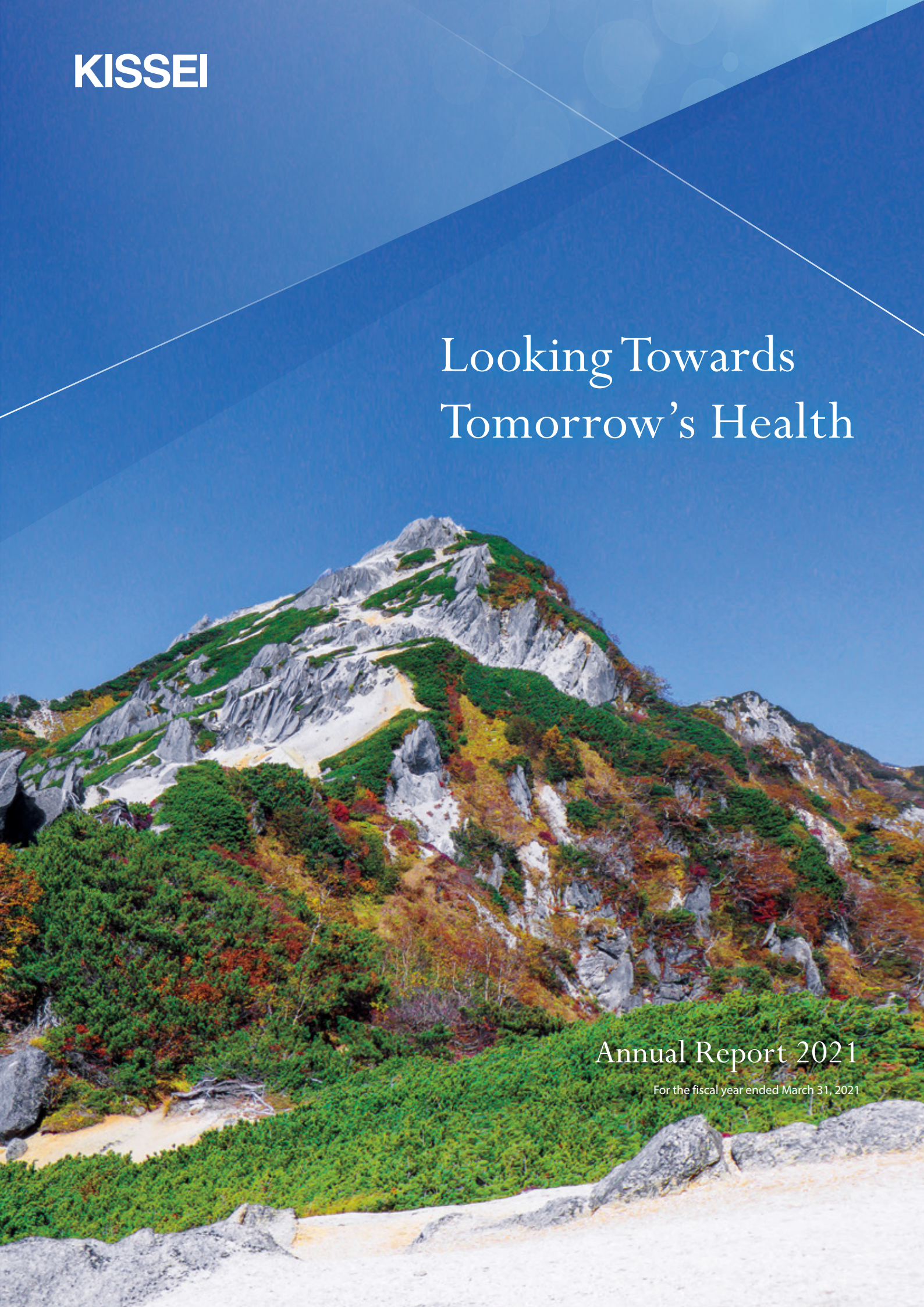
KISSEI

Looking Towards Tomorrow's Health



Annual Report 2021

For the fiscal year ended March 31, 2021

Contents

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.

Cover Photo: Mt. Tsubakuro in early autumn (Azumino, Nagano)

Cautionary Notice

The financial forecasts, R&D plans, and other forward-looking statements that appear in this annual report are based on information available to the Company at the time of disclosure. For that reason, please be aware that actual results may vary greatly from these projections due to a variety of important factors.

Figures in this annual report are rounded down to the nearest unit.

Kissei Code of Conduct

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.
Therefore, based on the following principles, we pledge to respect human rights in Japan and overseas, comply with and adhere to the spirit of all laws and regulations, and act with high ethical standards.

1. We will develop and provide products that are useful to society in all our fields of business. In the pharmaceutical business, we conduct drug discovery R&D and provide a stable supply of high-quality, highly useful drugs with excellent safety and efficacy.
2. We will conduct clinical trials with the cooperation of medical institutions, giving the utmost effort to respecting the human rights of patients, ensuring safety, and conducting trials with scientific rigor.
3. We will provide accurate, scientifically backed information domestically and overseas regarding product quality, safety, and efficacy to ensure the proper use of drugs, and we will promptly collect, analyze, evaluate, and then communicate information after manufacturing and marketing said drugs.
4. We will engage in free competition in a fair and transparent manner. We will also maintain sound and proper relationships with medical professionals, business partners, governments, and administrations.
5. We will work to promote communication with shareholders and society as a whole, actively disclose appropriate information inside and outside the Company, and increase the transparency of corporate activities.
6. We will give due consideration to the protection of personal information and take every possible measure to protect it in light of the progress of advanced information technology.
7. We will respect the diversity, character, and individuality of all employees, aim to increase their ethical standards and abilities, and ensure for them a safe and comfortable working environment.
8. We will take an active approach toward the environment and make efforts of our own volition in recognition that tackling environmental issues is an important matter for all humanity and is crucial to the survival of the Company and its activities.
9. We will engage in social contribution activities as good corporate citizens.
10. We will stand adamantly against antisocial forces that threaten the order and safety of civil society.
11. We will comply with all international rules and local laws when conducting international business. Furthermore, we will also respect local cultures and customs and work to contribute toward local development.
12. We will listen to voices inside and outside of the Company to establish an effective system and ensure corporate ethics are thoroughly enforced. Management, in recognition of its duty to maintain the spirit of this Code of Conduct and to therefore lead in a way befitting of the Code, will take painstaking efforts to disseminate it on a Groupwide basis and make certain it is understood by business partners.
13. If there is a violation of the Code of Conduct, top management will work to resolve any problems, investigate the cause, and make efforts to prevent recurrence. Furthermore, we will disclose information in a timely manner to the public, hold ourselves accountable, clarify the Company's authority and responsibilities in light of the violation, discipline those responsible strongly, and accept discipline ourselves.

The History of Kissei Pharmaceutical

Since its founding in 1946, Kissei Pharmaceutical has been committed to the development of new drugs, with patients as its number one priority. Looking to the future, we will continue to conduct research and development and challenge ourselves to create new and unique drugs, guided by the belief that "a pharmaceutical company cannot exist without R&D."

1946

1946 Founded as Tachibana Seikagaku Institute Co., Ltd. (Matsumoto, Nagano)

1964 Corporate name changed to Kissei Pharmaceutical Co., Ltd.
1969 General Research Laboratories constructed (Matsumoto)
1973 General Research Laboratories expanded (Matsumoto)

1961 Launched GASCON, a gastrointestinal anti-gas agent

1980

1980 Manufacturing Plants constructed (Matsumoto)
1985 Second Research Laboratories constructed (Azumino, Nagano)
1988 Listed on the Second Section of the Tokyo Stock Exchange

1982 Launched RIZABEN, a treatment for allergic diseases

1986 Launched UTEMERIN, a treatment for threatened abortion and preterm labor
1988 Launched XANBON, a drug for improving cerebral circulation

1990

1990 Foodstuff Business Unit established
Construction of Central Research Lab in Azumino City completed
General Research Institute relocated

1991 Listed on the First Section of the Tokyo Stock Exchange
1994 Shiojiri Plants constructed (Shiojiri, Nagano)

1991 Launched BEZATOL, a treatment for hyperlipidemia
1992 Launched FRAGMIN, an anticoagulant
Launched DOMENAN, a treatment for bronchial asthma

2000

1995 Tokyo Head Office established
1996 Pharmaceutical Laboratory constructed (Azumino)
1997 Tokyo Head Office (Koishikawa) established
1999 Environmental Basic Policy established

2001 Nutritional Business Center constructed (Shiojiri)

2004 Kissei America, Inc., established
2007 Joetsu Chemical Laboratories constructed (Joetsu, Niigata)
2009 Silodosin (Japanese name: Urief®) launched in the United States

1995 Launched RIZABEN Eye Drops, a treatment for allergic conjunctivitis
1999 Launched RIZMON TG, a treatment for glaucoma

2004 Launched Glufast, a treatment for diabetes
2005 Launched SALAGEN, a treatment for dry mouth symptoms
2006 Launched Urief, a treatment for dysuria associated with benign prostatic hyperplasia

2010

2010 Silodosin (Urief®) launched in Europe
2015 Second Research Laboratories received full AAALAC International* accreditation

* The Association for Assessment and Accreditation of Laboratory Animal Care International

2010 Launched Epoetin Alfa BS Injection [JCR], a treatment for renal anemia
2011 Launched Glubes Combination Tablet, a treatment for diabetes
2014 Launched SAVENE, a treatment for anthracycline extravasation
2015 Launched P-TOL, a treatment for hyperphosphatemia
2017 Launched RECTABUL, a treatment for ulcerative colitis
2018 Launched Beova, a treatment for overactive bladder
2019 Launched Darbepoetin Alfa BS Injection [JCR], a treatment for renal anemia
2020 Began sales of MARIZEV, a treatment for diabetes
Began sales of MINIRIN MELT, DESMOPRESSIN Formulations, and other products

1946—Our Beginning

The story of Kissei starts with the establishment of the Tachibana Seikagaku Institute. The institute was founded in August 1946, in the wake of World War II, amid a lack of pharmaceuticals and other resources. During the war, a Tokyo-based pharmaceutical manufacturer was evacuated to Matsumoto City, in Nagano Prefecture, where it set up in a health foods factory and worked with local members of the pharmaceutical industry who had strong hopes of establishing a new pharmaceutical company in the area. With a great deal of cooperation from these local members, this company was created in Matsumoto City, with the purpose of manufacturing pharmaceutical drugs.

"The Two S's"

Kissei's logo is composed of the Company name, with the two S's supporting the surrounding circle.

The circle represents the harmony between the society of earth and our employees working to bring that society to its ideal state. The S's represent the two pillars of our Management Philosophy, which are to "contribute to society through high-quality, innovative pharmaceutical products" and to "serve society through our employees."

"A Pharmaceutical Company Cannot Exist Without R&D"

In August 1982, we launched RIZABEN®, a treatment for allergic diseases. We encountered several difficulties when conducting R&D for RIZABEN®. However, we were able to push through them, driven by the strong belief that a pharmaceutical company cannot exist without R&D, to produce the first anti-allergic drug to serve as an orally administered asthma treatment.

In subsequent drug discovery research, we launched Glufast®, a treatment for diabetes, in Japan in 2004, and Urief®, a treatment for dysuria associated with benign prostatic hyperplasia, in Japan in 2006. Urief® grew to become a major product that is sold in 59 countries, including the United States.

Our method for overseas development is to license out our technology. We are also engaged in in-licensing as part of active efforts to expand our development pipeline. Working with our partners in Japan and overseas, we have launched or began sales of several products in Japan since 2010.

We will continue to contribute to society by providing new treatment options to medical sites in Japan and overseas, so patients suffering from illness can regain their smiles and live more typical, happier lives.

Value Creation Process

Management Philosophy

Contribute to society through high-quality, innovative pharmaceutical products

Serve society through our employees

Management Vision

Kissei Code of Conduct

Social Issues / External Environment

- Declining birthrate and aging population
- Restrictions on medical and social security costs
- Diversifying medical needs
- Diversifying drug discovery modalities
- Diversifying work styles
- Consideration for the environment
- Revitalizing local communities

Kissei's Management Capital

Human Capital
Human resources with profound knowledge and technical skills

Intellectual Capital
Competitive intellectual property with a focus on small molecules

Social Capital
Relationships of trust with patients, medical professionals, local communities, and other stakeholders

Financial Capital
Strong capital structure via a high shareholders' equity ratio

Production Capital
Skilled and knowledgeable human resources, facilities such as factories and laboratories, and related equipment

Natural Capital
Co-existence with nature as a life-related company

Business Activities

Five-Year Medium-Term Management Plan "PEGASUS"

P. 8–9

- Pharmaceuticals
  - Research
  - Development
  - Production
  - Sales and marketing
  - Supply chain
  - Reliability assurance
- Therapeutic and care foods

The Three Categories of Materiality Related to Business Activities

P. 6–7

1. Development and provision of products useful to society
2. Steady supply of high-quality products
3. Communication with medical professionals and patients

The Four Categories of Materiality Related to Kissei's Management Base

P. 6–7

1. Strengthening and enhancement of governance
2. Creation of a fulfilling workplace environment
3. Environmental initiatives
4. Social contribution as a good corporate citizen

Created Value

Economic Value

- Expansion of stable earnings
- Stable and sustainable returns to shareholders

Social Value and Contributions to the SDGs Centered on SDG3*

- Creation and provision of innovative drugs and medical treatment solutions
- Improved quality of life for patients and their families
- Provision of appropriate drug and treatment-related information
- Provision of a motivating workplace and opportunities to develop abilities
- Reduction of environmental impact
- Contribution to local communities

* "Ensure healthy lives and promote well-being for all at all ages."

Create sustainable value through further accumulation and circulation of management capital

Kissei's Materiality

Kissei Pharmaceutical leverages its business activities to provide continuous value based on its Management Philosophy, which is to "contribute to society through high-quality, innovative pharmaceutical products" and "serve society through our employees." One of the basic policies of its five-year medium-term management plan, **PEGASUS**, is to "promote ESG and the SDGs." Under this policy, the Company is working to achieve sustainability in terms of society and the earth's environment, which is the ultimate goal of the SDGs. As part of this effort, we have once again plotted issues on two axes—relevance to company business and impact on stakeholders—to narrow down issues of importance. Based on the results, we have identified a series of priority issues (materiality) for the Company to focus its initiatives, which will contribute to the achievement of the SDGs.

Promotion System

Aimed at helping achieve the SDGs, the Company's promotion system for the SDGs is rooted in the SDGs Promotion Committee, which is chaired by the officer in charge of ethics and the environment. The committee formulates a variety of measures to promote the SDGs, which includes identifying materiality; implements these measures in cooperation with related departments; and proposes and reports details of these activities to the Board of Directors.

Process for Identifying Materiality

(current step as of August 2021) (to be completed)

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
Identify social and internal issues, making reference to international guidelines*	Have the heads of 35 departments prioritize the issues via an in-Company survey after receiving SDG training	Narrow down the number of priority issues through dialogues with external experts regarding the survey results	Have the SDGs Promotion Committee and the Board of Directors identify materiality	Revise materiality based on changes in the business environment and constructive dialogues with stakeholders

* SDGs, SASB Standards, GRI Standards, Access to Medicine Index.

The Seven Categories of Materiality (Priority Issues)

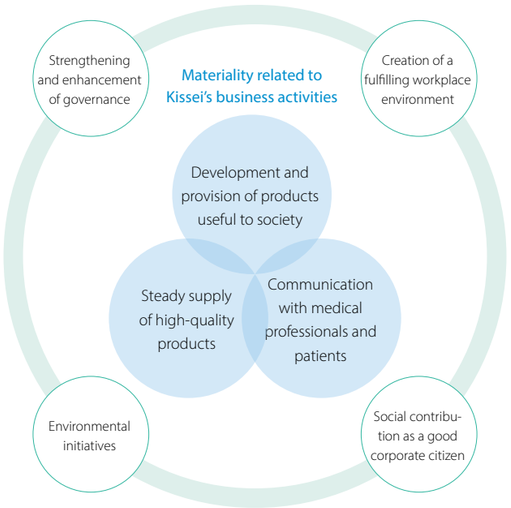
Based on our Management Philosophy, we consider it our mission and most pressing issue to contribute to the health and medical care of people around the world by providing ethical drugs and other high-quality, innovative pharmaceutical products. For patients suffering from illnesses to be able to use our products with peace of mind, it is highly important that we provide a steady supply of high-quality items coupled with appropriate information.

Therefore, we have created three categories of materiality related to business activities:

Development and provision of products useful to society
Steady supply of high-quality products
Communication with medical professionals and patients

We have also created four categories of materiality related to our management base, which supports the aforementioned business activities. These categories are "strengthening and enhancement of governance"; "creation of a fulfilling workplace environment"; "environmental initiatives," aimed at making the earth's environment sustainable; and "social contribution as a good corporate citizen," which centers on social development in the local area of Nagano where Kissei's head office is situated.

Materiality related to Kissei's management base



Kissei's Materiality

Main SDGs related to the seven categories	Description of materiality	Key initiatives
Materiality related to Kissei's business activities		
Development and provision of products useful to society	**Development of innovative products (drugs, foods)** P. 14, 18 We contribute to the health and medical care of people around the world by providing ethical drugs and other high-quality, innovative pharmaceutical products developed by the Company or through partnerships.	• Drug discovery initiatives • Promotion of clinical development projects • Promotion of licensing activities and overseas development
	Contribution to scientific technology P. 43 We contribute toward greater health and welfare by making patents and dissertations for innovative technology created through pharmaceutical research, and by open innovation with academic institutions and other entities.	• Joint research with academia and other pharmaceutical companies • Participation in consortiums sponsored by the Japan Pharmaceutical Manufacturers Association • Provision of research grants through the Kanzawa Medical Research Foundation
Steady supply of high-quality products	**Quality control and steady supply and procurement** P. 24 We build manufacturing and quality control systems that comply with the latest laws, regulations, and guidelines, procure environmentally friendly materials, and work to provide a steady supply of products in recognition of the fact that our products are related to people's very lives.	• Formulation and implementation of the "Stable Supply Manual" • COVID-19-related countermeasures • Implementation of the Kissei Pharmaceutical Quality System
Communication with medical professionals and patients	**Promote proper product usage (drugs, foods)** P. 20 We provide accurate information backed by science, understanding that offering proper information and promoting proper usage is essential for demonstrating the maximum value of our products.	• Promotion of activities to provide appropriate medical information • Creation of a sales system for rare disease treatments • Introduction of AI Detail • Immediate provision of safety information via the safety information provision system
	Improve customer satisfaction and provide patient support P. 42 We contribute to medical treatment by offering the solutions that medical professionals and patients really need.	• Operation of the medicine consultation window • Operation of a patient-oriented website
Materiality related to Kissei's management base		
Strengthening and enhancement of governance	**Strengthen governance** P. 30 We have positioned strengthening corporate governance as an important management issue for the continued improvement of corporate value, and we are working to create a system that can address changes inside and outside the Company quickly and flexibly.	• Formulation and implementation of the Kissei Basic Policy on Corporate Governance • Appointment of a female director • Increase of the number of outside directors
	Risk management P. 24, 37 We promote the smooth execution of corporate activities by properly managing risks that may hinder the realization of our Management Philosophy and the completion of our management plans and mounting an appropriate response to any risks that manifest.	• Creation of a risk management system • Development and update of business continuity plans to include disaster and pandemic countermeasures
	Compliance P. 38 We practice compliance when conducting corporate activities, understanding that this is fundamental to the sound development of the Company and earning stakeholder trust.	• Implementation of compliance program • Establishment of a whistleblowing and consultation system (Kissei Hotline) • Consideration given to animal welfare when conducting experimentation on animals
Creation of a fulfilling workplace environment	**Human resource cultivation** P. 40 We respect the individuality of each employee and provide a variety of opportunities for employees to develop their skills, focusing on individual abilities and aptitudes in an effort to develop human resources who can contribute to the development of the Company and society.	• Implementation of rank-based and job-specific training • Support for self-development • Establishment of interview system for skill and career development
	Promote diversity and gender equality P. 40 We are striving to improve the Company's working environment in terms of hiring practices, working styles, our human resource system, and other aspects to ensure that a wide range of employees can demonstrate a variety of abilities, based on the idea that when employees with different modes of thinking and value systems can recognize and inspire each other, they can add dynamism and creativity to a company.	• Initiatives to cultivate the next generation (Platinum Kurumin, etc.) • Initiatives to promote the success of women • Prevention of discrimination and harassment • Recruitment of people with disabilities
	Enhance workplace environment P. 40 We will create worthwhile workplace environment that gives employees a strong sense of motivation as work-style reforms and the response to COVID-19 bring major changes to working conditions.	• Recognition under the 2021 Certified Health & Productivity Management Outstanding Organizations Recognition Program (Large Enterprise Category) • Promotion of work–life balance • Initiatives related to occupational health and safety and maintaining employee health
Environmental initiatives	**Waste management and resource recycling** P. 39 We work to promote the conservation of a sustainable environment through the effective use of resources, preventing pollution and reducing environmental impact.	• Maintenance of environmental management systems (acquisition of ISO 14001 certification, etc.) • Implementation of environment conservation activities (management of chemical substances, etc.) • Priority purchasing of green products
	Initiatives toward biodiversity P. 39 We take care to ensure that our business activities do not adversely affect biodiversity and ecosystems and take action accordingly.	• Proper management of research and clinical trials that involve genetically modified organisms • Proper management over purchasing reagents (confirmation of whether reagents fall under the Cartagena Act)
	Climate change countermeasure P. 39 We promote environmental management that acknowledges that climate change is a risk factor, with the goal of sustainable growth for society and the Company, and in accordance with the Japan's Carbon Neutrality Declaration.	• Continued reduction of CO_2 emissions • Promotion of energy-saving measures and climate change countermeasures
Social contribution as a good corporate citizen	**Participate in social contribution activities** P. 43 We contribute to the sustainable development of society as an intrinsic part of our corporate activities. Moreover, we actively participate in social contribution activities and endeavor to realize our Management Philosophy as a corporate citizen and a member of society.	• Contribution to culture, the arts, and sports (support in exchange for naming rights, support for activities such as the Seiji Ozawa Matsumoto Festival, and the Matsumoto Yamaga Football Club) • Participation in local cleanup activities and offering factory and research institute tours • Donations to child welfare facilities and assistance for natural disasters

Five-Year Medium-Term Management Plan "**PEGASUS**"

In light of changing business conditions in Japan and overseas, Kissei Pharmaceutical embarked on a five-year medium-term management plan, "**PEGASUS**," from April 2020 and is making efforts under the four policies listed below. Under this plan, we aim to achieve sustainable growth as an R&D-oriented company.

The Basic Policies of "**PEGASUS**"

1. Increase domestic sales
2. Strengthen earnings base overseas
3. Expand development pipeline
4. Strengthen the management base to cope with the changes in the business environment

Products Scheduled to Be Launched or Filed for Approval during "**PEGASUS**"

		2017	2018	2019	2020	2021–2024 (FY)
Domestic	Urology		Beova® (overactive bladder)	MINIRIN MELT® 25μg / 50μg (nocturia due to nocturnal polyuria in males)	MINIRIN MELT®60μg / 120μg / 240μg (central diabetes insipidus (all versions), nocturnal enuresis resulted from decrease of urine osmolality or urine specific gravity (120μg / 240μg only))	
	Renal Diseases / Dialysis		P-TOL® Granules (hyperphosphatemia) Nalfurafine GE (pruritus in dialysis patients)	Darbepoetin Alfa BS Injection [JCR] (renal anemia)		**Difelikefalin (MR13A9)** (uremic pruritus in dialysis patients)
	Diabetes			Glubes® OD (combination drug of rapid insulin secretagogue / postprandial hyperglycemic agent)	MARIZEV® (sustained selective DPP-4 inhibitor)	
	Gastroenterology	RECTABUL® (ulcerative colitis)				**Carotegrast Methyl (AJM300)**【NDA filed】 (ulcerative colitis)
	Gynecology	Dienogest GE (endometriosis)				
	Rare Diseases				**Avacopan (CCX168)*** 【NDA filed】 (microscopic polyangiitis, granulomatosis with polyangiitis)	**Rovatirelin (KPS-0373)** (spinocerebellar ataxia) **Fostamatinib (R788)*** (chronic idiopathic thrombocytopenic purpura) **CG0070** (non-muscle invasive bladder cancer)
Overseas	Out-Licensing			Remogliflozin (type 2 diabetes mellitus / SGLT2 inhibitor) (launched in India by licensee)	**Linzagolix (OBE2109)** (uterine fibroids) 【MAA filed in Europe】	**Linzagolix (OBE2109)** (uterine fibroids (U.S.), endometriosis)

(Notes)
1. Blue: Launched / Red: Designated as an intractable disease / * Designated as an orphan drug
2. For products launched during the medium-term management plan directly prior to **PEGASUS**, please refer to page 16.

Under "**PEGASUS**," we will make investments in three directions. The first is "sales," aimed at market growth for strategically important products launched over the course of the previous medium-term management plan and the introduction of new products to be launched in the future. The second, "R&D," is specifically aimed at advancing drug discovery research and development projects. The third direction for investments is "in-licensing" of development themes and products aimed at expanding our development pipeline and product lineup. As a result of our investment efforts, we launched MINIRIN MELT® and MARIZEV®, in April 2020, with plans to either launch or submit applications to launch six products for domestic sale. Of these six products, four are in the area of rare diseases, which is an area we intend to build sales and information provision systems for in the future. Overseas, licensee ObsEva SA will submit an application of approval for Linzagolix, a GnRH receptor antagonist discovered by Kissei, with the expectation of launching the drug over the course of the medium-term management plan. We will develop a system to supply drug substances to ObsEva for this purpose.

Performance Outlook

	Fiscal 2020 Results (First year of the plan)	Fiscal 2021 forecast (Second year of the plan)	Targets for final year (Fiscal 2024)
Consolidated net sales	¥69.0 billion	¥63.5 billion	¥87.0 billion or higher
Net sales for the pharmaceutical business	¥56.4 billion	¥53.0 billion	¥75.0 billion or higher
Pharmaceuticals*1	¥48.1 billion	¥45.5 billion	¥62.5 billion or higher
Therapeutic and care foods	¥3.7 billion	¥3.6 billion	¥4.5 billion or higher
Others*2	¥4.5 billion	¥3.9 billion	¥8.0 billion or higher
Consolidated operating income	¥1.5 billion	¥(2.6 billion)	¥9.0 billion or higher
R&D investment	¥9.6 billion	¥9.5 billion	¥13.0 billion
ROE	2.6%	2.3%	5.0% or higher

1. Increase domestic sales
2. Strengthen earnings base overseas
3. Expand development pipeline
4. Strengthen the management base to cope with the changes in the business environment

*1. Including active pharmaceutical ingredients (API) and bulk exports.
*2. Includes supply to domestic sales partners and revenue from technical fees (contracting fees related to out-licensing, milestone payments, and running royalties).

1. Increase domestic sales

① Expand sales of new products ② Expand product portfolio by launching new products and in-licensing
③ Expand earnings in therapeutic and care foods

In the urology area, we are cultivating MINIRIN MELT® as a product to work alongside Beova® to increase our presence in the market. In the renal diseases and dialysis area, we are working to expand sales of P-TOL® and Darbepoetin Alfa BS Injection while advancing development of Difelikefalin. In the diabetes area, we are aiming to increase sales of Glubes® and MARIZEV®. In the rare diseases area, we are building sales and information provision systems for Avacopan and Fostamatinib to ensure smooth introduction to the market after launch. In therapeutic and care foods, we are seeking to enhance sales under the quality assurance system we have developed to date.

2. Strengthen earnings base overseas

① Establish new overseas earnings by our original product Linzagolix ② Out-license new drugs

We will establish Linzagolix as our new global product and fortify our overseas earnings base with new out-licensing initiatives. We will also secure overseas earnings for existing products in collaboration with partner companies.

3. Expand development pipeline

① Promote R&D focused on small molecules ② In-license according to therapeutic area strategies

We will draw from our medical chemistry* base, which is one of our strengths, and focus R&D on small molecules to prompt innovative drug discovery. To ensure that we can launch new drugs and products on a continuous basis, we will expand in-licensing of competitive themes and optimize our development pipeline.

* A research method for obtaining candidate compounds that involves establishing a screening system for therapeutic targets (receptors, etc.), utilizing a large number of compounds to find chemical structures that act on those targets, and using the data obtained to design and synthesize compounds that are well suited as drugs for evaluation.

4. Strengthen the management base to cope with the changes in the business environment

① Further strengthen corporate governance ② Promote compliance with laws and regulations
③ Continue the stable supply of high-quality products and reduce costs ④ Develop personnel for the next generation
⑤ Optimize cost structure ⑥ Promote ESG and the SDGs

By executing "**PEGASUS**" as planned, we will fulfill our social responsibilities and realize sustainable growth as an R&D-oriented company with a clear raison d'etre.

COO Interview

Yoshio Furihata
President and
Chief Operating Officer

Q Please tell us about fiscal 2020 in terms of Kissei Pharmaceutical's financial performance and as a year overall and about what changes you anticipate in the future?

The outlook for the Japanese economy remains uncertain, considering the prolonged impact of COVID-19 and the ongoing stagnation of the global economy. The pharmaceutical industry continued to be hit with harsh business conditions. In addition to the promotion of generic drug use and other measures to curb medical costs, the NHI drug price revisions implemented in April 2020 brought with them additional requirements for promoting new drug discovery and eliminating off-label drug use. Despite these additional requirements, the replacement rate of drugs by generic versions meant more drastic price cuts for drugs that have been listed in the NHI Drug Price Standard for a long period of time.

But, even under these conditions, we were able to fulfill the obligations of any pharmaceutical company, that is, to provide a steady drug supply, provide appropriate drug information, and collect safety information, in addition to conducting new drug R&D. In the future, we will continue to respond to business conditions with a mind toward life with COVID-19 and post-COVID-19.

One of the biggest external factors affecting business for pharmaceutical companies is the NHI drug pricing system. Previously, drug prices were revised once every two years, but in April 2021, drug prices were revised one year ahead of schedule for the first time. In other words, this is the first time that prices will have been revised in consecutive years. What is more, the range of these revisions—reductions, essentially—exceeded expectations. This means we have to pay close attention to a few matters. First, we need to consider whether drugs that are currently available will be subject to this scale of revision year after year. And, since we are developing several new drugs, we also need consider how their prices will be calculated. For any company planning to launch new drugs in the future, difficulties in predicting drug prices is a major issue, since these prices are directly tied to profits, and Kissei is no exception.

As social security costs rise every year, the sustainability of the social security system is a growing concern. Therefore, we need to consider a balanced solution to ensure its survival. This requires stakeholders of this system to work alongside the pharmaceutical companies to shoulder the costs. I think that the drugs pharmaceutical companies produce need to be given their due for the role they play in medical treatment and, more than ever, the companies need to realize that drug prices represent the financial value of our assets, and if these assets lose their financial value, our survival is at risk.

Q What is your impression of the first year of **PEGASUS**, the Company's five-year medium-term management plan?

PEGASUS is our medium-term management plan that spans from April 2020 to March 2025, and our growth strategy, aimed at recovery and regrowth from the negative impact on profits suffered as a result of the December 2018 patent expiration of Urief® (Japanese product name), a drug discovered by Kissei and a treatment of dysuria associated with benign prostatic hyperplasia.

PEGASUS was launched as Kissei was in the middle of its response to COVID-19, a response that became necessary at the beginning of 2020. Despite this timing, every division and department achieved their targets in the first year of the plan. In the domestic market, orders of Beova®, a treatment for overactive bladder, and Darbepoetin Alfa BS Injection JCR* , a treatment for renal anemia, exceeded expectations, requiring us to adjust shipping volume in order to keep up with demand. We deeply regret any inconvenience experienced by medical professionals as a result of any inability or delay in delivering products that can assist with patients' treatment and care. For Beova® in particular, we are looking into increasing production with the manufacturer and distributor to establish a steady supply system as soon as possible and to ensure that there is no need for shipping adjustments in fiscal 2022.

In terms of R&D, fiscal 2020 was an exciting year indeed, with great progress being made in several late-stage projects. New Drug Applications (NDAs) were submitted for projects after obtaining positive results from phase III clinical trials, the final stage of such trials. An NDA was submitted to the European Medicines Agency by licensee ObsEva SA for the approval of linzagolix (generic name), a treatment for uterine fibroids, in Europe. In addition, Kissei submitted an NDA in Japan for avacopan (generic name), a treatment for ANCA-associated vasculitis. We are also preparing to submit an application in Japan for rovatirelin, a treatment for spinocerebellar ataxia. Three projects are currently at the phase III clinical trial stage. These projects are for fostamatinib (generic name), a treatment for chronic idiopathic thrombocytopenic purpura, difelikefalin (generic name), a treatment for uremic pruritis in dialysis patients, and CG0070 (development code), a treatment for bladder cancer. Moreover, in early fiscal 2021 EA Pharma Co., submitted an NDA application in Japan for carotegrast methyl (generic name), a treatment for ulcerative colitis.

Likewise, in therapeutic and care foods, we have developed new approaches to our customers amid fierce competition and the effects of COVID-19, with progress going according to plan.

* Adjustments to shipping volume are no longer required as August 2021.

Q What specific measures do you have in store for fiscal 2021?

In the domestic market, we intend to ramp up efforts to promote MINIRIN MELT® (25μg/ 50μg), a treatment for nocturia, and MARIZEV®, a treatment for diabetes, since these efforts were previously stymied by COVID-19. MINIRIN MELT® is the first drug in Japan with an indication for nocturia due to nocturnal polyuria in males. It has been reported that nocturia can lead to poor sleep and a decreased quality of life (QOL), but I believe that the condition is not properly recognized in Japan. Because of this, we will utilize our website and public lectures in an effort to actively and steadily educate people about how treating nocturia can improve a person's QOL. Diabetes is another field that we have been involved in for several years, and we will promote fast-acting Glufast®, Glubes®, which is a combination tablet of Glufast® and voglibose (generic name), and MARIZEV®, which is administered once a week, as treatments we have created to accommodate patients' differing conditions and living situations.

In R&D, we will continue moving forward to ensure that projects with NDAs in process will receive approval, to submit applications that are in preparation, and to prove the efficacy and safety of projects that are in phase III clinical trials. We have more projects in the late stage of development than ever before and related divisions are putting in the extra work. Even if a project reaches the late stage, there is no guarantee that a new drug will be approved. However, I feel positive about the results coming from clinical trials.

Since we have late-stage projects targeting multiple rare diseases, we launched the Rare Diseases Project, dedicated to marketing treatments, within the Sales and Marketing Division in April 2021. It is estimated that each project in development for a rare disease drug treatment targets about 10,000 patients. Patients with rare diseases typically take multiple drugs as part of their treatment. In addition, the doctors who prescribe our drugs are

highly specialized experts who have long been involved in the pathology, diagnosis, and treatment of rare diseases, the latter of which includes drug therapy. To keep this small number of medical experts properly informed about these drugs, we must also be well acquainted with the pathology of these diseases as well as other drug treatments. This is why we have established the Rare Diseases Project—we believe that having a team with a deep well of expertise is crucial if we want to give any degree of comfort to patients via any new drugs we provide.

Q What is Kissei's financial strategy and how will it handle the allocation of capital?

Our fundamental financial strategy is to improve corporate value while maintaining a balance between providing stable returns to shareholders and giving top priority to investments that will lead to growth.

In **PEGASUS**, growth investments are divided into three categories. The first is "sales," for investments aimed at expanding the market for key strategic products launched under the previous medium-term management plan, and for introducing new products that will be launched going forward. The second category is "R&D," for investments aimed at drug discovery research and driving development projects. The third investment category is "in-licensing," investments in development themes and product in-licensing aimed at expanding both the development pipeline and our product portfolio. We are taking a flexible approach to shareholder returns, continuing to provide stable dividend payouts with an emphasis on total return ratio while purchasing treasury stock.

In fiscal 2021, we will prioritize up-front investments to promote growth and anticipate operating and ordinary losses as a result. That said, we expect to launch multiple late-stage projects to the market in the near future, meaning that we can also expect to recover income with a high degree of certainty. In light of this, we are planning to increase dividends for the 14th consecutive fiscal year. Although we expect performance to bottom out in fiscal 2021, we expect to return to profitability by fiscal 2022, the third year of **PEGASUS**, by increasing sales of new product groups, including Avacopan and Beova®, anticipating no need for shipping adjustments to the latter.

Our approach to financial assets is driven by the belief that we need an amount of on-hand liquidity in the form cash, deposits and securities that will allow us to actively and flexibly promote our business strategy. This includes a suitable amount of funds needed for in-licensing development themes and products. However, we intend to utilize our cross-shareholdings and other investment securities both systematically and effectively to reduce the amount of investment securities held, while using the extraordinary income recorded from selling these securities to secure net income and resources for dividends. With the cash generated from these sales, we will make investments with priority given to those that will lead to growth.

One of the targets set within **PEGASUS** is to achieve an ROE of 5.0% or higher by the final year of the plan. We are aiming for higher capital efficiency while being careful to keep a stable management base over the long term.

Q The five-year medium-term management plan highlights promoting ESG and the SDGs. What initiatives are you focusing on in this regard?

Increasing corporate value with ESG management is not something that can be done solely at the executive level or by relying on one part of the organization. If our initiatives are to help achieve the SDGs, it is vital that not only top management but also each and every employee, those people working every day on the front lines, understand the importance of these initiatives, and take it upon themselves to help resolve ESG-related issues. Therefore, we are utilizing in-house newsletters and online training as ways to inform employees, from management to general employees, on ways that the Company and they as individuals can help resolve social issues. In fiscal 2021, Kissei's SDGs Promotion Committee has been playing a central role in identifying materiality and promoting other initiatives in line with the SDG Compass, a guide for business action to advance the SDGs. As a member of top management, I will continue working actively to promote ESG and the SDGs. For more information on materiality, please refer to page 6 of this report.

Joetsu Chemical Laboratories

COVID-19 has caused massive harm worldwide, with a major impact on social activities. While the surrounding conditions have changed considerably, we will work in accordance with **PEGASUS** to contribute to people's health. Therefore, we will enhance new drug R&D efforts to treat rare diseases and other maladies even further. Moreover, we will develop therapeutic and care foods and foods for the elderly, working on the belief that a healthy diet leads to a healthy body. In terms of the environment and society, we will make an active effort to reduce energy consumption, create a rewarding work environment, and conduct activities that contribute to local communities and society. As for governance-related efforts, we are working under the guidance of the Kissei Basic Policy on Corporate Governance and the Compliance Program Manual to ensure transparency by complying with the laws and internal regulations relevant to the various aspects of management and to promote highly ethical corporate activities in good faith, in recognition of our social responsibility to all stakeholders.

Q Finally, is there something you would like to communicate to stakeholders?

My background is in the clinical development of new drugs. As part of this work, I have spoken with patients with rare diseases, for which there are few treatments, and their doctors, who spend their days and nights looking for changes in their patients' symptoms. While it is still important to develop more effective, safer, and more convenient treatments for lifestyle-related diseases, it is also imperative that we develop treatments, which are few in number, for these rare diseases. And so, we will continue to research, develop, manufacture, and sell drugs, empowered by our "passion for patients"—the desire to alleviate a patient's symptoms by whatever degree is possible. As a first step, we will do our utmost to bring projects in the late stages of development to our patients as soon as we can.

As we take on this challenge, we look to you all for your continued understanding and support.

August 2021

Yoshio Furihata
President and Chief Operating Officer

Research and Development (R&D)

Basic Policy

As an R&D-oriented pharmaceutical company, Kissei Pharmaceutical aims to develop and provide a steady stream of new drugs through drug discovery research and in-licensing of development themes in key areas.

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.

Shinji Kikuchi
Director, General Manager of Research Division

Drug Discovery Research

Kissei engages in research focused on small molecule-based drug discovery, driven by its mission to contribute to society through the creation of highly competitive and innovative drugs that meet medical needs.

Although therapeutic modalities have diversified in recent years, the creation of new small molecule drugs has been receiving attention once again. An advantage of small molecules is that they can be applied to a variety of target molecules within tissue, regardless of whether these molecules are inside or outside of a cell. Therefore, small molecules are being reexamined, not only for their potential to develop drugs that can replace monoclonal antibody drugs or nucleic acid drugs, but also for their convenience and impact on medical economics. Another major point of appeal for small molecules is that it is possible to create entirely new classes of drugs that exert new effects by binding to different areas of target molecules than conventional drugs, even in typical targets such as enzymes or receptors. Moreover, research on the groundbreaking idea of small molecules for inducing proteolysis has reached the clinical trial stage and is expected to show practical applications. Thanks to technical innovations, the possibilities of drug discovery stemming from small molecules continues to grow. For instance, growing sophistication of the chemical structure of small molecule drugs and technological developments related to middle molecule drugs have opened the door for drug discovery aimed at protein–protein interactions responsible for transmitting and regulating intracellular signals, with hundreds of thousands of interactions as potential targets.

Our strength when it comes to drug discovery research is our molecular design technology for small molecule drug discovery, which brings together the work of researchers in structural biology and other fields conducted over the course of many years. In particular, we have accumulated a track record of in silico drug discovery, having succeeded in both optimizing chemical compounds and creating new mother nucleus compounds through a combination of target protein discovery, structural analysis, and computational chemistry. We believe that by combining in silico technology with high-throughput screening technology and by employing a screening process that emphasizes scientifically valid mechanisms, we can increase the accuracy of innovative drug discovery.

On the other hand, if we, as a company rooted in drug discovery research, are to keep increasing our corporate value when technological innovation is moving forward with each passing day, we need to continue our work to build a strong technology base and innovate our drug discovery research process. One of these technological innovations is drug discovery conducted using AI. We are working with consortiums that utilize open innovation to develop AI with practical applications and as part of industry-academic collaborations aimed at developing the next generation of AI for drug discovery, with hopes of acquiring the resulting technology. We are also focused on building a new drug discovery platform that aims to create drugs with new mechanisms of action by making full use of cryo-electron microscopes and other advanced structural analysis technology.

We intend to enhance our development pipeline, which includes gene therapy, and positioned as key strategic fields are urology, renal diseases and dialysis, diabetes, and rare diseases. However, our drug discovery research is not locked into these fields and is instead aimed at creating new drugs that can be expanded globally and responding to increasingly diverse and complex medical needs of today, while bearing in mind a medium- to long-term perspective. KSP-0243 is an example of a drug created by Kissei that is keeping with this approach as a treatment for inflammatory bowel disease that is currently in phase I clinical trials.

Going forward, we will continue to fulfill our mission to treat diseases without full-fledged treatments with drug discovery that can only be achieved with a small molecule-based approach.

Yuji Kiyono
General Manager and Division Director of Clinical Development Division

Developments in Clinical Trials

The Clinical Development Division is committed to new drug development with a division-wide policy of professionalism and a broad perspective, as well as a mission in keeping with Kissei's Management Philosophy—to contribute to society through high-quality innovative pharmaceutical products and to serve society through its employees. All members of the division adhere to this policy and are always conscious of their duty "to serve every patient."

In fiscal 2021, we will move forward with the review of two projects that have been submitted for New Drug Application (NDA) approval, with the goal of receiving certification. These projects concern avacopan as a treatment for anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV) and carotegrast methyl as a treatment for ulcerative colitis. We will also continue to prepare an application for the approval of rovatirelin as a treatment for spinocerebellar ataxia, working in collaboration with licenser Shionogi & Co., Ltd. There are also three projects in the final stage of development, with phase III clinical trials underway for fostamatinib as a treatment for chronic idiopathic thrombocytopenic purpura, difelikefalin as a treatment for uremic pruritis in dialysis patients, and CG0070 as an oncolytic viral therapy for non-muscle-invasive bladder cancer. CG0070 is particularly notable as it marks Kissei's first global phase III clinical trials for regenerative medicine. Since several projects in late-stage development involve new territory for the Company, the members of the Clinical Development Division are putting their utmost effort into bringing each project to the next stage.

The spread of COVID-19 has brought with it major changes in the way clinical trials are conducted, and we have stepped beyond the bounds of our pool of knowledge and experience to actively introduce new approaches and initiatives to a variety of clinical trials. These efforts will enable us to make steady progress in the growth strategy included in **PEGASUS**, our five-year medium-term management plan.

In February 2021, we submitted an NDA for the approval of avacopan, a selective complement C5a receptor antagonist discovered by U.S.-based ChemoCentryx, Inc., as a treatment for microscopic polyangiitis and granulomatosis with polyangiitis classified as ANCA-associated vasculitis. ANCA-associated vasculitis has been designated as an intractable inflammatory disease by the Ministry of Health, Labour and Welfare (MHLW). In 2017, Kissei obtained sublicensing rights from Swiss-based Vifor Fresenius Medical Care Renal Pharma Ltd. Due to the low number of domestic patients suffering from the disease—around 12,000—avacopan was designated as an orphan drug by the MHLW in March 2019.

When making such developments in the area of rare diseases, many cases arise when it is difficult to build the clinical data package necessary for submitting an application for approval using clinical trials conducted exclusively in Japan owing to the small number of domestic patients. Therefore, the effective use of overseas clinical trial results and global clinical trials are crucial for ensuring both early application and approval. In the case of avacopan, the drug was already undergoing global phase III clinical trials (the ADVOCATE trial) when it was in-licensed in Japan. Therefore Japan's participation in the ADVOCATE trial was very difficult in terms of the schedule. However, thanks to prompt discussions with the Pharmaceuticals and Medical Devices Agency (PMDA), preparations for Japan's participation in the ADVOCATE trial moved forward quickly. As a result, it was possible to incorporate a number of Japanese patient cases (agreed upon with the PMDA in advance) in the ADVOCATE trial within the case registration deadline. Moreover, since the trial yielded positive results, we were able to submit an application for approval in Japan without significantly delaying the application for approval in Europe and the United States.

At present, limited options remain for the treatment of intractable and rare diseases. In this light, our efforts to develop rovatirelin as a treatment for spinocerebellar ataxia, designated as an intractable disease by the MHLW, serve as a reminder of our mission to listen to the voices of those suffering from these illnesses and to promptly develop and deliver drugs that can provide even a minor form of treatment to these patients.

"To serve every patient"—it is with this phrase in mind that we will keep striving to develop new drugs to fulfill unmet needs.

R&D Pipeline (as of August 2021)

Generic name / Development code	Expected indications	Development stage: Phase I	Phase II	Phase III	Preparation to submit application	NDA in process	Remarks
Avacopan / CCX168	Microscopic polyangiitis, granulomatosis with polyangiitis						
Carotegrast Methyl / AJM300	Ulcerative colitis						
Rovatirelin / KPS-0373	Spinocerebellar ataxia						
Fostamatinib / R788	Chronic idiopathic thrombocytopenic purpura						
Difelikefalin / MR13A9	Uremic pruritis in dialysis patients						
CG0070	Non-muscle-invasive bladder cancer						(Joint global Phase III clinical trial)
Discovered products							
Linzagolix / KLH-2109	Uterine fibroids	(Europe)					(Conducted by ObsEva SA)
		(U.S.)					
	Endometriosis	(U.S. and Europe)					(Conducted by ObsEva SA)
		(Japan)					
KDT-3594	Parkinson's disease	(China, other countries)					(Conducted by Affamed Therapeutics Limited)
		(Japan)					
KSP-0243	Inflammatory bowel disease						

Changes compared with *Annual Report 2020*

Major R&D Projects

Selective complement C5a receptor antagonist
Avacopan
(generic name, development code: CCX168)

Avacopan is a small molecule agent developed by U.S.-based ChemoCentryx, Inc. The drug is a first-in-class orally administered selective complement 5a receptor inhibitor exerting an anti-inflammatory effect for the treatment of patients with anti-neutrophil cytoplasmic auto-antibody (ANCA)-associated vasculitis (AAV). In June 2017, Kissei obtained the development and marketing rights in Japan of avacopan from Vifor Fresenius Medical Care Renal Pharma Ltd. (VFMCRP). Subsequently, Kissei participated with VFMCRP in the global double-blind phase III clinical trial (ADVOCATE trial), which was sponsored by ChemoCentryx. Based on the positive results of the trial, in February 2021, Kissei submitted an NDA for approval for manufacturing and marketing in Japan. The Ministry of Health, Labour and Welfare has granted avacopan orphan drug designation for microscopic polyangiitis and granulomatosis with polyangiitis, which are two forms of AAV. Overseas, ChemoCentryx has submitted an NDA for avacopan as a treatment for AAV in the United States, and VFMCRP has filed an NDA in Europe.

Treatment for ulcerative colitis
Carotegrast Methyl
(generic name, development code: AJM300)

Carotegrast methyl is a small molecule agent that acts as an alpha-4 integrin antagonist that was discovered by EA Pharma Co., Ltd. (formerly known as Ajinomoto Pharmaceuticals Co., Ltd.) Since entering into a domestic alliance in 2015, EA Pharma and Kissei have jointly developed the drug and aim to launch it as the first commercial orally administered small molecule alpha-4 integrin antagonist product in the world. In May 2021, EA Pharma filed an application for marketing approval in Japan based on the results of the phase III clinical study AJM300/CT3 and other studies conducted domestically.

In July 2021, the results of the AJM300/CT3 study were presented during the 16th Congress of the European Crohn's and Colitis Organisation (ECCO '21).

Treatment for spinocerebellar ataxia
Rovatirelin
(generic name, development code: KPS-0373)

Rovatirelin is an orally administered derivative of thyrotropin-releasing hormone (TRH) discovered by Shionogi & Co., Ltd. Kissei conducted an initial phase III clinical trial of rovatirelin's indication for spinocerebellar ataxia from 2013 to 2015. Based on the results of the initial phase III clinical trial, Kissei conducted an additional phase III clinical trial starting from 2016 to 2018. The primary endpoint of these trials was the mean change from baseline in total SARA*1 score for the assessment of ataxia. However, a statistically significant difference from the placebo-controlled group was not determined. To review the results of both phase III clinical trials, Kissei performed a pooled (post hoc) analysis with patients who met the inclusion criteria for the additional phase III trial, which comprised patients with a more severe condition. The change in total SARA score produced from this analysis indicated a statistically significant improvement compared with the placebo group. The results of these trials were published in the online version of *Journal of Neurology, Neurosurgery, and Psychiatry*.*2 Furthermore, Kissei is in preparations to submit an application for approval based on these results.

*1. Scale for the assessment and rating of ataxia
*2. Nishizawa M, Onodera O, Hirakawa A on behalf of the Rovatirelin Study Group, et al. Effect of rovatirelin in patients with cerebellar ataxia: two randomised double-blind placebo-controlled phase 3 trials. *Journal of Neurology, Neurosurgery & Psychiatry*, published online First: 14 January 2020. doi: 10.1136/jnnp-2019-322168

Small molecule tyrosine kinase inhibitor
Fostamatinib
(generic name, development code: R788)

In October 2018, Kissei acquired the development and commercialization rights for fostamatinib, an orally available small molecule, in Japan, China, Korea, and Taiwan from Rigel Pharmaceuticals, Inc. Kissei is currently conducting domestic phase III clinical trials for the drug as a treatment for patients with chronic idiopathic thrombocytopenic purpura (chronic ITP).

Treatment for uremic pruritis
Difelikefalin
(generic name, development code: MR13A9)

Difelikefalin is a kappa opioid receptor agonist discovered by U.S.-based Cara Therapeutics, Inc. In April 2013, Maruishi Pharmaceutical Co., Ltd., in-licensed the drug to Japan from Cara Therapeutics, and in March 2017, Kissei and Maruishi entered into a collaboration agreement for the development and sale of the drug, which has an indication for uremic pruritis in dialysis patients. Kissei and Maruishi completed a late-stage phase II clinical study of difelikefalin, an intravenous injection formulation administered during dialysis through the dialysis circuit for the treatment of uremic pruritus in hemodialysis patients. This study has produced favorable results and phase III clinical trials have been underway since 2020.

Treatment for non-muscle-invasive bladder cancer
CG0070

CG0070 is an oncolytic immunotherapy in which adenovirus is genetically modified to enhance the selectivity and anticancer activity of bladder tumor cells. It does not replicate in normal cells, but it replicates inside the tumor cells selectively, causing tumor cell lysis and immunogenic cell death. In March 2020, Kissei acquired the exclusive development and marketing rights for the agent from CG Oncology, Inc., for 20 Asian countries and regions, such as Japan, South Korea, and Taiwan with the exception of China.

Following in-licensing of the drug, Kissei began preparations for clinical trials in Japan, which took place in March 2021 as part of the BOND3 study, a global phase III clinical trial led by CG Oncology conducted across four countries but focused in the United States.

Treatment for inflammatory bowel disease
KSP-0243

KSP-0243 is a small molecule agent discovered by Kissei that is currently undergoing phase I clinical trials.

Overseas Expansion and In-Licensing

Basic Policy

Kissei's basic strategy for overseas expansion is to obtain profits from supplying drug substances and royalty income by licensing out its original products. As part of our five-year medium-term management plan **PEGASUS**, we will establish linzagolix as a new global product and strengthen our overseas earnings base by licensing out new products.

Kousuke Nakada
Department Manager of Business Development Department

Partnerships with Overseas Companies

Getting approval in Europe and the United States for linzagolix, a treatment for uterine fibroids and endometriosis, is a realistic prospect thanks to our partner company ObsEva SA. ObsEva is a biotech company based in Switzerland founded by an obstetrician / gynecologist and is focused on developing new drugs in the field of obstetrics and gynecology. The company has a group of human resources with a strong track record in new drug development and has been able to push the development of linzagolix to the application stage in Europe and the United States. In 2020, ObsEva introduced a new CEO from the United States with extensive experience in marketing new drugs and is making preparations to sell linzagolix under his leadership. One of the benefits of teaming up with a biotech company is that the very best human resources can be gathered from around the world, instead of being limited to people from within one company, and their contributions can be used to research, develop, and market new drugs. Going forward, we are planning to create new partnerships to promote the development of linzagolix in Asian regions in addition to Japan, the United States, and Europe.

Ahead of this move, we are developing KDT-3594, another important drug discovered by the Company as a treatment for Parkinson's disease, in the Asian regions first. In 2020, we entered into a licensing agreement with Chinese biotech company Affamed Therapeutics Limited (hereinafter Affamed), granting the company the right to develop and commercialize the drug in China and several other Asian countries. In 2021, Phase II clinical trials began in Asia. In recent years, people with R&D experience for novel drug development gained at global companies based in the United States and Europe have been establishing biotech companies in China. These companies have been developing an increasing number of novel drugs in Asia and globally. Affamed is just such a company, and with its leading group of professionals working on KDT-3594, we expect prompt development of the drug in Asia. In the future, we plan to utilize data obtained in Japan and Asia to select licensees for KDT-3594 in Europe and the United States.

We are also actively engaged in in-licensing with overseas companies to incorporate global innovation as one of our major strategies to increase sustainable corporate value. Over the last few years, in-licensing has been focused on rare diseases with small numbers of patients and on intractable diseases that are difficult to treat. In the past five years, we have conducted in-licensing for avacopan,* fostamatinib,* and CG0070,* which are drugs that target rare and intractable diseases. These are drugs being developed by biotech companies based on the west coast of the United States. Kissei is contributing to the efficient development of these drugs by working closely with its overseas partners and participating in global clinical trials from Japan, or by utilizing global data to conduct smaller-scale but more efficient development efforts. As a result, we anticipate prompt delivery to patients in Japan suffering from these intractable diseases.

When difficult problems arise and our own capabilities will not suffice, we know that such problems can be overcome through cooperation—this means accepting the help of those around us and giving the best of ourselves in return. When dealing with a difficult disease, a limit exists to what one person can do on their own, and likewise, we as a company may not be able to handle a disease alone. However, similar to Kissei, there are many pharmaceutical and biotech companies around the world with the same desire to tackle intractable diseases and deliver novel drugs to patients. Many such companies have their eyes on Kissei, a company with a strong track record in out-licensing, to see whether we will put forth any drug discovery seeds that can be developed globally. We intend to work with these companies and utilize the support of scientists and medical professionals around the world to provide patients with high-quality drugs as quickly as possible to provide these patients with some relief. With this goal in mind, the Kissei Pharmaceutical Business Development Department search for partnerships with people around the world.

* Please refer to the R&D pipeline on page 16.

Out-Licensing (for drugs discovered by Kissei) (as of August 2021)

Generic name / Development code	Expected indications	Country / Region	Development stage: Phase I	Phase II	Phase III	Preparation to submit application	NDA in process	Partner company
Silodosin	Dysuria associated with benign prostatic hyperplasia	Vietnam, other countries						Eisai Co., Ltd. (Japan)
Linzagolix	Uterine fibroids	Europe						ObsEva SA (Switzerland)
Linzagolix	Uterine fibroids	U.S.						ObsEva SA (Switzerland)
Linzagolix	Endometriosis	Europe, U.S.						ObsEva SA (Switzerland)
Bedoradrine	Acute exacerbation of asthma	U.S.						MediciNova, Inc. (U.S.)
KDT-3594	Parkinson's disease	China, other countries						Affamed Therapeutics Limited (China)

Changes compared with *Annual Report 2020*

Development of Linzagolix in Europe and the U.S.

Linzagolix is a novel, orally administered GnRH receptor antagonist. Linzagolix acts by binding to and blocking the GnRH receptor in the pituitary gland, ultimately reducing estrogen production by the ovaries. In November 2015, Kissei licensed out exclusive rights to develop and market linzagolix in countries worldwide, excluding Japan and other parts of Asia, to ObsEva SA. ObsEva has been conducting phase III clinical trials for the indications of uterine fibroids and endometriosis. The phase III clinical trials for uterine fibroids have been completed, and an NDA was submitted for approval in Europe in November 2020. Of the two phase III clinical trials conducted for indications of endometriosis, EDEWEISS 2, which was being conducted in the United States, was canceled due to the impact of COVID-19, whereas EDEWEISS 3, which is being conducted in Europe and the United States, is ongoing.

Uterine fibroids, one of the expected indications for linzagolix, are benign tumors that form in the muscle tissue of the uterus and are frequently observed in females of childbearing age. Menorrhagia, anemia, pain, pelvic pressure, and frequent urination are some of the symptoms that occur and affect the daily life of patients. According to an overseas study, more than 70% of women in the United States experience uterine fibroids by age 50.* In the United States, the long-term medical treatment is scarce and therefore surgery is a common option. There are 300,000 hysterectomies conducted annually as a treatment of uterine fibroids.

* Am J Obstet Gynecol. 2012 March; 206 (3): 211

Out-licensing of KDT-3594 to China-Based Affamed Therapeutics

KDT-3594 is a novel orally administrable non-ergot dopamine agonist, which acts by stimulating dopamine receptors in the basal ganglia, thereby ameliorating the symptoms of Parkinson's disease caused by insufficient action of dopamine. It has also been confirmed as a new therapeutic agent for Parkinson's disease that reduces the risk of the characteristic side effects of existing ergot and non-ergot dopamine agonists.

In October 2020, Kissei granted China-based Affamed Therapeutics Limited exclusive rights for the development and commercialization of KDT-3594 in China, Taiwan, Hong Kong, Macao, and six Southeast Asian countries (Singapore, Malaysia, Thailand, Indonesia, Vietnam, and the Philippines). Affamed is currently conducting phase II clinical trials (as of August 2021).

Sub-Licensing Agreement for Fostamatinib

Since acquiring the development and sales rights for fostamatinib in Japan, China, Korea, and Taiwan from Rigel Pharmaceuticals, Inc., Kissei has been responsible for conducting phase III clinical trials in Japan as well as partnering activities outside of Japan in areas where it has obtained such rights. As a result, in June 2021, Kissei entered into a sub-licensing agreement with South Korea-based JW Pharmaceutical Co., Ltd., to license development and sales rights in South Korea. In August of that same year, Kissei entered into a similar sub-licensing agreement with China-based Inmagene Biopharmaceuticals, granting them the same rights in China.

Providing Drug Information

Suminori Sagara
Director, General Manager of Sales and Marketing Division

The Closest Partners of Medical Professionals in the Mission to Improve Patients' Lives

We have positioned urology, renal diseases and dialysis, and diabetes as key areas for marketing, with a lineup of multiple products coupled with activities to provide drug information appropriate for each disease and condition.

In the urology field, MINIRIN MELT® was positioned as a grade A recommended treatment for nocturia due to nocturnal polyuria in males after 2020 revisions to guidelines for the treatment of nocturia. In addition to providing drugs such as Urief® and Beova®, we will contribute to the treatment of patients as a manufacturer of multiple treatments for lower urinary tract symptoms (LUTS) through activities to provide information, which includes increasing awareness of these ailments.

In renal diseases and dialysis, study after study has been published stressing the importance of phosphorous management for dialysis patients. P-TOL®, a treatment for hyperphosphatemia, can help patients maintain strict phosphorous control. In June 2021, Kissei entered into a co-promotion agreement with SANWA KAGAKU KENKYUSHO Co., Ltd., for UPASITA® Injection Syringe, a treatment for secondary hyperparathyroidism. Both companies have begun providing information on the treatment. Since the patients targeted by P-TOL® and UPASITA® Injection Syringe overlap, we expect to see synergies appear between the two drugs.

We have been working with doctors working in the area of diabetes treatments since our launch of Glufast® more than 17 years ago. In April 2020, we added MARIZEV®, a once-weekly sustained selective DPP-4 inhibitor to our lineup, in addition to Glubes® Combination Tablet. In these ways, we will help with the treatment of patients by putting forth drug treatments that suit their pathological conditions and lifestyles.

There is a growing need to provide information digitally to keep pace with changes in the external environment that include work-style reforms among doctors and the spread of COVID-19. In response, we have been enhancing our digital tools. For instance, we introduced "AI-Detail," a service on our site for medical professionals that utilizes AI to provide voice information regarding our products. However, the role of medical representatives (MRs) has not changed, which is to act as the medical professionals' closest partners by listening to medical issues and working with them to resolve these issues and help patients recover their health. In the future, we will continue with the hybrid style of providing information and utilizing the benefits of both in-person and digital methods.

In addition to these three key areas, we are developing multiple treatments for rare diseases. The foremost example of these efforts is our Feburualy 2021 submission of an NDA for avacopan, a treatment for ANCA-associated vasculitis. Aiming to bring treatments for rare diseases to market, we launched the "Rare Diseases Project" in April 2021. This project is devoted to marketing, education, and other activities in the area of rare diseases, and preparations to introduce the treatments are ongoing.

While rare diseases are handled by a limited number of medical experts and facilities, these diseases can cause a high degree of suffering for patients and can be life-threatening if not treated properly. To address this problem, we will build a stable sales and distribution system that can ensure a steady supply of drugs for difficult-to-treat patients. We are also working to train our human resources, particularly our MRs. These MRs are responsible for providing medical information and work with doctors as partners, so we are making sure that they have the specialized knowledge to discuss treatment policies and other matters. In addition to utilizing our ability to propose solutions, an ability cultivated in our key areas, we intend to shift toward a patient-oriented approach to providing information that is more mindful of the patient journey.*

The Sales and Marketing Division will adhere to Kissei's Management Vision—to be an R&D-oriented pharmaceutical company that contributes to the health of people around the world through innovative pharmaceutical products—and fulfill its duty as the anchor in providing drugs to medical professionals and patients.

* The process during which patients acknowledge their illnesses and share their actions, thoughts, and emotions over their care period, from medical examinations to treatment.

Introducing AI-Detail

AI-Detail is a new automated information system for medical professionals seeking information on our products. Users can perform a keyword search on the Company's website for necessary drug information, and the system will automatically select slides with related information. Users can choose slides based on necessity and interest. Slides that are chosen are presented to the user along with a voice explanation. In addition to having their inquiries answered via our MRs and our Product Customer Service Center, we believe this service will allow medical professionals to obtain necessary information in any place and at any time.

Establishment of the Rare Diseases Project

We have multiple late-stage development projects in the area of rare and designated intractable diseases. In April 2021, we established the Rare Diseases Project within the Sales and Marketing Division as a way to facilitate the smooth entry of these new products resulting from these projects into the market. Due to the small number of patients in the area of rare diseases, there are a limited number of medical experts and suitable facilities. We set up this project department to build a specialized and advanced information provision system for medical experts and staff so the maximum number of patients suffering from an intractable disease can receive appropriate treatment, even if that disease affects just one person.

By bringing new drugs to the market that can function as new treatment options for rare and intractable diseases, we can help improve medical care for those people suffering from these diseases.

Treatments for Rare Diseases Scheduled to Be Launched or Filed during **PEGASUS**

Generic name / Development code	Development stage	Expected indications
Avacopan / CCX168	New Drug Application	Microscopic polyangiitis and granulomatosis with polyangiitis
Rovatirelin / KPS-0373	Preparation to submit application	Spinocerebellar ataxia
Fostamatinib / R788	Phase III clinical trials	Chronic idiopathic thrombocytopenic purpura
CG0070	Phase III clinical trials	Non-muscle-invasive bladder cancer

- Lineup of late-stage development projects in the area of rare and intractable diseases
- Construction of a specialized and advanced information provision system for the limited number of medical experts and suitable structure to ensure patients can receive appropriate treatment

Main Products (as of August 2021)

Urology

		Results for fiscal 2020 (millions of yen)*1	Projected sales in fiscal 2021 (millions of yen)*1
Overactive Bladder Treatment Beova® 	**Active ingredient:** Vibegron **Indications:** Urinary urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder **Month of release:** November 2018 (tablet) ● Joint development and marketing with KYORIN Pharmaceutical Co., Ltd.	7,024	8,300
DESMOPRESSIN Formulations MINIRIN MELT®, etc. 	(MINIRIN MELT® OD tablets 25μg/50μg/60μg/120μg/240μg) **Active ingredient:** Desmopressin acetate hydrate **Indications:** Nocturia due to nocturnal polyuria in males (OD tablets 25μg/50μg) Central diabetes insipidus (OD tablets 60μg/120μg/240μg) Nocturnal enuresis resulting from decrease of urine osmolality or urine specific gravity (OD tablets 120μg/240μg) **Month of release by the Company:** April 2020 (OD tablets) ● Marketing and distribution operations transferred from Ferring Pharmaceutical Co., Ltd., with co-promotion by both Ferring and Kissei	3,464*2	4,000*2
Dysuria Treatment Urief® 	**Active ingredient:** Silodosin (Japanese Pharmacopoeia) **Indications:** Dysuria associated with benign prostatic hyperplasia **Month of release:** May 2006 (capsules*3), February 2009 (tablets), January 2016 (OD tablets) ● Joint development and marketing with Daiichi Sankyo Company, Limited	3,671	2,900

Renal diseases and dialysis

Hyperphosphatemia Treatment P-TOL® 	**Active ingredient:** Sucroferric oxyhydroxide **Indications:** Improvement of hyperphosphatemia in patients with chronic kidney disease on dialysis **Month of release:** November 2015 (chewable tablets), November 2018 (granules)	5,885	6,600
Treatment for Renal Anemia Darbepoetin Alfa BS Injection [JCR] 	**Active ingredient:** Darbepoetin alfa (genetic recombination) [darbepoetin alfa biosimilar 1] **Indications:** Renal anemia **Month of release:** November 2019 (syringe) ● Joint development with JCR Pharmaceuticals Co., Ltd.	4,883	3,500
Treatment for Renal Anemia Epoetin Alfa BS Injection [JCR] 	**Active ingredient:** Epoetin kappa (genetic recombination) [epoetin alfa biosimilar 1] **Indications:** 1. Renal anemia during dialysis 2. Immature infant anemia **Month of release:** May 2010 (syringe) ● Joint development with JCR Pharmaceuticals Co., Ltd.	4,416	2,900

Diabetes

		Results for fiscal 2020 (millions of yen)*1	Projected sales in fiscal 2021 (millions of yen)*1
Treatment for Diabetes Glubes® 	**Active ingredient:** Mitiglinide calcium hydrate (Japanese Pharmacopoeia), Voglibose (Japanese Pharmacopoeia) **Indications:** Type 2 diabetes, limited to cases where a treatment with a combination of mitiglinide calcium hydrate and voglibose is deemed appropriate **Month of release:** July 2011 (combination tablet), June 2019 (combination OD tablet)	4,308	4,000
Treatment for Diabetes Glufast® 	**Active ingredient:** Mitiglinide calcium hydrate (Japanese Pharmacopoeia) **Indications:** Type 2 diabetes **Month of release:** May 2004 (tablet), June 2016 (OD tablets)	1,161	1,000
Treatment for Diabetes MARIZEV® 	**Active ingredient:** Omarigliptin **Indications:** Type 2 diabetes **Month of release by the Company:** April 2020 (tablet) ● Distribution operations transferred from MSD K.K.	1,547	1,700

Gastroenterology, etc.

Treatment of Dry Mouth Symptoms SALAGEN® 	**Active ingredient:** Pilocarpine hydrochloride (Japanese Pharmacopoeia) **Indications:** 1. Improvement of dry mouth symptoms associated with radiotherapy to the head and neck 2. Improvement of dry mouth symptoms in patients with Sjogren's syndrome **Month of release:** September 2005 (tablet), December 2014 (granules)	1,526	1,400
Treatment for Ulcerative Colitis RECTABUL® 	**Active ingredient:** Budesonide **Indications:** Ulcerative colitis (except for severe cases) **Month of release:** December 2017 (injectable foam) ● Joint development with EA Pharma Co., Ltd.	791	800

*1. Based on sales figures for fiscal 2020 announced in May 2021.
*2. Combined total for MINIRIN MELT® OD tablets 25μg/50μg/60μg/120μg/240μg, DESMOPRESSIN Intranasal 0.01% Kyowa, DESMOPRESSIN Spray 2.5 Kyowa, DESMOPRESSIN Spray 10 Kyowa, and DESMOPRESSIN Injection 4 Kyowa.
*3. Currently not for sale.

Production, Supply, and Reliability Assurance

Basic Philosophy of the Kissei Quality Policy

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

Tsuyoshi Naganuma
General Manager of Pharmaceutical Manufacturing

Providing a Stable Supply of High-Quality Drugs, Drawing from Our Management Philosophy as the Source of Our "Quality Culture"

The spread of COVID-19 has brought with it significant changes to economic activities and lifestyles. Successive cases of drug recalls from other companies and the suspension of supply during these times have been strong reminders of the need to provide high quality drugs to patients in a stable manner. Therefore, we have drawn from our experience of the Great East Japan Earthquake of 2011 to enhance our business continuity plans (BCP), while formulating a stable supply manual referencing the guidelines for ensuring a steady drug supply put forth by The Federation of Pharmaceutical Manufacturers' Associations of Japan. Based on these measures, we store a sufficient inventory of drugs divided among several locations to ensure that we can maintain a stable supply system even if natural disasters, a pandemic, or other factors prevent plant operations. Similarly, we work to uncover risks that might hinder continued procurement and the quality of raw materials for drugs, particularly drug substances and the materials produced from those substances, and strive to enhance supply chain management with measures that include production at multiple locations and maintaining inventory. In keeping with the issuance of the Guidelines on Good Distribution Practice (GDP), a GDP management organization has been set up within the Company to determine basic control items to ensure that the Production Division carries out the proper distribution of drugs within Japan and exports of drugs overseas and to operate and continuously improve the Company's system to maintain drug integrity.

Measures related to COVID-19 are also of great importance. Such measures can be separated into two categories: measures to prevent infection, and those for when infection is confirmed. The basis of preventing infection is self-control of one's behavior to prevent illness. For us, preventing infection is rooted in our shared mission within the Production Division to provide stable supply and procurement and the earnest spirit that is part of the corporate climate of Kissei and pervades each and every member of the department. With this spirit, combined with Groupwide understanding and cooperation, we are making efforts to protect employees involved in the manufacture and supply of drugs from infection. One such measure is staggering lunch times at the cafeteria shared with employees outside the Production Division to reduce contact with employees outside the Production Division and lower the risk of bringing a virus into the plant. We have also produced separate procedure manuals for each department, so even if an infection is confirmed, we have measures in place to minimize its spread, promptly establish a mitigation system, and maintain plant operations. For departments that handle drug manufacturing, quality control, the procurement of products and raw materials, and placing orders, we have installed remote working environments, separated offices, and set up cooperative systems with other divisions. The sum of these efforts is a system that ensures that the occurrence of an infection within the Company will not affect drug supply.

Our Management Philosophy is to "contribute to society through high-quality, innovative pharmaceutical products" and to "serve society through our employees." This philosophy is the source of our "Quality Culture" and permeates the thoughts and actions of each person involved in drug manufacturing at Kissei. This mindset, combined with our quality-focused production and carried out in line with the three principles of the Good Management Practice (GMP) system, ensures that we can provide a stable supply of quality drugs.

Of the 17 Sustainable Development Goals (SDGs) adopted by the UN to be achieved by 2030, we, as the Production Division of an R&D-oriented pharmaceutical company, are committed to achieving Goal 3, which is to "ensure healthy lives and promote well-being for all at all ages." To do so, we will continue to provide a stable supply of high-quality drugs supported by advanced technological capabilities and a broad wealth of knowledge and experience, combined with the latest science and information technology and risk-based thinking.

Kaoru Kaneko
General Manager and Division Director of Quality, Safety, and Regulatory Affairs (General Marketing Compliance Officer)

Secure and Safe Delivery of High-Quality Drugs to Patients

To fulfill one of the missions contained within its Management Philosophy, to "contribute to society through high-quality, innovative pharmaceutical products," Kissei Pharmaceutical has established an internal system within the Reliability Assurance Division to ensure compliance with Good Quality Practice (GQP) standards and Good Vigilance Practice (GVP) standards.

Regarding quality control, we promote quality assurance activities by bearing in mind our greatest mission, to provide high-quality drugs that patients can trust in and take with peace of mind. We started operation of the "Kissei Pharmaceutical Quality System" in April 2014 to continuously improve quality and ensure stable supplies of pharmaceutical products over their life cycles. Moreover, we continue to conduct quality assurance activities day-to-day to actualize the Basic Philosophy of the Kissei Quality Policy, "to contribute to the health of people around the world by actively operating its pharmaceutical quality system, established with a high sense of ethics, and providing high-quality, innovative pharmaceutical products that are continuously improving."

Specifically, we conduct regular quality audits at each plant where drugs are manufactured and confirm that change management and deviation management are properly implemented in addition to subsequent corrective and preventive actions in compliance with pharmaceutical regulations. We also identify any issues based on product quality information from medical institutions and make necessary improvements. Pharmaceutical products are subject to regular monitoring to ensure proper stability and quality within their shelf life. The results of evaluation and analysis of annual pharmaceutical quality reviews reports from each manufacturer are reported to the Company president and reviewed periodically. Based on the outcomes of the review, measures are then put in place for enhancing quality assurance systems, and suitable management resources are allocated to improve drug quality further. In the unlikely event that concerns are raised regarding drug quality or safety, we have established a strictly enforced procedure to ensure that measures, including product recall, are taken to handle the situation promptly, and training for recalls is carried out regularly to be able to perform a recall quickly and properly if an incident occurs abruptly.

On the other hand, for patients to use drugs with peace of mind, it is necessary to continue collecting and evaluating information on the safety and efficacy after launch, since safety information that exists up the point of approval is collected from clinical trials, conducted under controlled conditions. We have established a Safety Management Control Department at our head offices in Matsumoto and Tokyo and are promoting drug safety monitoring activities in cooperation with Safety Management Implementation Departments, focusing on 10 domestic branch offices. Specifically, MRs engage in post-marketing surveillance and other activities to collect a wide variety of information on the efficacy and safety of our products. The Safety Management Control Department subsequently works with doctors to conduct a close review of this information. After this review, if we determine that new safety measures are necessary, we will promptly notify medical professionals. In this way, we work on collecting and evaluating safety information and then devising safety measures on a daily basis, keeping our mission close to heart and with high ethical standards in our minds so that medical professionals and patients utilize our drugs securely and safely.

Furthermore, overseas partners with licensing rights to our drugs collect safety information in their respective territories and promptly share their information with each company. In addition, we discuss safety measures and work to ensure safe usage globally.

Information collected from clinical trials regarding the safety and efficacy of treatments for rare diseases is particularly limited, which makes it much more important to collect such information after launch. Therefore, we will perform this task with a continued sense of responsibility and enthusiasm that will bring peace of mind to those patients who use our products.

Financial and Non-Financial Highlights

Kissei Pharmaceutical Co., Ltd., and its subsidiaries	Millions of yen, except per share data					Thousands of U.S. dollars, except per share data
FY	2016	2017	2018	2019	**2020**	**2020**
Financial Results						
Net Sales	¥ 71,706	¥ 74,009	¥ 72,297	¥ 63,234	**¥ 69,044**	**$ 622,018**
R&D Expenses	13,877	14,179	15,711	10,767	**9,626**	**86,721**
Operating Income	8,491	9,887	6,202	1,857	**1,505**	**13,559**
Profit Attributable to Owners of Parent	7,726	9,045	5,481	2,817	**5,285**	**47,613**
Financial Condition						
Total Assets	¥186,801	¥ 210,821	¥213,522	¥231,794	**¥268,861**	**$2,422,171**
Total Net Assets	157,783	176,092	182,707	192,970	**219,953**	**1,981,559**
Other Indicator						
Capital Investment	¥ 1,477	¥ 1,989	¥ 1,177	¥ 970	**¥ 1,180**	**$ 10,631**
Per Share (Yen and U.S. Dollars)						
Profit Attributable to Owners of Parent	¥ 158.74	¥ 188.26	¥ 117.33	¥ 60.31	**¥ 113.25**	**$ 1.02**
Cash Dividends	46.0	48.0	50.0	52.0	**54.0**	**0.49**
Key Ratios (%)						
Operating Income Ratio	11.8	13.4	8.6	2.9	**2.2**	
R&D Expenses Ratio	19.4	19.2	21.7	17.0	**13.9**	
Return on Assets (ROA)	4.1	4.3	2.6	1.2	**2.0**	
Return on Equity (ROE)	4.9	5.4	3.1	1.5	**2.6**	
Shareholders' Equity Ratio	84.3	83.3	85.4	83.0	**81.6**	
Dividend Payout Ratio	29.0	25.5	42.6	86.2	**47.7**	
Others						
Number of Employees	1,905	1,903	1,907	1,892	**1,863**	
Number of Shares Issued	54,311,185	51,811,185	51,811,185	51,811,185	**51,811,185**	

Kissei Pharmaceutical Co., Ltd.					
FY	2016	2017	2018	2019	**2020**
Non-Financial Data					
Energy Used (kL)	8,945	8,694	8,489	8,257	**8,021**
CO_2 Emissions (tons)	19,701	19,162	18,516	17,767	**16,894**
Amount of Waste Generated (tons)	366	424	461	385	**369**
Final Disposal Amount (tons)	13	12	15	11	**39***

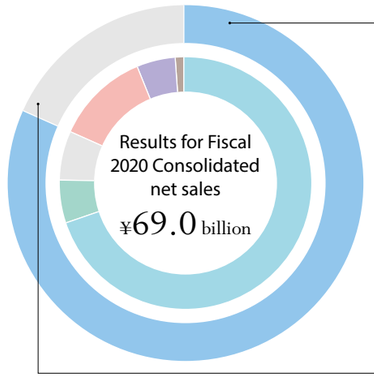
* The volume of residue produced after intermediate treatment is being reassessed following the adoption of the electronic manifest system in fiscal 2020.

(Notes)

1. U.S. dollar amounts are converted at the rate of ¥111 = $1 USD, the approximate effective rate of exchange at March 31, 2021.
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 fiscal year.
3. The Partial Amendments to Accounting Standard for Tax Effect Accounting (ASBJ Statement No. 28, issued February 16, 2018) have been applied from the start of fiscal 2018. Major management indicators from fiscal 2017 have been presented after retroactively applying these amended accounting standards.

The Kissei Group's Business

The Kissei Group comprises Kissei Pharmaceutical Co., Ltd., three consolidated subsidiaries in Japan, one non-consolidated subsidiary in Japan, and one non-consolidated subsidiary overseas, for a total of six companies. The main focus of the Kissei Group is the pharmaceutical business, but it is also engaged in the purchasing and sale of related materials, the manufacture, production, and sale of noodle products, system integration and system resource services, general construction, factory and building management, information gathering and development support, and other services.



Pharmaceutical Business

¥56.4 billion 81.7% (percentage of consolidated net sales)

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 centered in ethical drugs to improve the quality of life for patients and their families around the world.

Furthermore, we are developing and marketing therapeutic and care foods (food for special dietary uses, etc.) to contribute to health through food.

Breakdown of Business Results

- Pharmaceuticals*1 ¥48.1 billion
- Therapeutic and Care Foods (food for special dietary uses, etc.) ¥3.7 billion
- Other*2 ¥4.5 billion

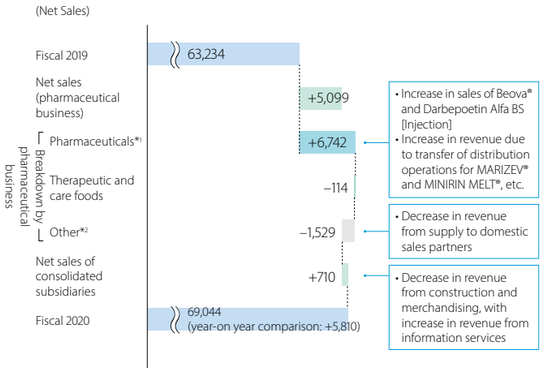
Other businesses

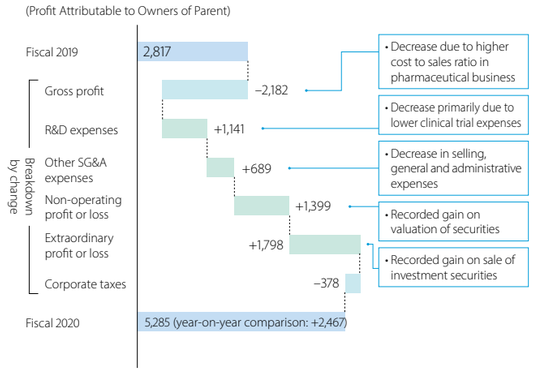
¥12.6 billion 18.3% (percentage of consolidated net sales)

Breakdown of Business Results

- Information Services Business ¥8.4 billion
- Construction Business ¥3.5 billion
- Merchandising Business ¥0.6 billion

Net Sales and Profit Attributable to Owners of Parent Compared with Fiscal 2019 (millions of yen)





Net sales in the pharmaceutical business increased ¥5,099 million from the previous fiscal year, to ¥56,407 million. Although the prolonged effects of COVID-19 restricted conventional drug information activities, net sales increased for Beova® Tablets, an overactive bladder treatment; Darbepoetin Alfa BS Injection [JCR], a treatment for renal anemia; P-TOL® Chewable Tablets and P-TOL® Granules, treatments for hyperphosphatemia; and other products. Earnings also received a boost after distribution operations were transferred to Kissei in April 2020 for MINIRIN MELT® OD tablets 25μg and 50μg for the treatment of nocturia due to nocturnal polyuria in males; MINIRIN MELT® OD tablets 60μg, 120μg, and 240μg and DESMOPRESSIN Formulations, for the treatment of nocturia enuresis and central diabetes insipidus; and MARIZEV®, for the treatment of diabetes.

Net sales for consolidated subsidiaries rose ¥710 million, due to an increase in information services, despite a decrease in revenue in construction and merchandising. As a result, consolidated net sales for the Group totaled ¥69,044 million, a year-on-year increase of ¥5,810 million.

*1. Including active pharmaceutical ingredients (API) and bulk exports.
*2. Includes supply to domestic sales partners and revenue from technical fees (contracting fees related to out-licensing, milestone payments, and running royalties).

Therapeutic and Care Foods

Charged by the desire to contribute to society through food, the Nutrition Division develops and sells various food products, such as energy supply foods and protein controlled foods that are useful for groups such as the elderly and patients undergoing dialysis for chronic kidney disease or other reasons.

The keys to a medical diet are nutritional balance, ease of consumption, and a delicious flavor. Our products are made with consideration given to flavor, convenience, and storage capability so that people who have had to re-evaluate the quality of their meals as a result of dietary restrictions stemming from illness or dysphagia, or people unable to eat as much as they would like, can enjoy meals with peace of mind. The product lineup has a wide variety of foods, from staple items to desserts. Useful information and product descriptions can be accessed from home via our website and mail-order catalog "Delicious 365 Days," which also provides 24-hour ordering services for delivery by mail.

The Kissei Group

The Kissei Group Management Philosophy:
Make greater contributions to society by creating harmony among the Group's working parts.

The Kissei Group aims to increase corporate value by aligning the growth vectors of Kissei Pharmaceutical and its three consolidated subsidiaries. Therefore, these subsidiaries have developed and are promoting their own five-year medium-term management plans, which, similar to Kissei Pharmaceutical, began in April 2020.

Kissei Shoji Co., Ltd. (Merchandising)

Description

- Manufacturing, production, and sale of noodle products
- Purchase and sale of materials
- Insurance agency services

Kissei Shoji draws from its Management Philosophy to "contribute to society through trading activities rooted in customer needs" and to "pursue corporate prosperity and employee happiness," and it is therefore engaged in the development, production, and sale of noodle products centered on Shinshu soba, sale of a variety of equipment, vehicles and fuel, insurance agency services, and other activities.

As initiatives aimed at the SDGs, the company promotes food recycling by utilizing food residue from its noodle production areas for animal feed or compost. Moreover, the company has been certified as meeting JFS-B food safety management standards and strives for quality assurance in line with these standards.

KISSEI COMTEC CO., LTD. (Information Services)

Description

- System integration services
- System resource services
  (information-related equipment rentals, network setup, etc.)
- Development and sale of medical systems

Based on its Management Philosophy of "management with respect for human beings" and "management with a sense of challenge and creativity," KISSEI COMTEC creates and offers information services that combine an abundance of knowledge and advanced technology to develop society with a rich sense of humanity.

To meet the expectations and needs of our customers and to live up to their trust, the company has acquired ISO/IEC 27001 certifications for the protection of information based assets, as well as certifications for meeting international standards ISO 9001 and ISO 14001. To work toward achieving the SDGs, the company has also introduced paperless solutions to support diverse work styles and energy/resource saving, and is taking steps to create and produce products and services that will help resolve social issues.

HASHIBA TECHNOS CO., LTD. (Construction)

Description

- General construction services
- Factory and building management

As its Management Philosophy states, HASHIBA TECHNOS "contributes to the development of local communities with its technology and sincerity." Therefore, the company engages in a wide range of general construction services, from building construction to the maintenance and management of equipment and facilities that utilize advanced technology, while staying closely attuned to the needs of local communities.

As part of its efforts to achieve the SDGs, the company has acquired ISO 14001 certification for environmental management systems and ISO 9001 certification for quality management systems. In recognition of its environment-related efforts, in July 2020, Matsumoto City recognized the company as an "eco Office Matsumoto" business establishment, receiving the highest 3-star ranking.

Letter from the CEO

Mutsuo Kanzawa
Chairman and Chief Executive Officer

We will achieve sustainable growth and increase corporate value over the medium to long term, which in turn will contribute to society and the health of people around the world.

Kissei's Management Philosophy is to "contribute to society through high-quality, innovative pharmaceutical products" and to "serve society through its employees." Under our 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 mission of manufacturers of new drugs, such as Kissei, is to research and develop drugs that are useful to patients. While remarkable progress has been made in the fields of medicine and pharmaceutics in recent years, there remain several illnesses for which no treatment exists, meaning our role is becoming increasingly important. Since our founding in 1946, we have been committed to the development of new drugs, with patients as our number one priority. I believe that when we conduct all company activities with a sense of social responsibility and high ethical standards, whether they are drug discovery, development, production, or appropriate information provision regarding medical care, we are practicing one half of our Management Philosophy, which is to "contribute to society through high-quality, innovative pharmaceutical products." As CEO, I recognize that my duty is to draw from our Management Philosophy and Management Vision to help the Company achieve sustainable growth and increase corporate value over the medium to long term, which in turn will contribute to the health of society and the people of the world.

One recent initiative aimed at enhancing corporate governance was the establishment of the Nomination and Compensation Deliberation Committee in 2015. The committee deliberates on candidates for appointment or dismissal as directors and levels of director compensation, which are proposed to the Board of Directors. As for the Board of Directors, in 2020 we invited a female outside director to the fold, bringing the total number of outside directors to three and helping to ensure diversity.

However, with the revisions made to the Corporate Governance Code in 2021, and with the Tokyo Stock Exchange scheduled to be restructured in 2022, it is more important than ever that we establish a high level of governance, work toward sustainable growth, and improve corporate value even further. We will continue to examine ways to make governance better for the Company, based on issues that are raised during evaluations of the effectiveness of the Board of Directors and constructive feedback provided by shareholders and investors aimed at improving corporate value, with an understanding that in the future we will need to address issues surrounding sustainability that include the environment, employee health, the promotion of the SDGs, and a human resource strategy that involves reforms to our human resources system to emphasize diversity and future potential.

With COVID-19 came major changes to the world. Great expectations have been laid upon pharmaceutical companies to develop new drugs, and the pandemic has reaffirmed that Kissei's reason for being is to meet these expectations. My message to all employees in 2020 was that they need to show "pliability" in the face of these changing times but also have the "pluck" to create change in themselves. It is the time to build Kissei into a flexible and strong company with a clear vision—one that rewards people who take on challenges. I want develop the Company further, hand in hand with all employees. Human resources who can serve society are vital when it comes to developing pharmaceutical products and delivering them to patients. We will work to cultivate human resources capable of dealing with any situation, with the goal of providing new drugs for intractable diseases or other ailments to patients around the world as soon as possible.

The pharmaceutical business is at the heart of the Kissei Group, but each Group company will make an effort toward the SDGs and leverage its business to contribute to society.

We will continue striving to provide sustainable value to society and increase corporate value through constructive dialogues with our stakeholders. I ask for the ongoing understanding and support of all our stakeholders moving forward.

August 2021

Mutsuo Kanzawa
Chairman and Chief Executive Officer

Outside Directors Interview

In fiscal 2020, Kissei Pharmaceutical embarked on **PEGASUS**, its five-year medium-term management plan. One of the basic policies of this plan is to strengthen the management base to respond to changes in the business environment. Therefore, Kissei is working to strengthen governance. In this interview, the Company's three outside directors gave their assessment of Kissei's governance as it stands now, as well as any future issues and measures that can be taken to further enhance governance.

Sayuri Uchikawa
Outside director

Minoru Nomura
Outside director

Shigetaka Shimizu
Outside director

Q What is your opinion of Kissei Pharmaceutical's Board of Directors and the Company's particular characteristics?

Mr. Shimizu

Proposal materials that supplement the agenda for Board meetings contain clear points of discussion related to prior investigations and their procedures, as well as discussions that have taken place during meetings of the Business Execution Committee. Board meeting discussions are focused on these points. My opinion as an outside director is that Kissei stands out in that employees feel like they play a role in management, which builds a sense of unity between management and employees.

Mr. Nomura

I think this sense of unity that Mr. Shimizu is alluding to is thanks to the sincerity between Kissei's management and its employees. ESG management is drawing attention worldwide, but I don't think that a company can implement ESG management or enhance governance or any number of other initiatives without this sincerity.

Ms. Uchikawa

Before I was appointed to this position, my impression of the Company was that it was committed to drug discovery and providing drugs that could help patients. I also felt that the CEO, Mr. Kanzawa, seemed to have a sincere personality—as a manager, of course, but also when performing any other duty. After becoming an outside director and attending Board meetings, I feel that preparations are carried out well and that the environment is quite good. And, I feel that I am given my proper due as a woman. I think that the sincerity that Mr. Nomura mentioned is something that permeates the entire company, its employees' actions, and the Board of Directors.

Q How do you perceive your role in the Company, and what kind of opinions do you express? Also, what potential issues to you intend to speak on at future Board meetings?

Mr. Shimizu

While we are expected to express opinions and make proposals based on our experience and expertise, we are also expected to make statements based on some familiarity with what is going on within the industry and from the perspective of other industries. As for potential issues, during the second year of the five-year medium-term management plan, the R&D pipeline has expanded, and steady work has been made to promote progress; however, these projects have yet to be launched for sales, meaning that net sales are unlikely to increase, which makes its difficult to expect performance to recover in terms of net sales and earnings. This is a difficult situation, and to make it through I think Kissei needs to invest in a business promotion system that takes advantage of digital innovation and cultivate human resources with the leadership skills to help achieve the goals of the medium-term management plan. Moreover, the Company needs to continue its efforts to promote thorough compliance.

Mr. Nomura

I think that the role of an outside director is to strengthen a company's governance system and increase the effectiveness of its Board of Directors. "Maintaining and strengthening relationships of trust with stakeholders" is highlighted within the basic strategy of the medium-term management plan, and I think my role is to serve as a representative for a variety of stakeholders and apply both my experience as a company manager and my knowledge in international business to the deliberations and decision-making that take place during Board meetings. The basic strategy of the plan calls for the promotion of ESG and the SDGs, so I would also like to have full discussions during Board meetings as to whether the Company's strategy and vision are rational, realistic, and effective in terms of helping the world and pleasing people as well as to whether important investment decisions are consistent with this strategy.

Ms. Uchikawa

Like Mr. Nomura, I think the role of outside directors is to reflect the stakeholders' perspective during Board meetings. As a woman, I recognize my duty to state opinions as a voice for diversity and for women inside and outside the Company. Kissei's mission, as it says in its Management Philosophy, is to "contribute to society through high-quality, innovative pharmaceutical products," and I believe that by pursuing this mission, it is in the pursuit of health for people all over the world and is in line with SDG 3, which aims for "good health and well-being." In the future, I would like to put forth proposals during Board meetings that will help stakeholders see the value of Kissei and also increase diversity at the Company even further by giving opportunities for female employees to express their true opinions.

Kissei's Basic Approach to Corporate Governance

Kissei considers strengthening and enhancing corporate governance to be an important management issue for fulfilling its social responsibilities as well as maintaining good relations with its stakeholders, including shareholders, investors, customers, local community members, business partners, and employers, thereby fulfilling its goal of increasing corporate value and achieving sustainable growth as a company with significance and value to society.

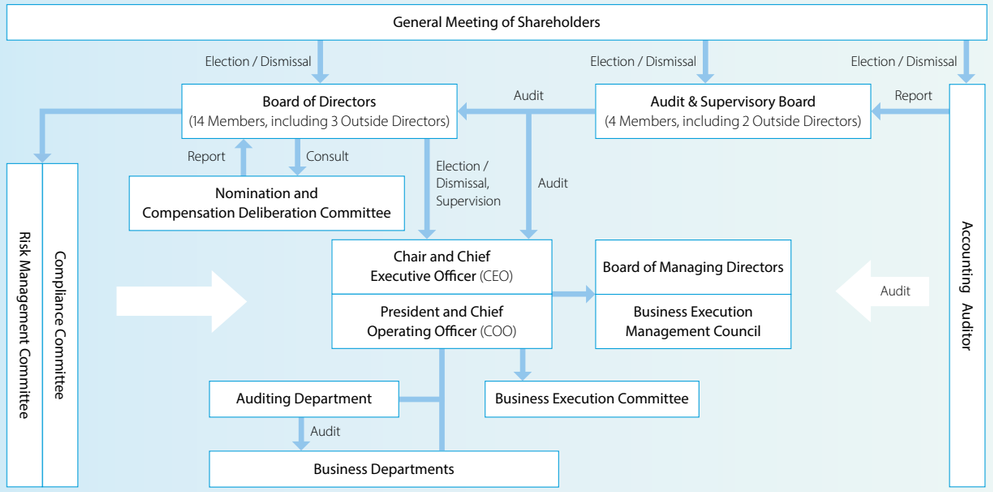
Although Kissei has adopted the Audit & Supervisory Board system, the Company has also deemed it reasonable to incorporate the appointment of outside directors within its current governance system to supplement the function of Audit & Supervisory Board members and enhance the supervisory function of the Board of Directors over management.

Therefore, of the Board of Directors' 14 members, three are outside directors. These outside directors have diverse experience as company management in the finance, precision equipment, and education sectors in Japan and overseas, as education specialists, or as members of a Board of Directors or Audit & Supervisory Board at other companies. With this experience, outside directors play an important role in enhancing the decision-making and supervisory functions of the Board of Directors. To further strengthen ties between the outside directors and Audit & Supervisory Board members, the Company holds regular non-executive officer liaison meetings. These meeting are part of the Company's efforts to further enhance monitoring over management and supervisory functions.

Under the current governance system, the Chair and Chief Executive Officer (CEO) is given authority over all matters pertaining to management, whereas the President and Chief Operating Officer (COO) is responsible for all matters related to business execution. This division ensures a stronger management system, high mobility, and greater management capabilities related to business execution entrusted to the Board of Directors. Furthermore, the Business Execution Committee has been established as an advisory committee to the COO to aid them with decision-making and to assist in examining management-related matters to be proposed or reported to the Board of Directors.

Of the four members of the Audit & Supervisory Board, two are outside Audit & Supervisory Board members. These two outside Audit & Supervisory Board members audit the legality and soundness of management by drawing on their respective expertise and experience—one as a lawyer and the other as a certified public accountant and tax accountant.

Corporate Governance Bodies and Internal Control System



Director Compensation

1. Policies for Determining Compensation Amounts for Individual Directors and Calculation Methods

Director compensation comprises a base salary and a bonus; the following section explains the policy for determining individual compensation amounts.

Base salary is determined by director rank (position) as a member of the Board and also includes an additional amount based on individual experience as a director. When setting base salaries, consideration is given toward ensuring that each rank receives fair and balanced compensation, while also taking Company performance into account. Bonuses for directors are proposed and approved at the annual General Meeting of Shareholders after taking into consideration the Company's performance for the fiscal year, in addition to other factors. Similar to base salary, when determining individual bonus amounts, consideration is given toward ensuring that each rank receives fair and balanced compensation.

The Board of Directors has the authority to decide the policy regarding the determination of individual compensation for the directors of the Company. The Nomination and Compensation Deliberation Committee—consisting of outside directors, the CEO, the COO, and the director in charge of personnel—conducts comprehensive examinations and deliberations regarding compensation amounts, which include checking for consistency between these amounts and the aforementioned policy. After this process, the individual amounts are proposed to the Board of Directors.

2. Method for Determining Compensation for Audit & Supervisory Board Members

Compensation for members of the Audit & Supervisory Board is determined after consulting with the Audit & Supervisory Board. Bonuses are proposed and approved at the annual General Meeting of Shareholders.

Outside Director Skill Matrix

All outside officers are independent officers who are unlikely to have a conflict of interest with general shareholders.

	Name	Age (years)	Duration of Appointment (years)	Independent Officer	Business Management	Finance and Accounting	Legal / Compliance	ESG / Sustainability	International
Outside Director	Shigetaka Shimizu	72	7	○	○	○		○	○
	Minoru Nomura	74	5	○	○	○		○	○
	Sayuri Uchikawa	70	1	○	○		○	○	○
Outside Supervisory Board Members	Kando Nakagawa	72	10	○			○	○	
	Michio Iwabuchi	65	1	○		○	○	○	○

List of Directors (as of June 24, 2021)

▶ Standing, From Left Michio Iwabuchi, Makoto Yonekubo, Takahide Kitahara, Shinji Kikuchi, Eiichi Matsushita, Suminori Sagara, Masayuki Isaji, Kando Nakagawa

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

Board of Directors

Mutsuo Kanzawa — Chairman and CEO

1976 Joined the Company
1982 Director, Corporate Strategy & Planning Office
1984 Managing Director
1987 Executive Managing Director
1992 President and CEO
2014 Chairman and CEO (current position)

Yoshio Furihata — President and COO

1984 Joined the Company
2000 Representative Director and President of Kissei Pharma Europe, Ltd.
2008 Director, Department Manager of Business Development Department
2010 Director, Department Manager of Corporate Strategy & Planning Department
2016 Managing Director, General Manager of Clinical Development Division
2018 President and COO (current position)

Hiroe Sato — Executive Vice President

1975 Joined the Company
2006 Director, General Manager of Corporate Strategy & Planning Division, Department Manager of Corporate Finance Department
2012 Managing Director
2014 Executive Managing Director
2016 Executive Vice President (current position)

Keiji Fukushima — Executive Managing Director

1979 Joined the Company
2012 Director, General Manager of Sales & Marketing Division, Department Manager of Promotion Support Department
2014 Managing Director, General Manager of Sales & Marketing Division
2020 Executive Managing Director (current position)

Yasuo Takehana — Managing Director

1984 Joined the Company
2012 Director, General Manager of Research Division, Department Manager of Research Planning Department
2016 Managing Director, Department Manager of Corporate Strategy & Planning Department
2020 Managing Director (current position)

Tetsu Takayama — Managing Director

1985 Joined the Company
2014 Director, Department Manager of Human Resources Department
2020 Managing Director, Department Manager of Human Resources Department (current position)

Masaki Morozumi — Director and Senior Adviser

1980 Joined the Company
2008 Director, Deputy General Manager of Sales Division, General Manager of Marketing Division
2012 Managing Director, General Manager of Sales & Marketing Division
2014 President and COO
2018 Director and Senior Adviser (current position)

Shinji Kikuchi — Director

1988 Joined the Company
2016 Director, General Manager of Research Division (current position)

Takahide Kitahara — Director

1986 Joined the Company
2018 Director, Department Manager of Corporate Finance & Management Department (current position)

Minoru Nomura — Outside Director (independent)

1969 Joined Nomura Kogyo Co., Ltd.
1989 President and Representative Director of Nomura Kogyo Co., Ltd.
1989 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 (France) (current position)
2016 Outside Director at the Company (current position)

Eiichi Matsushita — Director

1983 Joined the Company
2016 Director, Department Manager of General Administration Department (current position)

Suminori Sagara — Director

1982 Joined the Company
2018 Director, General Manager of Sales & Marketing Division, Department Manager of Promotion Support Department, General Manager of Dialysis Area Project Division
2020 Director, General Manager of Sales & Marketing Division (current position)

Shigetaka Shimizu — Outside Director (independent)

1972 Joined The Hachijuni Bank, Ltd.
2007 Managing Director at The Hachijuni Bank, Ltd.
2011 President and CEO of Hachijuni Lease Co., Ltd., and Hachijuni Auto Lease, Co., Ltd.
2013 Auditor at HACHIJUNI SECURITIES Co., Ltd.
2014 Outside Director at the Company (current position)

Sayuri Uchikawa — Outside Director (independent)

1973 Joined Marunouchi Typist School (currently Marunouchi College of Business)
1996 Principal of Marunouchi College of Business (current position)
2012 Establisher of Marunouchi College of Business
2013 Outside Director at The Nagano Bank, Ltd. (current position)
2018 Chairwoman and Principal of Kosumosukai Marunouchi College of Business (became an incorporated educational institution) (current position)
2020 Outside Director at the Company (current position)

Board of Corporate Auditors

Masayuki Isaji — Corporate Auditor (full-time)

1980 Joined the Company
2010 Director, Department Manager of Research Planning Department
2012 Managing Director, Department Manager of Corporate Strategy & Planning Department
2018 Corporate Auditor (full-time) (current position)

Kando Nakagawa — Outside Corporate Auditor (independent)

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

Makoto Yonekubo — Corporate Auditor

1970 Joined the Company
2004 Deputy Department Manager of Corporate Finance & Management Department
2011 Corporate Auditor (full-time)
2019 Corporate Auditor (current position)

Michio Iwabuchi — Outside Corporate Auditor (independent)

1983 Registered as a Certified Public Accountant
2018 Registered as a Tax Accountant
2018 Outside Director (Audit and Supervisory Committee Member) of Takeuchi Mfg. Co., Ltd., Outside Corporate Auditor of R&C Holdings Co., Ltd. (current position)
2020 Outside Corporate Auditor (current position)

Risk Factors

The following are the most significant risks that could potentially affect the Kissei Group's operating results and financial position. Forward-looking statements are based on the judgments the Group has made from the consolidated financial statements for fiscal 2020.

The degree and timing of a risk materializing, and the impact of such a risk on operating results, have not been published due to the difficulty of making a reasonable prediction. As part of its Risk Management Regulations, Kissei Pharmaceutical has established a Basic Risk Management Policy and a risk management system. In addition, the Company has established a Risk Management Committee, which serves as an advisory body to the Board of Directors comprising primarily directors in charge of divisions and departments. Under the guidance of this committee, the Kissei Group has put a management system in place to prevent the occurrence of possible risks and monitors its progress.

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. Kissei estimates its medium- to long-term business performance based on an anticipated drug discovery schedule that is regularly revised, from non-clinical trials to clinical trials, application for approval, and acquisition of approval. However, when developing new drugs, the chances of discovering beneficial indications are limited. In addition, Kissei can neither guarantee that a new drug undergoing development or an additional indication will have its intended benefit nor predict when or whether the drug will be approved.

② Medical System Reform

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 drastic reforms of medical and pharmaceutical administrative systems that go beyond Kissei's expectations, including revisions to Japan's health insurance system, 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, Kissei faces price competition with generic products of the same composition. 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, if a quality problem causes a drug to be recalled, or if shipments have to be adjusted because supply cannot keep up with demand, there could be a negative impact on Kissei's operating results and financial position.

⑥ Intellectual Property Rights

If the Kissei Group is unable to appropriately protect its intellectual property, a third party may be able to use the Group's technology, which would undermine its competitive superiority in the market. Conversely, if the Group's business activities are with intellectual property rights owned by third parties, it may lead to associated disputes and damages or the suspension of said business activities.

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 Group could face lawsuits in the future both at home and abroad regarding patents, product liability, the environment, labor matters, fair trade, or other issues.

⑧ Environmental Conservation

Pharmaceutical chemical substances used in research and manufacturing processing could have an impact on the environment. Every department and work site of 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 undo the environmental damage caused, which would negatively impact Kissei's operating results and financial position.

⑨ Information Security Management

Business may be hindered by cyberattacks on the various information systems used by the Kissei Group. The Group is therefore 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, there is the possibility that an unexpected incident occurs in which information is improperly disclosed. In such an event, the Kissei Group's image may be tarnished, which could negatively impact Kissei's operating results and financial position.

⑩ Large-Scale Disasters and Pandemics

Business activities could be suspended due to damage incurred by Kissei or its partners caused by fires, floods, and accidents stemming from natural disasters, such as earthquakes or typhoons, or pandemic outbreaks of new strains of influenza or other diseases. As a result, Kissei may experience losses in terms of time and money, which could negatively impact its operating results and financial position.

Regarding the COVID-19 pandemic, Kissei has newly formulated its Standards Related to the Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response and the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases, which is based on its Risk Management Regulations. Using these standards, Kissei is implementing measures to emphasize the safety of employees and related parties and ensuring a stable supply of its products.

⑪ Assets Under Possession

Kissei evaluates its business assets, investment securities, and other assets quarterly in accordance with its accounting policy. If there is no reasonable expectation of recovering the value of a business asset, the Group may be forced to record an impairment loss. Regarding investment securities, there is the possibility that the Group records an impairment loss after taking a comprehensive account of its business plan, or looking at market conditions for investment securities with a market price, or the net worth of companies with unlisted shares and no market price.

⑫ Recoverability of Deferred Tax Assets

If there is insufficient taxable income to deem deferred tax assets as recoverable, a reversal of deferred tax assets may be issued.

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

Compliance

Compliance Promotion System

Kissei has established the Compliance Committee to optimize compliance promotion, implement the Compliance Program, and serve as an advisory body to the Board of Directors. The committee is chaired by the director in charge of ethics and the environment and is composed of managers from each division. It discusses and determines a specific implementation plan for the Compliance Program for each fiscal year. Once this plan has been determined, the CSR Promotion Office (which serves as the compliance department), the division managers (who are in charge of compliance promotion and are also members of the Compliance Committee), and the Compliance Promotion Supervisor develop and conduct specific activities for compliance education and understanding.

In addition, the Kissei Group engages in Groupwide compliance practices led by compliance officers appointed by each Group company. The Kissei Group Compliance Officers' Meeting is held regularly, during which these compliance officers share implementation plans, report results, and exchange information. At these meetings, officers also receive education and training.

As a member of a life-related industry, the high ethical standards demanded of the Group are a given. However, if we can commit to not only complying with the law but also maintaining these high ethical standards and fulfilling our social responsibilities, we stand to gain a greater degree of trust from society, which is true for Group companies as well. Therefore, we are working to practice compliance on a daily basis with this goal in mind.

Compliance Promotion Activities

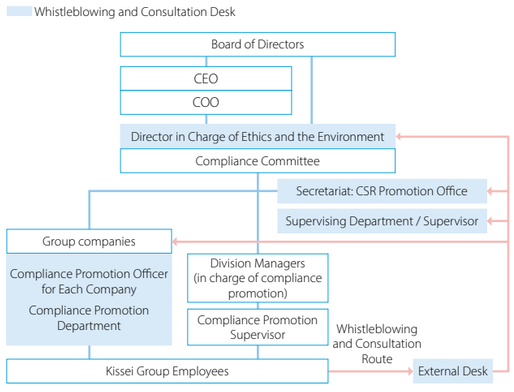
Continued compliance education and training is essential to firmly entrench the importance of observing the law and internal regulations as well as corporate ethics, and to ensure that all officers and employees fulfill their responsibility toward proper compliance. The Company provides rank-based education to officers, division and department managers, newly appointed managers and supervisors, and new employees. In addition, employees also receive education and training for work directly related to their duties, covering the Pharmaceutical and Medical Device Act and guidelines regarding the provision of sales information for pharmaceutical drugs. Additional focus has been placed on the topic of harassment, an important issue for companies with the growing awareness of different forms of harassment in recent years.

Other efforts to raise employee awareness regarding compliance include regular messages from top management, and the Company's Compliance Program Manual, which is distributed to every employee and serves as a guide to daily activities and conduct for ensuring proper compliance.

Whistleblowing and Consultation System "Kissei Hotline"

In response to amendments to the Whistleblower Protection Act (Act No. 51 of 2020), the Kissei Group has established the Kissei Hotline, its whistleblowing and consultation system. The goal of the Kissei Hotline is to protect whistleblowers while preventing the violation of laws and regulations within the Group, as well as any damage or losses that could result from these violations. Moreover, the hotline serves to heighten self-regulation among Group companies. Officers, employees, and retirees can file a report or consult with an external contact independent of the Company regarding legal violations or harassment within the Group. The external contact can be reached by phone, email, sending a physical document, or via a dedicated website. Furthermore, users of the hotline can opt to remain anonymous, in which case the Company will not know who is filing the report.

Compliance Promotion System



Compliance Status Questionnaire

Every year, we conduct a Compliance Status Questionnaire targeting all employees. This questionnaire allows employees to check their level of understanding, while allowing the Company to confirm whether proper compliance is being carried out, and work toward even more thorough compliance practices. The response rate to the questionnaire has remained high since it was introduced in 2005, with the response rate in fiscal 2020 reaching 94.3%.

The results of the questionnaire are collected and analyzed and then feedback is provided to each division and department, which the Division Manager in charge of compliance promotion, the Compliance Promotion Supervisor, and other persons in charge use to provide appropriate compliance education to employees.

Going forward, we will continue to utilize these questionnaire results and improve our workplace environment while striving to raise awareness of compliance further.

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 good 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.

Environmental Initiatives

Environmental Management

As stated in the Kissei Code of Conduct, which is based on the Group's Management Philosophy, the Group recognizes the importance of environmental problems and will voluntarily and proactively work toward its conservation. Drawing from this resolution, Kissei Pharmaceutical has determined its Basic Environmental Policy and, based on this policy, works actively and continuously to incorporate environmental conservation in all its corporate activities while reducing the environmental impact of those activities.

Basic Environmental Policy

1. Basic Philosophy

As an R&D-oriented company that is always "Looking Towards Tomorrow's Health" and aims to help people worldwide, Kissei will actively work to preserve the environment as part of its corporate social responsibility and contribute to creating an affluent and comfortable society.

2. Basic Policy

(1) We will promote activities to reduce environmental burdens and evaluate the various effects on the environment through a series of corporate activities, such as research, development, production, distribution, sales, usage, and disposal of the products.
(2) We will set environmental objectives and targets regarding global environmental conservation efforts and periodically revise our objectives, seeking to improve continually.
(3) We will actively promote saving energy, saving resources, waste reduction, and recycling, and we will strive to reduce environmental burdens and prevent pollution.
(4) We will comply with environmental laws, regulations, agreements, and other requirements to which the Company has agreed, and we will endeavor to conserve the environment by setting our own standards.
(5) Every individual employee will aim to heighten consciousness and improve ethics through environmental education, and we will aggressively promote activities for the prevention of environmental pollution.
(6) We take global environmental issues seriously, so all Kissei Group companies will strive to protect the environment.

Environmental Management System

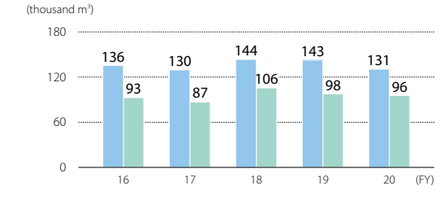
Kissei promotes environmental management based on the ISO 14001 standards for environmental management systems. The various plants and laboratories of Kissei Pharmaceutical and Group companies KISSEI COMTEC CO., LTD., and HASHIBA TECHNOS CO., LTD., acquired ISO 14001 certification between 2000 to 2007 and then transitioned to the ISO 14001: 2015 standard from 2017 to 2018.

ISO 14001 Certification Status

Kissei Pharmaceutical	Month of Acquisition	Transition to 2015 Standard
Head Office / Matsumoto Plants	September 2000	September 2018
Shiojiri Plants	September 2000	September 2018
Nutritional Business Center	September 2000	September 2018
Second Research Laboratories	September 2006	September 2018
Tokyo Head Office, Tokyo Head Office (Koishikawa)	September 2006	September 2018
Central Research Laboratories	September 2007	September 2018

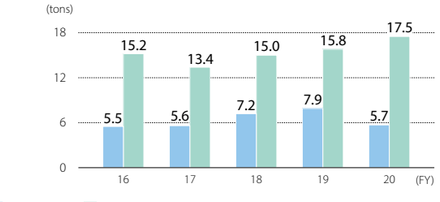
Group Company	Month of Acquisition	Transition to 2015 Standard
KISSEI COMTEC CO., LTD.	June 2002	November 2017
HASHIBA TECHNOS CO., LTD. Head Office	February 2002	February 2018
Facility Management Headquarters (shared with Kissei Pharmaceutical)	September 2000	September 2018

Water Resources*1



*1. Total amounts are based on the data from eight business locations (the Matsumoto Head Office/Matsumoto Plants, Shiojiri Plants, Central Research Laboratories, Second Research Laboratories, Joetsu Chemical Laboratories, the Nutritional Business Center, the Tokyo Head Office, and the Tokyo Head Office (Koishikawa). Total usage is the total amount of drinking water, groundwater, and industrial water used.

Gas Emissions*2



*2. Data collected from boiler emissions at the eight business locations listed in Note 1.

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 basic 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 establish a working environment that encompasses employment, labor conditions, and human resources management, we have adopted a multi-selective human resources system that gives consideration to our employees' aptitudes and life plans. In addition, we are introducing multiple flexible working styles to our departments, such as flextime and deemed working hours, to allow a variety of personnel to work to their fullest capability. We are also aiming to introduce a post-retirement re-employment system as a way to allow many employees to utilize the experience, skills, and knowledge they have acquired over their careers after they retire.

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 the objective of its Vision for Human Resources Cultivation. To achieve this vision, we are organically developing measures to help cultivate each type of human resource in a continuous and systematic manner over the medium to long term.

Vision for Human Resources Cultivation

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

Cultivating the Next Generation

Kissei is a company that enables employees to balance work and home life, including childcare, and by creating an environment that is easy for all employees to work in, they are able to demonstrate their full potential. Kissei is making every effort to establish this type of work environment. These efforts were evaluated and recognized in 2008, 2011, and 2015 with certification (Kurumin) as a standards-compliant general business owner based on the Act on Advancement of Measures to Support Raising Next-Generation Children.* Furthermore, in 2017 Kissei was granted special certification (Platinum Kurumin) in recognition of reaching an even higher standard in providing exemplary childcare support.

* 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.

Promoting the Success of Women

Kissei has formulated its 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.

Major Initiatives

- Increase the number of women who want to join the company by actively publicizing that we maintain a workplace where women play an active role
- Promote a system of reduced working hours for female MRs returning to work from childcare leave

Promoting Work–Life Balance

To promote the usage of annual paid leave, Kissei Pharmaceutical has established a systematic paid leave usage system, which covers an annual Companywide leave period of two days and a leave period of three days for commemorative occasions, such as wedding anniversaries and birthdays. To reduce overtime work, head offices and laboratories have set every Wednesday and salary payment day as "no-overtime" days, while sales branches and offices promote days without out-of office travel and salary payment days as days to go home on time. These initiatives to reduce overtime work and improve efficiency are part of our constant effort to promote a work–life balance.

Occupational Health and Safety

In addition to complying with the Industrial Safety and Health Act and other related laws and regulations as well as in-Company work regulations, Kissei implements health and safety measures guided by the Environment, Health, and Safety Committee, an in-house organization, to ensure a safe, secure, and reliable workplace environment for its employees.

Health and safety initiatives are implemented at head offices, plants, and laboratories, led by the Subcommittee for Health and Safety at each location. These initiatives include efforts to maintain a safe workplace environment through safety training for new employees, regular patrols, and recording metrics of the work environment in addition to basic first-aid training and efforts to impart safety information, such as posting internal newsletters and in-Company posters. The minutes of Subcommittee for Health and Safety meetings are posted on the Company intranet and are available to all employees.

Enactment of the Kissei Pharmaceutical Health Declaration

To realize the goals stated in our Management Philosophy and Code of Conduct, Kissei established the Kissei Pharmaceutical Health Declaration in April 2017, based on the belief that each and every employee must be healthy in both mind and body.

Recognized under the 2021 Certified Health & Productivity Management Outstanding Organizations Recognition Program (Large Enterprise Category)

Kissei Pharmaceutical makes efforts to promote health management with the goal of creating a workplace where Kissei works closely with the Kissei Group Health Insurance Society, while striving to maintain and improve the health of employees and their families and to promote health management, the goal of which is to establish a workplace that is both healthy and vital and where employees can put their abilities on full display with a feeling of purpose and drive. In recognition of these efforts, Kissei Pharmaceutical was certified as a 2021 Organization with Outstanding Health & Productivity Management (Large Enterprise Category) in March 2021.

Health Management Promotion System

The Department Manager of the Human Resources Department has been appointed as the General Manager in Charge of Health Promotion, and the Subcommittee for Health and Productivity Management has been established to further promote drafting and the implementation of measures as well as verifying their effects.

Major Health Management Initiatives

- Medical testing exceeding legal requirements and subsidization of cancer screening and other testing costs in cooperation with the Kissei Health Insurance Society
- Stress checks for all business establishments, including those with fewer than 50 employees
- Healthy menus provided at employee cafeterias, etc.

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 in both mind and body.

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

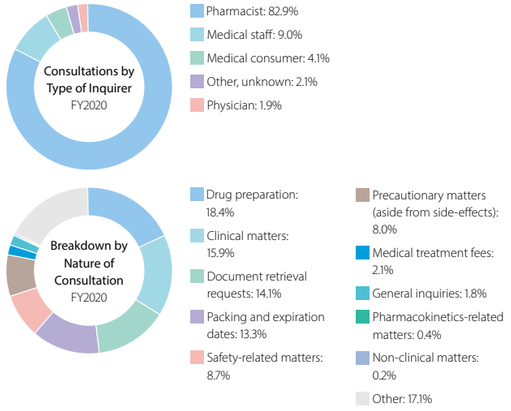
1. The Company and the health insurance society recognize the health problems of employees as important management issues and will therefore provide opportunities for employees to maintain and improve the health of their minds and bodies and create a workplace that is both healthy and easy to work in.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

Our Relationship with Medical Professionals and Patients

Collection and Appropriate Provision of Drug Information

Drug information obtained from the point of approval until launch is collected from clinical trials under limited conditions. Therefore, to ensure patients can use drugs properly after launch, there must be a continuous effort to check for safety and effectiveness. Information about a drug post-launch can be accessed by medical professionals and patients by contacting the Product Customer Service Center, and medical professionals can also acquire this information via the information provision activities carried out by our medical representatives (MRs). In addition, after we launch new drugs for sale, we systematically collect information on safety and efficacy by conducting post-marketing surveillance and post-marketing clinical trials targeting between hundreds and thousands of patients. If we determine that it is necessary to provide information on new safety measures and proper usage based on the information collected, we will promptly inform medical professionals and patients.

Consultations by Type of Inquirer and Nature of Consultation



Product Customer Service Desk

We have established the Product Customer Service center to encourage the proper use of pharmaceutical products in a safe and effective manner, and we have responded to inquiries not only from healthcare professionals but also patients. In fiscal 2020, we responded to 12,405 such inquiries. In addition, we are working to build a dedicated phone line for SAVENE®, a treatment for anthracycline extravasation, and RECTABUL®, Japan's first injectable foam treatment for ulcerative colitis, in anticipation of urgent inquiries and to facilitate easy consultation.

Number of Consultations (Inquiries answered by the Product Customer Service Center from outside the Company)

KISSEI KUR Magazine

Since July 1983, Kissei Pharmaceutical has published issues of *KISSEI KUR*, a quarterly magazine dedicated to providing medical information. About 30,000 copies of each issue are published, with the goal of providing unique medical information to medical professionals.

The aim of the magazine is to offer enjoyable reading material while also providing useful information. Within its pages, readers can find articles from some of the most important voices related to diseases that Kissei is involved with and learn about medical institutions that are putting forth unique initiatives. We also take advantage of our heritage as a company founded in the Shinshu (Nagano) area of Japan to introduce readers to its natural beauty. The name of the magazine comes from the German word *kur*, which is "cure" in English, and the magazine delivers interesting information about cures to many medical professionals, including doctors, pharmacists, nurses, and others.

KISSEI KUR Magazine

Patient-Oriented Information Website

Kissei works actively to communicate information to patients in its key fields, such as renal diseases and dialysis and urology. We established and currently operate an information website through our corporate web page for use by patients and their families. The goal of this site is to help people who are undergoing dialysis or suffering urinary symptoms to live their lives more happily.

Its concept as a site is to help patients and their families to enjoy living their daily lives. Accordingly, the site uses a Q&A format to give specific advice focused on the various situations that patients experience day-to-day. On the section for dialysis patients, the site provides information on dietary management, which is crucial for these patients. This section includes alternatives to cooking from scratch, with easy-to-understand tips on dietary management, items to purchase when shopping at the supermarket or the convenience store, or when eating out.

Relationships with Society

Contributions to Medical Treatments and Health

Kanzawa Medical Research Foundation

Kanzawa Medical Research Foundation was established on June 27, 1997, on the basis of private assets offered by Kunio Kanzawa, then Chairman of Kissei Pharmaceutical, and funds provided by Kissei Pharmaceutical Co., Ltd., in commemoration of its 50th anniversary in business.

When the foundation was established, there was the expectation that the drop in birthrate and growth in life expectancy at that time would result in a declining birthrate and aging society phenomenon and become an important socioeconomic issue in the near future. From a medical perspective, it was believed that a highly significant part of solving this problem was the maintenance and promotion of women's health. Against this backdrop, the foundation promotes the development of healthcare and medical science by encouraging studies (hereinafter referred to as subjected studies) from various angles on the causes, prevention, diagnoses, and therapies, etc., of various diseases that occur in women of reproductive age with a focus on the perinatal period and elderly/senile women, thereby contributing to the enhancement of people's health and welfare.

To achieve these goals, the foundation conducts the following activities related to the above subjected studies:

(1) Research grants
(2) Overseas study grants
(3) Awards for excellent results-bearing research (Kanzawa Medical Award)
(4) Organization of seminars on subjected studies

The total number of rewards and grants and the amount of money awarded to date (1997–2020) are shown in the following table.

	Total number	Total amount of money
Kanzawa Medical Award	22	¥65 million
Research Grants	237	¥282 million
Overseas Study Grants	90	¥45 million

Number of Awards and Grants in Fiscal 2020

Kanzawa Medical Award

Recipient: Associate Professor Masahito Tachibana
Research Institution: Tohoku University Graduate School of Medicine, Center for Perinatal and Neonatal Medicine
Research Theme: Establishment of gene therapy for genetically inherited mitochondrial diseases using cytoplasmic substitution and possible use of mitochondrial replacement therapy to overcome intractable infertility

Research Grants: 10

Overseas Study Grants: 4

Contributions to Social Well-Being

Since 2006, we have conducted fundraising activities and charity drives at culture festivals held in the Matsumoto and Shiojiri areas (locations of the Head Office, Matsumoto Plants, Shiojiri Plants, and the Nutritional Business Center), with proceeds going to the Matsumoto Children's Garden, a children's welfare facility. In fiscal 2020, culture festivals were canceled to prevent the spread of COVID-19, but donations were made to the facility using proceeds from remote events and contributions from employees.

This donation also includes the proceeds from the sale of organic compost, an environmentally friendly recycled organic fertilizer made from kitchen waste from the employee cafeterias at the Head Office and Matsumoto Plants.

Culture Festival (fiscal 2019)

Contributions to Local Communities

Since 2009, we have supported Parent and Child Science Workshops hosted by Matsumoto City, where the head office is located, by providing employee volunteers. These workshops, designed for elementary school students and their parents, aim to teach about the joy of science through play and prevent people from losing their love of science. Employees plan and conduct lessons on days when they are held by Kissei. Participants are able to wear lab coats and use the actual equipment used in research as if they were conducting experiments themselves, providing an enjoyable experience for parents as well as children.

The workshops are also a valuable experience for employees who participate as instructors and staff, as they can draw inspiration from the children's serious efforts to perform the experiments and their smiles when they succeed.

Parent and Child Science Workshops

Contributions to Sports and Culture

Support for the Matsumoto Yamaga Football Club

Kissei is the official sponsor of the Matsumoto Yamaga Football Club.

The club was formed in Matsumoto City in 1965 and is currently fighting as a team to return to J. League Division 1 status. Kissei supports the club with a vision toward contributing to "town development," "human development," and "future development" through soccer, which brings vigor and vitality to local communities and supplies dreams and excitement to the community and its promising children.

© Matsumoto Yamaga FC

Seiji Ozawa Matsumoto Festival

Music is a language common to the world. We believe that companies play an important role in the support and cultivation of cultural activities that bring people together and touch them emotionally.

Since September 1992, the annual music festival Seiji Ozawa Matsumoto Festival (formerly the Saito Kinen Festival Matsumoto) has been held in Matsumoto City under the guidance of internationally renowned conductor Maestro Seiji Ozawa. This festival gathers elite musicians from around the world to form the Saito Kinen Orchestra, performing operas and concerts and producing music of the highest levels transmitted from Japan to the world, resounding in the hearts of all who hear it. The festival is held in various places in Matsumoto City, including the Kissei Culture Hall (naming rights acquired for the formerly named Nagano Prefectural Matsumoto Cultural Hall in 2012).

In 2020, the event had to be canceled due to the spread of COVID-19 in Japan and overseas.

Kissei Pharmaceutical has supported the festival since its inception.

Opera *Eugene Onegin* by Tchaikovsky (performed in 2019)
© Michiharu Okubo

Financial Review

Financial Position

Assets

For the fiscal year under review, ended March 31, 2021, assets stood at ¥268,861 million, up ¥37,066 million from the previous consolidated fiscal year-end. Total current assets decreased ¥3,711 million, to ¥92,965 million, mainly due to a contraction in cash on hand, which offset an increase in inventories, notes and accounts receivable, and marketable securities. Total non-current assets were up ¥40,778 million, to ¥175,895 million, mainly reflecting an increase in investment securities and long-term prepaid expenses.

Liabilities

Total liabilities amounted to ¥48,907 million at the fiscal year-end, up ¥10,083 million from the previous consolidated fiscal year-end. Total current liabilities stood at ¥18,245 million, up ¥1,221 million, mainly due to an increase in notes and accounts payable and income tax payable, despite a decrease in accounts payable listed under other current liabilities. Total long-term liabilities were up ¥8,861 million, to ¥30,662 million, due to an increase in deferred tax liabilities.

Shareholders' Equity

Total net assets amounted to ¥219,953 million at the consolidated fiscal year-end, an increase of ¥26,983 million compared with the previous fiscal year-end. This increase mainly reflected a rise in retained earnings, net unrealized holding gains on securities, in addition to other factors.

As a result, the shareholders' equity ratio was 81.6%, down from 83.0% at the previous fiscal year-end.

Financial Results

Net sales for the fiscal year ended March 31, 2021 increased 9.2% year on year, to ¥69,044 million. Accounting for the majority of net sales, the segment sales of the Kissei Group's core pharmaceutical business were up 9.9%, to ¥56,407 million. Although the prolonged effects of COVID-19 have restricted efforts to provide drug information, net sales increased for products including Beova®, a treatment for overactive bladder, Darbepoetin Alfa BS Injection [JCR], a treatment for renal anemia, and P-TOL® Chewable Tablets and P-TOL® Granules, treatments for hyperphosphatemia. Segment sales were also boosted after distribution operations were transferred to Kissei in April 2020 for MINIRIN MELT® OD Tablets 25μg and 50μg, a treatment for nocturia due to nocturnal polyuria in males; MINIRIN MELT® OD Tablets 60μg, 120μg, and 240μg and DESMOPRESSIN formulations, treatments for nocturnal enuresis and central diabetes insipidus; and MARIZEV® Tablets, a treatment for type 2 diabetes.

Net sales for information services increased 28.0% year on year, to ¥8,489 million, net sales for construction decreased 2.0% year on year, to ¥3,538 million, and net sales for merchandising fell 63.8% year on year, to ¥609 million. Despite this increase in net sales and a decrease in selling, general and administrative expenses, operating income decreased due to a higher cost of sales ratio. However, ordinary income and profit attributable to owners of parent increased. Gain on valuation of securities is recorded as non-operating income, and gain on sales of investment securities is recorded as extraordinary income.

The cost of sales ratio was up 7.8 percentage points. As a result, gross profit decreased ¥2,182 million, or 6.3% year on year, to ¥32,722 million.

Selling, general and administrative expenses decreased overall, including R&D expenses, due to the effects of COVID-19. However, operating income decreased ¥352 million, or 19.0%, to ¥1,505 million, due to a decrease in gross profit.

In non-operating income or loss, income expanded ¥1,399 million year or year, due to recording a gain on valuation of securities. Consequently, ordinary income increased 43.1% year on year, or ¥1,047 million, to ¥3,476 million.

Extraordinary income or loss rose ¥1,798 million due to an increased gain on sales of investment securities.

As a result of the above, profit before income taxes and non-controlling interests was up ¥2,845 million, or 61.5% year on year, to ¥7,476 million, and profit attributable to owners of parent increased ¥2,467 million, or 87.6% year on year, to ¥5,285 million.

Basic Policy on the Distribution of Profits / Dividends

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

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

In the fiscal year under review, the Group made the decision to pay an interim cash dividend of ¥27.0 per share and a year-end cash dividend of ¥27.0 per share, giving a full-year cash dividend of ¥54.0 per share.

For the coming fiscal year, the Group plans to pay an interim cash dividend of ¥28.0 per share and a year-end cash dividend of ¥28.0 per share, giving a full-year cash dividend of ¥56.0 per share.

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

Consolidated Balance Sheet

Kissei Pharmaceutical Co., Ltd., and its subsidiaries
At March 31, 2020 and 2021

	Millions of yen		Thousands of U.S. dollars (Note 03)
Assets	2020	**2021**	**2021**
Current Assets:			
Cash on hand and in banks (Notes 04 and 05)	¥ 36,329	**¥ 20,456**	**$ 184,288**
Notes and accounts receivable (Note 05)	19,462	**23,058**	**207,730**
Marketable securities (Notes 04, 05 and 06)	23,342	**23,998**	**216,198**
Inventories (Note 07)	13,439	**20,119**	**181,252**
Other current assets	4,103	**5,332**	**48,036**
Total current assets	96,677	**92,965**	**837,523**
Property, Plant and Equipment:			
Buildings and structures (Note 12)	38,746	**38,855**	**350,045**
Less: accumulated depreciation	(29,347)	**(29,991)**	**(270,189)**
Buildings and structures, net	9,398	**8,863**	**79,847**
Land (Note 12)	12,622	**12,622**	**113,712**
Construction in progress	1	**98**	**883**
Other	16,601	**16,820**	**151,532**
Less: accumulated depreciation	(14,018)	**(14,114)**	**(127,153)**
Other, net	2,582	**2,705**	**24,369**
Total property, plant and equipment	24,605	**24,290**	**218,829**
Intangible Assets:			
Software for internal use	975	**1,175**	**10,586**
Other	536	**465**	**4,189**
Total intangible assets	1,511	**1,640**	**14,775**
Investments and Other Assets:			
Investment securities (Notes 05 and 06)	105,158	**138,133**	**1,244,441**
Long-term loans receivable	36	**14**	**126**
Long-term prepaid expenses	2,103	**10,262**	**92,450**
Deferred tax assets (Note 09)	677	**585**	**5,270**
Other	1,060	**1,002**	**9,027**
Allowance for doubtful accounts	(36)	**(34)**	**(306)**
Total investments and other assets	108,999	**149,964**	**1,351,027**
Total assets	¥231,794	**¥268,861**	**$2,422,171**

The accompanying notes are an integral part of these statements.

	Millions of yen		Thousands of U.S. dollars (Note 03)
Liabilities and Net Assets	2020	**2021**	**2021**
Current Liabilities:			
Notes and accounts payable	¥ 5,237	**¥ 7,909**	**$ 71,252**
Short-term bank loans (Note 08)	1,730	**1,730**	**15,586**
Current portion of long-term debt (Note 08)	16	**13**	**117**
Income taxes payable	196	**1,487**	**13,396**
Accrued bonuses to employees	1,858	**1,816**	**16,360**
Accrued bonuses to directors and corporate auditors	8	**14**	**126**
Reserve for sales returns	6	**6**	**54**
Reserve for sales rebates	273	**320**	**2,883**
Reserve for sales promotion expenses	163	**149**	**1,342**
Other current liabilities	7,532	**4,796**	**43,207**
Total current liabilities	17,024	**18,245**	**164,369**
Long-Term Liabilities:			
Long-term debt (Note 08)	13	**—**	**—**
Deferred tax liabilities (Note 09)	17,191	**28,480**	**256,577**
Net defined benefit liability (Note 10)	3,572	**1,234**	**11,117**
Accrued retirement benefits to directors and corporate auditors	175	**164**	**1,477**
Asset retirement obligations	117	**121**	**1,090**
Other long-term liabilities	729	**660**	**5,946**
Total long-term liabilities	21,800	**30,662**	**276,234**
Total liabilities	38,824	**48,907**	**440,604**
Net Assets:			
Shareholders' equity:			
Common stock:			
Authorized: 227,000,000 shares			
Issued: 51,811,185 shares	24,356	**24,356**	**219,423**
Additional paid-in capital	24,226	**24,226**	**218,252**
Retained earnings	106,461	**109,270**	**984,414**
Treasury stock (5,095,024 shares and 5,695,246 shares at March 31, 2020 and 2021, respectively)	(11,608)	**(12,911)**	**(116,315)**
Total shareholders' equity	143,435	**144,941**	**1,305,775**
Accumulated other comprehensive income:			
Unrealized holding gains on securities	50,706	**74,351**	**669,829**
Retirement benefits liability adjustments	(1,676)	**22**	**198**
Total accumulated other comprehensive income	49,029	**74,373**	**670,027**
Non-controlling interests	504	**638**	**5,748**
Total net assets	192,970	**219,953**	**1,981,559**
Total liabilities and net assets	¥231,794	**¥268,861**	**$2,422,171**

Consolidated Statement of Income and Consolidated Statement of Comprehensive Income

Kissei Pharmaceutical Co., Ltd., and its subsidiaries
For the years ended March 31, 2020 and 2021

Consolidated Statement of Income

	Millions of yen		Thousands of U.S. dollars (Note 03)
	2020	2021	2021
Net Sales	¥63,234	**¥69,044**	**$622,018**
Cost of Sales	28,329	**36,322**	**327,225**
Gross profit	34,905	**32,722**	**294,793**
Selling, General and Administrative Expenses (Note 15)	33,048	**31,217**	**281,234**
Operating income	1,857	**1,505**	**13,559**
Other Income (Expenses):			
Interest and dividend income	1,227	**1,273**	**11,468**
Interest expense	(23)	**(23)**	**(207)**
Gain on sales of investment securities	2,236	**4,084**	**36,793**
Gain on sales and loss on disposal of property, plant and equipment, net	(35)	**(10)**	**(90)**
Gain (loss) on valuation of securities	(803)	**720**	**6,486**
Loss on valuation of investment securities	—	**(77)**	**(694)**
Foreign exchange gain (loss)	51	**(130)**	**(1,171)**
Other, net	119	**134**	**1,207**
Total other income	2,773	**5,971**	**53,793**
Profit before income taxes and non-controlling interests	4,630	**7,476**	**67,351**
Income Taxes (Note 09)**:**			
Current	390	**1,510**	**13,604**
Deferred	1,351	**587**	**5,288**
	1,741	**2,098**	**18,901**
Profit	2,888	**5,378**	**48,450**
Profit Attributable to Non-Controlling Interests	71	**93**	**838**
Profit Attributable to Owners of Parent (Note 16)	¥ 2,817	**¥ 5,285**	**$ 47,613**

The accompanying notes are an integral part of these statements.

Consolidated Statement of Comprehensive Income

	Millions of yen		Thousands of U.S. dollars (Note 03)
	2020	2021	2021
Profit	¥ 2,888	**¥ 5,378**	**$ 48,450**
Other Comprehensive Income:			
Unrealized holding gains on securities	10,379	**23,652**	**213,081**
Retirement benefits liability adjustments	(622)	**1,732**	**15,604**
Total other comprehensive income (Note 11)	9,757	**25,384**	**228,685**
Comprehensive Income	¥12,646	**¥30,762**	**$277,135**
Comprehensive income attributable to:			
Owners of parent	¥12,585	**¥30,629**	**$275,937**
Non-controlling interests	60	**133**	**1,198**

The accompanying notes are an integral part of these statements.

Consolidated Statement of Changes in Net Assets

Kissei Pharmaceutical Co., Ltd., and its subsidiaries
For the years ended March 31, 2020 and 2021

	Millions of yen								
		Shareholders' equity				Accumulated other comprehensive income			
	Number of shares of common stock	Common stock	Additional paid-in capital	Retained earnings	Treasury stock	Unrealized holding gains on securities	Retirement benefits liability adjustments	Non-controlling interests	Total net assets
Balance at April 1, 2019	51,811,185	¥24,356	¥24,226	¥106,026	¥(11,607)	¥40,326	¥(1,065)	¥444	¥182,707
Profit attributable to owners of parent for the year	—	—	—	2,817	—	—	—	—	2,817
Cash dividends paid	—	—	—	(2,382)	—	—	—	—	(2,382)
Treasury stock purchased (270 shares)	—	—	—	—	(0)	—	—	—	(0)
Disposal of treasury stock (52 shares)	—	—	0	—	0	—	—	—	0
Net changes in items other than those in shareholders' equity	—	—	—	—	—	10,379	(611)	60	9,828
Balance at March 31, 2020	51,811,185	¥24,356	¥24,226	¥106,461	¥(11,608)	¥50,706	¥(1,676)	¥504	¥192,970
Profit attributable to owners of parent for the year	**—**	**—**	**—**	**5,285**	**—**	**—**	**—**	**—**	**5,285**
Cash dividends paid	**—**	**—**	**—**	**(2,475)**	**—**	**—**	**—**	**—**	**(2,475)**
Treasury stock purchased (600,296 shares)	**—**	**—**	**—**	**—**	**(1,303)**	**—**	**—**	**—**	**(1,303)**
Disposal of treasury stock (74 shares)	**—**	**—**	**(0)**	**—**	**0**	**—**	**—**	**—**	**0**
Net changes in items other than those in shareholders' equity	**—**	**—**	**—**	**—**	**—**	**23,645**	**1,699**	**133**	**25,477**
Balance at March 31, 2021	**51,811,185**	**¥24,356**	**¥24,226**	**¥109,270**	**¥(12,911)**	**¥74,351**	**¥ 22**	**¥638**	**¥219,953**

	Thousands of U.S. dollars (Note 03)								
		Shareholders' equity				Accumulated other comprehensive income			
	Number of shares of common stock	Common stock	Additional paid-in capital	Retained earnings	Treasury stock	Unrealized holding gains on securities	Retirement benefits liability adjustments	Non-controlling interests	Total net assets
Balance at April 1, 2020	51,811,185	$219,423	$218,252	$959,108	$(104,577)	$456,811	$(15,099)	$4,541	$1,738,468
Profit attributable to owners of parent for the year	**—**	**—**	**—**	**47,613**	**—**	**—**	**—**	**—**	**47,613**
Cash dividends paid	**—**	**—**	**—**	**(22,297)**	**—**	**—**	**—**	**—**	**(22,297)**
Treasury stock purchased (600,296 shares)	**—**	**—**	**—**	**—**	**(11,739)**	**—**	**—**	**—**	**(11,739)**
Disposal of treasury stock (74 shares)	**—**	**—**	**(0)**	**—**	**0**	**—**	**—**	**—**	**0**
Net changes in items other than those in shareholders' equity	**—**	**—**	**—**	**—**	**—**	**213,018**	**15,306**	**1,198**	**229,523**
Balance at March 31, 2021	**51,811,185**	**$219,423**	**$218,252**	**$984,414**	**$(116,315)**	**$669,829**	**$ 198**	**$5,748**	**$1,981,559**

The accompanying notes are an integral part of these statements.

Consolidated Statement of Cash Flows

Kissei Pharmaceutical Co., Ltd., and its subsidiaries
For the years ended March 31, 2020 and 2021

	Millions of yen		Thousands of U.S. dollars (Note 03)
	2020	2021	2021
Cash Flows from Operating Activities:			
Profit before income taxes and non-controlling interests	¥ 4,630	**¥ 7,476**	**$ 67,351**
Depreciation and amortization	2,562	**3,148**	**28,360**
Increase (decrease) in allowance reserves	(140)	**(12)**	**(108)**
Increase (decrease) in net defined benefit liability	(73)	**155**	**1,396**
Interest and dividend income	(1,227)	**(1,273)**	**(11,468)**
Interest expense	23	**23**	**207**
Foreign exchange (gain) loss	0	**(0)**	**(0)**
(Gain) loss on sales of securities	—	**(0)**	**(0)**
(Gain) loss on valuation of securities	803	**(720)**	**(6,486)**
(Gain) loss on sales of property, plant and equipment	(27)	**(0)**	**(0)**
(Gain) loss on sales of investment securities	(2,236)	**(4,084)**	**(36,793)**
(Gain) loss on valuation of investment securities	—	**77**	**694**
Loss on disposal of property, plant and equipment	62	**10**	**90**
(Increase) decrease in notes and accounts receivable	7,500	**(3,595)**	**(32,387)**
(Increase) decrease in inventories	525	**(6,679)**	**(60,171)**
(Increase) decrease in other current assets	599	**(509)**	**(4,586)**
Increase (decrease) in notes and accounts payable	890	**2,671**	**24,063**
Increase (decrease) in other current liabilities	(5)	**279**	**2,514**
Increase (decrease) in other long-term liabilities	0	**4**	**36**
Other	8	**6**	**54**
Subtotal	13,896	**(3,024)**	**(27,243)**
Receipt of interest and dividends	1,110	**1,157**	**10,423**
Payment of interest	(23)	**(23)**	**(207)**
Payment of income taxes	(1,048)	**(652)**	**(5,874)**
Net cash provided by (used in) operating activities	13,934	**(2,542)**	**(22,901)**
Cash Flows from Investing Activities:			
Time deposits received	76	**78**	**703**
Time deposits paid	(75)	**(78)**	**(703)**
Reduction of investments in specified trusts	97	**98**	**883**
Acquisition of property, plant and equipment	(879)	**(931)**	**(8,387)**
Proceeds from sales of property, plant and equipment	70	**3**	**27**
Acquisition of intangible assets	(423)	**(554)**	**(4,991)**
Acquisition of investment securities	(689)	**(3,761)**	**(33,883)**
Proceeds from sales of investment securities	2,755	**4,551**	**41,000**
Payments for loans	(76)	**(5)**	**(45)**
Collection of loans	168	**37**	**333**
Long-term advance payment costs	(503)	**(8,822)**	**(79,477)**
Other	(30)	**54**	**486**
Net cash provided by (used in) investing activities	490	**(9,329)**	**(84,045)**
Cash Flows from Financing Activities:			
Repayment of long-term debt	(1,934)	**(16)**	**(144)**
Repayment of finance lease obligation	(101)	**(204)**	**(1,838)**
Cash dividends paid	(2,382)	**(2,475)**	**(22,297)**
Treasury stock purchased	(0)	**(1,303)**	**(11,739)**
Proceeds from sale of treasury stock	0	**0**	**0**
Net cash used in financing activities	(4,419)	**(4,000)**	**(36,036)**
Effect of Exchange Rate Changes on Cash and Cash Equivalents	(0)	**0**	**0**
Increase (Decrease) in Cash and Cash Equivalents	10,004	**(15,872)**	**(142,991)**
Cash and Cash Equivalents at Beginning of Year (Note 04)	49,315	**59,319**	**534,405**
Cash and Cash Equivalents at End of Year (Note 04)	¥59,319	**¥43,447**	**$391,414**

The accompanying notes are an integral part of these statements.

Notes to the Consolidated Financial Statements

Kissei Pharmaceutical Co., Ltd., and its subsidiaries

Note 01 Basis of Presenting the Consolidated Financial Statements

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

Note 02 Summary of Significant Accounting Policies

(1) Scope of Consolidation

The Company had five subsidiaries in the year ended March 31, 2021, of which three were consolidated subsidiaries. Those subsidiaries 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**

The fiscal year-end for consolidated subsidiaries is the same date as the consolidated fiscal year-end for the Company.

(2) Consolidation and Elimination

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

(3) Investments in Unconsolidated Subsidiaries

Investments in unconsolidated subsidiaries (Kissei America, Inc., and PROS Co., Ltd.) are carried at cost, as there would be no significant effect in the consolidated statements of income if they were consolidated and/or 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 determined by the moving average method.

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

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

(5) Inventory Valuation

Inventories are primarily 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 for the Company is primarily calculated using the straight-line method, whereas the declining balance method is primarily used at consolidated subsidiaries. However, 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. The range of useful life for buildings and structures is principally from three to 50 years.

(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 five years) on a straight-line basis.

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

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

(iv) Long-term prepaid expenses

Long-term expenses are amortized in equal amounts over a period of time.

(7) Accounting for Consumption Tax

Consumption tax is imposed at the flat rate of 10% 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 statement 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 statement 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 uncollectible receivables estimated on an individual basis.

(ii) Accrued bonuses to employees

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

(iii) Accrued bonuses to directors and corporate auditors

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

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

(11) Accounting Method for Retirement Benefits
(i) Allocation of expected benefit payments
When calculating the retirement benefit obligation, the benefit formula method is used to allocate expected benefit payments to the period.
(ii) Actuarial differences and prior service cost
Prior service cost is amortized through the straight-line method over a term that does not exceed the average remaining service period of employees who are expected to receive benefits under the plans (10 years).
Net actuarial gains or losses are amortized from the following year through the straight-line method over a term that does not exceed the average remaining service period of employees who are expected to receive benefits under the plans (10 years).
(iii) Accounting treatment for unrecognized actuarial gains and losses and unrecognized prior service cost
Unrecognized actuarial gains and losses and unrecognized prior service cost are adjusted for tax effects and then recorded in retirement benefits liability adjustments under accumulated other comprehensive income in the net assets portion of the consolidated balance sheets.

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

(13) Profit and Dividends per Share
Profit attributable to owners of 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 changes in net assets represent dividends approved or declared as applicable to the respective years.

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

(15) Change in Presentation
Changes in accordance with "Accounting Standard for Disclosure of Accounting Estimates"
The Companies have adopted "Accounting Standard for Disclosure of Accounting Estimates" (ASBJ Statement, No. 31, issued March 31, 2020) beginning from the fiscal year ended March 31, 2021; therefore, the notes to the consolidated financial statements include disclosures regarding accounting estimates.
However, the notes do not include accounting estimates for the previous fiscal year, in accordance with the transitional method prescribed in paragraph 11 of the aforementioned accounting standard.

(16) Significant Accounting Estimates
(i) Significant accounting estimates
Recoverability of deferred tax assets
Amount recorded in the consolidated financial statements for the fiscal year
Deferred tax assets net (- million yen)
(Deferred tax assets before offsetting deferred tax liabilities were ¥4,649 million)
(ii) Other Information That Contributes to the Understanding of Financial Statements
1. Calculation method
In accordance with "Implementation Guidance on Recoverability of Deferred Tax Assets" (ASBJ Guidance, No. 26, issued March 28, 2016), deductible temporary differences that are judged to be recoverable are recorded as deferred tax assets. Recoverability is determined according to future profitability based on the medium-term management plan approved by the Board of Directors, and the future taxable income based on tax planning.
2. Key assumptions
Key assumptions for estimating taxable income related to the medium-term management plan are the revision rate of National Health Insurance ("NHI") on drug sales, the timing of the launch of new products, and the gains on sales of investment securities. The revision rate of NHI drug prices is estimated in consideration of past revisions and trends in pharmaceutical administration. The timing of the launch of new products includes estimations for drug prices as well as an estimated timeline that incorporates the progress of clinical trials, past performance, and cases from other companies and projections are made for submitting applications for approval, approval acquisition, and release. Regarding gains on sales of investment securities, the Company makes estimates based on the amount of unrealized gains on investment securities expected to be sold as of the end of the fiscal year under review. In making accounting estimates, the Company incorporates the expectation that the economic impact of COVID-19 will continue for a certain period during the next fiscal year. However, the Company believes the effect on key assumptions is immaterial.
3. Impact on consolidated financial statements for the following fiscal year
Expected the gains on sales of investment securities under the medium-term management plan have a significant impact on estimations for taxable income; therefore, the inability to sell stock intended for sale may trigger a reversal of deferred tax assets.

(17) Changes in Accounting Policies That Are Difficult to Distinguish from Changes in Accounting Estimates
Previously, depreciation of property, plant and equipment (excluding lease assets) was computed using the declining balance method, except for buildings acquired on or after April 1, 1998 (excluding facilities attached to buildings) and the straight-line method was used for both facilities attached to buildings and other non-building structures acquired on or after April 1, 2016. However, the straight-line method was adopted as the depreciation method for all plant, property and equipment beginning from the fiscal year ended March 31, 2021.
Under the medium-term management plan PEGASUS, which is being implemented from the fiscal year ended March 31, 2021 to the fiscal year ending March 31, 2025, the pharmaceutical business operated by the Company plans to enhance its product portfolio through the steady launch of late-stage development themes and product in-licensing, while also stabilizing the outsourced manufacturing of drugs, with a focus on authorized generics. This has caused major changes to the types of items in production and operating conditions at production headquarters. Similarly, the Research Division as a whole is experiencing major changes in the nature of its activities due to its focus on drug discovery research on small molecules and its work to optimize and regularly review its pipeline to ensure the continuous launch of new drugs. These initiatives have improved the quality of the pipeline while clarifying drug discovery themes in each research department.
These changes, brought on by the medium-term management plan, have been taken as an opportunity to confirm the operational status of production and research equipment, and it is expected that production and research equipment will continue to operate stably over its useful life. Therefore, it was determined that adopting the straight-line method for computing depreciation of property, plant and equipment (excluding leased assets) will more appropriately reflect actual usage and make calculations of profit or loss for the fiscal year more rational.
As a result of this decision, depreciation and amortization for the fiscal year under review decreased ¥165 million and operating income, ordinary income, and profit before income taxes and non-controlling interests each increased ¥165 million yen compared with the previous method.

(18) Accounting Standards Issued but Not Yet Effective
"Accounting Standard and Implementation Guidance on Revenue Recognition"
The ASBJ issued "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29) on March 31, 2020 and "Implementation Guidance on Accounting Standard for Revenue Recognition" (ASBJ Guidance No. 30) on March 26, 2021.
(i) Overview
This is a comprehensive accounting standard for revenue recognition. Specifically, the accounting standard establishes the following five-step model that will apply to revenue from customers:
1. Identify the contract(s) with a customer
2. Identify the performance obligations in the contract
3. Determine the transaction price
4. Allocate the transaction price to the performance obligations in the contract
5. Recognize revenue when (or as) the entity satisfies a performance obligation
(ii) Scheduled date of adoption
The Companies expect to adopt the accounting standard and implementation guidance from the beginning of the fiscal year ending March 31, 2022.
(iii) Impact of the adoption of accounting standard and implementation guidance
The Companies are currently evaluating the effect of the adoption of this accounting standard and implementation guidance on its consolidated financial statements.

Note 03 United States Dollar Amounts

The accompanying consolidated financial statements are expressed in yen, and, solely for the convenience of the reader, have been translated into U.S. dollars at the rate of ¥111=U.S.$1, the approximate rate of exchange prevailing at March 31, 2021. 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, 2020 and 2021 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2020	2021	2021
Cash on hand and in banks	¥36,329	**¥20,456**	**$184,288**
Marketable securities	23,342	**23,998**	**216,198**
Time deposits with original maturities of over three months	(48)	**(48)**	**(432)**
Claims with redemption period exceeding three months, etc.	(302)	**(959)**	**(8,640)**
Cash and cash equivalents	¥59,319	**¥43,447**	**$391,414**

Note 05 Financial Instruments

Overview

(1) Policy for financial instruments

The Companies manage temporary cash surpluses through low-risk financial assets. Further, the Companies raise short-term capital through bank borrowings. The Companies use derivatives for the purpose of avoiding the risks stated below and do not engage in transactions for speculative 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 the 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; however, they are managed in accordance with securities management regulations and the general manager of the Corporate Finance & Management Department reports the status of these holdings to the Board of Directors on a regular basis.

(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, 2020 and 2021 and unrealized gains (losses) are shown in the following tables. The following does not include financial instruments for which it is extremely difficult to determine the fair value. (Please refer to *2 in the following.)

	Millions of yen		
As of March 31, 2020	Carrying value	Estimated fair value	Unrealized gains (losses)
Assets:			
Cash on hand and in banks	¥ 36,329	¥ 36,329	¥—
Notes and accounts receivable	19,462	19,462	—
Marketable securities and investment securities	123,081	123,081	—
Total	¥178,872	¥178,872	¥—
Derivatives	¥ —	¥ —	¥—

	Millions of yen		
As of March 31, 2021	Carrying value	Estimated fair value	Unrealized gains (losses)
Assets:			
Cash on hand and in banks	**¥ 20,456**	**¥ 20,456**	**¥—**
Notes and accounts receivable	**23,058**	**23,058**	**—**
Marketable securities and investment securities	**156,655**	**156,655**	**—**
Total	**¥200,170**	**¥200,170**	**¥—**
Derivatives	**¥ —**	**¥ —**	**¥—**

	Thousands of U.S. dollars		
As of March 31, 2021	Carrying value	Estimated fair value	Unrealized gains (losses)
Assets:			
Cash on hand and in banks	**$ 184,288**	**$ 184,288**	**$—**
Notes and accounts receivable	**207,730**	**207,730**	**—**
Marketable securities and investment securities	**1,411,306**	**1,411,306**	**—**
Total	**$1,803,333**	**$1,803,333**	**$—**
Derivatives	**$ —**	**$ —**	**$—**

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

Cash on hand and in banks and notes and accounts receivable

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

Marketable securities and investment securities

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

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

	Millions of yen		Thousands of U.S. dollars
	2020	**2021**	**2021**
Unlisted stocks	¥4,529	**¥4,587**	**$41,324**
Investments in partnerships	—	**—**	**—**
Investments in unconsolidated subsidiaries	889	**889**	**8,009**

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 schedules for receivables and marketable securities with maturities at March 31, 2020 and 2021 are as follows:

	Millions of yen			
As of March 31, 2020	Due in one year or less	Due after one to five years	Due after five to ten years	Due after ten years
Assets:				
Cash on hand and in banks	¥36,329	¥ —	¥ —	¥ —
Notes and accounts receivable	19,462	—	—	—
Marketable securities and investment securities	23,348	1,954	2,261	1,000
Total	¥79,139	¥1,954	¥2,261	¥1,000

	Millions of yen			
As of March 31, 2021	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	**¥20,456**	**¥ —**	**¥ —**	**¥ —**
Notes and accounts receivable	**23,058**	**—**	**—**	**—**
Marketable securities and investment securities	**23,796**	**2,171**	**1,764**	**1,000**
Total	**¥67,311**	**¥2,171**	**¥1,764**	**¥1,000**

	Thousands of U.S. dollars			
As of March 31, 2021	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	**$184,288**	**$ —**	**$ —**	**$ —**
Notes and accounts receivable	**207,730**	**—**	**—**	**—**
Marketable securities and investment securities	**214,378**	**19,559**	**15,892**	**9,009**
Total	**$606,405**	**$19,559**	**$15,892**	**$9,009**

Note 06 Securities

Trading Securities

Unrealized gains for trading securities for the year ended March 31, 2021 amounted to ¥720 million ($6,486 thousand) and unrealized losses for trading securities for the year ended March 31, 2020 came to ¥803 million.

Other Securities

The acquisition cost, carrying amount, and gross unrealized holding gains and losses for securities with fair value by security type at March 31, 2020 and 2021 are as follows:

	Millions of yen			
	2020			
	Acquisition cost	Carrying amount	Gross unrealized holding gains	Gross unrealized holding losses
Equity securities	¥17,738	¥ 90,756	¥73,824	¥ 806
Corporate debt securities	1,550	1,519	2	32
Other	30,896	30,805	360	452
Total	¥50,185	¥123,081	¥74,187	¥1,291

	Millions of yen			
	2021			
	Acquisition cost	Carrying amount	Gross unrealized holding gains	Gross unrealized holding losses
Equity securities	**¥17,540**	**¥122,532**	**¥105,595**	**¥603**
Corporate debt securities	**1,750**	**1,759**	**12**	**2**
Other	**30,845**	**32,362**	**1623**	**107**
Total	**¥50,136**	**¥156,655**	**¥107,231**	**¥712**

	Thousands of U.S. dollars			
	2021			
	Acquisition cost	Carrying amount	Gross unrealized holding gains	Gross unrealized holding losses
Equity securities	**$158,018**	**$1,103,892**	**$951,306**	**$5,432**
Corporate debt securities	**15,766**	**15,847**	**108**	**18**
Other	**277,883**	**291,550**	**14,622**	**964**
Total	**$451,676**	**$1,411,306**	**$966,045**	**$6,414**

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, 2020 and 2021 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2020	2021	2021
Sales proceeds	¥2,731	**¥4,483**	**$40,387**
Gross realized gains	2,236	**4,119**	**37,108**
Gross realized losses	—	**34**	**306**

Note 07 Inventories

Inventories at March 31, 2020 and 2021 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2020	2021	2021
Merchandise	¥ 2,880	**¥ 6,417**	**$ 57,811**
Finished goods	2,712	**3,601**	**32,441**
Work-in-process	1,956	**1,510**	**13,604**
Raw materials	5,797	**8,247**	**74,297**
Supplies	93	**342**	**3,081**
Total	¥13,439	**¥20,119**	**$181,252**

Note 08 Summary of Loans and Debt

Classification	Balance at beginning of fiscal year (Millions of yen)	Balance at end of fiscal year (Millions of yen)	Balance at end of fiscal year (Thousands of U.S. dollars)	Average interest rate (%)	Repayment period
Short-term loans*1	¥1,730	¥1,730	$15,586	1.08	—
Current portion of long-term debt*2	16	13	117	0.28	—
Current portion of lease obligations	136	131	1,180	—	—
Long-term debt (excluding current portion)	13	—	—	—	—
Lease obligations (excluding current portion)	373	304	2,739	—	April 2022–February 2027
Total	¥2,269	¥2,180	$19,640	—	—

*1. Figures under average interest rate refer to the weighted-average interest rate applied to the balance at the end of the fiscal year.
*2. Average interest rate for 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.

Classification	Over one year, within two years (Millions of yen)	Over two years, within three years (Millions of yen)	Over three years, within four years (Millions of yen)	Over four years, within five years (Millions of yen)
Lease obligations	¥108	¥73	¥63	¥42

Classification	Over one year, within two years (Thousands of U.S. dollars)	Over two years, within three years (Thousands of U.S. dollars)	Over three years, within four years (Thousands of U.S. dollars)	Over four years, within five years (Thousands of U.S. dollars)
Lease obligations	$973	$658	$568	$378

Note 09 Income Taxes

Deferred tax assets and liabilities at March 31, 2020 and 2021 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2020	2021	2021
Deferred Tax Assets:			
Prepaid research and development expenses	¥ 2,596	**¥ 2,921**	**$ 26,315**
Net defined benefit liability	1,588	**766**	**6,901**
Inventory assets	661	**346**	**3,117**
Accrued bonuses to employees	566	**554**	**4,991**
Write-down of securities	440	**463**	**4,171**
Payment of retirement benefits to directors and corporate auditors	161	**158**	**1,423**
Impairment loss	149	**148**	**1,333**
Reserve for sales rebates	83	**97**	**874**
Accrued enterprise tax	68	**137**	**1,234**
Other	818	**831**	**7,486**
Total gross deferred tax assets	7,136	**6,426**	**57,892**
Valuation allowance	(1,390)	**(1,776)**	**(16,000)**
Total deferred tax assets	¥ 5,746	**¥ 4,649**	**$ 41,883**
Deferred Tax Liabilities:			
Unrealized holding gains on securities	¥(22,123)	**¥(32,153)**	**$(289,667)**
Other	(136)	**(390)**	**(3,514)**
Total deferred tax liabilities	(22,260)	**(32,544)**	**(293,189)**
Deferred tax assets (liabilities), net	¥(16,514)	**¥(27,894)**	**$(251,297)**

Note: The net amount of tax liabilities carried forward in the previous consolidated fiscal year and the fiscal year under review include the following items recorded on the consolidated balance sheet.

	Millions of yen		Thousands of U.S. dollars
	2020	2021	2021
Non-current assets—deferred tax assets	¥ 677	**¥ 585**	**$ 5,270**
Non-current liabilities—deferred tax liabilities	(17,191)	**(28,480)**	**(256,577)**

Reconciliation of the effective statutory tax rate and the actual tax rate for the years ended March 31, 2020 and 2021 is as follows:

	2020	2021
Effective statutory tax rate	30.5%	**30.5%**
Adjustments:		
Entertainment expenses and other non-deductibles	1.1	**0.2**
Dividend income not taxable	(1.8)	**(1.1)**
Tax benefits due to research and development expenses	(1.4)	**(7.3)**
Per capital levy of local inhabitants taxes	1.8	**1.1**
Valuation allowance	7.1	**5.2**
Other	0.3	**(0.5)**
Actual tax rate	37.6%	**28.1%**

Note 10 Funded Defined Benefit Plans

General Outline of Retirement Benefit Plans Implemented

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

For the years ended March 31, 2020 and 2021

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

	Millions of yen		Thousands of U.S. dollars
	2020	**2021**	**2021**
Defined benefit obligation at beginning of period	¥22,269	**¥22,754**	**$204,991**
Service cost	880	**891**	**8,027**
Interest cost	53	**52**	**468**
Actuarial gains and losses incurred this period	213	**(405)**	**(3,649)**
Retirement benefits paid	(662)	**(805)**	**(7,252)**
Defined benefit obligation at end of period	¥22,754	**¥22,487**	**$202,586**

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

	Millions of yen		Thousands of U.S. dollars
	2020	**2021**	**2021**
Plan assets at beginning of period	¥19,518	**¥19,181**	**$172,802**
Expected return on plan assets	487	**479**	**4,315**
Actuarial gains and losses incurred this period	(864)	**1,735**	**15,631**
Employer contribution	702	**661**	**5,955**
Retirement benefits paid	(662)	**(805)**	**(7,252)**
Plan assets at end of period	¥19,181	**¥21,252**	**$191,459**

(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
	2020	**2021**	**2021**
Defined benefit obligation for funded plan	¥ 22,754	**¥ 22,487**	**$ 202,586**
Plan assets	(19,181)	**(21,252)**	**(191,459)**
Net amount of defined benefit liability and asset on the consolidated balance sheets	¥ 3,572	**¥ 1,234**	**$ 11,117**
Defined benefit liability	3,572	**1,234**	**11,117**
Net amount of defined benefit liability and asset on the consolidated balance sheets	¥ 3,572	**¥ 1,234**	**$ 11,117**

(iv) The components of retirement benefit expense

	Millions of yen		Thousands of U.S. dollars
	2020	**2021**	**2021**
Service cost	¥ 880	**¥ 891**	**$ 8,027**
Interest cost	53	**52**	**468**
Expected return on plan assets	(487)	**(479)**	**(4,315)**
Amortization of actuarial gains and losses	437	**607**	**5,468**
Amortization of prior service cost	(255)	**(255)**	**(2,297)**
Other	62	**117**	**1,054**
Retirement benefit expense	¥ 690	**¥ 933**	**$ 8,405**

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

	Millions of yen		Thousands of U.S. dollars
	2020	**2021**	**2021**
Prior service cost	¥(255)	**¥ (255)**	**$ (2,297)**
Actuarial gains and losses	(640)	**2,748**	**24,757**
Total	¥(895)	**¥2,493**	**$22,459**

(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
	2020	**2021**	**2021**
Unrecognized prior service cost	¥(1,020)	**¥(765)**	**$(6,892)**
Unrecognized actuarial gains and losses	3,485	**736**	**6,631**
Total	¥2,464	**¥ (28)**	**$ (252)**

(vii) Plan assets information

Breakdown of plan assets

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

	2020	**2021**
Debt securities	21%	**21%**
Equity securities	21	**29**
Cash on hand and in banks	2	**1**
General accounts	47	**43**
Other	8	**6**
Total	100%	**100%**

Note: Total pension assets include a retirement benefit trust established as part of the Company's defined benefit corporate pension plans. The proportion of pension assets in this trust was 8.0% for the year ended March 31, 2020 and 5.7% for the fiscal year under review.

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)

	2020	**2021**
Discount rate	0.3%	**0.5%**
Expected rate of return on plan assets	2.5%	**2.5%**

Note 11 Other Comprehensive Income

Reconciling items with income tax effect relating to other comprehensive income for the years ended March 31, 2020 and 2021 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2020	**2021**	**2021**
Unrealized holding gains on securities:			
Amount recognized in the year	¥17,308	**¥ 37,688**	**$339,532**
Amount of recycling	(2,236)	**(4,004)**	**(36,072)**
Before income tax effect adjustment	15,071	**33,683**	**303,450**
Amount of income tax effect	(4,691)	**(10,031)**	**(90,369)**
Unrealized holding gains on securities	10,379	**23,652**	**213,081**
Retirement benefits liability adjustments:			
Amount recognized in the year	(1,077)	**2,141**	**19,288**
Amount of recycling	182	**352**	**3,171**
Before income tax effect adjustment	(895)	**2,493**	**22,459**
Amount of income tax effect	273	**(760)**	**(6,847)**
Retirement benefits liability adjustments	(622)	**1,732**	**15,604**
Total other comprehensive income	¥ 9,757	**¥ 25,384**	**$228,685**

Note 12 Government Grants

For the years ended March 31, 2020 and 2021

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

Note 13 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.

(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 segments				
As of March 31, 2020	Pharmaceuticals	Information solution services	Construction subcontracting	Sales of materials and other goods	Total
Net sales:					
Sales to third parties	¥ 51,308	¥6,631	¥3,610	¥1,684	¥ 63,234
Intersegment sales and transfers	—	1,853	1,095	1,208	4,157
Total	¥ 51,308	¥8,484	¥4,706	¥2,892	¥ 67,392
Segment profit	¥ 899	¥ 543	¥ 275	¥ 29	¥ 1,746
Segment assets	¥221,313	¥6,515	¥3,258	¥2,505	¥233,593
Other items:					
Depreciation*	¥ 2,292	¥ 358	¥ 29	¥ 27	¥ 2,708
Increase of property, plant and equipment and intangible assets*	1,564	403	10	2	1,980

* 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, 2021	Pharmaceuticals	Information solution services	Construction subcontracting	Sales of materials and other goods	Total
Net sales:					
Sales to third parties	**¥ 56,407**	**¥ 8,489**	**¥3,538**	**¥ 609**	**¥ 69,044**
Intersegment sales and transfers	**—**	**1,947**	**1,101**	**1,345**	**4,395**
Total	**¥ 56,407**	**¥10,437**	**¥4,639**	**¥1,955**	**¥ 73,439**
Segment profit	**¥ 355**	**¥ 837**	**¥ 309**	**¥ (10)**	**¥ 1,492**
Segment assets	**¥257,087**	**¥ 8,604**	**¥3,241**	**¥1,953**	**¥270,887**
Other items:					
Depreciation*	**¥ 2,866**	**¥ 357**	**¥ 26**	**¥ 24**	**¥ 3,274**
Increase of property, plant and equipment and intangible assets*	**11,010**	**341**	**21**	**12**	**11,385**

* Depreciation includes the amortization of long-term prepaid expenses. Increase of property, plant and equipment and intangible assets reflects the increase in long-term prepaid expenses.

	Thousands of U.S. dollars				
	Reportable segments				
As of March 31, 2021	Pharmaceuticals	Information solution services	Construction subcontracting	Sales of materials and other goods	Total
Net sales:					
Sales to third parties	**$ 508,171**	**$76,477**	**$31,874**	**$ 5,486**	**$ 622,018**
Intersegment sales and transfers	**—**	**17,541**	**9,919**	**12,117**	**39,595**
Total	**$ 508,171**	**$94,027**	**$41,793**	**$17,613**	**$ 661,613**
Segment profit	**$ 3,198**	**$ 7,541**	**$ 2,784**	**$ (90)**	**$ 13,441**
Segment assets	**$2,316,099**	**$77,514**	**$29,198**	**$17,595**	**$2,440,423**
Other items:					
Depreciation*	**$ 25,820**	**$ 3,216**	**$ 234**	**$ 216**	**$ 29,495**
Increase of property, plant and equipment and intangible assets*	**99,189**	**3,072**	**189**	**108**	**102,568**

* 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 of yen		Thousands of U.S. dollars
	2020	**2021**	**2021**
Net sales:			
Total of reportable segments	¥ 67,392	**¥ 73,439**	**$ 661,613**
Elimination of intersegment transactions	(4,157)	**(4,395)**	**(39,595)**
Reported on consolidated financial statements	¥ 63,234	**¥ 69,044**	**$ 622,018**
Segment profit:			
Total of reportable segments	¥ 1,746	**¥ 1,492**	**$ 13,441**
Elimination of intersegment transactions	71	**65**	**586**
Adjustments to depreciable assets	5	**(62)**	**(559)**
Other adjustments	32	**9**	**81**
Reported on consolidated financial statements	¥ 1,857	**¥ 1,505**	**$ 13,559**
Segment assets:			
Total of reportable segments	¥233,593	**¥270,887**	**$2,440,423**
Elimination of intersegment transactions	(1,798)	**(2,026)**	**(18,252)**
Reported on consolidated financial statements	¥231,794	**¥268,861**	**$2,422,171**

(ii) Other items for adjustments

	Millions of yen		Thousands of U.S. dollars
	2020	**2021**	**2021**
Depreciation:			
Total of reportable segments	¥2,708	**¥ 3,274**	**$ 29,495**
Adjustments	(145)	**(126)**	**(1,135)**
Reported on consolidated financial statements	¥2,562	**¥ 3,148**	**$ 28,360**
Increase of property, plant and equipment and intangible assets:			
Total of reportable segments	¥1,980	**¥11,385**	**$102,568**
Adjustments	(82)	**(245)**	**(2,207)**
Reported on consolidated financial statements	¥1,897	**¥11,139**	**$100,351**

(5) Related Information

(i) Product and service information

Item omitted since the same information is disclosed in the segment information section.

(ii) Geographical information

(1) Net sales

Item omitted since sales to external customers in Japan exceeded 90% of net sales shown on the consolidated statements of income.

(2) Property, plant and equipment

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

(iii) Major customer information

	Millions of yen		Thousands of U.S. dollars
	2020	**2021**	**2021**
Alfresa Corporation	¥9,714	**¥12,265**	**¥110,495**
SUZUKEN CO., LTD.	7,655	**9,066**	**81,676**
MEDICEO CORPORATION	6,569	**8,511**	**76,676**

Note: 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 years ended March 31, 2020 and 2021

No corresponding items.

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

For the years ended March 31, 2020 and 2021

No corresponding items.

(8) Information on the Remaining Balance and Gain on Negative Goodwill by Reportable Segment.
For the years ended March 31, 2020 and 2021
No corresponding items.

Note 14 Related Party Transactions

(1) Transaction with Companies in Which Executives and Their Close Relations Own a Majority of Voting Rights, Etc.
For the years ended March 31, 2020 and 2021
No corresponding items.

(2) Transaction with Executives of Important Subsidiaries and Their Close Relations, Etc.
For the years ended March 31, 2020 and 2021
No corresponding items.

Note 15 Selling, General and Administrative Expenses

Selling, general and administrative expenses for the years ended March 31, 2020 and 2021 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2020	**2021**	**2021**
Payroll costs	¥ 8,913	**¥ 8,488**	**$ 76,468**
Research and development expenses	10,767	**9,626**	**86,721**
Depreciation	985	**1,835**	**16,532**
Other	12,381	**11,267**	**101,505**
Total	¥33,048	**¥31,217**	**$281,234**

Note 16 Amounts Per Share

Amounts per share as of March 31, 2020 and 2021 and for the years then ended are as follows:

	Yen		U.S. dollars
	2020	**2021**	**2021**
Net assets	¥4,119.89	**¥4,755.74**	**$42.84**
Profit attributable to owners of parent	60.31	**113.25**	**1.02**
Cash dividends	52	**54**	**0.49**

Diluted profit attributable to owners of parent per share is not presented because there is 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 17 Subsequent Event

Execution of Contract
The Company has entered into the following contract with SANWA KAGAKU KENKYUSHO CO., LTD.
(1) Purpose of contract
The contract is for the co-promotion in Japan of UPASITA® IV Injection Syringe, developed by SANWA KAGAKU KENKYUSHO as a treatment for secondary hyperthyroidism
(2) Name of other contracting party
SANWA KAGAKU KENKYUSHO CO., LTD.
(3) Contract date
June 23, 2021
(4) Description of contract and significant effects of contract on business
Upon entering the contract, a lump sum will be paid to SANWA KAGAKU KENKYUSHO. In addition, Kissei Pharmaceutical will receive annual co-promotion payments according to sales.

Independent Auditor's Report

Ernst & Young ShinNihon LLC
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1-1-2 Yurakucho, Chiyoda-ku
Tokyo 100-0006, Japan

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Independent Auditor's Report

The Board of Directors
Kissei Pharmaceutical Co., Ltd.

Opinion

We have audited the accompanying consolidated financial statements of Kissei Pharmaceutical Co., Ltd. and its consolidated subsidiaries (the Group), which comprise the consolidated balance sheet as at March 31, 2021, and the consolidated statements of income, comprehensive income, changes in net assets, and cash flows for the year then ended, and notes to the consolidated financial statements.

In our opinion, the accompanying consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Group as at March 31, 2021, and its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with accounting principles generally accepted in Japan.

Basis for Opinion

We conducted our audit in accordance with auditing standards generally accepted in Japan. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Consolidated Financial Statements section of our report. We are independent of the Group in accordance with the ethical requirements that are relevant to our audit of the consolidated financial statements in Japan, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Key Audit Matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the consolidated financial statements of the current period. These matters were addressed in the context of the audit of the consolidated financial statements as a whole, and in forming the auditor's opinion thereon, and we do not provide a separate opinion on these matters.

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Recoverability of deferred tax assets	
Description of Key Audit Matter	Auditor's Response
"As described in Note 09 to the consolidated financial statements, the Company recorded deferred tax assets of ¥4,649 million as of March 31, 2021. The amount attributable to KISSEI PHARMACEUTICAL CO., LTD. of ¥4,050 million, or 87.2% of the total amount of deferred tax assets, is of particular significance. The Company determines the recoverability of deferred tax assets for future deductible temporary differences by estimating taxable income based on projected future profitability. The estimate of taxable income based on its projected future profitability is calculated based on the future business plan and the key assumptions include the future revision rate of National Health Insurance ("NHI") drug prices, the timing of the launch of new products, and the gains on sales of investment securities. The Company discloses the key assumptions as well as the impact of COVID-19 in Note 02(16). Given that the key assumptions applied in the future business plan involve uncertainties and require management judgement in assessing the recoverability of the deferred tax assets, we determined it to be a key audit matter."	"The audit procedures we performed to recoverability of deferred tax assets included the following, among others. ・ We obtained an understanding, evaluated the assess design, and tested the operating effectiveness of the controls over tax effect accounting process. ・ We examined the underlying future business plan to evaluate the estimates of future taxable income in evaluating the business plan we examined its consistency with the most recent budget approved by the Board of Directors. ・ We compared the business plans in previous fiscal years with actual results to evaluate the effectiveness of management's estimation process. ・ We discussed with management regarding the key assumptions including the future revision rate of NHI drug prices and the timing of the launch of new products, which serve as the basis of the business plan. We also discussed the impact of COVID-19 on key assumptions with management. ・ We analyzed the trend of previous NHI drug price revisions and read meeting minutes about NHI drug price revisions of the Central Social Insurance Medical Council, advisory body of Minister of Health, Labor and Welfare, to evaluate the future revision rate of NHI drug price estimated by management. ・ We compared clinical trial stages of main research and development programs with the related application documents for clinical trials and in-licensing contracts to evaluate the timing of the launch of new products estimated by management.

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	・ We read minutes of the meetings of the Board of Directors about the policy for sales of investment securities and planned sales of securities to evaluate the probability of future recognition of gains on sales of investment securities. We also compared the amount of gains on sales of investment securities detailed in business plan with the amount of unrealized gains on shares to be sold. ・ We performed a sensitivity analysis on the revision rate of NHI drug price to evaluate management's assessment of estimation uncertainties in the future business plan.

Responsibilities of Management, the Corporate Auditor and the Board of Corporate Auditors for the Consolidated Financial Statements

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

In preparing the consolidated financial statements, management is responsible for assessing the Group's ability to continue as a going concern and disclosing, as required by accounting principles generally accepted in Japan, matters related to going concern.

The Corporate Auditor and the Board of Corporate Auditors are responsible for overseeing the Group's financial reporting process.

Auditor's Responsibilities for the Audit of the Consolidated Financial Statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

As part of an audit in accordance with auditing standards generally accepted in Japan, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

・ Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion.

- Consider internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances for our risk assessments, while the purpose of the audit of the consolidated financial statements is not expressing an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation in accordance with accounting principles generally accepted in Japan.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with the Corporate Auditor and the Board of Corporate Auditors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the Corporate Auditor and the Board of Corporate Auditors with a statement that we have complied with the ethical requirements regarding independence that are relevant to our audit of the financial statements in Japan, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the Corporate Auditor and the Board of Corporate Auditors, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

Interest Required to Be Disclosed by the Certified Public Accountants Act of Japan

Our firm and its designated engagement partners do not have any interest in the Group which is required to be disclosed pursuant to the provisions of the Certified Public Accountants Act of Japan.

Convenience Translation

The U.S. dollar amounts in the accompanying consolidated financial statements with respect to the year ended March 31, 2021 are presented solely for convenience. Our audit also included the translation of Japanese yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made on the basis described in Note 03 to the consolidated financial statements.

Ernst & Young ShinNihon LLC
Matsumoto, Japan

June 24, 2021

Yoshihiro Sugimoto
Designated Engagement Partner
Certified Public Accountant

Tetsuya Tomita
Designated Engagement Partner
Certified Public Accountant

Corporate Information (as of March 31, 2021)

Corporate Data

KISSEI PHARMACEUTICAL CO., LTD.
19-48, Yoshino, Matsumoto, Nagano 399-8710, Japan
TEL: +81-263-25-9081
Established: August 9, 1946
Number of Employees: 1,442
URL: https://www.kissei.co.jp/

Unconsolidated Subsidiaries

KISSEI AMERICA, INC.
400 Kelby Street, 16FL Fort Lee, NJ 07024, USA

PROS. CO., LTD.
Hamamatsu Act Tower 12F, 111-2 Itaya-machi, Naka-ku, Hamamatsu, Shizuoka 430-7712, Japan

Consolidated Subsidiaries

Kissei Shoji Co., Ltd.
1-1, Hiratahigashi 2-chome, Matsumoto, Nagano 399-0014, Japan
Established: April 1977
Number of employees: 37

KISSEI COMTEC CO., LTD.
KIC Building, 4010-10 Wada, Matsumoto, Nagano 390-1293, Japan
Established: April 1985
Number of employees: 314

HASHIBA TECHNOS CO., LTD.
1-1, Hiratahigashi 2-chome, Matsumoto, Nagano 399-0014, Japan
Established: January 1955
Number of employees: 70

Investor Information

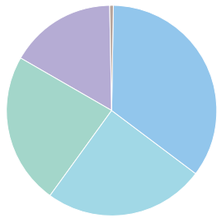
Stock Exchange Listing: First Section of the Tokyo Stock Exchange
Stock Code: 4547
Common Stock: Authorized **227,000,000** shares Issued: **51,811,185** shares
Number of Shareholders: **4,058** (Increase of 712 compared with previous fiscal year-end)

Principal Shareholders

Name	Number of shares held (hundreds)	Voting rights (%)
The Dai-ichi Life Insurance Company, Limited	32,000	6.9
Custody Bank of Japan, Ltd. (Trust account)	29,720	6.4
The Master Trust Bank of Japan, Ltd. (Trust account)	26,196	5.7
The Hachijuni Bank, Ltd.	23,333	5.1
Kanzawa Limited	16,782	3.6
Mutsuo Kanzawa	15,418	3.3
Kissei Group Employee Stockholders Committee	12,701	2.8
Mizuho Bank, Ltd.	12,334	2.7
NORTHERN TRUST CO. (AVFC) SUB A/C USL NON-TREATY	12,254	2.7
Nabelin Co., Ltd.	12,223	2.7

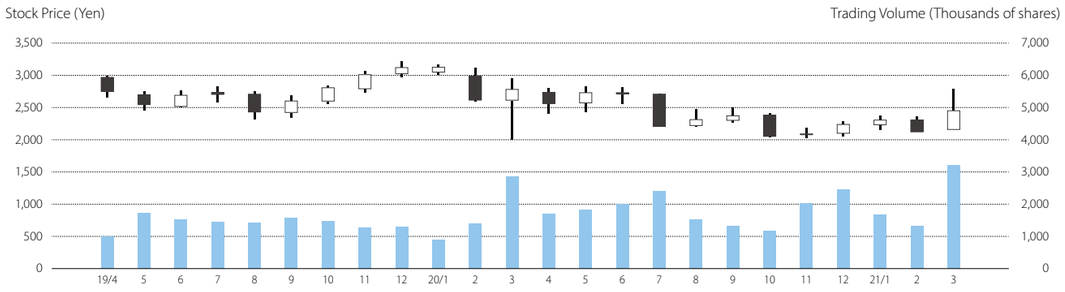
(Notes)
1. Kissei holds 5,695,246 shares of treasury stock but is not included in the above list of principal shareholders.
2. The calculation of voting rights percentages is based on total shares issued excluding treasury stock.

Composition of Shareholders by Category



- Securities companies: 32/3,514 hundred shares (0.7%)
- Other companies: 174/120,522 hundred shares (23.3%)
- Financial institutions: 41/181,039 hundred shares (34.9%)
- Non-Japanese institutions and individuals: 211/84,093 hundred shares (16.2%)
- Individuals and others: 3,600/128,911 hundred shares (24.9%)

Stock Price Range / Trading Volume



KISSEI PHARMACEUTICAL CO., LTD.

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

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This annual report has been printed using waterless printing methods that do not produce harmful liquid waste, and with 100% plant-derived vegetable oil ink that does not contain volatile organic compounds.

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