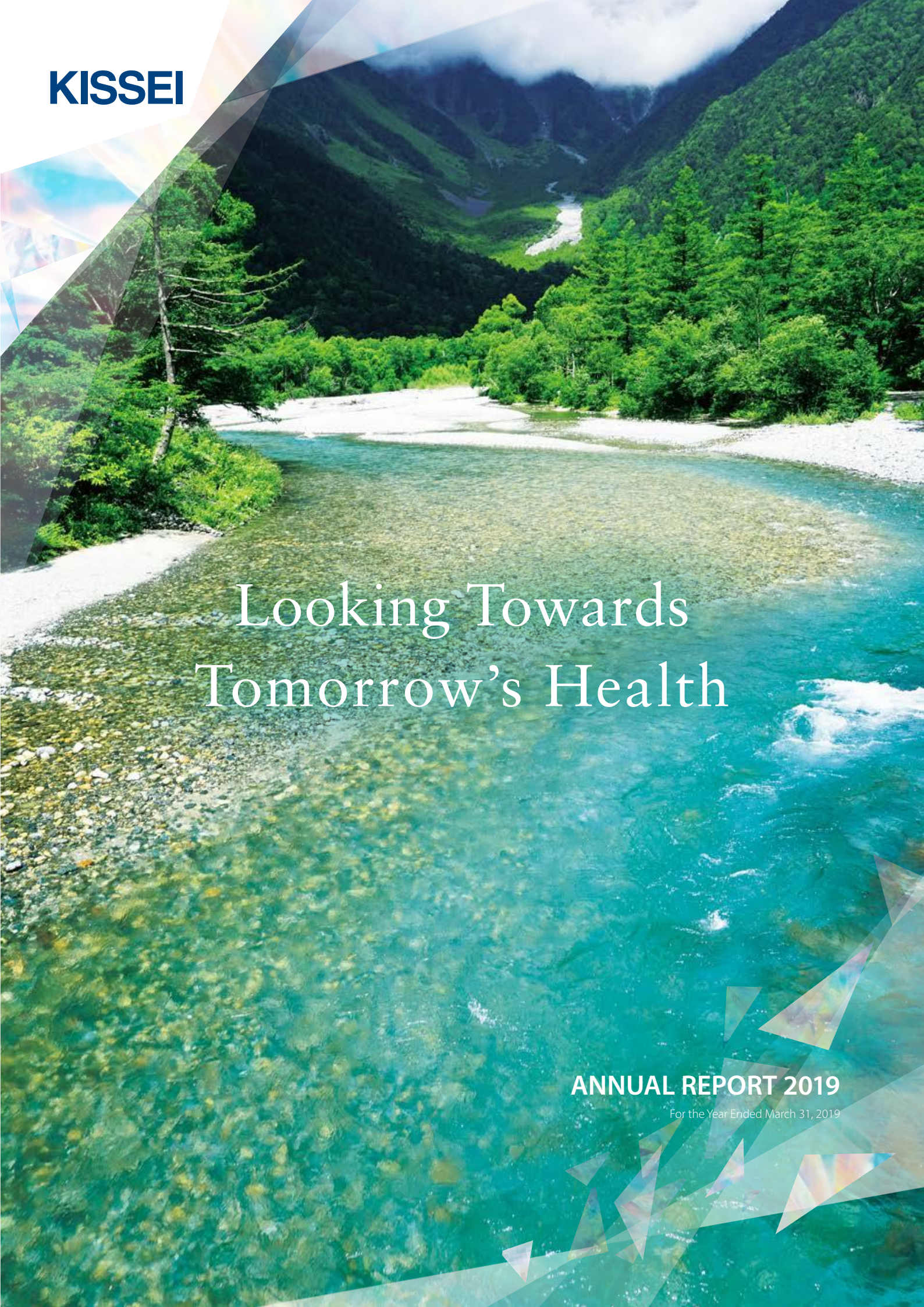
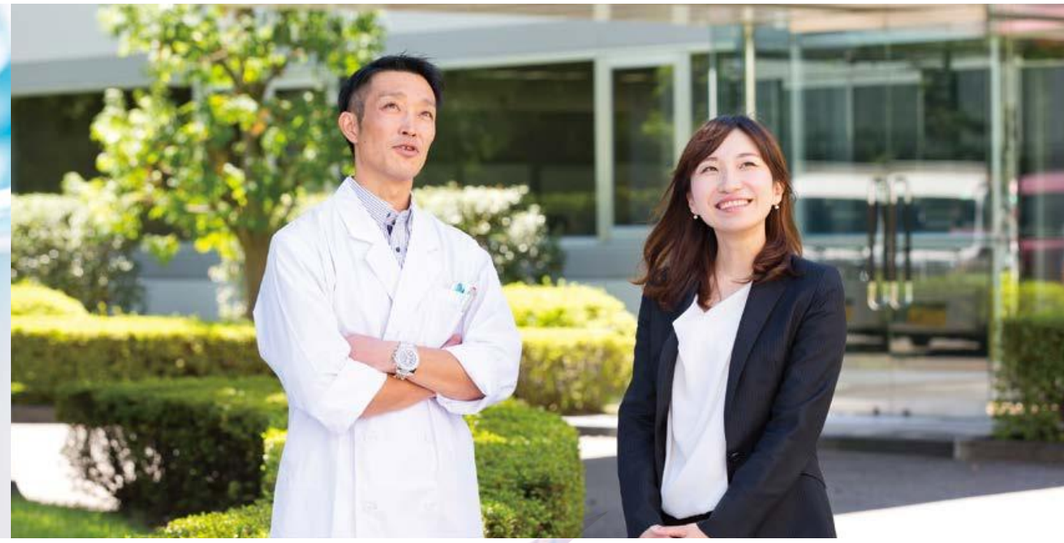
KISSEI



# Looking Towards Tomorrow's Health

## ANNUAL REPORT 2019

For the Year Ended March 31, 2019



Management Philosophy

## Contribute to society through high-quality, innovative pharmaceutical products Serve society through our employees

Management Vision

## We aim to be an R&D-oriented pharmaceutical company that contributes to the health of people around the world through innovative pharmaceutical products.

The Kissei Group's history began with the founding of Tachibana Seikagaku Institute Co., Ltd. in 1946. Since then, we have operated under two management philosophies: "contribute to society through high-quality, innovative pharmaceutical products" and "serve society through our employees." In 1982 we launched Rizaben®, the first oral drug for the treatment of allergic diseases in Japan. We later developed and launched Utemerin®, a drug for the treatment of threatened premature labor and threatened abortion; Bezatol®, a drug for the treatment of hyperlipidemia; and a variety of other high-quality new drugs.

In addition to these innovative pharmaceutical products, we also offer other successful pharmaceutical products, including Urief®, a drug for the treatment of dysuria associated with benign prostatic hyperplasia (BPH); Beova®, a drug for the treatment of overactive bladder; Epoetin Alfa BS Injection [JCR], a drug for the treatment of renal anemia; and P-TOL®, a drug for the treatment of hyperphosphatemia, in our priority areas of urology, and renal diseases and dialysis, where we perform strongly. At the same time, we are focused on R&D for rare diseases. Moreover, we are growing our nutritional business through development and sales of special therapeutic food products represented by the Yume Series of protein controlled foods.

We firmly believe that a pharmaceutical company cannot exist without R&D, an idea which has been passed on since our founding, and continue to develop and provide original pharmaceuticals to further improve global health.

## Contents



**Cautionary Notice regarding Forward-Looking Statements**

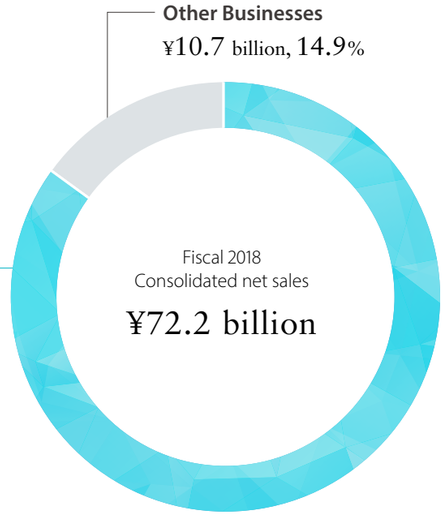
The financial forecasts, R&D plans, and other forward-looking statements that appear in this report are based on information available to the Company at the time of disclosure. In other words, such information forms the basis of our future outlooks. For that reason, projections may differ from actual financial and R&D results.

**Numerical Data**

Amounts in this report are rounded down. As a result, the sum and breakdown of data may not equal the total amounts.

# Kissei's Business

The Kissei Group consists of five companies, including a consolidated financial statement submitting company, three consolidated domestic subsidiaries, and one unconsolidated overseas subsidiary. The main focus of the Kissei Group is the manufacture and sale of ethical drugs, and the related materials. We are developing business activities such as purchase / sales, system development / information processing, construction contracting, facility / facility management, information gathering / development support service, and other services.




## Pharmaceutical Business

¥61.5 billion, 85.1%

Kissei is guided by its firm belief that a pharmaceutical company cannot exist without R&D, which has been passed on since its founding. As an R&D-oriented pharmaceutical company, Kissei is conducting research and development, manufacturing, and sales of mainly ethical drugs to improve the quality of life for patients and their families around the world.

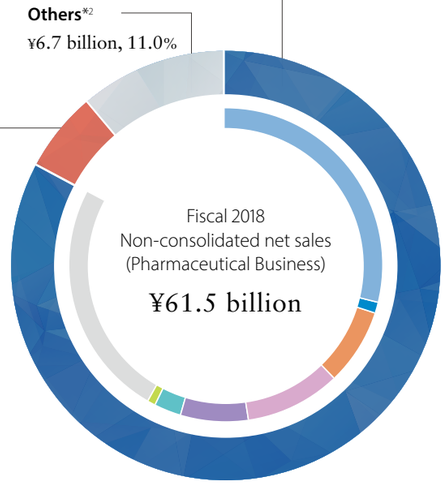
Furthermore, based on the principle that a healthy diet leads to a healthy body, we are also developing our nutritional business in order to contribute to medical care through food.

### Pharmaceuticals*1 ¥50.9 billion, 82.8%

In the pharmaceutical business, we are conducting research and development on pharmaceutical products in the priority areas of urology, renal diseases and dialysis, and rare diseases. We aim to develop innovative pharmaceutical products that contribute to the improvement of medicine and the health of people around the world by aggressive incorporation of leading-edge technology and joint research and collaborations with our foreign and domestic partners.

### Therapeutic and care foods ¥3.7 billion, 6.2%

We develop and sell various food products, such as protein controlled foods and energy supply foods, so that people who have restricted dietary habits, such as the elderly and patients suffering from renal diseases, will feel comforted by our foods and be able to enjoy eating them. By leveraging the technology and development know-how cultivated over many years in the pharmaceutical business, we are creating food products that are tasty, nutritionally balanced, easy to eat, and appropriate to a therapeutic diet.




### Sales of Major Domestic Pharmaceuticals in Fiscal 2018

| | | | |
|---|---|---|---|
| Urief® | ¥17.8 billion | Glubes® | ¥4.4 billion |
| Beova® | ¥0.7 billion | Glufast® | ¥1.6 billion |
| P-TOL® | ¥4.8 billion | RECTABUL® | ¥0.6 billion |
| Epoetin Alfa BS | ¥6.0 billion | Others | ¥14.8 billion |

*1: Including active pharmaceutical ingredients (API) and bulk exports
*2: Supply to domestic sales partners + revenue from technical fees (contract fees from out-licensing of R&D themes, milestone income, and running royalties)



# Kissei's Value Creation Process

Kissei conducts business activities while responding to changing external environments in pursuit of its management vision—to be an R&D-oriented pharmaceutical company that contributes to the health of people around the world through innovative pharmaceutical products. We are working to improve corporate value by sharing results with a range of stakeholders, building relationships of trust, and further enhancing management capital. Our goal is to achieve continuous growth as a company that is invaluable to society by means of enhancing this cycle throughout the medium to long term.

### Kissei's Management Philosophy

**Management Vision**

**Drug development** / **Technical ability** / **Drug observation** / **Human capital**

Contribute to society through high-quality, innovative pharmaceutical products

Serve society through our employees

**CSR Management**

### Kissei's Management Capital

**Financial capital**
Strong capital structure

**Natural capital**
Co-existing with nature as a company involved in life sciences

**Human capital**
Human resources with profound knowledge and technical skills

**Production capital**
Factory and laboratory equipment

**Intellectual capital**
Competitive intellectual property

**Social capital**
Partnerships with local communities and stakeholders

### Business Activities

Kissei's business processes and strengths

Procurement → Research and development → Quality assurance → Production → Sales and services → Patients and their families

Prescription drugs and special therapeutic food products

As an R&D-oriented pharmaceutical company, build a uniform value chain for drugs and therapeutic food products that spans from development to production and sales

### What Kissei Gives

Contribution to the health and medical care of people around the world

Safe and high-quality products using its technical abilities and human capital

**Achieve continuous, long-term growth by carrying out enhancements of management capital from business outcomes and strengthening competitiveness**

### What Kissei Gets (outcomes)

The establishment of its unique presence worldwide

Stable management base

The trust of its stakeholders

**Diversification of medical needs** / **Discovery of unmet medical needs** / **Policy in support of new drug development** / Etc.

### External Environments that Impact Operations

# Financial and Non-Financial Highlights

Kissei Pharmaceutical Co., Ltd. and its subsidiaries
Years ended March 31

| | Millions of yen, except per share data | | | | | Thousands of U.S. dollars, except per share data*1 |
|---|---|---|---|---|---|---|
| | 2015 | 2016 | 2017 | 2018 | **2019** | **2019** |
| **For the Year:** | | | | | | |
| Net Sales | ¥70,110 | ¥71,294 | ¥71,706 | ¥74,009 | **¥72,297** | **$651,324** |
| R&D Expenses | 14,488 | 14,106 | 13,877 | 14,179 | **15,711** | **141,541** |
| Capital Investment | 1,825 | 1,942 | 1,477 | 1,989 | **1,177** | **10,604** |
| Operating Income | 8,334 | 10,274 | 8,491 | 9,887 | **6,202** | **55,874** |
| Profit Attributable to Owners of Parent | 7,165 | 8,165 | 7,726 | 9,045 | **5,481** | **49,378** |
| **At Year-End:** | | | | | | |
| Total Assets | ¥181,484 | ¥193,345 | ¥186,801 | ¥210,821 | **¥213,522** | **$1,923,622** |
| Total Net Assets | 150,720 | 158,125 | 157,783 | 176,092 | **182,707** | **1,646,009** |
| **Per Share** (Yen and U.S. Dollars)**:** | | | | | | |
| Profit Attributable to Owners of Parent*2: | | | | | | |
| Primary | ¥142.14 | ¥166.89 | ¥158.74 | ¥188.26 | **¥117.33** | **$1.06** |
| Cash Dividends | 42.0 | 44.0 | 46.0 | 48.0 | **50.0** | **0.45** |
| **Key Ratios** (%)**:** | | | | | | |
| Operating Income Ratio | 11.9 | 14.4 | 11.8 | 13.4 | **8.6** | |
| R&D Expenses Ratio | 20.7 | 19.8 | 19.4 | 19.2 | **21.7** | |
| Return on Assets (ROA) | 4.0 | 4.4 | 4.1 | 4.3 | **2.6** | |
| Return on Equity (ROE) | 4.9 | 5.3 | 4.9 | 5.4 | **3.1** | |
| Shareholders' Equity Ratio | 82.9 | 81.6 | 84.3 | 83.3 | **85.4** | |
| Dividend Payout Ratio | 29.5 | 26.4 | 29.0 | 25.5 | **42.6** | |
| **Others:** | | | | | | |
| Number of Employees | 1,883 | 1,908 | 1,905 | 1,903 | **1,907** | |
| Number of Shares Issued | 56,911,185 | 54,311,185 | 54,311,185 | 51,811,185 | **51,811,185** | |
| **Non-Financial Data:** | | | | | | |
| Energy Used (kL) | 9,256 | 9,281 | 8,945 | 8,694 | **8,489** | |
| $CO_2$ Emissions (tons) | 20,916 | 20,695 | 19,701 | 19,162 | **18,516** | |
| Amount of Waste Generated (tons) | 439 | 398 | 366 | 424 | **461** | |
| Final Disposal Amount (tons) | 18 | 14 | 13 | 12 | **15** | |

*1: U.S. dollar amounts are translated at the rate of ¥111=U.S.$1, the approximate effective rate of exchange at March 31, 2019.
*2: Profit attributable to owners of parent per share is computed based on the weighted-average number of shares of common stock after subtracting the weighted-average number of shares of treasury stock for the year.



# Medium-Term Management Plan

## Medium-Term Management Plan "Co-Creation" (fiscal 2017 to fiscal 2021)

### Basic Policy

**Management Vision**

We aim to be an R&D-oriented pharmaceutical company that contributes to the health of people around the world through innovative pharmaceutical products.

I. Strengthening of drug discovery research

II. Expansion of product portfolios

III. Maximizing domestic sales of medical drugs

IV. Construction of stable earnings base overseas

### Financial Targets for the Final Year (fiscal 2021)

| | "Co-Creation" Targets |
|---|---|
| Consolidated net sales | Over ¥73.0 billion |
| Non-consolidated net sales | Over ¥61.0 billion |
| Pharmaceuticals*1 | Over ¥50.5 billion |
| Therapeutic and care foods | Over ¥ 4.5 billion |
| Others*2 | Over ¥ 6.0 billion |
| Consolidated operating income | Over ¥ 6.5 billion |
| R&D expenses | ¥13.0 billion |

*1: Including active pharmaceutical ingredients (API) and bulk exports
*2: Supply to domestic sales partners + revenue from technical fees (contract fees from out-licensing of R&D themes, milestone income, and running royalties)

### Issues to Address

The environment surrounding the pharmaceutical industry is one in the midst of a structural transformation. In the face of growing demand for development of medicine for both rare and intractable diseases, and as medical needs such as improved quality of life are becoming more sophisticated and diversified, the resource pool for new medicine is shrinking. In addition, lower success rates for new drug development, combined with growing R&D risks (which leads to growing R&D costs), have resulted in greater difficulty in the development of new medicine. In addition, Japan's population decline—brought on by a shrinking birthrate and an aging population—has led to an increasingly stringent supply of social security resources. This has also led to social security reforms, including measures to curb medical expenses through the promotion of generic drug use and other means. There is also fierce competition within the industry as companies adapt to a new market structure, spurred by major changes in the global market in the midst of instability overseas.

In order for us to overcome these changes in the business environment and achieve stable and sustainable growth, we will work to expand our product portfolio by producing innovative drugs as an R&D-oriented pharmaceutical company.

Fiscal 2018 marked the second year of our five-year medium-term management plan, "Co-Creation." As part of this plan, we will focus on realizing the following eight initiatives as soon as possible.

**1 Promote innovative drug discovery**

As we develop the strengths of the Company, we will use our ever-growing expertise and incorporate new technology from open innovation. This in turn will allow us to build a foundation for research and development that can continuously create new drugs.

**2 Expand product portfolio for future growth**

We will expand our portfolio by proactively investing management resources both into promoting R&D projects and into active in-licensing focused on strategies and future innovations in medical technology.

**3 Maximize domestic sales of medical drugs by strengthening strategies and launching and promoting new products**

We will take hold of the new drug market by prompt and steady acquisition of permission to manufacture and sell products in the later stages of development and by promoting drugs based on careful market analysis.

**4 Construct stable earnings base overseas through out-licensing of innovative drugs**

We aim to maximize our overseas profits by strengthening ties with our overseas licensing partners and build and expand a stable overseas earnings base by out-licensing new drug candidates.

**5 Construct an efficient production system to create a stable supply of high-quality drugs**

While improving the efficiency of manufacturing and distribution costs, we will promote the stable supply of safe and reliable high-quality pharmaceutical products to accommodate customer needs.

**6 Expand and secure profits in the nutritional business**

Increase profitability by continuously introducing food products to the nursing, eldercare, and renal diseases fields and by establishing a competitive advantage in the home healthcare market.

**7 Training personnel capable of executing strategies**

We will work toward measured cultivation of human resources who possess a high level of expertise and are able to execute strategies in response to changes in the business environment.

**8 Promote compliance**

We will fulfill our mission as a listed company and a company involved in the life sciences industry.

# Letter from the CEO

As an R&D-oriented company,
we will provide safe, high-quality products
driven by our technical prowess and
talented personnel in order to contribute to
the health and medical care of
people around the world.

Guided by its management philosophy, the Kissei Group is aiming to make significant contributions to society. The Group promotes management policies that emphasize the importance of shareholders, employees, local communities, history and culture, and the environment. The management vision underpinning its core pharmaceutical business challenges Kissei Pharmaceuticals Co., Ltd. (Kissei) to be an R&D-oriented pharmaceutical company that contributes to the health of people around the world through innovative pharmaceutical products. To that end, Kissei is actively pushing forward with patient-centered measures including the undertaking of R&D activities, high-quality drug manufacturing, the collection and provision of medical information necessary for the optimum use of its products, the implementation of efficient operations, and the construction of a total marketing system. In addition, each Kissei Group company assists in our pharmaceutical business and leverages its technologies to help develop our operations both domestically and internationally.

A combination of Japan's aging population, the need to keep medical technology up to date with the latest technological advancements, and the appearance of high drug prices have placed significant financial pressure on the medical insurance system, which has created increasingly harsh conditions surrounding the pharmaceutical industry. As part of the effort to alleviate some of this pressure and move to a more sustainable system, the National Health Insurance Drug Prices Standard System has undergone a major overhaul. With an ongoing zero-growth scenario expected for Japan's pharmaceutical market, it is clear that a company's survival hinges on whether it can produce a continuous stream of new drugs to the market or not. On the other hand, we are seeing major upheavals in conditions surrounding R&D in the pharmaceutical industry, as well as the general concept of R&D itself. Technological innovations in life sciences, for example, have shifted development toward more difficult targets, such as rare and intractable diseases. Furthermore, drug discovery methods are advancing at a rapid pace, and new treatment methods and medical technologies are entering into practical use. At the same time, society is keeping a strict eye on corporate governance within the pharmaceutical industry, as scandal and malpractice in the industry become a growing social problem, signaling a need for us to take note of our role as public institutions and take actions to correct our standing. I believe that in these times of drastic change, following our management philosophy—to contribute to society through high-quality, innovative pharmaceutical products and serve society through our employees—will guide us toward greater corporate value.

To this end, we are implementing our current five-year medium-term management plan "Co-Creation" (fiscal 2017–fiscal 2021), beginning in April 2017. In the second year of the plan, the fiscal year under review, the patent expired for Urief® (Japanese product name, generic name: silodosin), a drug treatment for dysuria with BPH and one of our main products. To address this management issue, in fiscal 2019 we are focusing on the steady launch of products in the late stages of the development pipeline to market. These include the releases of Beova®, a treatment for overactive bladder, and P-TOL® Granules, a new micro-tablet-type granule dosage form of the treatment for hyperphosphatemia, in November 2018, and acquiring approval for Glubes® Combination Orally Disintegrating Tablet in February 2019, a new dosage form of the treatment for type 2 diabetes which we launched in June 2019. In addition, an application for JR-131 (development code), a biosimilar of darbepoetin alfa (generic name), a long-acting erythropoiesis-stimulating agent for the treatment of renal anemia, was submitted for approval in September 2018 by co-developer JCR Pharmaceuticals Co., Ltd. Staying rooted in speed and quality, we focused on creating new research themes for drug discovery, and research directed at the early clinical stages. At the same time, we made an aggressive push with our licensing activities in order to expand our product portfolio. These include a contract signed in October 2018 with Rigel Pharmaceuticals, Inc. to secure exclusive development and marketing rights in Asian territories for the small molecule spleen tyrosine kinase inhibitor, R788 (development code, generic name: fostamatinib), and an agreement signed in June 2019 with Ferring Pharma Co., Ltd. for co-promotion in Japan of MINIRIN MELT® OD tablet 25μg and 50μg, for the treatment of nocturia due to nocturnal polyuria in men.

As an R&D-oriented company, we are working toward sustainable growth. Through the cooperation of our various stakeholders, we are also working to meet our responsibility to society as a company. To that end, in July 2019 we declared the following management policy in accordance with the UN's Sustainable Development Goals (SDGs), directed at making them a reality.

### The Kissei Group Policy for Achieving the SDGs

To realize our management philosophy—to contribute to society through high-quality, innovative pharmaceutical products and serve society through our employees—we will conduct business that maintains a proper balance between economic, environmental, and social aspects while keeping compliance our top priority. In doing so, we will contribute to achieving the SDGs.

Our governance system comprises a Board of Directors containing 14 members, including two independent outside directors. In addition, our system employs a corporate auditor system with four corporate auditors sitting on the Board of Corporate auditors, two of whom are outside auditors. We determine outside directors based on the independently determined criteria and necessary qualifications set forth in the Kissei Basic Policy on Corporate Governance. In addition, we have also established a Nomination and Compensation Deliberation Committee to propose candidates for dismissal or appointment as director, to deliberate over director compensation, and to propose candidates for the Board of Directors. This committee typically comprises the representative director, a Board member in charge of personnel, and an outside director, but will also include an outside corporate auditor when nominating a candidate for a corporate auditor position or when a corporate auditor is up for dismissal. As CEO, I am responsible for all matters related to management, while Mr. Furihata, the Company president, is responsible for all matters related to business execution.

We intend to build trust with society as a company with a clear raison d'être by maintaining a dialogue with our various stakeholders, be they patients, medical care providers, business partners, shareholders, investors, employees, or local community members. The patent expiration of Urief® and the negative effects it has had on performance are temporary setbacks from which we will achieve renewed growth. In doing so, we will achieve our aim of improving corporate value.

I ask for the ongoing understanding and support of all our stakeholders moving forward.

July 2019

**Mutsuo Kanzawa**
Chairman and Chief Executive Officer

# Message from the COO

**Yoshio Furihata**
President and
Chief Operating Officer

## Review of Operations

**Overview of Operations in the Year under Review**

Net sales for the fiscal year ended March 31, 2019 decreased 2.3%, to ¥72,297 million. Segment sales for the pharmaceutical business, the core business of the Kissei Group, were down 3.7%, to ¥61,520 million.

Looking at the pharmaceutical business, patents for Urief® Tablet and Urief® OD Tablet, a drug for the treatment of dysuria associated with benign prostatic hyperplasia, expired in December 2018. However, aggressive promotional activities resulted in higher sales of the aforementioned Urief® Tablet and Urief® OD Tablet; P-TOL® Chewable Tablet, a drug for the treatment of hyperphosphatemia; and RECTABUL® 2mg Rectal Foam 14 Doses, a treatment for ulcerative colitis. However, the April 2018 reforms to the NHI Drug Prices Standard System in Japan, coupled with lower revenue from technical fees, resulted in an overall drop in sales.

As for new drugs entering the domestic market, in November 2018 we began sales of both Beova®, a treatment for overactive bladder co-developed with KYORIN Pharmaceutical Co., Ltd., and P-TOL® Granules, a new dosage form of the Kissei-developed treatment for hyperphosphatemia. Furthermore, in August 2018, with the consent of Kissei, Daiichi Sankyo Espha Co., Ltd. received manufacturing and marketing approval for an authorized generic (AG) version of Urief® Tablet and OD Tablet, which were listed in the NHI price list in December 2018. Kissei will handle manufacturing of the AG version of the drug, while Daiichi Sankyo Espha will be responsible for sales. The drug was launched in March 2019.

Moving overseas, in the U.S., silodosin (generic name, brand name in Japan: Urief®), a drug for the treatment of dysuria associated with benign prostatic hyperplasia, was launched as a generic drug as a result of patent expiration. However, we have continued our licensing agreement in Europe, the Middle East, and Africa with Recordati S.p.A (Italy), which has continued to promote this product in these licensed areas in fiscal 2018.

In other businesses, net sales were up 6.5% year on year to ¥10,777 million, reflecting increased revenues in the information services, merchandising, and construction industries.

In terms of income, operating income and profit attributable to owners of parent both decreased as a result of lower revenue, a higher cost of sales ratio, and higher selling, general and administrative (SG&A) expenses, which were largely due to R&D expenses.





As for R&D in the pharmaceutical business, an application for approval was submitted for JR-131 (development code), a biosimilar of darbepoetin alfa (generic name), a long-acting erythropoiesis-stimulating agent for the treatment of renal anemia. The application was submitted in September 2018 by JCR Pharmaceuticals Co., Ltd., who co-developed the drug. In October 2018, Kissei signed a contract with Rigel Pharmaceuticals, Inc. for the exclusive development and marketing rights in Japan, China, Korea, and Taiwan for the small molecule spleen tyrosine kinase inhibitor, R788 (development code, generic name: fostamatinib). In addition, in February 2019, Kissei acquired approval for the development and marketing of Glubes® Combination Orally Disintegrating Tablet, a new dosage form of the drug, which is a treatment for type 2 diabetes. This product was listed in the NHI price list in June 2019 and was launched the same month. Results from the phase III clinical trial of KPS-0373 (development code, generic name: rovatirelin), a drug for the treatment of spinocerebellar ataxia, were deemed negative after the drug did not show significant differences from a placebo in terms of mean changes from baseline SARA* scores, the main tool for assessing ataxia and the primary endpoint for the trial. Because of this outcome, we are assessing the results of the trial in detail, including subgroup analysis, based on the severity of the obtained results.

* The SARA (Scale for the Assessment and Rating of Ataxia) is a tool for assessing ataxia. It has 8 categories with a cumulative score ranging from 0 (no ataxia) to 40 (most severe ataxia). When completing the outcome measure each category is assessed and scored accordingly. Scores for the 8 categories are as follows: 1. Gait, 2. Stance, 3. Sitting, 4. Speech disturbance, 5. Finger chase, 6. Nose-finger test, 7. Fast alternating hand movement, 8. Heel-shin slide.

## Outlook for the Current Fiscal Year

In the domestic pharmaceutical market, business conditions will likely remain difficult as the Japanese government continues to promote policies to reduce public medical treatment costs, such as by encouraging the use of generic drugs. In terms of other businesses, the pace of economic recovery has been sluggish, and they will continue to exist within a harsh economic climate.

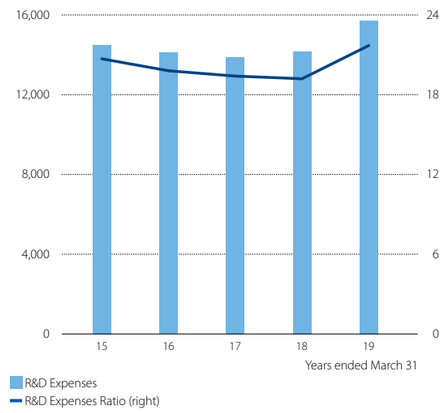
**Net Sales**

In the pharmaceutical business, we will continue our efforts to cultivate P-TOL®, Beova®, Glubes®, and other drugs. However, sales of Urief® are expected to fall due to the release of generic versions of the drug. As a result, we forecast a decrease in sales. We anticipate a decrease for other businesses as well.

**Income**

Selling, general and administration expenses will decrease, but we anticipate a decline in profit due to a decrease in sales and a rising cost of sales ratio. We do not anticipate any other noteworthy changes to profit and loss outside of a gain on sales of investment securities.

**R&D Expenses / R&D Expenses Ratio**



We are giving top priority to investing management resources toward continued expansion of our product portfolio. As we engage in vigorous R&D activities for drug discovery, we are also making active efforts to build alliances to match our strategies.

## Management Strategy

Kissei aims to contribute to society as an R&D-oriented pharmaceutical company that develops and offers innovative pharmaceutical products to support the health of people all over the world. By advancing the basic strategies of our five-year medium-term management plan "Co-Creation", launched in fiscal 2017, we are working to strengthen our business foundations in order to achieve stable growth into the future. Our management strategy focuses on the following key points.

(1) We will strengthen the functionality of our drug discovery efforts in order to spur the continuous creation of new drugs that are highly unique and competitive.
(2) We will expand our product portfolio that will carry us into the future by promoting research and development projects and active in-licensing.
(3) We will expand our presence in the urology, renal diseases and dialysis, and rare disease areas of medical treatment and increase the domestic sales of ethical drugs through the steady transition of products, from the late-development stage to application and approval and smooth introduction to the market.
(4) We will build a stable earnings base overseas through out-licensing new drug discovery.

Over the last two years, Kissei has seen the cancellation of development themes and changes in schedules, but we have been steadfast in our determination to overcome the patent expiration of Urief® and find renewed growth. To this end, we have worked as an entire Group to create new growth drivers. These efforts include the launch of RECTABUL®, P-TOL® Granules, and Glubes® Combination Orally Disintegrating Tablet, as well as the application for approval submitted for JR-131; the introduction and promotion of global trials for CCX168 (development code, generic name: avacopan), a selective inhibitor of the complement C5a receptor; the introduction of R788 (development code, generic name: fostamatinib) to Asian regions; the concurrent domestic and overseas development of KLH-2109 (development code, generic name: linzagolix), a GnRH antagonist discovered by Kissei; and the establishment of new research themes for drug discovery. These fledgling growth drivers will be what support Kissei in the future. In the fiscal year ending March 31, 2020, we will ensure that these growth drivers develop into supporting foundations quickly by clearly prioritizing each one in accordance with our business strategy, and allotting resources in a dynamic fashion. In doing so, we will steadily build a business foundation for regrowth.

We will rebuild domestic sales in the wake of the Urief® patent expiration via efforts to optimize our key strategic products—Beova®, P-TOL®, Glubes®, RECTABUL®, the dry mouth treatment SALAGEN®, and JR-131—for use in practical medical treatments. We will also move forward with plans to develop themes at the clinical development stage according to priorities to quickly and steadily bring new products to the Japanese market. In overseas earnings, we will work with partner companies to maintain and expand income from silodosin, while building a new income base with KLH-2109. Moreover, we will derive new development themes and products through flexible coordination between related departments.

To ensure continuous growth even further into the future, we will make bold investments toward creating promising research themes for drug discovery. We will also expand our pipeline by introducing new R&D themes concentrated on focus areas and areas we want to strengthen. At the same time, we will introduce products to the market that will add to Kissei's competitive edge. Working under an appropriate quality assurance system, we will achieve growth in the therapeutic and care foods business by improving the mail-order business and investing in new products.

As a pharmaceutical company involved in life sciences, we always bear in mind the need to conduct activities from a high ethical viewpoint. Therefore, we are careful to verify the business processes taking place in each department, with full awareness of the importance of maintaining compliance with laws and regulations, and securing trust. In particular, we perform activities in accordance with the Guidelines for Prescription Drug Marketing Information Provision implemented in April of this year, and the Work Style Reform Bill. Moreover, we will strive to fulfill our mission as a company involved in life sciences through appropriate management of corporate governance and internal control systems, as well as the promotion of our Compliance Program.

As we engage in vigorous R&D activities for drug creation, we are also actively engaged in alliances and are matching our products and R&D themes with our strategies. While the ongoing development of these R&D and alliance investments may have a temporary impact from the perspective of business performance, these are essential investments to establish our future profit structures. Ultimately, the goal of this process is to improve the ratio of sales to operating profit by pursuing efficiency from all points of view and improving profitability.

As for profit allocation, we stand rooted in making stable dividend payouts while taking care to secure lasting business foundations.

Going forward, we would like to ask for the continued understanding and support of our stakeholders.

July 2019

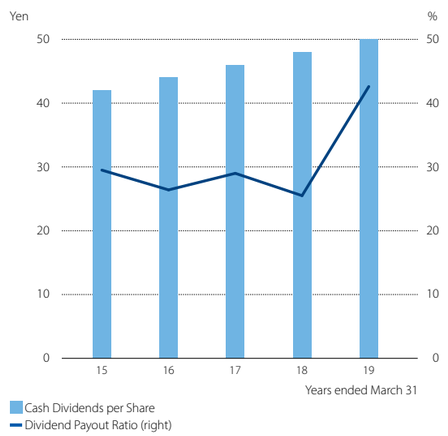
**Yoshio Furihata**
President and Chief Operating Officer

### Management Policy for the Fiscal Year under Review

I. Rebuild domestic sales by launching and increasing the value of new products
II. Promote domestic development of treatments for rare diseases
III. Promote drug discovery research and find openings into promising themes
IV. Build a new revenue base overseas
- Promote development of treatment for uterine fibroids and endometriosis in Europe and North America
- Derive new development themes and products

We strive for renewed growth by continuously releasing new drugs

### Cash Dividends per Share / Dividend Payout Ratio



# Research and Development (R&D)

## Basic Policy

As an R&D-oriented pharmaceutical company, Kissei aims to develop and provide innovative drugs by investing management resources predominantly in research on drug discovery. The driving force behind the Company's R&D efforts is the desire to help patients who are suffering from illnesses and contribute to the health of people around the world.

Kissei has adopted "strengthening of drug discovery research" as the first basic policy of our medium-term management plan, "Co-Creation," which went into effect in April 2017. Based on this policy, we are focusing on the key areas of urology, renal diseases and dialysis, as well as the field of rare diseases, where satisfaction with treatment is low, in pursuit of creating new, highly original, and innovative pharmaceutical products.

Our drug discovery research targets mainly revolve around small molecule compounds, but in recent years we have been researching biologics as well. In this way, we are working to improve our knowledge and technical skill in this field and thereby strengthen our overall research base.

We are proceeding with our efforts to pursue new research projects for drug discovery. These efforts are being aided within the R&D Division by the Drug Discovery Strategy Office, which was established in April 2019 and is responsible for managing proposals for research targets related to drug discovery, and the Drug Discovery Research Laboratory, which is responsible for managing all research projects related to drug discovery. By clearly delegating these responsibilities we will be better able to create new, highly original drugs that will drive the Company in the future. These two functions will maintain a cooperative relationship with other specialized laboratories, which will increase the mutual quality of their work, and allow us to allocate appropriate funds and research according to project priority and proceed with drug discovery research with a sense of speed.

We believe that open innovation is essential to discovering drug discovery seeds, acquiring new research themes, introducing new technology, and harnessing various research modalities. Maintaining active access to the various deliverables that academia provides will lead to creative drug discovery.

## In-Licensing New R&D Themes

R&D projects that are still under clinical development are moving forward according to priority, and we aim for the early and continuous launch of these products into the domestic market. The Company will make bold investments toward creating promising drug discovery, and will be in-licensing new R&D projects with an emphasis on the Company's focus areas and areas we are looking to strengthen. These actions will serve to expand the Company pipeline further and secure continuous growth for the future.

## Status of Main Research and Development Activities

The features and progress of the main R&D projects we are currently pursuing are as follows.

JR-131 (development code) is a biosimilar of darbepoetin alfa (generic name), a long-acting erythropoiesis-stimulating agent for renal anemia. Phase III clinical trials conducted by JCR Pharmaceuticals Co., Ltd. and Kissei in 2016 confirmed equivalence with darbepoetin alfa, the original biopharmaceutical of its type. In this trial, we verified the equivalence in efficacy and evaluated the safety of JR-131 compared to darbepoetin alfa. The results showed equivalence between JR-131 and darbepoetin alfa in the change in hemoglobin concentration, the primary efficacy endpoint, and also showed similarity with regard to the safety profile. Based on these trial results, JCR Pharmaceuticals Co., Ltd. filed a marketing application for this drug in September 2018.

KPS-0373 (development code, generic name: rovatirelin), an orally administered drug for the treatment of spinocerebellar ataxia, is a thyrotropin-releasing hormone (TRH) analog discovered by Shionogi & Co., Ltd. Additional phase III clinical trials conducted in 2016 showed no statistically significant changes in the total SARA score evaluating ataxia, the primary endpoint of the trial, when compared to a placebo. We have conducted detailed analysis based on the results of the two phase III clinical trials, including subgroup analysis based on the severity of results. This matter is currently being discussed with Japan's Pharmaceuticals and Medical Devices Agency (PMDA).

AJM300 (development code, generic name: carotegrast methyl), for the treatment of ulcerative colitis, began an additional phase III clinical trial based on consultations with the PMDA concerning the results of the prior phase III clinical trial and in order for Kissei and EA Pharma Co., Ltd. to gain approval for the drug.

With regard to CCX168 (development code, generic name: avacopan), a therapeutic agent for rare diseases in the renal disease field, we have participated in a phase III multi-regional clinical trial in patients with anti-neutrophil cytoplasmic antibody-associated vasculitis (AAV), which is being conducted by U.S.-based ChemoCentryx, Inc.

We have completed conducting late phase II clinical trials in Japan for the GnRH antagonist KLH-2109 (development code, generic name: linzagolix) for the treatment of endometriosis, and are investigating future development strategies. Overseas, phase III clinical trials are underway for the treatment of endometriosis and uterine fibroids by Swiss-based ObsEva SA, the out-licensee for this drug.

Phase II clinical trials of MR13A9 (development code, generic name: difelikefalin), a kappa opioid receptor agonist for the treatment of uremic pruritus in dialysis patients, are being carried out by Maruishi Pharmaceutical Co., Ltd., with whom we have a collaboration agreement with. This drug, which is delivered intravenously, is both convenient for patients and improves drug compliance, and shows promise as a new treatment option for pruritus.

KDT-3594 (development code) is a non-ergot dopamine agonist discovered by Kissei as a treatment for Parkinson's disease. It has been suggested that stimulation of dopamine receptors present in the basal ganglia ameliorate the symptoms caused by the lack of dopamine. We are currently conducting Phase II clinical trials.

We are conducting phase I / II clinical trials of YS110 (development code), a humanized anti-CD26 monoclonal antibody, in patients with malignant mesothelioma in Japan, based on the results of a clinical trial conducted in France.

## Promoting Clinical Development of Drugs for Treating Rare Diseases in Japan

We are going forward with late-stage development projects in the rare diseases field.

| | |
|---|---|
| Spinocerebellar ataxia<br>**KPS-0373** (development code)<br>**Generic name: Rovatirelin** | • Thyrotropin-releasing hormone (TRH) analog<br>• Phase III clinical trial results under analysis<br>• Aim to submit application for approval after discussions with PMDA |
| Microscopic polyangiitis, granulomatosis with polyangiitis, C3 glomerulopathy, atypical hemolytic uremic syndrome<br>**CCX168** (development code)<br>**Generic name: Avacopan** | • Selective inhibitor of the complement C5a receptor discovered by U.S.-based ChemoCentryx, Inc.<br>• Phase III multi-regional clinical trial in progress (subjects fully enrolled)<br>• Orphan designation in Japan, the U.S., and Europe (Japan designation received in March 2019. Priority review and reexamination period extended) |
| Idiopathic thrombocytopenic purpura, autoimmune hemolytic anemia, IgA nephropathy<br>**R788** (development code)<br>**Generic name: Fostamatinib** | • Small molecule spleen tyrosine kinase inhibitor developed by U.S.-based Rigel Pharmaceuticals, Inc.<br>• Exclusive development and marketing rights in Japan, China, Korea, and Taiwan<br>• Preparations for clinical trials in Japan in progress |

## R&D Pipeline As of July 2019

### In-House

| Development Code (Generic Name) | Expected Indications | Category | Development Classification | Stage: Phase 1 | Phase 2 | Phase 3 | NDA filed | Remarks |
|---|---|---|---|---|---|---|---|---|
| **Renal and dialysis** | | | | | | | | |
| JR-131 | Renal anemia | Increase the red blood cell (RBC) count | In-licensed / Co-development with JCR Pharmaceuticals (Japan) | | | | | A biosimilar of "darbepoetin alfa" |
| MR13A9 (Difelikefalin) | Uremic pruritus in dialysis patients | Kappa opioid receptor agonist | In-licensed / Co-development with Maruishi Pharmaceutical (Japan) | | | | | |
| **Unmet medical needs** | | | | | | | | |
| KPS-0373 (Rovatirelin) | Spinocerebellar ataxia | Product mimetic of TRH action | In-licensed / Shionogi (Japan) | | | | | |
| AJM300 (Carotegrast Methyl) | Ulcerative colitis | Alpha 4 integrin antagonist | In-licensed / Co-development with EA Pharma (Japan) | | | | | |
| CCX168 (Avacopan) | Microscopic polyangiitis Granulomatosis with polyangiitis | Selective inhibitor of complement C5a receptor | In-licensed / Vifor-Fresenius Medical Care Renal Pharma (Switzerland) | | | | | |
| YS110 | Malignant mesothelioma | Humanized anti-CD26 monoclonal antibody | In-licensed / Y's AC, University of Tokyo, AMED (Japan) | | Phase 1/2 | | | |
| **Other** | | | | | | | | |
| KLH-2109 (Linzagolix) | Endometriosis | GnRH antagonist | Kissei | | | | | |
| KDT-3594 | Parkinson's disease | Dopamine receptor stimulation | Kissei | | | | | |

### Out-Licensing

| Development Code (Generic Name) | Expected Indications | Category | Territory | Stage: Phase 1 | Phase 2 | Phase 3 | NDA filed | Development Company |
|---|---|---|---|---|---|---|---|---|
| **Urology** | | | | | | | | |
| Silodosin | Dysuria associated with benign prostatic hyperplasia | Alpha 1A-adrenoceptor blocker | ASEAN, India, Sri Lanka*1 | | | | | Eisai (Japan) |
| **Diabetes** | | | | | | | | |
| Mitiglinide | Type 2 diabetes mellitus | Rapid-acting insulin secretagogue | ASEAN *2 | | | | | Eisai (Japan) |
| **Other** | | | | | | | | |
| KLH-2109 (Linzagolix) | Uterine fibroids | GnRH antagonist | Worldwide, excluding some countries in Asia such as Japan | | | | | ObsEva SA (Switzerland) |
| KLH-2109 (Linzagolix) | Endometriosis | GnRH antagonist | Worldwide, excluding some countries in Asia such as Japan | | | | | ObsEva SA (Switzerland) |
| Bedoradrine | Acute exacerbation of asthma | Beta 2 adrenergic receptor agonist | Worldwide, except for Japan | | | | | MediciNova (U.S.) |

*1: Launched in Thailand, India, Indonesia, the Philippines, Cambodia, Myanmar, Malaysia/ NDA in 2 ASEAN countries
*2: Launched in Thailand, the Philippines, Cambodia, Myanmar/ Approved in Laos/ NDA in Vietnam

Progress after July 2018 covers the area inside the dashed lines.





## Topic 1

### CCX168 (Development Code, Generic Name: Avacopan), a Selective Inhibitor of the Complement C5a Receptor

Anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV) is a serious intractable disease causing inflammation and leading to damage of blood vessels, which causes damage to various organs including the kidneys due to ischemia and necrosis. Onset of AAV is associated with ANCA. AAV is categorized into microscopic polyangiitis (MPA), granulomatosis with polyangiitis (GPA), and eosinophilic granulomatosis with polyangiitis (EGPA).

Treatments for MPA and GPA are classified into remission induction aimed at resolving inflammation of blood vessels, and subsequent maintenance of the remission. The standard of care (SoC) for remission induction is a combination therapy with high-dose corticosteroids and cyclophosphamide or rituximab or other type of drug. The SoC for remission maintenance is a combination therapy with low-dose corticosteroids and azathioprine or other type of drug.

Avacopan is an orally-administered complement C5a inhibitor. Because the production of complement C5a (which is responsible for the immune response) is deeply involved in inflammation due to MPA and GPA, avacopan is expected to function as a therapeutic drug with a new mechanism that differs from existing drugs. Although corticosteroids that play a central role in current SoC are effective in MPA and GPA, there is an unmet medical need in that corticosteroids cause frequent and clinically significant adverse drug reactions. In a phase II clinical trial, avacopan showed non-inferiority compared to high-dose corticosteroids in a primary efficacy endpoint, with a lower incidence of adverse events associated with corticosteroids. Avacopan is expected to be highly useful as a drug that can reduce dosages of corticosteroids, shorten the duration of corticosteroid therapy, or replace corticosteroids altogether.

**Target indication: microscopic polyangiitis (MPA), granulomatosis with polyangiitis (GPA), forms of anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV)**

#### Number of patients in Japan:

11, 223 (designated as patients with an intractable disease)
(MPA 8,669, GPA 2,554)
(Based on number of recipients of specific medical expenses for intractable diseases in fiscal 2017)

#### Overseas Summary

- Discovered by U.S.-based ChemoCentryx, Inc.
- Not yet approved worldwide, a phase III multi-regional clinical trial in progress including in Japan
- Orphan drug designation in the U.S. and Europe (and designated in Japan in March 2019)
- Granted PRIority MEdicines (PRIME) eligibility by European Medicines Agency (EMA)

* PRIority MEdicines: a scheme launched to enhance support for the development of new medicines that are expected to show major benefits compared to existing treatments, or to benefit patients who lack treatment options.

## Topic 2

### R788 (Development Code, Generic Name: Fostamatinib), a Small Molecule Spleen Tyrosine Kinase Inhibitor

Kissei signed a contract in October 2018 with U.S.-based Rigel Pharmaceuticals, Inc. for exclusive development and marketing rights for the small molecule spleen tyrosine kinase (Syk) inhibitor R788 (development code, generic name: fostamatinib).

Based on the agreement, Kissei will have exclusive development and marketing rights of the drug in Japan, China, Korea, and Taiwan.

The drug, which has received an orphan drug designation for an indication of idiopathic thrombocytopenic purpura (ITP), was launched in the U.S. under Rigel in May 2018. In addition, EMA received a marketing authorization application (MAA) from Rigel in October 2018 that is currently under review.

ITP, which is one of the intended indications of this drug, is an autoimmune disease in which the number of circulating platelets in the body is heavily reduced by the appearance of auto-antibodies that target and destroy platelets. In Japan, ITP has been designated as an intractable disease by the Minister of Health, Labour and Welfare.

Currently, treatments of ITP are categorized into two types: treatments that suppress platelet destruction and treatments that promote platelet production. The suppressing platelet destruction therapies include corticosteroids, rituximab, and splenectomy; on the other hand, promoting platelet production therapies utilize thrombopoetin (TPO) receptor agonists.

Early treatment for ITP involves the administration of high-dose steroids and a splenectomy. Rituximab or TPO receptor agonists are used when these treatments prove to be ineffective.

Fostamatinib is an orally administered spleen tyrosine kinase inhibitor which inhibits phagocytosis and destruction of platelets by macrophages. The mechanism of action for fostamatinib differs from that of existing drugs and therefore may be effective in patients who have insufficient response to corticosteroids and other existing therapies. It is also believed that fostamatinib will have long-term effects through continuous administration.

Fostamatinib is expected to provide new benefits for patients with ITP.

**Target indication: idiopathic thrombocytopenic purpura (ITP)**

#### Number of patients in Japan:

17,618 (designated as patients with an intractable disease)
(Based on number of recipients of specific medical expenses for intractable diseases in fiscal 2017)

#### Overseas Summary

- Discovered by U.S.-based Rigel Pharmaceuticals, Inc.
- April 2018 – received approval in the U.S.
- May 2018 – launched in the U.S.
- July 2019 (current) – MAA is under review by EMA

# Major Domestic Pharmaceuticals



**Dysuria treatment:**

## Urief® Tablet and OD Tablet

Urief® is a selective alpha 1A-adrenoceptor blocker developed by Kissei for the treatment of dysuria associated with benign prostatic hyperplasia (BPH). By blocking alpha 1A-adrenoceptors in the prostate gland, it removes the tension of the prostate gland to improve urethral resistance. It has been co-marketed with Daiichi Sankyo Co., Ltd., since sales began in May 2006. Sales of Urief® in the form of an orally disintegrating (OD) tablet commenced in January 2016. In March 2019, with the consent of Kissei Pharmaceuticals, Daiichi Sankyo Espha Co., Ltd. began sales of an authorized generic (AG) version of Urief®. Kissei has been handling manufacturing of the AG version of the drug, while Daiichi Sankyo Espha will be responsible for sales.

**Overactive bladder treatment:**

## Beova® Tablet

KYORIN Pharmaceutical Co., Ltd. signed a license agreement with Merck & Co., Inc., (Head office: New Jersey, USA) in July 2014 concerning the grant of an exclusive license to develop, manufacture, and market Beova® in Japan. The product has been jointly developed by Kissei and KYORIN under a co-development and co-marketing agreement entered into as of March 2016. KYORIN subsequently received manufacturing and marketing approval in September 2018, and the two companies began drug sales in November 2018.

Vibegron, an active ingredient of Beova® Tablet, is a novel once-daily oral treatment for overactive bladder (OAB). It acts selectively on the bladder's β3-adrenergic receptor, relaxes the bladder, and enhances urine collection, and consequently improves the symptoms of urgency, urinary frequency, and urge incontinence associated with OAB.

**Hyperphosphatemia treatment:**

## P-TOL® Chewable Tablet, P-TOL® Granules

In November 2015, Kissei launched P-TOL® Chewable Tablet in Japan through Swiss-based Vifor Fresenius Medical Care Renal Pharma Ltd. (VFMCRP). P-TOL® decreases serum phosphate concentration by binding oxyhydroxide with phosphoric acid in the gastrointestinal tract and reducing internal phosphate absorption to treat hyperphosphatemia in patients on dialysis.

As part of life cycle management (LCM), Kissei received approval in September 2018 for the manufacture and sales of P-TOL® Granules, a new micro-tablet-type dosage form of the drug, and sales began in November 2018.

**Renal anemia treatment:**

## Epoetin Alfa BS Injection [JCR]

Epoetin Alfa BS Injection [JCR] is a biosimilar recombinant human erythropoietin co-developed by Kissei Pharmaceutical and JCR Pharmaceuticals. Kissei has been responsible for sales since May 2010.

**Diabetes treatment:**

## Glubes® Combination Tablet, Glubes® Combination OD Tablet

The Glubes® Combination Tablet, a combination of Glufast® and voglibose (generic name), was first sold in July 2011 by Kissei, acting independently. The tablet has been highly praised for providing aggressive treatment of postprandial glucose increases as well as being easy to administer and for reducing the economic burden on patients. In February 2018, Kissei received approval for the manufacture and sales of a new dosage form of the drug that rapidly disintegrates in the oral cavity. This orally disintegrating (OD) tablet began sales in June 2018.

**Ulcerative colitis treatment:**

## RECTABUL® Rectal Foam

RECTABUL® is a rectal foam-type product jointly developed by Kissei and EA Pharma launched in December 2017. This product is the first rectal foam in Japan that uses budesonide as an active ingredient. The delivery method makes it possible to administer in a standing position and prevents leakage afterward.

## Restructuring of Domestic Sales by New Products

**Urology**
- Manufacture & supply of Urief® AG
- Launch and increase in sales of Beova

| | | |
|---|---|---|
| Dysuria associated with BPH<br>Urief® | Manufacture & supply<br>Urief® AG* | Launched in November 2018<br>Overactive bladder<br>Beova® |

* Authorized generic

**Renal diseases and dialysis**
- Increase sales of additional dosage form: P-TOL® Granules
- Launch of Darbepoetin Alfa BS

| | |
|---|---|
| Hyperphosphatemia<br>P-TOL® Chewable Tablet | Renal anemia<br>Epoetin Alfa BS |
| Launched in November 2018<br>Hyperphosphatemia<br>P-TOL® Granules | Scheduled for launch in 2019<br>Renal anemia<br>Darbepoetin Alfa BS* |

* September 2018 NDA filed

**Metabolism**
- Launch and increase in sales of Glubes® OD tablet

| | |
|---|---|
| Type 2 diabetes<br>Glubes® Combination Tablet | Launched in June 2019<br>Type 2 diabetes<br>Glubes® OD Tablet |

**GI**
- Increase sales of RECTABUL®

| |
|---|
| Ulcerative colitis<br>RECTABUL® |

| | Sales in Fiscal 2018 | | Sales in Fiscal 2019 (forecast) |
|---|---|---|---|
| **Beova®** | 0.7 | → | 2.1 |
| **P-TOL®** | 4.8 | → | 6.7 |
| **Glubes®** | 4.4 | → | 4.7 |
| **RECTABUL®** | 0.6 | → | 1.1 |
| **Darbepoetin Alfa BS** | NDA | → | Launching |

(Billions of yen)

The current environment surrounding our business is quite harsh, for reasons including the drastic reform of the NHI Drug Prices Standard System that took place in April 2018 combined with the patent expiration of Urief®, one of our main products, in December 2018.

Our medium-term management plan employs various strategies to overcome this upcoming patent cliff. In order to achieve stable growth in the next medium-term management plan, we have positioned urology, renal diseases and dialysis, and rare diseases as three key fields to focus our management resources on and in which to expand our portfolio.

From fiscal 2018 through fiscal 2019, we are launching products in two of these areas. In urology, we released Beova®, an overactive bladder treatment, and in renal diseases and dialysis, we released a new granular formulation of P-TOL®. We are also planning to launch a biosimilar to darbepoetin alfa, a treatment for renal anemia. Moreover, we launched Glubes® Combination Orally Disintegrating Tablet, a new dosage form of the drug for the treatment of type 2 diabetes.

As a measure to overcome the Urief® patent cliff, we are working to quickly turn these four products into highly profitable commodities, and in doing so, we are rebuilding our domestic sales structure.

# Promoting Overseas Development

Kissei's basic strategy for overseas expansion is to obtain profits from supplying drug substances and obtain royalty income by out-licensing our products.

## Overseas Development of Silodosin

Silodosin has been sold in Japan by Kissei since May 2006 under the brand name of Urief®. It is a therapeutic drug for the treatment of dysuria associated with benign prostatic hyperplasia, and has earned a strong reputation around the world for its superior ability to relieve symptoms shortly after administration. This drug was launched in the United States in April 2009 by licensing partner Watson Pharmaceuticals, Inc. (currently Allergan plc), under the brand name RAPAFLO®. Furthermore, the drug was introduced in Germany in June 2010 under the brand name UROREC® by licensing partner Recordati S.p.A., of Italy. Recordati has received additional licensing rights to develop and sell the drug in 84 countries and regions such as Europe, the Middle East, Africa, and Oceania. In April 2013, licensing partner Daiichi Sankyo (Japan) began selling the drug in China through a local subsidiary under the name Youlifu®. As of July 2019, silodosin is being sold in 57 countries through these various partner companies around the world. Although the patent for silodosin expired in December 2018, the drug is still being promoted mainly in Europe, where the data protection period will last until January 2020.


## Out-Licensing of KLH-2109/OBE2109 (Development Code, Generic Name: Linzagolix) in European and North American Markets

Kissei promotes out-licensing of new drugs and aims to build future overseas earnings bases to succeed silodosin.

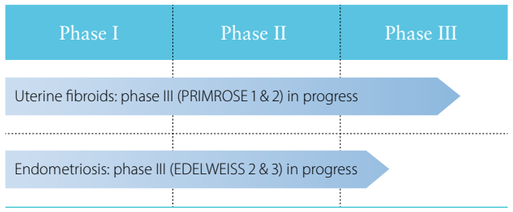
In November 2015, Kissei granted exclusive rights to Swiss-based ObsEva SA to develop and commercialize the novel drug candidate KLH-2109 (development code, generic name: linzagolix), a gonadotropin-releasing hormone (GnRH) antagonist discovered by Kissei, to all regions worldwide, excluding some countries in Asia, such as Japan. The Company will receive an upfront payment from ObsEva and will be eligible to receive milestone payments according to the development stage. In addition, the Company will supply drug substances to ObsEva.

ObsEva is a pharmaceutical company that specializes in the development of new drugs in the area of obstetrics and gynecology. The company is pursuing development of this drug (ObsEva development code: OBE2109) for European and North American markets. This candidate is currently under phase III clinical trials (EDELWEISS 2, EDELWEISS 3) for use as treatment for endometriosis as well as phase III trials (PRIMROSE 1, PRIMROSE 2) for use as a treatment for uterine fibroids.

KLH-2109 is a new orally administrable GnRH antagonist. It acts by antagonizing GnRH at the GnRH receptor located in the pituitary gland, thereby suppressing the secretion of gonadotropin, a gonadotropic hormone.

Kissei is focusing its efforts on R&D for new drugs and aims to expand globally by out-licensing original products overseas. Kissei will continue to actively develop new drugs that can contribute to the health of people around the world.

**Progress of Clinical Trials in Europe and the U.S.**




**Number of Patients**

| | | |
|---|---|---|
| **Uterine fibroids:** | U.S. | approx. 4,000,000 (with 200,000 requiring surgery)*1 |
| | Japan | approx. 116,000*2 |
| **Endometriosis:** | U.S. | approx. 2,500,000*1 |
| | Japan | approx. 67,000*2 |

*1: According to public documents provided by ObsEva
*2: According to 2017 patient survey by Ministry of Health, Labour and Welfare



# Production and Procurement

## Kissei's Production System

Kissei owns and operates two plants for producing pharmaceutical products, located in Matsumoto City and Shiojiri City in Nagano Prefecture. These plants are responsible for the entire manufacturing process, from procuring raw materials to shipping finished products. A portion of the finished products are concurrently outsourced to external parties, ensuring a stable supply of Kissei drugs to the market.

The Matsumoto Plants serve primarily as pharmaceutical preparation plants, focusing on drug formulation and the manufacture of the Company's high-quality drugs, including key strategic items such as Urief® and P-TOL®.

The Shiojiri Plants specialize in packaging for the drugs produced at Matsumoto Plants and other locations. After being subjected to thorough inspection, these packaged products are shipped.


Matsumoto Plants

Shiojiri Plants

## Stable Supply System

Because pharmaceutical products are life-related products, it is important to maintain and operate a continuous supply system. Therefore, we have established a supply chain management system that spans from the procurement of main components and other raw materials to drug manufacturing, inventory storage, and delivery. Procurement of raw materials can be fraught with unstable factors such as discontinued production stemming from reorganization of manufacturers and unprofitability. However, we implement measures to ensure stable procurement which include purchasing from multiple manufacturers and maintaining proper amounts of stock in accordance with risk.

We have also determined a business continuity plan so that even in the unlikely event of a major earthquake or other natural disaster, we have enough of our product in stock based on the amount of time it would take to restart operations at our plants. The amount of stock is determined based on the specific characteristics of each drug—for instance, we maintain an increased stock of drugs for emergency purposes and drugs of high importance. Furthermore, our stock storage sites are spread across three locations in Japan. These safeguards are part of our established supply system to ensure that provision of pharmaceutical drugs is not cut off. To further ensure continued implementation of these protocols, we have formalized them in a stable supply manual, and changes are made to protocol if necessary. Our in-house committee also conducts inspections in addition to self-checks.

In addition, we are committed to maintaining quality when storing and transporting drugs and strive to deliver drugs to our patients safely. We are also committed to measures against counterfeit drugs and strive to ensure traceability and prevent the influx of counterfeits. Furthermore, we are devising drug packaging that will act as a countermeasure to counterfeit drugs as well.

# Reliability Assurance

## Quality Assurance System

Under Kissei's Management Philosophy of "contribute to society through high-quality, innovative pharmaceutical products," our pharmaceutical products are manufactured with a rigorous manufacturing and quality control system in compliance with the Good Manufacturing Practice (GMP) system, to provide a stable supply of high-quality pharmaceutical products to patients. Each factory maintains an appropriate GMP system by conducting periodic quality audits, and the manufactured pharmaceutical products are shipped only after overall judgment of quality, efficacy, and safety.

Kissei also operates the Kissei Pharmaceutical Quality System (KPQS) to continuously improve the quality and stable supply of pharmaceutical products throughout their life cycles. Under the Kissei Quality Policy, we implement the appropriate management of change and deviation, and subsequent corrective and preventative actions at each plant. We have also established procedures for the handling of information on product quality from the market and the continuous improvement of quality based on a patient's perspective. Pharmaceutical products are subject to periodic monitoring for quality and these quality assurance activities are regularly reviewed by senior management to continuously improve pharmaceutical quality.

**The Basic Philosophy of the Kissei Quality Policy**

Kissei Pharmaceutical will contribute to the health of people around the world by actively operating our pharmaceutical quality system, established with a high sense of ethics, and providing high-quality, innovative pharmaceutical products that are continuously improving.

## Safety Information Management System

Information up to drug approval and sale is collected from clinical trials conducted under controlled conditions. In order for patients to use drugs more appropriately, it is necessary to continue to investigate safety and efficacy after approval for sale.

To ensure patients use drugs safely, we are continually conducting reviews based on safety information collected by medical representatives, which include safety and efficacy information collected through post-marketing surveillance in the use of these pharmaceutical products. If, as a result of these reviews, it is determined that it is necessary to provide new safety measures and information regarding appropriate use, information is provided to healthcare professionals quickly and extensively. In providing safety information, we have developed the Company Safety Information Provision System. This system can be used to provide information promptly to healthcare professionals in response to inquiries regarding side-effects of drugs.

Furthermore, Kissei actively promotes overseas development of its own products. To this end, Kissei has concluded agreements with overseas partner companies to exchange safety information, and is engaged in safety monitoring activities to make sure that patients can use drugs safely, not only in Japan, but also worldwide.



# Corporate Governance

Board of Directors and Board of Corporate Auditors
As of June 25, 2019

Standing, From Left
Kando Nakagawa, Masayuki Isaji, Takahide Kitahara, Shinji Kikuchi, Hiroshi Kusama, Tetsu Takayama, Eiichi Matsushita, Suminori Sagara, Makoto Yonekubo, Hiroshi Ueno

Seated, From Left
Minoru Nomura, Masaki Morozumi, Keiji Fukushima, Yoshio Furihata, Mutsuo Kanzawa, Hiroe Sato, Yasuo Takehana, Shigetaka Shimizu

## Board of Directors

### Mutsuo Kanzawa — Chairman and CEO

1976 Joined the Company
1982 Director
1992 President and CEO
2014 Chairman and CEO (current position)

### Yoshio Furihata — President and COO

1984 Joined the Company
2008 Director, Department Manager of Business Development Department
2010 Corporate Strategy and Planning Department
2012 General Manager of Clinical Development Division
2018 President and COO (current position)

### Hiroe Sato — Executive Vice President

1975 Joined the Company
2006 Director, Department Manager of Corporate Finance & Management Department
2016 Executive Vice President (current position)

### Keiji Fukushima — Managing Director

General Manager of Sales & Marketing Division

1979 Joined the Company
2012 Director
2014 Managing Director (current position)

### Yasuo Takehana — Managing Director

Department Manager of Corporate Strategy & Planning Department

1984 Joined the Company
2012 Director
2016 Managing Director (current position)

### Masaki Morozumi — Director and Senior Adviser

1980 Joined the Company
2008 Director
2010 General Manager of Sales & Marketing Division
2014 President and COO
2018 Director and Senior Adviser (current position)

### Tetsu Takayama — Director

Department Manager of Human Resources Department

1985 Joined the Company
2014 Director (current position)

### Hiroshi Kusama — Director

General Manager of Pharmaceutical Manufacturing Division

1983 Joined the Company
2016 Director (current position)

### Eiichi Matsushita — Director

Department Manager of General Administration Department

1983 Joined the Company
2016 Director (current position)

### Shinji Kikuchi — Director

General Manager of Research and Development Division

1988 Joined the Company
2016 Director (current position)

### Suminori Sagara — Director

Department Manager of Promotion Support Department

1982 Joined the Company
2018 Director (current position)

### Takahide Kitahara — Director

Department Manager of Corporate Finance & Management Department

1986 Joined the Company
2018 Director (current position)

### Shigetaka Shimizu — Outside Director (independent)

1972 Joined The Hachijuni Bank, Ltd.
2011 President and CEO at Hachijuni Lease, Co., Ltd. & Hachijuni Auto Lease, Co., Ltd.
2013 Auditor at HACHIJUNI SECURITIES Co., Ltd.
2014 Director at the Company (current position)

### Minoru Nomura — Outside Director (independent)

1969 Joined Nomura Kogyo Co., Ltd.
1989 President and Representative Director of Nomura Kogyo Co., Ltd.
President and Representative Director of SN SEIKI Co., Ltd.
1998 Chairman of NOMURA CORPORATION OF TAIWAN (current position)
2005 President and Representative Director of NOMURA UNISON Co., Ltd. (current position)
2008 President and Representative Director of Domaine de la Sénéchalière (current position)
2016 Director at the Company (current position)

## Board of Corporate Auditors

### Masayuki Isaji — Corporate Auditor (full-time)

1980 Joined the Company
2010 Director, Department Manager of Research and Development Planning Department
2012 Managing Director
2018 Corporate Auditor (current position)

### Makoto Yonekubo — Corporate Auditor

1970 Joined the Company
2004 Deputy Department Manager of Corporate Finance & Management Department
2011 Corporate Auditor (current position)

### Hiroshi Ueno — Outside Corporate Auditor (independent)

1969 Certified Public Accountant
1974 Certified Tax Accountant
2008 Outside Corporate Auditor (current position)

### Kando Nakagawa — Outside Corporate Auditor (independent)

1976 Attorney at Law
2011 Outside Corporate Auditor (current position)





## Our Basic Approach to Corporate Governance

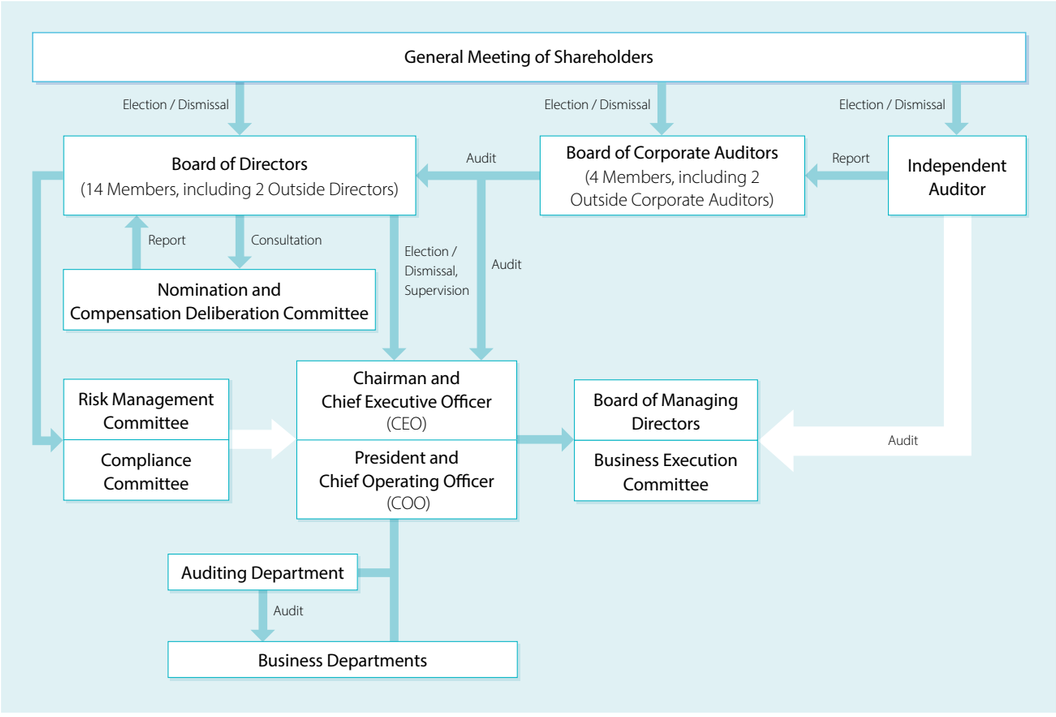
Kissei aims to improve its corporate value and realize sustainable growth as a company with a clear raison d'être. At the same time, the Company positions the enhancement and reinforcement of corporate governance as a core management issue in order to maintain a positive relationship with all of its stakeholders, including shareholders and other investors, customers, local communities, business partners, and employees, as well as to fulfill its social responsibility. As such, the Company established the Kissei Basic Policy on Corporate Governance in October 2015, which represents the Company's basic framework for corporate governance. To improve corporate value, Kissei continuously and periodically revises this policy at Board of Directors' meetings. In keeping with the revised 2018 Corporate Governance Code, we have partially altered our basic policy.

## Overview of Bodies

Kissei's Board of Directors sets basic strategies for Kissei and makes decisions on all important matters while also providing oversight of business execution. The Board of Directors strives to make prompt business decisions and increase the transparency of operations.

The Company employs a corporate governance management system under which the Board Chairman serves as chief executive officer (CEO), given authority over all matters pertaining to management, and the president serves as chief operating officer (COO), responsible for all matters related to business execution. This system delegates certain business execution responsibilities from the Board of Directors, and it was instituted with the aim of strengthening management systems and allowing for management to be conducted more flexibly. In addition, the CEO is responsible for convening meetings of the Board of Managing Directors, which consists of managing directors and directors of a higher rank and is responsible for discussing and ruling on items from a predetermined agenda. Furthermore, the Business Execution Committee

## Corporate Governance Bodies and Internal Control System



has been established as an advisory committee to the COO to aid the COO in decision making and to assist in examining the management matters to be proposed or reported to the Board of Directors.

The Company has adopted a corporate auditor system. This system was deemed rational as the corporate auditors together with the appointed outside directors effectively facilitate improvements in the functionality of the Board of Directors while strengthening management oversight functions.

The Company has 2 internal and 2 outside corporate auditors. Corporate auditors attend meetings of the Board of Directors and actively state opinions. One outside corporate auditor is a licensed attorney and the other is a certified public accountant. Consequently, they are able to conduct audits from a specialist perspective. Moreover, the 2 outside directors and 2 outside corporate auditors are designated independent officers in accordance with regulations of the Tokyo Stock Exchange, to which they report.

## Nomination and Compensation Deliberation Committee

The Company established the Nomination and Compensation Deliberation Committee as an advisory body to the Board of Directors in order to ensure the independence and objectivity of the Board of Directors in its deliberations as well as the transparency of the deliberation process. This committee holds meetings where it engages in discussions on director and corporate auditor candidates for appointment or dismissal as well as levels of director compensation and makes proposals to the Board of Directors.

## Analysis and Evaluation of the Effectiveness of the Board of Directors as a Whole

In an effort to maintain and improve effectiveness, all directors and auditors perform self-evaluations once a year, which are shared with the Board along with results of the analysis and evaluation of the effectiveness of the entire Board of Directors.

The evaluation focuses on eight different areas: (1) establishment of roles for the Board of Directors, directors, and auditors; (2) organizational frameworks for the Company as a whole; (3) content of proposals made by Board members and corresponding deliberation times; (4) information that should be pursued by the Board; (5) leadership shown by the Chairman of the Board; (6) directors' skills; (7) diversity of Board of Directors members; and (8) performance of the Board of Directors and directors.

In fiscal 2018, the Board was evaluated as being sufficiently effective, displaying effectiveness in decision-making, business execution, and supervisory functions. As we move forward, we will continue to work toward full functionality and improved effectiveness of the Board of Directors based on the results of this year's evaluation.

## Internal Control System and Risk Management Structure

Kissei operates under the management philosophy of "contribute to society through high-quality, innovative pharmaceutical products" and "serve society through our employees." The Kissei Code of Conduct guides employee conduct, with the aim of upholding high ethical standards in R&D, manufacturing, and sales activities, all of which are fundamental to our business as a company involved in life sciences. In addition, Kissei has established the Compliance Committee to provide advice to the Board of Directors to help ensure that all laws and regulations are followed both in letter and spirit. The Company's Compliance Program is conducted on a regular basis, and as part of this program Kissei Pharmaceutical's Compliance Program Manual is continually updated with employees receiving regular instruction on compliance related issues.

Kissei also created the Kissei Basic Policy on Internal Controls, in which every employee is trained. Based on this policy, in addition to maintaining all Company rules, the Risk Management Committee—which is an advisory body to the Board of Directors—was established, and risk management and other internal systems are consequently promoted.





## Audits

Kissei has established the Auditing Department, an independent body that reports directly to the Chief Operating Officer (COO). This 5-member body conducts internal audits for each department and all internal systems in Kissei based on the annual auditing plan, ensuring that all departments are carrying out business activities in an appropriate manner.

The Board of Corporate Auditors and the Auditing Department discuss the auditing systems and auditing plan at the beginning of each fiscal year. In addition, they meet every month to exchange opinions on the status of the audits being conducted.

Furthermore, 2 certified public accountants belonging to Ernst & Young ShinNihon LLC provide the Company with accounting services. An additional 9 certified public accountants and 8 other audit personnel provide assistance in the auditing of the Company.

Kissei regularly undergoes outside auditing by an independent auditor. The independent auditor engages in discussions with members of the Board of Directors, finance officers, the Auditing Department, and the Board of Corporate Auditors, which aids the strengthening and maintenance of the corporate governance structure. In addition, the Tripartite Auditing Council convenes periodically, providing an opportunity for corporate auditors, the Auditing Department, and the independent auditor to work together to make joint audit engagements more effective.

## Policies for Determining Director Compensation Amounts and Calculation Methods

Director compensation comprises a base salary and a bonus; the policy for determining the amount/calculation method is explained hereafter.

Base salary is determined by director rank (position) as a member of the Board, and also includes an additional amount based on individual experience and Company performance.

Bonus is determined by director rank within the Board, and takes into account the Company's performance for the period, with similar consideration given toward the amount of compensation according to position.

## Cross-Shareholdings

Kissei's basic policy is to maintain no cross-shareholdings unless it is deemed they will contribute to the Group's business stability and improve corporate value through the development and strengthening of business relationships and alliances. At the end of March 2019, the Board of Directors conducted both a quantitative and qualitative appraisal of the Company's cross-shareholdings. The quantitative factors included related revenue, such as dividends and transaction earnings, the impact of impairment probability, and stock price fluctuations on Company equity, in addition to a qualitative examination of holding necessity. After this appraisal, it was determined that all cross-shareholdings were consistent with the Company's basic policy.

### Total Compensation of Officers by Type and Classification and Number of Applicable Officers

| | Millions of yen | | | | | |
|---|---|---|---|---|---|---|
| | | Totals by compensation type | | | | |
| Classification | Total compensation | Base compensation | Stock options | Bonuses | Retirement benefits | Number of applicable officers |
| Directors (excluding outside directors) | 325 | 311 | — | 13 | — | 14 |
| Corporate auditors (excluding outside corporate auditors) | 37 | 34 | — | 3 | — | 3 |
| Outside officers | 28 | 27 | — | 1 | — | 4 |

## Interview with Outside Directors

**Shigetaka Shimizu**
Outside Director

**Minoru Nomura**
Outside Director

### What are your thoughts on your role as an outside director, as well as the decision-making process and efficacy of the Board of Directors? Q.1

**Director Shimizu:** I am committed to speaking at meetings of the Board of Directors from an objective standpoint, as a member of society, a shareholder, and a representative for stakeholders. I think that the Board of Directors has sufficient time to examine topics of discussion in advance, and their process—from preparation to decision-making—is solid. I feel that the atmosphere surrounding proceedings as led by the chairperson is very fair and open; there is no problem in regards to compliance, and governance is secure.

**Director Nomura:** My role is to give my opinion from the standpoint of an independent outside director based on my experience and knowledge so that Company management can move in the right direction. I also think it is my duty to advise the Board of Directors from the perspective of shareholders. The decision-making process of the Board of Directors (which takes into account prior deliberations in Executive Committee and other executive meetings) is well-organized and puts Company management on the right path. Proposals are brought before the Board of Directors after thorough consideration, and I think that the chairperson demonstrates the leadership necessary to conduct very efficient deliberation. Given these facts, I feel strongly that Kissei's corporate culture is based on diligence.

### What are Kissei's strengths? Q.2

**Director Shimizu:** For Kissei, an important management issue is the question of how to move past the negative effects of the silodosin patent expiration and recover performance. The type of discussions that take place at labor management council meetings show that employees possess a very strong sense of loyalty to the Company. I believe employees share the same sense of urgency toward this matter as management. That is Kissei's strength and what will lead to the Company's recovery.

**Director Nomura:** I also feel that employee loyalty is high, and if I am to think of why that is, I would have to say corporate culture. Kissei cherishes its employees and has built this culture by understanding that the Company will not improve unless the lives of its employees improve, and this culture has been fostered and spread throughout the Company. As a pharmaceutical company, corporate value is made by providing medicine for patients, but Kissei's strength is the same importance that it places on a corporate culture that cherishes employees.

### What are your thoughts on the Company's plans and initiatives regarding the silodosin patent expiration? Q.3

**Director Shimizu:** The timeline for the current medium-term management plan has been set at five years as opposed to the three in previous plans, and in this time we will indicate to stakeholders that we have a road map to recovery, and that we are taking measures to ensure regrowth. In addition, a sense of speed is important, but because equity ratio is high and strong, it is necessary to work with a medium- to long-term plan regardless of the prospects of the near future, and we have acknowledged that the plan can be executed at the current time. Kissei's employees are deeply loyal and share management's sense of urgency; through this, I am confident that they can overcome the deterioration of the Company's business results and recover.

**Director Nomura:** In our annual report, Kissei has named eight initiatives to be addressed. If these issues are firmly dealt with, it should be possible to rally back and find regrowth as an R&D-oriented pharmaceutical company. I think that these initiatives are properly communicated and addressed throughout the Company, starting with the R&D department. Given the patent expiration on core products, results may temporarily be severe, but Kissei has an admirable corporate culture. I fully believe that we can use this culture as a tailwind and be united as a company through the recovery process.



# Corporate Social Responsibility (CSR)

## CSR Management

Based on its management philosophy and vision, the Kissei Group has used its pharmaceutical products to contribute to the health of its customers for many years in addition to conducting a variety of initiatives as a corporate citizen and deepening its relationships of trust with each and every stakeholder. We are pushing ahead with CSR management as part of efforts to expand our business activities and our goal for continuous growth as a company that is truly needed by society.

## Relationships with Patients

### Activities to Spread Medical Information

**Spreading Information on the Proper Use of Pharmaceutical Products**

To ensure that pharmaceutical products are used accurately and properly, medical representatives (MRs) cooperate with the support departments, which are highly knowledgeable and experienced in the medical and pharmaceutical sciences, to deliver valid and precise information on pharmaceutical products to healthcare professionals. MRs also collect information on the safety and effectiveness of pharmaceutical products used at medical sites and offer feedback to the pharmacovigilance and post-marketing surveillance / R&D sections, which is applied to the development of better pharmaceutical products and product information updates.

MRs add to their wealth of knowledge by means of education and training. Through use of tablet PCs equipped for the safety information system, which offers quick access to safety information, and the "K-Net Conference" system, a service for online meetings and conference sessions, MRs can deliver higher quality information.

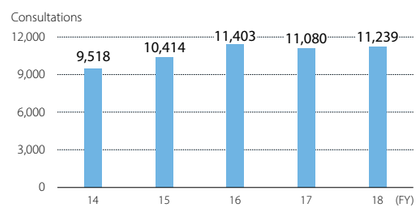
**Establishment of the Product Customer Service Center**

We have established the Product Customer Service Center to encourage proper use of pharmaceutical products and thus improve their efficacy. In fiscal 2018, we responded to 11,239 questions from patients and healthcare professionals.

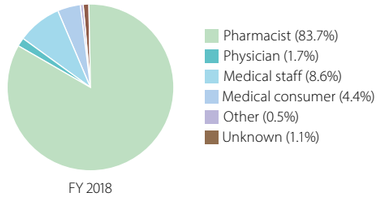
In addition, we are working to build more responsive systems, such as a dedicated phone line for urgent questions on pharmaceutical products that must be administered immediately after the appearance of symptoms.

**Number of Consultations**

**(Inquires answered by Product Customer Service Center from outside of Company)**

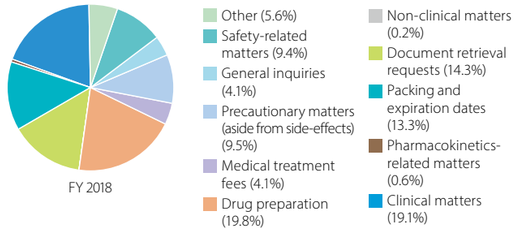



**Consultations by Type of Inquirer**




FY 2018

**Breakdown by Nature of Consultation**




FY 2018

## Relationships with Society

### Contributions to Medical Treatments and Health

**Public Interest Incorporated Foundation Kanzawa Medical Research Foundation**

Established in 1997, the Kanzawa Medical Research Foundation offers grants, awards, and lectures for multifaceted research on various diseases affecting women of reproductive age, particularly at the perinatal stage, and those of advanced age. In a society with declining birth rates and an aging population, developing medicine to maintain and improve the health of women is a vital contribution to improving the health and welfare of the population.

**Number and Total Amounts of Awards and Grants Offered between Fiscal 1997 and 2018**

| | Number | Total amount |
|---|---|---|
| Kanzawa Medical Award | 20 | ¥ 59 million |
| Research Grants | 217 | ¥247 million |
| Overseas Study Grants | 82 | ¥ 41 million |

**Establishment of Privately Funded University Courses including Joint Research**

We established a privately funded university course under the Shinshu University School of Medicine in 2010 to explore the etiology and pathology of intractable neurological diseases, such as spinocerebellar ataxia (SCA) and amyotrophic lateral sclerosis (ALS). In 2012, we worked together with the university to conduct courses with the aim of cultivating human resources and exploring possibilities for new drug creation. This course was different from the other highly dependable courses we have sponsored in that both university and Company resources were offered as part of its collaborative research nature. Through such courses, we are

promoting R&D to facilitate education, information exchange, possibilities for new drug creation, and commercialization. One of the achievements made through this effort was the support of research taking place at the Shinshu University Department of Pediatrics into immunotherapy utilizing CAR-T (chimeric antigen receptor-expressing T cells) technology for the treatment of cancer.

Another privately funded course we established, also in 2012, is on cutting-edge treatment of immunological diseases and cancer at the Graduate School of Medicine at Juntendo University, and is continuing as a joint research course from 2018. Our goal is to contribute to the development of research and new treatments for patients with cancer, immunological diseases, and allergies.

### Contribution to Music Culture

**Seiji Ozawa Matsumoto Festival**

We believe that supporting and encouraging cultural activities that move people is one of a company's crucial roles. As such, we have acted as a sponsor for the Seiji Ozawa Matsumoto Festival (formerly the Saito Kinen Festival Matsumoto), an international music festival held at the beginning of fall every year in Matsumoto City, since its inception in 1992.

Concert by the Saito Kinen Orchestra
©Takeshi Yamada

## Relationships with Our Employees

**Our Stance on Human Resources**

We are taking steps to cultivate human resources and create an environment where our diverse employees can display their skills to their utmost based on the stance that intellectual stimulation results from mutual respect for a variety of mindsets and values, inciting creativity and dynamism in the Company.

As part of our continued efforts to create a working environment that encompasses employment, labor conditions, and human resources management, we have adopted a multiselective human resources system which gives consideration to our employees' aptitudes and life plans. In addition, we are also introducing multiple systems to our departments, such as flextime and deemed working hours, in order to make worktime more flexible, and allowing a variety of personnel to work to their fullest capability. We are also working to construct a system that allows as many people as possible to work through job-sharing roles, which includes establishing a post-retirement re-employment system.

**Cultivating Human Resources**

The Kissei Group has set "enabling employees to demonstrate their strengths to the utmost degree as both an individual and a part of an organization" as an objective in its vision for human resources cultivation. To achieve this vision, we are developing policies for human resource cultivation based on employee-entered self-improvement, Company-centered environment creation, and management-centered guidance.

**Vision for Human Resources Cultivation**

1. Cultivate independent employees that understand the Company's social mission, contribute to the Company's development, and are highly creative, responsible, and capable.
2. Cultivate competent businesspeople capable of promoting organizational objectives for efficiency and work to enhance in them the knowledge and skills necessary to perform Company duties in light of management and technology reform.
3. Cultivate members of society with open-minded, refined, and amiable personalities who are capable of building strong relationships and are full of honesty and humanity.

**Cultivating the Next Generation**

Kissei is a company that enables employees to balance work and home life, including childcare, and by creating an environment that is easy for all employees to work in, they are able to demonstrate their full potential. Kissei is making every effort to establish this type of work environment.

These efforts were evaluated and recognized in 2008, 2011, and 2015 with certification as a standards-compliant general business owner (known as Kurumin) based on the Act on Advancement of Measures to Support Raising Next-Generation Children.*

Furthermore, in 2017 Kissei was granted special Platinum Kurumin certification in recognition of reaching an even higher standard in providing exemplary childcare support.


* Act on Advancement of Measures to Support Raising Next-Generation Children: Laws enacted by national and local public entities and businesses to promote measures to support raising next-generation children. These measures are designed to create an environment in which children, who will be responsible for society in the coming generation, can be born and raised in a healthy manner

**Workplace Health and Safety**

In order to guarantee a safe working environment where employees can do their jobs with peace of mind, we have established the Environment, Health and Safety Committee and are implementing safety- and health-related activities. The health and safety subcommittees at each respective workplace head up these initiatives and maintain safe working environments by training new hires in safety and disaster prevention, conducting regular patrols of worksites and work environment assessments, and through educational activities to raise safety awareness.

**Work-Related Accidents**

| (FY) | 2014 | 2015 | 2016 | 2017 | 2018 |
|---|---|---|---|---|---|
| Incidences of work-related accidents (resulting in time off from work) | 4 (0) | 3 (1) | 5 (0) | 2 (2) | 7 (2) |
| Rate of frequency*1 | 0.00 | 0.31 | 0.00 | 0.65 | 0.65 |
| Rate of severity*2 | 0.00 | 0.00 | 0.00 | 0.01 | 0.00 |

*1: Number of injuries resulting in one or more days off per 1 million hours worked
*2: Number of work days lost due to injury per 1,000 hours worked





**Enactment of the Kissei Health Declaration**

Kissei is committed to its management philosophy and will "contribute to society through high-quality, innovative pharmaceutical products" and "serve society through our employees." In order to realize the goals stated in our management philosophy, we established the Kissei Health Declaration in April 2017, based on the belief that each and every employee must be healthy both in mind and body.

Kissei strives to maintain and enhance the health of employees and their families, while instilling a sense of purpose and drive. At the same time, we aim to create a healthy and vibrant workplace environment where each and every employee is able to reach their full potential.

**Kissei Health Declaration**

Enacted on April 1, 2017

We will contribute to the health and medical care of people around the world by providing ethical drugs and other high-quality, innovative pharmaceutical products. (From the Kissei Code of Conduct)

To that end, each and every employee must be healthy both in mind and body.

Kissei strives to maintain and enhance the health of employees and their families while instilling a sense of purpose and drive. At the same time, we aim to create a healthy and vibrant workplace environment where each and every employee is able to reach their full potential.

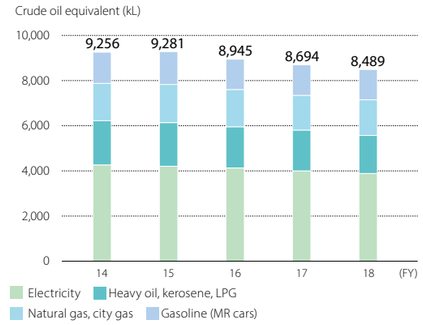
1. The Company and the health insurance association recognize health problems of employees as important management issues and will therefore provide opportunities for employees to maintain and improve the health of their mind and body, and create a workplace that is both healthy and easy to work in. We will actively engage in harmony (work-life balance) between company life and personal life of our employees.
2. Employees recognize the importance of self-care in terms of managing their own health, and will create a healthy body and mind by actively maintaining and promoting their own health.

## Environmental Initiatives

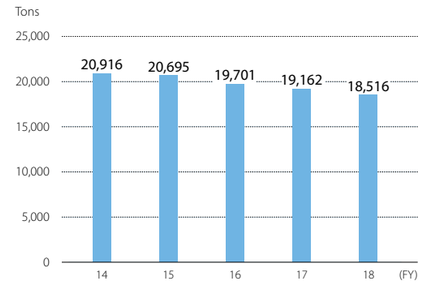
**Basic Stance**

Initiatives to address environmental problems are the responsibility of all of humanity and are an essential element of a company's survival and operations. In recognition of this, the Kissei Group is working to preserve the environment and reduce the environmental impact of all its business activities. Our basic environmental policy lays out our fundamental philosophy and six key principles. Every year, we establish specific environmental objectives on the basis of this policy. Some of those include efforts to reduce energy use and $CO_2$ emissions, as well as the amount of waste generated.

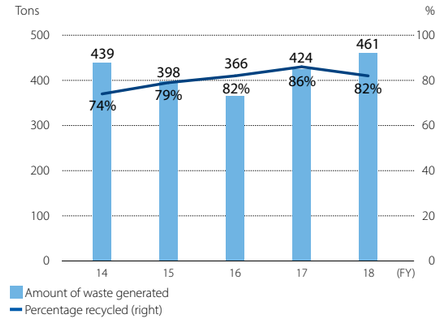
**Trend in Energy Usage**



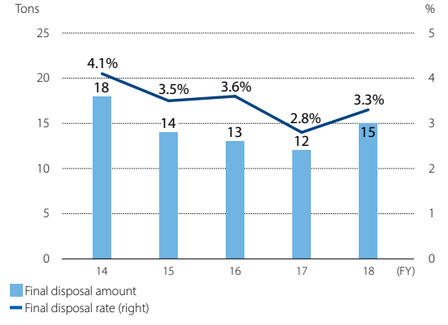

**$CO_2$ Emissions**




**Amount of Waste Generated and Percentage Recycled**




**Final Disposal Amount and Final Rate of Disposal**



# Financial Review

## Financial Position

For the fiscal year under review, ended March 31, 2019, total assets stood at ¥213,522 million, up ¥2,701 million from the previous fiscal year-end. Total current assets decreased ¥2,380 million, to ¥95,782 million, due to decreases in notes and accounts receivable, marketable securities, and inventories despite an increase in cash on hand and in banks. Total non-current assets were up ¥5,081 million, to ¥117,739 million, mainly reflecting an increase in investments in securities.

Total liabilities amounted to ¥30,814 million at the fiscal year-end, down ¥3,913 million from the previous fiscal year-end. Total current liabilities stood at ¥13,801 million, down ¥3,646 million, mainly due to decreases in income taxes payable and notes and accounts payable. Total long-term liabilities were down ¥267 million, to ¥17,013 million, despite an increase in deferred tax liabilities, as a result of a decrease in net defined benefit liability.

Total net assets amounted to ¥182,707 million at the fiscal year-end, an increase of ¥6,614 million compared with the previous fiscal year-end. This increase mainly reflected an increase in retained earnings and net unrealized holding gains on securities, in addition to other factors.

As a result, the shareholders' equity ratio was 85.4%, up from 83.3% at the previous fiscal year-end.

## Financial Results

Net sales for the fiscal year ended March 31, 2019 decreased 2.3% year on year, to ¥72,297 million. Accounting for the majority of net sales, the segment sales of the Kissei Group's core pharmaceutical business were down ¥2,371 million, or 3.7%, to ¥61,520 million. While patents for Urief® Tablet and Urief® OD Tablet expired in December 2018, aggressive promotional activities resulted in higher sales of our main products, such as Urief® Tablet and Urief® OD Tablet; P-TOL® Chewable Tablet, a drug for the treatment of hyperphosphatemia; and RECTABUL® 2mg Rectal Foam 14 Doses, a treatment for ulcerative colitis. However, reforms to the NHI Drug Prices Standard System in Japan, implemented in April 2018, and lower revenue from technical fees led to the overall drop. In other business segments, net sales were up ¥658 million, or 6.5% year on year, to ¥10,777 million due to increased revenues in information services, merchandising, and construction industries.

The cost of sales ratio was up 2.0 percentage points. As a result, gross profit decreased ¥2,554 million, or 5.3% year on year, to ¥45,566 million.

In selling, general and administrative expenses, while R&D expenses increased, selling, general and administrative expenses decreased. As a result, operating income decreased ¥3,684 million, or 37.3% year on year, to ¥6,202 million

Gain on sales of investment securities decreased, and valuation of securities went from a gain in the previous fiscal year to a loss in the fiscal year under review. As a result, total other income (expenses) came to ¥918 million, down ¥890 million compared to the previous fiscal year.

As a result of the above, profit before income taxes and non-controlling interests was down ¥4,575 million, or 39.1% year on year, to ¥7,121 million, and profit attributable to owners of parent decreased ¥3,564 million, or 39.4% year on year, to ¥5,481 million.

## Basic Policy on the Distribution of Profits / Dividends for the Current and Coming Fiscal Years

Kissei aims to secure a solid management base while providing stable, consistent returns to shareholders through cash dividends.

Kissei's basic dividend policy is to make twice-yearly dividend payments, comprised of interim and year-end cash dividends. The Board of Directors decides the amount of the interim cash dividend, while the General Meeting of Shareholders decides the amount of the year-end cash dividend. Also, Kissei's articles of incorporation stipulate that a resolution of the Board of Directors enables the payment of interim cash dividends with a date of record of September 30 each year.

In the fiscal year under review, the Group paid an interim cash dividend of ¥25.0 per share and a year-end cash dividend of ¥25.0 per share, giving a full-year cash dividend of ¥50.0 per share.

For the coming fiscal year, the Group plans to pay an interim cash dividend of ¥26.0 per share and a year-end cash dividend of ¥26.0 per share, giving a full-year cash dividend of ¥52.0 per share.

Internal funds are maintained to respond to expected changes in government policy, system reforms, and the challenges of increasing globalization. At the same time, Kissei will actively invest in R&D to develop drugs that patients need. Kissei believes this policy will not only contribute to future profits but also enable Kissei to distribute profits to its shareholders appropriately.



# Business Risks

The following are the most significant risks which could potentially affect the Kissei Group's operating results and financial position. Forward-looking statements are based on the judgments the Kissei Group has made from the consolidated financial statements for fiscal 2018.

### 1 R&D

The process of developing pharmaceuticals—from the R&D stage to approval and sales—requires large investments of both time and funds. When developing new drugs, the chances of discovering beneficial indications are limited. In addition, Kissei can guarantee neither that a new drug undergoing development or an additional indication will have its intended benefit nor predict when or if the drug will be approved.

### 2 Medical System Reform

The prices of pharmaceuticals in Japan are set based on the government's NHI drug prices and are revised on a regular basis. There may be revisions to Japan's health insurance system or reforms that go beyond Kissei's assumptions, such as the introduction of diagnosis procedure combinations or the promotion of generic drugs, which would negatively impact Kissei's operating results and financial position.

### 3 Competition with Other Companies' Products

The Kissei Group faces competition from companies selling products with the same application as its own. In addition, once a patent expires, price competition with generic products of the same composition intensifies. This competition could have a serious impact on the sales of existing drugs.

### 4 Unexpected Side-Effects

Unexpected side effects undiscovered at the R&D stage sometimes appear after a drug has already been marketed. If unexpected side effects or serious adverse events occur, the use of a drug may be limited, or sales of the drug may be terminated completely.

### 5 Manufacturing and Procurement

Malfunctions with production equipment or the inability to procure raw materials in a timely fashion could delay or shut down drug manufacturing. In addition, a quality problem may cause a drug to be recalled, which would negatively impact Kissei's operating results and financial position.

### 6 Intellectual Property Rights

In the event that the Kissei Group is unable to appropriately protect its intellectual property, a third party may be able to use the Kissei Group's technology, which would undermine its competitive superiority in the market.

### 7 Litigation

At present, there is no outstanding litigation affecting the Kissei Group's management. There is the possibility, however, that in the course of its business activities, the Kissei Group could face lawsuits in the future both at home and abroad regarding patent, product liability, environment, and labor matters.

### 8 Environmental Conservation

Pharmaceutical chemical substances used in research and manufacturing processing could have an impact on the environment. Every department and work site in the Kissei Group is working diligently to follow stringent substance management rules to protect the environment. However, if chemical substances were found to have polluted areas around a work site, legal action may be taken against the work site, and Kissei may be faced with large costs to restore the environment, which would negatively impact Kissei's operating results and financial position.

### 9 Information Management

The Kissei Group is paying close attention to the need to protect information by establishing strict rules for the management of personal and confidential information as well as providing education on this issue to employees. However, if an unexpected incident occurred in which information was improperly disclosed, the Kissei Group's image may be tarnished, which could negatively impact Kissei's operating results and financial position.

Besides the business risks mentioned above, there are various other risks faced by the Kissei Group.

# Consolidated Balance Sheets

Kissei Pharmaceutical Co., Ltd. and its subsidiaries
At March 31, 2018 and 2019



| | Millions of yen | | Thousands of U.S. dollars (Note 03) |
|---|---|---|---|
| **Assets** | **2019** | 2018 | **2019** |
| **Current Assets:** | | | |
| Cash on hand and in banks (Notes 04 and 05) | **¥ 26,325** | ¥ 24,371 | **$ 237,162** |
| Notes and accounts receivable (Note 05) | **26,963** | 28,873 | **242,910** |
| Marketable securities (Notes 04, 05 and 06) | **23,039** | 23,288 | **207,559** |
| Inventories (Note 07) | **13,965** | 15,933 | **125,811** |
| Other current assets | **5,491** | 5,698 | **49,468** |
| Allowance for doubtful accounts | **(1)** | (1) | **(9)** |
| Total current assets | **95,782** | 98,163 | **862,901** |
| **Property, Plant and Equipment:** | | | |
| Buildings and structures (Note 14) | **38,691** | 38,489 | **348,568** |
| Less: accumulated depreciation | **(28,754)** | (28,030) | **(259,045)** |
| Buildings and structures, net | **9,937** | 10,458 | **89,523** |
| Land (Note 14) | **12,716** | 12,913 | **114,559** |
| Construction in progress | **—** | 19 | **—** |
| Other | **16,088** | 15,703 | **144,937** |
| Less: accumulated depreciation | **(13,238)** | (12,698) | **(119,261)** |
| Other, net | **2,849** | 3,005 | **25,667** |
| Total property, plant and equipment | **25,503** | 26,396 | **229,757** |
| **Intangible Assets:** | | | |
| Software for internal use | **907** | 1,028 | **8,171** |
| Other | **612** | 687 | **5,514** |
| Total intangible assets | **1,519** | 1,716 | **13,685** |
| **Investments and Other Assets:** | | | |
| Investment securities (Notes 05 and 06) | **86,958** | 81,194 | **783,405** |
| Long-term loans receivable | **118** | 98 | **1,063** |
| Long-term prepaid expenses | **1,999** | 1,608 | **18,009** |
| Deferred tax assets (Note 10) | **644** | 670 | **5,802** |
| Other | **1,046** | 1,026 | **9,423** |
| Allowance for doubtful accounts | **(50)** | (54) | **(450)** |
| Total investments and other assets | **90,716** | 84,545 | **817,261** |
| Total assets | **¥213,522** | ¥210,821 | **$1,923,622** |

The accompanying notes are an integral part of these statements.

| | Millions of yen | | Thousands of U.S. dollars (Note 03) |
|---|---|---|---|
| **Liabilities and Net Assets** | **2019** | 2018 | **2019** |
| **Current Liabilities:** | | | |
| Notes and accounts payable | **¥ 4,347** | ¥ 4,894 | **$ 39,162** |
| Short-term bank loans (Note 08) | **1,730** | 1,730 | **15,586** |
| Current portion of long-term debt (Note 08) | **34** | 27 | **306** |
| Income taxes payable | **465** | 2,375 | **4,189** |
| Accrued bonuses to employees | **1,971** | 2,225 | **17,757** |
| Accrued bonuses to directors and corporate auditors | **18** | 26 | **162** |
| Reserve for sales returns | **17** | 22 | **153** |
| Reserve for sales rebates | **294** | 407 | **2,649** |
| Reserve for sales promotion expenses | **166** | 189 | **1,495** |
| Other current liabilities | **4,756** | 5,550 | **42,847** |
| Total current liabilities | **13,801** | 17,448 | **124,333** |
| **Long-Term Liabilities:** | | | |
| Long-term debt (Note 08) | **1,930** | 1,876 | **17,387** |
| Deferred tax liabilities (Note 10) | **11,388** | 9,935 | **102,595** |
| Net defined benefit liability (Note 11) | **2,750** | 4,623 | **24,775** |
| Accrued retirement benefits to directors and corporate auditors | **157** | 151 | **1,414** |
| Asset retirement obligations | **116** | 114 | **1,045** |
| Other long-term liabilities | **668** | 577 | **6,018** |
| Total long-term liabilities | **17,013** | 17,280 | **153,270** |
| Total liabilities | **30,814** | 34,728 | **277,604** |
| **Contingent Liabilities** (Note 13) | | | |
| **Net Assets:** | | | |
| Shareholders' equity: | | | |
| Common stock: | | | |
| Authorized: 227,000,000 shares | | | |
| Issued: 51,811,185 shares | **24,356** | 24,356 | **219,423** |
| Additional paid-in capital | **24,226** | 24,226 | **218,252** |
| Retained earnings | **106,026** | 102,834 | **955,189** |
| Treasury stock (5,094,713 shares and 5,094,806 shares at March 31, 2018 and 2019, respectively) | **(11,607)** | (11,607) | **(104,568)** |
| Total shareholders' equity | **143,001** | 139,809 | **1,288,297** |
| Accumulated other comprehensive income: | | | |
| Unrealized holding gains on securities | **40,326** | 36,752 | **363,297** |
| Retirement benefits liability adjustments | **(1,065)** | (859) | **(9,595)** |
| Total accumulated other comprehensive income | **39,261** | 35,892 | **353,703** |
| Non-controlling interests | **444** | 390 | **4,000** |
| Total net assets | **182,707** | 176,092 | **1,646,009** |
| Total liabilities and net assets | **¥213,522** | ¥210,821 | **$1,923,622** |

# Consolidated Statements of Income and Consolidated Statements of Comprehensive Income

Kissei Pharmaceutical Co., Ltd. and its subsidiaries
At March 31, 2018 and 2019

## Consolidated Statements of Income

| | Millions of yen | | Thousands of U.S. dollars (Note 03) |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| **Net Sales** | **¥72,297** | ¥74,009 | **$651,324** |
| **Cost of Sales** | **26,731** | 25,889 | **240,820** |
| Gross profit | **45,566** | 48,120 | **410,505** |
| **Selling, General and Administrative Expenses** (Note 17) | **39,363** | 38,232 | **354,622** |
| Operating income | **6,202** | 9,887 | **55,874** |
| **Other Income (Expenses):** | | | |
| Interest and dividend income | **1,112** | 1,081 | **10,018** |
| Interest expense | **(23)** | (23) | **(207)** |
| Gain on sales of investment securities | **3** | 320 | **27** |
| Loss on sales or disposal of property, plant and equipment | **(2)** | (37) | **(18)** |
| Gain (loss) on valuation of securities | **(176)** | 387 | **(1,586)** |
| Impairment loss (Note 18) | **(49)** | — | **(441)** |
| Foreign exchange gain (loss) | **(38)** | 0 | **(342)** |
| Other, net | **92** | 80 | **829** |
| Total other income (expenses) | **918** | 1,809 | **8,270** |
| Profit before income taxes and non-controlling interests | **7,121** | 11,697 | **64,153** |
| **Income Taxes** (Note 10)**:** | | | |
| Current | **1,634** | 3,223 | **14,721** |
| Deferred | **(47)** | (624) | **(423)** |
| | **1,586** | 2,598 | **14,288** |
| **Profit** | **5,535** | 9,098 | **49,865** |
| **Profit Attributable to Non-Controlling Interests** | **54** | 52 | **486** |
| **Profit Attributable to Owners of Parent** (Note 19) | **¥ 5,481** | ¥ 9,045 | **$ 49,378** |

The accompanying notes are an integral part of these statements.

## Consolidated Statements of Comprehensive Income

| | Millions of yen | | Thousands of U.S. dollars (Note 03) |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| **Profit** | **¥5,535** | ¥ 9,098 | **$49,865** |
| **Other Comprehensive Income:** | | | |
| Unrealized holding gains on securities | **3,578** | 15,484 | **32,234** |
| Retirement benefits liability adjustments | **(209)** | 461 | **(1,883)** |
| Total other comprehensive income (Note 12) | **3,368** | 15,945 | **30,342** |
| **Comprehensive Income** | **¥8,903** | ¥25,044 | **$80,207** |
| Comprehensive income attributable to: | | | |
| Shareholders of Kissei Pharmaceutical Co., Ltd. | **¥8,850** | ¥24,983 | **$79,730** |
| Non-controlling interests | **53** | 60 | **477** |

The accompanying notes are an integral part of these statements.



# Consolidated Statements of Changes in Net Assets

Kissei Pharmaceutical Co., Ltd. and its subsidiaries
For the years ended March 31, 2018 and 2019

| | Millions of yen | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Shareholders' equity | | | | Accumulated other comprehensive income | | | |
| | Number of shares of common stock | Common stock | Additional paid-in capital | Retained earnings | Treasury stock | Unrealized holding gains on securities | Retirement benefits liability adjustments | Non-controlling interests | Total net assets |
| **Balance at April 1, 2017** | 54,311,185 | ¥24,356 | ¥24,226 | ¥101,755 | ¥(12,838) | ¥21,268 | ¥(1,313) | ¥329 | ¥157,783 |
| Profit attributable to owners of parent for the year | — | — | — | 9,045 | — | — | — | — | 9,045 |
| Cash dividends paid | — | — | — | (2,270) | — | — | — | — | (2,270) |
| Treasury stock purchased (1,600,538 shares) | — | — | — | — | (4,464) | — | — | — | (4,464) |
| Cancellation of treasury stock (2,500,000 shares) | (2,500,000) | — | (0) | (5,695) | 5,695 | — | — | — | — |
| Net changes in items other than those in shareholders' equity | — | — | — | — | — | 15,483 | 454 | 60 | 15,998 |
| **Balance at April 1, 2018** | 51,811,185 | ¥24,356 | ¥24,226 | ¥102,834 | ¥(11,607) | ¥36,752 | ¥ (859) | ¥390 | ¥176,092 |
| Profit attributable to owners of parent for the year | **—** | **—** | **—** | **5,481** | **—** | **—** | **—** | **—** | **5,481** |
| Cash dividends paid | **—** | **—** | **—** | **(2,289)** | **—** | **—** | **—** | **—** | **(2,289)** |
| Treasury stock purchased (93 shares) | **—** | **—** | **—** | **—** | **(0)** | **—** | **—** | **—** | **(0)** |
| Net changes in items other than those in shareholders' equity | **—** | **—** | **—** | **—** | **—** | **3,574** | **(205)** | **53** | **3,422** |
| **Balance at March 31, 2019** | **51,811,185** | **¥24,356** | **¥24,226** | **¥106,026** | **¥(11,607)** | **¥40,326** | **¥(1,065)** | **¥444** | **¥182,707** |

| | Thousands of U.S. dollars (Note 03) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Shareholders' equity | | | | Accumulated other comprehensive income | | | |
| | Number of shares of common stock | Common stock | Additional paid-in capital | Retained earnings | Treasury stock | Unrealized holding gains on securities | Retirement benefits liability adjustments | Non-controlling interests | Total net assets |
| **Balance at April 1, 2018** | 51,811,185 | $219,423 | $218,252 | $926,432 | $(104,568) | $331,099 | $(7,739) | $3,514 | $1,586,414 |
| Profit attributable to owners of parent for the year | **—** | **—** | **—** | **49,378** | **—** | **—** | **—** | **—** | **49,378** |
| Cash dividends paid | **—** | **—** | **—** | **(20,622)** | **—** | **—** | **—** | **—** | **(20,622)** |
| Treasury stock purchased (93 shares) | **—** | **—** | **—** | **—** | **(0)** | **—** | **—** | **—** | **(0)** |
| Net changes in items other than those in shareholders' equity | **—** | **—** | **—** | **—** | **—** | **32,198** | **(1,847)** | **477** | **30,829** |
| **Balance at March 31, 2019** | **51,811,185** | **$219,423** | **$218,252** | **$955,189** | **$(104,568)** | **$363,297** | **$(9,595)** | **$4,000** | **$1,646,009** |

The accompanying notes are an integral part of these statements.

# Consolidated Statements of Cash Flows

Kissei Pharmaceutical Co., Ltd. and its subsidiaries
For the years ended March 31, 2018 and 2019

| | Millions of yen | | Thousands of U.S. dollars (Note 03) |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| **Cash Flows from Operating Activities:** | | | |
| Profit before income taxes and non-controlling interests | **¥ 7,121** | ¥11,697 | **$ 64,153** |
| Depreciation and amortization | **2,607** | 2,492 | **23,486** |
| Increase (decrease) in allowance reserves | **(397)** | 217 | **(3,577)** |
| Decrease in net defined benefit liability | **(2,174)** | (91) | **(19,586)** |
| Impairment loss | **49** | — | **441** |
| Interest and dividend income | **(1,112)** | (1,081) | **(10,018)** |
| Interest expense | **23** | 23 | **207** |
| Foreign exchange (gain) loss | **(1)** | 2 | **(9)** |
| (Gain) loss on valuation of securities | **176** | (387) | **1,586** |
| (Gain) loss on sales of property, plant and equipment | **(1)** | — | **(9)** |
| (Gain) loss on sales of investment securities | **(3)** | (320) | **(27)** |
| Loss on disposal of property, plant and equipment | **3** | 37 | **27** |
| (Increase) decrease in notes and accounts receivable | **1,910** | (4,142) | **17,207** |
| (Increase) decrease in inventories | **1,968** | 793 | **17,730** |
| (Increase) decrease in other current assets | **16** | 128 | **144** |
| Increase (decrease) in notes and accounts payable | **(546)** | 44 | **(4,919)** |
| Increase (decrease) in other current liabilities | **(219)** | 922 | **(1,973)** |
| Increase (decrease) in other long-term liabilities | **3** | 1 | **27** |
| Other | **(31)** | 0 | **(279)** |
| Subtotal | **9,391** | 10,336 | **84,604** |
| Receipt of interest and dividends | **995** | 985 | **8,964** |
| Payment of interest | **(23)** | (23) | **(207)** |
| Payment of income taxes | **(4,017)** | (2,453) | **(36,189)** |
| Net cash provided by operating activities | **6,346** | 8,845 | **57,171** |
| **Cash Flows from Investing Activities:** | | | |
| Time deposits received | **75** | 75 | **676** |
| Time deposits paid | **(74)** | (75) | **(667)** |
| Reduction of investments in specified trusts | **80** | 66 | **721** |
| Proceeds from sales of marketable securities | **—** | 1,999 | **—** |
| Acquisition of marketable securities | **—** | (1,999) | **—** |
| Acquisition of property, plant and equipment | **(1,093)** | (1,867) | **(9,847)** |
| Proceeds from sales of property, plant and equipment | **152** | 20 | **1,369** |
| Acquisition of intangible assets | **(240)** | (253) | **(2,162)** |
| Acquisition of investment securities | **(406)** | (1,130) | **(3,658)** |
| Proceeds from sales of investment securities | **126** | 574 | **1,135** |
| Payments for loans | **(71)** | (61) | **(640)** |
| Collection of loans | **72** | 99 | **649** |
| Long-term advance payment costs | **(682)** | (403) | **(6,144)** |
| Other | **(25)** | (4) | **(225)** |
| Net cash provided by (used in) investing activities | **(2,087)** | (2,959) | **(18,802)** |
| **Cash Flows from Financing Activities:** | | | |
| Short-term bank loans received | **—** | 80 | **—** |
| Repayment of short-term bank loans | **—** | (80) | **—** |
| Long-term debt received | **91** | 248 | **820** |
| Repayment of long-term debt | **(30)** | (70) | **(270)** |
| Repayment of finance lease obligation | **(77)** | (64) | **(694)** |
| Cash dividends paid | **(2,289)** | (2,270) | **(20,622)** |
| Treasury stock purchased | **(0)** | (4,464) | **(0)** |
| Net cash provided by (used in) financing activities | **(2,306)** | (6,621) | **(20,775)** |
| **Effect of Exchange Rate Changes on Cash and Cash Equivalents** | **1** | (2) | **9** |
| **Increase (Decrease) in Cash and Cash Equivalents** | **1,954** | (737) | **17,604** |
| **Cash and Cash Equivalents at Beginning of Year** (Note 04) | **47,360** | 48,098 | **426,667** |
| **Cash and Cash Equivalents at End of Year** (Note 04) | **¥49,315** | ¥47,360 | **$444,279** |

The accompanying notes are an integral part of these statements.



# Notes to the Consolidated Financial Statements

Kissei Pharmaceutical Co., Ltd. and its subsidiaries

## Note 01 Basis of Presenting the Consolidated Financial Statements

The accompanying consolidated financial statements of Kissei Pharmaceutical Co., Ltd. (the Company) and its subsidiaries (the Companies) are prepared on the basis of accounting principles generally accepted in Japan, which are different in certain respects as to application and disclosure requirements of International Financial Reporting Standards, and are compiled from the consolidated financial statements prepared by the Company as required by the Financial Instruments and Exchange Act of Japan.

## Note 02 Summary of Significant Accounting Policies

### (1) Scope of Consolidation

The numbers of subsidiaries the Company had for the years ended March 31, 2018 and 2019 were four, respectively, of which three were consolidated in the respective years. The subsidiaries that have been included in the scope of consolidation are listed below:

| Name of subsidiaries | % of voting rights owned | Paid-in capital, millions of yen |
|---|---|---|
| Kissei Shoji Co., Ltd. | **100%** | **¥ 50** |
| Kissei Comtec Co., Ltd. | **83%** | **¥334** |
| Hashiba Technos Co., Ltd. | **100%** | **¥ 45** |

### (2) Consolidation and Elimination

In preparing the accompanying consolidated financial statements, all significant intercompany transactions, account balances, and unrealized profits between the Companies have been eliminated, and the portion thereof attributable to non-controlling interests is charged to non-controlling interests.

### (3) Investments in Unconsolidated Subsidiaries

Investments in unconsolidated subsidiaries are carried at cost, cost being determined by the moving average method, as there would be no significant effect in the consolidated statements of income if they were accounted for by the equity method.

### (4) Valuation of Securities

Held-to-maturity debt securities are carried at amortized cost.

Marketable securities classified as other securities are carried at fair value as of the balance sheet date with changes in unrealized holding gain or loss, net of the applicable income taxes, included directly in net assets. The cost of securities sold is primarily determined by the moving average method.

Non-marketable securities classified as other securities are stated at cost primarily determined by the moving average method.

Short-term investments in specified trusts are stated at market value.

### (5) Inventory Valuation

Inventories are mainly valued at cost using the gross average method (the amount on the balance sheet is reduced to reflect decreased profitability).

### (6) Method of Depreciation of Significant Depreciable Assets

(i) Property, plant and equipment (excluding lease assets)

Depreciation is computed using the declining-balance method at rates based on the estimated useful lives of the assets. The range of useful lives is principally from 3 to 50 years for buildings and structures.

Depreciation for buildings acquired on or after April 1, 1998 (excluding facilities attached to buildings) and for both facilities attached to buildings and other non-building structures acquired on or after April 1, 2016 is computed using the straight-line method.

(ii) Intangible assets (excluding lease assets)

Depreciation is computed using the straight-line method.

Software costs for internal use are amortized over their expected useful lives (mainly 5 years) on a straight-line basis.

(iii) Lease assets (pertaining to lease transactions not involving the transfer of ownership)

Lease assets are depreciated by the straight-line method with the respective lease period and the residual value being zero.

### (7) Accounting for Consumption Tax

Consumption tax is imposed at the flat rate of 8% on all domestic consumption of goods and services (with certain exemptions).

Consumption tax withheld upon sale and consumption tax paid by the Companies on their purchases of goods and services are not included in the respective revenue and cost or expenses in the accompanying consolidated statements of income.

### (8) Foreign Currency Translation

Receivables and payables denominated in foreign currencies are translated into yen at the rates of exchange in effect at the balance sheet date, and differences arising from the translation are included in the consolidated statements of income.

Investments in unconsolidated subsidiaries denominated in foreign currencies are translated at the historical exchange rates prevailing at the time such transactions were made.

### (9) Income Taxes

Income taxes of the Companies consist of corporate income tax, local inhabitants taxes, and enterprise tax.

The asset and liability approach is used to recognize deferred tax assets and liabilities in respect of temporary differences between the carrying amounts and the basis of assets and liabilities.

### (10) Allowances, Accrued Bonuses to Employees and Reserves for Certain Expenses

(i) Allowance for doubtful accounts

The Companies provide an "Allowance for doubtful accounts" based on the percentage of their historical bad debt loss incurred against the balance of total receivables in addition to the amount of uncollectable receivables estimated on an individual basis.

(ii) Accrued bonuses to employees

"Accrued bonuses to employees" is provided for based on estimated amounts which the Companies should pay to employees for their services rendered during the six-month period ended on the balance sheet date.

(iii) Accrued bonuses to directors and corporate auditors

"Accrued bonuses to directors and corporate auditors" is provided for based on estimated payments for their performance during the year ended March 31.

(iv) Reserve for sales returns
"Reserve for sales returns" is estimated based on the percentage of the Companies' own actual return history against sales.
(v) Reserve for sales rebates
"Reserve for sales rebates" is provided for in an amount equivalent to the expected amount payable by the Companies to dealers in respect of the balance of accounts receivable at the balance sheet date based on current applicable rebate rates.
(VI) Reserve for sales promotion expenses
"Reserve for sales promotion expenses" is provided for in an amount equivalent to the expected amount payable by the Companies to dealers in respect of products held by dealers at the balance sheet date based on current applicable rates.
(VII) Accrued retirement benefits to directors and corporate auditors
"Accrued retirement benefits to directors and corporate auditors" are provided at the amount payable at year-end in accordance with the Companies' internal regulations.

**(11) Accounting Method for Retirement Benefits**
Accrued retirement benefits and prepaid pension cost for employees have been recorded mainly at the amount calculated based on the retirement benefit obligation and the fair value of the plan assets as of the balance sheet date.
(i) Allocation of expected benefit payments
When calculating retirement benefit obligation, the benefit formula method is used to allocate expected benefit payments to the period.
(ii) Actuarial differences and prior service cost
Prior service cost is amortized through the straight-line method over a term that does not exceed the average remaining service period of employees who are expected to receive benefits under the plans (10 years).

Net actuarial gains or losses are amortized from the following year through the straight-line method over a term that does not exceed the average remaining service period of employees who are expected to receive benefits under the plans (10 years).
(iii) Accounting treatment for unrecognized actuarial gains and losses and unrecognized prior service cost
Unrecognized actuarial gains and losses and unrecognized prior service cost are adjusted for tax effects and then recorded in retirement benefits liability adjustments under accumulated other comprehensive income in the net assets portion of the consolidated balance sheets.

**(12) Recognizing Revenues and Costs of Construction Contracts**
Revenues and costs of construction contracts for which contract revenues, contract costs and the percentage-of-completion can be reliably estimated are recognized by the percentage-of-completion method. The percentage-of-completion is calculated at the cost incurred as a percentage of the estimated total cost. The completed-contract method continues to be applied for construction contracts for which the percentage-of-completion cannot be reliably estimated.

**(13) Profit and Dividends per Share**
Profit attributable to owners of the parent per share is based upon the weighted-average number of shares of common stock outstanding during each fiscal year.

Cash dividends per share shown for each year in the accompanying consolidated statements of income represent dividends approved or declared as applicable to the respective years.

**(14) Research and Development Expenses**
Research and development expenses are recognized as an expense when incurred in accordance with Japanese accounting standards.

**(15) Accounting Standards Issued but Not Yet Effective**
"Accounting Standard and Implementation Guidance on Revenue Recognition"

On March 30, 2018, the ASBJ issued "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29) and "Implementation Guidance on Accounting Standard for Revenue Recognition" (ASBJ Guidance No. 30).
(i) Overview
This is a comprehensive accounting standard for revenue recognition. Specifically, the accounting standard establishes the following five-step model that will apply to revenue from customers:
1. Identify the contract(s) with a customer
2. Identify the performance obligations in the contract
3. Determine the transaction price
4. Allocate the transaction price to the performance obligations in the contract
5. Recognize revenue when (or as) the entity satisfies a performance obligation

(ii) Scheduled date of adoption
The Companies expect to adopt the accounting standard and implementation guidance from the beginning of the fiscal year ending March 31, 2022.
(iii) Impact of the adoption of accounting standard and implementation guidance
The Companies are currently evaluating the effect of the adoption of this accounting standard and implementation guidance on its consolidated financial statements.

**(16) Change in Presentation Methods**
Application of "Partial Amendments to Accounting Standard for Tax Effect Accounting"

The "Partial Amendments to Accounting Standard for Tax Effect Accounting" (ASBJ Statement No. 28, issued February 16, 2018) have been adopted from the beginning of the fiscal year ended March 31, 2019. Accordingly, the Companies have presented deferred tax assets under investments and other assets, and deferred tax liabilities under long-term liabilities.

As a result, ¥2,436 million in deferred tax assets listed under current assets and ¥2,266 million in deferred tax liabilities listed under long-term liabilities were reclassified and included in net calculations of ¥670 million for deferred tax assets under investments and other assets; and amounting the remaining amount of ¥9,935 million was recalculated and presented in deferred tax liabilities under long-term liabilities in the comparative year as at March 31, 2018.





## Note 03 United States Dollar Amounts

The accompanying consolidated financial statements are expressed in yen, and solely for the convenience of the reader, have been translated into U.S. dollars at the rate of ¥111=U.S.$1, the approximate rate of exchange prevailing at March 31, 2019. This translation should not be construed as a representation that all amounts shown could be converted into U.S. dollars at such a rate.

## Note 04 Cash and Cash Equivalents

Cash and cash equivalents at March 31, 2018 and 2019 are as follows:

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Cash on hand and in banks | **¥26,325** | ¥24,371 | **$237,162** |
| Marketable securities | **23,039** | 23,288 | **207,559** |
| Time deposits with original maturities of over three months | **(50)** | (50) | **(450)** |
| Claims with redemption period exceeding 3 months, etc. | **—** | (249) | **—** |
| Cash and cash equivalents | **¥49,315** | ¥47,360 | **$444,279** |

## Note 05 Financial Instruments

**Overview**
(1) Policy for financial instruments
The Companies manage temporary cash surpluses through low-risk financial assets. Further, the Companies raise short-term capital through bank borrowings. The Companies use derivatives for the purpose of reducing risk arising from fluctuations in foreign currency exchange rates and do not enter into derivatives for speculative or trading purposes.
(2) Types of financial instruments and related risk
Trade receivables—notes and accounts receivable—are exposed to credit risk in relation to customers. In accordance with the internal policies for managing credit risk of the Companies arising from receivables, each related division monitors credit worthiness of their main customers periodically, and monitors due dates and outstanding balances by individual customer.

Marketable securities and investment securities are exposed to market risk. Those securities are composed of mainly the shares of common stock of other companies with which the Companies have business relationships. The market value of these securities is periodically reported to the Board of Directors.
(3) Supplementary explanation of the estimated fair value of financial instruments
The fair value of financial instruments is based on their quoted market price, if available. When there is no quoted market price available, fair value is reasonably estimated. Since various assumptions and factors are reflected in estimating the fair value, different assumptions and factors could result in a different fair value.

**Estimated Fair Value of Financial Instruments**
Carrying value of financial instruments on the consolidated balance sheets as of March 31, 2018 and 2019 and unrealized gains (losses) are shown in the following tables. The following does not include financial instruments for which it is extremely difficult to determine the fair value.
(Please refer to *2 in the following.)

| | Millions of yen | | |
|---|---|---|---|
| **As of March 31, 2019** | Carrying value | Estimated fair value | Unrealized gains (losses) |
| **Assets:** | | | |
| Cash on hand and in banks | **¥ 26,325** | **¥ 26,325** | **¥—** |
| Notes and accounts receivable | **26,963** | **26,963** | **—** |
| Marketable securities and investment securities | **108,242** | **108,242** | **—** |
| Total | **¥161,531** | **¥161,531** | **¥—** |
| Derivatives | **¥ —** | **¥ —** | **¥—** |

| | Millions of yen | | |
|---|---|---|---|
| As of March 31, 2018 | Carrying value | Estimated fair value | Unrealized gains (losses) |
| **Assets:** | | | |
| Cash on hand and in banks | ¥ 24,371 | ¥ 24,371 | ¥— |
| Notes and accounts receivable | 28,873 | 28,873 | — |
| Marketable securities and investment securities | 102,709 | 102,709 | — |
| Total | ¥155,954 | ¥155,954 | ¥— |
| Derivatives | ¥ — | ¥ — | ¥— |

| As of March 31, 2019 | Thousands of U.S. dollars Carrying value | Estimated fair value | Unrealized gains (losses) |
|---|---|---|---|
| **Assets:** | | | |
| Cash on hand and in banks | **$ 237,162** | **$ 237,162** | **$—** |
| Notes and accounts receivable | **242,910** | **242,910** | **—** |
| Marketable securities and investment securities | **975,153** | **975,153** | **—** |
| Total | **$1,455,234** | **$1,455,234** | **$—** |
| Derivatives | **$ —** | **$ —** | **$—** |

*1: Methods to determine the estimated fair value of financial instruments and other matters related to securities and derivative transactions

Cash on hand and in banks and notes and accounts receivable

Since these items are settled in a short period of time, their carrying value approximates fair value.

Marketable securities and investment securities

The fair value of stocks is based on quoted market prices. For information on securities classified by holding purpose, please refer to Note 06 Securities.

*2: Financial instruments for which it is extremely difficult to determine the fair value are as follows:

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Unlisted stocks | **¥1,270** | ¥1,272 | **$11,441** |
| Investments in partnerships | **17** | 34 | **153** |
| Investments in unconsolidated subsidiaries | **467** | 467 | **4,207** |

Because no quoted market price is available and it is extremely difficult to determine the fair value, the above financial instruments are not included in "Marketable securities and investment securities."

*3: Redemption schedule for receivables and marketable securities with maturities at March 31, 2018 and 2019 are as follows:

| As of March 31, 2019 | Millions of yen Due in one year or less | Due after one year through five years | Due after five years through ten years | Due after ten years |
|---|---|---|---|---|
| **Assets:** | | | | |
| Cash on hand and in banks | **¥26,325** | **¥ —** | **¥ —** | **¥ —** |
| Notes and accounts receivable | **26,963** | **—** | **—** | **—** |
| Marketable securities and investment securities | **23,040** | **1,866** | **2,468** | **1,000** |
| Total | **¥76,328** | **¥1,866** | **¥2,468** | **¥1,000** |

| As of March 31, 2018 | Millions of yen Due in one year or less | Due after one year through five years | Due after five years through ten years | Due after ten years |
|---|---|---|---|---|
| **Assets:** | | | | |
| Cash on hand and in banks | ¥24,371 | ¥ — | ¥ — | ¥ — |
| Notes and accounts receivable | 28,873 | — | — | — |
| Marketable securities and investment securities | 23,243 | 1,378 | 2,162 | 1,299 |
| Total | ¥76,487 | ¥1,378 | ¥2,162 | ¥1,299 |

| As of March 31, 2019 | Thousands of U.S. dollars Due in one year or less | Due after one year through five years | Due after five years through ten years | Due after ten years |
|---|---|---|---|---|
| **Assets:** | | | | |
| Cash on hand and in banks | **$237,162** | **$ —** | **$ —** | **$ —** |
| Notes and accounts receivable | **242,910** | **—** | **—** | **—** |
| Marketable securities and investment securities | **207,568** | **16,811** | **22,234** | **9,009** |
| Total | **$687,640** | **$16,811** | **$22,234** | **$9,009** |

## Note 06 Securities

The acquisition cost, carrying amount, and gross unrealized holding gains and losses for securities with fair value by security type at March 31, 2018 and 2019 are as follows:

| | Millions of yen 2019 Acquisition cost | Carrying amount | Gross unrealized holding gains | Gross unrealized holding losses |
|---|---|---|---|---|
| Equity securities | **¥18,213** | **¥ 75,396** | **¥57,633** | **¥450** |
| Corporate debt securities | **1,350** | **1,362** | **14** | **1** |
| Other | **30,928** | **31,482** | **733** | **179** |
| Total | **¥50,493** | **¥108,242** | **¥58,381** | **¥632** |





| | Millions of yen 2018 Acquisition cost | Carrying amount | Gross unrealized holding gains | Gross unrealized holding losses |
|---|---|---|---|---|
| Equity securities | ¥18,115 | ¥ 69,658 | ¥51,634 | ¥ 91 |
| Corporate debt securities | 1,350 | 1,347 | 5 | 7 |
| Other | 30,689 | 31,703 | 1,092 | 78 |
| Total | ¥50,155 | ¥102,709 | ¥52,732 | ¥178 |

| | Thousands of U.S. dollars 2019 Acquisition cost | Carrying amount | Gross unrealized holding gains | Gross unrealized holding losses |
|---|---|---|---|---|
| Equity securities | **$164,081** | **$679,243** | **$519,216** | **$4,054** |
| Corporate debt securities | **12,162** | **12,270** | **126** | **9** |
| Other | **278,631** | **283,622** | **6,604** | **1,613** |
| Total | **$454,892** | **$975,153** | **$525,955** | **$5,694** |

Unlisted stocks are not included in the preceding tables because there were no quoted market prices available and it is extremely difficult to determine the fair value.

Sales proceeds of securities classified as other securities and the gross realized gains and losses for the years ended March 31, 2018 and 2019 are as follows:

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Sales proceeds | **¥16** | ¥528 | **$144** |
| Gross realized gains | **3** | 320 | **27** |
| Gross realized losses | **—** | — | **—** |

## Note 07 Inventories

Inventories at March 31, 2018 and 2019 are as follows:

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Merchandise | **¥ 2,013** | ¥ 1,439 | **$ 18,135** |
| Finished goods | **2,740** | 2,559 | **24,685** |
| Work-in-process | **1,950** | 2,043 | **17,568** |
| Raw materials | **7,131** | 9,274 | **64,243** |
| Supplies | **128** | 614 | **1,153** |
| Total | **¥13,965** | ¥15,933 | **$125,811** |

## Note 08 Short-Term Bank Loans and Long-Term Debt

Short-term bank loans outstanding at March 31, 2018 and 2019 represent one-year notes issued by the Companies to banks. Short-term bank loans made during the years ended March 31, 2018 and 2019 bore interest at an average annual rate of 1.08% and 1.08%, respectively.

Long-term debt outstanding of the Companies at March 31, 2018 and 2019 are as follows:

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Non-secured loans with financial institutions, bearing interest at rates ranging from 0.00% to 1.48% due from 2018 to 2022 | **¥1,964** | ¥1,904 | **$17,694** |
| Less: current maturities due within one year | **(34)** | (27) | **(306)** |
| Total | **¥1,930** | ¥1,876 | **$17,387** |

The aggregate annual maturities of long-term debt outstanding at March 31, 2019 are as follows:

| Year ending March 31 | Millions of yen | Thousands of U.S. dollars |
|---|---|---|
| 2021 | ¥16 | $144 |
| 2022 | 13 | 117 |
| 2023 | — | — |
| 2024 | — | — |

* Borrowings of ¥1,899 million ($17,108 thousand) as at March 31, 2019 and ¥1,858 million as at March 31, 2018 from the Japan Agency for Medical Research and Development, a National Research and Development Agency, are no interest bearing. The repayment schedule does not include these amounts as the repayment schedule for these borrowings will be determined upon approval dates for completion of development projects in the future.

## Note 09 Lease Obligations

Lease obligations outstanding of the Companies at March 31, 2018 and 2019 are as follows:

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Lease obligations due from 2018 to 2026 | **¥ 381** | ¥301 | **$3,432** |
| Less: current maturities due within one year | **(110)** | (79) | **(991)** |
| Total | **¥ 271** | ¥221 | **$2,441** |

* The average interest rate of lease obligations is not stated because lease obligations appear in the consolidated balance sheets as total amounts before deductions of interest equivalents included in lease payments.

The aggregate annual maturities of lease obligations (excluding current portion) outstanding at March 31, 2019 are as follows:

| Year ending March 31 | Millions of yen | Thousands of U.S. dollars |
|---|---|---|
| 2021 | ¥102 | $919 |
| 2022 | 83 | 748 |
| 2023 | 59 | 532 |
| 2024 | 26 | 234 |

## Note 10 Income Taxes

Deferred tax assets and liabilities at March 31, 2018 and 2019 are as follows:

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| **Deferred Tax Assets:** | | | |
| Prepaid research and development expenses | **¥ 3,545** | ¥ 3,155 | **$ 31,937** |
| Net defined benefit liability | **1,438** | 1,428 | **12,955** |
| Inventory assets | **626** | 492 | **5,640** |
| Accrued bonuses to employees | **601** | 678 | **5,414** |
| Write-down of securities | **438** | 438 | **3,946** |
| Payment of retirement benefits to directors and corporate auditors | **155** | 154 | **1,396** |
| Impairment loss | **150** | 190 | **1,351** |
| Accrued enterprise tax | **90** | 202 | **811** |
| Reserve for sales rebates | **89** | 124 | **802** |
| Other | **745** | 794 | **6,712** |
| Total gross deferred tax assets | **7,882** | 7,659 | **71,009** |
| Valuation allowance | **(1,059)** | (1,100) | **(9,541)** |
| Total deferred tax assets | **¥ 6,822** | ¥ 6,558 | **$ 61,459** |
| **Deferred Tax Liabilities:** | | | |
| Unrealized holding gains on securities | **¥(17,430)** | ¥(15,810) | **$(157,027)** |
| Other | **(137)** | (13) | **(1,234)** |
| Total deferred tax liabilities | **(17,567)** | (15,823) | **(158,261)** |
| Deferred tax assets (liabilities), net | **¥(10,744)** | ¥ (9,264) | **$ (96,793)** |

Reconciliation of the actual tax rate for the years ended March 31, 2018 and 2019 are as follows:

| | **2019** | 2018 |
|---|---|---|
| Effective statutory tax rate | **30.5%** | 30.7% |
| Adjustments: | | |
| Entertainment expenses and other non-deductibles | **1.0** | 0.7 |
| Dividend income not taxable | **(1.0)** | (0.6) |
| Tax benefits due to research and development expenses | **(9.1)** | (9.5) |
| Per capital levy of local inhabitants taxes | **1.2** | 0.7 |
| Valuation allowance | **(0.6)** | (0.0) |
| Other | **0.3** | 0.2 |
| Actual tax rate | **22.3%** | 22.2% |





## Note 11 Funded Defined Benefit Plans

**General Outline of Retirement Benefit Plans Implemented**

The Companies have introduced cash balance plans into their defined benefit corporate pension plans. In certain cases, the Companies pay additional retirement benefits for employees that are not included in the retirement benefit obligations determined actuarially in accordance with the accounting standard for retirement benefits. In addition, a retirement benefit trust has been established as part of the Company's defined benefit corporate pension plans.

For the years ended March 31, 2018 and 2019

(i) Reconciliation of defined benefit obligation at beginning and end of period

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Defined benefit obligation at beginning of period | **¥21,511** | ¥21,021 | **$193,793** |
| Service cost | **863** | 861 | **7,775** |
| Interest cost | **61** | 61 | **550** |
| Actuarial gains and losses incurred this period | **367** | (5) | **3,306** |
| Retirement benefits paid | **(534)** | (426) | **(4,811)** |
| Defined benefit obligation at end of period | **¥22,269** | ¥21,511 | **$200,622** |

(ii) Reconciliation of balance of plan assets at beginning and end of period

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Plan assets at beginning of period | **¥16,887** | ¥15,641 | **$152,135** |
| Expected return on plan assets | **422** | 391 | **3,802** |
| Actuarial gains and losses incurred this period | **(188)** | 253 | **(1,694)** |
| Employer contribution | **1,031** | 1,028 | **9,288** |
| Retirement benefits paid | **(534)** | (426) | **(4,811)** |
| Establishment of employee retirement benefit trust | **1,900** | — | **17,117** |
| Plan assets at end of period | **¥19,518** | ¥16,887 | **$175,838** |

(iii) Reconciliation of defined benefit obligation and plan assets with net defined benefit liability and asset reflected on the consolidated balance sheets

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Defined benefit obligation for funded plan | **¥ 22,269** | ¥ 21,511 | **$ 200,622** |
| Plan assets | **(19,518)** | (16,887) | **(175,838)** |
| Net amount of defined benefit liability and asset on the consolidated balance sheets | **¥ 2,750** | ¥ 4,623 | **$ 24,775** |
| Defined benefit liability | **2,750** | 4,623 | **24,775** |
| Net amount of defined benefit liability and asset on the consolidated balance sheets | **¥ 2,750** | ¥ 4,623 | **$ 24,775** |

(iv) The components of retirement benefit expense

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Service cost | **¥ 863** | ¥ 861 | **$ 7,775** |
| Interest cost | **61** | 61 | **550** |
| Expected return on plan assets | **(422)** | (391) | **(3,802)** |
| Amortization of actuarial gains and losses | **508** | 660 | **4,577** |
| Amortization of prior service cost | **(255)** | (255) | **(2,297)** |
| Other | **50** | 24 | **450** |
| Retirement benefit expense | **¥ 807** | ¥ 960 | **$ 7,270** |

(v) The components of retirement benefit liability adjustment included in other comprehensive income (before tax effect)

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Prior service cost | **¥(255)** | ¥(255) | **$(2,297)** |
| Actuarial gains and losses | **(46)** | 919 | **(414)** |
| Total | **¥(301)** | ¥ 664 | **$(2,712)** |

(vi) The components of retirement benefit liability adjustment included in accumulated other comprehensive income (before tax effect)

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Unrecognized prior service cost | **¥(1,275)** | ¥(1,530) | **$(11,486)** |
| Unrecognized actuarial gains and losses | **2,845** | 2,798 | **25,631** |
| Total | **¥ 1,569** | ¥ 1,267 | **$ 14,135** |

(vii) Plan assets information

Breakdown of plan assets

Ratio of each component of plan assets to amount of total pension assets

| | **2019** | 2018 |
|---|---|---|
| Debt securities | **18%** | 21% |
| Equity securities | **25** | 27 |
| Cash on hand and in banks | **11** | 1 |
| General accounts | **46** | 51 |
| Other | **0** | 0 |
| Total | **100%** | 100% |

* Total pension assets include a retirement benefit trust established as part of the Company's defined benefit corporate pension plans. The proportion of pension assets in trust was 9.7% for the fiscal year ended March 31, 2019.

The expected return on assets has been estimated based on the anticipated allocation to each asset class and the expected long-term returns on assets held in each category.

(viii) Assumptions used in accounting for the above plans (discount rate is displayed as a weighted average)

| | **2019** | 2018 |
|---|---|---|
| Discount rate | **0.4%** | 0.5% |
| Expected rate of return on plan assets | **2.5%** | 2.5% |

## Note 12 Other Comprehensive Income

Reconciling items with income tax effect relating to other comprehensive income for the years ended March 31, 2018 and 2019 were as follows:

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Unrealized holding gains on securities: | | | |
| Amount recognized in the year | **¥ 5,201** | ¥22,543 | **$46,856** |
| Amount of recycling | **(3)** | (320) | **(27)** |
| Before income tax effect adjustment | **5,198** | 22,223 | **46,829** |
| Amount of income tax effect | **(1,620)** | (6,739) | **(14,595)** |
| Unrealized holding gains on securities | **3,578** | 15,484 | **32,234** |
| Retirement benefits liability adjustments: | | | |
| Amount recognized in the year | **(555)** | 259 | **(5,000)** |
| Amount of recycling | **253** | 404 | **2,279** |
| Before income tax effect adjustment | **(301)** | 664 | **(2,712)** |
| Amount of income tax effect | **92** | (202) | **829** |
| Retirement benefits liability adjustments | **(209)** | 461 | **(1,883)** |
| Total other comprehensive income | **¥ 3,368** | ¥15,945 | **$30,342** |

## Note 13 Contingent Liabilities

For the year ended March 31, 2019

No corresponding items.

For the year ended March 31, 2018

No corresponding items.

## Note 14 Government Grants

For the years ended March 31, 2018 and 2019

Government grants of ¥798 million ($7,189 thousand) for buildings and ¥113 million ($1,018 thousand) for land are deducted in calculating the carrying amounts of these assets.





## Note 15 Segment Information

**(1) Overview of Reportable Segments**

The Reportable segments of the Companies are components for which discrete financial information is available and whose operating results are regularly reviewed by the Board of Directors to make decisions about resource allocation and to assess their performance.

As the Companies' primary business is the pharmaceutical business, its reportable segment is the pharmaceuticals segment.

**(2) Method of Calculating Sales and Profit (Loss), Identifiable Assets / Liabilities, and Other Items by Reportable Segment**

The accounting procedure for Reportable segments is the same as that described in Note 02 Summary of Significant Accounting Policies.

Segment profit is calculated based on operating income.

Intersegment sales are recognized based on the price in an arm's-length transaction.

**(3) Changes in Presentation Methods**

Referring Note 02 (16), the Partial Amendments to Accounting Standard for Tax Effect Accounting (ASBJ Statement No. 28, issued February 16, 2018) were applied to consolidated financial results from the beginning of the fiscal year ended March 31, 2019. The comparative amount of segment assets for the fiscal year ended March 31, 2018 has been adjusted accordingly.

**(4) Information on Sales and Profit (Loss), Identifiable Assets / Liabilities, and Other Items by Reportable Segment**

| | Millions of yen | | | |
|---|---|---|---|---|
| | Reportable segments | | | |
| **As of March 31, 2019** | Pharmaceuticals | Total | Other*1 | Total |
| Net sales: | | | | |
| Sales to third parties | **¥ 61,520** | **¥ 61,520** | **¥10,777** | **¥ 72,297** |
| Intersegment sales and transfers | **—** | **—** | **4,647** | **4,647** |
| Total | **¥ 61,520** | **¥ 61,520** | **¥15,424** | **¥ 76,944** |
| Segment profit | **¥ 5,487** | **¥ 5,487** | **¥ 622** | **¥ 6,110** |
| Segment assets | **¥203,818** | **¥203,818** | **¥11,676** | **¥215,494** |
| Other items: | | | | |
| Depreciation*2 | **¥ 2,357** | **¥ 2,357** | **¥ 408** | **¥ 2,765** |
| Increase of property, plant and equipment and intangible assets*2 | **1,899** | **1,899** | **325** | **2,224** |

*1: The Other segment is not a reportable segment; it includes sales of materials and other goods, information solution services, and construction subcontracting.
*2: Depreciation includes the amortization of long-term prepaid expenses. Increase of property, plant and equipment and intangible assets reflects the increase in long-term prepaid expenses.

| | Millions of yen | | | |
|---|---|---|---|---|
| | Reportable segments | | | |
| As of March 31, 2018 | Pharmaceuticals | Total | Other*1 | Total |
| Net sales: | | | | |
| Sales to third parties | ¥ 63,891 | ¥ 63,891 | ¥10,118 | ¥ 74,009 |
| Intersegment sales and transfers | — | — | 5,124 | 5,124 |
| Total | ¥ 63,891 | ¥ 63,891 | ¥15,242 | ¥ 79,134 |
| Segment profit | ¥ 9,205 | ¥ 9,205 | ¥ 632 | ¥ 9,837 |
| Segment assets | ¥200,715 | ¥200,715 | ¥11,883 | ¥212,559 |
| Other items: | | | | |
| Depreciation*2 | ¥ 2,290 | ¥ 2,290 | ¥ 366 | ¥ 2,656 |
| Increase of property, plant and equipment and intangible assets*2 | 2,449 | 2,449 | 497 | 2,947 |

*1: The Other segment is not a reportable segment; it includes sales of materials and other goods, information solution services, and construction subcontracting.
*2: Depreciation includes the amortization of long-term prepaid expenses. Increase of property, plant and equipment and intangible assets reflects the increase in long-term prepaid expenses.

| | Thousands of U.S. dollars | | | |
|---|---|---|---|---|
| | Reportable segments | | | |
| **As of March 31, 2019** | Pharmaceuticals | Total | Other*1 | Total |
| Net sales: | | | | |
| Sales to third parties | **$ 554,234** | **$ 554,234** | **$ 97,090** | **$ 651,324** |
| Intersegment sales and transfers | **—** | **—** | **41,865** | **41,865** |
| Total | **$ 554,234** | **$ 554,234** | **$138,955** | **$ 693,189** |
| Segment profit | **$ 49,432** | **$ 49,432** | **$ 5,604** | **$ 55,045** |
| Segment assets | **$1,836,198** | **$1,836,198** | **$105,189** | **$1,941,387** |
| Other items: | | | | |
| Depreciation*2 | **$ 21,234** | **$ 21,234** | **$ 3,676** | **$ 24,910** |
| Increase of property, plant and equipment and intangible assets*2 | **17,108** | **17,108** | **2,928** | **20,036** |

*1: The Other segment is not a reportable segment; it includes sales of materials and other goods, information solution services, and construction subcontracting.
*2: Depreciation includes the amortization of long-term prepaid expenses. Increase of property, plant and equipment and intangible assets reflects the increase in long-term prepaid expenses.

**(5) Reconciliation Items between Segment Information and the Consolidated Financial Statements**

(i) Major items for adjustments

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Net sales: | | | |
| Total of reportable segments | **¥ 61,520** | ¥ 63,891 | **$ 554,234** |
| Other segments | **15,424** | 15,242 | **138,955** |
| Elimination of intersegment transactions | **(4,647)** | (5,124) | **(41,865)** |
| Reported on consolidated financial statements | **¥ 72,297** | ¥ 74,009 | **$ 651,324** |
| Segment profit: | | | |
| Total of reportable segments | **¥ 5,487** | ¥ 9,205 | **$ 49,432** |
| Other segments | **622** | 632 | **5,604** |
| Elimination of intersegment transactions | **69** | 65 | **622** |
| Adjustments to depreciable assets | **56** | (22) | **505** |
| Other adjustments | **(33)** | 7 | **(297)** |
| Reported on consolidated financial statements | **¥ 6,202** | ¥ 9,887 | **$ 55,874** |
| Segment assets: | | | |
| Total of reportable segments | **¥203,818** | ¥200,715 | **$1,836,198** |
| Other segments | **11,676** | 11,883 | **105,189** |
| Elimination of intersegment transactions | **(1,972)** | (1,777) | **(17,766)** |
| Reported on consolidated financial statements | **¥213,522** | ¥210,821 | **$1,923,622** |

(ii) Other items for adjustments

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Depreciation: | | | |
| Total of reportable segments | **¥2,357** | ¥2,290 | **$21,234** |
| Other segments | **408** | 366 | **3,676** |
| Adjustments | **(157)** | (163) | **(1,414)** |
| Reported on consolidated financial statements | **¥2,607** | ¥2,492 | **$23,486** |
| Increase of property, plant and equipment and intangible assets: | | | |
| Total of reportable segments | **¥1,899** | ¥2,449 | **$17,108** |
| Other segments | **325** | 497 | **2,928** |
| Adjustments | **(102)** | (301) | **(919)** |
| Reported on consolidated financial statements | **¥2,122** | ¥2,645 | **$19,117** |

**(6) Related Information**

(i) Product and service information

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Pharmaceuticals | **¥61,520** | ¥63,891 | **$554,234** |
| Other | **10,777** | 10,118 | **97,090** |
| Total | **¥72,297** | ¥74,009 | **$651,324** |

(ii) Geographical information

(1) Net sales

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Japan | **¥66,143** | ¥65,666 | **$595,883** |
| Europe | **4,176** | 5,402 | **37,622** |
| Other | **1,977** | 2,941 | **17,811** |
| Total | **¥72,297** | ¥74,009 | **$651,324** |

(2) Property, plant and equipment

There are no corresponding items as the Companies do not possess any property, plant or equipment outside of Japan.





(iii) Major customer information

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Alfresa Corporation | **¥11,612** | ¥11,797 | **$104,613** |
| SUZUKEN CO., LTD. | **10,053** | 10,455 | **90,568** |
| MEDICEO CORPORATION | **7,737** | 8,027 | **69,703** |

* Related segment for each major customer is the pharmaceuticals segment.

**(7) Information on Loss on Impairment of Property, Plant and Equipment by Reportable Segment**

For the year ended March 31, 2019

| | Millions of yen | | | |
|---|---|---|---|---|
| | Reportable segment | | | |
| | Pharmaceuticals | Total | Other* | Total |
| Impairment loss | 49 | 49 | — | 49 |

* The Other segment is not a reportable segment; it includes sales of materials and other goods, information solution services, and construction subcontracting.

For the year ended March 31, 2019

| | Thousands of U.S. dollars | | | |
|---|---|---|---|---|
| | Reportable segment | | | |
| | Pharmaceuticals | Total | Other* | Total |
| Impairment loss | 441 | 441 | — | 441 |

* The Other segment is not a reportable segment; it includes sales of materials and other goods, information solution services, and construction subcontracting.

For the year ended March 31, 2018

No corresponding items.

**(8) Information on Amortization of Goodwill and Remaining Unamortized Balance by Reportable Segment**

For the years ended March 31, 2018 and 2019

No corresponding items.

**(9) Information on the Remaining Balance and Gain on Negative Goodwill by Reportable Segment**

For the years ended March 31, 2018 and 2019

No corresponding items.

## Note 16 Related Party Transactions

**(1) Transaction with Companies in which Executives and Their Close Relations Own a Majority of Voting Rights, etc.**

For the year ended March 31, 2019

No corresponding items.

For the year ended March 31, 2018

| Category | Name/ Name of Company | Location | Common stock or Investments in capital (millions of yen) | Type of business or occupation | Ratio of voting rights holding (held)*1 (%) | Relationship with related party | Details of transaction | Transaction amount (millions of yen) | Account | Outstanding amount at the end of the year (millions of yen) |
|---|---|---|---|---|---|---|---|---|---|---|
| Companies in which executives and their close relations own a majority of voting rights | Kanzawa Limited | Matsumoto City, Nagano Prefecture | 10 | Real estate rental, insurance agency | 6.6 (held) | — | Acquisition of treasury stock*2 | ¥4,183 | — | — |

*1: Ratio of voting rights holding (held) is based on total shares issued net of treasury stock.
*2: Terms and conditions of the transaction and its policies: The above transaction was conducted through the Tokyo Stock Exchange Trading Network System for Off-Auction Own Share Repurchase Trading (ToSTNeT-3).

**(2) Transaction with Executives of Important Subsidiaries and Their Close Relations, etc.**

For the year ended March 31, 2019

No corresponding items.

For the year ended March 31, 2018

| Category | Name/ Name of Company | Location | Common stock or Investments in capital (millions of yen) | Type of business or occupation | Ratio of voting rights holding (held) (%) | Relationship with related party | Details of transaction | Transaction amount (millions of yen) | Account | Outstanding amount at the end of the year (millions of yen) |
|---|---|---|---|---|---|---|---|---|---|---|
| Executives of important subsidiaries and their close relations | Yuki Kanzawa | — | — | — | — | *1 | Acquisition of treasury stock*2 | ¥278 | — | — |

*1: He is a close relative of the president and representative director of KISSEI COMTEC CO., LTD., Eiji Kanzawa

*2: Terms and conditions of the transaction and its policies: The above transaction was conducted through the Tokyo Stock Exchange Trading Network System for Off-Auction Own Share Repurchase Trading (ToSTNeT-3).

## Note 17 Selling, General and Administrative Expenses

Selling, general and administrative expenses for the years ended March 31, 2018 and 2019 are as follows:

| | Millions of yen | | Thousands of U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Payroll costs | **¥ 9,245** | ¥ 9,399 | **$ 83,288** |
| Research and development expenses | **15,711** | 14,179 | **141,541** |
| Depreciation | **909** | 784 | **8,189** |
| Other | **13,497** | 13,869 | **121,595** |
| Total | **¥39,363** | ¥38,232 | **$354,622** |

## Note 18 Impairment Loss

The following is a breakdown of the impairment losses for the fiscal year ended March 31, 2019.

| Location | Purpose of Use | Classification | Amount (millions of yen) (thousands of U.S. dollars) | |
|---|---|---|---|---|
| Azumino City, Nagano Prefecture | Idle asset | Land | ¥30 | $270 |
| Takamatsu City, Kagawa Prefecture | Leased asset | Land | ¥14 | $126 |
| Fukuoka City, Fukuoka Prefecture | Idle asset | Buildings and structures, Land | ¥4 | $36 |

The Companies categorize assets by the smallest unit that generates independent cash flow. The Companies assess impairment losses on their business units, whereas idle and leased assets are separately evaluated for impairment.

The Companies made decision and have recognized an impairment loss of ¥49 million ($441 thousand) for idle and leased assets due to a significant decline in their market value by reducing their net book value to the respective net realizable value each asset.

Furthermore, the net realizable value of the idle and leased assets was estimated based on their appraisal value or disposition value.

## Note 19 Amounts Per Share

Amounts per share as of March 31, 2018 and 2019 are as follows:

| | Yen | | U.S. dollars |
|---|---|---|---|
| | **2019** | 2018 | **2019** |
| Net assets | **¥3,901.49** | ¥3,761.03 | **$35.15** |
| Profit attributable to owners of parent | **117.33** | 188.26 | **1.06** |
| Cash dividends | **50.0** | 48.0 | **0.45** |

Diluted profit attributable to owners of parent per share is not presented because there are no dilutive potential of shares of common stock.

Net assets per share are computed based on the net assets excluding non-controlling interests and the number of common stock outstanding at the year end.

Profit attributable to owners of parent per share is computed based on the profit attributable to owners of parent and the average number of shares of common stock outstanding during the year.

Cash dividends per share represent the cash dividends proposed by the Board of Directors together with the interim cash dividends paid.

## Note 20 Subsequent Events

No corresponding items.





Ernst & Young ShinNihon LLC

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Nagano, Japan 390-0874

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Building a better working world

# Independent Auditor's Report

The Board of Directors
Kissei Pharmaceutical Co., Ltd.

We have audited the accompanying consolidated financial statements of Kissei Pharmaceutical Co., Ltd. and its consolidated subsidiaries, which comprise the consolidated balance sheet as at March 31, 2019, and the consolidated statements of income, comprehensive income, changes in net assets, and cash flows for the year then ended and a summary of significant accounting policies and other explanatory information, all expressed in Japanese yen.

*Management's Responsibility for the Consolidated Financial Statements*

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in Japan, and for designing and operating such internal control as management determines is necessary to enable the preparation and fair presentation of the consolidated financial statements that are free from material misstatement, whether due to fraud or error.

*Auditor's Responsibility*

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in Japan. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. The purpose of an audit of the consolidated financial statements is not to express an opinion on the effectiveness of the entity's internal control, but in making these risk assessments the auditor considers internal controls relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

*Opinion*

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Kissei Pharmaceutical Co., Ltd. and its consolidated subsidiaries as at March 31, 2019, and their consolidated financial performance and cash flows for the year then ended in conformity with accounting principles generally accepted in Japan.

*Convenience Translation*

We have reviewed the translation of these consolidated financial statements into U.S. dollars, presented for the convenience of readers, and, in our opinion, the accompanying consolidated financial statements have been properly translated on the basis described in Note 03.

June 25, 2019
Matsumoto, Japan

Ernst & Young ShinNihon LLC

# Corporate Information

As of March 31, 2019

## Corporate Data

Head Office

### Company Name
KISSEI PHARMACEUTICAL CO., LTD.

### Established
August 9, 1946

### Capital
¥24,356 million

### Number of Employees
1,504 (Non-consolidated)

### URL
https://www.kissei.co.jp/e_contents/

## Major Business Locations/Consolidated Subsidiaries

### Headquarters

Head Office
19-48, Yoshino, Matsumoto, Nagano 399-8710, Japan
+81-263-25-9081

Tokyo Head Office
8-9, Nihonbashi-Muromachi 1-chome, Chuo-ku,
Tokyo 103-0022, Japan
+81-3-3279-2761

Tokyo Head Office (Koishikawa)
1-3, Koishikawa 3-chome, Bunkyo-ku, Tokyo 112-0002, Japan
+81-3-5684-3530

### Laboratories

Central Research Laboratories
4365-1, Hotakakashiwabara, Azumino, Nagano 399-8304, Japan

Safety Research Laboratories
2320-1, Hotakamaki, Azumino, Nagano 399-8305, Japan

Pharmaceutical Laboratories
4365-1, Hotakakashiwabara, Azumino, Nagano 399-8304, Japan

Joetsu Chemical Laboratories
197-5, Kamikichi, Kubiki-ku, Joetsu, Niigata 942-0145, Japan

### Plants

Matsumoto Plants
19-48, Yoshino, Matsumoto, Nagano 399-8710, Japan

Shiojiri Plants
9637-5, Kataoka, Shiojiri, Nagano 399-0711, Japan

### Centers

Nutritional Business Center
9637-6, Kataoka, Shiojiri, Nagano 399-0711, Japan

Information Center
4010-10, Wada, Matsumoto, Nagano 390-1293, Japan

### Subsidiaries

**Consolidated Subsidiaries**

KISSEI SHOJI CO., LTD.
1-1, Hiratahigashi 2-chome, Matsumoto, Nagano 399-0014, Japan

KISSEI COMTEC CO., LTD.
4010-10, Wada, Matsumoto, Nagano 390-1293, Japan

HASHIBA TECHNOS CO., LTD.
1-1, Hiratahigashi 2-chome, Matsumoto, Nagano 399-0014, Japan

**Unconsolidated Subsidiaries**

KISSEI AMERICA, INC.
400 Kelby Street, 16FL Fort Lee, NJ 07024, USA
+1-201-363-4630



# Investor Information

As of March 31, 2019

### Stock Exchange Listing
Tokyo

### Stock Code
4547

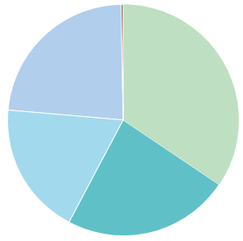
### Common Stock
**Authorized**
227,000,000 shares
**Issued**
51,811,185 shares
**Number of Shareholders**
3,341
(Year-on-year change: 475 decrease)

### Principal Shareholders

| | Number of shares held (hundreds) | Voting rights (%) |
|---|---|---|
| The Dai-ichi Life Insurance Company, Limited | 32,000 | 6.8 |
| Japan Trustee Services Bank, Ltd. (Trust account) | 27,420 | 5.9 |
| The Hachijuni Bank, Ltd. | 23,333 | 5.0 |
| Mizuho Bank, Ltd. | 18,334 | 3.9 |
| Kanzawa Limited | 16,782 | 3.6 |
| The Master Trust Bank of Japan, Ltd. (Trust account) | 15,468 | 3.3 |
| Mutsuo Kanzawa | 15,414 | 3.3 |
| Kissei Group Employee Stockholders Committee | 12,356 | 2.6 |
| Nabelin Co., Ltd. | 12,223 | 2.6 |
| THE NAGANO BANK, LTD. | 11,260 | 2.4 |

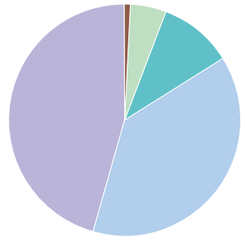
Note: Kissei holds 50,948 hundred shares of treasury stock but is not included in the above list of principal shareholders. Further, the calculation of voting rights percentages is based on total shares issued net of treasury stock.

### Composition of Shareholders by Category



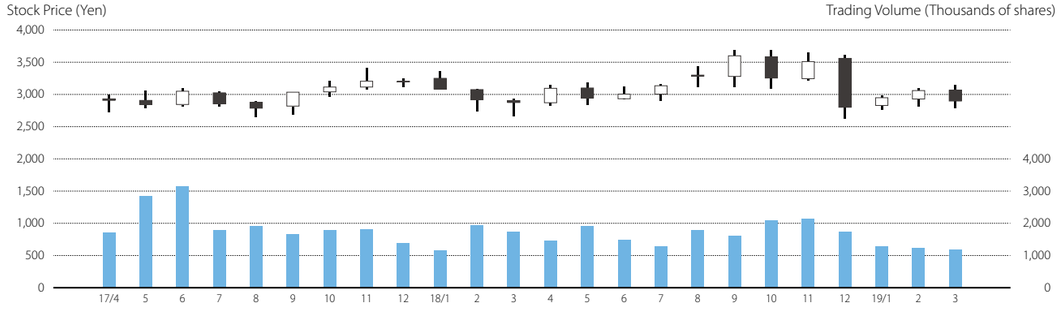
- Securities companies: 25/ 240 thousand shares (0.5%)
- Financial institutions: 44/ 17,842 thousand shares (34.4%)
- Other companies: 171/ 12,145 thousand shares (23.4%)
- Non-Japanese institutions and individuals: 253/ 9,581 thousand shares (18.5%)
- Individuals and others: 2,848/ 12,001 thousand shares (23.2%)

### Composition of Shareholders by Number of Shares Held



- 1–999 shares: 1,949/ 472 thousand shares (0.9%)
- 1,000–9,999 shares: 1,141/ 2,584 thousand shares (5.0%)
- 10,000–99,999 shares: 180/ 5,319 thousand shares (10.3%)
- 100,000–999,999 shares: 60/ 19,880 thousand shares (38.4%)
- 1,000,000 and over shares: 11/ 23,554 thousand shares (45.4%)

### Stock Price Range / Trading Volume



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