KISSEI

Looking Towards Tomorrow's Health

Annual Report 2022

For the fiscal year ended March 31, 2022

CONTENTS

Cover Photo:
Mt. Shiroumadake and Daisekkei in early summer
(Hakuba village, Kitaazumi-gun, 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 as of August 2022. 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.

Value Creation Process

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.

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.

Social Issues / External Environment

- Declining birthrate and aging population
- Restrictions on medical and social security costs
- Diversifying medical needs
- Diversifying drug discovery modalities
- Diversifying workstyles
- 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

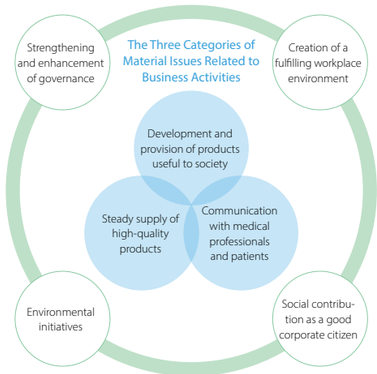
Business Activities

Five-Year Medium-Term Management Plan "**PEGASUS**"
P.10

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

Kissei's Materiality
P.8–9

The Four Categories of Material Issues Related to Kissei's Management Base



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

The History of Kissei Pharmaceutical

Since its founding in 1946, Kissei Pharmaceutical Co., Ltd., 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."

From April 2020, Kissei embarked on "**PEGASUS**," its five-year medium-term management plan, amid rapidly changing business conditions. We continue to promote this plan as we transition to a new phase of growth.

Key Milestones

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

1964 Corporate name changed to Kissei Pharmaceutical Co., Ltd.
1969 General Research Laboratory constructed (Matsumoto)
1973 General Research Laboratory expanded (Matsumoto)
1980 Manufacturing Plant constructed (Matsumoto)
1985 Second Research Laboratory constructed (Azumino, Nagano)
1988 Listed on the Second Section of the Tokyo Stock Exchange

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

1991 Listed on the First Section of the Tokyo Stock Exchange
1994 Shiojiri Plant constructed (Shiojiri, Nagano)
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
2006 Mitiglinide (Japanese name: Glufast®) launched in South Korea
2007 Joetsu Chemical Laboratory constructed (Joetsu, Niigata)
2009 Silodosin (Japanese name: Urief®) launched in the United States
2010 Silodosin (Urief®) launched in Europe
Mitiglinide (Glufast®) launched in China
2015 Second Research Laboratories received full AAALAC International* accreditation

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

2019 Remogliflozin (generic name) launched in India

2022 Transitioned from the First Section of the Tokyo Stock Exchange to the Prime Market segment

Major Products Launched

1961 Launched GASCON®, a gastrointestinal anti-gas agent

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

1991 Launched BEZATOL®, a treatment for hyperlipidemia
1992 Launched FRAGMIN®, an anticoagulant
Launched DOMENAN®, a treatment for bronchial asthma
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 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
2022 Launched CAROGRA®, a treatment for ulcerative colitis
Launched TAVNEOS®, a treatment for microscopic polyangiitis and granulomatosis with polyangiitis

1946 1980 1990 2000 2010 2020

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 60 countries, including the United States.

In fiscal 2022, Kissei launched CAROGRA®, a treatment for ulcerative colitis, and TAVNEOS®, a treatment for microscopic polyangiitis and granulomatosis with polyangiitis. These launches are part of our ongoing work to commercialize growth drivers and transition to a new phase of growth.

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.

COO Interview

Yasuo Takehana
President and Chief Operating Officer

Newly Appointed

As the newly appointed president and chief operating officer (COO) of Kissei Pharmaceutical, I, Yasuo Takehana, would like to express my sincere gratitude to you all for your continued support and understanding of our business activities.

I joined the Company in 1984, starting my career in the Research Division as a pharmacological researcher, after which I managed research projects and joint research in the Research Strategy and Planning Department. After 32 years of working in research at Kissei, I transitioned to Companywide management in 2016 as department manager of the Corporate Strategy and Planning Department. Now, in my new role as COO, I would like more than ever for Kissei to be a place where every employee derives personal growth from their day-to-day work, which then extends to growth of their department or division, and then to the Company.

Q What do you consider to be the significance of Kissei Pharmaceutical's existence?

Since it was founded in 1946, Kissei has been driven by the belief that a pharmaceutical company cannot exist without R&D. Therefore, every passing day has been spent working as an R&D-oriented pharmaceutical company to deliver pharmaceutical products that will contribute to the lives of patients and their families worldwide. With our focus on drug discovery research, in 1982 we launched RIZABEN®, the world's first orally administered treatment for allergic diseases. This was the first of many novel drugs that we would later provide to the world, which include Glufast®, a treatment for diabetes in 2004, and Urief® in 2006, a product that achieved global growth as a treatment for dysuria associated with benign prostatic hyperplasia. In recent years, we have also set our sights on rare diseases with a focus on in-licensing products, and this effort has started to bear fruit. I think that these achievements make it clear that the significance of Kissei's existence is in its ability to develop pharmaceutical products with strong ingenuity, with patients as our number one priority. More important than anything is that we take this torch, passed to us from the Company's founding, and pass it to the next generation.

Q What are your thoughts on fiscal 2021? Also, please tell us about the state of R&D.

Much like fiscal 2020, COVID-19 restricted our ability to visit medical institutions in fiscal 2021. On top of that, revisions to National Health Insurance (NHI) drug prices were implemented in April 2021 in an effort to curb drug costs, all of which made for another year of difficult business conditions. The impact of these revisions, combined with limited shipments of Beova®, a treatment for overactive bladder and one of our mainstay products, and a decrease in export sales meant a drop in net sales. This, combined with R&D expenses primarily associated with late-stage development themes, led to an operating loss being recorded for the year.

On the other hand, in the same year, many of our development themes moved to the next stage in the pipeline thanks to active investment in R&D. We participated in global clinical trials for TAVNEOS®, a treatment for microscopic polyangiitis and granulomatosis with polyangiitis, and the drug was launched in June 2022 after acquiring manufacturing and marketing approval in Japan, the first country to grant such approval. The small molecule agent is the world's first orally administered drug to inhibit complementary receptors and thereby inhibit the migration of inflammation-causing leukocytes. In March 2022, we also obtained manufacturing and marketing approval for CAROGRA®, a treatment for ulcerative colitis that we co-developed with EA Pharma Co., Ltd., and launched the drug in May of the same year. Both TAVNEOS® and CAROGRA® are drugs used to treat diseases designated as intractable by the Japanese government, and TAVNEOS® was granted orphan drug designation by the Ministry of Health, Labour and Welfare in March 2019.

We have also filed new drug applications (NDAs) in Japan for rovatirelin (generic name), a treatment for spinocerebellar ataxia and fostamatinib (generic name), a small molecule tyrosine kinase inhibitor that suppresses platelet destruction, a unique mechanism of action that is the first of its kind. We have sublicensed fostamatinib to Inmagene Biopharmaceuticals, in China, and JW Pharmaceutical Co., Ltd., in South Korea, and development for the drug in Asian regions is ongoing.

We also achieved the primary endpoint for difelikefalin (generic name), a treatment for pruritus in hemodialysis patients, in a Phase III clinical study and are making preparations to file an NDA in Japan. CG0070 (development code), an oncolytic immunotherapy, is undergoing global joint trials that Kissei is taking part in, and clinical trials have also begun in Japan.

One of our basic policies for drug discovery research is to expand our development pipeline through drug discovery research and in-licensing, so in addition to our specialty, which is small molecule drugs, we are focusing on creating innovative drug discovery themes. As a result, we endeavor to assess multiple projects in the late stage of drug discovery research promptly so we can then start clinical trials, and establish a means to create original products on a continuous basis.

So again, as I mentioned earlier, fiscal 2021 was a year in which we succeeded in building future drivers of growth. TAVNEOS® and CAROGRA® are the start of us launching one of these growth drivers after another as pharmaceutical products and building a new earnings base.

With regard to linzagolix (generic name), a gonadotropin-releasing hormone (GnRH) receptor antagonist, one of the companies to which we had granted exclusive development and marketing rights to, Swiss-based ObsEva SA, decided to initiate insolvency proceedings and subsequently withdrew its NDA with the U.S. Food and Drug Administration (FDA). This means we have had to put together a new development strategy in the United States for the drug, which is one we have been trying to expand globally to acquire overseas revenue. However, we obtained marketing approval for Europe in June 2022, and intend to launch the drug in that region as planned, with further intentions to launch in other regions as well. In Japan, Kissei will proceed with clinical trials, and in China, the licensee Bio Genuine will proceed with the clinical trials with no change in plans.

Q How will you tackle drug discovery research in the future in order to keep producing original products?

Since its very beginning, Kissei has dedicated itself to being "the first." By this I mean Kissei has always conducted R&D with the goal of creating highly original products in-Company that are the first of their kind, spurred on by a passion to create pharmaceutical products and contribute to society.

Since the launch of Urief® in 2006, our drug discovery research has led to the creation of multiple original products, and we have out-licensed products to companies worldwide while also proceeding with in-Company development in Japan. On the other hand, while we have engaged in development overseas, we have yet to manage the launch of an original product overseas outside of Urief®. In this sense, it is hard to say that we have truly achieved sustainable growth as an R&D-oriented pharmaceutical company. This leads me to believe that we need to reform our drug discovery research process.

We are currently conducting research focused on small molecule drug discovery with the aim of creating innovative and competitive new drugs for diseases with high unmet medical needs. In recent years, antibody drugs, cell therapy, regenerative medicine, and other existing therapeutic methods have become more

diverse, but we have also seen new possibilities for pharmaceutical products. One of the keys to unlocking these possibilities is small molecule agents, which offer new approaches and mechanisms to new targets. The industry is taking another look at the merits of these small molecule agents, namely target diversity, convenience, and economic efficiency. To build up our ability to discover drugs that capitalize on the great potential of these agents, we will boost target search and concept creation capabilities as well as our highly original screening and assessment system. Moreover, we will make use of in silico drug discovery technology, protein structure analysis, and molecular design so that we can better discover new compounds. These are functions that we have amplified through efforts within the Company and by accumulating expertise through multiple cases of joint research and joint development conducted with academia, venture companies, and other pharmaceutical companies. However, in the future we intend to engage actively in joint research with external drug discovery platform companies, which I expect will synergize with our research technology and result in a process that can discover small molecule drugs with both quality and speed, and increase our drug discovery capabilities overall.

At our company, researchers involved in computational science, medicinal chemistry,* pharmacology, pharmacokinetics, safety, and drug substances and formulations are working from a single location, our Central Research Laboratory in Azumino City, Nagano Prefecture, on drug discovery research. By bringing all these different research functions together and keeping them closely linked, we are able to develop and flesh out ideas without any noise. This is an advantage that we will make full use of to move forward with drug discovery processes.

* 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

Q One of the basic policies under the five-year medium-term management plan is to "strengthen the management base to cope with the changes in the business environment." How is progress in this regard?

The business environment that surrounds the Company is always changing, be it in terms of laws and regulations affecting the pharmaceutical business or therapeutic and care foods in Japan or overseas, changes in competitive market conditions, or some other aspect. Add to this the spread of COVID-19, the worsening situation in Ukraine, and other factors, and the global economic outlook is all the harder to ascertain. This all means we need to be flexible in the face of sudden events. In light of these rapid changes, we introduced an executive officer system in June 2022. I believe that introducing this system will further strengthen corporate governance and lead to more flexible execution of business.

In April 2022, we introduced a new human resource system rooted in the concept of helping employees design their various future plans, helping with career development, and helping them achieve self-fulfillment. Through this system, I believe we have built a foundation that makes the direct link between employee growth and the Company's growth very clear, as I mentioned in the outset. We have long tried to instill among our employees the importance of having a "fire within." This means having the burning desire to improve one's self, plus the driving force to show one's strengths. In addition, as each type of work becomes more specialized and sophisticated, there is a demand for professional human resources with a higher level of expertise, originality, and excellence. To respond promptly in a rapidly changing business environment, we will provide a space for employees to develop into autonomous and professional human resources who can play an active role in the Company. We intend to communicate these thoughts and ideas to our employees.

We also promote disclosure based on the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD). In an effort to strategically and proactively reduce CO_2 emissions, we started using Shinshu Green Electricity, CO_2-free electricity produced in Nagano Prefecture, from April 2022. For over 20 years, Kissei has maintained its ISO 14001 certification and continues to promote environment-friendly activities. I believe that a company that claims to make patients its number one priority has no value if its activities have a negative impact on society and the environment. Although we promote the SDGs and ESG initiatives, there is no true "end" to our efforts to improve—therefore, we will continue to promote reforms going forward.

Q In fiscal 2021, Kissei identified a series of materialities (material issues). What are your next steps?

In the case of one material issue, "quality control and steady supply and procurement," we faced some problems in the form of shipping controls that needed be implemented for Beova® and other products, as well as recalls on some therapeutic and care foods. I sincerely apologize to patients and anyone else inconvenienced by these circumstances. Going forward, we will make sure we have a stronger procurement and supply system in place, which includes stable supply systems for new products TAVNEOS® and CAROGRA®, and in the European market, linzagolix.

Due to COVID-19, there are still cases where medical representatives (MRs) are unable to visit medical institutions in person. In response, we are utilizing ICT to provide timely and appropriate information to "promote proper product usage" of drugs and foods, another material issue. Now, we combine ICT with in-person visits to provide information of an even higher quality. With our plans to launch multiple orphan drugs to the market, we will need to provide more specialized information to doctors at medical institutions, who are experts in treating these diseases. To live up to the expectations of patients and their families in a prompt fashion, we are working with medical experts to review the ways that we provide information.

In 2022, we set new key performance indicators (KPIs) for each material issue. We will use these KPIs to check our progress, as we work to ingrain cognizance of these material issues throughout the Company and enhance initiatives.

Q Finally, how do you view Kissei's future?

We have continued to grow thanks to products that have been discovered in-house or licensed in. As the level of sophistication and difficulty required to develop new drugs increases, so does the risk of drug discovery and development. These conditions call for large investments. However, there is also a plethora of innovation taking place outside the Company. Knowing this, we will keep working to actively incorporate the innovations that gel with the research assets we have accumulated and open up new research fields. As someone who started in the Research Division, I consider it my responsibility to keep expanding our pipeline with both original in-house products and in-licensed products.

With the steady progress we have made to our development pipeline, we have entered a new phase where we can continuously launch new drugs in domestic and overseas markets. There have been major changes, both inside and outside the Company, and we will not be able to grow if we keep going forward with the same mindset. To fulfill our social responsibilities, which include strengthening our governance system, we have already taken steps to transform ourselves. We will turn up the dial on this progress to become a company that displays a unique combination of technology and quality. As an R&D-oriented pharmaceutical company, we will devote ourselves to delivering pharmaceutical products as soon as possible to the patients who urgently need them, and, all the while, we will stay true to our conviction that a pharmaceutical company cannot exist without R&D.

As we take on this challenge, I ask for your continued understanding and support.

August 2022

Yasuo Takehana
President and Chief Operating Officer

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.

MESSAGE

Contributing to Achievement of the SDGs through Efforts to Address Material Issues

Fumie Taya
Department Manager of General Administration Department
(Officer in Charge of Environmental Management)

Kissei Pharmaceutical considers its mission and most pressing issue to be contributing to the health and medical care of people around the world by providing ethical drugs and other high-quality, innovative pharmaceutical products. It is extremely important that we continue to deliver high-quality items coupled with appropriate information so that patients suffering from illnesses can use our products with peace of mind.

There are a great number of patients around the world without access to proper medical treatment. In addition to promoting business activities as a pharmaceutical company, which is highlighted as a material issue, we hope to meet the expectations of all our stakeholders by ramping up efforts to enhance governance, the basis for these activities, to create rewarding workplaces, and to address climate change and other environmental issues.

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 environmental management. The committee formulates a variety of measures to promote the SDGs, which include identifying material issues, setting key performance indicators (KPIs) for activities, and checking the progress of these activities. The committee also implements these measures in cooperation with related departments, and proposes and reports details of these activities to the Board of Directors.

Process for Identifying Material Issues

STEP 1	STEP 2	STEP 3	STEP 4 (current step as of August 2022)	STEP 5 (to be completed)
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 material issues	Revise material issues 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 Material Issues

Kissei identifies material issues by narrowing down issues that need to be addressed to realize a sustainable society according to two axes—relevance to the Company's business (the medium-term-management plan, etc.) and the degree of impact on stakeholders. The most important issues are identified as material issues.

We have classified these material issues according to their relevance to one of seven categories. Three of these categories—"development and provision of products useful to society", "steady supply of high-quality products", and "communication with medical professionals and patients"—are related to business activities. The remaining four categories are related to Kissei's management base, which supports the aforementioned 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.

Major Initiatives and KPIs Related to Material Issues

Kissei Pharmaceutical has identified 15 material issues from a management perspective, sorted into seven categories. In addition, we have set key performance indicators (KPIs) for each material issue identified for fiscal 2021. This will ensure that our unique business activities contribute toward the realization of a sustainable society, while also serving their main purpose, which is to embody Kissei as an R&D-oriented pharmaceutical company. Key information is provided below.

	Main SDGs related to the seven categories	Material issues (excerpt)	Key initiatives	KPIs
Material issues related to Kissei's business activities	Development and provision of products useful to society P.16, 18, 30, 31	Development of innovative products (drugs, foods)	• Drug discovery initiatives and promotion of clinical development projects • Promotion of licensing activities and overseas development	• Number of items in the research and development pipeline and progress • Number of New Drug Applications and marketing authorization approvals • Total number of countries where new drugs are launched via partnering, and sales

	Steady supply of high-quality products
	P.28
		Quality control and steady supply and procurement	• Formulation and implementation of the "Stable Supply Manual"
			• COVID-19-related countermeasures
			• Implementation of the Kissei Pharmaceutical Quality System
				• Number of months of inventory (by product)
				• Implementation of management review and improvement to instructions
				• Progress toward developing a system to ensure a steady supply of high-quality pharmaceutical products
				• Product recalls
				  ◦ Zero recalls of pharmaceutical products
				  ◦ Complaint rate of 7.0 ppm (parts per million) or less for food products

	Communication with medical professionals and patients P.24, 47	Promote proper product usage (drugs, foods)	• Creation of a sales system for rare disease treatments • Promotion of activities to provide appropriate medical information	• Progress of activities for the Rare Diseases Project • Construction of an efficient and effective system to provide information utilizing digital tools
Material issues related to Kissei's management base	Strengthening and enhancement of governance P.32	Strengthen governance	• Formulation and implementation of the Kissei Basic Policy on Corporate Governance • Appointment of a female director • Increase of the number of outside directors	• Appropriate responses to Japan's revised Corporate Governance Code • Improvement of Board of Directors' functions through dialogue with stakeholders and evaluations of the effectiveness of the Board of Directors
	Creation of a fulfilling workplace environment P.41	Human resource cultivation	• Implementation of rank-based and job-specific training • Support for self-development • Establishment of an interview system for skill and career development	• Implementation of rank-based and job-specific training • Implementation of DX-based education for human resource development • Rate of participation in correspondence courses • Implementation of the Company's interview system for skill and career development

	Environmental initiatives
	P.44
		Climate change countermeasure	• Continued reduction of CO_2 emissions
			• Promotion of energy-saving measures and climate change countermeasures
				• Reduction of CO_2 emissions
				  ◦ Fiscal 2024 reduction target for CO_2 emissions (Scopes 1 and 2): 39% reduction compared with fiscal 2013
				  ◦ Fiscal 2030 reduction target for CO_2 emissions (Scopes 1 and 2): 46% reduction compared with fiscal 2013
				• Rate of renewable energy utilization
				  ◦ Fiscal 2024 target for renewable energy utilization rate: 59% or more of total electricity consumption
				  ◦ Fiscal 2030 target for renewable energy utilization rate: 74% or more of total electricity consumption
				• Promotion of risk and opportunity assessments for climate change

	Social contribution as a good corporate citizen P.48	Participate in social contribution activities	• Contribution to culture, the arts, and sports • Participation in local cleanup activities and offering of factory and research institute tours • Donations to child welfare facilities and assistance for natural disasters	• Number of sponsorships and donations that contribute to society and local communities • Number of social contribution activities by region

For details regarding Kissei's material issues, please refer to the corporate website. https://www.kissei.co.jp/e_contents/sustainability/materiality/

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**"

		2018	2019	2020	2021	2022	2023–2024 (FY)
Domestic	Urology	Beova® (overactive bladder)	MINIRIN MELT® 25 μg / 50 μg (nocturia due to nocturnal polyuria in males)	MINIRIN MELT® 60 μg / 120 μg / 240 μg (central diabetes insipidus (all versions), nocturnal enuresis resulting from decrease of urine osmolality or urine specific gravity (120 μg / 240 μg only))			
	Renal Diseases / Dialysis	P-TOL® Granules (hyperphosphatemia) Nalfurafine GE (pruritus in dialysis patients)	Darbepoetin Alfa BS Injection [JCR] (renal anemia)			**Difelikefalin (MR13A9)** (pruritus in hemodialysis patients)	
	Diabetes		Glubes® OD (combination drug of rapid insulin secretagogue / postprandial hyperglycemic agent)	MARIZEV® (sustained selective DPP-4 inhibitor)			
	Gastroenterology					CAROGRA® (product launched) (ulcerative colitis)	
	Rare Diseases				Rovatirelin (KPS-0373) (NDA in process) (spinocerebellar ataxia)	TAVNEOS®* (product launched) (microscopic polyangiitis and granulomatosis with polyangiitis) **Fostamatinib (R788)*** (NDA in process) (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)** (NDA approved in Europe) (uterine fibroids)	

(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 pages 21–22.

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. In addition, we plan to either launch or submit applications to launch six products for domestic sale over the five-year span of "**PEGASUS**." In fiscal 2021, all six products progressed one stage further down the pipeline.

Overseas, Kissei submitted an application for approval in Europe for linzagolix (generic name), a GnRH receptor antagonist discovered by Kissei, which was approved in June 2022. We are currently making preparations for launch.

Status of Product Launches and Products Submitted for Approval under the Medium-Term Management Plan

	Fiscal 2020	Fiscal 2021
TAVNEOS®	NDA in process	NDA approved
CAROGRA®	Preparing to submit application	NDA approved
Rovatirelin	Preparing to submit application	NDA in process
Fostamatinib	Phase III clinical trials	Phase III clinical trials (primary endpoint achieved)
Difelikefalin	Phase III clinical trials	Phase III clinical trials (primary endpoint achieved)
CG0070	Global Phase III clinical trials (submitted application for trials)	Global Phase III clinical trials (begun drug treatments)

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 Beova® and MINIRIN MELT® to increase our presence in the market. In the renal diseases and dialysis area, we are working to expand sales of P-TOL® while advancing development of difelikefalin (generic name). In the diabetes area, we are aiming to increase sales of Glubes® and MARIZEV®. We are also working to facilitate the smooth introduction of two new products into the market: CAROGRA® in the gastroenterology area, and TAVNEOS® in the rare diseases area. Regarding development themes, we are promoting the review of rovatirelin (generic name) and fostamatinib (generic name, NDA submitted in April 2022), both of which are in the rare diseases area. In therapeutic and care foods, we are seeking to enhance sales under our current quality assurance system.

2. Strengthen earnings base overseas

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

We will establish linzagolix (generic name) as our new global product and fortify our overseas earnings base with newly discovered drugs as well as in-licensing and 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.

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.

Financial Strategy

In order to increase sustainable corporate value, Kissei will secure net income through the effective use of cross-shareholdings and other financial assets and actively expand and bolster capital investment. This includes investment in R&D—such as drug discovery research—milestone payments for existing development themes, the introduction of new development themes, and the enhancement of R&D facilities, strategic investment into digital transformation (DX) and other forms of ICT, and investment in production facilities. We believe that this strategy will contribute to future profits for the Company and the appropriate distribution of profits to shareholders. In addition, this strategy will help reduce cross-shareholdings. Regarding profit attributable to owners of parent, our goal is to achieve a return on equity (ROE) of 5.0% or higher, in line with the target put forth under "**PEGASUS**."

The Company plans to pay a full-year dividend of ¥80.0 per share in fiscal 2022, comprising an interim dividend of ¥40.0 per share and a year end-dividend of ¥40.0 per share, after taking a comprehensive look at the Company's dividend payout ratio in the past and the industry average.

Kissei has also identified three material issues pertaining to its business activities under three categories: development and provision of products useful to society, steady supply of high-quality products, and communication with medical professionals and patients. We will continue to make investments to ensure that our business activities can help resolve these important social issues. It is particularly important that we expand our R&D pipeline to develop and provide new and useful drugs for patients worldwide. Enhancing drug discovery research for the creation of new products is one half of our dual approach—the other half involves expanding our in-licensing pipeline, which includes development themes, with active and flexible licensing efforts. This dual approach requires us to maintain a certain amount of on-hand liquidity.

As a company listed on the Prime Market, we aim to secure a solid management base for the future while providing stable, consistent returns to shareholders. We will approach acquisition and disposal of treasury stock in a flexible manner and take action when, according to a resolution of the Board of Directors, it is deemed necessary in terms of business development, and after first giving consideration to increasing shareholder value.

Investments, Dividends, and ROE

	Fiscal 2018	Fiscal 2019	Fiscal 2020	Fiscal 2021	Fiscal 2022 (forecast)
R&D expenses (millions of yen)	15,711	10,767	9,626	10,363	9,000
R&D expenses ratio (%)	21.7	17.0	13.9	15.9	13.2
Capital investment (millions of yen)	1,177	970	1,180	1,488	780
Cash dividend (yen)	50.0	52.0	54.0	56.0	80.0
Dividend payout ratio (%)	42.6	86.2	47.7	20.0	36.9
ROE (%)	3.1	1.5	2.6	6.1	5.0 or higher

Final-Year Targets for "**PEGASUS**"

	Fiscal 2020 Results (First year of the plan)	Fiscal 2021 Results (Second year of the plan)	Fiscal 2022 Forecast (Third year of the plan)	Fiscal 2024 Targets (Final year of the plan)
Consolidated net sales	¥69.0 billion	¥65.3 billion	¥68.0 billion	¥87.0 billion or higher
Net sales for the Pharmaceutical Business	¥56.4 billion	¥54.1 billion	¥57.0 billion	¥75.0 billion or higher
Pharmaceuticals*1	¥48.1 billion	¥45.7 billion	¥44.7 billion	¥62.5 billion or higher
Therapeutic and care foods	¥3.7 billion	¥3.5 billion	¥3.6 billion	¥4.5 billion or higher
Technical fees*2	¥0.8 billion	¥0.5 billion	¥4.2 billion	¥8.0 billion or higher*4
Others*3	¥3.6 billion	¥4.2 billion	¥4.5 billion	¥9.0 billion or higher
Consolidated operating profit	¥1.5 billion	¥(1.4 billion)	¥2.8 billion	¥13.0 billion
R&D expenses	¥9.6 billion	¥10.3 billion	¥9.0 billion	5.0% or higher
ROE	2.6%	6.1%	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 (APIs) and bulk exports
*2 Total amount of contracting fees related to out-licensing, milestone payments, and running royalties
*3 Total amount of revenue from supply to domestic sales partners and co-promotion fees
*4 Target for technical fees and others combined

MESSAGE

DX Initiatives

The use of digital technology exploded as a result of the COVID-19 pandemic, and the phrase "digital transformation," or "DX," has become commonly used around the world. Each company, organization, and person has their own approach to DX, but I think we have placed too much emphasis on the "digital" aspect of DX.

At Kissei Pharmaceutical, top management has communicated its stance on DX as "an initiative to create a new Kissei Pharmaceutical unbound by conventional thinking and methods." In other words, as we look to the future, we are focused on "transformation."

Kissei allots over ¥2.0 billion per year to its ICT budget. We at the Corporate Information System Department believe that this amount is an investment into the future, and not simply an annual cost, and it is our duty to make an active effort to propose investments that are important for the Company.

At present, our focus is on facilitating collaboration and updating the Company's security infrastructure to ensure that all employees can hasten toward making this transformation happen. We are on track to essentially finishing this work by fiscal 2022. Furthermore, we emphasize that the ability to form a creative vision and highlight appropriate issues are important skills when transformation is the goal, so we are working on ways to link business-related issues to digital technology that can solve them, and to find and develop human resources who will be the driving force of this transformation as well.

Masahiko Uchida
Executive Officer, General Manager, Corporate Information System Department

Financial and Non-Financial Highlights

Kissei Pharmaceutical Co., Ltd., and its subsidiaries

FY	2017	2018	2019	2020	2021	Thousands of U.S. dollars, except per share data 2021
	Millions of yen, except per share data					
Financial Results						
Net Sales	¥ 74,009	¥ 72,297	¥ 63,234	¥ 69,044	**¥ 65,381**	**$ 534,071**
R&D Expenses	14,179	15,711	10,767	9,626	**10,363**	**84,651**
Operating Profit	9,887	6,202	1,857	1,505	**(1,402)**	**(11,452)**
Profit Attributable to Owners of Parent	9,045	5,481	2,817	5,285	**12,921**	**105,546**
Financial Condition						
Total Liabilities and Net Assets	¥210,821	¥213,522	¥231,794	¥268,861	**¥238,087**	**$1,944,837**
Total Net Assets	176,092	182,707	192,970	219,953	**202,180**	**1,651,528**
Other Indicator						
Capital Investment	¥ 1,989	¥ 1,177	¥ 970	¥ 1,180	**¥ 1,488**	**$ 12,155**
Per Share (Yen and U.S. Dollars)						
Profit per Share	¥ 188.26	¥ 117.33	¥ 60.31	¥ 113.25	**¥ 280.20**	**$ 2.29**
Cash Dividends	48.0	50.0	52.0	54.0	**56.0**	**0.457**
Key Ratios (%)						
Operating Profit Ratio	13.4	8.6	2.9	2.2	**(2.1)**	
R&D Expenses Ratio	19.2	21.7	17.0	13.9	**15.9**	
Return on Assets (ROA)	4.3	2.6	1.2	2.0	**5.4**	
Return on Equity (ROE)	5.4	3.1	1.5	2.6	**6.1**	
Shareholders' Equity Ratio	83.3	85.4	83.0	81.6	**84.6**	
Dividend Payout Ratio	25.5	42.6	86.2	47.7	**20.0**	
Others						
Number of Employees	1,903	1,907	1,892	1,863	**1,828**	
Number of Shares Issued	51,811,185	51,811,185	51,811,185	51,811,185	**51,811,185**	

Kissei Pharmaceutical Co., Ltd.

FY	2017	2018	2019	2020	2021
Non-Financial Data					
Energy Used (kL)	8,694	8,489	8,257	8,021	**8,205**
CO_2 Emissions (Tons)	19,162	18,516	17,767	16,894	**16,946**
Amount of Waste Generated (Tons)	424	461	385	369	**390**
Final Disposal Amount (Tons)	12	15	11	39*	**27***

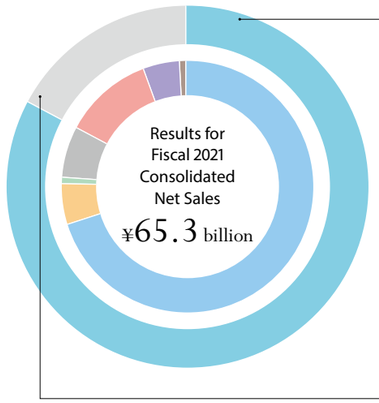
* The volume of residue produced after intermediate treatment is being reassessed following the adoption of the electronic manifest system in fiscal 2020.

(Notes)
1. U.S. dollar amounts are converted at the rate of ¥122.42 = $1 USD, the approximate effective rate of exchange at March 31, 2022.
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.

For details regarding non-financial data (ESG data), please refer to the corporate website. https://www.kissei.co.jp/e_contents/sustainability/esg/

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

¥54.1 billion 82.8% (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 on 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

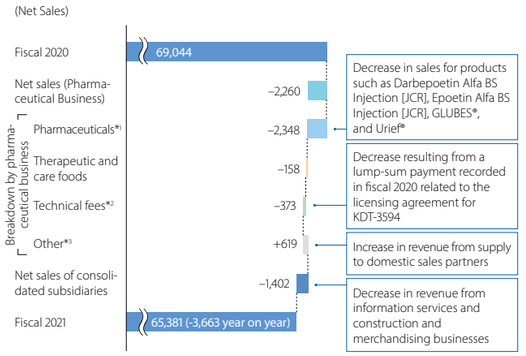
- Pharmaceuticals*1 ¥45.7 billion — P.16–29
- Therapeutic and care foods (food for special dietary uses, etc.) ¥3.5 billion — P.30
- Technical fees*2 ¥0.5 billion
- Other*3 ¥4.2 billion

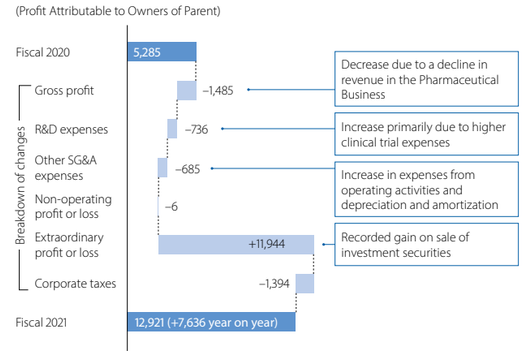
Other businesses ¥11.2 billion 17.2% (percentage of consolidated net sales) — P.31

Breakdown of Business Results

Information Services Business ¥9.5 billion Construction Business ¥4.3 billion Merchandising Business ¥0.7 billion

Net Sales and Profit Attributable to Owners of Parent Compared with Fiscal 2020 (millions of yen)





In the Pharmaceutical Business, net sales decreased 4.0% year on year, to ¥54,147 million. Much like the previous fiscal year, drug information was provided with due consideration for preventing the spread of COVID-19. As a result, sales increased for Beova® Tablets, an overactive bladder treatment, MINIRIN MELT® OD Tablets 25 μg and 50 μg for the treatment of nocturia due to nocturnal polyuria in males, and MINIRIN MELT® OD tablets 60 μg, 120 μg, and 240 μg and DESMOPRESSIN formulations, for the treatment of nocturia enuresis and central diabetes insipidus. However, NHI drug price revisions in April 2021 and a drop in export sales led to the overall decrease, among other causes.

Net sales for consolidated subsidiaries decreased 11.1% year on year, to ¥11,234 million. As a result, consolidated net sales for the Group decreased 5.3% year on year, to ¥65,381 million.

Regarding profits, the Group recorded an operating loss due to higher selling, general and administrative expenses, with a particular increase in R&D expenses. This increase, coupled with the drop in revenue, resulted in a decrease in ordinary profit. On the other hand, profit attributable to owners of parent was ¥12,921 million (up 144.5% from the previous fiscal year) due to recording a gain on sale of investment securities.

*1 Including active pharmaceutical ingredients (APIs) 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)
*3 Total amount of revenue from supply to domestic sales partners and co-promotion fees

TOPIC 01 Newly Launched Drugs

▶ Material issue related to Kissei's business activities
Development and provision of products useful to society

Treatment for ulcerative colitis

CAROGRA®

In May 2022, Kissei launched CAROGRA® (generic name: carotegrast methyl), a treatment for ulcerative colitis.

This drug is a small molecule agent discovered by EA Pharma Co., Ltd. (formerly Ajinomoto Pharmaceuticals Co., Ltd.), and is the world's first orally administered alpha-4 integrin antagonist. It acts on both the α4β1 and α4β7 integrins expressed on the surface of inflammatory cells to exert anti-inflammatory effects by suppressing excessive aggregation and invasion of inflammatory cells into the inflamed site of colonic mucosa in ulcerative colitis.

The superiority of CAROGRA®, a drug co-developed with EA Pharma, to a placebo was demonstrated in a placebo-controlled, double-blind comparative study*1 in patients with moderate ulcerative colitis with an inadequate response or intolerance to 5-aminosalicylic acid (the standard treatment for ulcerative colitis). The CAROGRA® group proved superior to the placebo group in terms of patients' Mayo scores at eight weeks of administration, the primary endpoint of the study.

Ulcerative colitis is an inflammatory disease that causes ulcers and erosions in the colonic mucosa. Major symptoms include abdominal pain, diarrhea, and bloody stools. In many cases, there is a cycle between a remission stage where the symptoms improve and a relapse stage where the symptoms worsen, and patients suffer from a decline in their quality of life (QOL). Currently, the mechanism of onset is unknown. The disease has been designated as an "intractable disease" by the Ministry of Health, Labour and Welfare, affecting approximately 220,000 registered patients in 2019, with numbers rising in recent years.*2 By providing a drug with a new mechanism not found in existing drugs, it is possible to expand the range of treatment methods and improve the QOL of patients with ulcerative colitis. Kissei is handling distribution of the drug and is co-promoting it with EA Pharma.

*1 Katsuyoshi Matsuoka et al. AJM300 (carotegrast methyl), an oral antagonist of a4-integrin, as induction therapy for patients with moderately active ulcerative colitis: a multicenter, randomized, double-blind, placebo-controlled Phase III study, *The Lancet Gastroenterology & Hepatology*, 2022 July; 7 (7): 648-657
*2 "Basic Knowledge for the Treatment of Ulcerative Colitis That Everyone Needs to Know," (revised March 2020) produced by the Research Group for Intractable Inflammatory Bowel Disease as part of the Research Program on Rare and Intractable Diseases, funded by the Ministry of Health, Labour and Welfare's Health Labor and Welfare Sciences Research Grants system

Treatment for microscopic polyangiitis and granulomatosis with polyangiitis

TAVNEOS®

In June 2022, we released TAVNEOS® (generic name: avacopan), a selective complement C5a receptor antagonist.

TAVNEOS® is a small molecule agent discovered by U.S.-based ChemoCentryx, Inc. In June 2017, Kissei acquired the exclusive license to develop and commercialize the drug in Japan from Swiss-based Vifor Fresenius Medical Care Renal Pharma Ltd. (VFMCRP).

The drug is a first-in-class, orally administered agent that selectively blocks the complement C5a receptor, which is closely related to microscopic polyangiitis (MPA) and granulomatosis with polyangiitis (GPA). Onset of MPA and GPA is related to antineutrophil cytoplasmic antibodies (ANCAs), and they are classified as types of ANCA-associated vasculitis (AAV). AAV is a severe and intractable disease characterized by damage to blood vessels caused by inflammation, leading to ischemia, kidney damage due to necrosis, and a variety of other organ disorders. There are 10,681 patients suffering from MPA and 3,196 suffering from GPA in Japan as of March 31, 2021, for a total of approximately 14,000 patients. Left untreated, 93% of patients die of granulomatosis with polyangiitis within two years, with an even lower survival rate for microscopic polyangiitis.

Treatments for both diseases include remission induction therapy (treatment to reduce or eliminate symptoms in the first few months of illness) and remission maintenance (treatment that prevents relapse after symptoms have been reduced or gone away). Both types of treatments involve a combination of corticosteroids and immunosuppressive agents, but there is a known risk of infections and other serious side effects. For this reason, 11% of patients die within one year after being diagnosed with AAV, despite the mortality rate improving after beginning treatment.

The ADVOCATE trial was a global Phase III clinical trial for TAVNEOS® that included Japanese patients with MPA and GPA. Compared with the control group, who received the standard treatment that includes corticosteroids, TAVNEOS® demonstrated non-inferiority in terms of the percentage of patients who achieved remission at week 26, and a statistically significant degree of superiority in terms of remission maintenance at week 52. In addition, the TAVNEOS® group showed good tolerability overall, with a significant reduction in corticosteroid-related toxicity scores compared with the control group. The results of the trial were published in the February 18, 2021, edition of *The New England Journal of Medicine*, one of the world's most authoritative comprehensive medical journals. These results confirm TAVNEOS® as a highly useful drug that can both reduce the required dosages and shorten the administration period of corticosteroids. In addition, the drug has been designated as an orphan drug in Japan in March 2019.

TOPIC 02 Providing Early-Stage Treatments for Rare Diseases

Treatment for spinocerebellar ataxia

Rovatirelin (generic name)

(Development code: KPS-0373)

Development stage

Phase I | Phase II | Phase III | **NDA in process**

Rovatirelin is an orally administered derivative of a thyrotropin-releasing hormone in-licensed from Shionogi & Co., Ltd. Kissei conducted a Phase III clinical trial for the drug for efficacy in treating spinocerebellar ataxia from 2013 to 2015, and another Phase III clinical trial from 2016 to 2018 based on the first trial. No statistically significant improvement was observed in the total SARA*1 score, the primary endpoint for assessing ataxia in both trials, compared with a placebo group. On the other hand, a pooled analysis (post hoc analysis) that involved a detailed analysis of these trials, which included subgroup analysis by severity, revealed that patients with more severe conditions showed a statistically significant improvement in the change in total SARA score compared with the placebo-treated group. The results of this clinical trial were published online in the *Journal of Neurology, Neurosurgery & Psychiatry*.*2 An NDA was also submitted in December 2021 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 randomized, double-blind, placebo-controlled Phase III trials." *Journal of Neurology, Neurosurgery & Psychiatry*, first published online: 14 January 2020. doi i: 10.1136/ jnnp-2019-322168

Small molecule tyrosine kinase inhibitor

Fostamatinib (generic name)

(Development code: R788)

Development stage

Phase I | Phase II | Phase III | **NDA in process**

Fostamatinib is an orally administered small molecule agent discovered by U.S.-based Rigel Pharmaceuticals, Inc. In October 2018, Kissei acquired development and commercialization rights for the drug in Japan, China, South Korea, and Taiwan from Rigel Pharmaceuticals. Patients with chronic idiopathic thrombocytopenic purpura took part in a Phase III clinical trial comprising a placebo-controlled, double-blind period of 24 weeks (Period 1), an extension treatment period in which fostamatinib was continuously administered for up to 52 weeks (Period 2), and a long-term treatment period (Period 3). Analysis of Period 1 results proved that the primary endpoint ratio of stable platelet response for the fostamatinib group was higher than in the placebo group to a statistically significant degree. Based on these results, the Company has submitted an NDA for manufacturing and marketing approval. Furthermore, fostamatinib was granted orphan drug status in Japan in February 2020.

In June 2021, Kissei entered into a sublicensing agreement with South Korea-based JW Pharmaceutical Co., Ltd., and with China-based Inmagene Biopharmaceuticals in August of the same year. These agreements grant development and marketing rights to the two companies in South Korea and China, respectively.

Treatment for non-muscle-invasive bladder cancer

CG0070

Development stage

Phase I | Phase II | **Phase III**

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 clinical trials in Japan as part of the BOND3 study, a global Phase III clinical trial led by CG Oncology, Inc., conducted across four countries but focused on the United States.

Research and Development (R&D)

▶ Material issue related to Kissei's business activities

Development and provision of products useful to society

Drug Development

Keiji Miyazawa

Director, General Manager of Research Division

At the Research Division, we want Kissei to be the best in the world when it comes to small molecule drug discovery. This means we have our sights set on game-changing drug discovery to deliver new drugs that can transform existing treatment methods and reach patients suffering without effective treatment around the world. To create such innovative products, I believe it is absolutely key that we closely adhere to an approach to drug discovery that tries to draw out what drug discovery targets, mechanisms of action, and disease themes to pursue, and then refine compound creation technology even further in order to achieve them.

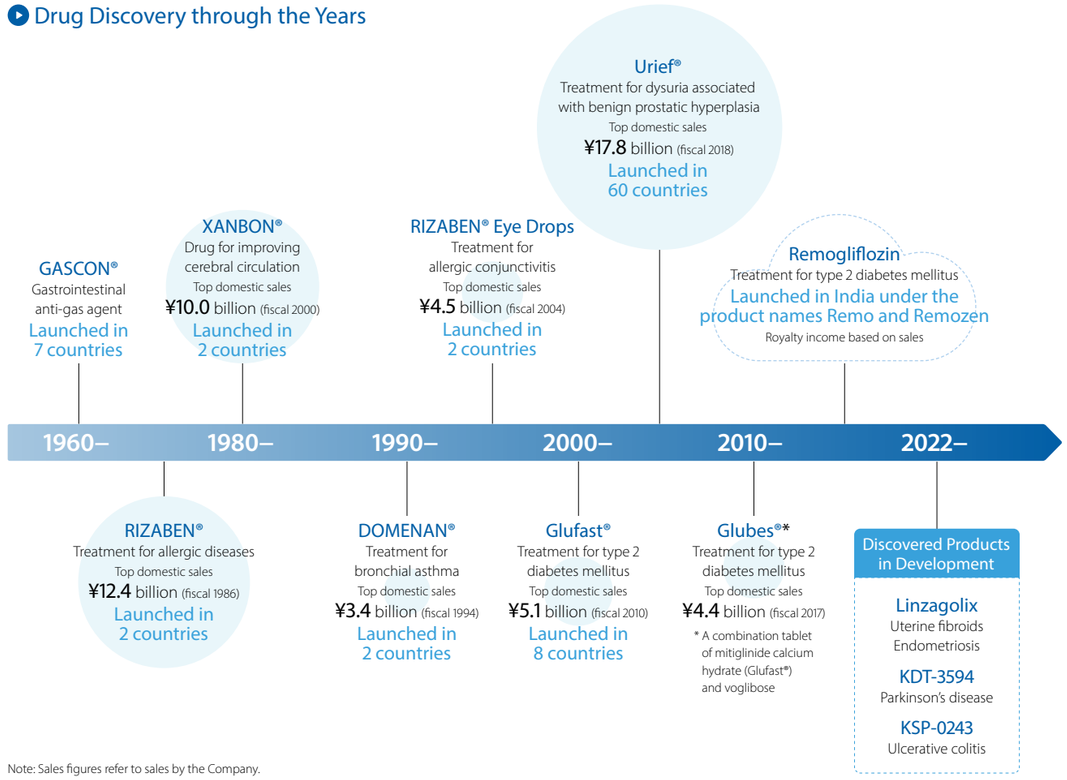
We search for drug discovery themes using a frontier, fast, and follower ("3F") strategy, which involves using all the means at our disposal, including open innovation, and innovative cutting-edge technology to bring us to our target. This drug discovery concept that we are so deeply committed to is particularly drawn to themes that are creative, challenging, and competitive ("3 C's"). Small molecules suit this concept perfectly in comparison with pharmaceutical products derived from other modalities, such as antibodies and nucleic acids. In one drug discovery theme, we are conducting drug discovery research to investigate the use of small molecules to bind to certain suitable sites and thereby restore a pathologically abnormal condition back to a near-normal state. This is a groundbreaking pharmacological effect that is unthinkable via existing mechanisms of action. In addition, since small molecules easily pass through the blood-brain barrier and have significant manufacturing cost advantages, we will focus on research into new drugs in the fields of inflammation and immunity as well as the nervous system, both of which have high unmet medical needs.

In our effort to enhance our technical capabilities related to compound creation, our work must first stress originality in our screening and assessment system. In particular, assessment systems for clinical specimens and pathological models can be used to infer both efficacy and safety in humans. The more original the assessment system is, the more likely that we will be able to find highly original creations that cannot be imitated by other companies. Second, selecting excellent researchers as drug discovery project leaders, regardless of age, will positively influence and bring the most out of each team member, which will help create promising new compounds. To date, in addition to products that have been launched to market such as Glufast®, Urief®, and remogliflozin (generic name), in-development products such as linzagolix (generic name), KDT-3594 (development code), and KSP-0243 (development code) are all original products created in-house via our research laboratories. We take great pride in the strength of our adventurous style of research, in which excellent medicinal chemists play a central role in creating compounds as a team. Third, we will increase our focus on enhancing the core technologies that will bring true innovation. This means taking the in silico drug discovery technology launched in the 1990s and the fusion of target protein expression, structural analysis, and computational chemistry that has since accelerated drug discovery research and incorporating structural analysis using cryo-electron microscopes and other methods into our work.

Furthermore, I believe that DX is both innovative and a catalyst for drug discovery concept planning and improvements to our technical compound creation capabilities. Therefore the Research Division has developed and implemented a five-year DX Master Plan, comprising three main pillars: 1) utilize DX to find innovative themes; 2) utilize large-scale computing to shorten drug discovery periods; and 3) promote digital use of non-clinical and chemistry, manufacturing, and control research to reform operations. The key when implementing measures under this plan is to create a foundation that can store, organize, and utilize data and records related to pharmacy informatics, AI-driven drug discovery, and research using the latest technology. We are planning to accelerate the practical applications of measures using this base, while also looking into introducing external resources.

The last is human resource development, which is the bedrock of future drug discovery research. Knowing this, we have developed a system in which teams working on drug discovery projects are led by a team manager from each specialized organization. This is one of the ways that we are trying to emphasize and incorporate several team activities that help individuals increase their own value and initiative, thereby cultivating leadership and developing the comprehensive capabilities that drive drug discovery. Put together, these are efforts that will form a system within our division that produce game-changing drugs in the future.

Drug Discovery through the Years



Note: Sales figures refer to sales by the Company.

Intellectual Property Strategy

Nobuko Yanagi

Senior Director of Intellectual Property Department (Patent Attorney)

One of the pillars of Kissei is small molecule drug discovery, and we protect any breakthrough compounds we discover with tight-clad substance patents in order to secure a stable period of exclusivity. We have also acquired rights to several original creations and processes generated as part of our effort to deliver high-quality pharmaceutical products to patients, including drug applications, dosages, salts and crystals, manufacturing methods, and formulations, all of which help us maintain a competitive business.

We also aim to monetize global patent rights in Japan through our own business and overseas by way of out-licensing. Annual NHI drug price revisions mean that we have to curb our expectations for growth in the domestic market, so we are placing an even greater emphasis on increasing overseas earnings by leveraging our intellectual property rights.

Selection of drug discovery themes is an extremely important part of the drug discovery research strategy promoted by the Research Division. The Intellectual Property Department, utilizing the intellectual property landscape, takes active part in target searches and works with researchers to select themes that can be deployed globally.

We also conduct clearance searches on the intellectual property of others from the beginning stages of research and take appropriate measures to ensure that we can start engaging in business at an early stage and maintain it stably.

By actively implementing intellectual property awareness activities and cross-departmental collaboration tailored to each department and position, and improving intellectual property literacy throughout the Company, we are building a system where we can work together in a timely manner to address various issues related to the creation and utilization of intellectual property.

Developing New Drugs

Tokuhisa Yamato
Senior Director of Development Department, Clinical Development Division

The Clinical Development Division is committed to new drug development with a division-wide policy of professionalism and a broad perspective, driven by a mission in keeping with Kissei's Management Philosophy—to "contribute to society through high-quality innovative pharmaceutical products" and to "serve society through our employees." Every member of the division adheres to this policy and is ever diligent in their duty "to serve every patient."

Fiscal 2021 saw several achievements in new drug development. New Drug Applications (NDAs) were approved for TAVNEOS®, a treatment for microscopic polyangiitis and granulomatosis with polyangiitis, CAROGRA®, a treatment for ulcerative colitis jointly developed with EA Pharma Co., Ltd., and rovatirelin (generic name), a treatment for spinocerebellar ataxia. In addition, primary endpoints were achieved in Phase III clinical trials for fostamatinib (generic name), a treatment for chronic idiopathic thrombocytopenic purpura, and difelikefalin (generic name), a treatment for pruritus in hemodialysis patients.

When Kissei joined the global Phase III clinical trial for TAVNEOS®, an in-licensed product, it was already underway in Europe and the United States—in fact, the Company was last to join the trial. However, Japan was the first country to have the NDA for TAVNEOS® approved, making the date of this approval the day that TAVNEOS® was truly introduced to the world. Participating in a global trial such as this one and then having the project go according to plan makes it clear that we have managed to improve our new drug development capabilities.

We submitted an NDA for fostamatinib in April 2022, with plans to submit an NDA for difelikefalin in the fall of the same year. We are working with Shionogi & Co., Ltd., Rigel Pharmaceuticals, Inc. (U.S.), and Maruishi Pharmaceutical Co., Ltd., licensors of rovatirelin, fostamatinib, and difelikefalin to obtain approval for these drugs, so that we can provide patients with these new drugs as early as possible.

Three examples represent two domestic NDAs filed and one being prepared for submission, but right behind these drugs are several new development projects that are making good progress. Two projects are in the final stages of Phase III clinical trials: CG0070 (development code), an oncolytic immunotherapy drug for bladder cancer, and linzagolix (generic name), a drug developed by Kissei for the treatment of uterine fibroids. The project for CG0070 is particularly notable, as Kissei is taking part in a global joint Phase III clinical trial for regenerative medicine. We have several projects in late-stage development, and will call upon the know-how we have built up over the past few years, the full strength of the Clinical Development Division, and its connections with related divisions to move these projects forward in the pipeline.

Under our policy of out-licensing for overseas expansion, overseas licensee Swiss-based ObsEva SA received approval for the uterine fibroid treatment linzagolix from the European Medicines Agency in June 2022. Linzagolix is a novel, orally administered gonadotropin-releasing hormone (GnRH) receptor antagonist that acts by binding to the GnRH receptor in the pituitary gland and consequently suppressing the secretion of gonadotropin. This process reduces estrogen production at the ovaries, improving symptoms of uterine fibroids and endometriosis. Phase III clinical trials conducted in both Europe and the United States confirmed the efficacy of linzagolix in combination with add-back therapy (ABT), a form of hormone replacement therapy, and without ABT. As the only GnRH antagonist that can be used to treat patients with uterine fibroids unable to take hormonal agents, the drug is expected to be a new means to ensure treatment that matches the particular conditions and needs of individual patients. In China, Kissei out-licensed development and marketing rights in China to Bio Genuine in September 2021, and the company is currently preparing to start clinical trials.

In October 2020, Kissei out-licensed development and commercial rights of KDT-3594 (development code), a treatment for Parkinson's disease discovered by the Company, to China-based Affamed Therapeutics Limited. These rights cover China, Taiwan, Hong Kong, Macao, and six Southeast Asian countries (Singapore, Malaysia, Thailand, Indonesia, Vietnam, and the Philippines). We have also sublicensed fostamatinib, a treatment for chronic idiopathic thrombocytopenic purpura, which we originally licensed from Rigel Pharmaceuticals. In June 2021, we sublicensed the drug to South Korea-based JW Pharmaceutical Co., Ltd., and to China-based Inmagene Biopharmaceuticals in August of the same year.

Amid concerns about the shrinking of the domestic market due to annual NHI drug price revisions, it will become increasingly important to utilize partnerships to develop and market new drugs overseas and to acquire profits from overseas markets. We intend to ramp up our focus on overseas development activities through the ties we create with these partner companies.

The Clinical Development Division is also making active efforts toward sustainability. To ensure thorough compliance with laws and regulations, which is at the heart of sustainability, general managers and department managers of each division and department, including the Legal Affairs Department, work with the CSR Promotion Office to ascertain the legal compliance status of each organization and conduct training. When engaged in clinical development activities, we comply with the Declaration of Helsinki, the Good Clinical Practice (GCP) standard, and other relevant laws and regulations. We are also careful to consider the human rights of patients and conduct clinical trials only after ethical and scientific integrity have been thoroughly examined and verified by inside and outside examination boards. We conduct the necessary education and training for both inside and outside members in charge of this task, and move forward with clinical trials with appropriate compliance. To ensure transparency, we also disclose information on ongoing clinical trials and results in a suitable manner.

Currently, drug options to treat intractable and rare disease are still quite limited. We are listening to the calls of patients and doctors looking for effective new drugs with the development of rovatirelin, a treatment for spinocerebellar ataxia, designated as an intractable disease by the Ministry of Health, Labour and Welfare, and fostamatinib to treat chronic idiopathic thrombocytopenic purpura. Our mission is to provide patients with new drugs that can help treat those suffering from diseases as soon as possible.

"To serve every patient"—it is this spirit that we will draw on as we strive to develop new drugs that can satisfy unmet medical needs.

R&D Pipeline (As of August 2022)

New Drug Development (In-Company)

Generic name / Development code	Expected indications	Development stage: Phase I	Phase II	Phase III	NDA in process	Development classification
Rovatirelin / KPS-0373	Spinocerebellar ataxia					In-licensed / Shionogi & Co., Ltd.
Fostamatinib / R788	Chronic idiopathic thrombocytopenic purpura					In-licensed / Rigel Pharmaceuticals, Inc. (U.S.)
Difelikefalin / MR13A9	Pruritus in hemodialysis patients					In-licensed / Maruishi Pharmaceutical Co., Ltd.
CG0070	Non-muscle-invasive bladder cancer					In-licensed / CG Oncology, Inc. (U.S.) Joint global Phase III clinical trial
Linzagolix / KLH-2109	Uterine fibroids					Original product
	Endometriosis					Original product
KDT-3594	Parkinson's disease					Original product
KSP-0243	Ulcerative colitis					Original product

New Drug Development (Out-Licensing)

Generic name / Development code	Expected indications	Countries and regions	Development stage: Clinical trials under preparation	Phase I	Phase II	Phase III	Preparation to submit application	NDA in process	NDA approved	Partner company
Linzagolix / KLH-2109	Uterine fibroids	Europe								ObsEva SA
		China								Bio Genuine
	Endometriosis	Europe and U.S.								ObsEva SA
		China, other countries								Bio Genuine
Silodosin	Dysuria associated with benign prostatic hyperplasia	Vietnam, other countries								Eisai Co., Ltd.
KDT-3594	Parkinson's disease	China, other countries								Affamed Therapeutics Limited
Bedoradrine	Acute exacerbation of asthma	U.S.								MediciNova, Inc.
Fostamatinib	Chronic idiopathic thrombocytopenic purpura	South Korea								JW Pharmaceutical
		Hong Kong								Inmagene Biopharmaceuticals
		China, other countries								Inmagene Biopharmaceuticals

Major R&D Projects

Treatment for uterine fibroids and endometriosis

Linzagolix (generic name)

(development code: KLH-2109)

Linzagolix is an orally administered GnRH (gonadotropin-releasing hormone) receptor antagonist discovered by Kissei.

In November 2015, Kissei licensed out exclusive rights to develop and market in countries excluding Japan and other parts of Asia to Swiss-based ObsEva SA. Development of the drug as a treatment for uterine fibroids and endometriosis is underway in Europe and the United States, with the drug receiving marketing authorization approval for uterine fibroids in June 2022 by the European Commission (EC), Medicines and Healthcare products Regulatory Agency (MHRA), and other regulatory bodies. Preparations for launch have also been made by U.K.-based Theramex, which had entered a sublicensing agreement with ObsEva to commercialize the drug outside of North America and Asia. In the United States, an NDA was submitted to the Food and Drug Administration (FDA) for the indication of uterine fibroids in September 2021. However, on July 27, 2022, ObsEva made a release stating that deficiencies identified by the FDA during the review may not be feasibly solved by the Prescription Drug User Fee Act (PDUFA), dated of September 13, 2022, and that ObsEva had therefore decided to terminate the license agreement with Kissei for linzagolix and began corporate restructuring. Following this announcement, ObsEva withdrew the NDA. For the development of linzagolix in the United States, Kissei will consider the development strategy after reassessing the submitted data.

First, Kissei will work with Theramex to commercialize the drug in Europe and then launch the drug in other regions sequentially. In China, development of the drug is proceeding via China-based Bio Genuine, which has exclusive development and marketing rights in China.

In Japan, Phase II clinical trials have been completed for endometriosis, and Phase III clinical trials for uterine fibroids are underway.

Treatment for pruritus in hemodialysis patients

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 pruritus in dialysis patients. Kissei and Maruishi completed the double-blind period of a jointly conducted Phase III clinical trial for the drug. During this period, the primary endpoint, change in the Numerical Rating Scale (NRS) score*1 for itching, and the secondary endpoint, change in the Shiratori severity criteria score*2 for itching, showed significant improvement from the baseline in comparison with the placebo group. Difelikefalin also demonstrated a safe and well-tolerated profile.

*1 The NRS score for itching evaluates the most intense itching felt throughout the day with a value from 0 (no itching) to 10 (severe itching).
*2 The Shiratori severity criteria score for itching evaluates the degree of itching felt during the day and at night, ranging from 0 (no symptoms) to 4 (severe itching).

Treatment for Parkinson's disease

KDT-3594

KDT-3594 is a novel orally administrated non-ergot dopamine agonist discovered by Kissei. The drug acts by stimulating dopamine receptors in the basal ganglia, thereby ameliorating the symptoms of Parkinson's disease caused by insufficient action of dopamine. It is also confirmed as a new therapeutic agent for Parkinson's disease that KDT-3594 reduces the risk of the characteristic side effects of existing ergot and non-ergot dopamine agonists. Phase II clinical trials for KDT-3594 have been completed, and preparations for the next stage of trials are underway.

In October 2020, Kissei granted China-based Affamed Therapeutics Limited the exclusive right for development and commercialization 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.

Treatment for ulcerative colitis

KSP-0243

KSP-0243 is a small molecule agent discovered by Kissei with a new mechanism of action different from current treatments. The drug is expected to improve the symptoms of ulcerative colitis and other inflammatory bowel diseases. Phase I clinical trials have been completed, and Phase II clinical trials with patients with ulcerative colitis have begun.

Providing Drug Information

▶ Material issue related to Kissei's business activities

Communication with medical professionals and patients

Providing Drug Information

Hiroshi Noake

Director, General Manager of Sales and Marketing Division

Fulfilling Our Role as the "Anchor Runner"

Launching Orphan Drugs for Intractable Diseases

Over the five-year period of "**PEGASUS**," our medium-term management plan, we aim to launch or submit NDAs for six new pharmaceutical products to the market. On May 30, 2022, we launched CAROGRA®, a treatment for ulcerative colitis, marking our first step toward this goal. The drug, which was developed in Japan, is the world's first alpha-4 integrin antagonist available in an orally administered dosage and is currently being co-promoted with gastroenterology specialist EA Pharma Co., Ltd., with information provision activities underway. We have positioned the drug as a new treatment option for patients with an inadequate response to 5-ASA, the standard treatment for ulcerative colitis. We intend to promote CAROGRA® and thereby help improve the QOL of these patients.

On June 7, 2022, we launched TAVNEOS®, a treatment for microscopic polyangiitis and granulomatosis with polyangiitis, both of which are classified as ANCA-associated vasculitis. TAVNEOS® is a first-in-class formulation that works by selectively blocking the C5a receptor. The drug has been highly touted for its potential to resolve problems related to existing treatments that center on corticosteroids. We intend to work with doctors to position TAVNEOS® as a treatment for ANCA-associated vasculitis going forward. Both ulcerative colitis and ANCA-associated vasculitis are designated as rare or intractable diseases that require medical experts and specialized facilities to treat. Prior to drug launches, we train MRs tasked with providing information. These MRs acquire highly specialized and advanced knowledge to ensure they can provide doctors with treatment policies that correspond to the condition of each patient. As we make preparations to launch orphan drugs, we will continue to develop human resources who can help with our response to rare and intractable diseases.

Activities in Key Areas

We have positioned urology and renal diseases and dialysis as key marketing areas, and conduct information provision activities with the goal of being in the top three when it comes to the companies and MRs chosen by doctors in either area. In urology, we were required to limit shipments of Beova® for a long duration after restrictions on the drug's prescription period were lifted in December 2019, which resulted in more prescriptions than we had anticipated. We apologize for the trouble that this misstep caused doctors and patients wishing to prescribe or take the drug. In August 2022, we resumed normal shipping after our manufacturers established a stable production system. Overactive bladder is estimated to affect more than 10 million people, meaning there are many patients who need this drug. We see fiscal 2022 as a "reboot" of Beova®, and plan to provide information to a wide area and establish the drug as the top treatment for overactive bladder in terms of market share.

In renal diseases and dialysis, we are conducting information provision activities for the hyperphosphatemia treatment P-TOL® and UPASITA®, a treatment for secondary hyperparathyroidism that is being co-promoted with SANWA KAGAKU KENKYUSHO Co., Ltd. Due to the COVID-19 pandemic, access to dialysis facilities has been highly restricted, but our long-standing reputation in this field has allowed us to maintain our trust with doctors. In September 2022, we submitted an application for marketing approval for difelikefalin (generic name), a treatment for pruritus in hemodialysis patients. We will continue to utilize our lineup of multiple products to help improve the QOL of dialysis patients.

Provision of Drug Information Going Forward

The ongoing COVID-19 pandemic has brought an end to the time when MRs were free to visit medical institutions and doctors in favor of a time when doctors pick and choose which MRs they want to meet. This puts into question the true value of information provided by MRs. As the closest partner to medical professionals, we listen to medical issues and work together to solve them in order to improve the QOL of patients. We also have a strong attachment to the products we handle and will continue to provide information with value on par with these products. There have been great leaps in digital technology over the past few years, and the channels for collecting and providing information have expanded as a result. If we are to meet the needs of medical professionals in a precise and timely manner, we need to take advantage of digital tools, such as online consultations and details via email. We must also promote digital transformation (DX) that includes specialized websites for these professionals. In a relay race in which the baton—our product—passes from R&D and then production, the Sales and Marketing Division will continue to play the role of the anchor runner, the one who brings the product to the finish line, where the medical professionals and their patients await.

Rare Diseases Project

Itaru Miyashita

Senior Director of Rare Diseases Project, Sales and Marketing Division

Contributing to the Treatment of Rare and Intractable Diseases

In April 2021, the Rare Diseases Project was established within the Sales and Marketing Division with the goals of enhancing our sales system in the area of rare disease and facilitating the smooth introduction of CCX168 (development code; product name TAVNEOS®) to the market. The Rare Diseases Project formulates promotion strategies for orphan drugs, provides in-Company education regarding rare diseases and treatment methods, and provides information to medical experts. Information provision to medical experts is carried out in cooperation with our branch offices.

Orphan drugs are characterized by a smaller scale of clinical trials at the development stage when compared with drugs developed for primary care, meaning the amount of evidence of a drug's efficacy available at the time of approval is sparse. This makes it important to work with medical experts to build a case for the drug from a clinical perspective to increase the drug's clinical value. This requires evidence, so branch offices and the MRs in charge work with doctors post-launch to review the product-use experience on a case-by-case basis and utilize information collection and provision activities regarding proper use to accumulate this evidence.

In addition to TAVNEOS®, other development projects scheduled for application filing or marketing over the course of the "**PEGASUS**" medium-term management plan include rovatirelin for the treatment of spinocerebellar ataxia, fostamatinib for the treatment of chronic idiopathic thrombocytopenic purpura, and CG0070, for the treatment of non-muscle-invasive bladder cancer.

By helping introduce new treatment options for rare and intractable diseases to the medical field in the form of new drugs, this department will make further contributions to patients suffering from these diseases and to the improvement of medical care.

Marketing System for Orphan Drugs

Status of Rare and Intractable Disease Treatments over the Period of "PEGASUS"

Product name / Generic name / Development code	Development stage	Expected indications
TAVNEOS®/ avacopan	June 2022: Drug launch	Microscopic polyangiitis and granulomatosis with polyangiitis
Rovatirelin / KPS-0373	April 2021: NDA	Spinocerebellar ataxia
Fostamatinib / R788	April 2022: NDA	Chronic idiopathic thrombocytopenic purpura
CG0070	Phase III clinical trials	Non-muscle-invasive bladder cancer

- We will create a lineup of development projects in the area of rare and intractable diseases.
- We will establish a specialized and advanced system for providing information to a limited number of facilities and medical experts to ensure patients can receive appropriate treatment.

The Rare Diseases Project was newly established in April 2021 for the smooth market introduction of TAVNEOS® and other products in the area of rare and intractable diseases.

- Planning and developing marketing for rare and intractable disease treatments
- Building a system for providing information to specialists and medical experts in collaboration with MRs

By helping introduce new treatment options for rare diseases to the medical field in the form of new drugs, we will make further contributions to patients suffering from these diseases and to the improvement of medical care.

Main Products (As of August 2022)

Urology

		Results for fiscal 2021 (millions of yen)*1	Projected sales in fiscal 2022 (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 (tablets) ● Joint development and marketing with KYORIN Pharmaceutical Co., Ltd.	8,141	11,000
DESMOPRESSIN Formulations MINIRIN MELT®, etc. 	(MINIRIN MELT® OD tablets 25 μg/50 μg/60 μg/120 μg/240 μg, DESMOPRESSIN Intranasal,*2 DESMOPRESSIN Spray, and DESMOPRESSIN Injection) **Active ingredient:** Desmopressin acetate hydrate **Indications:** Nocturia due to nocturnal polyuria in males (OD tablets 25 μg/50 μg) Central diabetes insipidus (OD tablets 60 μg/120 μg/240 μg, DESMOPRESSIN Spray) Nocturnal enuresis resulting from decrease of urine osmolality or urine specific gravity (OD tablets 120 μg/240 μg), etc. **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	3,965*3	3,900*3
Dysuria Treatment Urief® 	**Active ingredient:** Silodosin (*Japanese Pharmacopoeia*) **Indications:** Dysuria associated with benign prostatic hyperplasia **Month of release:** May 2006 (capsules*2), February 2009 (tablets), January 2016 (OD tablets) ● Joint development and marketing with Daiichi Sankyo Company, Limited.	2,878	2,200

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)	5,784	6,300
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.	3,730	3,600
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.	3,834	2,200

Rare Diseases

		Results for fiscal 2021 (millions of yen)*1	Projected sales in fiscal 2022 (millions of yen)*1
Treatment for MPA*4 and GPA*5 TAVNEOS® 	**Active ingredient:** Avacopan **Indications:** MPA*4 and GPA*5 **Month of release:** June 2022 (capsules)	—	700

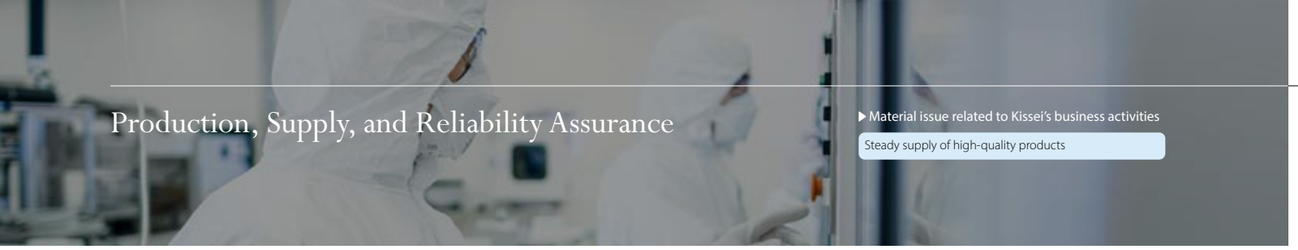
Metabolism and Endocrinology

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 tablets), June 2019 (combination OD tablets)	3,838	3,400
Treatment for Diabetes Glufast® 	**Active ingredient:** Mitiglinide calcium hydrate (*Japanese Pharmacopoeia*) **Indications:** Type 2 diabetes **Month of release:** May 2004 (tablets), June 2016 (OD tablets)	1,151	1,000
Treatment for Diabetes MARIZEV® 	**Active ingredient:** Omarigliptin **Indications:** Type 2 diabetes **Month of release by the Company:** April 2020 (tablets) ● Distribution operations transferred from MSD K.K.	1,234	1,200

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 (tablets), December 2014 (granules)	1,412	1,100
Treatment for Ulcerative Colitis CAROGRA® 	**Active ingredient:** Carotegrast methyl **Indications:** Moderate ulcerative colitis, limited to patients who had inadequate response to 5-aminosalicylic acid **Month of release:** May 2022 (tablets) ● Joint development with EA Pharma Co., Ltd., with co-promotion by both EA Pharma and Kissei	—	350

*1 Based on sales figures for fiscal 2021 announced in May 2022
*2 Currently not for sale
*3 Combined total for MINIRIN MELT®, DESMOPRESSIN Intranasal, DESMOPRESSIN Spray, and DESMOPRESSIN Injection
*4 Microscopic polyangiitis
*5 Granulomatosis with polyangiitis



Production, Supply, and Reliability Assurance

▶ Material issue related to Kissei's business activities

Steady supply of high-quality products

Production and Supply

Tetsuji Shinobe

Senior Director, Matsumoto Plant, Pharmaceutical Manufacturing

With the launch of TAVNEOS® and the submission of an NDA for fostamatinib (generic name), we are on a good pace to build a production system for new products, one of the pillars of "**PEGASUS**" entrusted to Pharmaceutical Manufacturing. At the Matsumoto Plant, in charge of the formulation process for pharmaceutical products and quality testing, we ensure that the data, knowledge, and technical expertise acquired during the research stage is carried over into production, where we take these gains and refine them further, manage them carefully, and update them. This process allows us to keep manufacturing high-quality pharmaceutical products.

As part of promoting digital transformation (DX), we updated the computer system that controls manufacturing and quality in fiscal 2021. This has improved operational efficiency and the reliability of data, which has improved our quality control capabilities. We will promote DX further, focusing on our computer system for document management, which is scheduled to be updated in the future.

We have also made efforts to prepare for risks to business continuity. To minimize risks related to the procurement of raw materials, we procure these materials from multiple suppliers and store them in decentralized locations. In addition, we have secured a sufficient inventory of machine parts used in manufacturing to safeguard against equipment issues. To address risks to the stable supply of drugs, we have put in place a production plan aimed at maintaining an inventory of products to ensure that we respond to any sudden changes in market demand.

Drawing from Kissei's Management Philosophy, to "contribute to society through high-quality, innovative pharmaceutical products" and "serve society through our employees," we are committed to fostering a culture of high quality and sincerity among Company members, while continuing to engage in production that is both safe and environment-friendly.

Mari Tatai

Senior Director, Shiojiri Plant, Pharmaceutical Manufacturing

At the Shiojiri Plant, we began external screenings for imported formulations of the new product TAVNEOS® starting in fiscal 2022, and have been packaging it in press-through-packaging (PTP). Based on Kissei's Management Philosophy, and as the plant responsible for the manufacture and packaging of pharmaceutical products, we have made it our mission to create a stable supply of high-quality pharmaceutical products, and are therefore constantly working to build a system to increase product quality and to foster a "Quality Culture."

Recent quality issues with pharmaceutical manufacturers have led to supply shortages, which have caused disorder in the medical field and affected the lives of patients. This, in addition to the shortage of resources as a result of COVID-19 and changing global situations, have exposed risks to the stable supply of drugs.

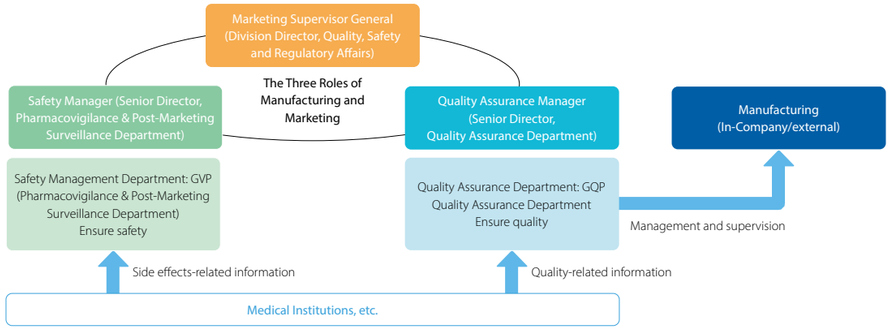
Involved with plants that manufacture pharmaceutical products, I recognize the absolute importance of having both employees and managers who are mindful of quality and a strong quality assurance system. To that end, we are working to raise awareness of quality, while assessing risks and improving resilience based on examples from other companies, and using discussions to share important values. A Quality Culture survey of employees confirmed that they have a high level of understanding of the Company's philosophy, the importance of placing top priority on quality, and a strong intolerance toward fraud.

In addition, to mitigate the risk of resource shortages, we diligently update information, secure inventory, prioritize manufacturing, and perform regular equipment maintenance in order to provide a stable drug supply. At the same time, we are also looking into ways to streamline operations and reduce losses, and we are making improvements that will help save energy, raw materials, and other resources.

Reliability Assurance

To fulfill one of the missions 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.

Manufacturing and Marketing System



We have also made various efforts to enhance our compliance system. These efforts include revising our rules related to drug manufacturing and marketing in June 2021, and incorporating Company measures to address any remarks made by the marketing supervisor general.

Regarding quality control, we promote quality assurance activities as part of our ultimate mission of providing high-quality pharmaceutical products that patients can use with peace of mind. In April 2014, we began implementation of the Kissei Pharmaceutical Quality System to ensure continuous improvement of quality and stable supplies of pharmaceutical products over their life cycles. We also continue to conduct quality assurance activities day after day in order to actualize the Basic Philosophy of the Kissei Quality Policy, which states that "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."

Specifically, we audit quality at each plant where drugs are manufactured on a regular basis 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 quality-related information from medical institutions and make necessary improvements. Pharmaceutical products are subject to regular monitoring to ensure proper stability and quality over their shelf life. The results of evaluation and analysis of pharmaceutical quality checks, submitted regularly by each manufacturer, are reported to the Company president and reviewed. Based on this 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 recalls, are taken to handle the situation promptly, and training for recalls is carried out regularly to be able to perform such an action quickly and properly if the need to execute a voluntary recall should occur.

On the other hand, for patients to use drugs with peace of mind, we need to continue collecting and evaluating information on efficacy and safety after launch, since safety information that exists up to the point of approval is collected from clinical trials and conducted under controlled conditions. We have established Safety Management Control Departments 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 Departments subsequently work 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 efficacy and safety of treatments for rare diseases—whether they are already being manufactured and marketed, or whether they are in the NDA stage—is particularly limited, which makes it much more important to collect such information after launch. Therefore, we will continue to carry out this responsibility with an enthusiasm that will put patients who use these products at ease.

Nutrition Division

▶ Material issue related to Kissei's business activities
Development and provision of products useful to society

Message from the General Manager

Yasumasa Mishima
Executive Officer, General Manager of the Nutrition Division

In addition to pharmaceutical products, Kissei established the therapeutic and care foods business in 1990, with the desire to contribute to society through the development and sale of foods for special dietary uses. The KISSEI HEALTHY FOODS (KHF) brand embodies our determination to use food products to help raise the quality of life of elderly people, those who require nursing care, and people with kidney disease.

According to an investigation based on market research, the market for chewable, easy-to-swallow therapeutic foods is on the rise as the population grows older. As of fiscal 2018, the market is valued at an estimated ¥47.3 billion and ¥9.4 billion for foods made for people with kidney disease. Relative to competing manufacturers, we have the eighth-largest share of the overall market, at 4.6%, and the top share of foods for people with kidney disease, at 25.5%.

In fiscal 2021, therapeutic and care foods generated ¥3.5 billion in net sales, with 44% of net sales coming from foods for the elderly and those receiving nursing care, 29% from protein-controlled foods, 22% from energy supply foods, and 5% from other foods.

The Nutrition Division has four policies for the medium term: 1) establish KHF as a high-quality brand by enhancing our quality assurance system, 2) develop products with high added value and improve existing products, 3) increase sales by utilizing digital tools and other new methods, and 4) expand mail-order customers via our customer service center. We believe that these polices will lead us steadily to solid results.

Our mission is to fulfill Kissei's Management Philosophy, to "contribute to society through high-quality, innovative pharmaceutical products" and to "serve society through our employees." We will do our part on the back of therapeutic and care foods with high added value.

Kissei Pharmaceutical's Therapeutic and Care Products

Protein-Controlled Foods 29%
These food products provide people undergoing diet therapy for chronic kidney disease with the energy they need, while carefully controlling protein and salt content.

Other Foods 5%

Foods for the Elderly and Those Receiving Nursing Care 44%
These food products are made with the intention of being easy to chew, swallow, and digest, while offering appropriate nutrition to consumers.

Energy Supply Foods 22%
These food products make it easy for consumers to replenish their energy levels for a power boost.

The Kissei Healthcare Net Shop

We have revamped our online shop for therapeutic and care products to be more user-friendly. We have also added new features, including a subscription option for making regular purchases.

https://healthcare.kissei.co.jp/shop/default.aspx (Japanese only)

Other Businesses

▶ Material issue related to Kissei's business activities
Development and provision of products useful to society

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 COMTEC CO., LTD. (Information Services)

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.

KISSEI COMTEC has acquired ISO/IEC 27001 certification for the protection of information-based assets, as well as certifications for meeting international standards ISO 9001 and ISO 14001 in order to meet the expectations and needs of its customers and to live up to their trust. In February 2022, the company also became the first in Nagano Prefecture to acquire certification as a "DX-certified operator" based on the DX certification system established by the Ministry of Economy, Trade and Industry. As an ICT solution partner, KISSEI COMTEC is transforming to adapt to the new digital age.

The company promotes the creation and provision of products and services that solve social issues to help achieve the SDGs. These include the creation of paperless solutions such as Smart Discussion, a system that can help save energy and resources by removing the need for paper from any kind of meeting. The company has also introduced teleworking and staggered working hours, as well shorter working hours for employees with children who are yet to enter elementary school. These initiatives aim to enable diverse styles of working and help employees balance work and childcare. In addition to building this work environment, the company received certification for having completed the Work–Life Balance Course under Nagano Prefecture's Companies for the Advancement of a Lively Workplace certification system.

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

HASHIBA TECHNOS CO., LTD. (Construction)

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 three-star ranking.

Description
- General construction services
- Factory and building management

Kissei Shoji Co., Ltd. (Merchandising)

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 manufacturing, production, and sales 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.

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

Letter from the CEO

▶ Material issue related to Kissei's management base

Strengthening and enhancement of governance

Mutsuo Kanzawa
Chairman and Chief Executive Officer

We strive to provide sustainable value to society and increase corporate value through continued R&D endeavors toward innovative drug discovery and constructive dialogues with our stakeholders.

We live in a time when technological innovation is taking place in every field, and people's values and behaviors are changing in major ways. In recent years, the world has been fraught with a pandemic, fluctuating geopolitical situations on a global stage, climate change, and problems related to energy and food, all of which have led to greater and greater unpredictability, uncertainty, and instability. In times such as these, we as a company are faced with a question—we need to ask ourselves what our significance in society truly is. Kissei's Management Philosophy is to "contribute to society through high-quality, innovative pharmaceutical products" and to "serve society through our employees," and we have made it our social mission to contribute to the health of people around the world through innovative pharmaceutical products. It is this mission that drives our actions.

Looking at the state of the pharmaceutical industry today, one continues to see a difficult business environment marked with increasingly complex drug development and greater development risks amid restrictions on activity due to COVID-19, annual revisions to NHI drug pricing, and concerns about the supply of pharmaceutical products. In fiscal 2021, under these circumstances, we advanced six late-stage projects one step further in development and production. Two of these products, TAVNEOS®, a treatment for microscopic polyangiitis and granulomatosis with polyangiitis, and CAROGRA®, a treatment for ulcerative colitis were launched in the first half of 2022. These achievements indicate that fiscal 2021 was a year in which we were able to fulfill our reason for being and live up to our Management Philosophy of contributing to society through high-quality, innovative pharmaceutical products.

In line with the restructuring of the markets operated by the Tokyo Stock Exchange (TSE) in April 2022, Kissei transitioned to the Prime Market segment. In anticipation of this restructuring, Japan's Corporate Governance Code was revised in June 2021, with different principles and supplementary principles applicable to each of the TSE's new market segments: the Prime Market, Standard Market, and Growth Market. In particular, the Prime Market segment is expected to garner particular attention globally as a collection of investment targets in the form of premier and representative Japanese companies. We are enhancing our governance system and promoting sustainability initiatives as part of this segment.

In 2015, we established the Nomination and Compensation Deliberation Committee, which deliberates on candidates for appointment or dismissal as directors and levels of director compensation, which are then proposed to the Board of Directors. In 2020, we appointed a female outside director to the Board, and at the annual General Meeting of Shareholders held in June 2022, we increased the ratio of outside directors to one-third and adopted the executive officer system to create a more flexible system for business execution. We will continue to pursue other means to enable more effective governance.

As for sustainability, one of the basic policies of the five-year medium-term management plan, "**PEGASUS**," is to promote ESG and the SDGs. Under this policy, the Company is also working to achieve a sustainable society and environment, which is what the SDGs ultimately strive for. Therefore, we have plotted issues on two axes—relevance to Company business and impact on stakeholders—to narrow down matters of importance. Based on the results, we have formulated a series of material issues for the Company to focus its initiatives, and set key performance indicators (KPIs) to track progress for each issue. We intend to instill the importance of these material issues in every employee and bring our efforts to the next level.

Kissei was founded in 1946; in August 2022 it celebrated its 76th anniversary. We will continue to strive, first toward our 80th year, and then toward our 100th, to provide sustainable value to society and increase corporate value through continued R&D endeavors toward innovative drug discovery and constructive dialogues with our stakeholders.

I ask for the ongoing understanding and support of our stakeholders as we move forward.

August 2022

Mutsuo Kanzawa
Chairman and Chief Executive Officer

Messages from Outside Directors

Shigetaka Shimizu
Outside Director

Kissei employs a system of governance under which the chief executive officer has authority over all matters related to management, and the chief operating officer is responsible for all matters related to business execution. In 2014, I became the Company's first outside director in an effort to make the system even stronger. Since then, three more outside directors have been added to our numbers, accounting for one-third of the Board of Directors. This has made governance stronger still. The Company has made revisions to this system in response to revisions to Japan's Corporate Governance Code. In particular, the Company has made remarkable strides in terms of "ensuring appropriate information disclosure and transparency" and "responsibilities of the Board," and it is clear that it is taking self-initiated steps to increase sustainable growth and corporate value.

During Board meetings, I make comments and proposals not only drawing from my own experience and expertise but also bearing in mind the perspectives of other industries and public sensibilities as well. I also make remarks based on my interest in systems that lead to sustainable growth, such as the PDCA cycle, which can be applied to measures after they are decided upon and can lead to results. I am also keen to check on the progress of these measures.

Kissei has reached the halfway point of its five-year medium-term management plan, "**PEGASUS**," which began in April 2020 and was primarily drafted by Mr. Takehana, the current president of Kissei, when he was department manager of the Corporate Strategy and Planning Department. In fiscal 2021, Kissei launched two new products, had NDAs approved for two more, and is preparing an NDA for one product after achieving the primary endpoint in Phase III clinical trials. In terms of the first of the plan's four basic policies, "increase domestic sales" and one of the measures under this policy, "expand the product portfolio by launching new products and in-licensing," the plan is progressing well. All the achievements I have mentioned above have been proposed, discussed, approved and developed by the Board of Directors since I assumed an outside director position. I believe that Mr. Takehana in his new role as president will steer the Company toward another basic policy within "**PEGASUS**," to "expand the development pipeline," specifically the strategy "promote R&D focused on small molecules."

Minoru Nomura
Outside Director

My credo as a manager is to earn the deep trust of our stakeholders, including customers, employees, shareholders, local communities, government agencies, and financial institutions, and to never waver from this path. Therefore, I try to speak from the perspective of a stakeholder during Board meetings as a way to supervise and audit the other Board members. In addition, the Nomination and Compensation Deliberation Committee adopts a stakeholder point of view when it selects candidates for directors or Audit & Supervisory Board members and when examining and judging each candidate's background and qualifications for performing their main duties.

Director and Audit & Supervisory Board member candidates recommended by the Nomination and Compensation Deliberation Committee were elected at the annual General Meeting of Shareholders in June 2022. At the following Board of Directors' meeting, Chairman Kanzawa and President Takehana were selected as representative directors, and the Company adopted a new governance system. Mr. Furihata, the former president, had been elected after serving as department manager of the Business Development Department, Corporate Strategy and Planning Department, and Clinical Development Division, respectively. All the products in the Company's development pipeline that he was involved with have reached their final stages of development over the course of "**PEGASUS**" so far, meaning they have been launched or an NDA has been submitted. The former managing director and current president, Mr. Takehana, has worked in drug discovery research as part of the Research Division and was the one behind formulating "**PEGASUS**" in his role as department manager of the Corporate Strategy and Planning Department. I believe he was appointed as president because the steps he has taken to enhance Kissei's ability to discover new drugs on the upstream side of drug manufacturing. This has allowed the Company to take great strides based on its belief that "a pharmaceutical company cannot exist without R&D." In a VUCA world—one that faces volatility, uncertainty, complexity, and ambiguity—and with measures to curb medical expenditures and other factors abound, business conditions are expected to remain difficult. Even under these conditions, I believe that Mr. Takehana will help Kissei deliver unique products to the world on the back of his strong leadership, which will make the Company's earnings base even stronger.

Sayuri Uchikawa
Outside Director

When I was appointed as outside director two years ago, I didn't know much about the pharmaceutical industry or the technical terminology, but I believe I have come to understand the overall picture of the Company in recent time. At Board of Directors' meetings, Chairman Kanzawa always speaks in a calm manner, but what he says is very astute and never complacent. These past two years have been difficult ones, as they included the patent expiration for Urief® and sales-related difficulties brought on by the COVID-19 pandemic. However, from my perch as outside director, I could see how valiantly everyone rallied behind former President Furihata to face these troubles. There has been solid communication among officers throughout this period. Outside directors also hold meetings with the Audit & Supervisory Board members, and I believe the Board of Directors is set up in a way that allows the free exchange of opinions among its members, while maintaining an appropriate distance between it and the Audit & Supervisory Board.

Following the annual General Meeting of Shareholders in June 2022, the Company adopted a new governance structure, and I believe this good balance will remain intact. Although I realize an outside director is supposed to speak on such matters without being restricted by relationships within the Company, I believe that I am best suited to speak on the cultivation of human resources and its progress as seen through the eyes of the general public. To promote diversity and inclusion, the Cabinet Office of Japan has set a goal of 30% of executive positions being filled by women. I believe that Kissei is making gradual efforts to develop female executives. However, going forward, the Company should aim for an environment that allows people from a variety of backgrounds, such as foreign nationals and mid-career hires, to take an active part, regardless of gender. I intend to help in this effort, in whichever way I can.

Yoshinori Otsuki
Outside Director

Kissei Pharmaceutical has always struck me as a forward-thinking company that also moves alongside society, which one can see by its devotion to culture, through its support for the Seiji Ozawa Matsumoto Festival and other activities, and its passion for helping local communities. Having actually attended meetings of the Board of Directors, the sincere discussions I have witnessed regarding compliance with Japan's Corporate Governance Code, laws, and regulations confirm the impression I had from the outside looking in—that Kissei is a company with solid corporate management.

Globally, it is becoming more common to establish a clear link between non-financial information, such as sustainability-related information, and corporate value. In addition to improving corporate earnings, I believe that Kissei's track record of enthusiastic efforts to serve the public interest will improve its corporate value even further.

As someone with a background in administration, I may lack financial knowledge and experience, but in my new role as an outside director I will use the knowledge and experience in local administration and government to measure the connectivity between financial and non-financial information, as well as the Company's significance within society and make recommendations from a different angle. In addition to this duty, I believe my particular role is to improve corporate value by helping Kissei become a company where employees are happy and enjoy their work.

I believe that the Company faces some challenges and some questions in regard to its future development, namely how to take an active approach to non-financial information disclosure, and how Kissei, as a company with strengths as a Japanese drug manufacturer, can apply its experience and know-how to the global market as Japan's population ages at an unprecedented rate. Amid the declining birthrate and aging population, I believe the key to future development lies in acquiring top-notch human resources from overseas.

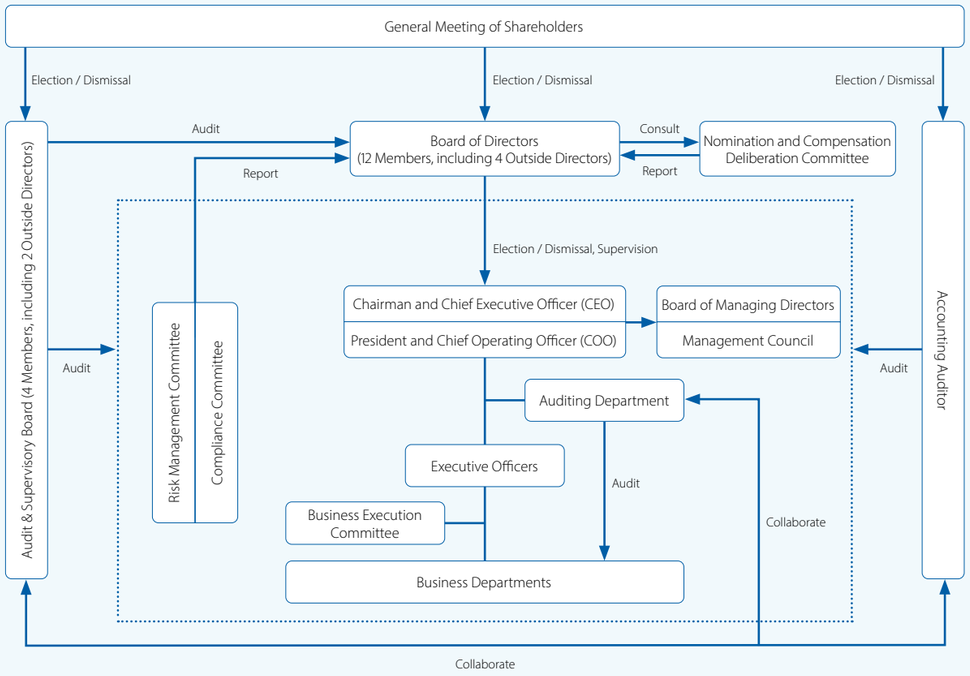
Kissei's Basic Approach to Corporate Governance

Kissei Pharmaceutical has formulated the Kissei Basic Policy on Corporate Governance. Through implementation of the items stipulated in this policy, Kissei aims to comply with Japan's Corporate Governance Code, foster the trust of shareholders and other stakeholders, and develop as a sound and sustainable company that plays a necessary role in society.

Following the annual General Meeting of Shareholders held on June 2022, the Company reduced its number of internal directors by three and increased its number of outside directors by one, and-decreasing the number of Board members by two, for a total of 12, four of whom are outside directors. This change was made in order to increase the Board's effectiveness, thereby improving its supervisory function and increasing corporate value over the medium to long term. Under the current governance system, the chairman 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 ensures a stronger management system, high mobility, and greater management capabilities related to business execution entrusted to the Board of Directors. In addition, the CEO convenes the Board of Managing Directors, which consists of directors of managing director rank and above, to discuss and decide on predetermined items for discussion. We also established the Business Execution Committee as an advisory body to the COO for the purpose of assisting the COO in making decisions and considering management issues to be proposed and reported to the Board of Directors. Furthermore, the Company established the Management Council, which is attended by the Company's directors, Audit & Supervisory Board members, executive officers, managers of executive divisions, representative directors of affiliated companies, and executive directors. During meetings of the council, attendees share management-related information, the latest industry trends, and business activities of the Group. In light of the rapid changes in the business environment, we also adopted an executive officer system in June 2022 with the aim of further strengthening corporate governance and building a more flexible business execution system.

We also established the Nomination and Compensation Deliberation Committee, comprising outside directors (and outside Audit & Supervisory Board members in cases of selecting Audit & Supervisory Board members), the CEO, and the COO in an effort to ensure the independence and objectivity of the Board of Directors and to ensure transparency of nomination and compensation processes. The Nomination and Compensation Deliberation Committee deliberates upon the appointment and dismissal of officers and proposes its recommendations to the Board of Directors. The committee also deliberates on compensation levels for directors and proposes those recommendations to the Board.

▶ Corporate Governance Bodies and Internal Control System



List of Directors (As of June 24, 2022)

Standing, From Left Michio Iwabuchi, Shinji Kikuchi, Yoshinori Otsuki, Keiji Miyazawa, Hiroshi Noake, Sayuri Uchikawa, Masayuki Isaji, Kando Nakagawa
Seated, From Left Minoru Nomura, Yoshio Furihata, Tetsu Takayama, Yasuo Takehana, Mutsuo Kanzawa, Keiji Fukushima, Takahide Kitahara, Shigetaka Shimizu

Board of Directors

Mutsuo Kanzawa — Chairman and CEO

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

Yasuo Takehana — President and COO

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 and Planning Department
2020 Managing Director
2022 President and COO (current position)

Keiji Fukushima — Executive Vice President

1979 Joined the Company
2012 Director, General Manager of Sales and Marketing Division, Department Manager of Promotion Support Department
2014 Managing Director, General Manager of Sales and Marketing Division
2020 Executive Managing Director
2022 Executive Vice President (current position)

Tetsu Takayama — Executive Managing Director

1985 Joined the Company
2014 Director, Department Manager of Human Resources Department
2020 Managing Director, Department Manager of Human Resources Department
2022 Executive Managing Director (current position)

Takahide Kitahara — Managing Director

1986 Joined the Company
2018 Director, Department Manager of Corporate Finance and Management Department
2022 Managing Director, Department Manager of Corporate Finance and Management Department (current position)

Yoshio Furihata — Director and Senior Adviser

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 and Planning Department
2016 Managing Director, General Manager of Clinical Development Division
2018 President and COO
2022 Director and Senior Adviser (current position)

Hiroshi Noake — Director

1987 Joined the Company
2014 Director of Sales Planning Department, Sales and Marketing Division
2016 Regional Director of Kanetsu Regional Office, Sales and Marketing Division
2018 Senior Director of Sales Planning Department, Sales and Marketing Division
2020 Director of Sales and Marketing Division, Senior Director of Sales Planning Department
2022 Director, General Manager of Sales and Marketing Division (current position)

Keiji Miyazawa — Director

1993 Joined the Company
2017 Director of Business Development Department
2018 Director of Research Strategy and Planning Department, Research Division
2021 Senior Director of Research Strategy and Planning Department, Research Division
2022 Director, General Manager of Research 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)

Minoru Nomura — Outside Director (independent)

1969 Joined Nomura Kogyo Co., Ltd.
1989 President and Representative Director of Nomura Kogyo Co., Ltd.
President and Representative Director of SN SEIKI Co., Ltd.
1998 Chairman of NOMURA CORPORATION OF TAIWAN
2005 President and Representative Director of NOMURA UNISON Co., Ltd.
2008 President and Representative Director of Domaine de la Sénéchalière (France) (current position)
2016 Outside Director at the Company (current position)
2021 Chairman and Representative Director of NOMURA UNISON Co., Ltd. (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 Chair of Shuoukai (incorporated educational institution) (current position)
2020 Outside Director at the Company (current position)

Yoshinori Otsuki — Outside Director (independent)

1984 Joined Nagano Prefectural Government
2016 Director General in charge of international matters, Citizens and Cultural Affairs Department Nagano Prefectural Government
2018 Director General of Health and Welfare Department of Nagano Prefectural Government
2020 General Manager of Local Cooperation Enhancement Department of Japan Suicide Countermeasures Promotion Center
2021 Senior Managing Director of Academy of International Social Sound Development Co., Ltd. (current position)
Director of NAGANO NIHON DAIGAKU (current position)
2022 Councilor and Auditor of Social Welfare Corporation Keiroen (current position)
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 and Planning Department
2018 Corporate Auditor (full-time) (current position)

Shinji Kikuchi
Corporate Auditor (full-time)

1988 Joined the Company
2011 Director of Drug Discovery Research Laboratory I
2012 Senior Director of Drug Discovery Research Department
2016 Director, General Manager of Research Division
2022 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)

Michio Iwabuchi
Outside Corporate Auditor (independent)

1983 Registered as a Certified Public Accountant
2018 Registered as a Tax Accountant
2018 Outside Director (Audit & 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)

Director Skill Matrix

Directors are required to have the qualities that will contribute to Kissei Pharmaceutical's sustainable growth and enhance its corporate value, as well as the qualities that will allow them to excel in the execution of their main duties, and meet the mandate of shareholders.

Name	Independent Outside Status	Corporate Management	Global	Research and Development	Sales and Marketing	Finance and Accounting	Legal Affairs and Compliance	Personnel Affairs and Human Resource Development	ESG and Sustainability	Credentials, etc.
Mutsuo Kanzawa		●	●			●	●	●	●	Pharmacist
Yasuo Takehana		●	●	●			●		●	PhD (Pharmaceuticals), Pharmacist
Keiji Fukushima		●			●		●	●	●	
Tetsu Takayama		●					●	●	●	
Takahide Kitahara		●				●	●		●	
Yoshio Furihata		●	●	●			●		●	
Hiroshi Noake					●		●	●	●	
Keiji Miyazawa			●	●			●		●	PhD (Pharmaceuticals), MBA, Pharmacist
Shigetaka Shimizu	●	●	●			●	●		●	
Minoru Nomura	●	●	●			●	●		●	
Sayuri Uchikawa	●	●	●				●	●	●	PhD (Business Administration)
Yoshinori Otsuki	●	●	●				●	●	●	

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 2021.

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 established the Basic Risk Management Policy and a risk management system. In addition, the Company established the Risk Management Committee, which serves as an advisory body to the Board of Directors. Under the guidance of this committee, the Kissei Group 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. Regarding chemical compounds and products that we have licensed out the development and marketing rights for overseas, there is a possibility that development or compliance with pharmaceutical regulations in the licensed region may not proceed as planned.

2 Medical System Reform
Prices of pharmaceuticals in Japan are set based on the government's NHI drug prices and are revised on an annual 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 Product Quality
Although the Company strives to develop manufacturing and quality management systems in compliance with the latest laws, regulations, and guidelines, if a quality-related issue were to cause a drug to be recalled, 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 worksite 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 worksite, legal action may be taken against the worksite, 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 Supply Chain Issues
Business activities could be minimized or suspended due to direct or indirect damage incurred by Kissei or its partners or due to the interruption of supply chains caused by fires, floods, or accidents stemming from earthquakes, floods, or other natural disasters, or the effects of regional conflicts 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 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 are 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.

10 Assets under Possession
Kissei evaluates its business assets, investment securities, and other assets quarterly in accordance with its accounting policy. If there is no expectation of recovering the amount invested in 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 looking at changes in quoted market prices for investment securities with a market price, or the net worth of companies with unlisted shares and no market price, and then taking a comprehensive account of its business plan.

11 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.

12 The Environment
Chemical substances used in the research and manufacturing of pharmaceutical products include substances that could have an adverse effect on the environment. Every department and worksite 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 worksite, legal action may be taken against it, 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.

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. Specifically, Kissei Pharmaceutical promotes the acquisition of ISO 14001 certification for environmental management systems at the Company and its Group companies, and has introduced Shinshu Green Electricity, which comes from 100% renewable energy sources. The Company is also making preparations to disclose climate change risks related to environmental conservation in line with the recommendations put forth by the Task Force on Climate-related Financial Disclosures (TFCD).

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, promote the Compliance Program, and serve as an advisory body to the Board of Directors. The committee is chaired by the department manager of the General Administration Department 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.

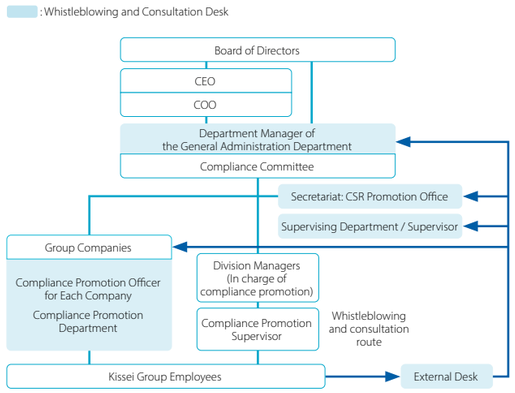
In addition, the Kissei Group engages in Groupwide compliance practices led by compliance officers appointed by each Group company. The Kissei Group Compliance Officers' Meeting is held regularly, during which these compliance officers share implementation plans, report results, and exchange information.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

Whistleblowing and the 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, post, 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 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 receive education and training for work directly related to their duties, covering the Pharmaceutical and Medical Device Act. 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 serves as a guide to daily activities and conduct for ensuring proper compliance.

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 2021 reaching 96.9%.

The results of the questionnaire are collected and analyzed and then each division and department is provided with feedback, which the division manager (in charge of compliance promotion), the compliance promotion supervisor, and other persons in charge use to deliver appropriate compliance education to employees.

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

Relationships with Our Employees

▶ Material issue related to Kissei's management base

Creation of a fulfilling workplace environment

Human Resource Systems Emphasizing Employee Engagement

At Kissei Pharmaceutical, we strive to create a work environment where employees' work gives them a sense of satisfaction, accomplishment, and mission as well as a feeling of personal growth—we believe that this is the driving force of sustainable growth for the Company. Therefore, we regularly conduct a Human Resources Awareness Survey to understand how employees perceive their work, the Company, and its various human resource systems, and to learn what is important to them.

The survey comprises 36 questions in total, including one question regarding overall satisfaction, plus 35 questions in five categories—engagement, job satisfaction, goal management system, treatment of employees and career, and human resource system and work situation. Employees answer each question with a rating of 1 (strongly disagree), 2 (somewhat disagree), 3 (somewhat agree), or 4 (strongly agree), and then the Company aggregates the average score of all the surveys. The most recent survey results are disclosed Companywide via in-house newsletters and other means. The high level of engagement and willingness to collaborate shown in the results reflect a strong sense of unity within the corporate culture.

We conduct a portfolio analysis based on both the degree of satisfaction and degree of importance, meaning how important the subject of each question is to life at the Company. Using the results of this portfolio analysis, we have formulated and implemented a variety of new human resource-related measures. For instance, we have developed the "Guide to Expectations for Each Role," which clarifies the expectations for employees according to their level of qualification and other criteria. Other examples include the introduction of a role-based conduct evaluation applicable to all levels of employees, which focuses on conduct as opposed to ability, and a list of work and duties by division that gives employees information to help them think about their careers independently. The analysis has also allowed us to systemize skill and career development that we conduct after an employee is promoted.

Results of the Human Resources Awareness Survey

(Questions regarding Engagement, 4-Point Maximum)

Questions regarding Engagement	Fiscal 2019
I want to make Kissei a better company	3.61
I am proud to be a Kissei employee	3.26
I want to grow together with Kissei	3.40
I agree with Kissei's Management Vision	3.53

Introducing a New Human Resource System (April 2022 Onward)

To date, our human resource system has aimed to balance time (age and years of employment) and contributions (actions and results). This system has given employees a strong sense of camaraderie, which has manifested itself in a corporate culture characterized by a willingness to cooperate and a strong sense of unity throughout the Company. Since we have implemented this system, we have been very mindful of the "time" aspect.

However, current business conditions are in a constant state of flux, making them difficult to predict. To ensure the Company can achieve sustainable growth under these conditions while maintaining the positive corporate culture we have cultivated to this point, we want to encourage employees to put their individual strengths and expertise on display at an early stage, regardless of their age or years of employment, and develop an even higher level of unity, the kind that arises when a full spectrum of human resources inspire one another. Moreover, we encourage employees to reframe their values and mindset toward work to help them become proactive, self-motivated, and self-reliant in the pursuit of their dreams and goals. To encourage employees in this way, we need to evolve our corporate culture toward a healthy sort of drive that makes a person think of what actions they should perform and what results they should achieve.

Therefore, we have introduced a new, dual-track human resource system from April. This new system will take some of the emphasis off of the time aspect of human resources and place more on contributions—one's actions and results, and role. This will make sure that employees who act proactively and boldly to fulfill their roles and produce the results expected of them receive the recognition they deserve, and will allow the Company and employees to soar toward a dream-filled future on the wings of diversity and potential.

The Concept of Our New Human Resource System

Evolution of our dual-track system
Emphasize diversity and future potential

1 Recognizing the fulfillment of duties
Recognizing employees in terms of the actions and duties they perform in their roles within the organization, regardless of age or years of employment, will help foster the desire to contribute to the Company and will support a variety of future plans.

2 Increasing opportunities for specialists to flourish
We will evaluate employees in terms of their willingness to contribute in an increasingly complex and sophisticated business environment, and support development toward a variety of careers by giving specialists recognition commensurate with the greater roles they are expected to play.

3 Encouraging people to take on challenges
Reflecting employee efforts to take on new or ambitious challenges and subsequent delivery of results in evaluations and treatment will encourage employees to contribute to the Company and support them in their various paths toward self-fulfillment.

Key Points of Our New Human Resource System

1. Qualification grading system

- Shift of emphasis from qualifications based on professional ability to a role-centric qualification system that is focused on actions and duties required to fulfill a role
- Elimination of a set number of years of employment as a requirement for a role
- Establishment of the new Professional Manager Group to ensure recruitment, training, and commensurate recognition of highly specialized human resources

2. Payment system

- Reorganization of salary system for employees, eliminating the "personal compensation" aspect paid according to age in favor of new role-based and action-based compensation

3. Evaluation system

- Establishment of a new evaluation of professional duties that is based on the performance of assigned duties
- Creation of a list of work and duties by division that categorizes the work of each division into three categories according to the work characteristics, and use of the list in performance evaluations
- Introduction of an application requirement for a promotion in order to make promotions more self-initiated

Cultivating Human Resources

The Kissei Group has set "enabling employees to demonstrate their strengths to the utmost degree as both an individual and as 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 managerial 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.

Key Human Resources Cultivation Measures

1. Position-based training (instruction for new managers and supervisors, managerial and evaluation training for managers, education for new employees) and ability-based training (MR selection training, specialized English training, etc.)
2. Interview system for skill and career development (encouragement for changing roles, and mindset and conduct transformation, primarily targeting newly promoted employees)
3. Educational programs to cultivate leaders and human resources who can promote DX
4. Correspondence courses (support for voluntary skill development)
5. Self-assessment system (opportunities for employees to think actively about their careers)

Promoting Diversity and Gender Equality

We strive 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.

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, employees 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, part of an active effort to encourage all employees, regardless of gender, to take advantage of childcare leave.

* 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

Measure to Secure Past-Retirement Age Employees

Kissei Pharmaceutical has introduced a continuous employment system that allows employees to work until age 65, and we are working to create a system that will allow many employees to continue working even after retirement so that Kissei can make the most of their experience, skills, and knowledge.

Recruitment of People with Disabilities

Kissei Pharmaceutical actively promotes the employment of people with disabilities. As of March 31, 2022, we have met the legally mandated employment rate, with 26 such employees.

Promotion of Health Management

We work to create a workplace environment that gives employees a strong sense of motivation as workstyle reforms and the response to COVID-19 bring major changes to working conditions. As part of this effort, and 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.

In addition, 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 and in continuation of fiscal 2021, Kissei Pharmaceutical was certified as a 2022 Organization with Outstanding Health & Productivity Management (Large Enterprise Category) in March 2022.

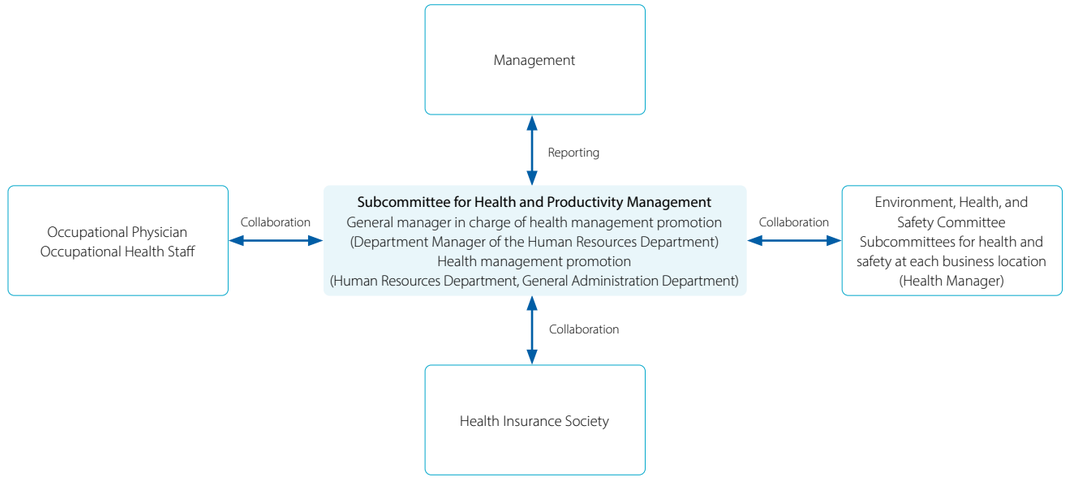
Major Health Management Initiatives

- Medical testing exceeding legal requirements and subsidization of cancer screening and other testing costs in cooperation with the Kissei Group Health Insurance Society
- Stress checks for all business establishments, including those with fewer than 50 employees
- Implementation of calisthenics in the workplace to establish exercise habits, holding of sporting events for improving health and physical fitness at each workplace, and subsidization of expenses for these events

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.

Subcommittee for Health and Productivity Management



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 Group 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.

Environmental Initiatives

▶ Material issue related to Kissei's management base

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.

The Environment and Kissei

The figures below show the input of resources into Kissei Pharmaceutical for fiscal 2021, as well output in the form of emissions and wasted generated in processes such as research, development, production, and sales. We are working to reduce our environmental impact based on this data.

Input

Raw materials for pharmaceutical products

Raw materials	44 tons
Additives, etc.	100 tons

Packaging materials

Pharmaceutical products	163 tons
Therapeutic and care foods	229 tons

Energy (crude oil equivalent)

Energy used	8,205 kL
Electricity purchased	3,708 kL (14,805,000 kWh)
Fuel used	4,496 kL
Heavy oil, kerosene, LPG, etc.	1,875 kL
City gas	1,527 kL
Gasoline for medical representative (MR) vehicles	1,094 kL

Water

Total input	135,000 m³
Drinking water	62,000 m³
Groundwater	69,000 m³
Industrial water	3,000 m³

Chemical substances (reported to the PRTR)

Amount handled	23.5 tons

* Data from business locations that handle amounts of 1 ton or more (including methylnaphthalene in heavy oil)

Research

Development

Production

Sales

Office work

Output

Waste

Waste generated	390 tons
Amount recycled	341 tons
Final landfill amount	27 tons
Chemical substances (reported to the PRTR)	3.0 tons

Emissions

CO_2 emissions	16,925 tons
NOx* emissions	15.3 tons
SOx* emissions	4.5 tons
Fine particles*	0.5 tons
Methylnaphthalene*	0.1 tons

* Total output in Matsumoto City, Shiojiri City, Azumino City, and Joetsu City

Emissions to water

Total wastewater	109,000 m³
To public bodies of water	59,000 m³
To groundwater	50,000 m³
Biological oxygen demand (BOD)*	0.8 tons

* Total output in Matsumoto City, Shiojiri City, Azumino City, and Joetsu City

Disclosure Based on the Recommendations of the Task Force on Climate-related Financial Disclosures (TCFD)

Global warming caused by greenhouse gas emissions poses serious global risks, which are expected to have an impact across multiple economic sectors. The need to evaluate and analyze the effect of climate change on business, enhance resilience to related risks, and take advantage of related opportunities are all important issues for the Company.

We have positioned responding to climate change as a material issue for our management base. Therefore, we have examined the risks and opportunities related to climate change from a medium- to long-term perspective and analyzed the future impact of climate change on our business activities, based on the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD).

Understanding the TCFD

The TCFD was established in 2015 by the Financial Stability Board (FSB) to investigate ways to disclose climate-related information and manage financial institutions. The TCFD recommends that companies disclose the risks and opportunities related to climate change according to the following four categories.

1. Governance

Regarding environmental problems, Kissei engages in efforts aimed at realizing a sustainable society. In addition, the SDGs Promotion Committee manages the planning and progress of a variety of measures and reports its discussions to the Board of Directors.

A cross-departmental TCFD Project Team was set up within the committee to conduct a specific investigation into major climate change-related issues and has identified, analyzed, and assessed business risks and opportunities.

2. Strategy

Regarding the impact of climate change on the Company's business, we conducted a scenario analysis in fiscal 2021 focused on the impact of climate change on our business locations in the Pharmaceutical Business, which is the core business of the Group. We also created 1.5℃*1 and 4℃*2 climate change scenarios and identified risks and opportunities for both.

These risks and opportunities were analyzed and assessed in terms of their financial impact and their likelihood of occurrence, and then possible measures were investigated, prioritized by the impact on our business strategy. As a result of analysis and assessment, there were no risks identified that could have a significant impact on the business strategy.

*1 The 1.5℃ scenario was created with reference to the International Energy Agency's (IEA's) Net Zero Emissions by 2050 Scenario (NZE) and others.
*2 The 4℃ scenario was created with reference to the Intergovernmental Panel on Climate Change's (IPCC's) RCP8.5 scenario and others.

▶ Results of Scenario Analysis

Classification		High-Priority Risks	Impact on the Company	Impact Level	Countermeasures	Business Risks
1.5℃ Scenario	Transition Risks	Enhanced policies and regulations related to decarbonization	Addition of carbon pricing Company could incur an estimated cost of approximately ¥200 million due to carbon pricing (based on estimated CO_2 emissions in fiscal 2030 of 11,355 tons at a rate of US$130 per ton*1)	Medium	• Reduce CO_2 by introducing renewable energy, upgrading to energy-saving equipment, and further promoting activities to save energy	Minimal
			Capital investment costs could increase as a result of new or enhanced decarbonization policies such as CO_2 emission regulations	Low	• Systematically switch to energy-efficient equipment when upgrading and consider taking advantage of subsidies and other avenues	Minimal
		Requirement to implement climate change initiatives	Stakeholders' evaluation of the Company could decline due to insufficient efforts to address climate change	High	• Gain stakeholder trust via sustainable efforts to address climate change-related issues and through appropriate disclosure	Minimal
4℃ Scenario	Physical Risks (Immediate)	Intensification and increased frequency of natural disasters	Flooding could cause damage to key locations, leading to suspended operations and expenses to restore these operations, and could also affect the development pipeline and impact the steady supply of products	High	• Take appropriate measures to minimize damage to locations from floods and other disasters	Low
			Disasters could disrupt manufacturing due to damage incurred by suppliers, or hinder the steady supply of drugs by affecting the transportation network	High	• Maintain and improve the system for steady drug supply by keeping an inventory of drugs in conditions suited to their respective characteristics, and in decentralized locations • Reduce procurement risks by establishing multiple supply lines	Low
			Increased frequency of natural disasters could lead to higher insurance premiums	Low	• Make appropriate judgments that balance insurance premiums with actual risk, and take out policies that hedge risks	Low
	Physical Risks (Long-Term)	Rising temperatures	Rising temperatures could lead to higher air-conditioning costs	Low	• Continue activities to instill the importance of saving energy among employees, and promote new activities • Introduce and shift to high-efficiency and energy-saving equipment	Low
		Water shortages	A lack of water resources could lead to restrictions on water use, thereby disrupting operations, while costs related to securing water resources could increase	Low	• Increase information collection related to water withdrawal in surrounding areas and construct an emergency response system that factors in the risk of acquiring water resources*2	Low

*1 Carbon prices in 2030 for advanced economies under the NZE scenario according to the IEA's *World Energy Outlook 2021*
*2 Water risks determined with reference to the Aqueduct Water Risk Atlas

Classification	Item	Impact on the Company	Impact Level
Opportunity	Resource efficiency	Costs for energy procurement and raw materials could be reduced by introducing new high-efficiency technology and equipment	Low
	Energy	The introduction of renewable energy could ensure stability of business versus future depletion of fossil fuels	Low
	Products and services	Demand could increase for existing pharmaceutical products in disease areas where morbidity increases as temperatures rise	Low
	Market	Demand and development opportunities could increase for treatment in disease areas where morbidity increases as temperatures rise	—
	Resilience	Climate change risk assessments and the continued implementation of climate change-related measures could minimize risks and enhance business stability	—
	Other	Active efforts to address climate change and conduct appropriate disclosure could build stakeholder trust (from customers, employees, investors, and students) and increase the Company's reputation, thereby creating corporate value	—

3. Risk Management

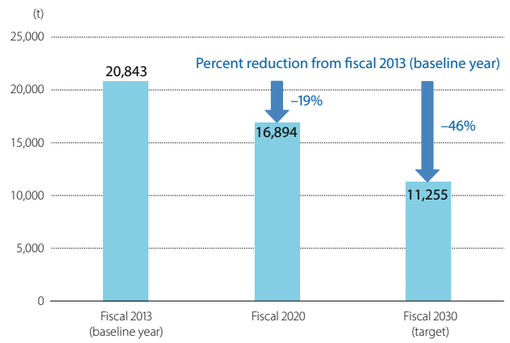
Risks related to climate change have also been positioned as important management risks, and the risks identified and assessed within the TCFD framework are reviewed at least once a year for their impact on business activities. When risks have a relatively large impact on business activities, we prioritize them in terms of cost effectiveness and degree of urgency, then investigate and implement countermeasures.

The SDGs Promotion Committee will discuss and report on the management status of these risks to the Board of Directors, and will also report to the Risk Management Committee, an advisory body to the Board of Directors, to promote comprehensive Companywide risk management.

4. Metrics and Targets

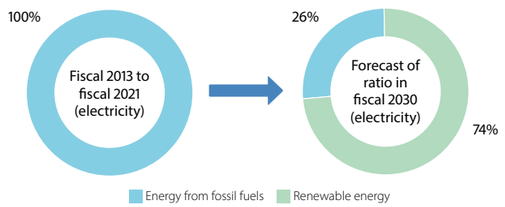
We have set the utilization rate of renewable energy and reduction of CO_2 emissions as KPIs under "responding to climate change," a material issue for our management base. We have also set the following medium-term targets to contribute toward the government of Japan's 2050 Carbon Neutrality Declaration and its fiscal 2030 goal of a 46% reduction of greenhouse gas emissions compared with fiscal 2013 levels.

▶ CO_2 Emissions and Medium-Term Targets (Scope 1 and 2 Emissions)



Fiscal 2030 reduction target for Scopes 1 and 2 CO_2 emissions:
46% reduction compared with fiscal 2013

▶ Ratio of Sustainable Energy Use and Medium-Term Goals



Fiscal 2030 target for renewable energy utilization rate:
74% or more of total electricity consumption

In addition to reducing CO_2 emissions in our business activities, we utilize renewable energy both strategically and actively. In April 2022, we started using Shinshu Green Electricity, CO_2-free electricity produced in Nagano Prefecture, at our head office and Matsumoto Plant and Shiojiri Plant. These bases utilized a total of 5,192 MWh of electricity in fiscal 2021, and it is expected that the switch from electricity derived from thermal power generation to CO_2-free electricity derived from hydroelectric power generation will reduce emissions by approximately 2,200 tons per year.

Our Relationship with Medical Professionals and Patients

▶ Material issue related to Kissei's business activities
Communication with medical professionals and patients

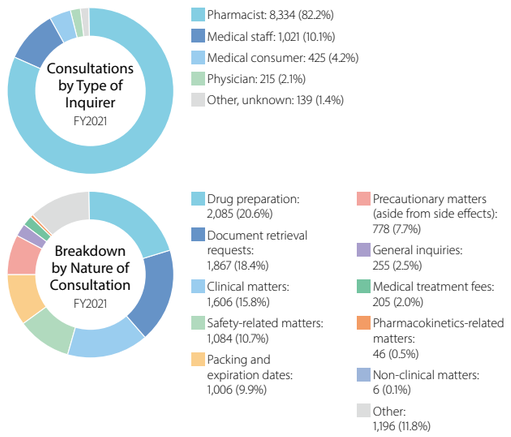
Collection and Appropriate Provision of Drug Information

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

Product Customer Service Center

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 2021, we responded to 10,134 such inquiries. In addition, we are working to build dedicated phone lines for TAVNEOS®, launched in June 2022 as a treatment for microscopic polyangiitis and granulomatosis with polyangiitis, and SAVENE®, a treatment for anthracycline extravasation. This step has been taken in anticipation of questions requiring expertise on rare diseases in the case of TAVNEOS®, and of urgent inquiries regarding SAVENE®.

▶ Consultations by Type of Inquirer and Nature of Consultation



Total inquiries in fiscal 2021: **10,134**

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.

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.

Its concept as a site is to help patients and their families enjoy living their daily lives. Accordingly, the site contains activity and diet-related content that can help improve the daily lives of patients. In addition, the site uses a Q&A format to give specific advice focused on the various situations that they may experience.

In August 2022, we launched a site dedicated to patients with ANCA-associated vasculitis. This site provides medically accurate information in an easy-to-understand manner to address the questions and concerns that arise when faced with unfamiliar illnesses.

These information websites provide an avenue for use to deliver information that is highly relevant to the lives of patients with these diseases and their families.

Relationships with Society

▶ Material issue related to Kissei's management base

Social contribution as a good corporate citizen

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 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 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 (1997–2021) are shown in the following table.

	Total number	Total amount of money
Kanzawa Medical Award	23	¥68 million
Research Grants	247	¥302 million
Overseas Study Grants	94	¥47 million

Number of Awards and Grants in Fiscal 2021

Kanzawa Medical Award

- Recipient: Associate Professor Osamu Hiraike
- Research Institution: The University of Tokyo Graduate School of Medicine, Department of Obstetrics and Gynecology
- Research Theme: A multifaceted approach to clarify anti-aging mechanisms in women

Research Grants: 10
Overseas Study Grants: 4

Contributions to Sports and Culture

Support for the Matsumoto Yamaga Football Club

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

The Matsumoto Yamaga Football Club was formed in Matsumoto City in 1965 and is currently a member of the Japan Professional Football League (J-League). 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 and 2021, the festival had to be canceled due to the spread of COVID-19 in Japan and overseas, but returned in 2022 to ring in its 30th year.

Kissei Pharmaceutical has supported the festival since its inception.

"The Marriage of Figaro" by Mozart (performed in 2022)
(Photo by Tsuyoshi Yamada)

Financial Review

Financial Position

Assets

For the fiscal year under review, ended March 31, 2022, total assets stood at ¥238,087 million, down ¥30,773 million from the previous consolidated fiscal year-end. Total current assets increased ¥6,376 million, to ¥99,342 million, mainly due to an increase in cash on hand, despite decreases in inventories and marketable securities. Total non-current assets were down ¥37,150 million, to ¥138,745 million, mainly reflecting a decrease in investment securities.

Liabilities

Total liabilities amounted to ¥35,907 million at the fiscal year-end, down ¥12,999 million from the previous consolidated fiscal year-end. Total current liabilities stood at ¥18,744 million, up ¥499 million, mainly due to an increase in income taxes payable, despite a decrease in notes and accounts payable. Total non-current liabilities were down ¥13,498 million, to ¥17,163 million, due to a decrease in deferred tax liabilities.

Shareholders' Equity

Total net assets amounted to ¥202,180 million at the consolidated fiscal year-end, a decrease of ¥17,773 million compared with the previous fiscal year-end. This increase mainly reflects a decline in net valuation difference on available-for-sale securities. As a result, the shareholders' equity ratio was 84.6%, up from 81.6% at the previous fiscal year-end.

Financial Results

Net sales for the fiscal year ended March 31, 2022, decreased 5.3% year on year, to ¥65,381 million, with segment sales of the Kissei Group's Pharmaceutical Business down 4.0%, to ¥54,147 million. We continued to provide drug information while taking care to prevent the spread of COVID-19. Net sales increased for products including Beova® Tablets, a treatment for overactive bladder, MINIRIN MELT® OD Tablets 25 μg and 50 μg, a treatment for nocturia due to nocturnal polyuria in males, and MINIRIN MELT® OD Tablets 60 μg, 120 μg, and 240 μg and DESMOPRESSIN formulations, treatments for nocturnal enuresis and central diabetes insipidus. However, overall net sales decreased mainly because of the impact of the NHI drug price revisions implemented in April 2021 and a decrease in export sales. UPASITA® IV Injection Syringes for the treatment of secondary hyperparathyroidism for which the Company concluded a co-promotion agreement in Japan with SANWA KAGAKU KENKYUSHO Co., Ltd., was launched by SANWA KAGAKU KENKYUSHO in August 2021. In addition, we launched CAROGRA® Tablets 120mg, a treatment for ulcerative colitis jointly developed by EA Pharma Co., Ltd., in May 2022, after the drug received manufacturing and marketing approval in March of the same year. In June 2022, we also launched TAVNEOS® Capsules 10 mg for the treatment of microscopic polyangiitis and granulomatosis with polyangiitis, for which the Company received marketing authorization approval in Japan in September 2021.

Sales to third parties of the Information Services Business were ¥7,742 million, a decrease of 8.8% year on year, sales to third parties of the Construction Business were ¥2,948 million, a decrease of 16.7% year on year, and sales to third parties of the Merchandising Business were ¥543 million, a decrease of 10.9% year on year. As a result of adopting the Accounting Standard for Revenue Recognition, etc., compared with the figures under the previous accounting standard, net sales of the Pharmaceutical Business decreased ¥456 million, net sales of the Information Services Business increased ¥96 million, net sales of the Construction Business increased ¥517 million, and net sales of the Merchandising Business decreased ¥363 million.

The cost of sales ratio saw a 0.4 percentage point decrease, and net sales declined 5.3% year on year. As a result, gross profit decreased ¥1,484 million, or 4.5% year on year, to ¥31,238 million.

In addition to the decline in net sales, selling, general and administrative expenses increased ¥1,423 million (4.6%) from the previous fiscal year, resulting in an operating loss of ¥1,402 million.

Ordinary profit fell 83.8% year on year, or ¥2,913 million, to ¥562 million.

Total extraordinary income rose ¥11,944 million due to higher gain on sale of investment securities.

As a result of the above, profit before income taxes and non-controlling interests was up ¥9,031 million, or 120.8% year on year, to ¥16,507 million, and profit attributable to owners of parent increased ¥7,636 million, or 144.5% year on year, to ¥12,921 million.

Basic Policy on the Distribution of Profits / 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 amount of the year-end cash dividend is decided at the General Meeting of Shareholders. 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. Share buyback and retirement are conducted with the primary intention of enhancing shareholder value, and are flexibly implemented when necessary for business development based on resolutions by the Board of Directors.

Kissei effectively utilizes its financial assets, including cross-shareholdings, to secure net income and fund aggressive spending on R&D (drug discovery research, milestone payments for existing research themes, introduction of new research themes, upgrading of R&D facilities, etc.), other IT strategic investments such as digital transformation (DX), and capital investments in production equipment, for example. The Company believes these investments will contribute to future profits and facilitate the proper allocation of profits to shareholders. Management has set a target for ROE of at least 5.0% based on profit attributable to owners of parent.

In the fiscal year under review, the Group made the decision 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. For the current fiscal year, the Group plans to pay an interim cash dividend of ¥40.0 per share and a year-end cash dividend of ¥40.0 per share, giving a full-year cash dividend of ¥80.0 per share.

Kissei's basic policy is to distribute a stable dividend while ensuring it has a business foundation for future growth.

Consolidated Balance Sheet

Kissei Pharmaceutical Co., Ltd., and its subsidiaries
At March 31, 2021 and 2022

	Millions of yen		Thousands of U.S. dollars
Assets	2021	**2022**	**2022**
Current Assets			
Cash and deposits	¥ 20,456	**¥ 30,013**	**$ 245,164**
Notes and accounts receivable - trade	23,058	**—**	**—**
Notes receivable - trade	—	**233**	**1,903**
Accounts receivable - trade	—	**21,723**	**177,446**
Contract assets	—	**850**	**6,943**
Securities	23,998	**23,139**	**189,013**
Merchandise and finished goods	11,066	**10,491**	**85,697**
Work in process	462	**63**	**515**
Raw materials and supplies	8,590	**8,433**	**68,886**
Other	5,332	**4,392**	**35,876**
Total current assets	92,965	**99,342**	**811,485**
Non-Current Assets			
Property, plant and equipment			
Buildings and structures	38,855	**39,132**	**319,654**
Accumulated depreciation	(29,991)	**(30,525)**	**(249,347)**
Buildings and structures, net	8,863	**8,607**	**70,307**
Land	12,622	**12,611**	**103,014**
Construction in progress	98	**—**	**—**
Other	16,820	**16,469**	**134,529**
Accumulated depreciation	(14,114)	**(13,613)**	**(111,199)**
Other, net	2,705	**2,856**	**23,330**
Total property, plant and equipment	24,290	**24,074**	**196,651**
Intangible Assets			
Software	1,175	**1,179**	**9,631**
Other	465	**389**	**3,178**
Total intangible assets	1,640	**1,569**	**12,817**
Investments and Other Assets			
Investment securities	138,133	**96,631**	**789,340**
Long-term loans receivable	14	**3**	**25**
Long-term prepaid expenses	10,262	**12,480**	**101,944**
Retirement benefit asset	—	**2,460**	**20,095**
Deferred tax assets	585	**524**	**4,280**
Other	1,002	**1,024**	**8,365**
Allowance for doubtful accounts	(34)	**(23)**	**(188)**
Total investments and other assets	149,964	**113,101**	**923,877**
Total non-current assets	175,895	**138,745**	**1,133,352**
Total assets	¥268,861	**¥238,087**	**$1,944,837**

	Millions of yen		Thousands of U.S. dollars
Liabilities	2021	**2022**	**2022**
Current Liabilities			
Notes and accounts payable - trade	¥ 7,909	**¥ 4,104**	**$ 33,524**
Short-term borrowings	1,743	**1,640**	**13,397**
Income taxes payable	1,487	**3,497**	**28,566**
Provision for bonuses	1,816	**1,707**	**13,944**
Provision for bonuses for directors (and other officers)	14	**14**	**114**
Provision for sales returns	6	**—**	**—**
Provision for sales rebates	320	**—**	**—**
Provision for sales promotion expenses	149	**137**	**1,119**
Contract liabilities	—	**2,696**	**22,023**
Other	4,796	**4,946**	**40,402**
Total current liabilities	18,245	**18,744**	**153,112**
Non-Current Liabilities			
Deferred tax liabilities	28,480	**16,259**	**132,813**
Provision for retirement benefits for directors (and other officers)	164	**181**	**1,479**
Retirement benefit liability	1,234	**—**	**—**
Asset retirement obligations	121	**138**	**1,127**
Other	660	**583**	**4,762**
Total non-current liabilities	30,662	**17,163**	**140,198**
Total liabilities	48,907	**35,907**	**293,310**
Net Assets			
Shareholders' equity			
Share capital	24,356	**24,356**	**198,954**
Capital surplus	24,226	**24,226**	**197,893**
Retained earnings	109,270	**118,183**	**965,390**
Treasury shares	(12,911)	**(12,912)**	**(105,473)**
Total shareholders' equity	144,941	**153,854**	**1,256,772**
Accumulated other comprehensive income			
Valuation difference on available-for-sale securities	74,351	**45,095**	**368,363**
Remeasurements of defined benefit plans	22	**2,435**	**19,891**
Total accumulated other comprehensive income	74,373	**47,531**	**388,262**
Non-controlling interests	638	**794**	**6,486**
Total net assets	219,953	**202,180**	**1,651,528**
Total liabilities and net assets	¥268,861	**¥238,087**	**$1,944,837**

Consolidated Statement of Income and Consolidated Statement of Comprehensive Income

Kissei Pharmaceutical Co., Ltd., and its subsidiaries
For the years ended March 31, 2021 and 2022

Consolidated Statement of Income

	Millions of yen		Thousands of U.S. dollars
	2021	2022	2022
Net Sales	¥69,044	**¥65,381**	**$534,071**
Cost of sales	36,322	**34,143**	**278,901**
Gross profit	32,722	**31,238**	**255,171**
Selling, General and Administrative Expenses	31,217	**32,640**	**266,623**
Operating profit and loss	1,505	**(1,402)**	**(11,452)**
Non-Operating Income			
Interest income	30	**42**	**343**
Dividend income	1,242	**1,544**	**12,612**
Gain on sale of securities	0	**—**	**—**
Gain on valuation of securities	720	**180**	**1,470**
Other	160	**325**	**2,655**
Total non-operating income	2,154	**2,092**	**17,089**
Non-Operating Expenses			
Interest expenses	23	**23**	**188**
Foreign exchange losses	130	**60**	**490**
Other	29	**44**	**359**
Total non-operating expenses	183	**127**	**1,037**
Ordinary Profit	3,476	**562**	**4,591**
Extraordinary Income			
Gain on sale of non-current assets	0	**0**	**0**
Gain on sale of investment securities	4,084	**16,601**	**135,607**
Other	3	**—**	**—**
Total extraordinary income	4,087	**16,601**	**135,607**
Extraordinary Losses			
Loss on sale of fixed non-current assets	—	**0**	**0**
Loss on disposal of non-current assets	10	**35**	**286**
Loss on sale of investment securities	—	**1**	**8**
Loss on valuation of investment securities	77	**619**	**5,056**
Total extraordinary losses	87	**656**	**5,359**
Profit before income taxes	7,476	**16,507**	**134,839**
Income taxes - current	1,510	**4,017**	**32,813**
Income taxes - deferred	587	**(542)**	**(4,427)**
Total income taxes	2,098	**3,475**	**28,386**
Profit	5,378	**13,032**	**106,453**
Profit Attributable to Non-Controlling Interests	93	**110**	**899**
Profit Attributable to Owners of Parent	¥ 5,285	**¥12,921**	**$105,546**

Consolidated Statement of Comprehensive Income

	Millions of yen		Thousands of U.S. dollars
	2021	2022	2022
Profit	¥ 5,378	**¥ 13,032**	**$ 106,453**
Other Comprehensive Income			
Valuation difference on available-for-sale securities	23,652	**(29,253)**	**(238,956)**
Remeasurements of defined benefit plans, net of tax	1,732	**2,456**	**20,062**
Total other comprehensive income	25,384	**(26,796)**	**(218,886)**
Comprehensive Income	¥30,762	**¥(13,764)**	**$(112,433)**
Comprehensive income attributable to			
Comprehensive income attributable to owners of parent	¥30,629	**¥(13,920)**	**$(113,707)**
Comprehensive income attributable to non-controlling interests	133	**156**	**1,274**

Consolidated Statement of Changes in Equity

Kissei Pharmaceutical Co., Ltd., and its subsidiaries
For the years ended March 31, 2021 and 2022

	Millions of yen									
	Shareholders' equity					Accumulated other comprehensive income				
	Share capital	Capital surplus	Retained earnings	Treasury shares	Total shareholders' equity	Valuation difference on available-for-sale securities	Remeasurements of retirement benefit plans	Total accumulated other comprehensive income	Non-controlling interests	Total net assets
Balance at April 1, 2020	¥24,356	¥24,226	¥106,461	¥(11,608)	¥143,435	¥ 50,706	¥(1,676)	¥ 49,029	¥504	¥192,970
Cumulative effects of changes in accounting policies										—
Restated balance	24,356	24,226	106,461	(11,608)	143,435	50,706	(1,676)	49,029	504	192,970
Changes during period										
Dividends of surplus			(2,475)		(2,475)					(2,475)
Profit attributable to owners of parent			5,285		5,285					5,285
Purchase of treasury shares				(1,303)	(1,303)					(1,303)
Disposal of treasury shares		(0)		0	0					0
Net changes in items other than shareholders' equity						23,645	1,699	25,344	133	25,477
Total changes during period	—	(0)	2,809	(1,303)	1,505	23,645	1,699	25,344	133	26,983
Balance at March 31, 2021	24,356	24,226	109,270	(12,911)	144,941	74,351	22	74,373	638	219,953
Cumulative effects of changes in accounting policies			**(1,472)**		**(1,472)**					**(1,472)**
Restated balance	**24,356**	**24,226**	**107,798**	**(12,911)**	**143,469**	**74,351**	**22**	**74,373**	**638**	**218,481**
Changes during period										
Dividends of surplus			**(2,536)**		**(2,536)**					**(2,536)**
Profit attributable to owners of parent			**12,921**		**12,921**					**12,921**
Purchase of treasury shares				**(0)**	**(0)**					**(0)**
Disposal of treasury shares		**0**		**0**	**0**					**0**
Net changes in items other than shareholders' equity						**(29,255)**	**2,413**	**(26,842)**	**156**	**(26,686)**
Total changes during period	—	**0**	**10,385**	**(0)**	**10,385**	**(29,255)**	**2,413**	**(26,842)**	**156**	**(16,300)**
Balance at March 31, 2022	**¥24,356**	**¥24,226**	**¥118,183**	**¥(12,912)**	**¥153,854**	**¥ 45,095**	**¥2,435**	**¥ 47,531**	**¥794**	**¥202,180**

	Thousands of U.S. dollars									
	Shareholders' equity					Accumulated other comprehensive income				
	Share capital	Capital surplus	Retained earnings	Treasury shares	Total shareholders' equity	Valuation difference on available-for-sale securities	Remeasurements of retirement benefit plans	Total accumulated other comprehensive income	Non-controlling interests	Total net assets
Balance at April 1, 2021	$198,954	$197,893	$892,583	$(105,465)	$1,183,965	$ 607,344	$ 180	$607,523	$5,212	$1,796,708
Cumulative effects of changes in accounting policies			**(12,024)**		**(12,024)**					**(12,024)**
Restated balance	**198,954**	**197,893**	**880,559**	**(105,465)**	**1,171,941**	**607,344**	**180**	**607,523**	**5,212**	**1,784,684**
Changes during period										
Dividends of surplus			**(20,716)**		**(20,716)**					**(20,716)**
Profit attributable to owners of parent			**105,546**		**105,546**					**105,546**
Purchase of treasury shares				**(0)**	**(0)**					**(0)**
Disposal of treasury shares		**0**		**0**	**0**					**0**
Net changes in items other than shareholders' equity						**(238,972)**	**19,711**	**(219,262)**	**1,274**	**(217,987)**
Total changes during period	—	**0**	**84,831**	**(0)**	**84,831**	**(238,972)**	**19,711**	**(219,262)**	**1,274**	**(133,148)**
Balance at March 31, 2022	**$198,954**	**$197,893**	**$965,390**	**$(105,473)**	**$1,256,772**	**$ 368,363**	**$19,891**	**$388,262**	**$6,486**	**$1,651,528**

Consolidated Statement of Cash Flows

Kissei Pharmaceutical Co., Ltd., and its subsidiaries
For the years ended March 31, 2021 and 2022

	Millions of yen		Thousands of U.S. dollars
	2021	2022	2022
Cash flows from operating activities			
Profit before income taxes	¥ 7,476	**¥16,507**	**$134,839**
Depreciation	3,148	**3,730**	**30,469**
Increase (decrease) in provisions	(12)	**(431)**	**(3,521)**
Increase (decrease) in retirement benefit liability	155	**(161)**	**(1,315)**
Interest and dividend income	(1,273)	**(1,586)**	**(12,955)**
Interest expenses	23	**23**	**188**
Loss (gain) on sale of securities	(0)	**—**	**—**
Loss (gain) on valuation of securities	(720)	**(180)**	**(1,470)**
Loss (gain) on sale of non-current assets	(0)	**0**	**0**
Loss on disposal of non-current assets	10	**35**	**286**
Loss (gain) on sale of investment securities	(4,084)	**(16,600)**	**(135,599)**
Loss (gain) on valuation of investment securities	77	**619**	**5,056**
Decrease (increase) in trade receivables	(3,595)	**—**	**—**
Decrease (increase) in trade receivables and contract assets	—	**250**	**2,042**
Decrease (increase) in inventories	(6,679)	**1,130**	**9,231**
Decrease (increase) in other current assets	(509)	**1,128**	**9,214**
Increase (decrease) in trade payables	2,671	**(3,804)**	**(31,073)**
Increase (decrease) in contract liabilities	—	**1,224**	**9,998**
Increase (decrease) in other current liabilities	279	**766**	**6,339**
Increase (decrease) in other non-current liabilities	4	**14**	**114**
Other, net	6	**(22)**	**(180)**
Subtotal	(3,024)	**2,644**	**21,598**
Interest and dividends received	1,157	**1,479**	**12,081**
Interest paid	(23)	**(23)**	**(188)**
Income taxes paid	(652)	**(2,567)**	**(20,969)**
Net cash provided by (used in) operating activities	(2,542)	**1,533**	**12,522**
Cash flows from investing activities			
Payments into time deposits	(78)	**(75)**	**(613)**
Proceeds from withdrawal of time deposits	78	**75**	**613**
Proceeds from withdrawal of investments in specified trusts	98	**97**	**792**
Purchase of property, plant and equipment	(931)	**(1,489)**	**(12,163)**
Proceeds from sale of property, plant and equipment	3	**23**	**188**
Purchase of intangible assets	(554)	**(430)**	**(3,512)**
Purchase of investment securities	(3,761)	**(5,682)**	**(46,414)**
Proceeds from sale and redemption of investment securities	4,551	**22,073**	**180,306**
Loan advances	(5)	**(3)**	**(25)**
Proceeds from collection of loans receivable	37	**25**	**204**
Purchase of long-term prepaid expenses	(8,822)	**(3,802)**	**(31,057)**
Other, net	54	**(34)**	**(278)**
Net cash provided by (used in) investing activities	(9,329)	**10,776**	**88,025**
Cash flows from financing activities			
Repayments of short-term borrowings	—	**(90)**	**(735)**
Repayments of long-term borrowings	(16)	**(13)**	**(106)**
Repayments of lease liabilities	(204)	**(115)**	**(939)**
Dividends paid	(2,475)	**(2,536)**	**(20,716)**
Purchase of treasury shares	(1,303)	**(0)**	**(0)**
Proceeds from sale of treasury shares	0	**0**	**0**
Net cash provided by (used in) financing activities	(4,000)	**(2,756)**	**(22,513)**
Effect of exchange rate change on cash and cash equivalents	0	**4**	**33**
Net increase (decrease) in cash and cash equivalents	(15,872)	**9,557**	**78,067**
Cash and cash equivalents at beginning of period	59,319	**43,447**	**354,901**
Cash and cash equivalents at end of period*1	¥ 43,447	**¥53,004**	**$432,968**

Corporate Information (As of March 31, 2022)

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: 1,399
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: 35

KISSEI COMTEC CO., LTD.
KIC Building, 4010-10, Wada, Matsumoto, Nagano 390-1293, Japan
Established: April 1985
Number of employees: 325

HASHIBA TECHNOS CO., LTD.
1-1, Hiratahigashi 2-chome, Matsumoto, Nagano 399-0014, Japan
Established: January 1955
Number of employees: 69

Investor Information

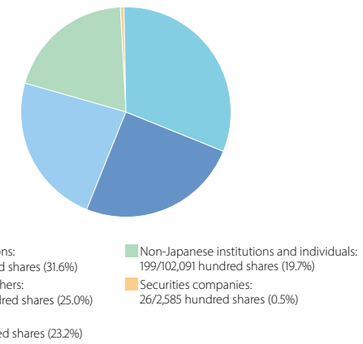
Stock Exchange Listing: Prime Market of the Tokyo Stock Exchange (As of April 4, 2022)
Stock Code: 4547
Common Stock: Authorized **227,000,000** shares Issued: **51,811,185** shares
Number of Shareholders: **3,986** (Decrease of 72 compared with previous fiscal year-end)

Principal Shareholders

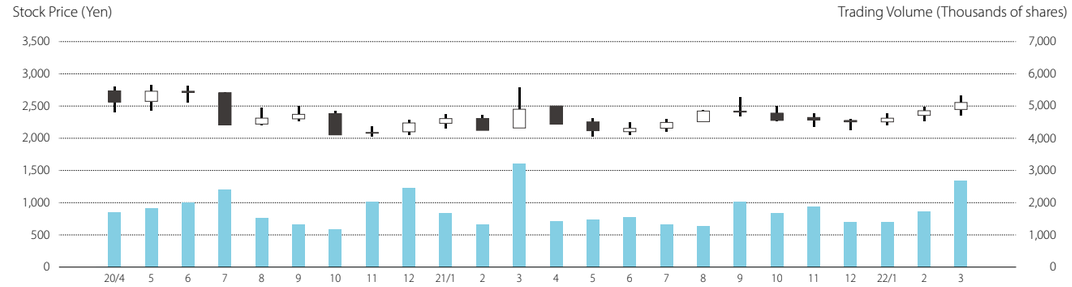
Name	Number of shares held (hundreds)	Voting rights (%)
The Master Trust Bank of Japan, Ltd. (Trust account)	46,278	10.0
The Dai-ichi Life Insurance Company, Limited	25,600	5.6
Custody Bank of Japan, Ltd. (Trust account)	25,585	5.5
The Hachijuni Bank, Ltd.	23,004	5.0
Kanzawa Limited	16,782	3.6
Mutsuo Kanzawa	15,421	3.3
NORTHERN TRUST CO. (AVFC) SUB A/C USL NON-TREATY	14,405	3.1
Kissei Group Employee Stockholders Committee	13,122	2.8
Nabelin Co., Ltd.	12,223	2.7
THE NAGANO BANK, LTD.	11,260	2.4

(Notes)
1. Kissei holds 5,695,353 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 shares.

Composition of Shareholders by Category



Stock Price Range / Trading Volume



KISSEI PHARMACEUTICAL CO., LTD.

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

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