

The KISSEI logo is displayed in a bold, white, sans-serif font. The background of the entire page is a photograph of a mountain valley with a river, overlaid with a blue geometric pattern of triangles and squares in the upper left corner.

KISSEI

Looking Towards Tomorrow's Health

Annual Report 2024

For the fiscal year ended March 31, 2024

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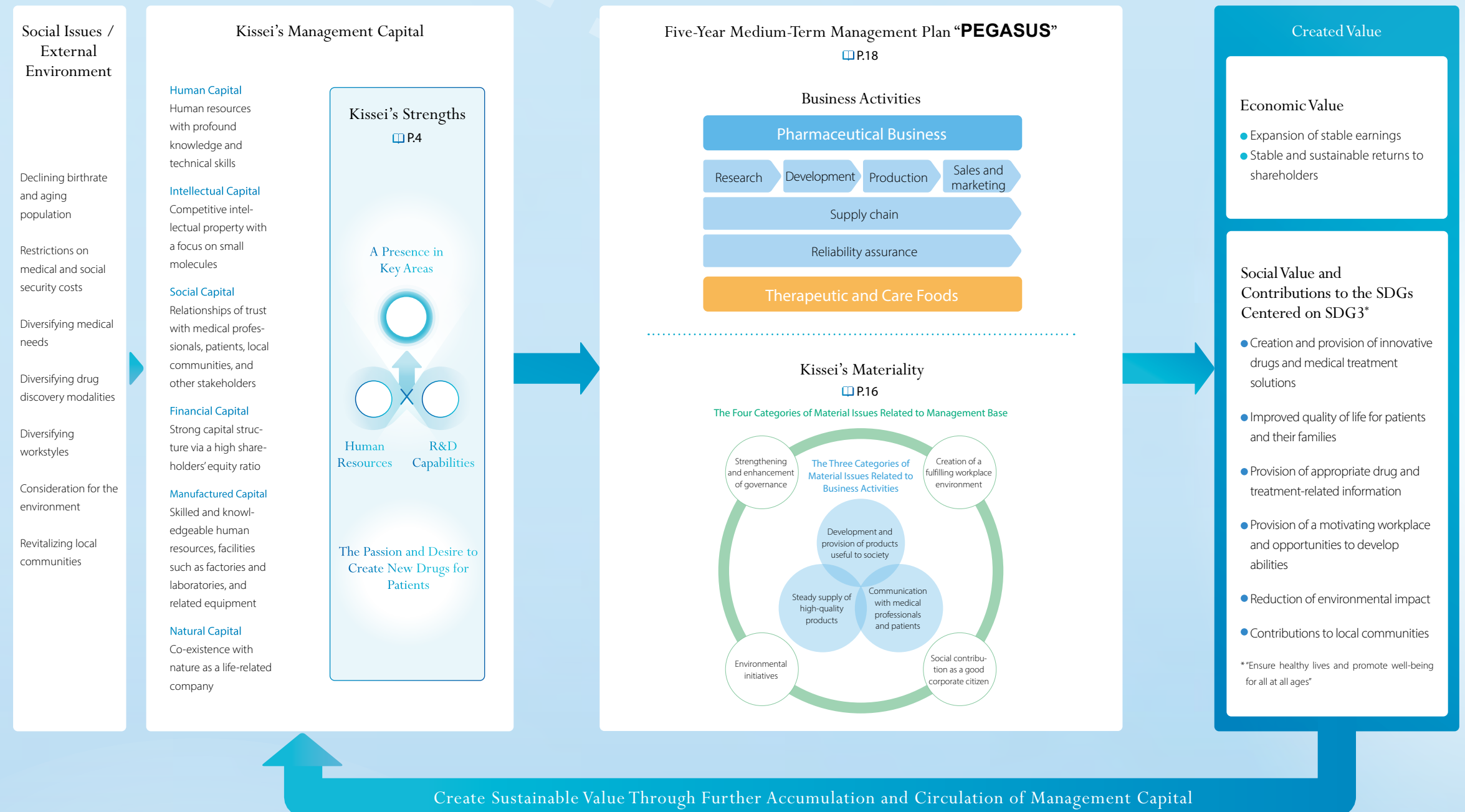
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Cautionary Notice
The financial forecasts, R&D plans, and other forward-looking statements that appear in this annual report are based on information available to the Company as of August 2024. For that reason, please be aware that actual results may 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

Since its founding, Kissei Pharmaceutical has aimed to provide a constant stream of new drugs, believing that “a pharmaceutical company cannot exist without R&D.”



Management Philosophy

Management Vision

Kissei Code of Conduct

- Contribute to society through high-quality, innovative pharmaceutical products
- Serve society through our employees
- We aim to be an R&D-oriented pharmaceutical company that contributes to the health of people around the world through innovative pharmaceutical products.
- 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.

The History of Kissei Pharmaceutical

1946 1980 1990 2000 2010 2020

Urology

1988
Launched MICTROL®, a treatment for urinary incontinence*²

Renal Diseases
and Dialysis

1992
Launched FRAGMIN®,
an anti-coagulant

Rare and Intractable Diseases

2014
Launched SAVENE®,
a treatment for anthracy-
cline extravasation

2017
Launched RECTABUL®,
a treatment for ulcerative
colitis*4

2022
Launched CAROGRA®, a treatment for ulcerative colitis
Launched TAVNEOS®, a treatment for MPA*5 and GPA*6

2023
Launched TAVALISSE®,
a treatment for
Chronic ITP*7

 Metabolism and Endocrinology

1991
Launched BEZATOL®,
a treatment for hyperlipidemia

1986
Launched UTEMERIN®, a treatment for threatened abortion and preterm labor.

1995
Launched RIZABEN® Eye Drops,
a treatment for allergic conjunctivitis

Other Areas

1961
Launched GASCON®,
a gastrointestinal anti-gas agent



1982
Launched RIZABEN®,
a treatment for allergic diseases



1988
Launched XANBON®,
a drug for improving
cerebral circulation*8

1992
Launched
DOMENAN®,
a treatment for
bronchial asthma

1999
Launched RYSMON® TG,
a treatment for
glaucoma and high
intraocular pressure

2005
Launched SALAGEN®,
a treatment for dry mouth symptoms

2011
Launched GLUBES® Combination Tablet,
a treatment for diabetes

2020
Began sales of MARIZEV®,
a treatment for diabetes

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

*2 Sales ended in 1991
*3 DESMOPRESSIN Intranasal, DESMOPRESSIN Spray, and DESMOPRESSIN Injection

*4 Co-promotion only from fiscal 2022

- *5 Microscopic polyangiitis
- *6 Granulomatosis with polyangitis
- *7 Idiopathic thrombocytopenic purpura
- *8 Manufacturing and sales ended in 2022

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 and amid a lack of pharmaceuticals and other resources. During the war, a Tokyo-based pharmaceutical manufacturer was evacuated to Matsumoto City, 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”

“A pharmaceutical company cannot exist without R&D.” It is this belief that drives Kissei Pharmaceutical to place such a focus on R&D, which it uses to support its ongoing challenge to provide patients with novel drugs.

Inspired by this challenge, in 1982, we launched RIZABEN®, a treatment for allergic diseases, and the first orally administered anti-allergic drug to serve as a bronchial 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 approximately 60 countries, including the United States.

We are currently placing an emphasis on rare and intractable diseases, which has resulted in the fiscal 2022 launch of CAROGR[®], a treatment for ulcerative colitis, and TAVNEOS[®], a treatment for microscopic polyangiitis and granulomatosis with polyangiitis, as well as the fiscal 2023 launches of TAVALLISSE[®], a treatment for chronic idiopathic thrombocytopenic purpura, and KORSIVA[®], a treatment for uremic pruritis in dialysis patients.

By promoting our five-year medium-term management plan “PEGASUS,” now in its final year, we will achieve sustainable growth for the Company and contribute to society as an R&D-oriented pharmaceutical company.

Kissei's Strengths

Kissei Pharmaceutical utilizes two key strengths in its efforts to manifest its Management Philosophy. These strengths are its **human resources**, who share the belief that “a pharmaceutical company cannot exist without R&D” and have an earnest drive to work for the sake of patients, and its **R&D capabilities**, as demonstrated in the Company's original and in-licensed products. Kissei has combined these strengths to establish **a presence in key areas** in which it possesses considerable know-how: urology, renal diseases and dialysis, and rare and intractable diseases.

Strength

Human Resources

The human resources at Kissei Pharmaceutical enjoy a deep-rooted camaraderie that comes from a shared belief in the Company's Management Philosophy and the idea that “a pharmaceutical company cannot exist without R&D,” as well as an earnest drive to work for the sake of patients. This creates a strong sense of unity as these human resources take part in the research, development, manufacturing, and sales of ethical drugs.

Sources of Strength

Unified Human Resources with an Earnest Drive

Our Research Division is concentrated in Azumino City, Nagano Prefecture, which enables a quick turnaround of our Design-Make-Test-Analyze cycle for compound synthesis, evaluation, and feedback during drug discovery research.

The Clinical Development Department has worked together to bring four products to market over the course of “**PEGASUS**” and continues to build know-how and experience through repeated NDA submission and approval.

We have also incorporated chemistry, manufacturing, and controls* (CMC) functions into the Pharmaceutical Technology Division, which was established in October 2023 and is responsible for managing and maintaining the manufacture and supply of items ranging from drug substances to marketed products. In total, this constitutes a product supply system that integrates research, development, and manufacturing.

* A series of processes required to create pharmaceutical products, including drug substances research, formulation research, quality assurance, and quality control

Medical Representatives Working with Academics and the Rare Diseases Project to Provide Information

Medical representatives (MRs) work with academics, who work at branch offices, and the Rare Diseases Project, which develops promotional strategies for drugs targeting rare diseases and provides information to medical experts. Together they provide information regarding rare disease treatments.

Human Resource Development

Our primary goal is to develop autonomous human resources. This refers to excellent human resources who are self-reliant and professional, possess high levels of expertise and originality, and can respond accurately and swiftly to changes in the operating environment. [P.43](#)

Results of the Human Resources Awareness Survey

Average score for engagement and job satisfaction: 3.28 (fiscal 2022) (4-point maximum) [P.43](#)

Message from a Development Chief



Takuma Uchiyama
Chief, Clinical Projects Management, Clinical Projects Management Department, Clinical Development Division

Turning Development Products into Pharmaceutical Products

I am the project manager for CG0070 (development code), a treatment for non-muscle invasive bladder cancer. During the pharmaceutical development stage, it is important to verify the efficacy and safety of a potential product through clinical trials and obtain data that proves a drug can meet medical needs. Our mission is to apply our passion for new drug development toward getting drugs approved, or, put more simply, to develop them into pharmaceutical products. Using the recent experience we have gained in getting NDA approvals for TAVNEOS®, TAVALLISSE®, and KORSUVA®, our goal is to get the same outcome for CG0070, and get it quickly.

A Presence in Key Areas



Human Resources



R&D Capabilities



The Passion and Desire to Create New Drugs for Patients

Magnifying Kissei's Strengths Through Synergy

A Presence in Key Areas

Kissei Pharmaceutical has a lineup of new drugs in key areas and provides information on new treatment options to patients and medical professionals.

Key Areas

Urology

We have a lineup of drugs for three conditions in the area of urology: overactive bladder, nocturia, and benign prostatic hyperplasia. Each drug has been positioned as a grade-A recommended treatment in the applicable clinical guidelines. Additionally, in the field of urology, we have the second-highest presence* in the category of “MRs requested by doctors.”

* Monthly Mix, February 2024 edition

Renal Diseases and Dialysis

We have been continuously releasing dialysis-related products in the area of renal diseases and dialysis for over 30 years, which has led to better dialysis treatments and has made it easier for patients to adhere to their treatment regimen. This long track record has made us a recognized name in the renal diseases and dialysis area, leading to relationships of trust with doctors and medical professionals.

Rare and Intractable Diseases

We offer new treatment options targeting designated rare and intractable diseases for which steroids are used as the primary treatment strategy in order to help solve the dilemma of choosing between the efficacy of steroids and facing the side effects.

Strength

R&D Capabilities

We conduct active R&D for original products with the intention of providing new drugs for patients suffering from illnesses. We also actively conduct R&D for products in-licensed from other companies.

Both of these R&D-based efforts allow us to create new drugs for patients.

Sources of Strength

Original Products

Since our founding, we have brought seven new original products to market. This achievement has not only cultivated a high level of expertise and technical skills among our researchers, but has also helped us create a development system that allows researchers to work as a unified whole to seamlessly generate and develop ideas.

In-Licensed Products

Using the knowledge we have gained in areas where we have launched original products, we have demonstrated a full spectrum of development capabilities from in-licensing to launch, with steady offerings of new, in-licensed drugs. We will continue to build a strong track record while improving our development capabilities to put us one step ahead when licensees look for a company to in-license their product.

Ratio of R&D expenses to sales

14.9%
(average from fiscal 2019 to fiscal 2023)

Percentage of employees engaged in R&D

21.5%
(as of March 31, 2024)

Letter from the CEO

To achieve our vision as an R&D-oriented pharmaceutical company, we will ramp up growth investment and continue to engage in constructive dialogue as we work toward sustainable growth and greater corporate value.

Mutsuo Kanzawa

Chairman and
Chief Executive Officer (CEO)



After spreading worldwide, COVID-19 was reclassified as a Class 5 infectious disease under the Infectious Diseases Control Law in May 2023. Although the pandemic caused major changes to the way we live our lives, we are finally getting back a sense of normalcy. COVID-19 has left an indelible mark on society. At the same time, it has taught us many valuable lessons and enabled society to take several leaps forward thanks to rapid advances in AI and information communications technology (ICT). With society primed for major changes in the future, I believe people's desire for good health will continue to increase.

Since its founding, Kissei has been dedicated to the research and development of new drugs, upholding its Management Philosophy to "contribute to society through high-quality, innovative pharmaceutical products" and "serve society through our employees" while charged by the belief that "a pharmaceutical company cannot exist without R&D." Although our social environment is still undergoing drastic change, our raison d'être is to contribute to the health of people around the world through the R&D of new drugs, regardless of the era. Kissei is a group of people united under its Management Philosophy and each of us has honed our respective expertise to move the R&D of original new drugs forward. Accordingly, we have made particularly large investments in drug discovery research. This will never change. We will further scale up our efforts toward open innovation, which include introducing AI drug discovery and other new technologies, and joint research. These actions will help us realize our Management Vision, to be "an R&D-oriented pharmaceutical company that contributes to the health of people around the world through innovative pharmaceutical products."

Fiscal 2024 marks the final year of "PEGASUS," our five-year medium-term management plan. To overcome the patent cliff of URIEF®, one of our original products, and establish a model for stable growth, we have adopted a growth strategy that involves the development and launch of new drugs. Under this strategy, we have launched several new drugs as planned in the area of rare and intractable diseases. I believe that being able to address unmet medical needs is a major milestone in terms of materializing our

Management Philosophy. The sales structure that we established ahead of launching these rare disease and intractable disease treatments is working as expected, and we will continue to focus on new drug development and take new steps to increase our presence in this field as well as primary care fields, such as urology and renal diseases and dialysis.

We are also working to enhance governance based on Japan's Corporate Governance Code out of the importance we place on our social responsibility to both improve corporate value and realize a sustainable society. The Board of Directors has established Kissei's Basic Stance on Sustainability and is actively working to address climate change-related issues and invest in human capital. We are working to develop diverse human resources and improve our working environment by taking on new information disclosure initiatives, such as supporting the recommendations put forth by the Task Force on Climate-Related Financial Disclosures (TCFD) and responding to the Carbon Disclosure Project's (CDP) climate change questionnaire. To these same ends, we have also thoroughly revised our human resource systems and training programs.

Furthermore, to ensure management mindful of both capital costs and share prices, we have set goals indicative of achieving our vision, namely ROE of 8% or more, P/B ratio of 1.0 or higher, and cross-shareholdings to net assets ratio of 10% or less. To hit these targets, we will ramp up investments toward future growth and work to improve return on capital. As we pursue these goals, we will continue to increase transparency and fairness of management by providing information in a timely and appropriate manner, engage in constructive dialogue with shareholders and investors, contribute to society, and strive for sustainable growth and greater corporate value.

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

August 2024

Mutsuo Kanzawa
Chairman and Chief Executive Officer

Letter from the COO

Having continuously launched novel drugs, Kissei Pharmaceutical will further enhance its new drug development capabilities through a virtuous cycle facilitating continuous growth as an indispensable pharmaceutical company.

Yasuo Takehana

President and
Chief Operating Officer (COO)



Continuously Delivering High-Quality, Innovative Pharmaceutical Products to Patients, Establishing a Position as an Indispensable Company

All Kissei Pharmaceutical employees work as one to develop business based on our Management Philosophy of “contributing to society through high-quality, innovative pharmaceutical products” and “serving society through our employees,” as well as our belief that “a pharmaceutical company cannot exist without R&D.” But what do we mean by high-quality, innovative pharmaceutical products? Only high-quality drugs with excellent efficacy and safety, provided in a stable manner and accompanied by high-quality information for proper usage, can be considered high-quality, innovative pharmaceutical products. We engage in new drug R&D activities with the desire to provide patients with high-quality, innovative pharmaceutical products that bring peace of mind and hope for the future.

This philosophy and belief is the intersection between what we want to do and what we can and must do, clearly indicating the way forward. Our unchanging mission is to provide patients

with high-quality, innovative pharmaceutical products, an ideal that has been inculcated in all employees who conduct business with a single-minded purpose—this is Kissei’s greatest strength. We will continue capitalizing on this strength to develop new drugs that meet unmet medical needs.

In the past two years, we have launched sales of four new drugs; CAROGRA® for ulcerative colitis, TAVNEOS® for microscopic polyangiitis and granulomatosis with polyangiitis, TAVALLISSE® for chronic idiopathic thrombocytopenic purpura, and KORSUVA® for pruritus in hemodialysis patients. Of these, three are treatments for rare and intractable diseases. Although KORSUVA® is not a rare disease drug, it is the first new pruritus treatment for dialysis patients in 14 years, offering a new treatment option to patients suffering from this condition.

Looking at our current R&D pipeline (□ P.33), readers will note that Kissei is currently developing drugs that patients need. Oncolytic immunotherapy CG0070 (development code) is a drug that makes it possible to provide bladder-preserving treatment for patients who would otherwise have to undergo total cystectomy in the event that existing treatments have failed. Furthermore, we were able to

develop gonadotropin-releasing hormone (GnRH) antagonist linzagolix (generic name) so that it can be used appropriately in Europe in line with patient needs and backgrounds. The Parkinson’s disease treatment drug KDT-3594 (development code) is expected to be a new best-in-class dopamine agonist that can reduce the risk of side effects associated with existing drugs. Although ulcerative colitis treatment KSP-0243 (development code) is in a field where many drugs have already been developed and released, we believe that it will be a drug that approaches inflammation with a new mechanism of action.

Efforts to expand our pipeline through proactive R&D investments and the ongoing launch of new drugs enabled us to overcome the patent cliff for dysuria treatment URIFEF®, which occurred in and after fiscal 2018. In continuing to bring valuable drugs to market, Kissei aims to become an indispensable pharmaceutical company in the pharmaceutical industry. Rather than being the “one and only,” we aim to become a pharmaceutical company that is extremely important and indispensable to society. To this end, my mission is to look five to ten years beyond “PEGASUS” and enhance corporate value by expanding domestic sales centered on new products and acquiring new overseas earnings, while building a robust pipeline comprising both original and in-licensed products.

Continuous New Drug Development Facilitates the Virtuous Cycle of R&D Capabilities

The purpose of pharmaceutical companies is to research, develop, manufacture, and sell new drugs. These four divisions are solidly supported by a foundation of indirect departments, including Quality Assurance, Business Development, Intellectual Property, Legal Affairs, Accounting, Human Resources, and General Affairs. Each of these roles is important, but I think the key to developing people and ensuring an organization and company grow stronger is the quantity and quality of the pipeline that runs through said organization.

Since joining Kissei in 1984, I have seen three periods of growth driven by our robust development pipeline. The first was over a period of 11 years from 1982 to 1992, when we launched seven products, including original products RIZABEN®, XANBON®, and DOMENAN®. The second time was over a period of four years from 2004 to 2007, when we launched three products, including original products GLUFAST® and URIFEF®. We sell URIFEF® in over 60 countries overseas, providing us with opportunities to gain experience in overseas expansion. With the launch of four new drugs, as well as the overactive bladder treatment drug Beova® and DESMOPRESSIN formulation MINIRINMELT®, I now see

“PEGASUS” as the third period of growth. In addition to acquiring knowledge in the new field of rare diseases, we were able to accumulate experience through our first participation in an international joint clinical trial, as well as through discussions and drug price negotiations with the Pharmaceuticals and Medical Devices Agency and the Ministry of Health, Labour and Welfare. In Europe, we also took over the development of linzagolix from a license and in the process of working with sales partners in preparation for the launch of sales, we also put in place a system that ensures we comply with European Good Manufacturing Practice (GMP) standards for the manufacture and supply of pharmaceutical products. The same applies to dealings with regulatory authorities in each country. Additionally, we improved the quality of information provided in Japan, particularly in the field of rare diseases.

In this way, by constantly taking on new challenges while researching, developing, manufacturing, and selling new drugs, we have gained a wealth of experience and incrementally improved our capabilities as a pharmaceutical company in a virtuous cycle. As our capabilities increase, our appeal to overseas pharmaceutical companies also increases, creating a virtuous cycle leading to new in-licensing negotiations. To accelerate the current virtuous cycle trajectory and lead to further growth, it is important we strengthen our pipeline and promote the development and enhancement of human resources who are able to maintain this momentum.

Achieved Record-High Sales in Fiscal 2023 While Also Focusing Efforts on Human Resource Development and Drug Discovery Processes Transformation

Despite positive developments for pharmaceutical companies in fiscal 2023, including the establishment of early launch premiums in line with NHI drug price revisions, the abolition of corporate requirements for price maintenance premiums, and the expansion of evaluation items for usefulness premiums, we believe the trend toward annual price revisions will remain unchanged. This means growth is impossible without continually launching new drugs amid ongoing challenges in the business environment. Companies are increasing resources in their in-licensed product evaluation departments and strengthening overseas bases, and competition over the acquisition of in-licensed products is expected to become even more intense going forward. In September 2023, we increased staff in the business development and in-licensed product departments and formed an in-licensed product review team that reports directly to the president as well as spans corporate planning, R&D, and business

development departments, as well as Kissei America, with the aim of building a pipeline to continuously bring to market both original and in-licensed products.

In terms of business performance, Beova® and four new drugs have achieved steady market penetration leading to record-high sales in fiscal 2023. Beova® has already established a presence as the number one overactive bladder treatment, with a 40.5%* market share. We aim to increase this to 50% going forward, achieving further growth in conjunction with joint marketing partner KYORIN Pharmaceutical Co., Ltd. TAVNEOS® is also achieving steady market penetration and we expect to reach our initial 2027 target of ¥9.0 billion ahead of schedule. TAVALISSE® has maintained a presence in the market even after restrictions on the duration of treatment were lifted in April 2024 and KORSUVA® has also gotten off to a good start, being adopted by approximately 50% of dialysis facilities within six months of its release. There is intense competition for CAROGRA® and, despite delays in adoption at target facilities, we plan to promote and expand its use by emphasizing its treatment position, which has been clarified in the treatment guidelines for ulcerative colitis. Although results exceeded targets in the domestic Pharmaceutical Business during fiscal 2023, we were unable to achieve our operating income target for overseas expansion due to a delay in obtaining milestone payments for the launch of linzagolix in Europe, which occurred later than originally planned. We expect this to contribute to higher profits going forward.

One of the challenges the company faced in fiscal 2023 was an inability to expand its pipeline with original and in-licensed products. In fiscal 2024, we plan to add one new theme to each pipeline. To maintain the virtuous cycle, it is essential we strengthen our pipeline in fiscal 2024.

In terms of original products, we are focused on three goals: exploring innovative drug discovery themes, shortening compound creation periods, and optimizing assessment systems. We are pursuing enhanced quality and speed in drug discovery research by dispatching researchers and introducing external systems such as SciBite for discovering innovative themes, Iktos, an AI system for compound creation, and KNIME for building evaluation systems. Although it will be some time before these efforts bear fruit, we have high hopes for the immediate outcome of a drug discovery project that is scheduled to begin clinical trials during fiscal 2024. We will continue to focus on bringing it to market as quickly as possible.

Fiscal 2023 was also the first year in which we introduced new human resource and education systems aimed at cultivating autonomous human resources. The personnel system introduced in fiscal 2022 allows for promotion based on ability, regardless of seniority, and has a self-application system in addition to applying through superiors. In fiscal 2023, many junior employees utilized the self-application system with the aim of becoming a section chief or

manager, and I was very encouraged to see that motivated employees were making effective use of these new systems to receive evaluations and promotions. I also attended training for manager-level staff who were promoted in the fall of 2023. I received feedback from employees who were passionate about their own career development and the growth of the organization and the company, and I felt that we had succeeded in introducing a beneficial personnel system.

Further, in October 2023, we undertook a major organizational restructuring, the first of its kind since Kissei's founding. To take on new challenges, such as developments in the rare disease field and licensing out linzagolix overseas, it was necessary for us to transform our organization and our way of thinking. To this end, we established a new organization called the Pharmaceuticals Technology Division, which is responsible for all CMC processes, from drug discovery to R&D, commercialization, and distribution (□ P.22). The aim is to respond quickly to increasingly strict regulations on distribution, as well as to issues that have become apparent throughout the industry, such as ensuring a stable supply, reducing costs, and complying with overseas GMP. Up to now, research and production were conducted separately, but going forward we intend to conduct research with an awareness of commercialization, transportation procedures, and management methods from the early stages of drug discovery to reduce costs and create drugs that are easy to handle. From the perspective of changing employee awareness, the Pharmaceuticals Technology Division is already functioning as expected, and I am looking forward to future developments.

Additionally, we have implemented organizational reforms in three related departments with the aim of strengthening compliance, sustainability initiatives, and reliability assurance. With regard to new products for rare diseases, having sufficiently prepared to commence sales, we established the Rare Disease Project in April 2021 as a specialized team handling rare diseases within the Sales and Marketing Division. Through the provision of appropriate information, we have been able to achieve steady market penetration.

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Aiming for sustainable growth, we will consider results in the final year of “PEGASUS” and the outlook for the next medium-term plan

Under “PEGASUS,” we promoted a growth strategy with four basic policies. Regarding the first point, increasing domestic sales, although the actual number of products launched was only four out of the targeted six, we expect sales in fiscal 2024 to reach a record high. With regard to the second policy aimed at

The Basic Policies of “PEGASUS”

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

strengthening the earnings base overseas, despite falling short of this objective due the withdrawal of our application for linzagolix approval in the United States and launch delays in Europe, we plan to launch linzagolix in Europe in fiscal 2024. In line with the third policy, expanding the development pipeline, we are moving forward with plans to add one in-licensed product and one new, original product to the pipeline. Regarding the fourth policy, strengthening our management base to cope with changes in the business environment, we will respond to requests from the Tokyo Stock Exchange and shareholders while promoting sustainability management.

In fiscal 2023, we were able to break out of two consecutive fiscal years of operating losses and get back on track for renewed growth. That being said, in fiscal 2024, the final year of “PEGASUS,” we do not expect to achieve our numerical targets of ¥87.0 billion in net sales and ¥9.0 billion in operating profit. This is due to delays in the overseas expansion of linzagolix, which we forecast at the start of “PEGASUS,” as well as proactive R&D investments made to acquire drivers of future growth.

During the next medium-term management plan period, we plan to launch linzagolix and CG0070 amid the ongoing introduction of new drugs that are needed in the domestic market. As almost all our current mainstay products, including four new drugs, have nearly 10 years left on their patent and sales exclusivity periods, we will continue to steadily expand our market share and aim to increase domestic pharmaceutical sales while launching new drugs under the next medium-term plan. We will continue to develop KDT-3594 and KSP-0243, add new development products to our pipeline, and create an environment enabling the continuous launch of new drugs going forward. In terms of overseas earnings, we will expand our earnings base by adding linzagolix alongside the dysuria treatment drug Silodosin, as well as by out-licensing Kissei products in other Asian countries as well as North America. I envision Kissei achieving sustainable growth driven by a combination of domestic and overseas earnings that increase the size and scale of the company.

In taking on many new challenges during “PEGASUS,” we were able to amass the capabilities needed to achieve further growth as a pharmaceutical company. In the next medium-term plan, we want to fully leverage these capabilities to make significant leaps forward.

Message to Shareholders

We take seriously the fact that our P/B ratio is below 1.0 as an objective assessment by the stock market. Board of Directors meetings were conducted with an awareness of capital costs and stock price, defining our vision as ROE of 8% or higher, P/B ratio of 1.0 or higher, and a ratio of cross-shareholdings to net assets of 10% or lower. To this end, we will first increase sales of Beova®, which is a growth driver in the Pharmaceuticals Business, as well as the sale of four new drugs, while increasing operating profit through the establishment of an overseas earnings base with linzagolix. In addition to cash generated by the Pharmaceuticals Business, cash generated by the effective use of financial assets and cash on hand will be invested in R&D, external systems, and joint developments, as we enhance the R&D pipeline to create future drivers of growth. We plan to provide an annual dividend of ¥90.0 per share in fiscal 2024, the 17th consecutive fiscal year of dividend increases, and are also considering flexible share buybacks. We will continue providing stable dividends and strive to enhance corporate value while firmly allocating capital entrusted to us by our shareholders to R&D, digital transformation, and capital investments.

Kissei will maintain efforts to research and develop new drugs and provide the medical field with the treatments it requires as we continue to grow with the aim of becoming an indispensable pharmaceutical company. As we take on this challenge, we ask our shareholders for their continued understanding and support.

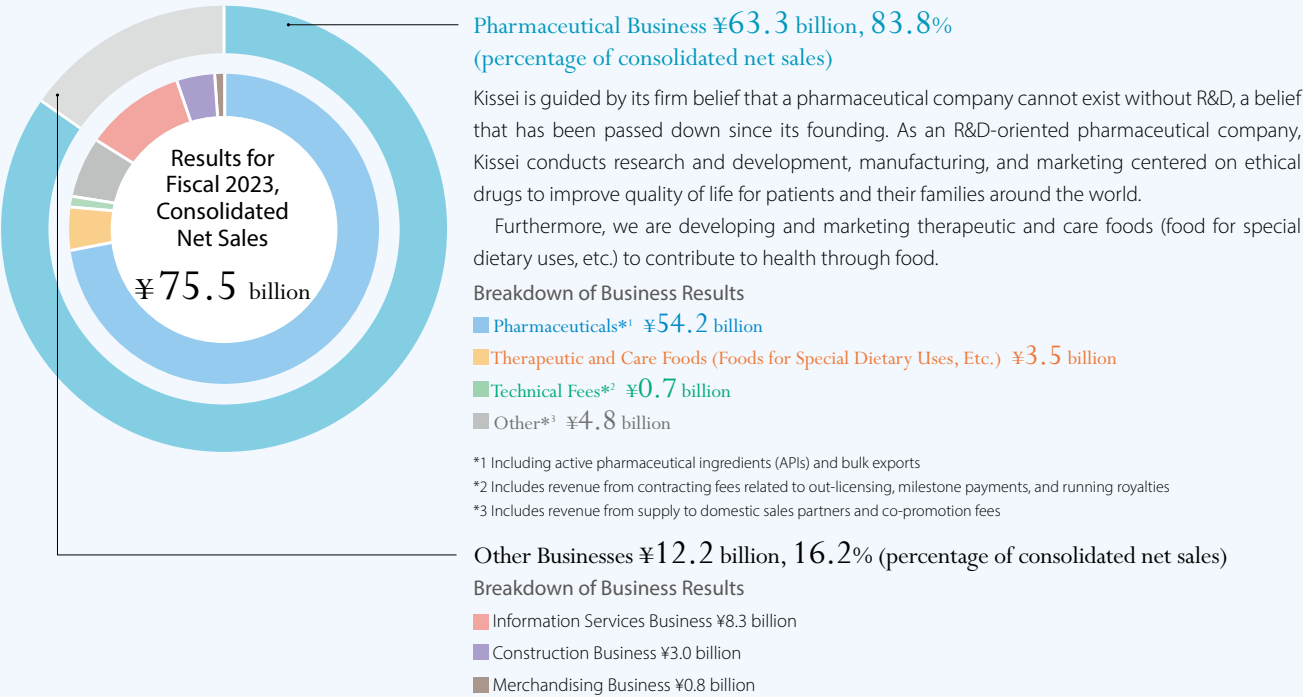
August 2024

Yasuo Takehana
President and Chief Operating Officer

Financial and Non-Financial Highlights

Financial Highlights (Kissei Pharmaceutical Co., Ltd. and its Consolidated Subsidiaries)

Business Portfolio



Message from the Chair of the Sustainability Promotion Committee



Sustainability Management That Can Adapt to Change, Create New Value, and Stay True to Tradition

Tetsu Takayama
Executive Managing Director in Charge of the Human Resources Department and General Administration Department, Chair of the Sustainability Promotion Committee

Kissei Pharmaceutical's Initiatives for a Sustainable Society

Our Management Philosophy, which implores us to “contribute to society through high-quality, innovative pharmaceutical products” and to “serve society through our employees,” captures our desire to create new drugs for patients currently without adequate treatments and our dedication to help the Earth, the place where we were born and raised, with our own hands.

Kissei’s environment conservation efforts have a long history, reaching back to the 1970s. One notable example is the Anada River Clean Up Association, an effort sparked by the Company that brought industry, government, and the community together to cleanse and beautify a local river, an effort that has continued for over half a century, to the present day.

Those of us at pharmaceutical companies work every day to contribute to people’s health. At the same time, we must not do anything that would adversely affect the Earth’s environment, the very source of life itself, or hinder people’s safety and prosperity. For companies, the realization of a sustainable society is an imperative responsibility and important issue that must be addressed continuously and from a long-term perspective, alongside the pursuit of sustainable corporate growth.

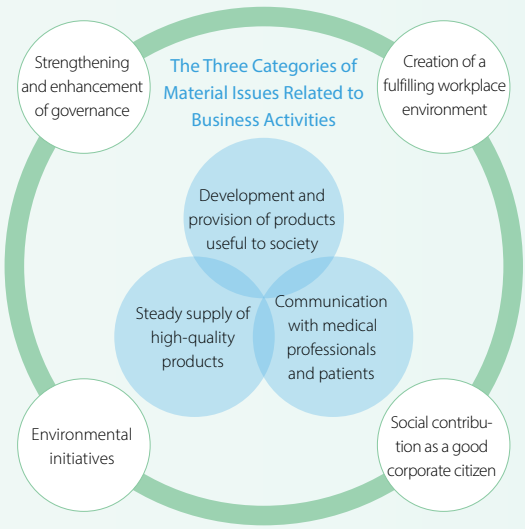
We have divided priority issues that the Company should address (material issues) into categories. Material issues related to Kissei’s business activities are categorized as the “development and provision of products useful to society,” which lies at the heart of an R&D-oriented pharmaceutical company, the “steady supply of high quality products,” to ensure products can reach patients, and “communication with medical professionals and patients,” to make sure these drugs are used properly. Furthermore, material issues related to Kissei’s management base—those which support business activities—are categorized as “strengthening and enhancement of governance,” “creation of a fulfilling workplace environment,” “environmental initiatives,” and “social contribution as a good corporate

citizen.” In total, we have identified 15 specific issues under these categories and are promoting a wide range of sustainability activities to address them.

At Kissei, both the passion for drug discovery and environmental conservation are realized and passed from person to person. People are the source of value creation, and the inner growth of each individual supports the growth of the Company. In addition to educational training, we consider social contribution activities to be important learning opportunities, be they environmental beautification activities, participation in science courses run with local governments, or otherwise.

While we must quickly adapt to today’s rapidly changing business environment, we will continue working as a united whole to create new value through sustainability management while cherishing the Kissei spirit rooted in tradition.

The Four Categories of Material Issues Related to Management Base



Basic Stance on Sustainability (Established August 1, 2023)

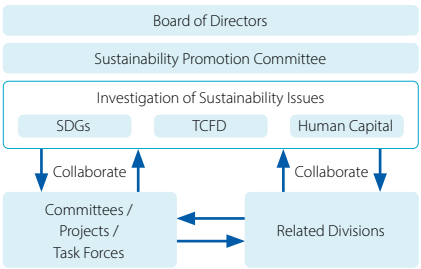
Kissei Pharmaceutical leverages our business activities to support the health of people around the world, resolve environmental and social issues, and promote environmental conservation. We draw inspiration from our Management Philosophy to “contribute to society through high-quality, innovative pharmaceutical products” and “serve society through our employees.” These efforts serve to realize a sustainable society while also increasing corporate value.

- We will contribute to the health and medical care of people around the world through innovative products (drugs and foods), which we will develop and provide proactively to achieve these goals.
- We understand that environmental issues are shared by all humankind and therefore dedicate ourselves to voluntarily and actively engaging in activities that protect the environment, whether in the form of climate change countermeasures or otherwise.
- We will respect the human rights of all people involved in our business activities and strive to create a rewarding workplace that respects the diversity, personality, and individuality of our employees.
- We will strengthen and enhance corporate governance, maintain fair and good relationships with stakeholders, and increase sustainable corporate value through highly ethical, transparent, and fair corporate activities.

Sustainability Promotion System (Governance)

Kissei’s sustainability activities are mainly promoted by the Sustainability Promotion Committee. The committee, which is chaired by a director well-versed in sustainability-related issues, is integrated into the Company’s corporate governance system, along with the Risk Management Committee and the Compliance Committee, all of which work closely with the Board of Directors as advisory bodies. **P.52**

This committee has a variety of sustainability-related roles, such as identifying material issues, setting KPIs for major initiatives, and confirming progress. At the same time, the committee collaborates with related departments to promote these initiatives. The details of these activities are reported to the Board of Directors and the Audit & Supervisory Board at least once every six months, with the activities in question managed and supervised by the Board of Directors.



Risk Management

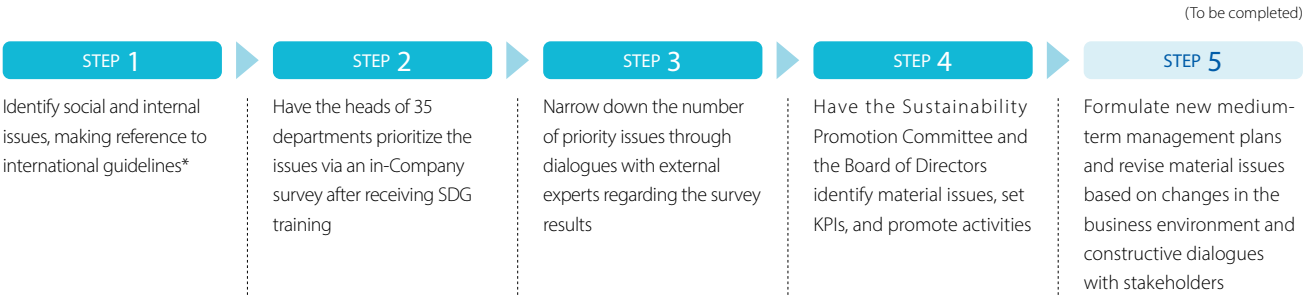
As part of its Risk Management Regulations, Kissei Pharmaceutical established the Basic Risk Management Policy and a risk management system covering the entire Kissei Group. In addition, the Company established the Risk Management Committee, which serves as an advisory body to the Board of Directors. Under the guidance of this committee, the Group’s risk management system is designed and monitored to prevent the occurrence of possible risks applicable to Kissei Pharmaceutical and Group companies. Other relevant advisory bodies to the Board of Directors include the Compliance Committee and the Sustainability Promotion Committee. The Compliance Committee implements the Group’s compliance program and works to ensure proper compliance is taking place.

Kissei has positioned sustainability-related risks as important management risks, and the risks identified by the Sustainability Promotion Committee are reviewed 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 implement countermeasures. The Sustainability Promotion Committee will discuss and report on the management status of these risks to the Board of Directors and the Risk Management Committee to integrate and promote comprehensive Companywide risk management.

Identifying Material Issues and Setting KPIs

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.

Potential targets and key performance indicators (KPIs) linked to the medium-term management plan “**PEGASUS**” are discussed by departments with relevance to each material issue. The Sustainability Promotion Committee examines the findings of these discussions and sets provisional KPIs and targets to be reported to the Board of Directors for final approval.



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

Progress in addressing each material issue is managed using corresponding KPIs. Fiscal 2023 results are listed below.

	Category	Material issues	Key initiatives	KPIs	Fiscal 2023 Results (as of March 31, 2024)
Material issues related to business activities	Development and provision of products useful to society P28-33, 38   	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 NDAs submitted/ number of NDAs approved)	- Domestic development (in-house): 8 themes, 2 new products, and 1 application - Overseas development (out-licensing): 5 themes, NDA for 1 theme
		Contribution to scientific technology	Joint research with academia and other pharmaceutical companies	Promotion of open innovation	Participating in AMED-sponsored industry-academia collaboration projects to develop a next-generation AI system for drug discovery and to build an innovative screening platform for DNA-encoded libraries (DELs)
	Steady supply of high-quality products P34, 35   	Quality control and steady supply and procurement	- Formulation and implementation of the “Stable Supply Manual” - Implementation of the Kissei Pharmaceutical Quality System	Number of months of inventory (by product)	Secured adequate inventory, despite limited shipping for some products
				- Progress toward developing a system to ensure a steady supply of high-quality pharmaceutical products - Zero recalls of pharmaceutical products - Complaint rate of 7.0ppm (parts per million) or less for food products	- Introduced a quality event management system - Investigated the construction of a new building for formulations to strengthen production system - Conducted regular risk assessments and implemented countermeasures related to raw materials, bearing in mind global situations and other factors - Pharmaceutical product recalls: 0 - Nutrition Division complaint rate: 1.32ppm
	Communication with medical professionals and patients P36, 37, 46  	Promotion of proper product usage (drugs, foods)	Promotion of activities to provide appropriate medical information	- Provision of appropriate science-based information - Construction of an efficient and effective system to provide information utilizing digital tools	- No issues identified in the monitoring of sales information provision activities for prescription drugs - Number of monitoring and material reviews: 1,742,525 (instances of inappropriate provision of information that lead to serious improper use or misuse: 0) - Began operations of the KISSEI Safety Link safety information system
		Improvement of customer satisfaction and provision of patient support	- Operation of the medicine consultation window - Operation of patient-oriented website	- Provision of information - Progress of website production	- Responses to telephone inquiries from patients: 342 - Enhanced existing patient-oriented website with 14 additional articles - Number of facilities registered in searchable database for medical institutions offering treatment for ANCA-associated vasculitis: 150 (39 facilities added in fiscal 2023)
Material issues related to management base	Strengthening and enhancement of governance P48-55 	Strengthening governance	Formulation and implementation of the Kissei Basic Policy on Corporate Governance	Appropriate responses to Japan's revised Corporate Governance Code	Complied with all principles required by Japan's revised Corporate Governance Code and disclosed them in the Corporate Governance Report
		Risk management	Creation of a risk management system	Appropriate review of risk management items and examination and implementation of appropriate countermeasures	The Risk Management Committee evaluated and confirmed the response status of 318 total risk items as reviewed by each department, and reported to the Board of Directors that they were being appropriately managed
			Development and update of disaster and pandemic countermeasures	Development and operation of business continuity management (BCM) and business continuity plan (BCP)	Implementing awareness-raising, education, training, etc. in accordance with the BCM Basic Policy and the BCM manual
	Creation of a fulfilling workplace environment P43-45   	Human resource cultivation	Implementation of rank-based training and job specific education	- Implementation status of rank-based training - Implementation of job specific education	- Education for new employees: 39 participants - Education for new division directors: 14 participants - Education for mid-level managers: 16 participants - Education for new managers: 29 participants - Basic education for management: 35 participants - Participants in the Research Division's Human Resources Development Program: 206 - Pharmaceutical English training (elective): 7 participants from the Clinical Development Division, 9 participants from the Quality, Safety and Regulatory Affairs Division - Specialized MR development education: 23 participants from the Sales and Marketing Division
			Establishment of interview system for skill and career development	Implementation of interview system for skill and career development	Interview-based skill and career development: 211 participants (employees who were promoted in fiscal 2023, executives who reached retirement age, etc.)
		Diversity and gender equality	Initiatives to cultivate the next generation	Percentage of employees taking childcare leave	Women: 100% Men: 62.0%
			Initiatives to promote the success of women	Ratio of average length of employment for female employees to average length of employment for male employees (70% or higher)	81.6%
		Enhancement of workplace environment	Recognition under the Certified Health & Productivity Management Outstanding Organizations Recognition Program	Recognition under the Certified Health & Productivity Management Outstanding Organizations Recognition Program	Recognized under the Certified Health & Productivity Management Outstanding Organizations Recognition Program (Large Enterprise Category)
			Promotion of work-life balance	Percentage of employees who took stress checks, percentage of employees who took commemorative leave	Percentage of employees who took stress checks: 97.2% Percentage of employees who took commemorative leave: 99.3%
			Occupational health and safety initiatives	Number of work-related accidents	Number of work-related accidents: 2 incidents (including 2 that required leave), analyzed the causes of each incident and implemented measures to prevent recurrence
	Environmental initiatives P40-42    	Waste management and resource recycling	Maintenance of environmental management systems	ISO 14001 recertification and maintenance	Maintained ISO 14001 certification (deemed to maintain compliance)
			Implementation of environmental conservation activities	Waste reduction, improvement of recycling rate, and final disposal rate reduction (improve rate 1% every fiscal year)	- Amount of waste: decreased 2.5% year on year Recycling rate: 91.2% (decreased 0.3% year on year) - Final disposal rate: 3.0% (improved 1.2% year on year)
		Initiatives toward biodiversity	Proper management of research and clinical trials that involve genetically modified organisms	Implementation status of proper research and clinical trials based on internal regulations, procedure manuals, and other guidance	- Number of Genetic Recombination Experiment Safety Committee meetings: 2 - Number of violations of laws / regulation: 0 - Number of deviations from procedural manuals: 3 - Number of accidents: 0 - Provided education and training for new staff, and provided regular education for researchers and purchasing staff
		Climate change countermeasures	- Continued reduction of CO₂ emissions - Promotion of energy-saving measures and climate change countermeasures	- Reduction of Scope 1 and 2 CO₂ emissions (fiscal 2030 target: 46% reduction compared with fiscal 2013) - Rate of renewable energy utilization (fiscal 2030 target: 74% or more of total electricity consumption) - Assessment of risks and opportunities associated with climate change	- Introduced a greater volume of Shinshu Green Electricity in areas under Chubu Electric Power Co. Ltd., jurisdiction; introduced Yorisou renewable energy in areas under the jurisdiction of Tohoku Electricity Power Co., Ltd. - Fiscal 2023 CO₂ emissions: 11,245 tons (39% reduction compared with fiscal 2013) - Fiscal 2023 ratio of renewable energy use: 77%
	Social contribution as a good corporate citizen P47  	Participation in social contribution activities	- Contribution to culture, the arts, and sports - Relief for natural disasters	Number of sponsorships and donations that contribute to society and local communities	Number of sponsorships / donations: 49
			Participation in local cleanup activities, and offering of factory and research institute tours	Number of social contribution activities by region	Cleaning activities around the company, river cleanup, environmental law training with local students, etc.

Five-Year Medium-Term Management Plan “PEGASUS”

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

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

At its core, the growth strategy under the five-year medium-term management plan, “PEGASUS,” aims to overcome the patent cliff facing Urief® and transition to a new growth phase by successively launching new products in Japan while building a new earnings base overseas with original product linzagolix (generic name).

In terms of domestic pharmaceutical products, during the five years covered by the plan, in addition to MINIRIN MELT® and MARIZEV® that were launched in April 2020, we launched TAVNEOS® and CAROGRA® in fiscal 2022 and TAVALISSE® and KORSUVA® in fiscal 2023. In fiscal 2023, the fourth year of “PEGASUS,” alongside the sales expansion of Beova® in the field of urology, four new products were launched in or after fiscal 2022—mainly in the field of rare and intractable diseases. These became powerful drivers of growth and overcame the patent cliff facing Urief®, thereby achieving record-high sales. In fiscal 2024, the final year of the plan, we aim to further expand new product sales in order to surpass fiscal 2023 earnings.

With regard to development themes, we are currently carrying out the global Phase III clinical trial of CG0070 (development code) and the Phase III clinical trial of linzagolix for uterine fibroids.

In the Nutrition Division, we are working to rebuild our business and earnings bases centered on new product by establishing a system enabling us to continuously launch innovative new products that contribute to society and help maintain and improve people's health through high-value-added therapeutic and care foods.

⑤ Status of Product Launches and Products Submitted for Approval Under the Medium-Term Management Plan “PEGASUS”

	Rare and Intractable Diseases					Renal Diseases and Dialysis
	TAVNEOS**	TAVALISSE**	CG0070 (development code)	Rovatiirelin (generic name)	CAROGRA®	KORSUVA®
	Microscopic polyangiitis and granulomatosis with polyangiitis	Chronic idiopathic thrombocytopenic purpura	Non-muscle invasive bladder cancer	Spinocerebellar ataxia	Ulcerative colitis	Pruritus in hemodialysis patients
Fiscal 2020						
Fiscal 2021	Approved			NDA application	Approved	
Fiscal 2022	Sales launched	Approved			Sales launched	
Fiscal 2023		Sales launched		NDA withdrawal		Approved and sales launched
Fiscal 2024			Global Phase III clinical trial (drug treatment stage)	Possibility of conducting additional clinical trials is being considered		

Notes: 1. Blue text: Designated as an intractable diseases / *: Designated as an orphan drug
2. New drug development status, please refer to P.33.

2. Strengthen earnings base overseas

- 1 Establish new overseas earnings for our original product linzagolix

2 Out-license new drugs

Having obtained NDA approval to launch linzagolix in Europe in June 2022, partner company Theramex HQ UK Limited is making preparations to commence sales in the region during fiscal 2024 under the name Yselty®.

Additionally, we are strengthening our overseas earnings base by promoting the out-licensing of original products and in-licensed products, while securing 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

Under “PEGASUS,” Kissei will leverage its strength in medical chemistry* to promote small molecule drug discovery research, expand in-licensing of competitive themes, and optimize its development pipeline. Additionally, we plan to introduce new development themes through in-licensing and commence original product clinical trials in fiscal 2024.

* A research method for obtaining candidate compounds by establishing a screening system for receptors and other treatment targets, identifying chemical structures that act on these targets using a large number of compounds, then utilizing the large amount of data obtained to design, synthesize, and evaluate compounds that are most suitable for pharmaceutical products

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 activities and the SDGs

Through the successful execution of “PEGASUS,” we will fulfill our social responsibilities and realize sustainable growth as an R&D-oriented company with a clear raison d’etre. In October 2023, we achieved the following functional enhancements through organizational changes aimed at strengthening our management foundation.

- Integrated and reorganized chemistry, manufacturing, and control as well as supply chain functions while establishing a Pharmaceuticals Technology Division (P.22) responsible for all aspects of pharmaceutical manufacturing, from active pharmaceutical ingredients to the supply, maintenance, and management of commercially available products
- Reorganized existing departments into a four-department structure (reliability assurance, quality assurance, safety information, and product information) as an organization responsible for management and assurance functions represented by the three-role structure of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Pharmaceuticals and Medical Devices Act) while conducting activities aimed at providing materials and information on quality and safety assurance as well as on proper usage in research, development, drug applications, and sales
- Established a Legal Compliance Office in the Legal Department to strengthen compliance with various laws and regulations
- Established a Sustainability Management Office in the General Administration Department to strengthen sustainability activities and disclose information

⑤ “PEGASUS” Performance and Final Fiscal Year (Fiscal 2024) Forecast and Targets

	Fiscal 2020	Fiscal 2021	Fiscal 2022	Fiscal 2023	Fiscal 2024 forecast	Final Year Targets
Consolidated net sales	¥69.0 billion	¥65.3 billion	¥67.4 billion	¥75.5 billion	¥83.0 billion	¥87.0 billion or higher
Net sales for the Pharmaceutical Business	¥56.4 billion	¥54.1 billion	¥56.2 billion	¥63.3 billion	¥70.5 billion	¥75.0 billion or higher
Pharmaceuticals*1	¥48.1 billion	¥45.7 billion	¥47.0 billion	¥54.2 billion	¥60.0 billion	¥62.5 billion or higher
Therapeutic and care foods	¥3.7 billion	¥3.5 billion	¥3.4 billion	¥3.5 billion	¥3.6 billion	¥4.5 billion or higher
Technical fees*2	¥0.8 billion	¥0.5 billion	¥1.0 billion	¥0.7 billion	¥2.1 billion	¥8.0 billion or higher*4
Other*3	¥3.6 billion	¥4.2 billion	¥4.6 billion	¥4.8 billion	¥4.8 billion	
Consolidated operating profit (loss)	¥1.5 billion	¥(1.4 billion)	¥(1.1 billion)	¥4.0 billion	¥4.2 billion	¥9.0 billion or higher
R&D expenses	¥9.6 billion	¥10.3 billion	¥10.3 billion	¥9.4 billion	¥12.0 billion	¥13.0 billion
ROE	2.6%	6.1%	5.3%	5.4%	5.0% or higher	5.0% or higher

*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 other combined

In the final year of “PEGASUS,” we will build upon our achievements to date, bring the plan to a successful conclusion, and take the first steps toward further growth. However, due to delays in the overseas launch of linzagolix and R&D investments aimed at acquiring future growth drivers, which include the introduction of new development themes and the commencement of clinical trials for new products, we expect to fall short of the plan's fiscal 2024 numerical targets. Nevertheless, we will double our efforts to increase domestic pharmaceutical product sales, acquire overseas earnings, and expand our development pipeline to achieve sustainable growth.

Message from the CFO



Optimal Allocation of Management Resources and Maximization of Corporate Value

Business performance is steadily improving in line with growth in the domestic pharmaceutical business centered on new products and with the acceleration of overseas business expansion through out-licensing.

Under these conditions, to achieve further growth and realize our Management Vision, “to be an R&D-oriented pharmaceutical company that contributes to the health of people around the world through innovative pharmaceutical products,” we will optimally allocate various management resources in line with changes in the business environment and execute effective financial strategies to maximize corporate value.

Takahide Kitahara
Managing Director, Department Manager of Corporate Finance and Management Department and CFO

Basic Approach

The Company’s financial strategy is based on maintaining a balance between prioritizing growth investment and ensuring the stable, ongoing provision of dividends to shareholders, with the aim of enhancing corporate value. In implementing financial strategies, we will place an even greater emphasis on balance sheet management and work to further improve return on capital.

First, in terms of investment aimed at achieving our growth strategy, which is our top priority, we will make R&D investment in AI-driven drug discovery and other drug discovery research, new in-licensing themes, the development and promotion of clinical themes, and R&D equipment improvements, thereby expanding our R&D pipeline. Furthermore, we will proactively develop and enhance strategic investment in ICT, including digital transformation and capital investment in production equipment and other assets.

Furthermore, regarding shareholder returns, we aim for a dividend payout ratio of 40% or higher and will continue to flexibly acquire treasury shares.

The sources of cash for investment will come from cash flows from operating activities, funds obtained from the sale of investment securities, regardless of whether they are cross-shareholdings or pure investment shareholdings, and cash on hand.

Basic Policy on the Distribution of Profits

Our basic policy is to ensure a solid management base for the future while continuing to provide stable dividends. In fiscal 2023, the Company paid a full-year dividend of ¥82.0 per share, comprising an interim dividend of ¥41.0 per share and a year-end dividend of ¥41.0 per share. After comprehensively considering the purchase of treasury shares in fiscal 2024 and the target dividend payout ratio of 40% or higher, in fiscal 2024, we plan to pay a full-year dividend of ¥90.0 per share, comprising an interim dividend of ¥45.0 per share and a year-end dividend of ¥45.0 per share. Succeeding in this regard will mark the 17th consecutive year of dividend increases.

The acquisition, disposal, and cancellation of treasury shares will be executed flexibly in accordance with business developments based on a resolution by the Board of Directors, with the primary consideration being the enhancement of shareholder value.

Cash Allocation

Cash allocation under the “PEGASUS” five-year medium-term management plan is as follows.

Cash in (sources of capital)	Cash out (investment)
Cash flows from operating activities (before R&D expenses) ¥55.0 billion	R&D Drug discovery ¥33.0 billion
Financial assets (reduction of cross-shareholdings) ¥65.0 billion	R&D In-licensing ¥43.0 billion
Cash on hand ¥4.0 billion or higher	ICT investment ¥13.0 billion
	Investment in production facilities and other investments ¥12.0 billion
	Stable dividends Share buyback ¥23.0 billion or higher
Total ¥124.0 billion or higher	Total ¥124.0 billion or higher

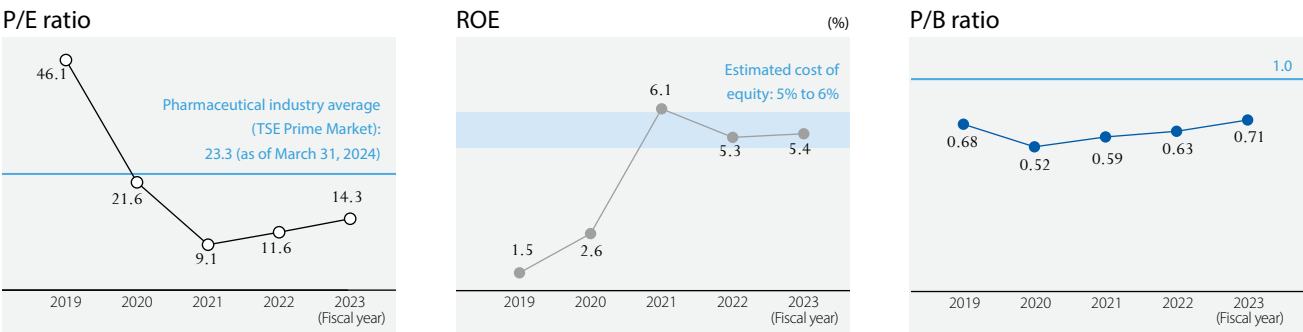
Action to Implement Management that is Conscious of Cost of Capital and Stock Price

In addition to creating sustainable value as an R&D-oriented pharmaceutical company, we are making efforts to increase return on capital, with a greater awareness of capital costs and share price, targeting an ideal financial position comprising return on equity (ROE) of 8% or higher, a price-to-book ratio (P/B ratio) of 1 or higher, and a cross-shareholdings to net assets ratio of 10% or lower.

- Vision
- Create sustainable value as an R&D-oriented pharmaceutical company

ROE of 8% or higher, P/B ratio of 1 or higher, and a cross-shareholdings to net assets ratio of 10% or lower

Current Situation Analysis and Issues



Asymmetric Information
Providing Information to Support Growth Strategies

Although our P/B ratio bottomed out in fiscal 2020 and has since been on an upward trend, it remains below 1. A contributing factor may be that, as of March 31, 2024, our P/E ratio is below 23.3, the average for the pharmaceutical industry on the Prime Market segment of the Tokyo Stock Exchange, which we suspect is because shareholders have low expectations for Kissei's growth. One of the challenges we face is to eliminate information asymmetry by providing more specific and effective information that supports the feasibility of our growth strategy.

Profitability of Core Business
Deviation From Shareholders' Expected Return on Capital

Since fiscal 2021, ROE has remained in line with our estimated cost of equity of 5% to 6%, but we cannot deny the possibility that ROE has yet to reach the level sought by shareholders. In terms of operating profit, despite a temporary decline in performance, with new products as growth drivers, we have recovered to a point where we can sense the trend shifting toward a growth phase. Going forward, our task will be to further enhance profitability in the Pharmaceutical Business, the Kissei Group's core business, to achieve the return on capital that shareholders expect.

Capital Policy
Increase in Shareholders' Equity Mainly from Financial Assets

An analysis of the balance sheet shows that shareholders' equity is on the rise due to unrealized gains on investment securities and an increase in retained earnings, which are affecting return on capital. Going forward, we need to implement a capital policy that appropriately controls shareholders' equity.

Initiatives for the next three to five years (Fiscal 2025 and beyond)

Policies		
- Formulate investment policies that support growth strategy - Conduct IR activities to publicize growth strategy	- Increase medium- to long-term profit levels - Emphasize return on capital target	- Continue to provide stable dividends - Acquire treasury shares with the primary goal of increasing shareholder value - Reduce cross-shareholdings
Details		
- Clear disclosure of cash allocation - Consideration into and holding of R&D meetings	- Expansion of the market for new drugs and the R&D pipeline - Gradual improvement of ROE (from 6% to 8%)	- Dividend payout ratio of 40% or higher - Flexible share buybacks (ongoing) 30% decrease in cross-shareholdings compared to market price as of March 31, 2023 (decrease of ¥10,560 million)

Improve P/E Ratio

Improve ROE

Improve P/B ratio

The Newly Established Pharmaceutical Technology Division

Realizing Consistent Manufacturing Based on the Same Goals and Values

Organizational changes executed on October 1, 2023, included the establishment of the Pharmaceutical Technology Division. This new division integrates the CMC Research Department—which, as part of the Research Division, has hitherto been responsible for active pharmaceutical ingredient and formulation research, quality assurance, and other activities—and the Pharmaceutical Manufacturing Division, which has been engaged in manufacturing and logistics. With all employees involved in production sharing the same values with regard to the quality and cost of drug substances and formulations, we have strengthened and rebuilt a system that facilitates consistent manufacturing.

Message from the Pharmaceutical Technology Division Director



Tsuyoshi Naganuma
Executive Officer, Pharmaceutical Technology
Division Director

Kissei Pharmaceutical is an R&D-oriented pharmaceutical products manufacturer that positions manufacturing at the core of its business activities. The Pharmaceutical Technology Division was established as an organization responsible for consistent manufacturing activities from initial R&D to the manufacture and supply of commercially available products.

More than simply making products, manufacturing involves devising new development methods, adding new value, and incorporating better services into product manufacturing processes. Furthermore, as a company involved in making pharmaceutical products, Kissei complies with Good Manufacturing Practice (GMP) regulations in the course of its manufacturing activities, facilitates the stable supply of pharmaceutical products of suitable quality in required quantities at all times, and pursues productivity enhancements that prevent loss or waste in the manufacture of pharmaceutical products. Accordingly, we believe it is important that everyone involved in manufacturing shares the same values and design and manufactures and supplies products based on a consistent philosophy.

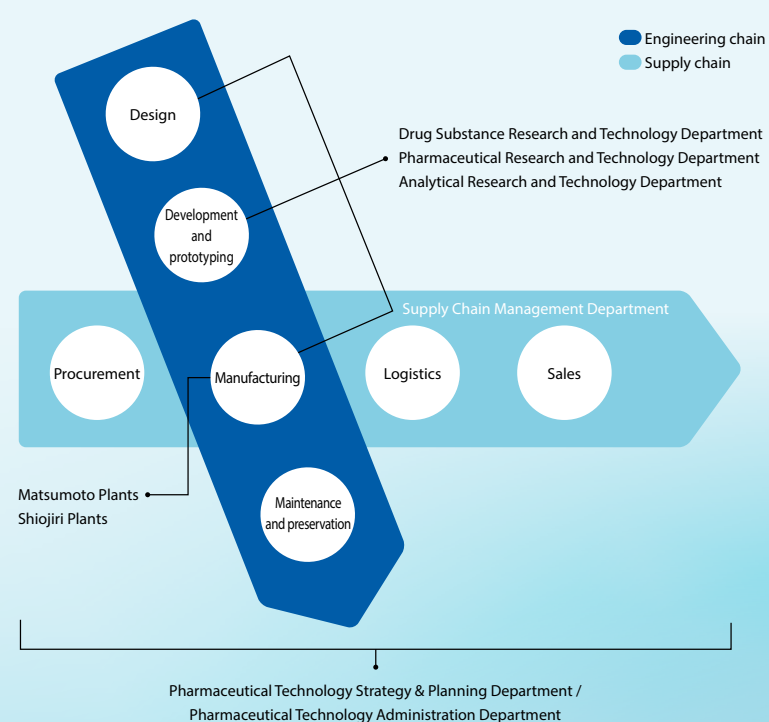
The Pharmaceutical Technology Division is a large organization comprising eight departments separated by function. Accordingly, the question “what is our mission?” will always be our starting point as we align department vectors and contribute to society through the appropriate discovery, creation, manufacture, and stable supply of pharmaceutical products based on broad perspectives and marketing, thereby achieving product realization.

The Future of Kissei's Pharmaceutical Manufacturing

Pharmaceutical manufacturing can be broadly divided into two flows; the engineering chain and the supply chain.

The engineering chain involves the so-called manufacturing flow, which covers pharmaceutical product design, manufacturing processes, equipment, development and prototyping, actual manufacturing, maintenance, and preservation. The supply chain, meanwhile, involves the flow of goods, encompassing the process from raw materials procurement to manufacturing, logistics, sales, and finally the delivery of pharmaceutical products to patients.

The Pharmaceutical Technology Division will be solely responsible for both of these flows, realizing consistent manufacturing in the process.



Interview

The Current State and Future of the Pharmaceutical Technology Division



Nobuyuki Isshiki
Senior Director, Pharmaceutical Technology Strategy
& Planning Department
Pharmaceutical Technology Division



Mitsuaki Aizawa
Senior Director, Pharmaceutical Technology
Administration Department
Pharmaceutical Technology Division

This section features an interview with the senior directors of the Pharmaceutical Technology Strategy & Planning Department and the Pharmaceutical Technology Administration Department, who are responsible for the overall management of the Pharmaceutical Technology Division, with regard to the purpose of its establishment, the business it will engage in, and its future prospects.

The Engineering Chain and the Supply Chain The Two Missions of the Pharmaceutical Technology Division

Scope of Activities of the Pharmaceutical Technology Strategy & Planning Department and Pharmaceutical Technology Administration Department

Isshiki The Pharmaceutical Technology Strategy & Planning Department is a new entity established within the Pharmaceutical Technology Division. The department leads manufacturing and is responsible for the total management of the product

life cycle, from initial research to discontinuation of sales.

When hearing the term “pharmaceutical product research,” one might assume this means “drug discovery research,” similar to the discovery and synthesis of compounds carried out by the Research Division. However, the research conducted by the Pharmaceuticals Division focuses mainly on chemistry, manufacturing, and control (CMC) research. CMC refers to a series of processes involving

everything from research on active pharmaceutical ingredients and formulations to quality control.

Specifically, CMC research primarily involves mass-producing compounds created by the Research Division, designing easy-to-use products for patients and medical professionals, examining methods for evaluating whether product quality is appropriate, and establishing methods for stable product manufacturing. This is nothing less than research into manufacturing.

This manufacturing flow, which includes formulation design, quality control, and production, is referred to as the engineering chain.

Aizawa As the Pharmaceutical Technology Division's overall back-office function supporting manufacturing, the Pharmaceutical Technology Administration Department is responsible for facility management, operational support, and employee development at plants and laboratories.

In addition to the engineering chain, the Pharmaceutical Technology Division comprises supply chain workflows. As many would imagine, the supply chain is a series of workflows that procure pharmaceutical raw materials, manufacture them at plants, and, ultimately, deliver products. We strive to improve productivity through reviews of the efficiency of procurement and manufacturing activities and related costs, and our role is to create manufacturing and logistics systems able to reliably deliver pharmaceutical products to patients, even in times of emergency.

Under the Key Words “Seamlessness” and “Diversity,” Shared Awareness and Knowledge Strengthens the Pharmaceutical Technology Division.

What are the merits of having the Pharmaceutical Technology Division be solely responsible for the engineering chain and supply chain flows?

Isshiki The biggest merit is that it clarifies the ideal state toward which all employees involved in manufacturing are aiming, making it easier to share values. In the past, along the workflow from the CMC Research Department to

the Pharmaceutical Manufacturing Department, my impression was that CMC research ended where production began. However, with this work being done under a single division, CMC researchers involved in the upstream stages of manufacturing began viewing problems at the production stage as their own concern.

Furthermore, it has become easier for employees in charge of production to



share issues with CMC researchers, creating a system that efficiently facilitates the provision of feedback from downstream to upstream in the manufacturing process. Integrating departments in this way has unified employees to work as one to engage in manufacturing, enabling more consistent product development and production.

Aizawa Another merit is the more proactive exchange of information. Previously, the departments involved in CMC research were within the Research Division, and the departments involved in manufacturing belonged to the Pharmaceutical Manufacturing Division, resulting in only a few meetings per year where the two departments could exchange opinions directly. Since the establishment of the Pharmaceutical Technology Division, however, meetings have been held several times a month with heads of the division's eight departments in attendance. This enables eight perspectives to be exchanged on

a single issue, increasing the diversity of solutions.

How do employees from the eight departments comprising the Pharmaceutical Technology Division interact with one another?

Aizawa They participate in cross-departmental projects, and I feel that cooperation among employees is growing stronger by the day. To eliminate barriers between departments, it is important to understand one another's work. The Pharmaceutical Technology Administration Department supports the creation of cooperative relationships among employees by providing opportunities for CMC researchers to tour plants, as well as by holding study sessions for Production Department employees to learn about CMC research. My opinion is that the creation of a single Pharmaceutical Technology Division has further strengthened the awareness among employees to learn about and understand one another's work.

Isshiki Personnel exchanges are also taking place between the engineering and supply chains. For example, in the relationship between the Active Pharmaceutical Ingredient Technologies Department and the Supply Chain Management Department, the manufacture of active pharmaceutical ingredients designed by the former are sometimes outsourced. The latter is in charge of managing the procurement of active pharmaceutical ingredients. In the event of subcontractor problems or changes, technical support may be required, and at the moment, many employees from the Active Pharmaceutical Ingredient Technologies Department are working in the Supply Chain Management Department, facilitating seamless response capabilities. As awareness of technical issues related to active pharmaceutical ingredients increases in the Supply Chain

Management Department, feedback is provided to the Active Pharmaceutical Ingredient Technologies Department when more specialized responses are required, putting into place a system in which the two chains work together to solve problems.

Aizawa I think the establishment of the Pharmaceutical Technology Division will also have merits in terms of research and development, for example, in relation to manufacturing and marketing approval documents. As a general rule, pharmaceutical products must be manufactured in accordance with procedures and methods specified in manufacturing and marketing approval documents. In other words, manufacturing that incorporates non-specified procedures and methods is not permitted. In combining the engineering and supply chains, manufacturing site issues are immediately fed back to CMC research, enabling the rapid formulation of optimal manufacturing solutions. Once manufacturing and marketing approval documents have been finalized, any changes require a significant amount of effort; thus, it is important to find optimal solutions at the initial stage to avoid regretting not being able to manufacture more efficiently using better solutions

Isshiki Kissei is working on in-licensed products without imposing any restrictions on modalities, but the manufacturing of pharmaceutical products is actually carried out by the Pharmaceutical Technology Division. By ensuring that the Pharmaceutical Technology Division is able to handle the manufacture of pharmaceutical products in various modalities, Research and Development Department personnel will be able to take on the challenge of various modalities with peace of mind. We believe that this will greatly expand the possibilities for research and development.

The Pharmaceutical Technology Division Enhances Kissei Pharmaceutical How the Senior Directors Envision the Future of Manufacturing at Kissei Pharmaceutical

Future Prospects of the Pharmaceutical Technology Division

Isshiki We want to further strengthen the sense of unity within the Pharmaceuticals Division and enhance management of the production stage to optimize manufacturing. When a new product is released, we want to manufacture as much as possible, but naturally there are capacity constraints at our plants. Considering all the products that Kissei Pharmaceutical manufactures, which should be manufactured in-house, and in what volumes? And, if it is not possible to manufacture everything in-house, which products should be outsourced? To answer these questions, we want to create a system that takes efficiency and profitability into consideration, while making timely adjustments to stably deliver products of appropriate quality to as many patients as possible.

Optimizing the manufacturing system and maintaining a certain amount of leeway in manufacturing will enable Kissei to respond to sudden demand, while enabling investigational new drugs currently manufactured at the CMC research facility to be manufactured at the Matsumoto Plants, which has passed GMP inspections by regulatory authorities, enabling us to supply investigational new drugs overseas with more flexibility. We believe that this will result in accelerating our development speed and further refining our research and development capabilities.

Aizawa I believe that, in addition to developing products, the mission of the



Pharmaceutical Technology Administration Department is to develop people. To this end, we are currently working on the creation of a database for educational materials.

After establishing the Pharmaceutical Technology Division, we collected all the educational materials from each department, amounting to nearly 2,000 different items. Despite the accumulation of this much know-how by the Pharmaceutical Technology Division, up to now, education had been conducted on a site-by-site basis, and employees in different departments were unable to access educational materials. In response, the Pharmaceutical Technology Administration Department is amassing this information and, with the help of AI, it is promoting the creation of a system that can provide the necessary knowledge and know-how to people who need it. The concept of “quality culture” is currently attracting attention in the pharmaceutical industry as a way of expressing a corporate culture related to quality. To cultivate this culture, it is essential that all employees involved in pharmaceutical manufacturing understand and respect each other and share the same values. Through the development of people, we will provide educational support enabling Pharmaceutical Technology Division personnel to enhance their individual knowledge and expertise, better understand the work engaged in by their colleagues, and share awareness and knowledge, thereby contributing to pure manufacturing.

Main Products (As of August 2024)

		Sales in fiscal 2023 (millions of yen)	Projected sales in fiscal 2024*1 (millions of yen)
 Urology			
Treatment for Overactive Bladder: Beova® 	Active ingredient: Vibegron Indications: Urinary urgency, urinary frequency, and urge urinary incontinence associated with an overactive bladder Month of release: November 2018 (tablets) ● Joint development and marketing with KYORIN Pharmaceutical Co., Ltd.	15,335	17,500
DESMOPRESSIN Formulations, MINIRIN MELT®, etc. 	(MINIRIN MELT® OD tablets 25 µg/50 µg/60 µg/120 µg/240 µg, DESMOPRESSIN Spray, and DESMOPRESSIN Injection) Active ingredient: Desmopressin acetate hydrate Indications: Nocturia due to nocturnal polyuria in males (OD tablets 25 µg/50 µg) Nocturnal enuresis resulting from decrease of urine osmolality or urine specific gravity (OD tablets 120 µg/240 µg) Central diabetes insipidus (OD tablets 60 µg/120 µg/240 µg, DESMOPRESSIN Spray), etc. Month of release by the Company (following initial release and transfer to Kissei): April 2020 ● Marketing and distribution operations transferred from Ferring Pharmaceuticals Co., Ltd., with co-promotion by both Ferring and Kissei	3,662*2	3,200*2
Treatment for Dysuria: URIEF® 	Active ingredient: Silodosin (<i>Japanese Pharmacopoeia</i>) Indications: Dysuria associated with benign prostatic hyperplasia Month of release: May 2006 (capsules*3), February 2009 (tablets), January 2016 (OD tablets) ● Joint development and marketing with Daiichi Sankyo Company, Limited	2,076	1,400

 Renal Diseases and Dialysis			
Treatment for Hyperphosphatemia: 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)	5,241	5,300
Treatment for Pruritis in Dialysis Patients: KORSUVA® 	Active ingredient: Difelikefalin acetate Indications: Improvement of uremic pruritis in dialysis patients (limited to patients with inadequate response to conventional treatments) Month of release: December 2023 (syringe) ● Joint development with Maruishi Pharmaceutical Co., Ltd.	757	3,600
Treatment for Renal Anemia: Darbepoetin Alfa BS Injection [JCR] 	Active ingredient: Darbepoetin alfa (genetic recombination) [darbepoetin alfa biosimilar 1] Indications: Renal anemia Month of release: November 2019 (syringe) ● Joint development with JCR Pharmaceuticals Co., Ltd.	4,077	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, vial) ● Joint development with JCR Pharmaceuticals Co., Ltd.	2,336	1,800

		Sales in fiscal 2023 (millions of yen)	Projected sales in fiscal 2024*1 (millions of yen)
 Rare and Intractable Diseases			
Treatment for Microscopic Polyangiitis and Granulomatosis with Polyangiitis: TAVNEOS® 	Active ingredient: Avacopan Indications: Microscopic polyangiitis and granulomatosis with polyangiitis Month of release: June 2022 (capsules)	5,161	7,000
Treatment for Chronic Idiopathic Thrombocytopenic Purpura: TAVALISSE® 	Active ingredient: Fostamatinib sodium hydrate Indications: Chronic idiopathic thrombocytopenic purpura Month of release: April 2023 (tablets)	818	2,500
Treatment for Ulcerative Colitis: CAROGRA® 	Active ingredient: carotegrast methyl Indications: Moderate ulcerative colitis (limited to those 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	1,091	1,800

 Metabolism and Endocrinology			
Treatment for Diabetes: GLUBES® 	Active ingredients: Mitiglinide calcium hydrate (<i>Japanese Pharmacopoeia</i>), voglibose (<i>Japanese Pharmacopoeia</i>) 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)	3,806	3,300
Treatment for Diabetes: GLUFAST® 	Active ingredient: Mitiglinide calcium hydrate (<i>Japanese Pharmacopoeia</i>) Indications: Type 2 diabetes Month of release: May 2004 (tablets), June 2016 (OD tablets)		
Treatment for Diabetes: MARIZEV® 	Active ingredient: Omarigliptin Indications: Type 2 diabetes Month of release by the Company (following initial release and transfer to Kissei): April 2020 (tablets) ● Distribution operations transferred from MSD K.K.	1,073	1,100

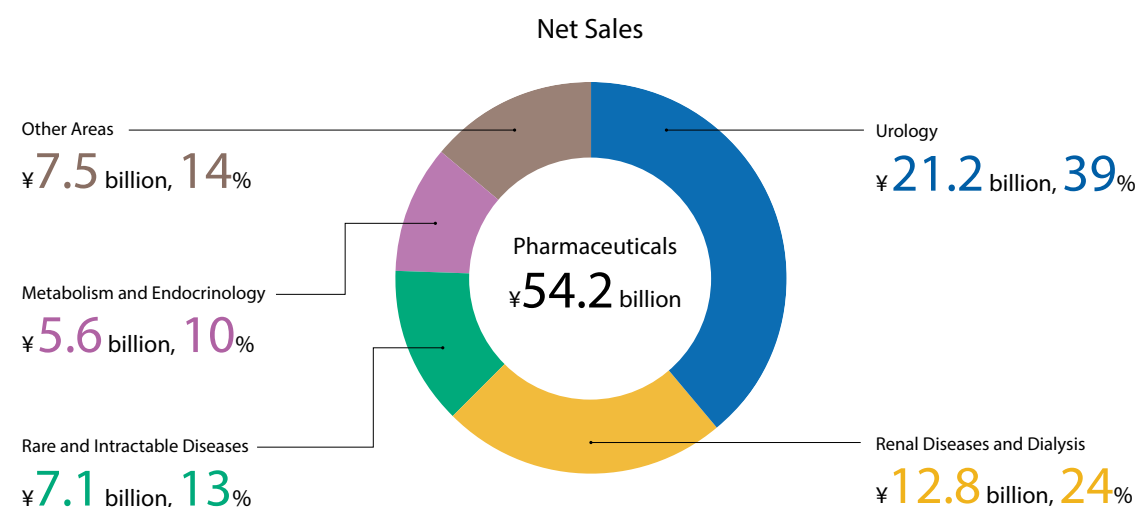
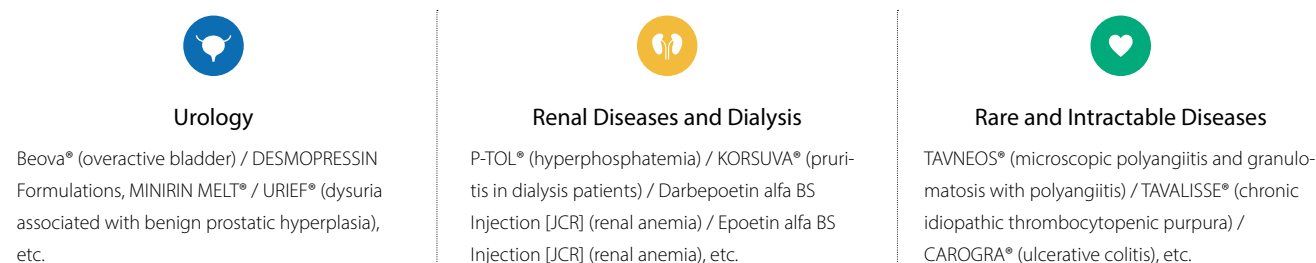
*1 Figures from financial results for fiscal 2023 (announced May 2024)
*2 Combined total for MINIRIN MELT®, DESMOPRESSIN Spray, and DESMOPRESSIN Injection
*3 Currently not for sale

Pharmaceutical Business Pharmaceutical Products

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

▶ Material issues related to business activities
Development and provision of products useful to society

Key Areas



▶ Pharmaceutical Business Activities



New drugs are only delivered to patients after going through a long process of basic scientific research, clinical trials, and government approval. At Kissei Pharmaceutical, we develop new drugs via a collaborative process that involves each department and person in charge. It covers every aspect of business, from pharmaceutical R&D to manufacturing, marketing, and safety monitoring, in an effort to deliver better drugs to patients as quickly as possible.

> Research

For Kissei, which strives to be an R&D-oriented pharmaceutical company, drug discovery research capabilities are the most important source of value creation. The Research Division has built upon its foundation for drug discovery—one built up over many years—to promote a drug discovery research strategy that leads to excellent value proposals, and to challenge itself to discover innovative new drugs by conducting multiple drug discovery projects, with small molecules as our core technology, backed by peripheral technology platforms. By actively utilizing open innovation and digital technology and focusing on speed and quality, we are working to strengthen our drug discovery research capabilities so that we can compete on the global stage.

The Foundations of Kissei's Drug Discovery and Research



Keiji Miyazawa

Member of the Board,
Division Director of Research
Division

▶ The Foundation of Kissei's Drug Discovery

At Kissei Pharmaceutical, researchers in medicinal chemistry, computational chemistry, biology, pharmacology, drug metabolism & pharmacokinetics, and safety related to drug discovery research work together at our Central Research Laboratories in Azumino City, Nagano Prefecture. Kissei's drug discovery research is underpinned by the strong technical capabilities of each researcher, an extension of the Company's long history of R&D, market launches, and sales dating back to the Company's founding. Another fundamental element of drug discovery research is our organizational structure and system, which enables researchers to work closely together to seamlessly develop and deepen their ideas. We believe that “a pharmaceutical company cannot exist without R&D.” Accordingly, we are working to hone our strength in medicinal chemistry and then engage in small-molecule drug discovery that leverages this strength.

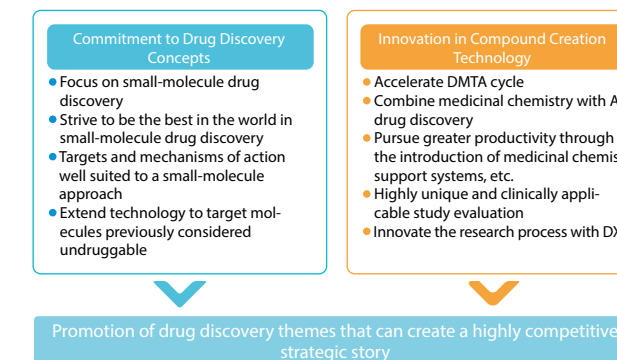
▶ Drug Discovery Research Strategy

The Research Division emphasizes drug discovery along two axes: drug discovery concepts and compound creation technology. Using this framework, it aims to create game-changing pharmaceutical products—new, highly competitive drugs with a strong strategic story.

For the Drug Discovery Concepts axis, our primary focus is on small-molecule drug discovery, with the ambitious goal of being the best in the world in this area. We are also focused on drug discovery concepts based on targets and mechanisms of action that are particularly well suited to small-molecule treatments, as well as efforts to gain a competitive edge. To this end, we intend to further develop our core, small-molecule drug discovery technology to address “undruggable” targets, thereby challenging ourselves to discover innovative new drugs that can exert ideal pharmacological effects to treat target diseases.

With regard to Compound Creation Technology, we plan to shorten our compound creation periods by accelerating our Design-Make-Test-Analyze (DMTA) cycle, thereby strengthening our competitiveness in drug discovery research. Going deeper, in the Design stage, we will combine the knowledge and experience cultivated by our medicinal chemists with AI drug discovery, and utilize computational chemistry based on three-dimensional structural analysis made possible by cryo-electron microscopes to take our design capabilities to the next level. In the “Make” stage, we will continue to pass on and develop the in-house synthesis technology used by our medicinal chemists and we will also introduce a support system for them to maximize research productivity to the greatest extent possible.

Pursuing Competitive Advantages Along Both Axes



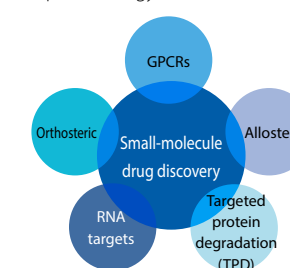
▶ Drug discovery research conducted on a multi-technology platform with small-molecule drug discovery as the core technology

Treating small molecules as our core technology, we are working to build a comprehensive technology platform that can handle G protein-coupled receptors (GPCRs), orthosteric sites, allosteric sites, targeted protein degradation (TPD), and RNA-targeted drug discovery, based on the expertise and capabilities we have built in small molecule to date, which will help us as we seek to harness the infinite possibilities of small-molecule drug discovery. First, our company has been engaged in GPCR drug discovery for over 30 years, and has previously developed silodosin (generic name) and linzagolix (generic name) as original products. GPCR drug discovery constitutes our most proven technology platform, and we are now applying our successes to general drug discovery research for orthosteric sites (binding sites for orthodox endogenous ligands) in addition to GPCRs.

As an extension of orthosteric drug discovery, we are also focusing on research into the discovery of allosteric modulators that target unknown binding sites instead of the active site. This allosteric drug discovery is expected to produce breakthrough pharmacological effects that are difficult to achieve with existing mechanisms of action.

We will advance our efforts in TPD drug discovery. TPD drug discovery technology can be applied to shallow-pocket targets that were previously considered undruggable, fundamentally expanding the capabilities of small-molecule drug discovery.

While all of the targets mentioned above are proteins, it has become clear that it is possible to develop new drugs that can regulate protein expression by targeting RNA. We will work to develop technology in this direction as well, seeing it as a potential growth area in the future of small-molecule drug discovery. This will facilitate the creation of new orally-administered drugs for diseases such as genetic disorders that have traditionally been treated with gene therapy.



▶ Enhancing Open Innovation

Unlike traditional closed research systems, open innovation improves the speed and efficiency of drug discovery by allowing experts and researchers from outside companies and research institutions to collaborate and share knowledge and resources with each other. In addition, open innovation means that if one of these companies has a particular technology, it can use it to solve more difficult research problems that arise. If there are certain technologies that are difficult to access internally, we will actively promote open innovation with external organizations to create innovative new drugs.

In addition, open innovation allows multiple companies and research institutions to participate, allowing more ideas and methods to be tried, diversifying risk, and increasing the chances of success. We are one of 17 domestic pharmaceutical companies participating in the Development of a Next-Generation Drug Discovery AI through the Industry-Academia Collaboration (DAIA) initiative of the Japan Agency for Medical Research and Development (AMED). Together, we are working to build and utilize an all-Japan, AI-driven system for small-molecule drug discovery, with roles shared between industry and academia. We are also participating in AIMGAIN, an innovative medical technology research and development promotion project and industry-academia-government collaboration involving DNA-encoded libraries (DELs), a technology that facilitates efficient exploration of drug seeds. The goal of AIMGAIN is to develop an innovative DEL platform that can be used by both industry and academia in a non-competitive manner. In this way, we are helping enhance open innovation as an important tool to brighten the future of drug discovery research.

▶ Leveraging Digital Technology

Digital technology has become an essential tool for drug discovery research, enabling researchers to analyze vast amounts of data and achieve greater successes. The Research Division is working to transform its research processes by raising up the three pillars of its DX Master Plan—exploring innovative drug discovery themes, shortening compound creation periods, and reforming non-clinical research operations through digital technology.

Regarding the first pillar, exploring innovative drug discovery themes, coming up with innovative and highly original drug discovery concepts and identifying drug discovery targets require the analysis of large

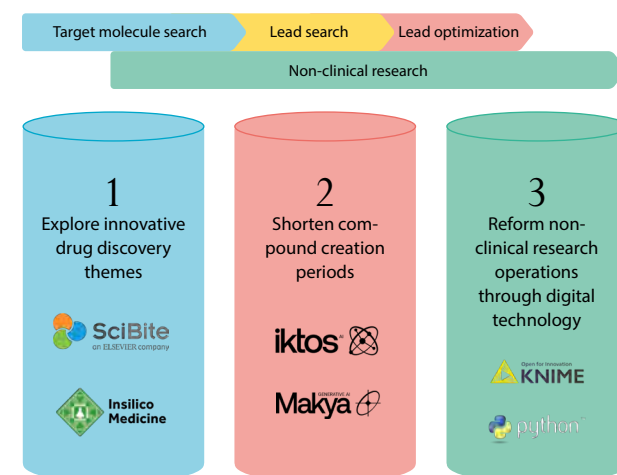
amounts of data. Doing this using traditional methods requires considerable time and effort. However, informatics tools such as the natural language processing AI system SciBite Search make it possible to process and extract useful information from large amounts of data in a short period of time, making drug discovery research more efficient.

To address the second pillar, shortening compound creation periods, we use Makya™. This is an AI platform for drug discovery developed by Iktos, a company with extensive experience in developing specialized algorithms for drug discovery. This platform helps create conditions that enable medicinal chemists to maximize their compound design capabilities and shorten the time it takes to create drug candidate compounds.

The third pillar, reforming non-clinical research operations through digital technology, involves the use of data analytics to improve researchers' data literacy and thereby accelerate and streamline data processing. Machine learning will also be used to predict pharmacokinetic parameters at an early stage.

In this way, we will continue to apply the most appropriate digital technologies to our research as part of our never-ending quest to stay ahead of the curve and challenge ourselves to discover new, game-changing drugs.

DX Master Plan for Drug Discovery Research: Three Pillars and Processes



💬 Message from a Researcher



Naohide Morita

Chief, Drug Discovery Chemistry Research Laboratories, Research Division

In July 2023, Kissei Pharmaceutical introduced Makya™, an AI drug discovery platform produced by the French company Iktos to transform drug design. I studied at Iktos for three months to learn about AI drug discovery technology and explore effective ways to use this system in our drug discovery efforts. I went through a process of trial and error while trying to envision how we could use the technology in our drug discovery research, and initially struggled to get the results we were hoping for. However, after having in-depth discussions with Iktos researchers, I was able to overcome these doubts then and there and gain a better understanding of how the platform worked. Over time, these results began to materialize. Currently, we are able to design new small-molecule compounds that make the grade even from an expert's perspective, ones that I would never have come up with on my own, and I have come to realize just how useful a system like this can be. By combining the drug discovery research capabilities of our researchers that we have built up over time with this AI technology, I hope to further enhance drug discovery research and create original, high-quality drug candidate compounds.

The Clinical Development Division is made up of the Clinical Projects Management Department, which drafts Target Product Profiles (TPPs*) for development themes as well as development policies and plans, and the Clinical Research Department, which plans and promotes efficient clinical trials to determine TPPs. The division is committed to its mission, to "contribute to society through high-quality, innovative pharmaceutical products" and "serve society through our employees" as stipulated by Kissei's Management Philosophy. It works diligently to develop new drugs that will satisfy unmet medical needs, always mindful that it is working "for the patients."

* A document that indicates characteristics of the target product during the development of a new drug and eventually becomes the package insert when the drug is launched on the market. The document is prepared at the start of a project or during a project's early stages, and is revised based on the results of clinical trials or for other reasons.

The Current State of Clinical Development



Yuji Kiyono

Senior Executive Officer,
Division Director of Clinical
Development Division

▶ Promoting Clinical Development

The mission of the Clinical Development Division is to uphold Kissei's Management Philosophy—to contribute to society through high-quality, innovative pharmaceutical products and to serve society through our employees. Charged with this mission, we work to develop new drugs, ever mindful of our duty to serve every patient. Over the course of "PEGASUS," our medium-term management plan, we received NDA approvals and launched four new drugs to the market: TAVNEOS®, a treatment for microscopic polyangiitis and granulomatosis with polyangiitis, CAROGR®, a treatment for ulcerative colitis, TAVALISSE®, a treatment for chronic idiopathic thrombocytopenic purpura, and KORSUVA®, a treatment for uremic pruritis in dialysis patients.

Right behind these four approved drugs, progress is underway in Japan to develop new drugs. Two projects are in the final stages of Phase III clinical trials: CG0070 (development code), an oncolytic viral therapy drug for bladder cancer, and linzagolix (generic name), a drug developed by Kissei for the treatment of uterine fibroids. The CG0070 project is particularly notable, as it represents our first foray into regenerative medicine, with us taking part in global Phase III clinical trials. For late-stage development projects, we will utilize the expertise we have gained in recent years in dealing with NDA applications and reviews, and work with relevant departments through cross-departmental projects to apply for and obtain NDA approval as early as possible.

Meanwhile, for KDT-3594 (development code), our new drug treatment for Parkinson's Disease, and KSP-0243 (development code), a treatment for ulcerative colitis, we are going ahead with Phase II clinical trials that will provide a swift proof of concept (PoC) and pave the way for overseas expansion.

▶ Quality Management

Good clinical practice (GCP) guidelines for conducting clinical trials have been revised in light of the diversification and digitalization of clinical trials, among other factors. Now, the guidelines recommend more efficient monitoring with effective application of risk-based monitoring to ensure reliability. A comprehensive "concept of quality management" has also been compiled, encompassing quality control and quality assurance. Quality management systems for clinical trials must focus on important activities that take place within the trial, and are recommended to ensure greater efficiency while still protecting trial subjects and ensuring reliable results.

Based on the aforementioned concept of quality management, we work with each department in the Clinical Development Division to implement risk-based monitoring. Starting from protocol development, we identify processes and data critical to the protection of participants and the reliability of trial results, and work to avoid unnecessary complexity, procedures, and data collection within the protocol. We then look at these critical processes and data and identify and assess risks, making a concerted effort to take measures for risks that are particularly high. Other aspects of quality management include efforts to monitor and implement quality control that does not rely solely on visits to the medical institutions where the trials are being conducted. These efforts were implemented for clinical trials of TAVALISSE® and KORSUVA® and became a useful means of ensuring quality even in situations where visits to medical institutions were restricted due to COVID-19.

Revisions to GCP guidelines are currently underway to ensure that they are both suitable and flexible enough to accommodate an increasing variety of study types and data sources. We will continue to comply with these guidelines and make every effort to conduct highly efficient clinical trials while making sure to protect subjects and ensure the reliability of clinical trial results.

As it stands, there are still very few treatment options for rare and intractable diseases, and we are strongly aware that our mission in this regard is to develop new drugs quickly and deliver them to patients as soon as possible to help with their treatment however much we can. It is this spirit, "to serve every patient," that we will draw upon as we challenge ourselves to develop new drugs that can satisfy unmet medical needs.

Collection, Analysis, and Provision of Information on Pharmaceutical and Medical Systems



Yutaka Takeuchi
Senior Director of R&D
Regulatory Affairs
Department

To strengthen drug price negotiations and R&D strategy support functions from a pharmaceutical administration standpoint, the Regulatory Affairs Department, which was within the Quality, Safety, and Regulatory Affairs Division, was separated from the Division in October 2023 and renamed the R&D Regulatory Affairs Department. The department provides support for promoting development themes, provides responses to requests from government organizations for NDA approval, and works to secure appropriate drug prices under the NHI system.

With the changing environment surrounding the pharmaceutical industry, problems such as drug lag and drug loss have come to light in recent years. The Ministry of Health, Labour and Welfare has been investigating specific countermeasures related to pharmaceutical regulations at sessions of the Study Group on Pharmaceutical Regulations to Strengthen Drug Discovery and Ensure Stable Supply, implementing a number of them. On our end, we promptly collect and analyze information on pharmaceutical and medical

systems, which are constantly changing. We actively provide this information to relevant departments within the Company in order to support R&D efforts and enhance drug price calculations.

Over the course of **“PEGASUS”**, which began in April 2020, we have acquired NDA approval for four products.

Of these, TAVALISSE® and TAVNEOS® are designated orphan drugs. To be designated as an orphan drug, there must be fewer than 50,000 patients in Japan eligible for the drug or the disease indicated must be designated as an intractable disease, there must be a particularly high medical need, and there must be a high possibility of drug development. TAVNEOS® and TAVALISSE® were deemed to meet these conditions and were designated as orphan drugs, making them eligible for priority review and a shortened review period. Moreover, when calculating NHI drug prices, TAVNEOS® and TAVALISSE® were both recognized for their new and clinically useful mechanisms of action, while KORSUVA® was recognized for its effectiveness in patients who did not respond adequately to conventional treatments. As a result, these drugs received a usefulness premium (II) designation plus eligibility for the Price Maintenance Premium.

We are currently trying to increase collaboration with relevant departments to obtain early NDA approval for linzagolix (generic name), which is in late-stage development, and CG0070 (development code), our first regenerative medicine product, so that we can deliver them to patients as soon as possible.

> Intellectual Property Strategy

Using Intellectual Property from Companywide and Managerial Perspective to Increase Corporate Value



Nobuko Yanagi
Senior Director of Intellectual
Property Department

We aim to be an R&D-oriented pharmaceutical company that contributes to the health of people around the world through innovative pharmaceutical products. Fueled by this Management Vision, we engage in a series of business activities covering the R&D, manufacturing, and marketing of new drugs using original and in-licensed products. During this process, we accumulate and utilize a variety of intellectual property.

In terms of small-molecule drug discovery, we intend to obtain global patents for substances, uses, dosage and administration, salts and crystals, manufacturing methods, formulations, and other kinds of intellectual property in an effort to build a portfolio that will support our business by providing the basis for long-term research while strengthening our foundation for growth by improving added value. The Research Division is working to shorten the time it takes to create small molecules by combining its strengths in compound creation technology with AI and open innovation. In addition, the Clinical Development Division is also working to shorten the time it takes to conduct clinical trials by way of a development strategy oriented toward overseas out-licensing. These concerted efforts, combined with early out-licensing, will enable widespread commercialization in countries around the world and help us realize our Management Vision. In cases of in-licensed products, we also actively obtain patents based on knowledge gained through clinical and formulation development to maximize profits and continue our business.

As the competitive environment intensifies, innovation and intellectual property created by people are an important competitive edge, crucial for us to continue moving forward as an R&D-oriented pharmaceutical company. Knowing this, we will work with related departments to strengthen our ability to acquire and utilize patent rights for R&D themes through human resource development and digital transformation. In addition, we will work to improve corporate value by visualizing our intellectual property from a broader, Companywide and managerial perspective, then strengthening and utilizing it; this includes intellectual property in the form of technology, designs, brands, data, know-how, customer networks, and any organizational capabilities that are used to create these intellectual properties. As the role of the Intellectual Property Department evolves in this direction, we are working to envision how intellectual property, which is used to create, protect, and level the strengths of Company, can contribute to solving management issues, and to actively engage in dialogue with other departments and management. Our goal is to manage intellectual property in a way that is mindful of how intellectual property impacts management issues and in a way that promotes strategies pertaining to the use of intellectual property as an active part of management-related decision-making. The Invention Review Committee, which is made up of representatives from the Research Division, Clinical Development Division, Business Development Department, Pharmaceuticals Technology Division, Sales and Marketing Division, Medical Department, Corporate Strategy and Planning Department, and Intellectual Property Department, has long been responsible for deliberating matters related to investment and compensation for patents and design rights and submitting recommendations to management. I believe that in the future, the Invention Review Committee will go beyond handling intellectual property rights to also become a forum for dialogue that will lead to broader intellectual property management.

R&D Pipeline (as of July 2024)

In-Company New Drug Development

		Development stage				
Generic name / Development code	Expected indications	Phase			NDA in process	Development classification, etc.
		I	II	III		
CG0070	Non muscle-invasive bladder cancer					In-licensed / CG Oncology, Inc. (U.S.) 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

Note: NDA for rovatirelin (spinocerebellar ataxia) withdrawn, discussions into the possibility of additional clinical trials is being considered

Changes from Annual Report 2023 (published July 2023)

● Difelikefalin / MR13A9 NDA in process ▶ Launched December 2023 (removed from table)

Out-Licensing New Drug Development

Generic name	Expected indications	Countries and regions	Development stage			NDA in process	NDA approved	Partner company
			I	II	III			
Linzagolix	Uterine fibroids	Europe						Theramex HQ UK Limited
		China						Bio Genuine
		Taiwan						Synmosa Biopharma Corporation
	Endometriosis	Europe						Theramex HQ UK Limited
		China						Bio Genuine
Fostamatinib	Chronic idiopathic thrombocytopenic purpura	South Korea						JW Pharmaceutical
Silodosin	Dysuria associated with benign prostatic hyperplasia	Vietnam, other countries						Eisai Co., Ltd.

Changes from Annual Report 2023 (published July 2023)

● Linzagolix (Uterine fibroids / Taiwan) Preparation to submit application ▶ NDA in process

● Fostamatinib (South Korea) Preparation to submit application ▶ NDA in process

● Fostamatinib (China, other countries) Clinical trials under preparation ▶ Entered contract licensing with Inmagene Biopharmaceuticals (removed from table)

● KDT-3594 (China, other countries) Phase II clinical trials ▶ Entered licensing agreement with Affamed Therapeutics Limited (removed from table)

Enhancing Supply Chain Management



Hiroyuki Ishibashi
Senior Director of Supply Chain Management
Department, Pharmaceutical Technology Division

▶ Current State of Supply Chain Management and Notable Issues

As the effects of the global supply chain disruptions caused by the COVID-19 pandemic linger on, the situation surrounding supply chains is becoming even more complex and difficult to predict in light of rising prices for goods, resources, and energy worldwide, compounded by growing geopolitical risks overseas and the emergence of Japan's 2024 logistics problem domestically. In addition, there has been an ongoing shortage of pharmaceutical products triggered by scandals involving generic drug companies and, as of May 2024, approximately 20% of pharmaceutical products are subject to limited shipment, supply cutoffs, or other hindrances. Due to these factors, we have also been forced to continue limited shipments of some products.

▶ Kissei's Initiatives and Strengths

Organizational changes in October 2023 led to the establishment of an independent Pharmaceuticals Technology Division. This action was taken in order

to enhance supply chain management and, by extension, ensure stable and more precise procurement and supply of pharmaceutical products. This division casts a wide net, covering both the upstream and downstream sides of the supply chain for pharmaceutical products sold by the Company. These duties include creating pharmaceutical procurement plans based on the sales plans produced by the Sales and Marketing Division, using these procurement plans to procure drug substances and raw materials, and then coordinating production plans with Company-owned plants. In the case of TAVNEOS® and some other products, we receive supplies from partner companies in Japan or overseas then supply the manufactured or procured products to the market. We make sure to dissect the supply chain for each product to identify and analyze possible risks to ensure we can keep up the steady supply of high quality products, a material issues for the Company. From there, we work to avoid risks by communicating and exchanging information with partner companies to enhance our collaborative ties. We also implement detailed measures such as front-loading orders and increasing inventory. To overcome the increasingly complex challenges affecting the supply chain and ensure a continuous, steady supply of high-quality pharmaceuticals going forward, we intend to strengthen our supply chain management system and improve business operations. At the same time, we will take advantage of DX to improve the accuracy of risk analysis and planning.

Steady Supply of Pharmaceutical Products of Proper Quality



Masashi Yamazaki
Senior Director, Shiojiri Plants, Pharmaceutical Technology Division

▶ Steady Supply of High-Quality Products

Concerns about the supply of pharmaceuticals, which started with scandals involving generic drug companies and continue to this day, require urgent measures to be quickly resolved. For me, seeing these quality issues and how they affected society helped reaffirm the importance of factories and the position they hold.

Pharmaceutical manufacturing is based on the "Three Core Principles of GMP," which are realized through decisions and ideas that prioritize quality, including unchanging quality standards, high-quality systems, and an awareness rooted in Quality Culture. Both the Matsumoto Plants and the Shiojiri Plants maintain an unwavering commitment to our "craft" of creating pharmaceuticals, made possible by facilitating interaction between the various management systems involved, including production and quality, and through continued and proactive efforts to make improvements and provide education. These initiatives are key to maintaining high quality.

Accurate inventory information and demand forecasts are crucial factors for ensuring a steady supply, so collaboration with the Supply Chain Management Department is important. We obtain the latest information, staying up to date on the most recent changes to determine which

products to produce and required production quantities, then create efficient production plans between our Matsumoto and Shiojiri Plants. Although imported formulations such as TAVNEOS® and TAVALLISSE® are also subject to scheduling changes and other fluctuating variables, we are able to mount a flexible response to any changes that come our way, from the receipt of formulations to manufacturing, testing, and shipping. The most important thing in all of this is to ensure stable operations of the facilities and their equipment. During the manufacturing process and quality testing, we maintain stable operations through proper management over our equipment and through keeping it in the best condition.

▶ The Last Stage in the Craft of Creating Pharmaceuticals

The craft of creating pharmaceuticals is a series of steps in which technology obtained in the R&D stage is carried over to the plant, where the final process takes place. Between the formulation and quality testing at the Matsumoto Plants and appearance-based sorting and packaging at the Shiojiri Plants, we are able to commercialize our products while checking every item for defects, down to the last tablet. The products that come out of our plants are like a torch that has passed through many hands over many years, and we will be careful not to let it slip as we extend these products to the hands of patients.

The part of our craft that takes place at our plants remains rooted in the desire to "contribute to society through high-quality, innovative pharmaceutical products" and to serve society through our employees—our Management Philosophy. We will never stray from our mission to provide these high-quality pharmaceutical products in a steady supply.

The Quality, Safety, and Regulatory Affairs Division is made up of four departments: the Quality Assurance and Reliability Department, the Quality Assurance Department, the Pharmacovigilance & Post-Marketing Surveillance Department, and the Drug Information Department (Product Customer Service Center). At each stage of a pharmaceutical product's life cycle, from research through to clinical development, NDA application and approval, and marketing, the division is responsible for ensuring the safety, quality, and reliability of various materials and for providing information on proper use. The Pharmaceuticals Technology Division, established in fiscal 2023, is also involved in this "craft," from research to market launch, with the Quality, Safety, and Regulatory Affairs Division providing backup support for each step.

Reliability Guaranteed—from Research to Sales



Kaoru Kaneko
Senior Executive Officer,
Division Director (Marketing Supervisor General) of
Quality, Safety and
Regulatory Affairs Division

▶ Research Stage

During the research stage, source documents for NDAs related to safety, pharmacology, pharmacokinetics, drug substances, and formulations are prepared. The Research Division has a Quality Control Department that checks the quality of prepared documents, but the Quality Assurance and Reliability Department and Quality Assurance Department, which are separate from the Research Division, check that pharmaceutical application documents are prepared appropriately, based on source materials, and guarantee the reliability of the documents.

▶ Clinical Development Stage

The Quality Assurance Department ensures that investigational drugs, manufactured by the Pharmaceuticals Technology Division or outside manufacturing facilities, are manufactured in accordance with Good Manufacturing Practices (GMP) for investigational drugs and that quality is assured through on-site and written audits. We also ensure that clinical trials are conducted properly through audits based on Good Clinical Practices (GCP).

The Pharmacovigilance & Post-Marketing Surveillance Department works with the Clinical Development Division to assess and respond to adverse events, referring to any undesirable or unintended medical occurrences that occur in subjects administered an investigational drug and are temporally related to the administration of the drug that occur during clinical trials in accordance with GCP.

▶ NDA Application and Approval Stage

After submitting an NDA, we will respond to inquiries from the regulatory authorities, respond to compliance inspections of application documents, and respond to GMP inspections of manufacturing facilities. Each department within the Quality, Safety and Regulatory Affairs Division provides support to departments carrying out the application process.

▶ Post-Launch

To carry out its Management Philosophy, to "contribute to society through high-quality, innovative pharmaceutical products," Kissei has established an internal system within the Quality, Safety, and Regulatory Affairs Division to ensure compliance with Good Quality Practice (GQP) standards and Good Vigilance Practice (GVP) standards.

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 improve the overall level of quality-related information for pharmaceutical products on the market, as well as any connected procedures. If concerns arise 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 swiftly, and that training for recalls is carried out regularly to ensure action can be taken quickly and properly should a voluntary recall be deemed necessary.

On the other hand, for patients to use drugs with peace of mind, we must continue collecting and assessing information on safety and efficacy post-launch, since safety information that exists up to the point of approval is collected from clinical trials that are conducted under controlled conditions. In addition to information received from healthcare professionals via the Product Customer Service Center, the Pharmacovigilance & Post-Marketing Surveillance Department works with the Safety Management Implementation Division, which is made up of 10 offices across Japan, to promote safety monitoring activities for pharmaceutical products. Specifically, our consultation desk and medical representatives (MRs) engage in post-marketing surveillance and other activities to collect a wide variety of information on the efficacy and safety of our products. We then work with doctors to conduct a close review of this information. Following this review, we promptly notify medical professionals if we determine that new safety measures are necessary. In this way, we work on collecting and evaluating safety information and then devising safety measures on a daily basis. We keep our mission close to heart and with high ethical standards in our minds so that medical professionals and patients can utilize our drugs securely and safely.

Information collected from clinical trials regarding the safety and efficacy of recently launched orphan drugs is particularly limited, which makes it much more important to collect such information after they are brought to market. Therefore, we will keep performing these tasks with a continued sense of responsibility and enthusiasm, and contribute to society through high-quality, innovative pharmaceutical products, just as our Management Philosophy calls upon us to do.

Pharmaceutical Information Provision Activities Emphasizing Product Value Penetration and Information Gathering Capabilities



Hiroshi Noake

Member of the Board,
Division Director of Sales
and Marketing Division

Kissei positions urology and renal diseases and dialysis as key areas and has continuously aimed to become the company and medical representative (MR) provider of choice among medical professionals. Despite major changes in the environment, including restrictions on activities during the COVID-19 pandemic and medical professional workstyle reforms, I am pleased to say that we are now ranked among the top three, both as a company and as an MR, in a survey conducted by an external organization.*1

There are two points in particular that I want to emphasize with regard to our daily pharmaceutical information provision activities.

The first point is product value (brand image) penetration. Product value refers to the therapeutic benefit that a drug provides to patients, and brand image refers to the drug's reputation among medical professionals. For example, the drug Beova®, which is used to treat overactive bladder, is not only effective but also has high selectivity for β_3 receptors, approximately 8,000 times higher than β_1 and β_2 receptors, meaning that it has little effect on the circulatory system. The basic activity of an MR is to repeatedly communicate the value of products, along with information on appropriate use, through the use of supporting basic and clinical data. We also effectively utilize digital tools, such as e-promotions, the provision of details by email, and online seminars, to convey the same message through all media, ensuring thorough penetration of our product value (brand image). As a result, we hope that

doctors will remember Beova® as an effective, safe, and easy-to-use drug in their daily practice, and that patients will be able to enjoy its benefits.

The second point is information gathering capabilities. We have extensive product lineups in both areas, but if products do not address clinical challenges or needs, they will not be prescribed. For example, in the treatment of pruritus in hemodialysis patients, it is reported that approximately half of patients receiving treatment for itching are dissatisfied with existing treatments.*2 When KORSUVA® was launched in December 2023 as the first new drug for this indication in approximately 14 years, we thoroughly collected information on the challenges involved with existing treatments and the needs of patients through dialogues with doctors, pharmacists, nurses, technicians, and many other people involved in dialysis treatment. We proposed KORSUVA® as a solution to these challenges. Rather than simply providing information one way, the value of an MR lies in listening to the actual voices of those in the medical field, as well as in considering and proposing better treatment options, and I think this is why our MRs are so highly regarded.

In recent years, we have launched three products in the field of rare and intractable diseases, CAROGRA®, TAVNEOS®, and TAVALISSE®, and are strengthening our activities to provide medical information, primarily to specialists. The Rare Diseases Project was established in 2021 to develop promotional strategies and improve our MR training system. We have approximately 30 academic staff at 10 branches nationwide who work alongside MRs in activities at core hospitals, enabling us to provide specialized and advanced information. Going forward, we will continue contributing to the maintenance of patient health as the closest partner of medical professionals, while flexibly responding to changes in our product portfolio and the external environment.

*1 Survey conducted by Macromill Carennet, Inc.

*2 Journal of Japanese Society for Dialysis Therapy 57 (3): 111–122, 2024

Feedback on MR Activities



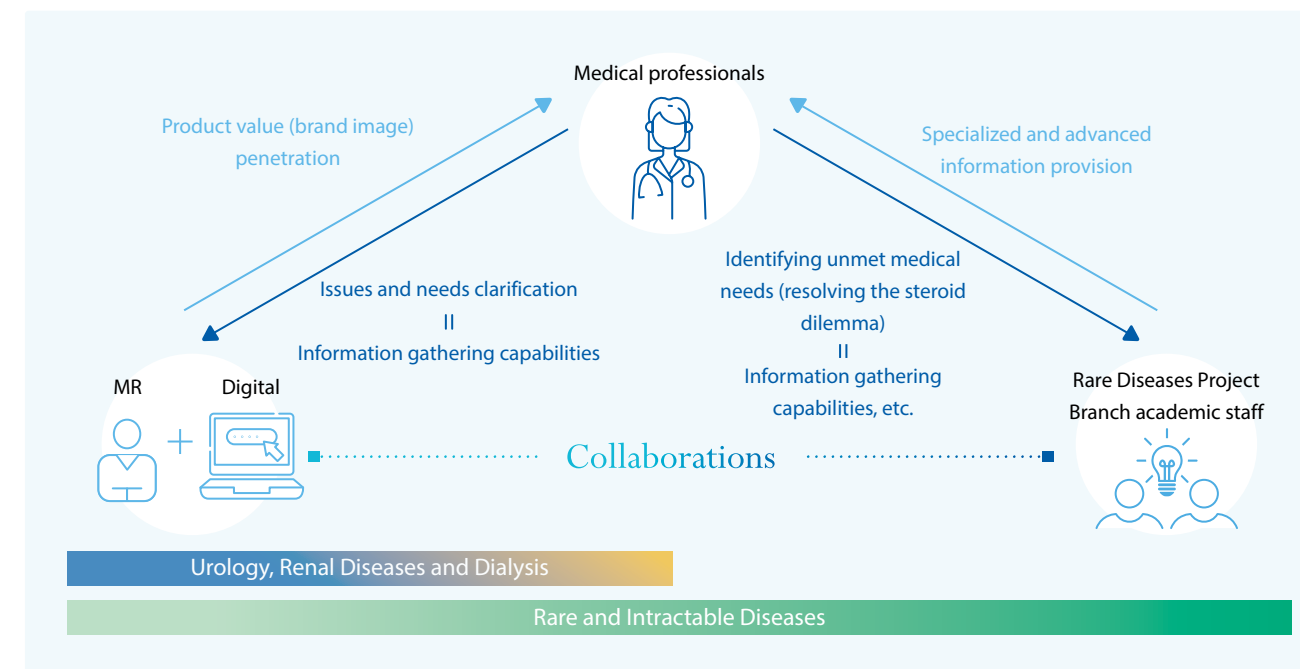
Shoichi Momose

Matsumoto Branch, Sales and Marketing Division

Through rare disease treatment drugs TAVNEOS® and TAVALISSE® recently launched for patients suffering from intractable diseases, we are focusing on both providing and collecting information to address unmet medical needs. In addition to acquiring new knowledge on a daily basis as a medical representative (MR), I also work closely with academic representatives and Rare Diseases Project members to share information in real time. I also accompany them during interviews so that

I can provide high-quality information to specialist physicians. In addition to confirming the progress of cases and making treatment proposals, we promote post-marketing surveillance during medical interviews. We share information on efficacy and safety obtained through interviews with academic staff and the Rare Diseases Project in a timely manner, and we are always conscious of providing the latest and most appropriate information. When I work with doctors to consider treatment options, help select patients for whom our medications are suitable, and then share the joy with doctors when treatments are confirmed to be effective, that is the moment I feel the greatest reward in my role as an MR. I will continue to work with specialist doctors as a partner in the pharmacological treatment of rare diseases, and approach work with a sense of responsibility and awareness to contribute to society through my role in healthcare.

To Become the Company and MR Provider of Choice Among Medical Professionals



Rare Diseases Project Activities



Itaru Miyashita

Senior Director of Rare
Disease Business Unit,
Sales and Marketing
Division

The Rare Diseases Project was established in April 2021 as a new business unit to strengthen the sales system for rare disease treatments and facilitate the smooth introduction of these treatments to market. At present, we are formulating promotional strategies, conducting education on disease and treatment methods for the Sales and Marketing Division, and engaging in the collection and provision of information from specialists for two products, TAVNEOS®, a treatment for microscopic polyangiitis and granulomatosis with polyangiitis, and TAVALISSE®, a treatment for chronic idiopathic thrombocytopenic purpura.

As the diseases targeted by these two products meet the requirements of a rare disease for which the mechanism of onset is unclear, no treatment method has been established, and long-term treatment is required, they have been designated as "intractable diseases" by the Ministry of Health, Labour and Welfare. To ensure our products are useful in the treatment of rare and intractable diseases for which limited data is available prior to approval, we must clarify the issues and needs of patients and medical professionals, create new evidence by utilizing the

results of clinical research and post-marketing surveillance that can answer clinical questions, and continuously provide information that meets the needs of medical professionals. To this end, it is also important to build relationships of trust through medical and scientific exchanges with influential physicians who possess outstanding insights in specialized fields related to these diseases and hold leading positions in academic societies and other organizations. At seminars and online lectures held in conjunction with academic societies, influential physicians share the latest medical information and provide their own personal prescription experiences, which facilitates the appropriate use of Kissei products.

Daily information provision activities are carried out in collaboration with medical representatives in charge of medical institutions and academic staff at branch offices. As promotional activities for orphan drugs require advanced medical and scientific knowledge, we support the provision of pharmaceutical information by MRs while working closely with branch office academic staff.

Going forward, we plan to apply for and launch oncolytic immunotherapy CG0070 (development code), a rare and intractable disease treatment for non muscle-invasive bladder cancer. In addition to acquiring knowledge about target diseases and treatment methods, promotional activities for regenerative medicine products, which are a new modality, require more specialized knowledge than ever before. The Rare Diseases Project will promote activities enabling patients to use novel drugs providing new treatment options for rare and intractable diseases, thereby further contributing to the improvement of medical care.

To contribute to society through high-quality, innovative pharmaceuticals, Kissei Pharmaceutical is expanding its therapeutic and care foods business, which develops and sells food for special dietary uses, with the mission of supporting health through medicine and food. The KISSEI HEALTHY FOODS (KHF) brand embodies our determination to use food products to help raise the quality of life of elderly people and those who require nursing care.

Message from the General Manager



Yasumasa Mishima
Executive Officer,
General Manager,
Nutrition Division

► Nutrition Division Current Conditions

The Nutrition Division is committed to contributing to society through food and is involved in activities that contribute to improving the quality of life of patients with kidney disease, people who require nursing care, and the elderly. As new product development is essential for contributing to society through food, we are currently working to quickly establish a system that will enable us to continuously launch new products (including the addition of new flavors), and we are rebuilding our business and profit structure around new products. We are also working to expand sales by strengthening activities targeting contract school lunch companies, central kitchen headquarters, and wide-area wholesale headquarters. Through efforts to ensure all division personnel understand the division's purpose and demonstrate their ability to create new products aimed at achieving sustainable growth, we will continue to provide innovative new products to patients.

According to a survey by a market research company*, the market for chewable, easy-to-swallow therapeutic foods, in which Kissei participates, is rising as the population grows older. As of fiscal 2021, this market was

valued at an estimated ¥54.5 billion, while the market for foods for kidney disease was estimated to be ¥8.0 billion. Relative to competing manufacturers, we have the eighth-largest share of the overall market, at 4.1%, and the top share of foods for people with kidney disease, at 28.0%.

► Nutrition Division Medium-Term Divisional Policies

The Therapeutic and Care Foods Division has set four medium-term divisional policies and is promoting the restructuring of its business and profit structure.

Policy	Progress
Enhance quality assurance systems to establish high-quality brands	The introduction of a new supplier auditing method has led to a significant decrease in the number of complaints, down 41% compared to the previous year.
Develop products with high added value and improve existing products	In fiscal 2024, we plan to launch two new flavors of Enepaku Jelly and other flavored products to the market.
Increase sales by utilizing digital tools and other new methods	In terms of the use of digital tools, we began posting recipe videos on YouTube in May 2024.
Expand mail-order customers via the customer service center	New initiatives at the customer service center have led to an increase in the number of mail-order customers.

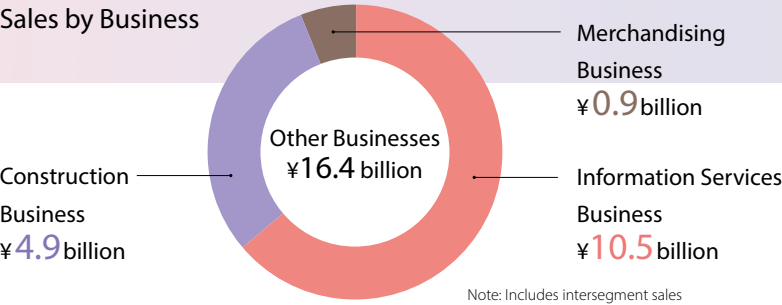
To fulfill Kissei's Management Philosophy of contributing to society through high-quality, innovative pharmaceutical products and serving society through our employees, we will contribute to and serve society through therapeutic and care foods with high added value.

* Source: Seed Planning Inc.



Kissei Group Management Philosophy: Kissei will Make Greater Contributions to Society by Creating Harmony Among the Group's Working Parts

Sales by Business



In addition to the Pharmaceutical Business, Kissei Pharmaceutical segments include the Information Services Business, the Construction Business, and the Merchandising Business. Each segment is in the final year of its medium-term management plan, and we are working to conclude these plans and enhance Kissei Group corporate value.

Information Services Business KISSEI COMTEC CO., LTD.

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 provides information services combining an abundance of knowledge and advanced technologies to develop a society with a rich sense of humanity.

KISSEI COMTEC acquired ISO/IEC 27001 certification for the protection of information-based assets, as well as ISO 9001 and ISO 14001 international standards certifications to meet the expectations and needs of customers and to live up to their trust. In February 2022, KISSEI COMTEC 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.

In fiscal 2024, the final year of its five-year medium-term management plan, KISSEI COMTEC will focus on promoting initiatives to establish a foundation for future growth, including the creation of solutions that contribute to resolving issues facing customers and society, the deepening of existing business, and the strengthening of human resources and technological capabilities that support business expansion. As an ICT solutions partner, we are promoting transformations for the new digital age.

- 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

Construction Business HASHIBA TECHNOS CO., LTD.

Based on its management philosophy of contributing to the development of local communities with technology and sincerity, HASHIBA TECHNOS provides comprehensive construction services, from building construction to the maintenance and management of equipment and facilities utilizing advanced technologies, while staying closely attuned to the needs of local communities.

In fiscal 2024, the final year of its five-year medium-term management plan, HASHIBA TECHNOS will make daily efforts to achieve its goal of establishing the HASHIBA brand and maximizing corporate value, as well as provide construction and services that result in high customer satisfaction. It will also focus efforts on improving workplace environments and developing human resources, creating healthy and comfortable workplaces, and retaining and developing young employees who will lead in the future.

- Description**
- General construction services
 - Registered first-class architect office
 - Real estate transactions
 - Factory and building management

Merchandising Business Kissei Shoji Co., Ltd.

Based on its management philosophy of contributing to society through trading activities rooted in customer needs and pursuing corporate prosperity and employee happiness, Kissei Shoji is engaged in the manufacturing, production, and sales of noodle products centered on Shinshu soba, various equipment, vehicle, and fuel sales, insurance agency services, and other activities. The noodle manufacturing and sales business meets JFS-B food safety management standards and strives to provide safe, secure products.

In fiscal 2024, the final year of its five-year medium-term management plan, Kissei Shoji will promote business based on a customer-first perspective and develop customer-oriented business activities by bringing potential customer needs to the fore. It will also focus on promoting digitalization and cultivating the next generation of human resources that will drive business forward, with the aim of becoming a company that can contribute to local communities and wider society.

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

Environmental Management

As stated in the Kissei Code of Conduct, which is based on the Group's Management Philosophy, the Group recognizes the severity of environmental problems and will voluntarily and proactively work toward environmental conservation. Drawing from this statement, Kissei Pharmaceutical has determined its Basic Environmental Policy. Based on this policy, it 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 also contribute to creating an affluent and comfortable society.

2. Basic Policy

(1) We will promote activities to reduce environmental burdens and evaluate our various effects on the environment through a series of corporate activities, such as research, development, production, distribution, sales, usage, and disposal of 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, recycling, and reducing waste, 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 protect 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. Under the organizational structure of Kissei's environmental management system, the vice-chair of the Sustainability Promotion Committee serves as the person in charge of environmental management. Therefore, the vice-chair is in charge of the maintenance, management, and operation of environmental management throughout the Company. In addition, each business location has a person in charge of environmental management who is responsible for the

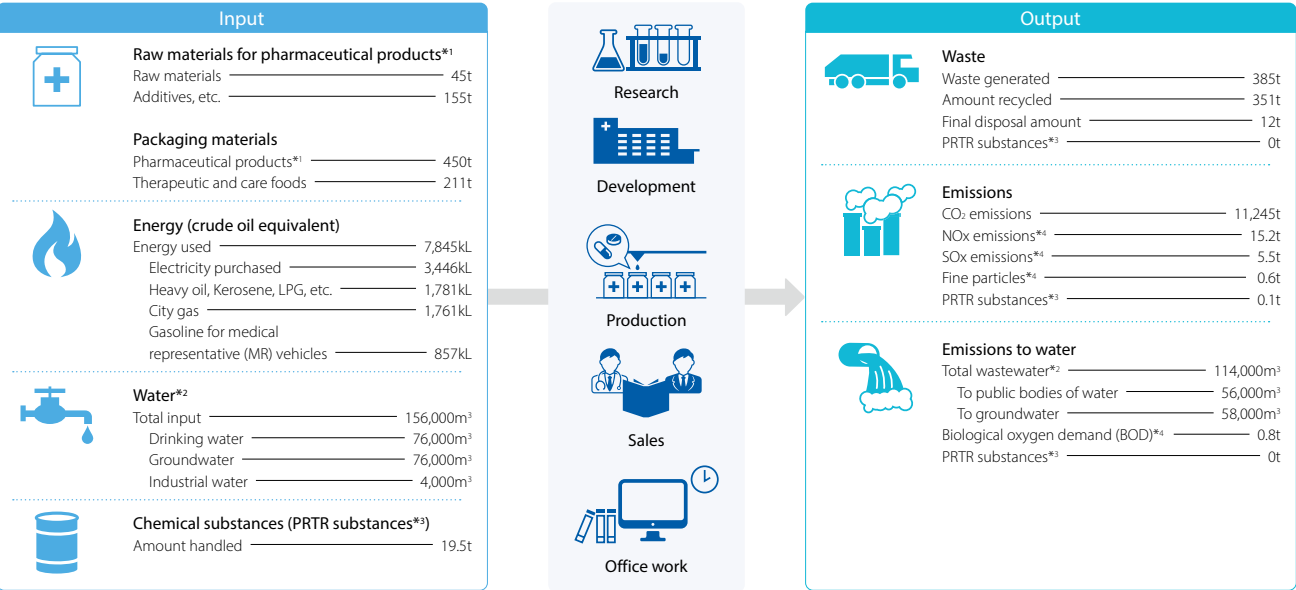
maintenance, management, and operation of the environmental management system for their specific location.

We have set specific targets for reducing our environmental impact at each location, including targets for energy usage, CO₂ emissions, and the amount of industrial waste generated. To achieve these targets, we are working to update to energy-saving equipment, expand the use of renewable electricity, and promote the 3Rs (Reduce, Reuse, Recycle).

The Environment and Kissei (Reducing Environmental Impact Companywide)

The figures below show the input of resources into Kissei Pharmaceutical for fiscal 2023, as well as the output in the form of emissions and waste generated in processes such as research,

development, production, and sales. We are working to reduce our environmental impact based on this data.



*1 The calculation method was revised following the launch of new products.
*2 Covering Head Office / Matsumoto Plants, Shiojiri Plants, Nutritional Business Center, Central Research Laboratories, Safety Research Laboratories, Joetsu Chemical Laboratories, Tokyo Head Office, Tokyo Head Office (Koishikawa)
*3 Data from business locations that handle one or more tons of applicable chemical substances annually
*4 Covering Head Office / Matsumoto Plants, Shiojiri Plants, Central Research Laboratories, Safety Research Laboratories, Joetsu Chemical Laboratories

Climate Change-Related Initiatives

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

We have identified "responding to climate change" as a material issue related to our management base and are promoting countermeasures accordingly. Since 2022, we have been disclosing information in line with the framework put forth by the TCFD, and, in June 2023, we officially endorsed the TCFD recommendations. Going forward, we will promote initiatives to address risks and opportunities related to climate change, prioritized by the degree of impact they may have on our business strategies.

1. Governance

Kissei's sustainability activities, including its responses to climate change, are led by the Sustainability Promotion Committee. This committee is chaired by a director with expertise in sustainability-related issues and is incorporated into the corporate governance system as an advisory body to the Board of Directors, and works closely with the Board in that role. It is tasked with

formulating various policies for sustainability activities and promoting them in cooperation with relevant departments. The details of these activities are reported to the Board of Directors and the Audit & Supervisory Board at least once every six months, with the activities in question managed and supervised by the Board of Directors.

2. Strategy

Regarding the impact of climate change on the Company's business, The TCFD Project Team, a subordinate organization to the Sustainability Promotion Committee, led the creation of 1.5°C*1 and 4°C*2 climate change scenarios. They then identified risks and opportunities for each, focusing on the impact on business sites in the Pharmaceutical Business, the central business of the Group. These risks and opportunities were analyzed and assessed in terms of their financial impact and their likelihood of occurrence, then possible measures were considered and prioritized by the impact on our business strategy.

Under the 1.5°C scenario, we face transition risks, such as higher costs stemming from enhanced policies and regulations related to decarbonization, and a fall in reputation in the eyes of stakeholders resulting from insufficient efforts to address climate change. The 4°C*2 scenario assumes that decarbonization is unsuccessful, leading to a 4°C*2 rise in the global average temperature. This introduces

physical risks, which break down further into immediate risks, such as water damage caused by typhoons and heavy rain, and long-term risks caused by rising temperatures, such as higher air conditioning costs and higher costs for securing water resources. On the other hand, we believe that climate change also brings opportunities. For example, it could lead to the introduction of highly efficient equipment and a rise in corporate value, thanks to proactive efforts to combat climate change and proper disclosure of these efforts. Knowing this, we will continue to promote decarbonization and increasing our resilience in order to improve corporate value sustainably.

As a result of analysis and assessment, there were no risks identified that could have a significant impact on the business strategy.

*1 Created with reference to the International Energy Agency's (IEA's) Net Zero Emissions by 2050 Scenario (NZE) and others.
*2 Created with reference to the International Energy Agency's (IPCC's) Net Zero Emissions by 2050 Scenario (NZE) and others.

For results of our environment conservation activities, please refer to the company website (Japanese only): <https://www.kissei.co.jp/sustainability/environment/>

Results of Scenario Analysis

Classification	High-Priority Risks	Impact on the Company	Degree of Impact*3	Countermeasures	Business Risks*4
1.5°C Scenario	Enhanced policies and regulations related to decarbonization	Addition of carbon pricing Company could incur an estimated cost of approximately ¥200 million in fiscal 2030 due to carbon pricing (at a rate of US\$130 t-CO ₂ *5)	Medium	• Reduce CO ₂ by introducing renewable energy, upgrading to energy-saving equipment, and further promoting activities to save energy	Low
		Capital investment costs could increase as a result of new or enhanced decarbonization policies such as CO ₂ emissions regulations	Low	• Systematically switch to energy-efficient equipment when upgrading and consider taking advantage of subsidies and other avenues	Low
	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	Low
4°C Scenario	Physical Risks (Immediate)	Flooding could cause damage to key locations, suspending operations, requiring the Company to incur expenses to restore these operations (approx. ¥3.6 billion total), and possibly affecting the development pipeline and impacting 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
	Physical Risks (Long-Term)	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
		Rising temperatures	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	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*6.	Low

*3 Degree of impact is based on the following criteria: high (over ¥500 million per year), medium (¥100-¥500 million per year), low (less than ¥100 million yen per year)
*4 Business risks are evaluated comprehensively, taking into consideration the degree of impact, frequency of occurrence, order of response, and other factors.
*5 Carbon prices in 2030 for advanced economies under the NZE scenario according to IEA World Energy Outlook 2021
*6 Water risks determined with reference to the AQUEDUCT Water Risk Atlas

Relationship with the Environment

Classification	Item	Impact on the Company	Degree of Impact*
Opportunity	Resource efficiency	Costs for energy procurement and raw materials could be reduced by introducing new, efficient technology and equipment	Low
	Energy	The Company uses heavy oil, gas, and electricity as energy resources. 77% of electricity used by the Company is derived from renewable energy sources. The introduction of renewable energy and shift away from fossil fuels could ensure business stability versus the future depletion of fossil fuels	Low
	Market for products and services	Demand could increase for existing pharmaceutical products in disease-prone areas where morbidity increases as temperatures rise	Low
	Market	Demand and development opportunities could increase for treatment in disease-prone 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	—

* Degree of impact is based on the following criteria: high (over ¥500 million per year), medium (¥100-¥500 million per year), low (less than ¥100 million yen per year)

3. Risk Management

Kissei has positioned risks related to climate change as important management risks, and the risks identified within the TCFD framework are reviewed at least once a year for their impact on business activities. Based on the level of impact, we consider cost-effectiveness and urgency, then prioritize, investigate, and implement response measures.

The Sustainability Promotion Committee will discuss and report on the management of these risks to the Board of Directors, the Audit & Supervisory Board, and the Risk Management Committee, an advisory body to the Board of Directors, to promote comprehensive Companywide risk management in an integrated manner.

4. Metrics and Targets

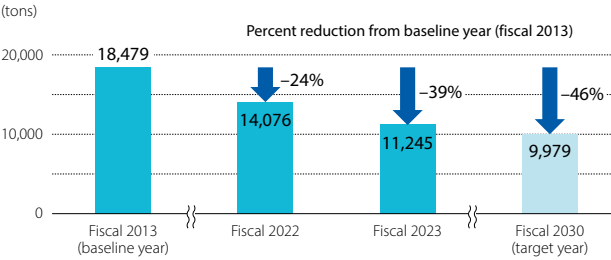
We have set the ratio of renewable energy use and reduction of CO₂ emissions as KPIs toward achieving carbon neutrality by 2050, as well as the following medium-term targets, with related activities underway.

- Fiscal 2030 reduction target for Scope 1 and 2 CO₂ emissions: 46% reduction compared with fiscal 2013

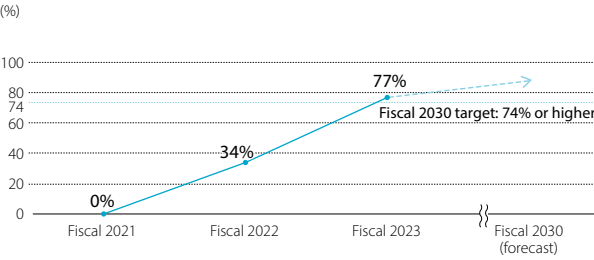
- Fiscal 2030 target for ratio of renewable energy use: 74% or more of total electricity consumption

Thanks to active efforts to introduce renewable energy, in fiscal 2023 we achieved a ratio of renewable energy usage of 77%, achieving our 2030 target ahead of schedule

CO₂ Emissions (Scope 1 + 2)



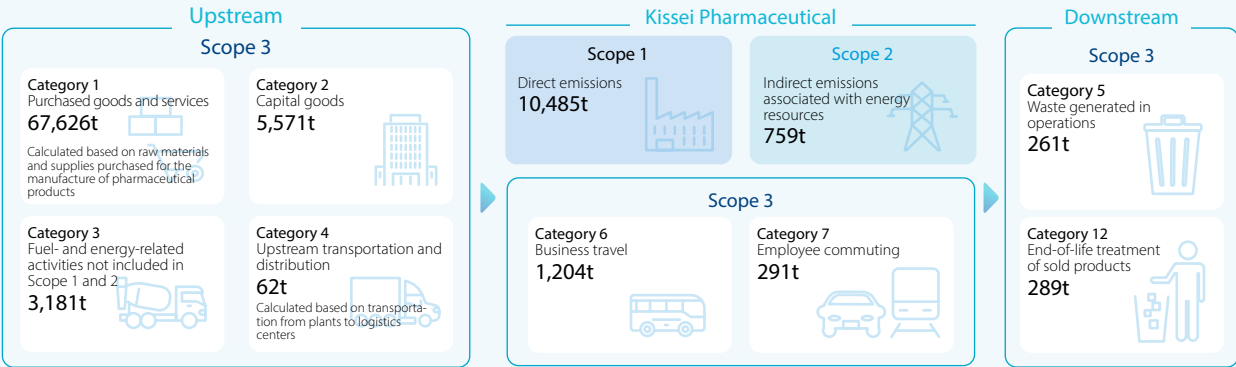
Rate of Renewable Energy Use



Scope 3 GHG Emissions in the Supply Chain

We calculate Scope 3 greenhouse gas (GHG) emissions based on the Basic Guidelines for Calculating Greenhouse Gas Emissions (Ver. 2.4), published by the Ministry of the Environment and the Ministry of Economy, Trade and Industry. In fiscal 2023, Scope 3 emissions amounted to 78,485 tons, whereas total emissions (Scope 1, 2 and 3) amounted to 89,730 tons. Of these emissions, Scope 3 Category 1 emissions (CO₂ emissions from purchased goods and services) accounted for 75.0% of total CO₂ emissions.

Going forward, we aim to reduce CO₂ emissions throughout our entire supply chain, and, in addition to efforts to reduce waste, we will also work to improve engagement with suppliers toward this goal.



Society

Relationships with Our Employees

► Material issues related to management base
Creation of a fulfilling workplace environment

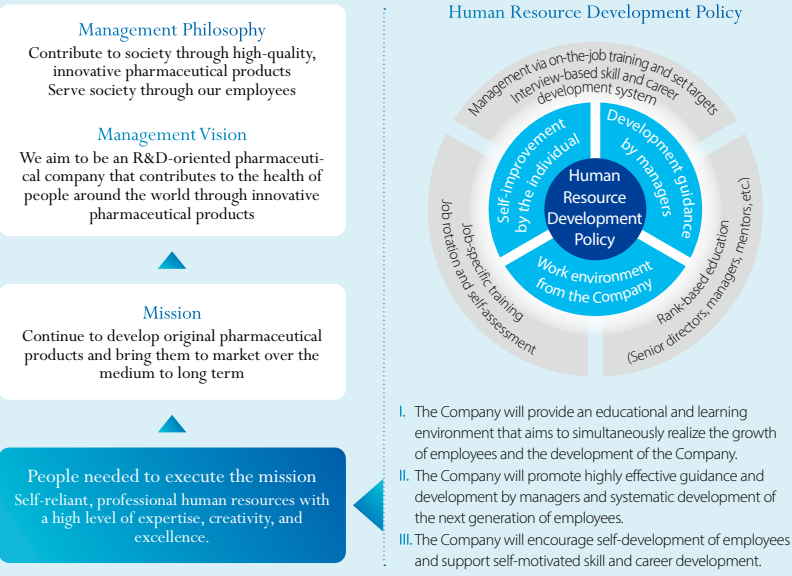
► Initiatives Related to Human Capital

Following in the spirit of the Kissei Group's Management Philosophy, which calls for us to "make greater contributions to society by creating harmony among the Group's working parts", the Kissei Code of Conduct stipulates that "we will respect the diversity, character, and individuality of all employees, aim to increase their ethical standards and abilities, and ensure a safe and comfortable working environment." Moreover, Kissei Pharmaceutical's basic approach to human capital is based on the idea that when employees with different modes of

thinking and value systems mutually accept and inspire each other, they can add dynamism and creativity to a company. We strive to improve the Company's working environment in terms of hiring practices and working styles, and have introduced an elective-based human resource system that allows employees to choose a workstyle that matches their aptitudes and life plans. These systems are part of our effort to ensure that a wide range of human resources can demonstrate their full abilities.

Human Resource Development Policy

As stated in Kissei Pharmaceutical's Management Philosophy, the Company exists to contribute to and serve society through its high-quality, innovative pharmaceuticals and its employees. As the development of new drugs becomes increasingly sophisticated, and as development risks increase, it is crucial that we cultivate autonomous and professional human resources with a high level of expertise, creativity, and excellence capable of accurately and quickly responding to changes in the environment. These human resources will make it possible to develop original pharmaceutical products and bring them to market over the medium to long term. Based on this idea, we have set "the development of autonomous human resources" as our main vision for human resources and have established three human resource development policies to achieve this goal.



Initiatives to Create a Fulfilling Workplace Environment and Raise Employee Engagement Levels

Kissei Pharmaceutical has identified the "creation of a fulfilling workplace environment" as a material issue as part of its efforts to create an environment that nurtures autonomous human resources. We measure the degree of satisfaction for each item and degree of importance, meaning how important the item is to life at the Company. We then conduct a portfolio analysis based on the degree of satisfaction and importance and identify "priority items to maintain," "items to maintain," "priority items to improve," and "items to improve." These

findings are then used to investigate, implement, and verify new human resources policies.

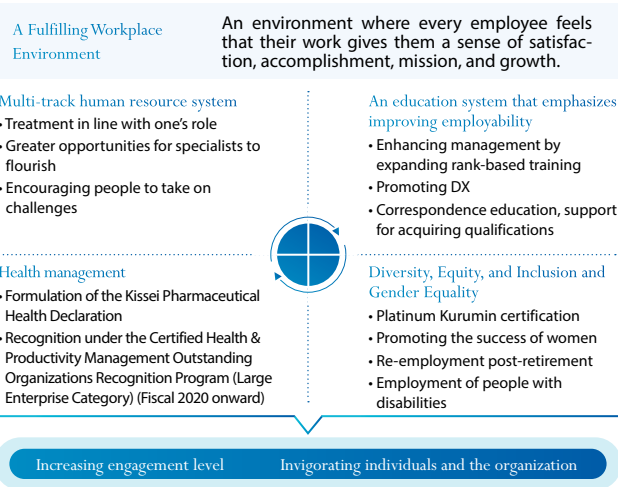
Results of the surveys conducted before fiscal 2019 and during fiscal 2022 the period of "PEGASUS," the current five-year medium-term management plan, are shown in the table below. In the survey scheduled to be conducted during the period of the next medium-term management plan, we aim to raise the average score for questions regarding engagement and job satisfaction to 3.30 points or higher through the operation of our human resources and training systems.

Results of the Human Resources Awareness Survey

Category	Items regarding Engagement and Job Satisfaction	Average Satisfaction Rating*	
		Fiscal 2019	Fiscal 2022
Engagement	I want to make Kissei a better company	3.61	3.56
	I am proud to be a Kissei employee	3.26	3.27
	I want to grow together with Kissei	3.40	3.38
	I agree with Kissei's Management Vision	3.53	3.58
Job Satisfaction	I make and carry out proposals to my superiors that I think are necessary, even if outside my target duties	3.22	3.23
	I find my work rewarding	3.18	3.22
	My work is important to achieving the Company's goals	3.40	3.42
	My work allows me to make full use of my abilities	3.15	3.17
	I feel a sense of accomplishment from my work	3.10	3.13
	I feel like I achieve personal growth through my work	3.09	3.12
	My work allows me to provide products and services that satisfy customers	2.97	3.00
	Average score	3.26	3.28

* Satisfaction rating scale: 4 (strongly agree), 3 (somewhat agree), 2 (somewhat disagree), 1 (strongly disagree)

Efforts to Create a Fulfilling Workplace Environment



▶ Operation of our Multi-Track Human Resource System

Current business conditions are in a constant state of flux, making them difficult to predict. For Kissei to achieve sustainable growth under these circumstances, we believe it is important to enable employees to fully demonstrate their abilities from an early stage, regardless of age or length of service, to foster a high level of unity among employees who actively motivate each other, and to encourage a shift away from outdated views on work and modes of thinking. Going forward, we need to evolve our corporate culture to one in which there is a healthy sense of excitement in the actions we should take and the results we should achieve, rather than comparing ourselves to others or readymade models. Based on this idea, we utilize a dual-track human resource system that emphasizes diversity and future potential based on the following three concepts:

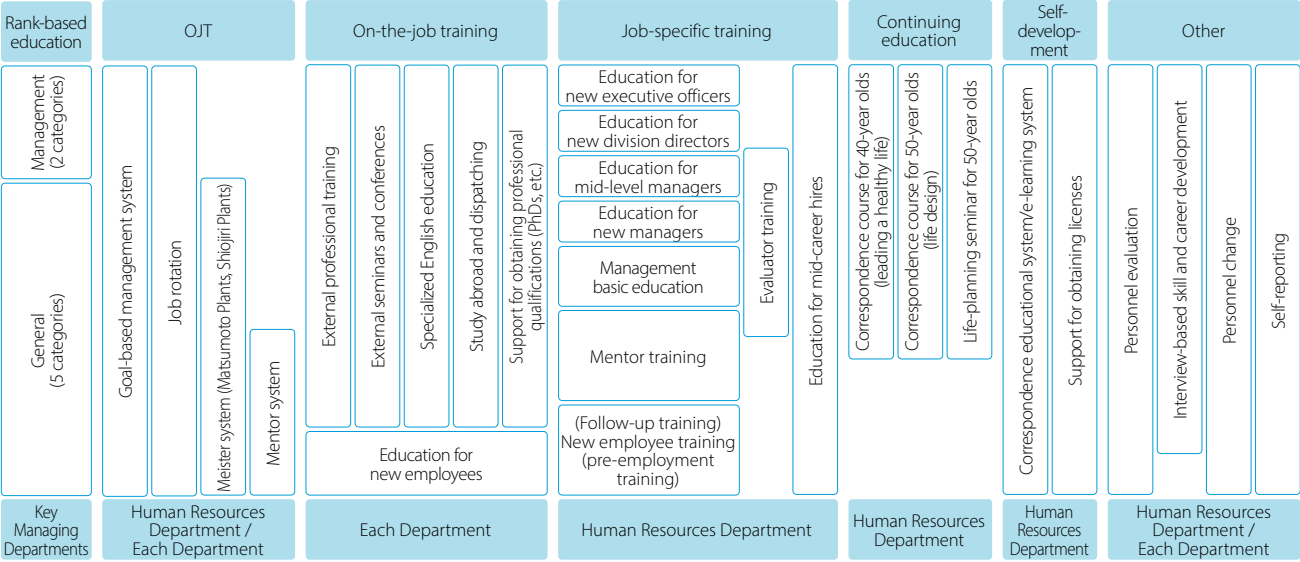
1. Treatment in line with one's role

We utilize a role-based qualification system that focuses on a person's "role", defined as one's actions and assigned duties. Employees receive certain benefits based on the results of a conduct-based evaluation, which assesses the suitability of a person's demonstrated actions, and a job-based evaluation, which assesses the scope of assigned duties and the performance record of the person carrying out those duties.

▶ Operation of Our Education System

In conjunction with our human resources system, we are expanding our rank-based training to enhance management-level employees. In addition, we are expanding e-learning to encourage more active learning and reskilling among employees by creating a learning environment unbound by time or place, and encouraging continuous learning of business and IT knowledge, English conversation, and more.

Kissei's Education System



Key Examples of Rank-Based Training and Results

Program	Goal	Participants in Fiscal 2023
Education for new division directors	Participants will learn the general expectations of a person serving as a division director and how to perform this role in practice, facilitating an early transition from organizational management to business management.	14
Education for mid-level managers	Participants will build upon their current managerial experience with the goal of developing policies and managing organizations from a higher and broader perspective.	16
Education for new managers	Participants will increase their knowledge required for managerial positions, advanced management knowledge, and specialized knowledge appropriate to the role, and receive support to help them fulfill their expected roles.	29
Basic education for management	Participants will acquire knowledge of management principles and human resource development, while also gaining motivation and positioning themselves in a central role as candidates for higher managerial positions.	35
Mentor training	Senior employees act as mentors during new employees' on-the-job training with the goal of helping new employees become productive quickly, while also improving the mentors' own leadership skills and helping them grow as leaders.	39

2. Greater opportunities for specialists to flourish

In an increasingly complex and sophisticated business environment, we are able to provide benefits properly suited to our highly specialized workers, for whom we have particularly high expectations. For managerial positions, in addition to line managers who are primarily responsible for managing organizations and people, we have established the role of professional manager, for which the primary focus is tackling management issues by utilizing their highly specialized skills. This creates multiple career paths as a result. This system enables us to reward employees who desire to contribute to the Company and support career development along a wide range of career paths.

3. Encouraging people to take on challenges

Under our qualification-based promotion system, we have abolished the standard number of years of work with the Company that was previously required to determine whether someone could be promoted to a higher grade, and have instead incorporated an application step into the system, facilitating the early promotion of highly motivated human resources.

▶ Promoting Diversity, Equity, Inclusion (DE&I) and Gender Equality

We are working to support the development of the next generation by maintaining our Platinum Kurumin certification, working to establish the groundwork for female employees to play an active role in accordance with the Act on Promotion of Women's Participation and Advancement in the Workplace, working to operate a system of continued employment up to the age of 65, and working to provide an environment in which people with disabilities can work while demonstrating their individual capabilities.



Platinum Kurumin certification and mark

Promoting the Success of Women

Kissei 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.

General Employers Action Plan

1. Period April 1, 2023–March 31, 2025

2. Goals and initiatives

- Goal 1: Increase the proportion of women hired
- Goal 2: Raise the average satisfaction level for all 36 items of the Human Resources Awareness Survey among female employees to 3.0 (somewhat agree) or higher
- Goal 3: Maintain a ratio for average length of employment for female employees to average length of employment for male employees of 80% or higher

DEI Indicators: Fiscal 2023 Results and Fiscal 2024 Targets

Item	Fiscal 2023 Results	Fiscal 2024 Targets
Percentage of female employees taking childcare leave	100%	100%
Percentage of women who remain employed one year after giving birth	100%	100%
Percentage of male employees taking childcare leave	62.0%	80% or higher
Ratio of average length of employment for female employees to average length of employment for male employees	81.6%	Maintain 80% or higher
Percentage of employees with disabilities	2.67%	2.5% or higher

Other Key Indicators: Fiscal 2022 and Fiscal 2023 Results

Item	Fiscal 2022 Results	Fiscal 2023 Results
Number of employees working shortened hours for childcare purposes	33	25
Number of employees working shortened hours for nursing care purposes	1	3

Promotion of Health Management

To realize the goals stated in our Management Philosophy and put the Code of Conduct into practice, Kissei established the Kissei Pharmaceutical Health Declaration, based on the belief that each and every employee must be healthy in both mind and body. In addition, Kissei Pharmaceutical works closely with the Kissei Group Health Insurance Society to maintain and improve the health of employees and establish a workplace that is healthy, fulfilling, and motivating so that employees are driven to put their abilities on full display. Moreover, in March 2024, we were recognized under the Certified Health & Productivity Management Outstanding Organizations Recognition Program (Large Enterprise category) for the fifth consecutive year since 2020.



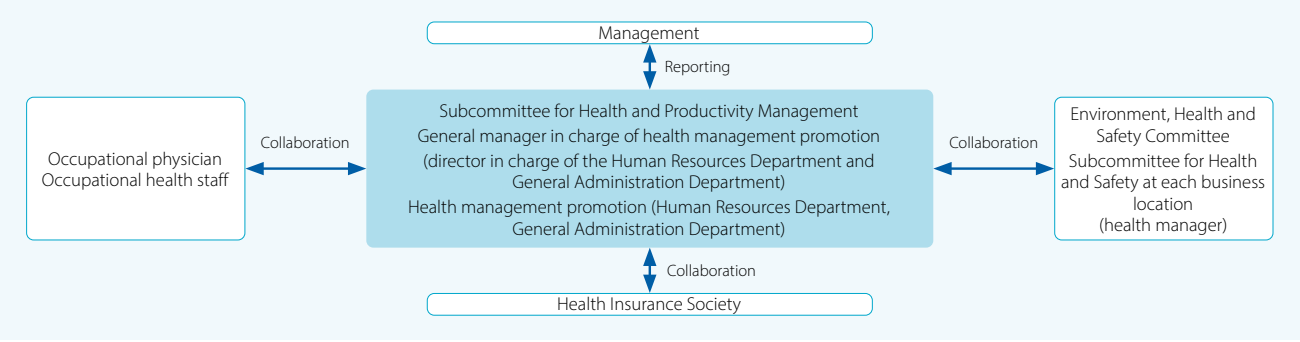
Health Management Indicators: Fiscal 2023 Results and Fiscal 2024 Targets

	Fiscal 2023 Results	Fiscal 2024 Targets
Percentage of employees who took stress checks	97.2%	100%
Percentage of employees who used commemorative leave*	99.3%	100%

* A system to encourage employees to take three days of paid annual leave for birthdays or other special days.

Health Management Promotion System

The Director in charge of the Human Resources Department and the General Administration Department is appointed as the general manager in charge of health and productivity management promotion. We have also established a Subcommittee for Health and Productivity Management to promote the planning, implementation, effectiveness, and verification of measures for health management.



Relationships with Medical Professionals and Patients

Material issues related to 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 to 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.

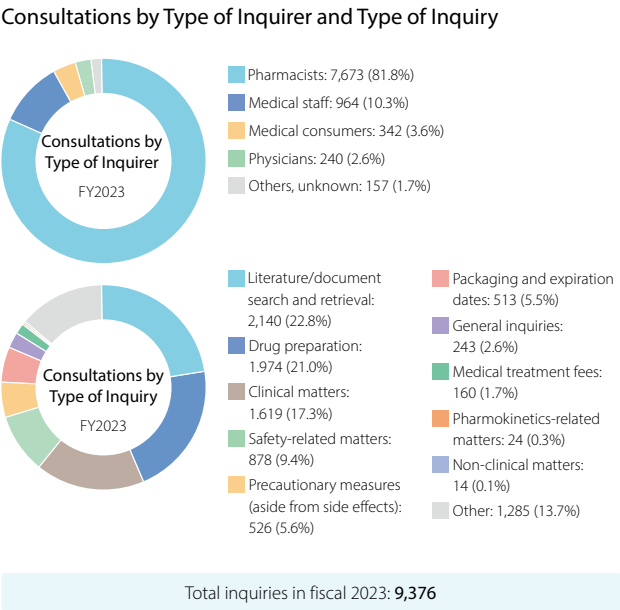
Furthermore, in September 2022, we updated KISSEI Medical Navi, a website for medical professionals, making it membership-based, which makes it possible to provide more detailed information. In October 2023, we released KISSEI Safety LINK, a system that allows medical professionals to search for and view safety information.



KISSEI Safety LINK (Japanese only)
<https://med.kissei.co.jp/>

KISSEI KUR Magazine
Since July 1983, Kissei Pharmaceutical has published issues of KISSEI KUR, a quarterly magazine dedicated to providing medical information. About 10,000 copies of each issue are published, with the goal of providing unique medical information to medical professionals. The aim of the magazine is to introduce the latest knowledge and future prospects from specialists on diseases and treatments in fields that Kissei is active in, as well as medical institutions and pharmacies that are taking unique initiatives to reach even greater heights. 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 information about "cures" to many medical professionals, be they doctors, pharmacists, nurses, or otherwise.

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 health care professionals but also patients. In fiscal 2023, we responded to 9,376 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, TAVALISSE®, launched in April 2023 as a treatment for chronic idiopathic thrombocytopenic purpura, and SAVENE®, a treatment for anthracycline extravasation. These steps have been taken to ensure prompt and accurate responses to questions requiring expertise on rare diseases in the case of TAVNEOS® and TAVALISSE®, and to urgent inquiries regarding SAVENE®.



Patient-Oriented Information Websites
Kissei has established patient-oriented websites to communicate information in its key fields of urology, renal diseases and dialysis, and rare and intractable diseases. These include dedicated websites for people with urinary disorders, dialysis patients, and patients suffering from the intractable disease ANCA-associated vasculitis (Japanese only). The concept behind these sites is to help patients and their families enjoy their lives. Accordingly, the sites contain activity and diet-related content that can help improve the daily lives of patients. In addition, the sites use a Q&A format to give specific advice focused on the various situations that they may experience. These sites provide an avenue to deliver information highly relevant to the lives of patients and their families as they deal specifically with the disease in question.

Relationships with Local Communities

Material issues related to management base
Social contribution as a good corporate citizen

A Good Corporate Citizen
Since its founding in Matsumoto, Shinshu (Nagano Prefecture) in 1946, Kissei Pharmaceutical has always valued its ties with the local community, and this love for its hometown remains deeply rooted in its corporate culture. We recognize that the role of a company is not only to revitalize the local economy, but also to address problems facing the region. Guided by our belief in helping people live healthy and fulfilling lives, we act as a good corporate citizen by continuing to contribute to society in areas such as local culture, medical treatment, health, welfare, the environment, and sports.

Contributions to Environmental Conservation
Anada River Cleanup Association
In the 1960s, the Anada River, a small river near the Kissei Pharmaceutical head office, quickly became polluted due to an increase in the local population and the expansion of businesses. Therefore, in 1972, we took the lead in establishing the Anada River Clean Up Association, a cleanup effort that brought together local residents, businesses, and the local government. Since its inception, this team has rolled up its sleeves to protect this beloved river, and, thanks to regular cleaning and public awareness raising activities in cooperation with local businesses and residents coupled with environmental beautification activities, which include the local government's efforts to establish a sewer system, the river has become one of the cleanest in Matsumoto City. River cleanups, which have been the key activity since day one, are still carried out four times a year over 50 years later.



Contributions to Medical Treatments and Health
The Kanzawa Medical Research Foundation
Since its establishment in 1997, the foundation has promoted the development of healthcare and medical science by encouraging 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.
1. Research grants
2. Overseas study grants
3. Awards for excellent results-bearing research (Kanzawa Medical Award)
4. Organization of seminars on subject studies
5. Other business necessary to achieve the foundation's goals
The total number of rewards and grants and the amount of money awarded to date (1997–2023) are shown in the following table.

	Total number	Total amount of money
Kanzawa Medical Award	25	¥76 million
Research grants	267	¥347 million
Overseas study grants	102	¥53 million

Number of Awards and Grants in Fiscal 2023
Kanzawa Medical Award
• Recipient: Professor Osamu Yoshino
• Research Institution: University of Yamanashi, Graduate Faculty of Interdisciplinary Research Faculty of Medicine Clinical Medicine (Obstetrics and Gynecology)
• Research Theme: Elucidation of follicle development and its application to endometrium, endometriosis, and bone, which are ovarian hormone target organs
Research Grants: 10 Overseas Study Grants: 4

Contributions to the Cultural Arts
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 reach them emotionally. The annual music festival Seiji Ozawa Matsumoto Festival (formerly the Saito Kinen Festival Matsumoto) is held in Matsumoto City, gathering 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, carrying on the spirit of the late, internationally renowned conductor Maestro Seiji Ozawa and resounding in the hearts of all who hear it. The festival is held in various places in Matsumoto City, including the Kissei Culture Hall, for which Kissei holds the naming rights. Kissei has supported the festival since its inception in 1992.



Photo © Michiharu Okubo, 2024 OMF

Contributions to Sports
Support for the Matsumoto Yamaga Football Club
Kissei Pharmaceutical 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 of using soccer as a means to contribute to "town development," "human development," and "future development," bringing vigor and vitality to local communities and supplying dreams and excitement to the community and its children, who have a promising future ahead of them.



Photo © Matsumoto Yamaga FC

Board of Directors



Chairman and CEO
Mutsuo Kanzawa

1976 Joined the Company
1982 Member of the Board, Senior Director of Corporate Strategy and Planning
1984 Managing Director, Senior Director of Corporate Strategy and Planning
1987 Executive Managing Director, Senior Director of Corporate Strategy and Planning
1992 President and Chief Operating Officer (COO)
2014 Chairman and CEO (current position)



President and COO
Yasuo Takehana

1984 Joined the company
2012 Member of the Board, Senior Director of Research Strategy and Planning Department, Research Division
2016 Managing Director, Senior Director of Corporate Strategy and Planning Department
2022 President and COO (current position)



Executive Vice President
Keiji Fukushima

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



Executive Managing Director
Tetsu Takayama

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



Managing Director
Takahide Kitahara

1986 Joined the Company
2018 Member of the Board, Senior Director of Corporate Finance and Management Department
2022 Managing Director, Department Manager, Senior Director of Corporate Finance and Management Department
2023 Managing Director, Department Manager, Senior Director of Corporate Finance and Management Department and CFO (current position)



Senior Adviser, Member of the Board
Yoshio Furihata

1984 Joined the Company
2000 Representative Director and President of Kissei Pharma Europe, Ltd.
2008 Member of the Board, Senior Director of Business Development Department
2010 Member of the Board, Senior Director of Corporate Strategy & Planning Department
2016 Managing Director, Division Director of Clinical Development Division
2018 President and COO
2022 Senior Adviser, Member of the Board (current position)



Member of the Board
Hiroshi Noake

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 Member of the Board, Division Director of Sales and Marketing Division (current position)



Member of the Board
Keiji Miyazawa

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 Member of the Board, Division Director of Research Division (current position)



Outside Director (Independent), Member of the Board
Shigetaka Shimizu

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 Outside Auditor at HACHIJUNI SECURITIES Co., Ltd.
2014 Outside Director at the Company (current position)

Audit & Supervisory Board Members



Audit & Supervisory Board Member (full-time)
Shinji Kikuchi

1988 Joined the Company
2011 Director of Drug Discovery Research Laboratories I
2012 Senior Director of Drug Discovery Research Department
2016 Member of the Board, Division Director of Research Division
2022 Audit & Supervisory Board Member of the Company (full-time) (current position)



Audit & Supervisory Board Member (full-time)
Naomi Koshihara

1989 Joined the Company
2019 Senior Director of Clinical Research Department, Clinical Development Division
2021 Director of Corporate Strategy & Planning Department
2022 Councilor of Corporate Strategy & Planning Department
2024 Audit & Supervisory Board Members of the Company (full-time) (current position)



Outside Audit & Supervisory Board Member (Independent)
Kando Nakagawa

1976 Registered as an Attorney-at-Law
2011 Outside Audit & Supervisory Board Member at the Company (current position)



Outside Director (Independent), Member of the Board
Minoru Nomura

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.
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)
2022 Chief Adviser of NOMURA CORPORATION OF TAIWAN (current position)



Outside Director (Independent), Member of the Board
Sayuri Uchikawa

1973 Joined Marunouchi Typist School (currently Marunouchi College of Business)
1996 Principal of Marunouchi College of Business (current position)
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)
2023 Outside Auditor at ALPICO HOLDINGS CO., LTD. (current position)



Outside Director (Independent), Member of the Board
Yoshinori Otsuki

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 (JSCP)
2021 Director of Nagano Prefectural Chapter of the United Nations Association of Japan (current position) Director of NAGANO NIHON DAIGAKU (current position)
2022 Auditor of Social Welfare Corporation Keiroen (current position) Outside Director at the Company (current position)
2024 Adviser for the Academy of International Social Sound Development Co., Ltd. (current position)



Outside Audit & Supervisory Board Member (Independent)
Michio Iwabuchi

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

Director Skill Matrix

Directors are required to have qualities that will contribute to Kissei Pharmaceutical's sustainable growth and enhance its corporate value, as well as 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	International	R&D	Sales and Marketing	Finance and Accounting	Legal / Compliance	Personnel Affairs and Human Resource Development	ESG / Sustainability
Mutsuo Kanzawa		●	●			●	●	●	●
Yasuo Takehana		●	●	●			●		●
Keiji Fukushima		●			●		●	●	●
Tetsu Takayama		●					●	●	●
Takahide Kitahara		●				●	●		●
Yoshio Furihata		●	●	●			●		●
Hiroshi Noake					●		●	●	●
Keiji Miyazawa			●	●			●		●
Shigetaka Shimizu	●	●	●			●	●		●
Minoru Nomura	●	●	●			●	●		●
Sayuri Uchikawa	●	●	●				●	●	●
Yoshinori Otsuki	●	●	●				●	●	●

Corporate Management	The person in question has extensive knowledge and experience in corporate management and business strategy, and is therefore deemed to possess skills required by a person responsible for overall management of the Company, such as the ability to make decisions from Companywide and medium- to long-term perspectives.
International	The person in question has extensive knowledge and experience in overseas business and is therefore deemed to possess skills required for corporate management, such as the ability to handle risk management from a global perspective as part of strategic planning, decision-making, and business execution.
R&D	The person in question has extensive knowledge and experience in R&D for pharmaceutical products and is therefore deemed to possess skills required by an R&D-oriented pharmaceutical company, such as the ability to develop strategies for, make decisions regarding, and facilitate advancement of drug discovery R&D.
Sales and Marketing	The person in question has extensive knowledge and experience in sales and marketing for pharmaceuticals and related products and is therefore deemed to possess the skills to accurately grasp trends in pharmaceutical and medical administrative systems, and to develop strategies, make decisions, and facilitate the advancement of sales and marketing.
Finance and Accounting	The person in question has extensive knowledge and experience in finance and accounting, and is therefore deemed to possess the skills to properly monitor and control business activities, management issues, and risks from a finance and accounting perspective.
Legal / Compliance	The person in question has extensive knowledge and experience in legal and compliance-related fields, and is therefore deemed to understand the spirit of legal systems and various regulations related to the Company's business activities, possesses the ability to take appropriate action to address them, and has the skills to promote awareness of compliance across all corporate activities.
Personnel Affairs and Human Resource Development	The person in question has extensive knowledge and experience in personnel affairs, human resources development, and organizational development and is therefore deemed to possess the skills to strategically manage and utilize human resources toward implementing our management strategies.
ESG / Sustainability	The person in question has been deemed to possess the skills to integrate efforts to tackle environmental and social issues, which is an integral part of the Company's foundation, with efforts to tackle material issues that affect the Company's business activities and promote sustainability in both management and business.

Messages from Outside Directors



Shigetaka Shimizu | Outside Director

As a result of the increase in the number of outside directors and as part of its efforts to promote diversity, Kissei has increased the ratio of outside directors to directors to one in three and has appointed a female outside director. Additionally, the establishment of the Nomination and Compensation Deliberation Committee, which comprises a majority of outside directors, and the introduction of an executive officer system have enabled the Company to reform its corporate governance structure in line with the revision of Japan's Corporate Governance Code. There have been significant improvements, particularly in relation to the "ensuring appropriate information disclosure and transparency" and "responsibilities of the Board" sections of the Code, and I understand that the Company is taking autonomous actions to achieve sustainable growth and increase corporate value. At Board meetings, we actively exchange opinions on issues without being bound by time constraints and decisions are made in a

Implementing Autonomous Reforms in Response to Revisions of Japan's Corporate Governance Code

transparent and fair manner. Depending on the agenda item, the chair may require the opinions of all members. At meetings of the Nomination and Compensation Deliberation Committee, proposals for the nomination of executive candidates and executive remuneration are discussed after the Company's current position on such matters is shared and a detailed explanation of the background and history of the proposals are given. In the discussions, I make comments and suggestions based on the knowledge I have gained over my years at a financial institution and experience gained through company management, as well as from the perspectives of other industries and the general public.

In response to the Tokyo Stock Exchange's 2023 request for companies to increase their corporate value, I believe it is necessary to establish a sustainable growth strategy that balances financial soundness and security, as well as capital profitability. The Company has set its ideal financial condition as ROE of at least 8%, price-to-book ratio (P/B ratio) of at least 1.0, and a ratio of cross-shareholdings to net assets of 10% or less. Concrete measures to achieve this ideal financial condition will be formulated in the next medium-term management plan. I would like to propose that, in doing so, the Company consider the involvement of outside directors in the Business Execution Committee, for example by utilizing the Outside Director Liaison Committee.



Sayuri Uchikawa | Outside Director

I have been teaching students and office workers at vocational schools for many years. I often find it surprising the extent to which a person's surrounding environment affects their growth. The Marunouchi College of Business, which I manage, was started three years after the end of World War II as a school to train women to become typists. During a period when opportunities for women to grow professionally were limited, the training of typists, a cutting-edge profession, was in line with the demands of the times, with graduates going on to work at city halls, courts, hospitals, and major corporations. All people, not just women, grow by learning; in doing so, they increase their potential for success.

The Board's agenda items are often outside my area of expertise. I am a complete novice when it comes to drug discovery, but I was able to attend study sessions for outside directors in fiscal 2023, in which the topic was explained in an easy-to-understand manner. I would like the

Improving Working Environments by Promoting DE&I in Addition to Financial Initiatives

study sessions to continue so that we can have a better understanding of the Company's vision for the future. It is also important for all employees, regardless of gender, to learn about their own perspectives, but the issue is whether everyone is getting the chance to do so. In the future, it will be necessary to offer a "management school" for prospective executive officers to younger employees.

Despite the relatively small number of women involved in Kissei's business activities, the Company has been fostering an environment where women are able to take general manager-level positions for some time, and the June 2024, General meeting of shareholders elected a new female Audit & Supervisory Board member—not an outside officer, a full-fledged inside officer. I think we will see an increase in Board meetings in which three women are in attendance: a female general manager, a female Audit & Supervisory Board member, and a female outside director. While three may be a small number, it will nevertheless make it easier for us women to voice our opinions. I am very pleased to see more male employees utilizing the parental leave system, and the progress being made in relation to diversity, equity, & inclusion (DE&I). A particular focus going forward will be on how we can promote equity. I will do my best to emphasize to the Board that a company is not evaluated based solely on its financial condition, but also on its efforts to create an environment where everyone can work comfortably.



Minoru Nomura | Outside Director

For 35 years, I have served as president and representative director of a company engaged in the manufacture of metal components, semiconductor manufacturing equipment, and industrial robots, as well as a company engaged in the sale of alcoholic beverages. I have served as an outside director on the Company's Board of Directors for eight years, since 2016, and I consider my role in this capacity to be providing support to the Board of Directors. For each agenda item, necessary materials and briefings are always provided in advance and sufficient time is set aside for discussions on important management issues, allowing for lively exchanges of opinions. The Board of Directors has been evaluated as functioning properly and effectively in terms of both decision-making and supervision. I would like to help to further enhance its effectiveness based on my

Supporting Management from an Objective Standpoint

own experience in company management, product development, and overseas expansion.

The Nomination and Compensation Deliberation Committee also operates in an effective manner, and I always strive to speak at meetings with an emphasis on getting to know people, which is my motto. In addition to the Board of Directors meetings, the Outside Directors Liaison Conference, comprised of outside directors, is held in the presence of Audit & Supervisory Board members, where opinions are freely and openly exchanged from the standpoints of the respective attendees. The meetings are aimed at acquiring and refining information and knowledge that is useful for management, and the results of the discussions are reflected in the management of the Company.

Looking at recent news reports about compliance violations by well-known companies, I am reminded of the phrase "the heavens are watching," which I take to mean that one should never go against basic human values. Even in companies where the board of directors is highly effective in its supervision, I feel it is necessary that they take these recent events as a lesson and further strengthen their corporate governance. I will continue to participate in board meetings, keeping in mind my role to support management from an objective standpoint.



Yoshinori Otuski | Outside Director

I believe that the Kissei's V-shaped recovery in fiscal 2023, in which it overcame the decline in business performance caused by Urief's patent cliff, among other factors, is the result of three of the Company's strengths—the relationship of trust between management and employees, the strong sense of purpose among employees, and the sense of unity to resolve issues. The chair conducts the proceedings at Board of Directors meetings with great care, allowing outside directors and outside Audit & Supervisory Board members to engage in lively exchanges of opinion. I find that the discussions in the Nomination and Compensation Deliberation Committee are of high quality, with the outside directors, who make up the majority of the committee, providing opinions based on their own corporate management and global experience and knowledge from a third-party standpoint. It also provides ample opportunities for outside directors and Audit & Supervisory Board members to exchange opinions and learn about any updates concerning the improvement of corporate value. As we enter the final year of our medium-term management plan "PEGASUS," we believe that our efforts toward our non-financial indicators on human capital will lead to higher stakeholder

Boldly Rising to the Challenge of Change in an Era of Diversity

appreciation and employee satisfaction, and we will strive to ensure that we check, speak up, and actively provide information based on our own experiences.

After retiring from the Nagano Prefectural Government, I am currently working with a blueberry garden in Matsumoto City, where our company's headquarters is located, to assist people with disabilities in playing an active role in society and securing employment. At a time when the labor shortage is a major constraint on economic development, I am also working to create a model for a harmonious global society that accepts technical interns not as cheap labor but as worthy partners, in cooperation with Ueda City, local companies, and the local community. I would like build on my experience to help strengthen the Company's human capital efforts.

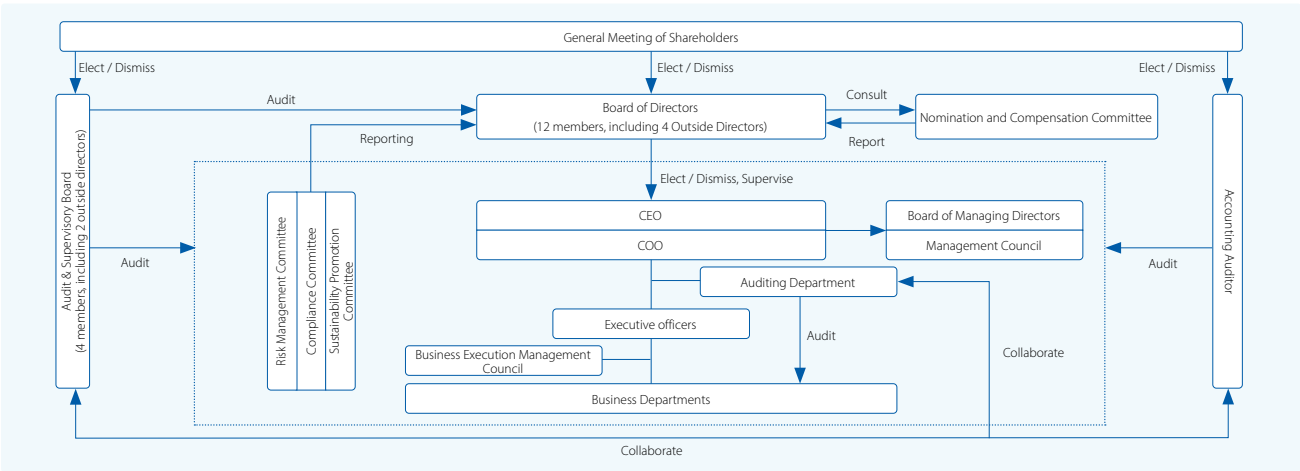
This year, Japan's Population Strategy Council released a striking analysis showing that 40% of the nation's municipalities could disappear by 2050 due to population decline, while a severe labor shortage has led to record number of foreign workers supporting local economies—more than 2 million nationwide and 25,000 in Nagano Prefecture last fiscal year. It is estimated that the number of foreigners living in Japan will exceed 10% of the total population in the future, and in the field of education, educational guidelines have undergone a major revision from an emphasis on children acquiring knowledge to the cultivation of problem-solving skills. In his theory of evolution, Darwin said that those who are most adaptable to change are the ones who survive. In an age where change is the norm and there is no right or wrong answer, I am determined to work in my capacity as an outside director to boldly confront change, even though it may be difficult and risky, together with the Company's employees.

Corporate Governance

Basic Approach

Kissei Pharmaceutical has formulated the Kissei Basic Policy on Corporate Governance under the belief that strengthening and enhancing corporate governance is an important management issue for the Company to increase corporate value and achieve sustainable growth while maintaining its significance and value to society. By implementing 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 a sound and sustainable company that plays a necessary role in society.

Corporate Governance System



At Kissei, the Board of Directors has been positioned as a body that makes decisions about basic management policies and key management issues and as a body for monitoring the status of business execution. Serving in this role, the Board strives to increase the speed of decision-making and enhance the transparency of management. Kissei has also established the Nomination and Compensation Deliberation Committee, comprising outside directors (and outside Audit & Supervisory Board members) in the case of selecting Audit & Supervisory Board members), the CEO, and 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 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. CEO Mutsuo Kanzawa chairs this committee.

Under the current governance system, the Chairman and CEO is given authority over all matters pertaining to management, whereas the President and 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 ranked managing director and above, to discuss and decide on pre-determined items for discussion. We have 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 has 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 Group 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 rapid changes in the business environment, we also adopted an executive officer system in June 2022, aiming to further strengthen corporate governance and build a more flexible business execution system.

Committees Directly Controlled by the Board of Directors

1. Risk Management Committee

This committee serves as an advisory body to the Board of Directors, deciding on policies, systems, and countermeasures related to risk management for Kissei and its Group companies and reporting to the Board about the management system for risks and its status.

2. Compliance Committee

This committee serves as an advisory body to the Board of Directors, establishing, revising, and removing internal rules and manuals, designing and implementing education and training programs, and analyzing the results of these programs for Kissei and its Group companies. The committee also reports to the Board of Directors regarding the state of compliance.

3. Sustainability Promotion Committee

This committee serves as an advisory body to the Board of Directors, and as an advisory body to the Board of Directors, proposes various measures within sustainability activities, such as identifying material issues that Kissei should address as a priority, setting KPIs for activities, and confirming progress. At the same time, the committee collaborates with related departments to promote these measures and regularly holds discussions with and reports to the Board of Directors.

Status of the Board of Directors

The Board of Directors is chaired by CEO Mutsuo Kanzawa and consists of 12 directors and four Audit & Supervisory Board members, including four independent outside directors and two independent outside Audit & Supervisory Board members. In addition to discussing and deciding on matters stipulated by law and the Articles of Incorporation, as well as matters related to organization and structure, the Board of Directors also monitors business execution, including business performance and risks. The Board of Directors meets once a month as a general rule and held 14 meetings in fiscal 2023. With the exception of one absence by Executive Vice President Keiji Fukushima, all directors and Audit & Supervisory Board members have attended every meeting. In addition, three written resolutions were submitted to the Board of Directors. In each case, all directors expressed their consent and no Audit & Supervisory members raised an objection. Therefore these resolutions are considered to be resolved.

Specific Items Discussed and Determined in Fiscal 2023

1. R&D

- Setting new drug discovery themes
- Direction going forward for the U.S. development of linzagolix, a treatment for uterine fibroids and endometriosis
- Withdrawal of NDA application for rovatirelin, a treatment for spinocerebellar ataxia

2. Sales and Marketing

- Support for investigator-initiated clinical research for Beova® Tablets, a treatment for overactive bladder
- Plan for introducing KORSUVA®, a treatment for pruritis in dialysis patients, to the market
- Changes to wholesale prices and sales rebates in line with 2024 NHI drug price revisions

3. Capital Investment

- Construction of a building for drug formulations to increase production capacity

4. Sustainability and SDGs

- Establishment of a Basic Stance on Sustainability

5. Capital Policy, Other

- Purchase and Cancellation of Treasury Stock
- Investigations aimed at establishing management conscious of the cost of capital and stock prices
- Sale of investment securities

Evaluation of the Effectiveness of the Board of Directors

Once a year, each director carries out a self-evaluation for the effectiveness of the Board. Gathering opinions from each director and holding discussions with outside directors, the CEO, the COO, and other directors, we leverage this information in enhancing and reinforcing corporate governance.

Items Evaluated

1. Set roles of the Board of Directors, Board members, and the Audit & Supervisory Board
2. Corporate organizational structure
3. Board meeting agenda and deliberation time
4. Information required for meetings
5. Leadership of the Board chair
6. Directors' skill
7. Member diversity
8. Performance analysis of the Board/directors

Results of Evaluation

The Company's Board of Directors was evaluated as sufficiently effective in fiscal 2023, having effectively performed its decision-making, business execution, and supervisory functions. In addition, discussions were held on improving and strengthening governance throughout the Kissei Group, including affiliated companies, and information was shared during meetings.

Director Compensation

Details of Compensation for Individual Directors

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

At the 63rd Annual General Meeting of Shareholders held on June 26, 2008, a resolution was passed setting the maximum compensation for directors at ¥50 million per month, not including employee salaries. The number of directors as of the conclusion of this Annual General Meeting of Shareholders was 14.

Policies for Determining Compensation Amounts for Individual Directors and Calculation Methods

The Board of Directors has the authority to decide the policy regarding the determination of individual compensation for the directors. The Nomination and Compensation Deliberation Committee—consisting of outside directors, the CEO, and the COO—conducts comprehensive examinations and deliberations regarding compensation amounts, which include checking for consistency between these amounts and the aforementioned policy. After this process, the individual amounts are proposed to the Board of Directors. As a general rule, the Board of Directors will follow the recommendations of the committee when determining individual compensation amounts, and therefore has determined that individual amounts for the fiscal year under review are in accordance with the determination policy.

Risk Management

Overview of Risk Management System

As part of its Risk Management Regulations, Kissei Pharmaceutical established the Basic Risk Management Policy and a risk management system. In addition, the Company has 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 the system's implementation.

Major Risks	Description
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 for which we have licensed out the development and marketing rights overseas, there is a possibility that there may be unexpected changes to licensee business conditions or portfolios, or that development or compliance with pharmaceutical regulations in the licensed region may not proceed as planned.
Medical System Reform	An overhaul of Japan's social insurance scheme is underway in an effort to address the declining birthrate and aging population. In the medical field, measures are being taken to maintain Japan's universal healthcare system that include stricter regulations in regard to the NHI drug pricing system, most notably the annual setting of the government's NHI drug prices. In the future, there may be drastic reforms or stricter regulations of medical and pharmaceutical administrative systems that go beyond Kissei's expectations, including revisions to Japan's health insurance system, which could negatively impact Kissei's operating results and financial position.
Competition with Other Companies' Products	The Kissei Group faces competition from companies selling products with the same applications 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.
Unexpected Side Effects	Side effects undiscovered at the R&D stage sometimes appear after a drug has already been released to the market. If such 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.
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, this could negatively impact Kissei's operating results and financial position.
Intellectual Property Rights	If the Kissei Group is unable to suitably protect its intellectual property, a third party may be able to use the Group's technology, which would undermine the Group's competitive superiority in the market. Conversely, if the Group's business activities involve intellectual property rights owned by third parties, it may lead to associated disputes and damages or the suspension of said business activities.
Litigation	At present, there is no outstanding litigation affecting the Kissei Group's management. The possibility exists, 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.
Information Security Management	Business may be hindered by cyberattacks on the various information systems used by the Kissei Group. The Group is therefore paying close attention to the need to protect information by establishing strict rules for the management of personal and confidential information, as well as providing education and training on this issue to employees. However, there is the possibility that an unexpected incident could occur in which information is leaked or improperly disclosed. In such an event, the Kissei Group's image may be tarnished, which could negatively impact Kissei's operating results and financial position.
Supply Chain Issues	Business activities could be minimized or suspended due to direct or indirect damage incurred by Kissei or its partners; 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 Kissei's operating results and financial position.
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 may record 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.
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.
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. This could negatively impact Kissei's operating results and financial position.

Note: Forward-looking statements are made based on judgments made by the Group as of the end of fiscal 2023.

Compliance

Compliance-Related Initiatives

As an R&D-oriented pharmaceutical company, Kissei Pharmaceutical strives to contribute to society through high-quality, innovative pharmaceutical products. Furthermore, as a company listed on the Prime Market segment of the Tokyo Stock Exchange, we are expected to be a role model for society.

Bearing this philosophy and these expectations in mind, we recognize that management in accordance with the law is the underlying premise and foundation of all our corporate activities.

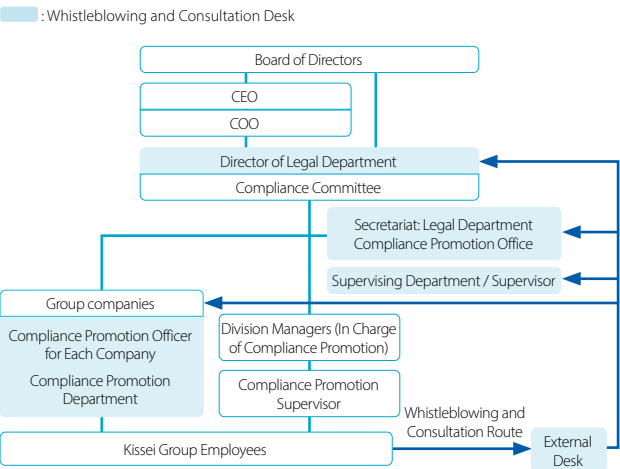
Therefore, we have formulated the Kissei Code of Conduct, which serves as a code of conduct for corporate activities, as well as our Compliance Program Manual, and use both to operate in a way that promotes management in accordance with the law and a high ethical standard.

Compliance Promotion System

Kissei Pharmaceutical has established a Compliance Committee under the direct control of the Board of Directors to promote and maintain management in accordance with the law. The committee is chaired by the director of the Legal 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 finalized, these action plans are implemented thoroughly by each department head. Moreover, the Compliance Promotion Office of the Legal Department develops and implements education and training activities.

The Kissei Group also engages in Groupwide compliance practices led by compliance officers appointed by each Group company under an internal control agreement. The Kissei Group Compliance Officers' Meeting is held regularly, during which these compliance officers share action plans, report results, and exchange related information. At these meetings, officers also receive education and training.

Compliance Promotion System



Whistleblowing and Consultation System (Kissei Hotline)

In response to amendments to the Whistleblower Protection Act (Act No. 51 of 2020), the Kissei Group has established the Kissei Hotline, its whistleblowing and consultation system. The goal of the Kissei Hotline is to protect whistleblowers, while preventing the violation of laws and regulations within the Group, as well as any damage or losses that could result from such violations. Moreover, the hotline serves to heighten self-regulation among Group companies.

Officers, employees, and people who have left the company 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 Activities (management in accordance with the law)

Continued education and training is crucial for employees to understand the importance of observing the laws and internal regulations, as well as the underpinning corporate ethics. This education and training also ensures that they can fulfill their respective roles and responsibilities under compliant management.

Efforts to encourage greater employee understanding and awareness regarding compliance include regular instructions and messages from top management about compliant management and the Company's Compliance Program Manual, which is distributed to every employee and officer and contains policies for ensuring proper compliance during daily activities and conduct. In addition, the Company provides rank-based education to officers, division and department managers, newly appointed managers and supervisors, and new employees. This education matches the relevant stage in their careers. Furthermore, employees receive education and training for work directly related to their duties, covering the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the Pharmaceuticals and Medical Devices Act).

In fiscal 2024, we began providing education and training to ensure we meet all legal requirements as laws and regulations become increasingly diverse and complex.

Main Compliance Education and Training Implemented in Fiscal 2023

Main Items Implemented	
Companywide training	• Reporting results of the Fiscal 2023 Compliance Status Questionnaire • Month-long training dedicated to understanding the Code of Practice (held annually) • Distribution of materials aimed at raising awareness of the Pharmaceutical and Medical Devices Act (Fifth Edition)
Rank-based training	• Training regarding the Guidelines for Sales Information Provision Activities for Ethical Drugs • Training regarding proper promotion of labor management • Training regarding a psychologically safe workplace • Promoting new compliance that is stronger and more controlled • Promoting management in accordance with the law in a new era • Countermeasures against power harassment (an abuse of power by superiors) to improve psychological safety in the workplace • New employee education (Management Philosophy, corporate code of conduct, etc.)
Departmental training	Conducted compliance-related training/education a total of 1,255 times in 152 departments, including training/education related to the Compliance Program Manual, promotional and drug information provision activities, Fair Competition Code case studies, etc.

Compliance Status Survey

Every year, we conduct a Compliance Status Questionnaire targeting all employees and workplaces. 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. Until fiscal 2023, the response rate to the questionnaire had increased every year following its introduction in fiscal 2005. However, at 93.1%, the rate remains high. 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 to improve compliance awareness.

Consolidated Balance Sheet

KISSEI PHARMACEUTICAL CO., LTD. and its subsidiaries
At March 31, 2023 and 2024

Assets	Millions of yen		Thousands of U.S. dollars
	2023	2024	2024
Current Assets			
Cash and deposits	¥ 25,893	¥ 22,894	\$ 151,215
Notes receivable - trade	173	126	832
Accounts receivable - trade	21,910	27,664	182,721
Contract assets	696	889	5,872
Securities	23,706	23,039	152,173
Merchandise and finished goods	12,679	14,310	94,518
Work in process	129	304	2,008
Raw materials and supplies	9,990	11,682	77,160
Other	5,461	3,640	24,042
Total current assets	100,641	104,551	690,561
Non-Current Assets			
Property, plant and equipment			
Buildings and structures	39,026	38,954	257,292
Accumulated depreciation	(30,848)	(30,954)	(204,452)
Buildings and structures, net	8,177	7,999	52,834
Land	13,615	13,594	89,789
Construction in progress	27	383	2,530
Other	16,116	16,855	111,328
Accumulated depreciation	(13,357)	(13,972)	(92,285)
Other, net	2,758	2,883	19,042
Total property, plant and equipment	24,579	24,861	164,207
Intangible Assets			
Software	1,192	1,444	9,538
Goodwill	—	309	2,041
Other	314	239	1,579
Total intangible assets	1,507	1,992	13,157
Investments and Other Assets			
Investment securities	74,769	106,361	702,517
Long-term loans receivable	5	5	33
Long-term prepaid expenses	15,209	14,219	93,917
Retirement benefit asset	3,089	7,311	48,289
Deferred tax assets	433	608	4,016
Other	983	1,034	6,830
Allowance for doubtful accounts	(18)	(18)	(119)
Total investments and other assets	94,472	129,523	855,502
Total non-current assets	120,558	156,377	1,032,873
Total assets	¥221,200	¥260,929	\$1,723,441

Liabilities	Millions of yen		Thousands of U.S. dollars
	2023	2024	2024
Current Liabilities			
Notes and accounts payable - trade	¥ 4,617	¥ 4,893	\$ 32,318
Short-term borrowings	1,490	1,340	8,851
Income taxes payable	408	2,380	15,720
Provision for bonuses	1,670	1,847	12,199
Provision for bonuses for directors (and other officers)	9	9	59
Provision for sales promotion expenses	149	143	945
Contract liabilities	1,846	1,486	9,815
Other	4,764	5,562	36,737
Total current liabilities	14,957	17,663	116,664

Non-Current Liabilities			
Deferred tax liabilities	10,426	21,188	139,947
Provision for retirement benefits for directors (and other officers)	192	209	1,380
Asset retirement obligations	139	143	945
Other	669	588	3,884
Total non-current liabilities	11,428	22,129	146,162
Total liabilities	26,385	39,793	262,834

Net Assets			
Shareholders' equity			
Share capital	24,356	24,356	160,872
Capital surplus	24,226	24,226	160,013
Retained earnings	125,576	127,310	840,885
Treasury shares	(12,912)	(13,209)	(87,246)
Total shareholders' equity	161,246	162,683	1,074,524
Accumulated other comprehensive income			
Valuation difference on available-for-sale securities	30,393	52,782	348,626
Remeasurements of defined benefit plans	2,259	4,562	30,132
Total accumulated other comprehensive income	32,653	57,344	378,758
Non-controlling interests	914	1,107	7,312
Total net assets	194,814	221,136	1,460,608
Total liabilities and net assets	¥221,200	¥260,929	\$1,723,441

Consolidated Statement of Income and
Consolidated Statement of Comprehensive Income

KISSEI PHARMACEUTICAL CO., LTD. and its subsidiaries
For the years ended March 31, 2023 and 2024

Consolidated Statement of Income

	Millions of yen		Thousands of U.S. dollars
	2023	2024	2024
Net Sales	¥67,493	¥75,579	\$499,201
Cost of sales	35,118	38,238	252,563
Gross profit	32,374	37,341	246,638
Selling, General and Administrative Expenses	33,503	33,324	220,106
Operating profit (loss)	(1,129)	4,017	26,532
Non-Operating Income			
Interest income	23	21	139
Dividend income	1,379	1,297	8,567
Gain on sale of securities	50	585	3,864
Gain on valuation of securities	65	307	2,028
Foreign exchange gains	186	—	—
Other	131	116	766
Total non-operating income	1,837	2,329	15,383
Non-Operating Expenses			
Interest expenses	20	18	119
Foreign exchange losses	—	103	680
Provision of allowance for doubtful accounts	15	—	—
Commission expenses	65	65	429
Other	8	16	106
Total non-operating expenses	109	203	1,341
Ordinary Profit	598	6,142	40,568
Extraordinary Income			
Gain on sale of non-current assets	67	121	799
Gain on sale of investment securities	13,018	8,228	54,346
Total extraordinary income	13,086	8,349	55,145
Extraordinary Losses			
Loss on disposal of non-current assets	4	41	271
Loss on sale of investment securities	0	—	—
Loss on valuation of investment securities	—	1	7
Total extraordinary losses	4	43	284
Profit before income taxes	13,680	14,449	95,436
Income taxes - current	2,113	3,263	21,552
Income taxes - deferred	932	(104)	(687)
Total income taxes	3,046	3,159	20,865
Profit	10,634	11,289	74,564
Profit Attributable to Non-Controlling Interests	105	128	845
Profit Attributable to Owners of Parent	¥10,528	¥11,160	\$ 73,712

Consolidated Statement of Comprehensive Income

	Millions of yen		Thousands of U.S. dollars
	2023	2024	2024
Profit	¥ 10,634	¥11,289	\$ 74,564
Other Comprehensive Income			
Valuation difference on available-for-sale securities	(14,688)	22,398	147,939
Remeasurements of defined benefit plans, net of tax	(174)	2,357	15,568
Total other comprehensive income	(14,863)	24,755	163,507
Comprehensive Income	¥ (4,229)	¥36,044	\$238,071
Comprehensive income attributable to:			
Owners of parent	¥ (4,349)	¥35,851	\$236,797
Non-controlling interests	120	192	1,268

Consolidated Statement of Changes in Equity

KISSEI PHARMACEUTICAL CO., LTD. and its subsidiaries
For the years ended March 31, 2023 and 2024

	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, 2022	¥24,356	¥24,226	¥118,183	¥(12,912)	¥153,854	¥45,095	¥2,435	¥47,531	¥794	¥202,180
Changes during period										
Dividends of surplus			(3,135)		(3,135)					(3,135)
Profit attributable to owners of parent			10,528		10,528					10,528
Purchase of treasury shares				(0)	(0)					(0)
Cancellation of treasury shares					—					—
Net changes in items other than shareholders' equity						(14,702)	(176)	(14,878)	120	(14,757)
Total changes during period	—	—	7,392	(0)	7,392	(14,702)	(176)	(14,878)	120	(7,365)
Balance at March 31, 2023	24,356	24,226	125,576	(12,912)	161,246	30,393	2,259	32,653	914	194,814
Changes during period										
Dividends of surplus			(3,722)		(3,722)					(3,722)
Profit attributable to owners of parent			11,160		11,160					11,160
Purchase of treasury shares				(6,000)	(6,000)					(6,000)
Cancellation of treasury shares		(0)	(5,704)	5,704	—					—
Net changes in items other than shareholders' equity						22,388	2,302	24,690	192	24,883
Total changes during period	—	(0)	1,734	(296)	1,437	22,388	2,302	24,690	192	26,321
Balance at March 31, 2024	¥24,356	¥24,226	¥127,310	¥(13,209)	¥162,683	¥ 52,782	¥4,562	¥ 57,344	¥1,107	¥221,136

	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, 2023	\$ 160,872	\$ 160,013	\$ 829,432	\$ (85,284)	\$ 1,065,033	\$ 200,746	\$ 14,921	\$ 215,674	\$ 6,037	\$ 1,286,750
Changes during period										
Dividends of surplus			(24,584)		(24,584)					(24,584)
Profit attributable to owners of parent			73,712		73,712					73,712
Purchase of treasury shares				(39,630)	(39,630)					(39,630)
Cancellation of treasury shares		(0)	(37,675)	37,675	—					—
Net changes in items other than shareholders' equity						147,873	15,205	163,078	1,268	164,353
Total changes during period	—	(0)	11,453	(1,955)	9,491	147,873	15,205	163,078	1,268	173,851
Balance at March 31, 2024	\$160,872	\$160,013	\$840,885	\$(87,246)	\$1,074,524	\$348,626	\$30,132	\$378,758	\$7,312	\$1,460,608

Consolidated Statement of Cash Flows

KISSEI PHARMACEUTICAL CO., LTD. and its subsidiaries
For the years ended March 31, 2023 and 2024

	Millions of yen	Thousands of U.S. dollars	
	2023	2024	2024
Cash flows from operating activities:			
Profit before income taxes	¥ 13,680	¥ 14,449	\$ 95,436
Depreciation and amortization	4,109	4,254	28,098
Increase (decrease) in provisions	(18)	180	1,189
Decrease (increase) in retirement benefit asset	(880)	(830)	(5,482)
Interest and dividend income	(1,402)	(1,319)	(8,712)
Interest expenses	20	18	119
Loss (gain) on sale of securities	(50)	(585)	(3,864)
Loss (gain) on valuation of securities	(65)	(307)	(2,028)
Loss (gain) on sale of non-current assets	(67)	(121)	(799)
Loss on disposal of non-current assets	4	41	271
Loss (gain) on sale of investment securities	(13,018)	(8,228)	(54,346)
Loss (gain) on valuation of investment securities	—	1	7
Decrease (increase) in trade receivables and contract assets	27	(5,863)	(38,725)
Decrease (increase) in inventories	(3,810)	(3,480)	(22,985)
Decrease (increase) in other current assets	(946)	(110)	(727)
Increase (decrease) in trade payables	513	275	1,816
Increase (decrease) in contract liabilities	(850)	(394)	(2,602)
Increase (decrease) in other current liabilities	466	1,086	7,173
Increase (decrease) in other non-current liabilities	(2)	(160)	(1,057)
Other, net	27	8	53
Subtotal	(2,262)	(1,086)	(7,173)
Interest and dividends received	1,302	1,261	8,329
Interest paid	(20)	(18)	(119)
Income taxes paid	(5,699)	(1,834)	(12,114)
Net cash provided by (used in) operating activities	(6,679)	(1,677)	(11,077)
Cash flows from investing activities:			
Payments into time deposits	(75)	(51)	(337)
Proceeds from withdrawal of time deposits	75	53	350
Payments into investments in specified money trusts	(800)	—	—
Proceeds from withdrawal of investments in specified money trusts	888	2,911	19,227
Purchase of property, plant and equipment	(2,103)	(1,201)	(7,933)
Proceeds from sale of property, plant and equipment	78	175	1,156
Purchase of intangible assets	(444)	(632)	(4,174)
Purchase of investment securities	(991)	(2,349)	(15,515)
Proceeds from sale and redemption of investment securities	14,022	11,849	78,263
Loan advances	(8)	(3)	(20)
Proceeds from collection of loans receivable	11	5	33
Purchase of long-term prepaid expenses	(4,688)	(1,256)	(8,296)
Payment due to absorption-type split	—	(750)	(4,954)
Other, net	35	(59)	(390)
Net cash provided by (used in) investing activities	6,001	8,690	57,398
Cash flows from financing activities:			
Repayments of short-term borrowings	(150)	(150)	(991)
Repayments of lease liabilities	(133)	(133)	(878)
Dividends paid	(3,135)	(3,722)	(24,584)
Purchase of treasury shares	(0)	(6,000)	(39,630)
Net cash provided by (used in) financing activities	(3,420)	(10,006)	(66,090)
Effect of exchange rate change on cash and cash equivalents	(21)	(3)	(20)
Net increase (decrease) in cash and cash equivalents	(4,120)	(2,997)	(19,795)
Cash and cash equivalents at beginning of period	53,004	48,884	322,880
Cash and cash equivalents at end of period	¥ 48,884	¥ 45,887	\$ 303,085

Corporate Information (as of March 31, 2024)

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: 1,333

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

Non-Consolidated Subsidiaries

KISSEI AMERICA, INC.

400 Kelby Street, 16FL Fort Lee, NJ 07024, USA

PROS CO., LTD.

Hamamatsu Act Tower 16F, 111-2 Itaya-machi, Chuo-ku, Hamamatsu,

Shizuoka 430-7716, Japan

Consolidated Subsidiaries

Kissei Shoji Co., Ltd.

1-1, Hiratahigashi 2-chome, Matsumoto, Nagano 399-0014, Japan

Established: April 1977

Number of employees: 38

KISSEI COMTEC CO., LTD.

KIC Building, 4010-10, Wada, Matsumoto, Nagano 390-1293, Japan

Established: April 1985

Number of employees: 339

HASHIBA TECHNIOS 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

Stock Code: 4547

Common Stock: Authorized: 227,000,000 shares Issued: 49,311,185 shares

Number of Shareholders: 4,188 (Decreased by 138 compared with the previous fiscal year-end)

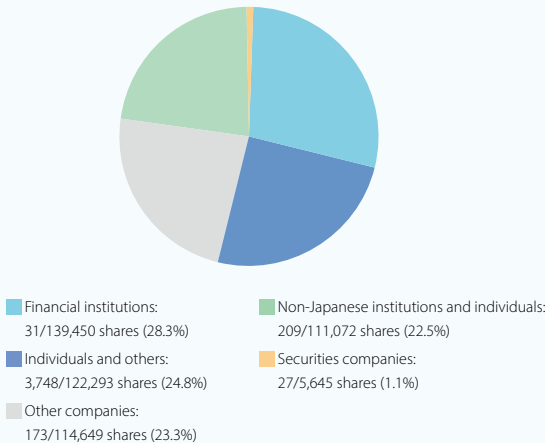
Principal Shareholders

Name	Number of shares held (hundreds)	Voting rights (%)
The Master Trust Bank of Japan, Ltd. (Trust account)	46,944	10.6
The Hachijuni Bank, Ltd.	22,034	5.0
Custody Bank of Japan, Ltd. (Trust account)	19,823	4.5
The Dai-ichi Life Insurance Company, Limited	19,200	4.3
Kanzawa Limited	16,782	3.8
Mutsuo Kanzawa	15,425	3.5
Kissei Group Employee Stockholders Committee	12,577	2.8
Nabelin Co., Ltd.	12,223	2.8
STATE STREET BANK AND TRUST COMPANY 505103	9,488	2.1
Shionogi & Co., Ltd.	9,140	2.1

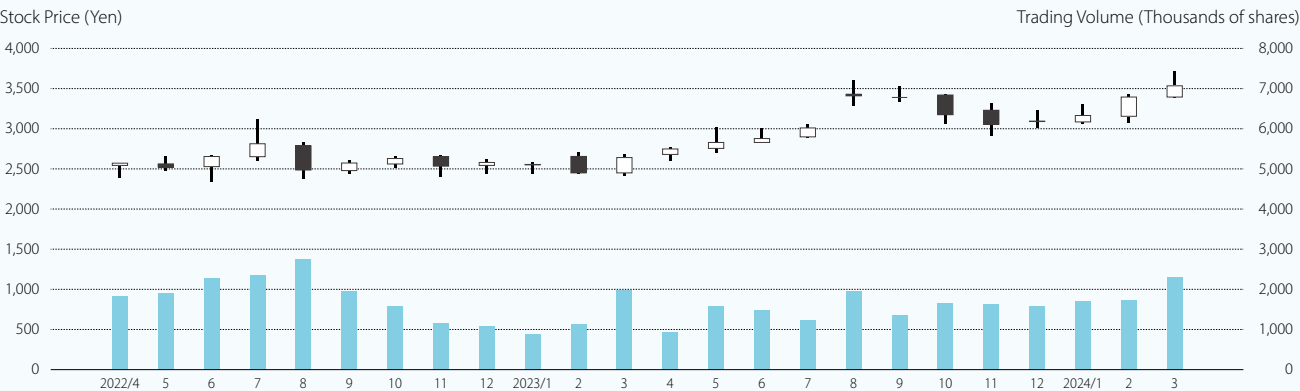
Notes:

- Kissei holds 5,105,798 shares of treasury stock but is not included in the above list of principal shareholders.
- 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





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

Cover Photo:



A midsummer view of Mt. Harinoki
and the Harinoki Snow Valley
(Omachi, Nagano)



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