rights.

JCR will promote collaborations with partner companies in terms of both licensing for the development and sales of new LSD therapeutic enzymes including JR-141, and licensing for the platform technology of J-Brain Cargo®. This will help JCR further proceed its swift overseas expansion.

PeptiDream

Sumitomo Dainippon Pharma

NanoCarrier

Eisai

## JCR's Platform Technologies

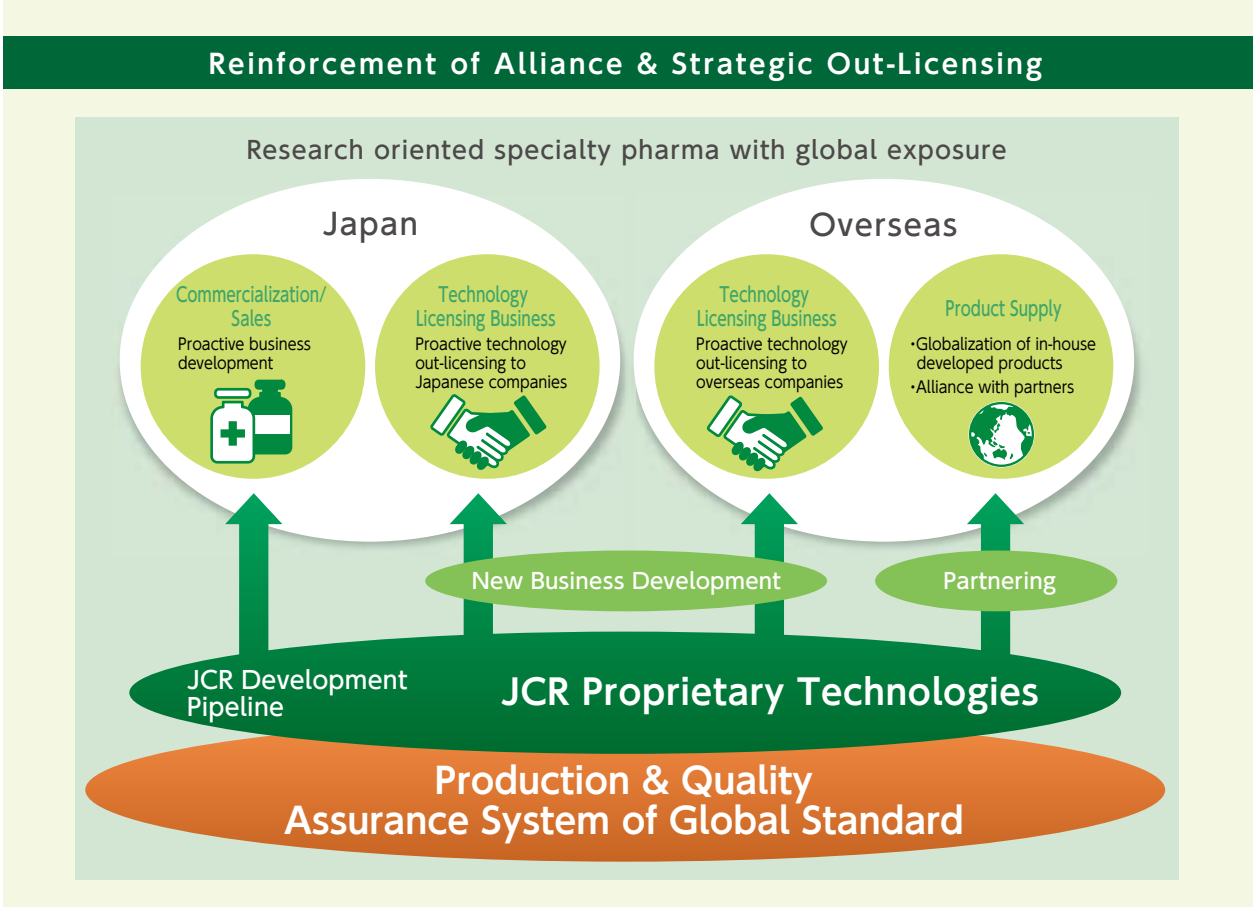
### J-Brain Cargo®

JCR's proprietary BBB penetration technology J-Brain Cargo® enables the delivery of intravenously administered drugs across the structural barrier protecting the brain. Please see page 25 for more details.

### J-mAb System®

In general, it is challenging to produce high-affinity antibodies to membrane proteins, especially polytopic proteins and subunit composition types. Many antibodies produced by conventional methods have issues, e.g. inability to fully recognize membrane proteins of native structure expressed on the cell membrane.

JCR has established J-mAb System®, which enables the production of antibodies with a significantly high affinity and specificity to the membrane protein antigens with weak immunogenicity. This is thanks to our J-MIG System®, a high-level protein expression technology, as well as to an optimized immune protocol and our proprietary high-throughput antibody screening technology. Anti-transferrin receptor antibodies used for J-Brain Cargo® were developed using this J-mAb System®.



## J-MIG System®

J-MIG System® is a technology enabling an efficient expression of recombinant DNA proteins by preferentially and intensively amplifying a target gene transfected into CHO cells. JCR established this high-level protein expression technology in the course of developing several recombinant pharmaceuticals using CHO cells as a host cell line. A novel expression vector system has been created by combining a target gene and GS gene in addition to a drug resistance gene with a modified internal ribosome entry site (modified-IRES), and is capable of high drug selection at a level that does not kill cells along with preferential amplification of the transfected GS gene.

We were awarded with the first prize for this technology at the IBC's 10th Annual Cell Line Development & Engineering event held in the United States in September 2014.

## J-GlycoM®/J-GlycoS®

Many secretory proteins are glycoproteins, constituent amino acids of which are bound to "sugar chains" that play an essential role in various functions in vivo. JCR developed J-GlycoM® and J-GlycoS®, as glycoengineering technologies to obtain targeted sugar chain structures.

J-GlycoM® is a technology to express the glycoproteins with high mannose-type sugar chains by transfecting into CHO cells the insect-origin chain trimming enzymes. This technology can target reticuloendothelial systems, such as macrophages, and lead to an application of J-GlycoM® for glucocerebrosidase, a therapeutic enzyme for Gaucher disease.

J-GlycoS® is a technology to enable an expression of highly sialylated glycoproteins in serum-free cultivation by adding, as medium components, multiple biological substances related to hexosamine biosynthesis and sialylation.

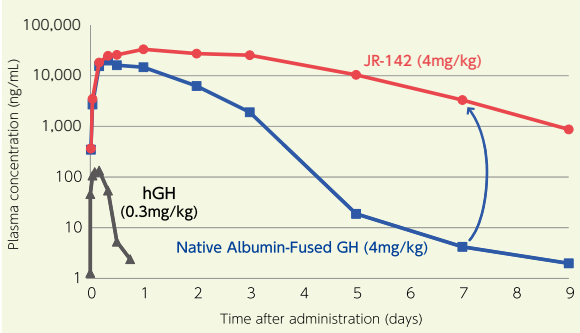
## Long-Acting Protein Technology with Modified Albumin

This technology improves the effect of biopharmaceuticals by extending their circulatory half-life. It utilizes neonatal Fc receptor (FcRn)-mediated recycling, a mechanism involved in the suppression of the degradation of immunoglobulin G (IgG), and fuses albumin to a target biopharmaceutical so that its circulatory half-life can be extended.

JCR has developed a special type of modified albumin and confirmed that a biopharmaceutical fused to this albumin showed a circulatory half-life significantly longer than the one fused to wild-type albumin. We applied this technology to growth hormones, our core product. The resultant growth hormone, JR-142, demonstrated a significantly longer circulatory half-life compared with the growth hormone fused to wild-type albumin. JR-142 at a low dose showed an effect comparable to the conventional growth hormone administered daily.

We will explore to maximize advantages of this technology by applying it both through the in-house pipeline products and out-licensing.

Long-Acting Human Growth Hormone Product (JR-142)
PK study in monkeys




# PRODUCTION SYSTEM

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

JCR handles a wide range of products including urine-derived drug substances, biopharmaceuticals, and regenerative medical products. 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. These sites carry 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 including Good Manufacturing Practice (GMP) and Good Gene, Cellular, and Tissue-based Products Manufacturing Practice (GCTP).

For drug substance manufacturing, we utilize cutting-edge technologies including single-use technology (use of disposable culture vessels or single-use bioreactors, etc.). Single-use technology eliminates significant amounts of cleaning between product change-over and enables the efficient production of many different small volume drug substances. Our unique production platform incorporates completely Serum-Free Cultivation Technology focused in the non-use of animal origin components.

The commercial production of TEMCELL® HS Inj., an allogeneic regenerative medical product, was launched in 2016, and conducted under newly enacted GCTP.

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, Ulinastatin and Leukoprol®, drug substances derived from urine, are manufactured by concentrating and purifying crude raw materials imported from our subsidiary in China. The purification technology cultivated in Seishin Plant is the foundation of JCR.

TEMCELL® HS Inj., a regenerative medical product, is manufactured by isolating and expanding human mesenchymal cells (MSCs) through strictly aseptic operations. Seishin Plant conducts testings and the packaging of medical devices, Twin-Jector® EZ II, a needle-free injector, for GROWJECT® and Babysense™, a respiratory monitor marketed by our subsidiary.

### Kobe Plant
**(finished products)**

Pharmaceuticals marketed by JCR (GROWJECT®, Epoetin Alfa BS Inj. JCR, etc.) are formulated, fill-finished and final packaged in Kobe Plant. Kobe Plant has two buildings on the same premise, where products in vials, lyophilized 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.

### 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 progressing steadily, we installed additional bioreactors in 2015 to scale up production for 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 plant equipped with a global standard manufacturing/quality assurance system and single-use equipment (single-use bioreactors). In this plant, we manufacture investigational products under development including JR-051 (a therapeutic enzyme product for Fabry disease), JR-131 (darbepoetin alfa), and JR-141 (blood-brain barrier penetrating therapeutic enzyme product for Hunter syndrome). The commercial production of these products in Kobe API Plant is planned in the future.

# Message

One of the special characteristics of our production of TEMCELL® HS Inj. is that almost every step of the manufacturing progress is carried out by hand. Because of this, we keep two points in mind as we go about our daily manufacturing operations:

1) Mutual understanding: Since upward of five people may be moving around the manufacturing room for certain processes, it is important to have good mutual understanding. To prevent errors due to manual work and improve operation efficiency, workers share their thinking and understanding with one another.

2) Process order: To minimize human error, it is important to observe the process order. We therefore always need to be conscious of working in the correct order and to think of systems to prevent errors. At the same time, we strive to increase productivity by eliminating unnecessary work.

In JCR's free corporate culture, everyone can speak their mind without restraint. All the employees provide opinions every day about how to increase the quality of our manufacturing.

**Erika Hosokawa**
Cellular Medicine Section, Seishin Plant, Production Division

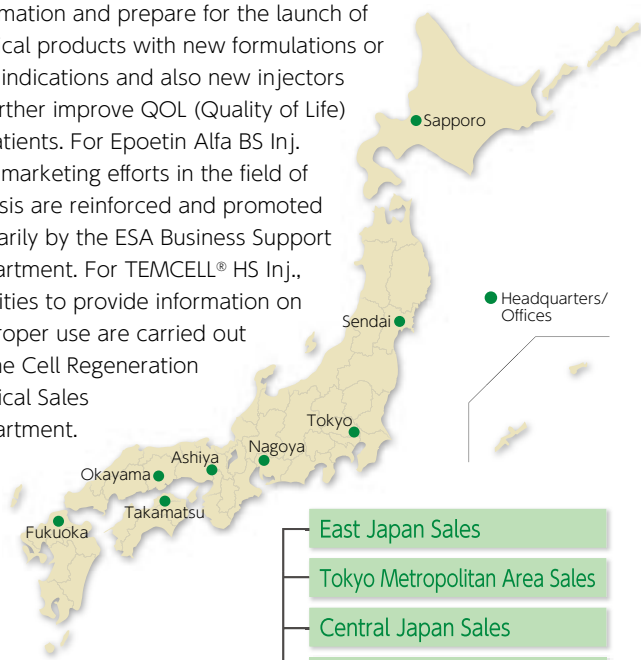
# MARKETING

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

We will further enhance our marketing system for the promotion of the proper use of medical products and the marketing of core products. We will also 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. The marketing of GROWJECT® is conducted by four 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. As a basis for the sustained growth of our company, we will enhance our activities to provide information and prepare for the launch of medical products with new formulations or new indications and also new injectors to further improve QOL (Quality of Life) of patients. For Epoetin Alfa BS Inj. JCR, marketing efforts in the field of dialysis are reinforced and promoted primarily by the ESA Business Support Department. For TEMCELL® HS Inj., activities to provide information on its proper use are carried out by the Cell Regeneration Medical Sales Department.




- Sales Div.
  - East Japan Sales
  - Tokyo Metropolitan Area Sales
  - Central Japan Sales
  - West Japan Sales
  - ESA Business Support
  - Cell Regeneration Medical Sales
  - Logistics Management
  - Sales Operations Administration
  - Marketing

## 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 an innovative 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 for the treatment of acute GVHD.

There are high expectations for TEMCELL® HS Inj. as a new therapeutic product for steroid-refractory acute GVHD. Supported in part by an increase in the number of medical institutions taking delivery of this product, sales of TEMCELL® HS Inj. in FY2017 were 1,544 million yen (up 124.3% from the previous fiscal year). 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.

Indication: • Acute graft-versus-host disease following hematopoietic stem cell transplantation

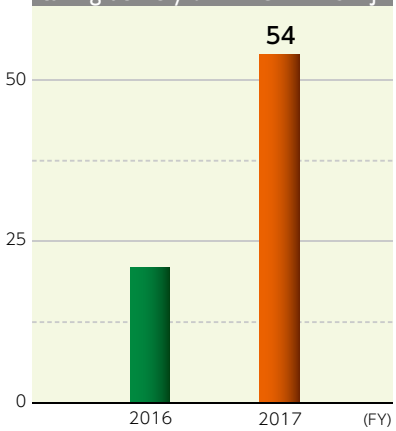
Sales in FY2017

**1,544 million yen**

Compared to the previous fiscal year

**↑ 124.3%**

Number of medical institutions taking delivery of TEMCELL® HS Inj.




# Message

JCR mainly focuses on the research and development of biopharmaceuticals, regenerative medical products, and pharmaceuticals for rare diseases such as inherited metabolic disorders. Notably, J-Brain Cargo®, a blood-brain barrier penetration technology, offers great promise as a new innovation in the field of central nervous system disorders.

As a JCR medical representative, I work on a daily basis to contribute to the wellbeing of as many patients as possible. During a discussion about GROWJECT®, one of our core products, a doctor once told me that "JCR's products have made it possible for my patient to continue treatment every day." In my daily duties, it is very encouraging to hear such positive comments from patients through healthcare professionals. As members of "Team JCR," we will work as one to contribute to the health of patients as much as possible.

Kenji Yamada
West Japan Sales, Sales Division

## GROWJECT®

Recombinant human growth hormone product

Sales in FY2017

**11,495 million yen**

Compared to the previous fiscal year

**↑ 7.6%**

GROWJECT® is one of our core products, approved for the manufacture and marketing in 1993. It improves symptoms such as short stature, caused by the deficiency of a growth hormone that regulates the body's growth and development. Since its launch, we have been stably providing high-quality products and continuing clinical studies to explore additional indications (e.g., Short Stature Homeobox-containing Gene (SHOX) deficiency) to maximize the value of the product.

Growth hormone is indicated for both pediatric and adult diseases, and require self-injection by patients at home on a daily basis. Most 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.

In January 2017, we launched the new liquid formulation of GROWJECT® along with the dedicated electronically-controlled injector, GROWJECTOR® L. GROWJECTOR® L offers enhanced usability by featuring a more compact design while maintaining the display size, as well as providing the highly rated functions of the previous model. It has thus evolved into an even more user-friendly injector. Moreover, JCR proactively supplies information on growth hormone therapy by, for example,

## Epoetin Alfa BS Inj. JCR

Recombinant erythropoietin product

Sales in FY2017

**4,115 million yen**

Compared to the previous fiscal year

**↑ 11.2%**

Epoetin Alfa BS Inj. JCR, a therapeutic product for renal anemia launched in May 2010, was developed utilizing our completely 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. In Japan, Epoetin Alfa BS Inj. JCR is co-promoted with Kissei Pharmaceutical.

Sales in FY2017 was 4,115 million yen (up 11.2% from the previous fiscal year) and its share of the market for short-acting erythropoietin in Japan has surpassed 60%. Sales have steadily increased and it is now one of our

regularly publishing "Child Nursing," a nursing support book on growth hormone therapy for healthcare professionals.

Sales in FY2017 increased to 11,495 million yen (up 7.6% from the previous fiscal year), and its market share hit another record high, following on from the previous fiscal year. We will constantly strive to add value to our product portfolio through such means as developing new patient-friendly injectors and supplying information on diseases, as we aim to further increase our market share by proactively performing strategic and systematic sales activities.

"Child Nursing," a nursing care support book on growth hormone therapy

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

core products thanks to the increasing awareness of the equivalence of this biosimilar to the originator drug in terms of efficacy and 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. We aim to file an application for marketing authorization in 2018.

Looking ahead, we will continue to carry out activities to provide high-quality pharmaceutical information based on the strong recognition our products have received in terms of their quality, thereby further increasing our market penetration.

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

# Close-up

## GROWJECTOR® L, an Electronically-Controlled Injector for the Liquid Formulation of GROWJECT®

GROWJECTOR® L is a new electronically-controlled growth hormone drug injector that was jointly developed by JCR and Panasonic Healthcare Co., Ltd. (currently 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 as an upgraded injector in addition to preserving the advantages of the previous models, including the automatic injection cycle of "inserting, injecting and retracting of the needle" and the ability to check the injection history. Injection with GROWJECTOR® L is an easy operation: users only need to load the drug cartridge, attach the injection needle, and press the injection button. This simple operation contributes to the improvement of patient compliance and QOL. In recognition of its outstanding user-friendliness and ease of operation, GROWJECTOR® L was awarded the Good Design Award 2017, following on from GROWJECTOR® 2, the second generation model.

GOOD DESIGN AWARD 2017

### About the Good Design Award

The Good Design Award is a comprehensive design evaluation and commendation system operated by the Japan Institute of Design Promotion (JDP). The Good Design Award seeks to enrich our lives, industry and society as a whole by selecting and commending "good designs" in various aspects of our lives.

# CSR

**JCR promotes Corporate Social Responsibility (CSR) activities under its corporate philosophy, "Contributing towards people's healthcare through pharmaceutical products." We aim to become a reliable pharmaceutical company contributing to the welfare of society.**

## Basic Approach to CSR

JCR works to promote a better work environment, fulfilling its responsibilities as a corporate citizen in the areas of the environment and society. At the same time, as a company that develops its business focusing on the field of biopharmaceuticals for rare diseases, our CSR activities also involve efforts to contribute to patients afflicted with those diseases.


## Work Environment

### Creating an ideal workplace environment

JCR believes it important to create a workplace environment where every employee is able to display their talent and actively engage in tasks with comfort. To achieve this, we will continue to promote creating such environments where it is possible for employees to balance the demands of work, child-rearing and nursing care, developing human resources for the company's sustainable growth, and also promoting the improvement of the company's compliance status while quickly responding to rapid changes in the social environment.

### Promoting Active Roles for Female Employees

Following the enforcement of the Act on Promotion of Women's Participation and Advancement in the Workplace, JCR established the action plans listed below. We will promote creating an ideal workplace environment for female employees by providing support for child-rearing. Along with further conducting proactive recruiting of women, we will increase professional ambition through education and training for candidates in managerial roles. We will also actively encourage women to assume roles in management.

Target 1: To increase the ratio of newly graduated female recruits to over 35%.

Target 2: To increase the ratio of female managers.

### Employment of Persons with Disabilities

We actively undertake initiatives to recruit persons with disabilities, and create work environments company-wide that are conducive to utilizing the individual talents of employees with disabilities as a part of Team JCR. In March 2017, we employed a visually impaired massager/practitioner in acupuncture and moxibustion (for blood circulation) and opened a massage room for our employees to prevent accumulating fatigue and enhance well-being.

### Introduction of New Performance Evaluation System

The most important constituents of "Team JCR" are people. Based on the idea of the management, "We value each employee," we introduced a human resource management system with compensation structure that is transparent and rational. Through measures like this, we are improving employees' motivation and our workplace environment to allow employees to fully demonstrate their capabilities.

### Introduction of an Indefinite Term Transfer System

In conjunction with revisions to the Labor Contract Act, JCR has introduced an indefinite term employment transfer system. Beginning in April 2018, we are proactively encouraging contract employees with more than five consecutive years of employment to switch to indefinite term employment to enable them to take an even more active role as members of "Team JCR." This will ensure we retain a stable pool of experienced, talented personnel and will lead to improved employee motivation.

### Reduction of Long Working Hours/Encouraging Paid Leave

Through company-wide activities led by our Safety and Health Committee, the company and employees work as one to maintain a safe workplace (such as introducing WEB cameras and a safety confirmation system), as well as the improving the work environment. To reduce long working hours, we hold a "no overtime day" once a week. In addition, our Safety and Health Committee keeps lists of employees who have worked longer than 30 hours of overtime a month to confirm their status and provide them with guidance to improve their situation. We also encourage our employees to take paid leave during major national holidays and extended leave to refresh themselves.

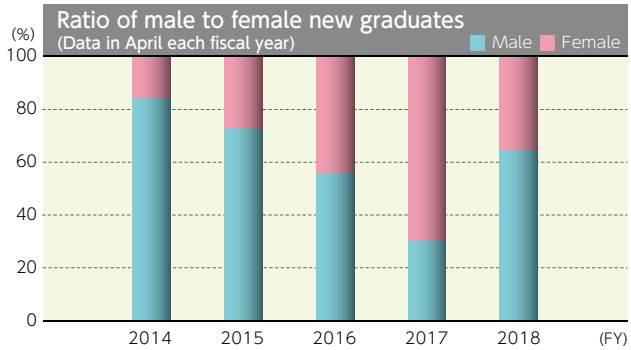
Employee training

### Introduction of Flextime System

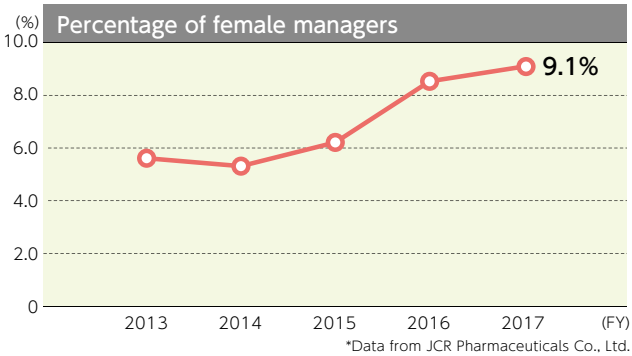
In April 2012, we introduced a flextime system that offers employees flexible work schedule under expectations that it will reduce the physical and mental burden on employees and accommodate employees' work and lifestyles.

### Establishment of In-House Training System

The spirit of undertaking new challenges is essential for all of our employees' growth, and for the sustainable development of JCR. To achieve this, we conduct employee training based on employees' management level and abilities. We focus our training programs not only on business skills directly related to employees' work, but also communication skills in order to create an open-minded organization that encourages employee growth and activity.




*Data from JCR Pharmaceuticals Co., Ltd.

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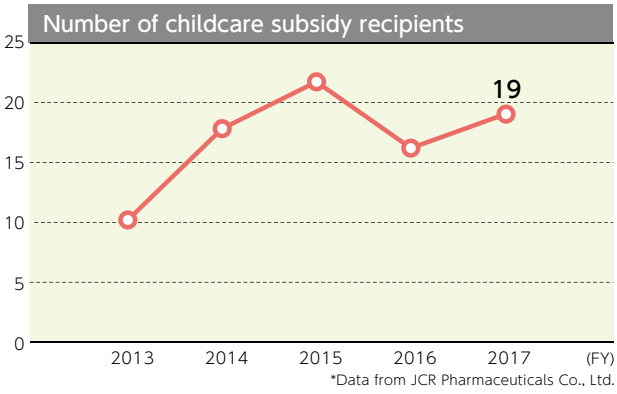


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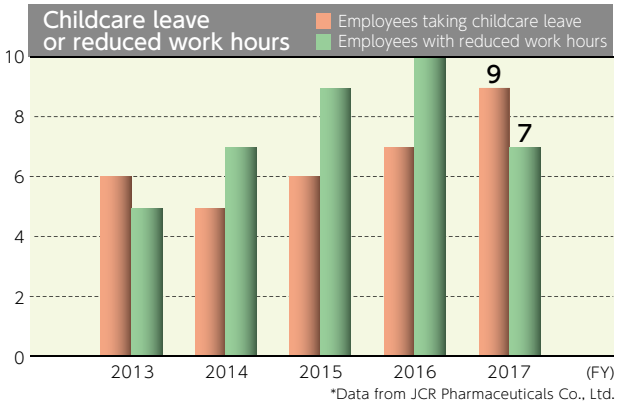



*Data from JCR Pharmaceuticals Co., Ltd.

### Child-Rearing Support

We are proactively engaged in improving our work environment so that our employees can fully demonstrate their abilities while maintaining a healthy balance between work, child-rearing, and nursing care. In addition to the revision of company rules to support parenting and nursing aged parents based on the law, we established a childcare subsidy in April 2011 and opened an in-house childcare center in November 2015.

"JCR Kids Land," in-house day-care center

### Employees' Healthcare and Improvement of Work Environment

To understand our employees' health status and eliminate health risk factors at our workplace, we provide periodical health checkup, stress check, and mental health care for our employees in addition to the assessment of their work environment.

For other non-financial information, please refer to the Work Environment page under the CSR Activities section of our website.
http://www.jcrpharm.co.jp/en/site/en/csr/index.html

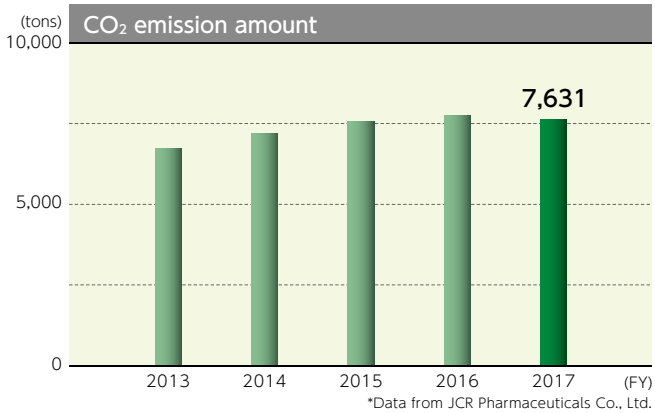
## Environment

### Company-Wide Activities

1. On a company-wide basis, we adhere to environmental laws and regulations through compliance training for the employees and other activities. We have been promoting activities to reduce $CO_2$ emissions to protect the environment and to save energy by installing LED lighting and heat storage units.
2. The Manufacturing Department makes concerted efforts to save water and energy resources such as electricity. One example is promoting the use of single-use bioreactors to avoid using a large quantity of washing water as otherwise required in conventional incubators. Efforts to reduce the consumption of resources and wastes are also made in production lines.
3. The Sales Division is switching to hybrid cars for commercial vehicles in efforts to reduce $CO_2$ emissions for a better global environment. A drive recorder is installed in each commercial vehicle to increase awareness towards eco-friendly and safe driving.

### Promotion of New Measures

As an added measure for reducing $CO_2$ emissions, we introduced electric vehicles in 2015 and installed power feed systems at our headquarters and at each place of business. The Sales Division will also sequentially switch over to electric vehicles as public charging stations become popular. In addition, in 2016 we installed a solar power generating system at our Research Institute (in Nishi-ku, Kobe) and keep up our efforts to maintain a sustainable society through reduction of $CO_2$ emissions. We continue to promote resource and energy saving, and recycling activities and contribute to environmental protection and the reduction of environmental burden for the society.




*Data from JCR Pharmaceuticals Co., Ltd.

# Society

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

JCR supports the "Award for Promotion of Maternal Child Health" (sponsored by the Mothers' and Children's Health and Welfare Association). This was established in 1979 in commemoration of the International Year of the Child. It aims for the further development of maternal and child health by encouraging the merits of individuals who have made great contributions to society and the field of community-based maternal and child health through their activities, the diffusion of and education on healthcare, practical education and guidance of healthcare, and the maintenance and expansion of healthcare facilities.

The judging committee selects and recognizes fifteen award winners every year among candidates working in the field of maternal and child health. These candidates include public health nurses, midwives, nurses, doctors, dentists, dieticians, dental hygienists, childcare workers and maternal and child health promoters who have received recommendation from the head of prefectures, cities designated by government ordinance, core cities and special wards. After the awards ceremony, the award winners are invited to the Crown Prince's Palace to meet His Imperial Highness the Crown Prince and receive words of encouragement. We will continue to contribute to the further development of maternal and child health by supporting the "Award for Promotion of Maternal and Child Health."

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

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

JCR continues to support the "Global Foundation for Life Sciences," a nonprofit foundation established in Switzerland in 1999. This foundation supports the advancement of life sciences, provides humanitarian assistance to various medically underprivileged countries and also provides support for the development of young researchers.

One example of the humanitarian assistance performed by this foundation is its support for the activities of the Swiss medical team of volunteers missioned to treat women suffering from obstetric fistula in West Africa every year. Obstetric fistula is a disorder that occurs as a result of obstructed labor, etc., and appropriate medical treatment is not given. A fistula forms because the pressure of the baby's head on the mother's pelvic bone for a sustained period of time causes necrosis of the tissue of the mother's bladder, vagina or rectum. There are around two million obstetric fistula patients around the world and every year 100,000 women are newly diagnosed with this condition.

The volunteer doctors regularly visit hospitals in Benin in West Africa and perform activities for the elimination of obstetric fistula, the surgical treatment of patients and technical guidance for local doctors. JCR contributes to people's health and the advancement of medical care through our support for this Foundation.

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

JCR supports "Momiji House," the first short-stay medical care facility built on the premises of the National Center for Child Health and Development (Setagaya-ku, Tokyo) as a public medical institution in April 2016. Momiji House provides 24-hour-a-day care for children who require medical care at home. Those with serious illness and disabilities 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.

## Support for the "2018 Job Yearbook"

JCR is a co-sponsor of the "2018 Job Yearbook," a career education tool published by the Asahi Shimbun Company. Aimed at elementary and middle schools, the Job Yearbook is designed to provide easy-to-understand, thoughtful answers from company representatives to a variety of simple questions children have about work, and copies have been donated to all public and private elementary and middle schools nationwide.

Content of the page introducing JCR included in the Job Yearbook can be seen in the Technology Land section ("Science and Technology Jobs that Create the Future") of the Oshigoto Museum Kids website (available in Japanese only).
https://www.oshihaku.jp/kids/

## Contribution to the Community

JCR provides support to its home prefecture, Hyogo, through co-sponsorship of events (such as Kobe Festival, Kobe Luminarie, and Relay for Life Japan in Ashiya) promoting the development of the region. Furthermore, we host site tours to local high school students as an activity to support the nurturing of the next generation. In addition to the site tour of JCR Research Institute, the students are introduced to JCR's business, receive lectures on innovative drug development, and participate in interactive discussion with our employees. We intend to actively receive students on these site tours going forward.

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

Action for RD Rare Disease

希少疾病に、
JCRのできること。

## 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 by further increasing our understanding of these diseases. We started this project with a sense of responsibility and pride as members of a company that is taking up the cause of fighting these diseases.

This is a cross-sectional internal awareness-raising project for all JCR employees to further increase their understanding of rare diseases, with “What JCR can do” as our motto. We collect information and share it internally to increase employees’ understanding of rare diseases. We also support and cooperate with self-help patient groups and support organizations that help people fight rare diseases.

At JCR, we promote awareness within the company by creating motivational posters with the handprints of all of our employees to express consideration for patients, issuing e-newsletters, performing fundraising activities and arranging lectures for our employees. For each lecture, we invite rare disease specialists and members of patient groups to talk about the mechanism of disease and experiences. 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.

# Message

The RARE DISEASE project is a cross-sectional internal awareness project that has been active since 2016. Today, a total of 13 members from various divisions within JCR are active as members of the project.

Our activities center on two areas: (1) Collection and internal dissemination of information intended to increase understanding of rare diseases and (2) Collaboration with and support for patient groups and rare disease support organizations. Specifically, our activities include participation and interaction with patient groups at seminars and distribution of reports on those activities within the company. We also hold in-house lectures and fundraising events, spread the word about Rare Disease Day events and participate in other nationwide events. Going forward, we are considering ways of expanding the range of our activities to include a point of contact for collaboration with patient groups, volunteering and other support activities, as well as awareness-building activities aimed at the general public through public lectures and other events.

**Takanori Nakajima** Manager, RARE DISEASE Project

RARE DISEASE Project team

Lecture

## Rare Disease Day

From FY2015, JCR is a supporter of "Rare Disease Day" (the world rare and intractable disease day). 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 quality of life through better diagnoses and treatments. It is hoped that these activities would create a bridge between the patients and the society and help increase awareness for rare and intractable diseases.


## Fundraising Activities

To commemorate the Rare Disease Day, JCR organizes an activity that encourages employees to wear a Rare Disease Day official badge and raise funds in the company in February every year. Funds raised are donated to organizations working for the provision of information to patients with rare diseases, cooperation with healthcare professionals, promotion of research to develop therapies, and awareness-raising in the society.

Donations from fundraising activities

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

As secretariat for the RARE DISEASE Project, my work primarily involves project-related general affairs and acting as a point of contact for those outside the company. I have been involved in rare and intractable disease educational activities since I first joined JCR, but the cross-sectional organizational structure of this team has made it easier for those activities to reach into our various divisions and departments. We were also able to participate in patient group seminars and Rare Disease Day events nationwide. We compiled a report bringing together all of the reports we had disseminated internally and distributed it to all employees, including those at our affiliates. This generated encouraging feedback that will be used in our planning and operations in the next fiscal year, including comments such as "I gained an understanding about patients in fields other than my own" and "My family read the report, which gave me an opportunity to talk about what JCR does and what my own work involves."

Working through a variety of plans going forward, we hope that our aspirations for addressing rare diseases spread, and that everyone on "Team JCR" takes part in doing "What JCR can do."

**Izumi Yamamoto** Manager, RARE DISEASE Project Secretariat

# CORPORATE GOVERNANCE

## 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, have established the Board of Directors consisting of nine Directors, including four Outside Directors, the Audit & Supervisory Board consisting of five Outside Audit & Supervisory Board Members, and Accounting Auditors.

In addition to these organs, we have established Management Control Committee, Advisory Committee for Nomination, Compensation, etc., Management Committee, Internal Audit Department, Internal Control Committee and Compliance Committee. Also, we have introduced the corporate officer system for business execution, promoting the separation of the management and business execution functions. As for the composition of corporate governance system, we believe it is at 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 securing the transparency, objectivity (impartiality) and independence of supervision over management.

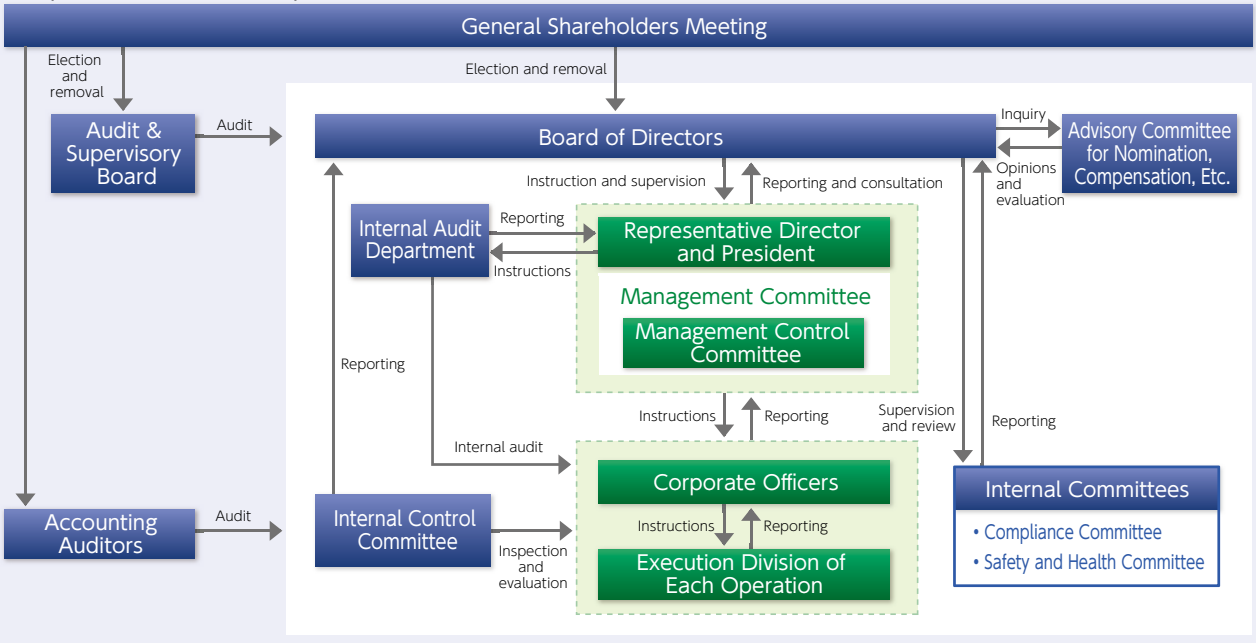
## Details of Organs of the Company

### 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

Corporate Governance System (As of June 27, 2018)



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 one Independent Outside Audit & Supervisory Board Member (full-time), and it deliberates 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 six 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. Five 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

Internal Audit Department directly under the control of Director and President performs audits on whether or not operations are executed by departments in line with laws and regulations as well as internal rules.

Internal Audit Department consists of four full-time employees, including one Director of Internal Audit Department, and the results of internal audits are submitted to Audit & Supervisory Board Members, in addition to 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, 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 FY2017

(As of end of FY2017)

| | | |
|---|---|---|
| Board of Directors | Composition | 8 members (5 Internal Directors, 3 Independent Outside Directors) |
| | Number of meetings held | 14 (including 2 extraordinary Board of Directors' meetings) |
| | Attendance rate | 96.09% (Absence: 2 Outside Directors, 5 times each) |
| Management Committee | Composition | 17 members (5 Internal Directors, 1 Independent Outside Director, 2 Independent Outside Audit & Supervisory Board Members, 8 Corporate Officers, 1 Adviser) |
| | Number of meetings held | 20 |
| | Attendance rate | 92.22 % (Absence: 1 Independent Outside Director, 13 times, and 1 Adviser, 5 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 | 5 |
| | Attendance rate | 84.00% (Absence: 3 Independent Outside Directors, 1 time each, and 1 Independent Outside Audit & Supervisory Board Member, 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 | 98.41% (Absence: 1 member, 1 time) |
| Internal Control Committee | Composition | 9 members (2 from Legal Affairs Dept., 3 from Internal Audit Dept., 2 from Accounting Dept., and 2 from Human Resources & General Affairs Dept.) |
| | Number of meetings held | 6 |
| | Attendance rate | 96.30% (Absence: 1 from Internal Audit Dept. and 1 from Human Resources & General Affairs Dept., 1 time each) |

# Outside Directors and Outside Audit & Supervisory Board Members

## Functions and Roles of Outside Directors

JCR has four Outside Directors and five 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. One of the Independent Outside Audit & Supervisory Board Members (full-time member) is a member of 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 due to a lengthy career in the pharmaceutical industry; we want to leverage his knowledge and experience as a pharmaceutical company manager in JCR's own management. |
| | Takashi Suetsuna | ○ | Appointed due to a wealth of experience and deep insight into administrative agencies; we want to leverage his expertise as an Outside Auditor and Outside Director for other companies in JCR's own management. |
| | Toshihide Yoda | | Appointed due to overwhelming demonstration of insights cultivated as a pharmaceutical sector analyst in the financial industry; we want to leverage his experience as a leading force in the creation of new businesses in JCR's own management. |
| | Yuko Hayashi, Ph.D. | ○ | Appointed due to a wealth of knowledge and experience in research activities related to advanced medicines; we want to leverage her wide-ranging wealth of experience, such as promoting diversity and active roles for female employees, in JCR's own management. |
| Outside Audit & Supervisory Board Members | Kazumasa Oizumi | ○ | Appointed to leverage his experience in the finance industry as well as experience as a company board member; we want him to perform audits from an experienced and well-informed standpoint. |
| | Kazuhiko Yamada | ○ | Appointed due to his experience and expertise as a certified tax accountant; we want him to perform audits from a taxation perspective. |
| | Kenjiro Miyatake | ○ | Appointed to utilize his experience as a corporate manager in the pharmaceutical industry; we want him to perform audits from an experienced and well-informed standpoint. |
| | Takeshi Komura | ○ | Appointed due to a wealth of experience in administrative agencies and broad insights into monetary and financial affairs; we want him to perform audits using his experience and knowledge as an Outside Director for other companies. |
| | Shuichi Tani | ○ | Appointed due to a wealth of experience related to public health, deep insights into medical welfare, and profound perspectives on medical institutions; we want him to perform audits using these experiences. |

# Compliance

## Compliance Committee

JCR has established a Compliance Committee as an organization to implement company management in line with social norms and corporate ethics as well as compliance with laws and regulations. An external lawyer serves as the chairperson of the Committee, and it consists of two sub-committees: a Compliance Control Committee with committee members equivalent to our Directors and Corporate Officers, and a Compliance Promotion Committee with employees who are in charge of departments. The Compliance Committee holds meetings on a regular basis, determines the Company's compliance action plans and policies, and provides employee training and education based on the Compliance Code of Conduct and the Compliance Handbook.

# Occupational Safety and Health

## Safety and Health Committee

JCR has set up 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 who represent each division of JCR, a licensed social insurance labor consultant, and industrial physicians as an outside committee members. The committee periodically holds meetings to report on the status of each workplace, and 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.

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.

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 FY2017

| | | | |
|---|---|---|---|
| Compliance Committee | Compliance Control Committee | Composition | 14 members (2 attorneys, 4 Directors, 8 Corporate Officers) |
| | | Number of meetings held | 1 |
| | | Attendance rate | 100.00% |
| | Compliance Promotion Committee | Composition | 16 members (2 from Business Development Div., 3 from HR Development & Compliance Dept., 1 from Human Resources & General Affairs Dept., 1 from Sales Div., 2 from Development Div., 1 from Research Div., 4 from Production Div., 1 from Quality Assurance Div., 1 from an affiliate company) |
| | | Number of meetings held | 2 |
| | | Attendance rate | 93.75% (Absence: 1 from Development Div., 1 from Production Div.) |
| Safety and Health Committee | | Composition | 16 members (1 licensed social insurance labor consultant, 2 industrial physicians, 5 from Human Resources & General Affairs Dept., 1 from Sales Div., 1 from Corporate Planning Div., 1 from Business Development Div., 1 from Quality Assurance Div., 2 from Production Div., 2 from Development Div.) |
| | | Number of meetings held | 12 |
| | | Attendance rate | 91.15% (Absence details omitted) |

# Operating Results

## Net Sales

Sales of our core product, GROWJECT®, a recombinant human growth hormone, continued growing from the previous fiscal year to 11,495 million yen (up 7.6% from the previous fiscal year) due to the detailed area marketing activities and the launch of its liquid formulation in January 2017. Sales of Epoetin Alfa BS Inj. JCR, a recombinant human erythropoietin product, as well as TEMCELL® HS Inj., a regenerative medical product, also increased favorably, accompanied by an increase in revenue from licensing, totalling 20,594 million yen (up 13.9% from the previous fiscal year) in FY2017. Sales from pharmaceuticals, JCR's main business sector, amounted to 20,177 million yen (up 14.1% from the previous fiscal year) and accounted for 98.0% of total sales.

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

| | | FY2016 | FY2017 |
|---|---|---|---|
| Pharmaceuticals | GROWJECT® | 10,682 | 11,495 |
| | Epoetin Alfa BS Inj. JCR | 3,702 | 4,115 |
| | TEMCELL® HS Inj. | 688 | 1,544 |
| | Urine-derived products | 1,145 | 834 |
| | Revenue from licensing | 1,283 | 2,137 |
| | Others | 175 | 50 |
| | Total | 17,677 | 20,177 |
| Medical devices and laboratory equipment | | 407 | 417 |
| Total | | 18,085 | 20,594 |

## Gross Profit

Due to the increase in net sales, gross profit increased 17.0% from the previous fiscal year to 14,465 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 1.9 percentage points from the previous fiscal year to 29.8%.

## Operating Income

R&D expenditures increased 3.5% from the FY2016, and selling, general and administrative expenses, including R&D expenditures, were 10,681 million yen (up 6.9% from the previous fiscal year). As a result, operating income was 3,784 million yen (up 60.2% from the previous fiscal year).

## Ordinary Income

Non-operating income decreased 131 million yen compared with the FY2016, mainly due to the decrease in gain on redemption of securities, while non-operating expenses decreased 17 million yen due to the decrease in expenses for purchase of treasury stock. As a result, ordinary income amounted to 3,843 million yen (up 51.7% from the previous fiscal year).

## Profit Attributable to Owners of Parent

Extraordinary income was 77 million yen (up 56 million yen from the previous fiscal year) due to the reasons such as gain on sale of non-current assets in FY2017. Furthermore, extraordinary losses came to 25 million yen (down 36 million yen from the previous fiscal year). As a result, income before income taxes was 3,895 million yen (up 56.3% from the previous fiscal year), and profit attributable to owners of parent amounted to 3,070 million yen (up 64.8% from the previous fiscal year).

# Financial Position

## Assets

Total assets at the end of FY2017 stood at 38,398 million yen (up 2,013 million yen from the previous fiscal year-end).

Current assets stood at 23,327 million yen (up 3,012 million yen from the previous fiscal year-end) due to the increase in inventories and securities, which offset a decrease in cash and deposits. Noncurrent assets stood at 15,070 million yen (down 998 million yen from the previous fiscal year-end) mainly due to the decrease in investment securities.

## Liabilities

Total liabilities at the end of FY2017 stood at 10,870 million yen (up 2,070 million yen from the previous fiscal year-end).

Current liabilities stood at 7,105 million yen (up 2,398 million yen from the previous fiscal year-end), mainly due to increases in short-term loans payable and income taxes payable. Noncurrent liabilities stood at 3,764 million yen (down 327 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 27,528 million yen (down 57 million yen from the previous fiscal year-end) due to an increase in treasury stock, despite recording profit attributable to owners of parent.

As a result, the equity ratio at the end of FY2017 was 70.3% (down 4.7 percentage points from the previous fiscal year-end).

## Cash Flow

Net cash provided by operating activities in FY2017 amounted to 3,133 million yen (up 482 million yen from the previous fiscal year). The main factors were income before income taxes of 3,895 million yen and depreciation and amortization of 1,382 million yen, partially offset by an increase in notes and accounts receivable-trade of 1,668 million and an increase in inventories of 1,314 million yen.

Net cash used in investing activities amounted to 1,587 million yen (up 745 million yen from the previous fiscal year). The main factors were purchase of property, plant,

and equipment of 922 million yen and purchase of securities of 611 million yen, partially offset by proceeds from sales and redemption of investment securities of 300 million yen.

Net cash used in financing activities amounted to 2,175 million yen (up 2,321 million yen from the previous fiscal year). The main factors were a net increase in treasury stock of 2,585 million yen, cash dividends paid of 748 million yen, partially offset by increase in short-term loans payable of 1,220 million yen.

As a result, cash and cash equivalents at the end of FY2017 stood at 4,850 million yen (down 614 million yen from the previous fiscal year-end).

## Forecast for FY2018

In terms of sales, we anticipate net sales growth on top of steady increases in sales volume for GROWJECT® and TEMCELL® HS Inj., in addition to our proactive efforts into the licensing business. Sales of Epoetin Alfa BS Inj. JCR are expected to decline with the impact of drug price revisions, however the overall sales forecast of JCR group is for 21,900 million yen (up 6.3% 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 4,290 million yen (up 13.3% from the current fiscal year), ordinary income of 4,360 million yen (up 13.4% from the current fiscal year) and profit attributable to owners of parent of 3,200 million yen (up 4.2% 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 of 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 FY2017, under our basic policy to provide continuous and stable dividends, we will provide term-end dividend of 14 yen per share. Together with the interim dividend of 12 yen per share, the total annual dividend is 26 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 FY2018 (the term ending in March 2019), we expect to distribute a full-year dividend of 26 yen per share (interim dividend of 13 yen and term-end dividend of 13 yen).

# Summary of Financial Data for Eleven Years

Consolidated fiscal years ended March 31

| | FY2007 | FY2008 | FY2009 | FY2010 |
|---|---|---|---|---|
| **Fiscal year** | | | | |
| Net sales | 11,871 | 12,082 | 14,387 | 14,457 |
| Operating income | 281 | 546 | 2,007 | 1,407 |
| Profit attributable to owners of parent | 399 | 539 | 1,302 | 926 |
| Comprehensive income | — | — | — | 783 |
| R&D expenditures | 2,776 | 2,804 | 2,325 | 2,017 |
| Capital investment | 553 | 876 | 2,369 | 2,417 |
| Depreciation and amortization | 575 | 694 | 743 | 975 |
| Cash flows from operating activities | 1,923 | 1,825 | 2,357 | (18) |
| Cash flows from investing activities | (571) | 121 | (3,396) | (2,211) |
| Cash flows from financing activities | (512) | (1,276) | 1,756 | (1,276) |
| **End of fiscal year** | | | | |
| Total assets | 24,218 | 24,767 | 29,148 | 29,817 |
| Net assets | 16,852 | 16,984 | 20,483 | 22,832 |
| Shareholders' equity | 16,840 | 16,879 | 20,462 | 22,762 |
| **Information per share** | | | | |
| Earnings per share (EPS) | 14.74 | 20.09 | 50.77 | 28.93 |
| Net assets | 623.22 | 635.20 | 700.80 | 704.96 |
| Dividends | 10.00 | 10.00 | 15.00 | 12.00 |
| **Financial indicators** | | | | |
| Equity ratio (%) | 69.5 | 68.2 | 70.2 | 76.3 |
| Return on equity (ROE) (%) | 2.3 | 3.2 | 7.0 | 4.3 |
| Dividend payout ratio (%) | 67.8 | 49.8 | 29.5 | 41.5 |
| Numbers of employees | 277 | 280 | 311 | 399 |

Unit: million yen

| FY2011 | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 | **FY2017** |
|---|---|---|---|---|---|---|
| 12,845 | 14,099 | 15,705 | 16,855 | 17,438 | 18,085 | **20,594** |
| 1,089 | 1,150 | 1,545 | 2,014 | 2,152 | 2,362 | **3,784** |
| 633 | 730 | 1,296 | 1,682 | 1,789 | 1,863 | **3,070** |
| 664 | 1,161 | 1,544 | 1,936 | 1,557 | 1,831 | **3,016** |
| 1,841 | 1,991 | 2,202 | 3,334 | 3,348 | 4,071 | **4,211** |
| 487 | 1,494 | 2,260 | 1,522 | 1,237 | 1,409 | **908** |
| 1,101 | 979 | 1,111 | 1,352 | 1,407 | 1,447 | **1,382** |
| (421) | 1,661 | 4,565 | 499 | 2,201 | 2,651 | **3,133** |
| 1,539 | (178) | (2,668) | (1,419) | (980) | (841) | **(1,587)** |
| (1,065) | (238) | (369) | (1,261) | (1,314) | 146 | **(2,175)** |
| 28,967 | 31,286 | 33,464 | 34,086 | 35,346 | 36,385 | **38,398** |
| 22,633 | 23,496 | 24,580 | 26,264 | 27,062 | 27,585 | **27,528** |
| 22,535 | 23,368 | 24,417 | 26,101 | 26,819 | 27,305 | **26,999** |

Unit: yen

| | | | | | | |
|---|---|---|---|---|---|---|
| 19.75 | 23.03 | 40.79 | 52.85 | 56.12 | 58.95 | **98.73** |
| 710.82 | 735.86 | 768.13 | 818.64 | 843.34 | 864.66 | **877.86** |
| 12.00 | 12.00 | 17.00 | 18.50 | 22.00 | 22.00 | **26.00** |
| 77.8 | 74.7 | 73.0 | 76.6 | 75.9 | 75.0 | **70.3** |
| 2.8 | 3.2 | 5.4 | 6.6 | 6.8 | 6.9 | **11.3** |
| 60.8 | 52.1 | 41.7 | 35.0 | 39.2 | 37.3 | **26.3** |
| 424 | 437 | 472 | 501 | 526 | 566 | **568** |

## Consolidated Balance Sheets

Unit: million yen

| | As of March 31, 2017 | As of March 31, 2018 |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash and deposit | 5,509 | 4,895 |
| Notes and accounts receivable-trade | 5,434 | 7,103 |
| Securities | 300 | 1,217 |
| Merchandise and finished goods | 1,757 | 1,759 |
| Work in process | 1,591 | 1,790 |
| Raw materials and supplies | 4,389 | 5,474 |
| Deferred tax assets | 390 | 496 |
| Other | 942 | 592 |
| Total current assets | 20,315 | 23,327 |
| Non-current assets | | |
| Property, plant and equipment | | |
| Buildings and structures, net | 4,938 | 4,755 |
| Machinery, equipment and vehicles, net | 1,204 | 1,044 |
| Land | 3,882 | 3,882 |
| Lease assets, net | 605 | 392 |
| Construction in progress | 31 | — |
| Other, net | 726 | 778 |
| Total property, plant and equipment | 11,387 | 10,853 |
| Intangible assets | 67 | 112 |
| Investments and other assets | | |
| Investment securities | 3,587 | 3,194 |
| Net defined benefit assets | 276 | 268 |
| Other | 773 | 665 |
| Allowance for doubtful accounts | (22) | (22) |
| Total investments and other assets | 4,614 | 4,104 |
| Total non-current assets | 16,069 | 15,070 |
| Total assets | 36,385 | 38,398 |

Unit: million yen

| | As of March 31, 2017 | As of March 31, 2018 |
|---|---|---|
| **Liabilities** | | |
| Current liabilities | | |
| Notes and accounts payable-trade | 700 | 585 |
| Short-term loans payable | 1,493 | 2,893 |
| Lease obligations | 230 | 193 |
| Income taxes payable | 69 | 887 |
| Provision for bonuses | 525 | 560 |
| Provision for directors' bonuses | 73 | 80 |
| Other | 1,614 | 1,904 |
| Total current liabilities | 4,706 | 7,105 |
| Non-current liabilities | | |
| Long-term loans payable | 2,713 | 2,500 |
| Lease obligations | 401 | 218 |
| Provision for loss on guarantees | 337 | 315 |
| Allowance for employee stock ownership benefits | — | 19 |
| Net defined benefit liability | 582 | 641 |
| Other | 56 | 69 |
| Total non-current liabilities | 4,092 | 3,764 |
| Total liabilities | 8,799 | 10,870 |
| **Net assets** | | |
| Shareholders' equity | | |
| Capital stock | 9,061 | 9,061 |
| Capital surplus | 10,964 | 10,947 |
| Retained earnings | 8,149 | 10,469 |
| Treasury stock | (1,486) | (4,042) |
| Total shareholders' equity | 26,689 | 26,435 |
| Accumulated other comprehensive income | | |
| Valuation difference on available-for-sale securities | 569 | 462 |
| Foreign currency translation adjustments | 149 | 169 |
| Remeasurements of defined benefit plans | (103) | (67) |
| Total accumulated other comprehensive income | 616 | 563 |
| Subscription rights to shares | 279 | 344 |
| Non-controlling interests | 0 | 185 |
| Total net assets | 27,585 | 27,528 |
| Total liabilities and net assets | 36,385 | 38,398 |

Unit: million yen

## Consolidated Statements of Income

| | FY2016 (From Apr. 1, 2016 to March 31, 2017) | FY2017 (From Apr. 1, 2017 to March 31, 2018) |
|---|---|---|
| Net sales | 18,085 | 20,594 |
| Cost of sales | 5,731 | 6,128 |
| Gross profit | 12,353 | 14,465 |
| Selling, general and administrative expenses | 9,991 | 10,681 |
| Operating income | 2,362 | 3,784 |
| Non-operating income | | |
| Interest income | 16 | 20 |
| Dividends income | 20 | 25 |
| Foreign exchange gains | 46 | — |
| Gain on sale of investment securities | 18 | 26 |
| Insurance income | — | 11 |
| Other | 133 | 21 |
| Total non-operating income | 236 | 105 |
| Non-operating expenses | | |
| Interest expenses | 28 | 27 |
| Foreign exchange losses | — | 7 |
| Other | 35 | 11 |
| Total non-operating expenses | 64 | 46 |
| Ordinary income | 2,534 | 3,843 |
| Extraordinary income | | |
| Gain on sale of non-current assets | — | 54 |
| Reversal of provision for loss on guarantees | 20 | 22 |
| Other | — | 0 |
| Total extraordinary income | 20 | 77 |
| Extraordinary losses | | |
| Special retirement money for affiliated companies | 59 | — |
| Loss on disposal of non-current assets | 3 | 25 |
| Total extraordinary losses | 62 | 25 |
| Profit before income taxes | 2,492 | 3,895 |
| Income taxes-current | 393 | 964 |
| Income taxes-deferred | 235 | (139) |
| Total income taxes | 629 | 825 |
| Profit | 1,863 | 3,069 |
| Profit attributable to non-controlling interests | 0 | (0) |
| Profit attributable to owners of parent | 1,863 | 3,070 |

## Consolidated Statements of Comprehensive Income

| | | |
|---|---|---|
| Profit | 1,863 | 3,069 |
| Other comprehensive income | | |
| Valuation difference on available-for-sale securities | (18) | (107) |
| Foreign currency translation adjustment | (56) | 19 |
| Remeasurements of defined benefit plans, net of tax | 42 | 35 |
| Total other comprehensive income | (31) | (53) |
| Comprehensive income | 1,831 | 3,016 |
| (Comprehensive income attributable to) | | |
| Comprehensive income attributable to owners of parent | 1,831 | 3,016 |
| Comprehensive income attributable to non-controlling interests | 0 | (0) |

## Consolidated Statements of Changes in Net Assets

From April 1, 2016 to March 31, 2017

Unit: million yen

| | Shareholders' equity | | | | |
|---|---|---|---|---|---|
| | Capital stock | Capital surplus | Retained earnings | Treasury stock | Total shareholders' equity |
| Beginning balance | 9,061 | 10,961 | 6,930 | (781) | 26,171 |
| Accumulative impact amount due to changes of accounting policies | | | 55 | | 55 |
| Beginning balance after reflection of changes of accounting policies | 9,061 | 10,961 | 6,985 | (781) | 26,226 |
| Changes during the year | | | | | |
| Dividends paid | | | (699) | | (699) |
| Net income attributable to owners of the parent | | | 1,863 | | 1,863 |
| Purchase of treasury shares | | | | (776) | (776) |
| Disposal of treasury shares | | 3 | | 71 | 75 |
| Changes of items other than shareholders' equity (net) | | | | | |
| Total changes for the year | — | 3 | 1,163 | (705) | 462 |
| Ending balance | 9,061 | 10,964 | 8,149 | (1,486) | 26,689 |

| | Accumulated other comprehensive income | | | | | | |
|---|---|---|---|---|---|---|---|
| | Valuation difference on available-for-sale securities | Foreign currency translation adjustments | Remeasurements of defined benefit plans | Total accumulated other comprehensive income | Subscription rights to shares | Non-controlling interests | Total net assets |
| Beginning balance | 587 | 205 | (145) | 648 | 242 | 0 | 27,062 |
| Accumulative impact amount due to changes of accounting policies | | | | | | | 55 |
| Beginning balance after reflection of changes of accounting policies | 587 | 205 | (145) | 648 | 242 | 0 | 27,118 |
| Changes during the year | | | | | | | |
| Dividends paid | | | | | | | (699) |
| Net income attributable to owners of the parent | | | | | | | 1,863 |
| Purchase of treasury shares | | | | | | | (776) |
| Disposal of treasury shares | | | | | | | 75 |
| Changes of items other than shareholders' equity (net) | (18) | (56) | 42 | (31) | 37 | 0 | 5 |
| Total changes for the year | (18) | (56) | 42 | (31) | 37 | 0 | 467 |
| Ending balance | 569 | 149 | (103) | 616 | 279 | 0 | 27,585 |

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) |
| Net income 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 | Total accumulated other comprehensive income | Subscription rights to shares | Non-controlling interests | Total net assets |
| Beginning balance | 569 | 149 | (103) | 616 | 279 | 0 | 27,585 |
| Changes during the year | | | | | | | |
| Dividends paid | | | | | | | (750) |
| Net income 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 |

## Consolidated Statements of Cash Flows

Unit: million yen

| | FY2016 (From Apr. 1, 2016 to March 31, 2017) | FY2017 (From Apr. 1, 2017 to March 31, 2018) |
|---|---|---|
| **Net cash provided by (used in) operating activities** | | |
| Income before income taxes | 2,492 | 3,895 |
| Depreciation and amortization | 1,447 | 1,382 |
| Increase (decrease) in provision for bonuses | 44 | 35 |
| Share-based compensation expenses | 79 | 77 |
| Increase (decrease) in provision for loss on guarantees | (20) | (22) |
| Increase (decrease) in net defined benefit liability | 65 | 75 |
| Interest and dividends income | (37) | (46) |
| Interest expenses | 28 | 27 |
| Foreign exchange losses (gains) | (31) | 13 |
| Decrease (increase) in notes and accounts receivable-trade | (50) | (1,668) |
| Decrease (increase) in accounts receivable-other | (324) | 290 |
| Decrease (increase) in inventories | (402) | (1,314) |
| Increase (decrease) in accounts payable-trade | (83) | (114) |
| Increase (decrease) in accounts payable-other | 313 | (14) |
| Increase (decrease) in accrued consumption taxes | (354) | 258 |
| Increase (decrease) in advanced received | (174) | 83 |
| Other, net | 780 | 288 |
| Subtotal | 3,773 | 3,246 |
| Interest and dividends income received | 33 | 48 |
| Interest expenses paid | (28) | (27) |
| Income taxes (paid) refund | (1,126) | (133) |
| Net cash provided by (used in) operating activities | 2,651 | 3,133 |
| **Net cash provided by (used in) investing activities** | | |
| Purchase of securities | — | (611) |
| Proceeds from sales and redemption of securities | 284 | 300 |
| Purchase of property, plant and equipment | (1,550) | (922) |
| Proceeds from sales of property, plant and equipment | — | 66 |
| Purchase of intangible assets | (13) | (77) |
| Purchase of investment securities | (42) | (494) |
| Proceeds from sales and redemption of investment securities | 451 | 150 |
| Other, net | 29 | 0 |
| Net cash provided by (used in) investing activities | (841) | (1,587) |
| **Net cash provided by (used in) financing activities** | | |
| Increase (decrease) in short-term loans payable | 50 | 1,220 |
| Proceeds from long-term loans payable | 2,300 | 200 |
| Repayment of long-term loans payable | (550) | (233) |
| Repayments of lease obligations | (210) | (212) |
| Net decrease (increase) in treasury stock | (743) | (2,585) |
| Proceeds from payment from non-controlling interests | — | 184 |
| Cash dividends paid | (699) | (748) |
| Net cash provided by (used in) financing activities | 146 | (2,175) |
| Effect of exchange rate change on cash and cash equivalents | (15) | 14 |
| Net increase (decrease) in cash and cash equivalents | 1,941 | (614) |
| Cash and cash equivalents at beginning of period | 3,523 | 5,464 |
| Cash and cash equivalents at end of period | 5,464 | 4,850 |

# Corporate Information

As of March 31, 2018

## 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**
568 (Consolidated) 540 (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)

* JCR approved a resolution to dissolve and liquidate on April 26, 2017.

## Stock Information

**Listed on**
Tokyo Stock Exchange First Section

**Securities Code**
4552

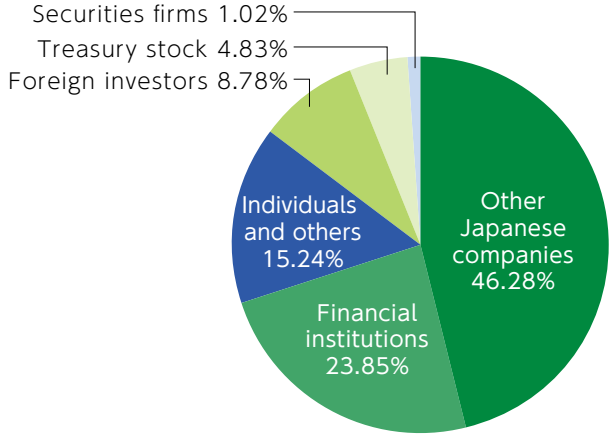
**Total Number of Outstanding Shares**
32,421,577

**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**
3,796

**Composition of Shareholders**




**Principal Shareholders**

(Unit: 1,000)

| Name of shareholder | Number of shares held |
|---|---|
| MEDIPAL HOLDINGS CORPORATION | 7,282 |
| Kissei Pharmaceutical Co., Ltd. | 3,800 |
| Future Brain Co., Ltd. | 2,177 |
| The Nomura Trust and Banking Co., Ltd. (Trust A Account) | 1,634 |
| The Master Trust Bank of Japan, Ltd. (Trust Account) | 1,577 |
| Japan Trustee Services Bank, Ltd. (Trust Account) | 1,448 |
| Sumitomo Dainippon Pharma Co., Ltd. | 850 |
| Mochida Pharmaceutical Co., Ltd. | 550 |
| Japan Trustee Services Bank, Ltd. (Trust 9 Account) | 489 |
| Trust & Custody Services Bank, Ltd. (Security Investment Trust Account) | 285 |

* The Company holds 1,566,530 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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