Looking Towards Tomorrow's Health

# **ANNUAL REPORT 2018**

For the Year Ended March 31, 2018



## **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 that have earned top shares, including Urief®, a drug

for the treatment of dysuria associated with benign prostatic hyperplasia (BPH); Epoetin Alfa BS Injection [JCR], a drug for the treatment of renal anemia; and P-TOL<sup>®</sup>, a drug for the treatment of hyperphosphatemia, in our priority areas of urology, and renal diseases and dialysis, where we perform strongly. We are also 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.

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#### 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.

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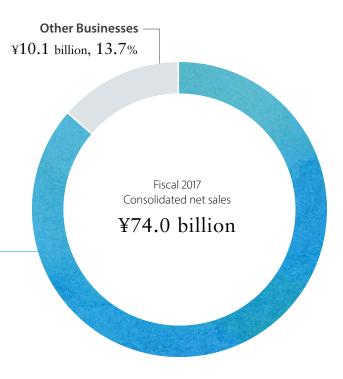
## Kissei's Business

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 ¥63.8 billion, 86.3%

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

In the pharmaceutical business, we are conducting research and development on pharmaceutical products in the priority areas of urology, renal diseases and dialysis, and unmet medical needs. 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.

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#### Therapeutic and care foods

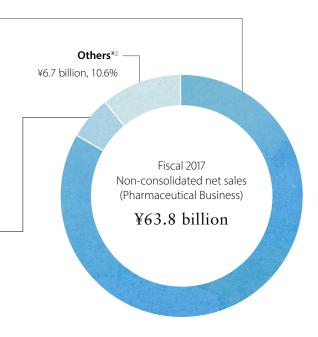
We develop and sell various food products, such as protein controlled foods and energy supply foods, so that people who have restricted dietary habits, such as the elderly and patients suffering from renal diseases, will feel comforted by our foods and be able to enjoy eating them. By leveraging the technology and devel-



¥3.7 billion, 5.9%

¥53.3 billion, 83.5%

opment knowhow 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.

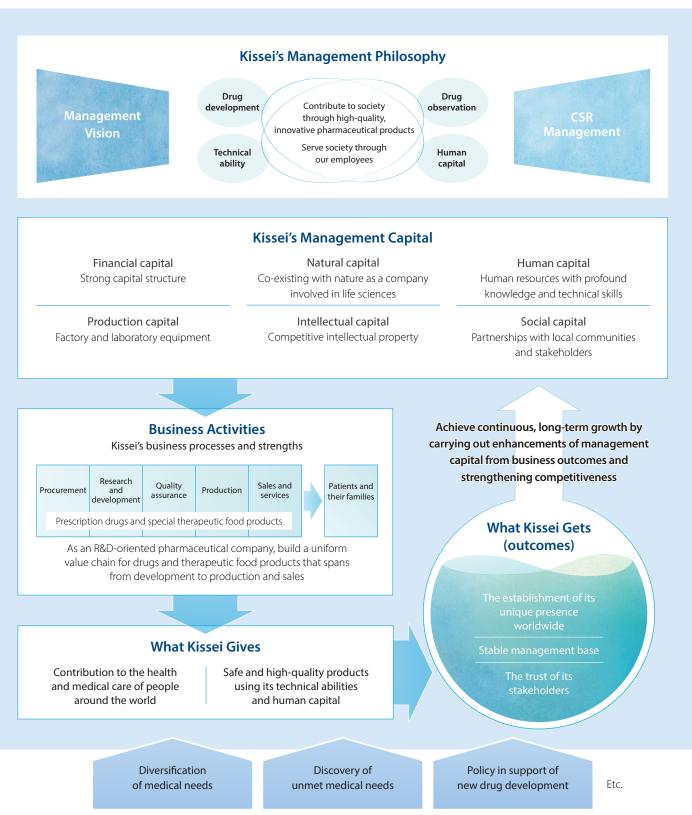


\*1: Including active pharmaceutical ingredients (API) and bulk exports

\*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.



## **External Environments that Impact Operations**

# Financial and Non-Financial Highlights

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

		Millio	ns of yen, except per sha	are data		Thousands of U dollars, excep per share data
	2014	2015	2016	2017	2018	2018
For the Year:						
Net Sales	¥70,399	¥70,110	¥71,294	¥71,706	¥74,009	\$698,198
R&D Expenses	11,298	14,488	14,106	13,877	14,179	133,764
Capital Investment	2,382	1,825	1,942	1,477	1,989	18,764
Operating Income	12,301	8,334	10,274	8,491	9,887	93,274
Profit Attributable to Owners of Parent	9,093	7,165	8,165	7,726	9,045	85,330
At Year-End:						
Total Assets	¥172,649	¥181,484	¥193,345	¥186,801	¥213,087	\$2,010,255
Total Net Assets	142,821	150,720	158,125	157,783	176,092	1,661,245
Per Share (Yen and U.S. Dollars):						
Profit Attributable to Owners of Parent*2:						
Primary	¥176.67	¥142.14	¥166.89	¥158.74	¥188.26	\$1.78
Fully Diluted	—	—	—	—	—	—
Cash Dividends	40.0	42.0	44.0	46.0	48.0	0.45
Key Ratios (%):						
Operating Income Ratio	17.5	11.9	14.4	11.8	13.4	
R&D Expenses Ratio	16.0	20.7	19.8	19.4	19.2	
Return on Assets (ROA)	5.5	4.0	4.4	4.1	4.2	
Return on Equity (ROE)	6.6	4.9	5.3	4.9	5.4	
Shareholders' Equity Ratio	82.6	82.9	81.6	84.3	82.5	
Dividend Payout Ratio	22.6	29.5	26.4	29.0	25.5	
Others:						
Number of Employees	1,883	1,883	1,908	1,905	1,903	
Number of Shares Issued	56,911,185	56,911,185	54,311,185	54,311,185	51,811,185	
Non-Financial Data:						
Energy Used (kL)	9,232	9,256	9,281	8,945	8,694	
CO <sub>2</sub> Emissions (tons)	20,843	20,916	20,695	19,701	19,162	
Amount of Waste Generated (tons)	406	439		366	424	

\*1: U.S. dollar amounts are translated at the rate of ¥106=U.S.\$1, the approximate effective rate of exchange at March 31, 2018.
\*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 "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

#### **Issues to Address**

In order for us to overcome 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.

#### 1 Promote innovative drug discovery

As we develop the strengths of the Company, we will use our evergrowing 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 regional strategies and future innovations in medical technology.

#### 3 Maximize domestic sales of medical drugs by strengthening regional 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. Fiscal 2017 marks the first year of our five-year medium-term management plan, "Co-Creation." As part of this plan, we will focus on realizing the following eight goals as soon as possible.

# 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 healthcare 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.

#### 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 outlicensing of R&D themes, milestone income, and running royalties) The period covered by our "Co-Creation" plan will see the expiration of the patent for Urief<sup>®</sup>, one of our main products. For that reason, we expect to see a drop in domestic and overseas earnings for that drug. In the midst of such a business environment, we have secure plans to launch drug candidates under late stage development, which were expanded under the previous medium-term management plan: "PROGRESS 3." By maximizing sales of these new drugs early on, we will overcome any temporary decreases in earnings. Our plan is to raise consolidated net sales to its current level by the final fiscal year of the new plan.

In order to recover growth at the start of the next medium-term management plan moving forward, our priority is to invest management resources in R&D and expand our product portfolio.

# Letter from the CEO

As an R&D-oriented company, we will make full use of our traditions and work to create new, original value in order to contribute to the healthy and affluent lifestyles 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 pushing forward with patient-centered measures including the undertaking of R&D activities, high-quality manufacturing, the collection and provision of 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.

Currently, 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 diseases 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. This, combined with growing R&D risks, which leads to growing R&D costs, have resulted in increased difficulties 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 led to several social security reforms, particularly in the health insurance and medical care provision systems, one of which is to implement measures to promote the use of generic drugs in order to curb healthcare expenses.

In particular, as part of this year's overhaul of the National Health Insurance Drug Prices Standard System, former systems intended to foster the creation of new drugs and eliminate off-label drug use have been throttled and prices of long-listed drugs are under substantial review. This new system bears a major negative impact on the pharmaceutical industry.

Furthermore, competition within the industry is fierce as companies adapt to a new market structure, spurred by major changes in the global market in the midst of instability overseas.

Amid these significant changes in the business environment, it is our duty as a part of the medical industry to reexamine our role and respond quickly to the coming changes. We believe that our management philosophy, to contribute to society through high-quality, innovative pharmaceutical products and serve society through our employees, will carry us through these changing times and to an even stronger position. We recognize the major turning point that the new Drug Pricing Standard represents, and even in the face of those changes, we plan to continue forward as an R&D-oriented company.

To this end, we have formulated and are implementing our five-year medium-term management plan, "Co-Creation" (fiscal 2017–fiscal 2021), to serve as a concrete roadmap for realizing our management philosophy and vision. In fiscal 2018, the second year of the plan, will see the patent expire for Urief<sup>®</sup>, a drug treatment for dysuria and one of our main products. In anticipation to this, one of the goals of

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"Co-Creation" is to steadily introduce products that are currently in the later stages of our development pipeline into the market. Accordingly, we will work to continuously create new drugs and move them to the early clinical stage with a combination of speed and quality. At the same time, we will expand our portfolio through vigorous licensing activities.

At the annual General Meeting of Shareholders held on June 27, 2018 and the Board of Directors' meeting held the same day, Yoshio Furihata was appointed President and Chief Operating Officer (COO). Reinforced marketing capabilities and a strengthened product portfolio established by Mr. Masaki Morozumi, the previous President and COO, provide the foundation for changes in our management structure. These changes aim to further strengthen R&D capabilities and stimulate the continuous creation of new drugs while establishing a management base for the future that will allow us to tackle new issues that may arise in the changing business environment.

As Chairman and CEO I will continue to oversee overall management and strengthen our framework for sustainable growth as an R&D-oriented company.

Our aim is to always be a highly trusted company that lives up to the expectations of all our stakeholders, including patients, their families, and healthcare professionals as well as our shareholders and employees and the local communities we serve. To accomplish this goal, we will relentlessly pursue our quest to realize Kissei's management vision while forging a path for creating future value through never-ending innovation.

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

June 2018

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

The outlook for the Japanese economy became unclear in fiscal 2017, the year ended March 31, 2018, due to concerns over the direction of U.S. trade policies and a strong yen, despite economic improvement in developed countries in North America and Europe as well as a pickup in economies in China and developing countries in Asia.

Conditions in the pharmaceutical business continue to be harsh, characterized by measures to promote the use of generic drugs aimed at curbing healthcare expenses on top of fierce market competition within the industry. Moreover, despite increasing corporate demand for investment in IT and capital investment in the information services, merchandising, and construction industries, and a gradual recovery of consumer spending, these were not enough to fully drive the economy, which still languishes in a highly competitive environment.

In the pharmaceutical business, net sales increased 4.0% year on year, to ¥63,891 million. While sales of long-listed drugs fell, thanks to efforts including vigorous promotional activities to spread medical information about our mainstay products, sales of P-TOL® chewable tablets for the treatment of hyperphosphatemia; Urief® and Urief® oral disintegration (OD) tablets for the treatment of dysuria associated with benign prostatic hyperplasia (BPH); Epoetin Alfa BS Injection [JCR] drug treatment for renal anemia; and other drugs increased. This, plus increased revenues from exports and technical fees led to an overall increase of pharmaceutical net sales. One of our new products, RECTABUL® 2mg Rectal Foam 14 Doses, jointly developed with EA Pharma Co., Ltd. as a treatment for ulcerative colitis, was released in December 2017. In addition, we have continued our licensing agreement for silodosin (generic name, brand name in Japan: Urief®) 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 2017.

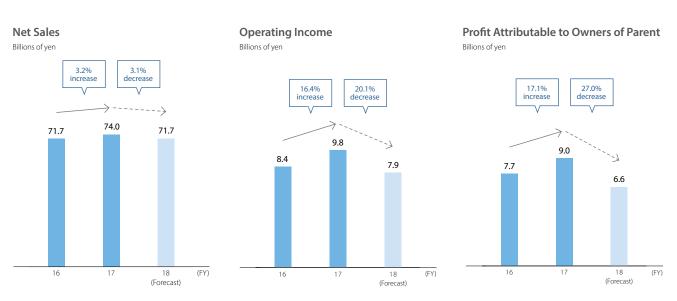
In other businesses, net sales decreased 1.3% year on year, to ¥10,118 million, reflecting a decrease in revenues for the merchandising and construction industries, despite an increase in information services.

Turning to income, selling, general and administrative (SG&A) expenses increased mainly due to R&D expenses, but operating income and profit attributable to owners of parent also increased due to increased revenues.

In terms of R&D, in September 2017 we applied for approval of an additional granular formulation of P-TOL® chewable tablets. In the same month, KYORIN Pharmaceutical Co., Ltd. applied for approval of KRP-114V (development code, generic name: vibegron), an overactive bladder medication co-developed with Kissei. In June 2017, we finalized a contract with Swiss company Vifor Fresenius Medical Care Renal Pharma, Ltd., granting us exclusive rights to develop and commercialize CCX168 (development code, generic name: avacopan), a selective inhibitor of the complement C5a receptor. We are currently participating in international phase III joint clinical trials for the drug with American company ChemoCentryx, Inc. Moreover, in other phase III clinical trials we were able to demonstrate equivalence for darbepoetin alfa (generic name), a long-acting erythropoiesis-stimulating agent for the treatment of renal anemia, in JR-131 (development

code), jointly developed with JCR Pharmaceuticals Co., Ltd. as a proposed biosimilar of darbepoetin alfa. In addition, an application for the approval of an additional dosage form of Glubes<sup>®</sup> (OD tablets) for the treatment of type 2 diabetes, submitted in July 2016, was temporarily withdrawn in June 2017 to conduct additional studies. We also began a phase III clinical trial for AJM300 (development code, generic name: carotegrast methyl), a treatment for ulcerative colitis which is being jointly developed with EA Pharma Co., Ltd. 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. Looking ahead, we will assess 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.



#### **Business Results and Forecast For Fiscal 2018**

## **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, they will continue to exist within a harsh economic climate, despite some signs of recovery.

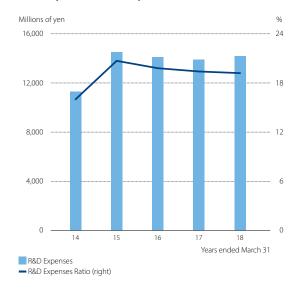
Amid these circumstances, the Kissei Group will focus its efforts on strengthening its management base through the creation of synergies among Group companies. At the same time, we will continue to strive for sustainable growth.

#### Net Sales

In the pharmaceutical business, we will continue our efforts to cultivate Urief®, Glubes®, P-TOL®, and other drugs. However, due to the impact of drug repricing that took place in April 2018, coupled with a decrease in technology sales, we forecast a decrease in sales. For other businesses, however, we anticipate an increase.

#### 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.



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



#### 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 mediumterm management plan "Co-Creation", launched in fiscal 2017, we will work to strengthen our business foundations in order to achieve stable growth into the future. Our management strategy focuses on the following key points.

- 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 way of promoting R&D projects and through dedicated licensing.
- (3) We will expand our presence in the urology, and renal diseases and dialysis 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 outlicensing new drug discovery.

Essential to expanding our product portfolio is maintaining a proper balance of speed and quality both from a drug discovery perspective, in terms of continuous creation and sending creations to early clinical trials, and from a development perspective, in terms of advancing production according to plan. In terms of licensing, we are focused on introducing products in the late stage of development and cultivating KLH-2109 as our new pillar for overseas earnings.

In order to maximize earnings both domestically and internationally, we will focus on maximizing sales on key strategic items, including Urief® and Urief® OD tablets; P-TOL® chewable tablets; Glubes® Combination Tablet; and RECTABUL® 2mg Rectal Foam 14 Doses. We will also continue careful preparations to introduce KRP-114V and granular formulations of P-TOL® into the market for prompt penetration. This action is designed to spark development of the two brands, which are expected to experience large growth in the future. In the therapeutic and care foods business we will establish a robust quality assurance system and improve profitability by strengthening the mail-order business and introducing new products.

In fiscal 2018, we will strengthen our management base and reform our cost structure. This will involve streamlining mediumto long-term costs in terms of Companywide optimization while performing a complete review of our business processes by reexamining all operations. It also involves optimal allotment of our resources—whether human, objects, money, or time—in order to improve quality. The increased resources generated by these endeavors will be prioritized for future growth drivers.

We will also cultivate highly specialized personnel capable of implementing our strategy through taking on challenging business in each organization and department, such as exploring new areas, employing new methods, and adopting new mechanisms, as well as promoting cross-organizational operations. By enabling each employee to reach their full potential, we can achieve our management goals.

As for profit allocation, we recognize the importance of making stable dividend payouts while taking care to secure lasting business foundations, a process based on ensuring that payouts are in line with earnings while working to improve capital efficiency. 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.

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

June 2018

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Yoshio Furihata President and Chief Operating Officer

# 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 unmet medical needs, 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 low molecular weight compounds, but in recent years we have been actively 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.

#### Strengthening Drug Discovery Research



## Reorganizing the R&D Division (April 2017)

Migrating to a matrix-type system that combines management based on the function of each specialized field of research with individual project management



# Early detection of drug candidate compounds by fusion of in silico drug discovery and high-throughput screening (HTS)



#### **Promoting Open Innovation**

Collaborating with biotech ventures, finding novel drug seeds by strengthening ties with industry-government-academia, and strengthening biologics research

Due to the drastic reforms of the NHI Drug Prices Standard System in Japan that took place in April 2018, it is more essential than before that the Company continues to release new drugs.

Our medium-term management plan, "Co-Creation," aims to add multiple original products to our development pipeline which will be responsible for renewed growth for the Company while we continue to introduce developed products to the market.

In April 2017, Kissei reorganized its R&D departmental systems into a cross-functional matrix-type system that combines management based on the function of each specialized field of research with individual project management. This system allows for each research institute to collaborate in each development project, and will ultimately lead to strengthened drug discovery research functions. In addition, we have been developing a high level of expertise of in silico drug discovery efforts spanning over 30 years. Because of the increased number of compound libraries that can be accessed, we are working on the fusion of HTS and in silico technologies to secure the early detection of candidate compounds.

In addition, we are finding more drug seeds through collaboration with biotech ventures and enhanced ties with the Japan Agency for Medical Research and Development (AMED) and Shinshu University. Furthermore, we are actively working to push open innovation forward in order to strengthen our biologics research.

At the present time, we are reviewing a number of drug discovery projects and are dedicated to reporting on them in the near 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.

In September 2017, applications were submitted for approval for manufacturing and sale of KRP-114V (development code, generic name: vibegron), a drug for the treatment of overactive bladder, and a new granular formation of P-TOL®, a drug for treating hyperphosphatemia in patients on dialysis.

KPS-0373 (development code, generic name: rovatirelin), an orally administered drug for the treatment of spinocerebellar ataxia, is a derivative of the thyrotropin-releasing hormone introduced 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. Moving forward, we will conduct detailed studies including subgroup analysis based on the severity of the results obtained from this trial.

JR-131 (development code) is a drug treatment for renal anemia and a biosimilar of darbepoetin alfa (generic name), a long-acting erythropoiesis-stimulating agent. Phase III clinical trials conducted jointly with JCR Pharmaceuticals Co., Ltd. in 2016 confirmed equivalence with darbepoetin alfa, the leading biopharmaceutical of its type. In this trial, we verified the equivalence in efficacy and evaluated the safety of JR-131 in comparison to darbepoetin alfa. Results verified equivalence for variations in hemoglobin concentration (the primary endpoint for efficacy), and similarity with regard to the safety profile was also confirmed. JCR Pharmaceuticals Co., Ltd. is preparing to file an application for approval of manufacturing and sale of this drug based on the trial results.

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 Pharmaceuticals and Medical Devices Agency (PMDA) concerning the results of the prior phase III clinical trial.

CCX 168 (development code, generic name: avacopan), a treatment for rare diseases in the renal disease field, is involved in phase III international joint clinical trials for use as a treatment for antineutrophil cytoplasmic auto-antibody-associated vasculitis (AAV).

We are conducting late phase II clinical trials in Japan for the GnRH antagonist KLH-2109 for the treatment of endometriosis. Overseas, development of the drug is 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 MRI3A9 (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 for pruritus.

Based on the results of a clinical trial focused on malignant mesothelioma held in France, we are conducting phase I and II clinical trials on YS110 (development code), a humanized anti-CD26 monoclonal antibody, on patients in Japan.



Central Research Laboratories



Safety Research Laboratories

## R&D Pipeline As of July 2018

					Stage Phase NDA				
Development Code					Phase	5	NDA prepa- NDA		
	Expected Indications	Category	Development Classification	1	2	3		filed	Remarks
Urology									
KRP-114V (Vibegron)	Overactive bladder	Beta 3 adrenergic receptor agonist	In-licensed / Co-development with KYORIN Pharmaceutical (Japan)						
Renal and dialy	rsis								
P-TOL® (Sucroferric Oxyhydroxide)	Hyperphosphatemia in hemodialysis patients	Phosphate binder	In-licensed / Vifor Fresenius Medical Care Renal Pharma (Switzerland)						Additional dosag form: Granule
JR-131	Renal anemia	Increase the red blood cell (RBC) count	In-licensed / Co-development with JCR Pharmaceuticals (Japan)						A biosimilar "darbepoetin alfa
CCX168 (Avacopan)	ANCA (anti-neutrophil cytoplasmic auto-antibody)- associated vasculitis	A selective inhibitor of the complement C5a receptor	In-licensed / Vifor Fresenius Medical Care Renal Pharma (Switzerland)						
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)						
YS110	Malignant mesothelioma	Humanized anti-CD26 monoclonal antibody	In-licensed / Y's AC, University of Tokyo, AMED (Japan)			Phase	1/2		
KLH-2109	Endometriosis	GnRH antagonist	Kissei						
KDT-3594	Parkinson's disease	Dopamine receptor stimulation	Kissei						

#### **Out-Licensing**

						Sta	ge		Development Company
Development Code					Phase NDA prepa- NDA	Dovelopment			
(Generic Name)	Expected Indications	Category	Territory	1	2	3	prepa- ration	filed	
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)
KLH-2109	Uterine fibroids	GnRH antagonist	Worldwide, excluding some Asian countries such as Japan						ObsEva SA (Switzerland)
KLH-2109	Endometriosis	GnRH antagonist	Worldwide, excluding some Asian countries such as Japan						ObsEva SA (Switzerland)
Bedoradrine	Acute exacerbation of asthma	Beta 2 adrenergic receptor agonist	Worldwide, except for Japan						MediciNova (U.S.)
Bedoradrine	COPD	Beta 2 adrenergic receptor agonist	Worldwide, except for Japan						MediciNova (U.S.)

\*1: Launched in Thailand, India, Indonesia, the Philippines, Cambodia, Myanmar ; Approved in Malaysia; NDA in 2 ASEAN countries \*2: Launched in Thailand, the Philippines, Cambodia, Myanmar ; NDA in 2 countries

Progress after August 2017 covers the area inside the dashed lines.

## Topic 1

Applying for Approval for Manufacturing and Sale of Vibegron (generic name, development code: KRP-114V)

Vibegron is a once daily overactive bladder (OAB) medication having selective beta 3 adrenergic receptor agonist activity which we jointly developed with KYORIN Pharmaceutical Co., Ltd. in Japan.

In phase III clinical trials conducted in Japan, superiority over a placebo was confirmed in average daily urinary frequency, the primary endpoint, and in all secondary endpoints as well. Results of this clinical trial were presented at the European Association of Urology Congress held in March 2018, and the paper was published in the medical journal, *European Urology*.

Application for approval for manufacturing and sale was submitted by KYORIN in September 2017, after acquiring approval and incorporating drug price standards, and the product will be jointly marketed by Kissei and KYORIN.

We consider the urology field to be one of our priority areas and are working to expand our product lineup and heighten our presence in the market. Moving forward, we will utilize our strengths and expertise to promote early market penetration of this drug and in doing so, we strive to further contribute to improving the quality of life of patients suffering from the various symptoms of OAB.

## Topic 2

Exclusive License Agreement and Participation in International Joint Clinical Trials for Avacopan (generic name, development code: CCX168), a Selective Inhibitor of the Complement C5a Receptor for Rare Kidney Diseases

In June 2017 we signed an agreement with Swiss-based Vifor Fresenius Medical Care Renal Pharma Ltd. (VFMCRP) for exclusive rights to develop and market the complement c5a receptor\*<sup>1</sup> (C5aR) avacopan in Japan.

Under the terms of this agreement, we acquired exclusive development rights and marketing rights in Japan from VFMCRP, which holds the global commercial rights of the drug outside of the United States and China. Kissei will conduct development in Japan and exclusively market avacopan once approval of sale is received.

Avacopan, an orally administered small-molecule agent for the treatment of rare kidney diseases, was developed by ChemoCentryx, Inc., in the US. It inhibits C5a receptors in leukocytes, including neutrophils, and exhibits anti-inflammatory properties by preventing the migration of leukocytes as well as the expression and induction of adhesion molecules. Anti-neutrophil cytoplasmic auto-antibody (ANCA)-associated vasculitis (AAV)\*<sup>2</sup>, which is one of the targets of avacopan, is a rare and severe autoimmune disease that is designated as an intractable disease by the Ministry of Health, Labour, and Welfare in Japan. The number of patients with AAV has increased rapidly in recent years, and in many cases, they present necrotizing glomerulonephritis.

Currently, phase III clinical trials are being conducted by ChemoCentryx in Europe, the United States, and other countries for the indication of AAV. Kissei is participating in this international joint clinical trial as it conducts a phase I clinical trial in Japan. Development for this drug is expected to proceed quickly and efficiently.

Phase II clinical trials around C3 glomerulopathy<sup>\*3</sup> are also in progress and phase II clinical trials regarding atypical hemolytic

uremic syndrome<sup>\*4</sup> are in the planning stage. These trials, being conducted overseas, are being handled by ChemoCentryx. Domestic developments regarding these two indications will be under the authority of Kissei.

We are working to expand our product portfolio in the areas of urology, renal and dialysis, and also in areas with high unmet medical needs. We will continue to further strengthen our efforts to treat rare diseases and aim to provide this drug to patients suffering from intractable diseases as soon as possible.

#### \*1: The complement C5a receptor:

A complement is a system of proteins found in blood and is involved in various immune responses and preventing infection. There are many kinds of complements, generally expressed as C by taking the initial letter of complement. Of these, C5a acts as a chemokine (chemotactic factor), attracting neutrophils to the inflamed area. Avacopan is thought to exhibit anti-inflammatory properties by inhibiting the C5a receptor, thereby suppressing the activity of neutrophils that damage blood vessels.

C3G, a designated intractable disease, is a type of primary membranoproliferative glomerulonephritis. It is caused by renal tissue disorders induced by abnormalities in the complement pathway. In Japan, the number of patients with primary membranoproliferative glomerulonephritis is estimated to be over 40 (based on the number of recipients of the certificates for special disease treatment in 2015). Currently, there are no drugs approved for the indication of C3 glomerulopathy.

#### \*4: Atypical hemolytic uremic syndrome (aHUS):

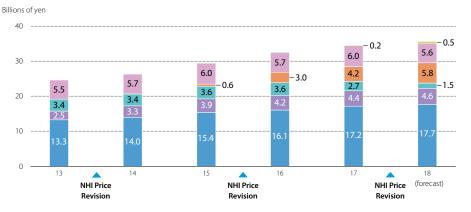
aHUS is a designated intractable disease caused by abnormalities in complement factors. It is characterized mainly by 1) hemolytic anemia, 2) decrease in platelets, and 3) acute nephropathy. In Japan, the number of patients with aHUS is estimated to be over 40 (based on the number of recipients of the certificates for special disease treatment in 2015). The biopharmaceutical eculizumab is currently used to treat aHUS.

<sup>\*2:</sup> Anti-neutrophil cytoplasmic auto-antibody (ANCA)-associated vasculitis (AAV): AAV is a rare and severe autoimmune disease characterized by no or very little immune complex deposition, necrotizing inflammation of the small blood vessels, and high ANCA-positive rates. It damages various organs, including the kidneys, lungs, and nervous system. The number of patients with AAV is estimated to be over 10,000 in Japan (based on the number of recipients of the certificates for special disease treatment in 2015). The current standard treatment for AAV is the concurrent use of adrenocorticosteroids and immunosuppressants. Steroid replacement with avacopan is expected to avoid the adverse events associated with steroid use. \*3:C3 glomerulopathy (C3G):

# Major Domestic Pharmaceuticals

## Sales of Major Domestic Pharmaceuticals by Fiscal Year -

Base financial results



Ulcerative colitis treatment: RECTABUL® Renal anemia treatment: Epoetin Alfa BS Hyperphosphatemia treatment: P-TOL® Diabetes treatment: Glufast® Diabetes treatment: Glubes® Dysuria treatment: Urief®

## 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.

## Diabetes treatment:

## **Glubes®** Combination 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.

## Glufast® Tablet and OD Tablet

Glufast<sup>®</sup> is a rapid-acting insulin secretagogue developed by Kissei that has been co-marketed with Takeda Pharmaceutical Co., Ltd., since May 2004. In September 2013, a partial revision to the indication for this agent was approved. It is now approved for treatment of type 2 diabetes, and can be used in conjunction with all oral hypoglycemic agents except sulfonylurea derivatives. Sales of Glufast<sup>®</sup> in the form of an OD tablet commenced in June 2016.

## Hyperphosphatemia treatment:

## P-TOL® Chewable Tablet

In November 2015, Kissei launched P-TOL® chewable tablets 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. Overseas, VFMCRP, the licensing company of P-TOL®, has received approval for P-TOL® in 40 countries around the world (as of July, 2018), not including Japan, and is currently marketing the drug under the brand name Velphoro® in the United States, Europe, and other countries and regions.









## 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. It has been co-marketed since May 2010.

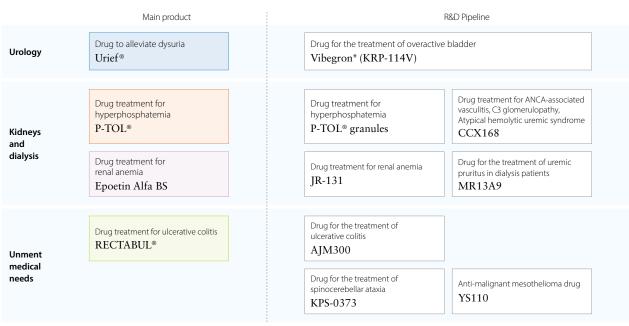
## Ulcerative colitis treatment:

## **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.



## Expansion of Product Portfolio in Key Fields



\*Generic name

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 upcoming patent expiration of Urief<sup>®</sup>, 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 will position urology, renal diseases and dialysis, and unmet medical needs as three key fields to focus our management resources on and in which to expand our portfolio. For fiscal 2018, we are planning launches in two of these areas. In urology, we are planning to release vibegron (generic name), an overactive bladder treatment, and in renal diseases and dialysis, we are planning to release a new granular formulation of P-TOL<sup>®</sup>.

We will also maximize sales of our main products, including RECTABUL®, launched in fiscal 2017. At the same time, we will work to move new drugs to market and advance projects in development past the early stages.

As we focus on in-licensing, we will continue expanding our product portfolio.

# 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 As of July 2018

#### Brand name:

Urief® / UROREC® / SILODYX™ / SILOSIN® / Youlifu® / Thrupas® / RAPAFLO®

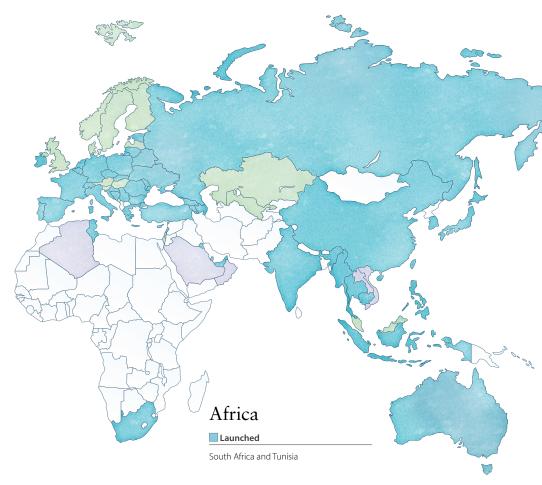
## Europe

#### Launched

Germany, Ireland, Spain, France, Portugal, Belgium, Romania, Italy, Greece, the Netherlands, Russia, the Czech Republic, Slovakia, Bulgaria, Cyprus, Turkey, Poland, the Ukraine, Georgia, Belarus, Croatia, Armenia, Serbia, Moldova, Azerbaijan, Malta, Bosnia and Herzegovina, Liechtenstein, Switzerland, Estonia, and Lithuania

#### Approval acquired but not yet launched

The U.K., Austria, Sweden, Slovenia, Denmark, Hungary, Finland, Latvia, Luxembourg, Norway, Iceland, Uzbekistan, Kazakhstan, and Montenegro



Filed an NDA but not yet approved

Algeria

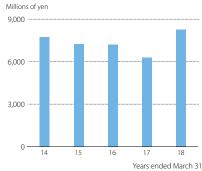
### **Overseas Development of Silodosin**

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®. To date, this company has received additional licensing rights to develop and sell the drug in 19 countries throughout the Americas. 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®.

Silodosin is currently sold in 51 countries including Australia, where it was released in July 2017, and active promotion is ongoing via our partners in Asia.

#### Past Exports\*



\* "Exports" is the total for overseas sales and revenue from dispensing fees (based on financial results).



## Out-Licensing of KLH-2109 (Development Code) to ObsEva SA

Kissei promotes out-licensing of new drugs and aims to build future overseas earnings bases following the U.S. patent expiration of Silodosin in fiscal 2018.

In November 2015, Kissei granted exclusive rights to Swissbased ObsEva SA to develop and commercialize the novel drug candidate KLH-2109 (development code), a GnRH antagonist discovered by Kissei, to all regions worldwide, excluding some countries in Asia, such as Japan. Moving forward, 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 (international development code: OBE2109) for European and North American markets. This candidate is currently under phase II clinical trials (EDELWEISS) 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 (gonadotropinreleasing hormone) 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.

# Corporate Governance

Board of Directors and Board of Corporate Auditors As of June 27, 2018



#### 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

1976 Joined the Company1982 Director1992 President and CEO2014 Chairman and CEO (current position)

#### Hiroe Sato

#### **Executive Vice President**

**Chairman and CEO** 

1975 Joined the Company

- 2006 Director, Department Manager of
- Corporate Finance & Management Department
- 2016 Executive Vice President (current position)

## Yasuo Takehana

Managing Director

Department Manager of Corporate Strategy & Planning Department

1984 Joined the Company

2012 Director

2016 Managing Director (current position)

#### Yoshio Furihata

## 1984 Joined the Company

2008 Director, Department Manager of Business Development Department

**President and COO** 

**Managing Director** 

**Director and Senior Adviser** 

- 2010 Corporate Strategy and Planning Department
- zoro corporate strategy and harming Department
- 2012 General Manager of Clinical Development Division
- 2018 President and COO (current position)

## Keiji Fukushima

General Manager of Sales & Marketing Division

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

## Masaki Morozumi

1980 Joined the Company

- 2008 Director 2010 General Manager of Sales & Marketing Division
- Conor General Manager of Sales & Marketing DIVISIO
- 2014 President and COO
- 2018 Director and Senior Adviser (current position)

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## Corporate Governance

Director

Director

Director

1985 Joined the Company 2014 Director (current position)		1983 Joined the Company 2016 Director (current posit
Eiichi Matsushita	Director	Shinji Kikuchi
Department Manager of General Administration D	epartment	General Manager of Researc
1983 Joined the Company		1988 Joined the Company
2016 Director (current position)		2016 Director (current posit
Suminori Sagara	Director	Takahide Kitahara
Department Manager of Promotion Support Depa	rtment	Department Manager of Cor
1982 Joined the Company		1986 Joined the Company
2018 Director (current position)		2018 Director (current posit
Shigetaka Shimizu Outsid	e Director (independent)	Minoru Nomura

Shigetaka Shimizu

Tetsu Takayama

Department Manager of Human Resources Department

**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)

1 mosm Rusama
General Manager of Pharmaceutical Manufacturing Division
1983 Joined the Company
2016 Director (current position)

ninji Kikuchi neral Manager of Research and Development Division

88 Joined the Company 16 Director (current position)

Hiroshi Kusama

Director

partment Manager of Corporate Finance & Management Department

18 Director (current position)

Minoru Nomura

**Outside Director (independent)** 

**Corporate Auditor (full-time)** 

- 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**

## Makoto Yonekubo

**Corporate Auditor (full-time)** 

- 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)

## Masayuki Isaji

- 1980 Joined the Company
- 2010 Director, Department Manager of Research and
  - Development Planning Department
- 2012 Managing Director
- 2018 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

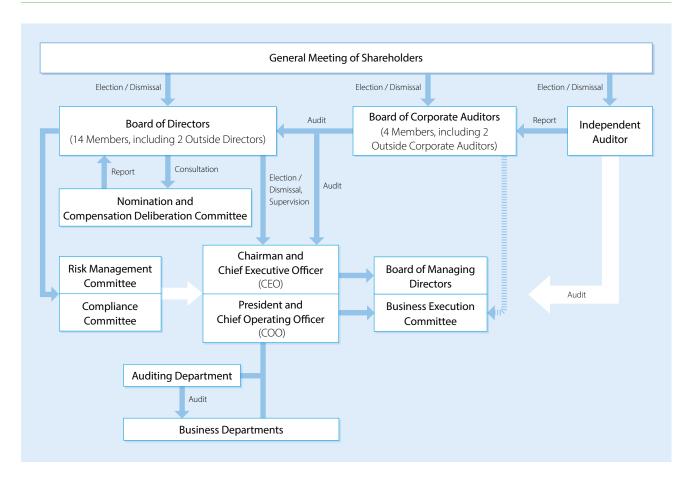
Kissei aims to improve its corporate value and realize sustainable growth as a company with a clear raison d'être. At the same time, the Company positions the enhancement and reinforcement of corporate governance as a core management issue in order to maintain a positive relationship with all of its 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.

## **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

## Corporate Governance Bodies and Internal Control System



Business Execution Committee 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 auditors are designated independent officers in accordance with regulations of the Tokyo Stock Exchange, to which they report.

## 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 2017, 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.

## **Internal 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.

## **Independent Auditor**

Kissei regularly undergoes outside auditing by an independent auditor. The independent auditor engages in discussions with members of the Board of Directors, finance officers, 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, Auditing Department staff, and the independent auditor to work together to make joint audit engagements more effective.

Furthermore, 2 certified public accountants belonging to Ernst & Young ShinNihon LLC provide the Company with accounting services. As well, 10 certified public accountants and 9 other audit personnel provide assistance in the auditing of the Company.

## Nomination and Compensation Deliberation Committee

To ensure the independence and objectivity of the Board of Directors' deliberations related to director compensation or the nomination of candidates for director and corporate auditor, as well as enhance the transparency of these processes, the Company established the Nomination and Compensation Deliberation Committee as an advisory body to the Board of Directors. This committee holds meetings where it engages in debate on nominating director and corporate auditor candidates as well as on determining director compensation. In addition, when nominating a candidate for the corporate auditor position, the Company has an outside corporate auditor attend these meetings as a committee member.

## Policies for Determining Director Compensation Amounts and Calculation Methods

Director compensation comprises a base salary and a bonus. Base salary is determined by director rank, and also includes an additional amount based on individual experience. Bonus is determined by director rank, and takes into account the director's performance for the period.

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

			Millions of yen			
			Totals by comp	pensation type		Number of
Classification	Total compensation	Base compensation	Stock options	Bonuses	Retirement benefits	applicable officers
Directors (excluding outside directors)	357	334	—	22	—	12
Corporate auditors (excluding outside corporate auditors)	28	25	_	2	_	2
Outside officers	28	27	_	1	_	4

## Message from Outside Directors



Shigetaka Shimizu Outside Director

In order for a company to continue its contributions to society, it is important to gain social trust while maintaining sustainable growth with it. Within this basic foundation, it is necessary to strengthen corporate governance. As an outside director, part of my role in this regard is to join meetings with the Board and participate in decision-making from a third-party point of view. It is possible to take common sense as it exists in society as a whole and apply it to advice given in terms of business and industry alike. Furthermore, I believe that incorporating the social point of view in managerial decisions across a variety of affairs can help maintain true competitive power.

Kissei provides information to its outside directors with as much advance notice as possible to allow them to participate in and contribute specialized knowledge vital to the decision-making process. Moving forward, I plan on applying my knowledge and experience gained from working in financial institutions and company management to Kissei's decision-making process while maintaining a required measure of independence as an outside director.



The overhaul of the National Health Insurance (NHI) Drug Prices Standard System, which took place in April of this year, has been a major shock to the pharmaceutical industry. As we move forward, it is believed that long-listed drugs will play a shrinking role in accordance with expected slowdown in domestic growth and active movement toward developing the international market. It is now necessary for new drug manufacturers to fully identify their strengths, which overseas markets they want to focus on, and for which disease areas they will develop new drugs.

In addition to the urology, and renal diseases and dialysis fields, Kissei is actively engaging in opportunities

toward making new drugs for unmet medical needs a vital field for cases where there are few effective drugs and new treatments are required. In the midst of sudden technological innovations and intensifying competition worldwide, quicker management decisions and accelerated business execution are necessary to stay ahead of other companies on the drug creation front. With a full understanding of the importance of maintaining independence from the Company, I will continue to make use of my many years of experience as a corporate manager and my knowledge in international business to contribute to the wider management of Kissei.

# 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.

# Contributions to the Development of Medical Treatments and Sciences

### 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 2017

	Number	Total amount
Kanzawa Medical Award	19	¥ 56 million
Research Grants	207	¥232 million
Overseas Study Grants	78	¥ 39 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

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

#### 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 2017, we responded to 11,080 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.

## **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.

### **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 employeeentered 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.
- 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.

#### Efforts to Promote the Success of Women in the Workplace

Kissei has formulated a General Employers Action Plan based on the Act on Promotion of Women's Participation and Advancement in the Workplace. We are working to further develop our infrastructure so that women are able to fully express their individuality and ability in their professional careers and see success in the workplace.

#### Our Primary Goals Regarding Women's Success (April 1, 2018—March 31, 2020)

- Increase number of female applicants
- Provide support for balancing work life and home life
- Facilitate the use of shortened workday policies among female medical representatives

#### 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.

In fiscal 2017, there were two incidences of work-related accidents resulting in time off of work.

#### Work-Related Accidents

	(FY)	2013	2014	2015	2016	2017
Incidences of work-related accidents (resulting in time off from work)		3 (0)		3 (1)	5 (0)	2 (2)
Rate of frequency*1		0.00	0.00	0.31	0.00	0.65
Rate of severity*2		0.00	0.00	0.00	0.00	0.01

\*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.

- 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.
- 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.

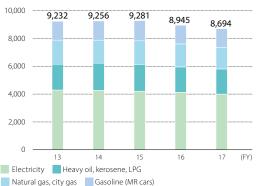
## **Environmental Initiatives**

#### **Basic Stance**

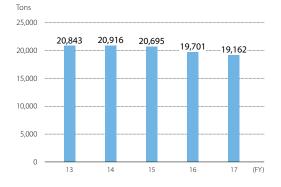
Initiatives to address environmental problems are the responsibility of all of humanity and are an essential element of a company's survival and operations. In recognition of this, the Kissei Group is working to preserve the environment and reduce the environmental impact of all its business activities. 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<sub>2</sub> emissions, as well as the amount of waste generated.

#### Trend in Energy Usage

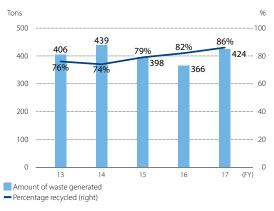




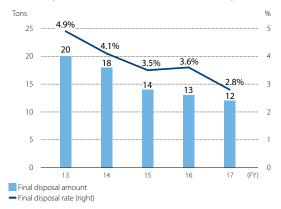
#### CO<sub>2</sub> Emissions



#### 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, 2018, total assets stood at ¥213,087 million, up ¥26,285 million from the previous fiscal year-end. Total current assets increased ¥3,381 million, to ¥100,599 million, due to an increase in notes and accounts receivable and marketable securities, which offset a decrease in cash on hand and in banks as well as inventories. Total non-current assets were up ¥22,904 million, to ¥112,487 million, mainly reflecting an increase in investments in securities.

Total liabilities amounted to ¥36,994 million at the fiscal year-end, up ¥7,976 million from the previous fiscal year-end. Total current liabilities stood at ¥17,448 million, up ¥1,791 million, mainly due to an increase in income taxes payable. Total long-term liabilities were up ¥6,184 million, to ¥19,546 million, due to an increase in deferred tax liabilities.

Total net assets amounted to ¥176,092 million at the fiscal year-end, an increase of ¥18,309 million compared with the previous fiscal year-end. This increase reflected an increase in net unrealized holding gains on securities and retained earnings in addition to the acquisition and cancellation of treasury stock.

As a result, the shareholders' equity ratio was 82.5%, down from 84.3% at the previous fiscal year-end.

## **Financial Results**

Net sales for the fiscal year ended March 31, 2018 increased 3.2% year on year, to ¥74,009 million. Accounting for the majority of net sales, the segment sales of the Kissei Group's core pharmaceutical business were up ¥2,436 million, or 4.0%, to ¥63,891 million. The reason for this increase is increased sales of P-TOL® Chewable Tablet for the treatment of hyperphosphatemia, Urief® Tablet and Urief® OD Tablet for the treatment of dysuria associated with benign prostatic hyperplasia, and Epoetin Alfa BS Injection [JCR] for the treatment of renal anemia, in addition to increased revenue from technical fees and export sales. In other business segments, net sales were down ¥132 million, or 1.3% year on year, to ¥10,118 million despite increased revenues in information services, due to decreased revenues in mer-chandising and construction industries.

The cost of sales ratio was up 0.4 percentage point in the pharmaceutical business while it fell in other businesses. As a result, gross profit increased ¥1,489 million, or 3.2% year on year, to ¥48,120 million.

In selling, general and administrative expenses, while selling expenses decreased, R&D and general and administrative expenses increased. As a result, operating income increased ¥1,396 million, or 16.4% year on year, to ¥9,887 million. While gain on sales of investment securities decreased, gain on valuation of securities increased and foreign exchange loss declined. As a result, total other income (expenses) came to total other income of ¥1,809 million, up ¥184 million compared to the previous fiscal year.

As a result of the above, profit before income taxes and noncontrolling interests was up ¥1,580 million, or 15.6% year on year, to ¥11,697 million, and profit attributable to owners of parent grew ¥1,319 million, or 17.1% year on year, to ¥9,045 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 considers working to make efficient use of capital while paying fair dividends to shareholders in accordance with profit levels to be a key management issue.

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.

For the fiscal year under review, Kissei will pay a year-end cash dividend of ¥24.0 per share, which when combined with an interim cash dividend of ¥24.0 per share gives a full-year cash dividend of ¥48.0 per share.

For the coming fiscal year, the Group plans to pay 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.

Giving first priority to increasing shareholder value, Kissei will acquire and dispose of treasury stock, based on resolutions of the Board of Directors, flexibly and as necessary in light of operational developments.

In the fiscal year ended March 31, 2018, based on a resolution of the Board of Directors, Kissei acquired 1.6 million shares of treasury stock, equivalent to ¥4,462 million, while cancelling 2.5 million of its own shares held as treasury stock.

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 2017.

#### 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.



# **Financial Section**

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## Consolidated Balance Sheets

Kissei Pharmaceutical Co., Ltd. and its subsidiaries At March 31, 2017 and 2018

	Million	Millions of yen		
lssets	2018	2017	2018	
Current Assets:				
Cash on hand and in banks (Notes 04 and 05)	¥ 24,371	¥ 27,109	\$ 229,915	
Notes and accounts receivable (Note 05)	28,873	24,730	272,387	
Marketable securities (Notes 04, 05 and 06)	23,288	21,039	219,698	
Inventories (Note 07)	15,933	16,726	150,311	
Deferred tax assets—current (Note 10)	2,436	2,179	22,981	
Other current assets	5,698	5,434	53,755	
Allowance for doubtful accounts	(1)	(1)	(9)	
Total current assets	100,599	97,218	949,047	

## Property, Plant and Equipment:

Buildings and structures (Note 14)	38,489	37,915	363,104
Less: accumulated depreciation	(28,030)	(27,326)	(264,434)
Buildings and structures, net	10,458	10,589	98,660
Land (Note 14)	12,913	12,933	121,821
Construction in progress	19	59	179
Other	15,703	14,742	148,142
Less: accumulated depreciation	(12,698)	(12,016)	(119,792)
Other, net	3,005	2,725	28,349
Total property, plant and equipment	26,396	26,308	249,019

#### Intangible Assets:

Software for internal use	1,028	1,082	9,698
Other	687	763	6,481
Total intangible assets	1,716	1,845	16,189

#### Investments and Other Assets:

Investment securities (Notes 05 and 06)	81,194	58,344	765,981
Long-term loans receivable	98	119	925
Long-term prepaid expenses	1,608	1,454	15,170
Deferred tax assets—non-current (Note 10)	500	517	4,717
Other	1,026	1,045	9,679
Allowance for doubtful accounts	(54)	(53)	(509)
Total investments and other assets	84,374	61,428	795,981

Total assets	¥213,087	¥186,801	\$2,010,255

The accompanying notes are an integral part of these statements.

	Millions	Millions of yen	
iabilities and Net Assets	2018	2017	dollars (Note 03) 2018
Current Liabilities:			
Notes and accounts payable	¥ 4,894	¥ 4,849	\$ 46,170
Short-term bank loans (Note 08)	1,730	1,730	16,321
Current portion of long-term debt (Note 08)	27	70	255
Income taxes payable	2,375	1,055	22,406
Accrued bonuses to employees	2,225	2,088	20,991
Accrued bonuses to directors and corporate auditors	26	25	245
Reserve for sales returns	22	11	208
Reserve for sales rebates	407	356	3,840
Reserve for sales promotion expenses	189	189	1,783
Other current liabilities	5,550	5,278	52,358
Total current liabilities	17,448	15,656	164,604
.ong-Term Liabilities:			
Long-term debt (Note 08)	1,876	1,656	17,698
Deferred tax liabilities—non-current (Note 10)	12,201	5,645	115,104
Net defined benefit liability (Note 11)	4,623	5,379	43,613
Accrued retirement benefits to directors and corporate auditors	151	134	1,425
Asset retirement obligations	114	112	1,075
Other long-term liabilities	577	433	5,443
Total long-term liabilities	19,546	13,361	184,396
Total liabilities	36,994	29,017	349,000
Contingent Liabilities (Note 13) Net Assets: Shareholders' equity: Common stock:			
Net Assets: Shareholders' equity:			
let Assets: Shareholders' equity: Common stock: Authorized: 227,000,000 shares			
<b>let Assets:</b> Shareholders' equity: Common stock:	24,356	24,356	229,774
Jet Assets: Shareholders' equity: Common stock: Authorized: 227,000,000 shares Issued: 54,311,185 shares and 51,811,185 shares	24,356 24,226	24,356 24,226	229,774 228,547
Jet Assets:     Shareholders' equity:     Common stock:     Authorized: 227,000,000 shares     Issued: 54,311,185 shares and 51,811,185 shares     at March 31, 2017 and 2018, respectively			228,547
let Assets: Shareholders' equity: Common stock: Authorized: 227,000,000 shares Issued: 54,311,185 shares and 51,811,185 shares at March 31, 2017 and 2018, respectively Additional paid-in capital	24,226	24,226	228,547 970,132
let Assets: Shareholders' equity: Common stock: Authorized: 227,000,000 shares Issued: 54,311,185 shares and 51,811,185 shares at March 31, 2017 and 2018, respectively Additional paid-in capital Retained earnings Treasury stock (5,994,175 shares and 5,094,713 shares at March 31, 2017 and 2018, respectively)	24,226 102,834 (11,607)	24,226 101,755 (12,838)	228,547 970,132 (109,500
let Assets: Shareholders' equity: Common stock: Authorized: 227,000,000 shares Issued: 54,311,185 shares and 51,811,185 shares at March 31, 2017 and 2018, respectively Additional paid-in capital Retained earnings Treasury stock (5,994,175 shares and 5,094,713 shares	24,226 102,834	24,226 101,755	228,547 970,132 (109,500
Iet Assets:     Shareholders' equity:     Common stock:     Authorized: 227,000,000 shares     Issued: 54,311,185 shares and 51,811,185 shares     at March 31, 2017 and 2018, respectively     Additional paid-in capital     Retained earnings     Treasury stock (5,994,175 shares and 5,094,713 shares     at March 31, 2017 and 2018, respectively)     Total shareholders' equity     Accumulated other comprehensive income:	24,226 102,834 (11,607)	24,226 101,755 (12,838) 137,499	228,547 970,132 (109,500 1,318,953
Iet Assets:     Shareholders' equity:     Common stock:     Authorized: 227,000,000 shares     Issued: 54,311,185 shares and 51,811,185 shares     at March 31, 2017 and 2018, respectively     Additional paid-in capital     Retained earnings     Treasury stock (5,994,175 shares and 5,094,713 shares     at March 31, 2017 and 2018, respectively)     Total shareholders' equity     Accumulated other comprehensive income:     Unrealized holding gains on securities	24,226 102,834 (11,607) 139,809 36,752	24,226 101,755 (12,838) 137,499 21,268	228,547 970,132 (109,500 1,318,953 346,717
Net Assets:     Shareholders' equity:     Common stock:     Authorized: 227,000,000 shares     Issued: 54,311,185 shares and 51,811,185 shares     at March 31, 2017 and 2018, respectively     Additional paid-in capital     Retained earnings     Treasury stock (5,994,175 shares and 5,094,713 shares     at March 31, 2017 and 2018, respectively)     Total shareholders' equity     Accumulated other comprehensive income:     Unrealized holding gains on securities     Retirement benefits liability adjustments	24,226 102,834 (11,607) 139,809 36,752 (859)	24,226 101,755 (12,838) 137,499 21,268 (1,313)	228,547 970,132 (109,500 1,318,953 346,717 (8,104
Vet Assets:     Shareholders' equity:     Common stock:     Authorized: 227,000,000 shares     Issued: 54,311,185 shares and 51,811,185 shares     at March 31, 2017 and 2018, respectively     Additional paid-in capital     Retained earnings     Treasury stock (5,994,175 shares and 5,094,713 shares     at March 31, 2017 and 2018, respectively)     Total shareholders' equity     Accumulated other comprehensive income:     Unrealized holding gains on securities	24,226 102,834 (11,607) 139,809 36,752	24,226 101,755 (12,838) 137,499 21,268	228,547 970,132 (109,500 1,318,953 346,717 (8,104 338,604
Jet Assets:     Shareholders' equity:     Common stock:     Authorized: 227,000,000 shares     Issued: 54,311,185 shares and 51,811,185 shares     at March 31, 2017 and 2018, respectively     Additional paid-in capital     Retained earnings     Treasury stock (5,994,175 shares and 5,094,713 shares     at March 31, 2017 and 2018, respectively)     Total shareholders' equity     Accumulated other comprehensive income:     Unrealized holding gains on securities     Retirement benefits liability adjustments     Total accumulated other comprehensive income	24,226 102,834 (11,607) 139,809 36,752 (859) 35,892	24,226 101,755 (12,838) 137,499 21,268 (1,313) 19,954	228,547 970,132 (109,500 1,318,953

# Consolidated Statements of Income and Consolidated Statements of Comprehensive Income Kissei Pharmaceutical Co., Ltd. and its subsidiaries At March 31, 2017 and 2018

#### **Consolidated Statements of Income**

	Millions of yen		Thousands of U.S. dollars (Note 03)	
	2018	2017	2018	
Net Sales	¥74,009	¥71,706	\$698,198	
Cost of Sales	25,889	25,075	244,236	
Gross profit	48,120	46,631	453,962	
Gross pront	48,120	40,031	453,902	
Selling, General and Administrative Expenses (Note 17)	38,232	38,140	360,679	
Operating income	9,887	8,491	93,274	
Other Income (Expenses):				
Interest and dividend income	1,081	963	10,198	
Interest expense	(23)	(24)	(217)	
Gain on sales of investment securities	320	652	3,019	
Loss on sales or disposal of property, plant and equipment	(37)	(31)	(349)	
Income (loss) from investments in partnerships	(0)	10	(0)	
Gain on sales of property, plant and equipment	—	18	—	
Gain on valuation of securities	387	226	3,651	
Impairment loss	—	(47)	—	
Foreign exchange gain (loss)	0	(94)	0	
Loss on valuation of stocks of subsidiaries and affiliates	—	(53)	—	
Loss on valuation of investments in capital of subsidiaries and affiliates	—	(59)	—	
Other, net	80	66	755	
Total other income (expenses)	1,809	1,625	17,066	
Profit before income taxes and non-controlling interests	11,697	10,116	110,349	
Income Taxes (Note 10):				
Current	3,223	2,291	30,406	
Deferred	(624)	59	(5,887)	
	2,598	2,351	24,509	
Profit	9,098	7,765	85,830	
Profit Attributable to Non-Controlling Interests	52	39	491	
Profit Attributable to Owners of Parent (Note 18)	¥ 9,045	¥ 7,726	\$ 85,330	

The accompanying notes are an integral part of these statements.

#### **Consolidated Statements of Comprehensive Income**

	Millions	Millions of yen	
	2018	2017	dollars (Note 03) 2018
Profit	¥ 9,098	¥ 7,765	\$ 85,830
Other Comprehensive Income:			
Unrealized holding gains on securities	15,484	(4,677)	146,075
Retirement benefits liability adjustments	461	420	4,349
Total other comprehensive income (Note 12)	15,945	(4,256)	150,425
Comprehensive Income	¥25,044	¥ 3,508	\$236,264
Comprehensive income attributable to:			
Shareholders of Kissei Pharmaceutical Co., Ltd.	¥24,983	¥ 3,463	\$235,689
Non-controlling interests	60	45	566

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, 2017 and 2018

	-				Milli	ons of yen			
	-		Sharehold	ers' equity		Accumula comprehens			
	Number of shares C 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, 2016	54,311,185	¥24,356	¥24,247	¥ 96,230	¥(11,189)	¥25,945	¥(1,730)	¥265	¥158,125
Profit attributable to owners of parent for the year	_	_	_	7,726	_	_	_	_	7,726
Cash dividends paid	_	_	_	(2,201)	_	_	_	_	(2,201
Treasury stock purchased (610,541 shares)	_	—	—	—	(1,649)	—	—	_	(1,649
Unrealized holding gains on securities	—	—	—	—	—	(4,677)	—	—	(4,677
Retirement benefits liability adjustments	_	_	_	_	_	_	416	_	416
Changes in equity of consolidated subsidiaries	_	—	(21)	_	—	_	—	_	(21
Net changes in items other than those in shareholders' equity	—	_	—	_	—	_	—	64	64
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	—	—	_	_
Unrealized holding gains on securities	_	_	_	—	—	15,483	—	_	15,483
Retirement benefits liability adjustments	_	_	_	—	—	-	454	—	454
Net changes in items other than those in shareholders' equity	_	_	_	_	—	_	_	60	60
Balance at March 31, 2018	51,811,185	¥24,356	¥24,226	¥102,834	¥(11,607)	¥36,752	¥ (859)	¥390	¥176,092

		Thousands of U.S. dollars (Note 03)							
			Sharehold	ers' equity		Accumula comprehen			
	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	\$229,774	\$228,547	\$959,953	\$(121,113)	\$200,642	\$(12,387)	\$3,104	\$1,488,519
Profit attributable to owners of parent for the year	_	_	—	85,330	—	—	—	—	85,330
Cash dividends paid	_	_	_	(21,415)	_	_	_	_	(21,415
Treasury stock purchased (1,600,538 shares)	—	_	—	—	(42,113)	_	—	_	(42,113
Cancellation of treasury stock (2,500,000 shares)		—	(0)	(53,726)	53,726	—	—	_	_
Unrealized holding gains on securities	-	-	—	—	—	146,066	—	—	146,066
Retirement benefits liability adjustments	—	—	—	—	—	—	4,283	—	4,283
Net changes in items other than those in shareholders' equity	_	_	_	_	_	_	_	566	566
Balance at March 31, 2018	51,811,185	\$229,774	\$228,547	\$970,132	\$(109,500)	\$346,717	\$ (8,104)	\$3,679	\$1,661,245

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, 2017 and 2018

	Millions	ofven	Thousands of U.S
	2018	2017	dollars (Note 03) 2018
ash Flows from Operating Activities:			
Profit before income taxes and non-controlling interests	¥11,697	¥10,116	\$110,349
Depreciation and amortization	2,492	2,370	23,509
Increase (decrease) in allowance reserves	217	(115)	2,047
Decrease in net defined benefit liability	(91)	(28)	(858)
Impairment loss		47	
Interest and dividend income	(1,081)	(963)	(10,198)
Interest expense	23	24	217
Foreign exchange (gain) loss	2	0	19
(Gain) loss on valuation of securities	(387)	(226)	(3,651)
(Gain) loss on sales of property, plant and equipment		(18)	
(Gain) loss on sales of investment securities	(320)	(652)	(3,019)
Loss on disposal of property, plant and equipment	37	31	349
(Increase) decrease in notes and accounts receivable	(4,142)	236	(39,075)
(Increase) decrease in inventories	793	650	7,481
(Increase) decrease in other current assets	128	342	1,208
Increase (decrease) in notes and accounts pavable	44	(979)	415
Increase (decrease) in other current liabilities	922	(979) (1,941)	8,698
Increase (decrease) in other long-term liabilities	922	(1,941)	0,090 9
Loss on valuation of stocks of subsidiaries and affiliates	1	·····	9
		53	
Loss on valuation of investments in capital of subsidiaries and affiliates	—	59	
Other	0	(3)	0
Sub total	10,336	8,990	97,509
Receipt of interest and dividends	985	883	9,292
Payment of interest	(23)	(24)	(217)
Payment of income taxes	(2,453)	(3,406)	(23,142)
Net cash provided by operating activities	8,845	6,441	83,443
ash Flows from Investing Activities:			
Time deposits received	75	77	708
Time deposits paid	(75)	(79)	(708)
Reduction of investments in specified trusts	66	56	623
Proceeds from sales of marketable securities	1,999	—	18,858
Acquisition of sales of marketable securities	(1,999)	(1,331)	(18,858)
Acquisition of property, plant and equipment	(1,867)	(1,201)	(17,613)
Proceeds from sales of property, plant and equipment	20	28	189
Acquisition of intangible assets	(253)	(1,331)	(2,387)
Acquisition of investment securities	(1,130)	(4,347)	(10,660)
Proceeds from sales of investment securities	574	2,069	5,415
Payments for loans	(61)	(111)	(575)
Collection of loans	99	113	934
Long-term advance payment costs	(403)	(7)	(3,802)
Other	(4)	60	(38)
Net cash provided by (used in) investing activities	(2,959)	(4,671)	(27,915)
ash Flows from Financing Activities:			
Short-term bank loans received	80	—	755
Repayment of short-term bank loans	(80)	—	(755)
Long-term debt received	248	238	2,340
Repayment of long-term debt	(70)	(85)	(660)
Repayment of finance lease obligation	(64)	(68)	(604)
Cash dividends paid	(2,270)	(2,201)	(21,415)
Treasury stock purchased	(4,464)	(1,649)	(42,113)
Net cash provided by (used in) financing activities	(6,621)	(3,766)	(62,462)
ffect of Exchange Rate Changes on Cash and Cash Equivalents	(2)	(0)	(02,402)
crease (Decrease) in Cash and Cash Equivalents	(737)	(1,996)	(6,953)
ash and Cash Equivalents at Beginning of Year (Note 04)	48,098	50,094	453,755

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

#### Note 02 Summary of Significant Accounting Policies

#### (1) Scope of Consolidation

The numbers of subsidiaries the Company had for the years ended March 31, 2017 and 2018 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.

In eliminating investments in the common stock of the consolidated subsidiaries against the underlying equity in the net assets of the subsidiaries, differences between the cost of the investments and the underlying equity in net assets were not recognized for the two years ended March 31, 2017 and 2018.

#### (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.

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.

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.

#### (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) 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.

#### (13) Research and Development Expenses

Research and development expenses are recognized as an expense when incurred in accordance with Japanese accounting standards.

#### (14) Accounting Standards Issued but Not Yet Effective

Implementation Guidance on Tax Effect Accounting and Implementation Guidance on Recoverability of Deferred Tax Assets

On February 16, 2018, the ASBJ issued "Implementation Guidance on Tax Effect Accounting" (ASBJ Guidance No. 28) and "Implementation Guidance on Recoverability of Deferred Tax Assets" (revised 2018) (ASBJ Guidance No. 26).

(i) Overview

The accounting treatment for taxable temporary differences related to investments in subsidiaries when an entity prepares separate financial statements was modified. In addition, the accounting treatment related to the recoverability of deferred tax assets in entities that qualify as Category 1 was clarified.

(ii) Scheduled date of adoption

The Companies expect to adopt the implementation guidance from the beginning of the fiscal year ending March 31, 2019.

(iii) Impact of the adoption of implementation guidance

The Companies are currently evaluating the effect of the adoption of this implementation guidance on its consolidated financial statements.

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
- 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.

# 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  $\pm 106=U.S.$ , 1, the approximate rate of

exchange prevailing at March 31, 2018. 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, 2017 and 2018 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2018	2017	2018
Cash on hand and in banks	¥24,371	¥27,109	\$229,915
Marketable securities	23,288	21,039	219,698
Time deposits with original maturities of over three months	(50)	(50)	(472)
Claims with redemption period exceeding 3 months, etc.	(249)	—	(2,349)
Cash and cash equivalents	¥47,360	¥48,098	\$446,792

#### Note 05 Financial Instruments

#### Overview

Derivatives

(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, 2017 and 2018 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	
	Carrying	Estimated	Unrealized
As of March 31, 2018	value	fair value	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	¥ —	¥ —	¥—
		Millions of yen	
A (14	Carrying	Estimated	Unrealized
As of March 31, 2017	value	fair value	gains (losses)
Assets:			
Cash on hand and in banks	¥ 27,109	¥ 27,109	¥—
Notes and accounts receivable	24,730	24,730	—
Marketable securities and investment securities	78,310	78,310	—
Total	¥130,150	¥130,150	¥—

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# Notes to the Consolidated Financial Statements

		Thousands of U.S. dollars			
As of March 31, 2018	Carrying value	Estimated fair value	Unrealized gains (losses)		
Assets:					
Cash on hand and in banks	\$ 229,915	\$ 229,915	\$—		
Notes and accounts receivable	272,387	272,387	—		
Marketable securities and investment securities	968,953	968,953	—		
Total	\$1,471,264	\$1,471,264	\$—		
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:

	Million	s of yen	Thousands of U.S. dollars
	2018	2017	2018
Unlisted stocks	¥1,272	¥572	\$12,000
Investments in partnerships	34	33	321
Investments in unconsolidated subsidiaries	467	467	4,406

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, 2017 and 2018 are as follows:

	Millions of yen					
As of March 31, 2018	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		

		Million	is of yen				
	Due in	Due after one year	Due after five years	Due after			
As of March 31, 2017	one year or less	through five years	through ten years	ten years			
Assets:							
Cash on hand and in banks	¥27,109	¥ —	¥ —	¥ —			
Notes and accounts receivable	24,730	—	—	—			
Marketable securities and investment securities	21,040	1,588	1,647	1,417			
Total	¥72,879	¥1,588	¥1,647	¥1,417			
	Thousands of U.S. dollars						
	Due in	Due after one year	Due after five years	Due after			
As of March 31, 2018	one year or less	through five years	through ten years	ten years			
Assets:							
Cash on hand and in banks	\$229,915	\$ —	\$ —	\$ —			
Notes and accounts receivable	272,387	_	—	_			
Marketable securities and investment securities	219,274	13,000	20,396	12,255			
Total	\$721,575	\$13,000	\$20,396	\$12,255			

#### 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, 2017 and 2018 are as follows:

		Million	s 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

		Million	s of yen			
		20	17			
	Acquisition cost	Carrying amount	Gross unrealized holding gains	Gross unrealized holding losses		
Equity securities	¥18,266	¥48,128	¥29,867	¥ 5		
Corporate debt securities	1,350	1,320	—	29		
Other	28,362	28,861	558	59		
Total	¥47,979	¥78,310	¥30,426	¥94		
	Thousands of U.S. dollars					
		20	18			
	Acquisition cost	Carrying amount	Gross unrealized holding gains	Gross unrealized holding losses		
Equity securities	\$170,896	\$657,151	\$487,113	\$ 858		
Corporate debt securities	12,736	12,708	47	66		
Other	289,519	299,085	10,302	736		
Total	\$473,160	\$968,953	\$497,472	\$1,679		

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, 2017 and 2018 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2018	2017	2018
Sales proceeds	¥528	¥1,449	\$4,981
Gross realized gains	320	652	3,019
Gross realized losses	—	—	—

#### Note 07 Inventories

Inventories at March 31, 2017 and 2018 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2018	2017	2018
Merchandise	¥ 1,439	¥ 1,340	\$ 13,575
Finished goods	2,559	3,109	24,142
Work-in-process	2,043	1,540	19,274
Raw materials	9,274	10,439	87,491
Supplies	614	296	5,792
Total	¥15,933	¥16,726	\$150,311

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

Short-term bank loans outstanding at March 31, 2017 and 2018 represent one-year notes issued by the Companies to banks. Short-term bank loans made during the years ended March 31, 2017 and 2018 bore interest at an average annual rate of 1.08% and 1.08%, respectively.

Long-term debt outstanding of the Companies at March 31, 2017 and 2018 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2018	2017	2018
Non-secured loans with financial institutions, bearing interest at rates ranging			
from 0.00% to 2.20% due from 2017 to 2020	¥1,904	¥1,726	\$17,962
Less: current maturities due within one year	(27)	(70)	(255)
Total	¥1,876	¥1,656	\$17,698

The aggregate annual maturities of long-term debt outstanding at March 31, 2018 are as follows:

Year ending March 31	Millions of yen	Thousands of U.S. dollars
2020	¥18	\$170
2021	_	_
2022	_	_
2023	_	

\* As approval dates for successful development projects and the like are not yet fixed, borrowings of ¥1,858 million (\$17,528 thousand) from the Japan Agency for Medical Research and Development, a National Research and Development Agency, are not included in the preceding scheduled repayment amounts.

## Note 09 Lease Obligations

Lease obligations outstanding of the Companies at March 31, 2017 and 2018 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2018	2017	2018
Lease obligations due from 2017 to 2023	¥301	¥120	\$2,840
Less: current maturities due within one year	(79)	(44)	(745)
Total	¥221	¥ 76	\$2,085

\* 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, 2018 are as follows:

Year ending March 31	Millions of yen	Thousands of U.S. dollars
2020	¥76	\$717
2021	67	632
2022	49	462
2023	27	255

## Note 10 Income Taxes

Deferred tax assets (both current and non-current) at March 31, 2017 and 2018 are as follows:

	Millions	Millions of yen	
	2018	2017	2018
Deferred Tax Assets:			
Prepaid research and development expenses	¥ 3,155	¥ 2,675	\$ 29,764
Net defined benefit liability	1,428	1,659	13,472
Accrued bonuses to employees	678	641	6,396
Inventory assets	492	441	4,642
Write-down of securities	438	438	4,132
Accrued enterprise tax	202	117	1,906
Impairment loss	190	206	1,792
Payment of retirement benefits to directors and corporate auditors	154	148	1,453
Reserve for sales rebates	124	109	1,170
Other	794	801	7,491
Total gross deferred tax assets	7,659	7,240	72,255
Valuation allowance	(1,100)	(1,102)	(10,377)
Total deferred tax assets	¥ 6,558	¥6,137	\$ 61,868
eferred Tax Liabilities:			
Unrealized gains on available-for-sale securities	¥(15,810)	¥(9,071)	\$(149,151)
Other	(13)	(14)	(123)
Total deferred tax liabilities	(15,823)	(9,085)	(149,274)
Deferred tax assets (liabilities), net	¥ (9,264)	¥(2,947)	\$ (87,396)

Reconciliation of the actual tax rate for the years ended March 31, 2017 and 2018 are as follows:

	2018	2017
Effective statutory tax rate	30.7%	30.7%
Adjustments:		
Entertainment expenses and other non-deductibles	0.7	0.9
Dividend income not taxable	(0.6)	(0.7)
Tax benefits due to research and development expenses	(9.5)	(8.5)
Per capital levy of local inhabitants taxes	0.7	0.8
Valuation allowance	(0.0)	(0.6)
Other	0.2	0.5
Actual tax rate	22.2%	23.2%

## Note 11 Funded Defined Benefits Plans -

#### **General Outline of Retirement Benefits Plans Implemented**

The Companies have introduced cash balance plans into their defined benefits corporate pension plans. In certain cases, the Group pays 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.

## For the years ended March 31, 2017 and 2018

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

	Millions of yen		Thousands of U.S. dollars
	2018	2017	2018
Defined benefit obligation at beginning of period	¥21,021	¥20,652	\$198,311
Service cost	861	792	8,123
Interest cost	61	61	575
Actuarial gains and losses incurred this period	(5)	93	(47)
Retirement benefits paid	(426)	(579)	(4,019)
Defined benefit obligation at end of period	¥21,511	¥21,021	\$202,934

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

	Millions of yen		Thousands of U.S. dollars
	2018	2017	2018
Plan assets at beginning of period	¥15,641	¥14,638	\$147,557
Expected return on plan assets	391	365	3,689
Actuarial gains and losses incurred this period	253	201	2,387
Employer contribution	1,028	1,014	9,698
Retirement benefits paid	(426)	(579)	(4,019)
Plan assets at end of period	¥16,887	¥15,641	\$159,311

(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
	2018	2017	2018
Defined benefit obligation for funded plan	¥ 21,511	¥ 21,021	\$ 202,934
Plan assets	(16,887)	(15,641)	(159,311)
Net amount of defined benefit liability and asset on the consolidated balance sheets	¥ 4,623	¥ 5,379	\$ 43,613
Defined benefit liability	4,623	5,379	43,613
Net amount of defined benefit liability and asset on the consolidated balance sheets	¥ 4,623	¥ 5,379	\$ 43,613

(iv) The components of retirement benefit expense

	Millions of yen		Thousands of U.S. dollars
	2018	2017	2018
Service cost	¥ 861	¥ 792	\$ 8,123
Interest cost	61	61	575
Expected return on plan assets	(391)	(365)	(3,689)
Amortization of actuarial gains and losses	660	753	6,226
Amortization of prior service cost	(255)	(255)	(2,406)
Other	24	35	226
Retirement benefit expense	¥ 960	¥1,021	\$ 9,057

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

	Millions of yen		Thousands of U.S. dollars
	2018	2017	2018
Prior service cost	¥(255)	¥(255)	\$(2,406)
Actuarial gains and losses	919	860	8,670
Total	¥ 664	¥ 605	\$ 6,264

(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
	2018	2017	2018
Unrecognized prior service cost	¥(1,530)	¥(1,786)	\$(14,434)
Unrecognized actuarial gains and losses	2,798	3,717	26,396
Total	¥ 1,267	¥ 1,931	\$ 11,953

(vii) Plan assets information

Breakdown of plan assets

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

	2018	2017
Debt securities	21%	21%
Equity securities	27	26
General accounts	51	52
Other	1	1
Total	100%	100%

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)

	2018	2017
Discount rate	0.5%	0.5%
Expected rate of return on plan assets	2.5%	2.5%

# Note 12 Other Comprehensive Income

Amounts of recycling and income tax relating to other comprehensive income for the years ended March 31, 2017 and 2018 were as follows:

	Millions	Millions of yen	
	2018	2017	2018
Unrealized holding gains on securities:			
Amount recognized in the year under review	¥22,543	¥(6,124)	\$212,670
Amount of recycling	(320)	(652)	(3,019)
Before income tax effect adjustment	22,223	(6,777)	209,651
Amount of income tax effect	(6,739)	2,100	(63,575)
Unrealized holding gains on securities	15,484	(4,677)	146,075
Retirement benefits liability adjustments:			
Amount recognized in the year under review	259	107	2,443
Amount of recycling	404	497	3,811
Before income tax effect adjustment	664	605	6,264
Amount of income tax effect	(202)	(184)	(1,906)
Retirement benefits liability adjustments	461	420	4,349
Total other comprehensive income	¥15,945	¥(4,256)	\$150,425

# Note 13 Contingent Liabilities

For the year ended March 31, 2018 No corresponding items.

For the year ended March 31, 2017 No corresponding items.

# Note 14 Government Grants -

For the years ended March 31, 2017 and 2018

Government grants of ¥798 million (\$7,528 thousand) for buildings and ¥113 million (\$1,066 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) Information on Sales and Profit (Loss), Identifiable Assets / Liabilities, and Other Items by Reportable Segment

		Millions of yen			
	Reportable	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	¥202,977	¥202,977	¥11,887	¥214,865	
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.

	Millions of yen				
	Reportable	segments			
As of March 31, 2017	Pharmaceuticals	Total	Other*1	Total	
Net sales:					
Sales to third parties	¥ 61,454	¥ 61,454	¥10,251	¥ 71,706	
Intersegment sales and transfers	—	—	4,975	4,975	
Total	¥ 61,454	¥ 61,454	¥15,227	¥ 76,682	
Segment profit	¥ 7,670	¥ 7,670	¥ 744	¥ 8,415	
Segment assets	¥178,393	¥178,393	¥10,618	¥189,011	
Other items:					
Depreciation*2	¥ 2,182	¥ 2,182	¥ 337	¥ 2,519	
Increase of property, plant and equipment and intangible assets*2	2,419	2,419	411	2,830	

\*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.

As of March 31, 2018		Thousands of U.S. dollars			
	Reportable segments				
	Pharmaceuticals	Total	Other*1	Total	
Net sales:					
Sales to third parties	\$ 602,745	\$ 602,745	\$ 95,453	\$ 698,198	
Intersegment sales and transfers	—	—	48,340	48,340	
Total	\$ 602,745	\$ 602,745	\$143,792	\$ 746,547	
Segment profit	\$ 86,840	\$ 86,840	\$ 5,962	\$ 92,802	
Segment assets	\$1,914,877	\$1,914,877	\$112,142	\$2,027,028	
Other items:					
Depreciation*2	\$ 21,604	\$ 21,604	\$ 3,453	\$ 25,057	
Increase of property, plant and equipment and intangible assets*2	23,104	23,104	4,689	27,802	

\*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.

# (4) Reconciliation Items between Segment Information and the Consolidated Financial Statements

(i) Major items for adjustments

	Millions	Millions of yen			
	2018	2017	2018		
Net sales:					
Total of reportable segments	¥ 63,891	¥ 61,454	\$ 602,745		
Other segments	15,242	15,227	143,792		
Elimination of intersegment transactions	(5,124)	(4,975)	(48,340)		
Reported on consolidated financial statements	¥ 74,009	¥ 71,706	\$ 698,198		
Segment profit:					
Total of reportable segments	¥ 9,205	¥ 7,670	86,840		
Other segments	632	744	5,962		
Elimination of intersegment transactions	65	54	613		
Adjustments to depreciable assets	(22)	17	(208)		
Other adjustments	7	4	66		
Reported on consolidated financial statements	¥ 9,887	¥ 8,491	\$ 93,274		
Segment assets:					
Total of reportable segments	¥202,977	¥178,393	\$1,914,877		
Other segments	11,887	10,618	112,142		
Elimination of intersegment transactions	(1,777)	(2,210)	(16,764)		
Reported on consolidated financial statements	¥213,087	¥186,801	\$2,010,255		

# (ii) Other items for adjustments

	Millions	Millions of yen	
	2018	2017	2018
Depreciation:			
Total of reportable segments	¥2,290	¥2,182	\$21,604
Other segments	366	337	3,453
Adjustments	(163)	(148)	(1,538)
Reported on consolidated financial statements	¥2,492	¥2,370	\$23,509
Increase of property, plant and equipment and intangible assets:			
Total of reportable segments	¥2,449	¥2,419	\$23,104
Other segments	497	411	4,689
Adjustments	(301)	(14)	(2,840)
Reported on consolidated financial statements	¥2,645	¥2,815	\$24,953

### (5) Related Information

(i) Product and service information

	Millions of yen		Thousands of U.S. dollars
	2018	2017	2018
Pharmaceuticals	¥63,891	¥61,454	\$602,745
Other	10,118	10,251	95,453
Total	¥74,009	¥71,706	\$698,198

# (ii) Geographical information

(1) Net sales

	Millions of yen		Thousands of U.S. dollars
	2018	2017	2018
Japan	¥65,666	¥65,387	\$619,491
Europe	5,402	3,419	50,962
Other	2,941	2,899	27,745
Total	¥74,009	¥71,706	\$698,198

(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

	Million	s of yen	Thousands of U.S. dollars	
	2018	2017	2018	
Alfresa Corporation	¥11,797	¥11,539	\$111,292	
SUZUKEN CO., LTD.	10,455	10,178	98,632	
MEDICEO CORPORATION	8,027	8,026	75,726	

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

#### (6) Information on Loss on Impairment of Property, Plant and Equipment by Reportable Segment

For the year ended March 31, 2018 No corresponding items.

For the year ended March 31, 2017

		Millions	of yen	
	Reportable s	egment		
	Pharmaceuticals	Total	Other*	Total
Impairment loss	47	47		47

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

#### (7) Information on Amortization of Goodwill and Remaining Unamortized Balance by Reportable Segment

For the years ended March 31, 2017 and 2018 No corresponding items.

#### (8) Information on the Remaining Balance and Gain on Negative Goodwill by Reportable Segment

For the years ended March 31, 2017 and 2018

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, 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 (%)	with related	Details of	Transa amc (millions) (thousands o	ount s of yen)	Account	Outstandin at the end o (millions (thousands of	of the year of yen)
Companies in which executives and their close relations own a majority of voting right	Kanzawa Limited s	Matsumoto City, Nagano Prefecture	10	Real estate rental, insurance agency	6.6 (held)	—	Acquisition of treasury stock*2	¥4,183	\$39,462	—	—	—

\*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).

For the year ended March 31, 2017

No corresponding items.

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

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	Transa amo (millions (thousands of	unt of yen) U.S. dollars)		Outstandir at the end (millions (thousands o	of the year of yen) f U.S. dollars)
Executives of important subsidiaries and their close relations	Kanzawa	—	—	—	—	*1	Acquisition of treasury stock*2	¥278	\$2,622	—	—	—

\*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).

For the year ended March 31, 2017

No corresponding items.

## Note 17 Selling, General and Administrative Expenses -

Selling, general and administrative expenses for the years ended March 31, 2017 and 2018 are as follows:

	Millions	Millions of yen	
	2018	2017	2018
Payroll costs	¥ 9,399	¥ 9,512	\$ 88,670
Research and development expenses	14,179	13,877	133,764
Depreciation	784	695	7,396
Other	13,869	14,054	130,840
Total	¥38,232	¥38,140	\$360,679

## Note 18 Amounts Per Share -

Amounts per share as of March 31, 2017 and 2018 are as follows:

	Ye	Yen		
	2018	2017	2018	
Net assets	¥3,761.03	¥3,258.76	\$35.48	
Profit attributable to owners of parent	188.26	158.74	1.78	
Cash dividends	48.0	46.0	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 19 Subsequent Events -

No corresponding items.

# Independent Auditor's Report



A member mini of Ernst & foung Global Limited

# Corporate Information

As of March 31, 2018

# Corporate Data



Head Office

Company Name KISSEI PHARMACEUTICAL CO., LTD.

Established August 9, 1946

Capital ¥24,356 million

# Number of Employees

1,512 (Non-consolidated)

URL https://www.kissei.co.jp/e\_contents/

# Major Business Locations/Consolidated Subsidiaries

# **Head Offices**

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, 2018

# **Stock Exchange Listing**

Tokyo

### **Stock Code**

4547

# **Common Stock**

Authorized 227,000,000 shares

Issued 51,811,185 shares Number of Shareholders 3,816 (Year-on-year change: 10 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)	27,226	5.8
The Hachijuni Bank, Ltd.	24,132	5.2
Mizuho Bank, Ltd.	18,334	3.9
Kanzawa Limited	16,782	3.6
The Master Trust Bank of Japan, Ltd. (Trust account)	16,338	3.5
Mutsuo Kanzawa	15,406	3.3
Kissei Group Employee Stockholders Committee	12,790	2.7
Nabelin Co., Ltd.	12,223	2.6
THE NAGANO BANK, LTD	11,260	2.4

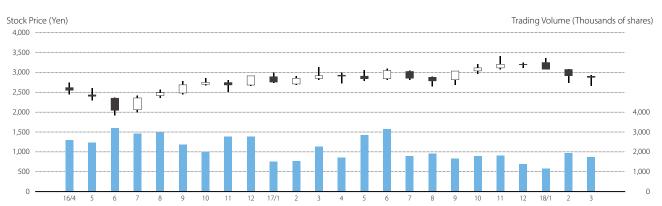
Note: Kissei holds 50,947 hundred shares of treasury stock but is not included in the above list of principal shareholders. Further, the calculation of voting rights percentages is based on total shares issued net of treasury stock.

# **Composition of Shareholders by Category**

# Composition of Shareholders by Number of Shares Held



# Stock Price Range / Trading Volume





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



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