KISSEI

Looking Towards Tomorrow's Health

Annual Report 2023

For the fiscal year ended March 31, 2023

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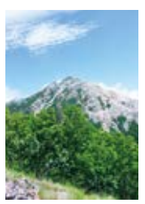


Cover Photo:
An early autumn view of Mt. Kaikoma from Mt. Senjo (Ina, Nagano Prefecture)

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 2023. For that reason, please be aware that actual results may vary greatly from these projections due to a variety of important factors.

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

Value Creation Process

Management Philosophy

Contribute to society through high-quality, innovative pharmaceutical products

Serve society through our employees

Management Vision

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

Kissei Code of Conduct

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

Social Issues / External Environment

- Declining birth-rate and aging population
- Restrictions on medical and social security costs
- Diversifying medical needs
- Diversifying drug discovery modalities
- Diversifying workstyles
- Consideration for the environment
- Revitalizing local communities

Kissei's Management Capital

Human Capital
Human resources with profound knowledge and technical skills

Intellectual Capital
Competitive intellectual property with a focus on small molecules

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

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

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

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

Kissei's Strengths
P.4

01: Human Resources

02: R&D Capabilities

03: Abundant Know-How in Specialized Areas

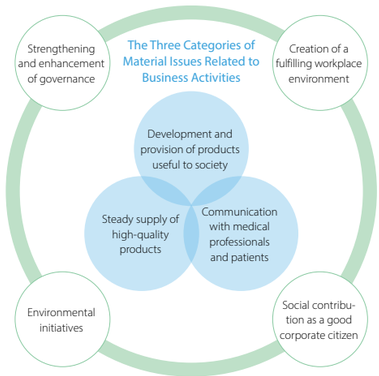
Business Activities

Five-Year Medium-Term Management Plan "PEGASUS"
P.14

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

Kissei's Material Issues
P.13

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



Created Value

Economic Value

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

Social Value and Contributions to the SDGs Centered on SDG3*

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

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

Create sustainable value through further accumulation and circulation of management capital

The History of Kissei Pharmaceutical

1946 Founded as Tachibana Seikagaku Institute Co., Ltd. (Matsumoto, Nagano)
1964 Corporate name changed to Kissei Pharmaceutical Co., Ltd.
1969 General Research Laboratory constructed (Matsumoto)
1973 General Research Laboratory expanded (Matsumoto)
1980 Manufacturing Plant constructed (Matsumoto)
1985 Second Research Laboratory constructed (Azumino, Nagano)
1988 Listed on the Second Section of the Tokyo Stock Exchange
1990 Foodstuff Business Unit established
Construction of Central Research Laboratory in Azumino City completed
General Research Laboratory relocated
1991 Listed on the First Section of the Tokyo Stock Exchange
1994 Shiojiri Plant constructed (Shiojiri, Nagano)
1995 Tokyo Head Office established
1996 Pharmaceutical Laboratory constructed (Azumino)
1997 Tokyo Head Office (Koishikawa) established
1999 Environmental Basic Policy established
2001 Nutritional Business Center constructed (Shiojiri)
2004 Kissei America, Inc., established
2006 Mitiglinide (Japanese name: Glufast®) launched in South Korea
2007 Joetsu Chemical Laboratory constructed (Joetsu, Niigata)
2009 Silodosin (Japanese name: Urief®) launched in the United States
2010 Silodosin (Urief®) launched in Europe
Mitiglinide (Glufast®) launched in China
2015 Second Research Laboratory received full AAALAC International*1 accreditation
2019 Remogliflozin (generic name) launched in India
2022 Transitioned from the First Section of the Tokyo Stock Exchange to the Prime Market segment

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

1946 — 1980 — 1990 — 2000 — 2010 — 2020

Urology

2006 Launched Urief®, a treatment for dysuria associated with benign prostatic hyperplasia

2018 Launched Beova®, a treatment for overactive bladder

2020 Began sales of MINIRIN MELT® and other products

Renal Diseases and Dialysis

1992 Launched FRAGMIN®, an anticoagulant

2010 Launched Epoetin Alfa BS Injection [JCR], a treatment for renal anemia

2015 Launched P-TOL®, a treatment for hyperphosphatemia

2019 Launched Darbepoetin Alfa BS Injection [JCR], a treatment for renal anemia

Metabolism and Endocrinology

1991 Launched BEZATOL®, a treatment for hyperlipidemia

2004 Launched Glufast®, a treatment for diabetes

2011 Launched Glubes®, a treatment for diabetes

2020 Began sales of MARIZEV®, a treatment for diabetes

Rare and Intractable Diseases

2022 Launched CAROGRA®, a treatment for ulcerative colitis
Launched TAVNEOS®, a treatment for MPA*2 and GPA*3

2023 Launched TAVALISSE®, a treatment for chronic ITP*4

Other Areas

1961 Launched GASCON®, a gastrointestinal anti-gas agent

1982 Launched RIZABEN®, a treatment for allergic diseases

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

1988 Launched XANBON®, a drug for improving cerebral circulation

1992 Launched DOMENAN®, a treatment for bronchial asthma

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

1999 Launched RIZMON® TG, a treatment for glaucoma

2005 Launched SALAGEN®, a treatment for dry mouth symptoms

2014 Launched SAVENE®, a treatment for anthracycline extravasation

2017 Launched RECTABUL®,*5 a treatment for ulcerative colitis

*2 Microscopic polyangiitis
*3 Granulomatosis with polyangiitis
*4 Idiopathic thrombocytopenic purpura
*5 Co-promotion only from April 1, 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, amid a lack of pharmaceuticals and other resources. During the war, a Tokyo-based pharmaceutical manufacturer was evacuated to Matsumoto City, in Nagano Prefecture, where it set up in a health foods factory and worked with local members of the pharmaceutical industry who had strong hopes of establishing a new pharmaceutical company in the area. With a great deal of cooperation from these local members, this company was created in Matsumoto City, with the purpose of manufacturing pharmaceutical drugs.

"The Two S's"

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

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

"A Pharmaceutical Company Cannot Exist without R&D"

"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 an 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 CAROGRA®, a treatment for ulcerative colitis, and TAVNEOS®, a treatment for microscopic polyangiitis and granulomatosis with polyangiitis, as well as the fiscal 2023 launch of TAVALISSE®, a treatment for chronic idiopathic thrombocytopenic purpura.

To navigate the drastic changes in management conditions, we embarked on "**PEGASUS**," our five-year medium-term management plan, in April 2020. Fiscal 2023 will take us forward toward a new phase of growth.

Kissei's Strengths

Kissei Pharmaceutical has cultivated three strengths aimed at manifesting its Management Philosophy. These strengths are its 1) 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, 2) R&D capabilities, which can be applied to both original and in-licensed products, and 3) abundant know-how in specialized areas, which we use to provide a lineup of products tailored to area strategies.

Kissei's Strengths

01: Human Resources

Kissei Pharmaceutical's head office and research laboratory have been located in Matsumoto City, Nagano Prefecture, since 1946, when the Company was founded. When the Company was listed on the Second Section of the Tokyo Stock Exchange, the research laboratory was moved to Azumino City, which is adjacent to Matsumoto City. People wishing to become medical representatives (MRs) and help increase corporate value by providing drug information, or those who want to work in R&D at the Central Research Laboratory in Azumino City, the source of value creation for the Company—come from all over Japan to converge in these areas.

Sources of Strength

- **Human Resources with a Unified and Earnest Drive**

  A strong sense of unity flows throughout Kissei Pharmaceutical thanks to the deep-rooted camaraderie that comes from the 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.

- **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.36

- **Results of the Human Resources Awareness Survey**

  Average engagement score: 3.44 (4-point maximum) P.36

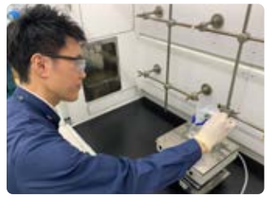
Passion and desire to create new drugs for patients

Strong relationships of trust with patients and medical professionals

Researcher Message Empathizing with the Belief That "a Pharmaceutical Company Cannot Exist without R&D"

I have had atopic dermatitis since I was a child, so topical creams have always been an inescapable part of my life. In junior high school, I lost my aunt to collagen disease; it was at that point I decided to become a drug researcher, hoping that I could help many people with new medicine. I grew up in Osaka Prefecture, and after graduating from Kyoto University Graduate School of Pharmaceutical Sciences, I chose to join Kissei Pharmaceutical out of a number of pharmaceutical companies. I made this decision because I could strongly empathize with the idea that "a pharmaceutical company cannot exist without R&D," a belief that Kissei has upheld since its founding days.

My main job is to look for active ingredients for new drugs. Although the work is rewarding and plays a central role in drug discovery, but there is only a one in 25,000 chance that a substance found in basic scientific research will result in a new drug. The road to the practical application of a drug is rocky, but I strive every day to make this dream come true.



Akihiro Moriyama

Synthesis Research Group, Synthesis Research Laboratory, Research Division

Kissei's Strengths

02: R&D Capabilities

Believing that "a pharmaceutical company cannot exist without R&D," 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 deliver new drugs to patients.

Sources of Strength

- **Original Products**

  We possess R&D capabilities for original products such as RIZABEN®, a treatment for allergic diseases, XANBON®, a drug for improving cerebral circulation, and Urief®, a treatment for dysuria associated with benign prostatic hyperplasia.

- **In-Licensed Products**

  We possess R&D capabilities for in-licensed products that align with the area strategy of our original products. Our R&D capabilities, from in-licensing to launch, are highly regarded by our licensors.

- **Ratio of R&D Expenses to Sales**

  15.1% (average from fiscal 2020 to fiscal 2022)

- **Percentage of Employees Engaged in R&D**

  20.4% (as of March 31, 2023)

Kissei's Strengths

03: Abundant Know-How in Specialized Areas

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

Sources of Strength

- **Urology Area Strategy**

  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.

- **Rare Diseases Area Strategy**

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

Letter from the CEO

We will achieve sustainable growth and increase corporate value by using constructive dialogue to maintain and build trust, while remaining ever mindful of our social responsibilities.

Mutsuo Kanzawa
Chairman and Chief Executive Officer

In recent years, we have found ourselves at the very peak of social change—international situations are deteriorating, supply chains are becoming increasingly fragile, the cost of raw materials is rising, and there are ongoing efforts to address climate change and biodiversity. Meanwhile, there are also new technologies appearing one after another, such as artificial intelligence (AI) and information and communication technology (ICT). All of these changes bring with them a mix of risks and opportunities. There is no easy way to predict what changes the future holds, but I believe that no matter what shape society takes, we will remain unchanging in our commitment to carrying out our reason for being—to create new drugs and contribute to the health of people around the world.

Kissei was founded in 1946; August 2023 marked its 77th anniversary. I believe our business has come this far for two reasons. One is the encouragement from our stakeholders, including patients, medical professionals, business partners, and shareholders; this includes the deep trust given to us. The other is our united, Groupwide efforts to develop new drugs, under the belief that "a pharmaceutical company cannot exist without R&D," and our Management Philosophy, "to contribute to society through high-quality, innovative pharmaceutical products" and "serve society through our employees." We will never change those convictions that lie at the heart of Kissei, no matter how times change. However, we will be flexible in our response to the social environment and set aside outdated ways of thinking and preconceived notions to increase corporate value.

To that point, in April 2020 we embarked on our five-year medium-term management plan, "**PEGASUS**." One of the key areas highlighted under the plan is rare and intractable diseases. Our achievements in this area include the May 2022 launch of CAROGRA®, a treatment for ulcerative colitis, followed by the launch of TAVNEOS®, a treatment for microscopic polyangiitis and granulomatosis with polyangiitis, in June 2022. In April 2023, we also launched TAVALISSE® as a treatment for chronic idiopathic thrombocytopenic purpura. Moreover, we have been able to move projects in late-stage development further up the development pipeline. These are some of the ways we are actively working to develop new drugs in the area of rare and intractable diseases for which there are inadequate treatment methods, but we are also promoting digital transformation (DX) throughout the Company through the use of digital tools and data. In particular, we are working to utilize AI drug discovery and other technologies as part of R&D. Although entering a new area of treatment comes with difficulties, we believe that responding to unmet medical needs—medical needs for diseases that still lack effective treatments—developing close relationships with patients, and leaving no stone unturned in our efforts to help them are all ways of realizing our Management Philosophy.

Regarding our sustainability-related initiatives to tackle environmental problems and social issues, in April 2023 we reorganized the previous SDGs Promotion Committee to form the Sustainability Promotion Committee, and set up a system to promote and manage these initiatives. We also determined the materiality of important issues to identify which ones to prioritize, then set key performance indicators (KPIs) for key initiatives and promoted a variety of sustainability-oriented activities. In June 2023, we endorsed the recommendations put forth by the Task Force on Climate-related Financial Disclosures. Based on these recommendations, we are analyzing and addressing the risks that climate change presents to our business, as well as the opportunities. As for investment in human capital, we intend to conduct a fundamental review of our human resource and training systems, cultivate a diverse group of human resources, and use their capabilities to the fullest. To that end, we are building a work environment that will allow them to show their full potential. These actions will ensure that the Company can respond accurately and promptly to changing conditions.

For shareholders and investors, we will increase the transparency and fairness of management by enhancing governance and disseminating information in a timely and appropriate fashion in keeping with Japan's Corporate Governance Code. We will continue to achieve sustainable growth, fulfill our social responsibilities, and increase corporate value by using constructive dialogue to maintain and build trust.

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

August 2023

Mutsuo Kanzawa
Chairman and Chief Executive Officer

COO Interview

Yasuo Takehana
President and Chief Operating Officer

Q What value does Kissei Pharmaceutical provide?

Our mission as a pharmaceutical company is to develop and provide pharmaceutical products to patients who lack effective treatment options or whose treatment is unsatisfactory. We are working to create new drugs by either developing original products or through in-licensing. In recent years, we have focused on drug development in the area of rare and intractable diseases, in addition to our key areas of urology and renal diseases and dialysis. From 2022 to 2023, we launched TAVNEOS® as a treatment of microscopic polyangiitis and granulomatosis with polyangiitis, CAROGRA® as a treatment for ulcerative colitis, and TAVALISSE® as a treatment for chronic idiopathic thrombocytopenic purpura. These drugs, all of which are treatments for rare and intractable diseases, provide new alternative options to conventional steroid treatments and their associated side effects. We intend to provide value by focusing drug development on rare and intractable diseases such as the ones I mentioned, as well as on areas where patients have ailments that have no treatment.

For background, in recent years there has been a growing awareness of "drug lag," which is when a treatment released overseas is late to release in Japan, and "drug loss," which is when these treatments are not released in Japan at all. It is difficult for major pharmaceutical companies to embark on efforts in the area of rare diseases due to drug prices and the market scale, but if we direct the R&D capabilities we have cultivated to date toward developing and launching products in a short period of time, we can help eliminate drug loss.

In addition to medical treatment, our Nutrition Division contributes to health through the development and provision of foods that help prevent diseases, including presymptomatic diseases, and the recurrence of diseases post-treatment. For example, protein-controlled foods and low-phosphorus/low potassium foods synergize with renal and dialysis treatments. Food can be an effective means of support for diseases and symptoms that are difficult to treat with pharmaceutical products. Sales from this business are still only about 6% of overall sales, but we are building it up to be a pillar of support for future earnings.

We will not waver in our resolve to develop new drugs for diseases without established treatments and to provide new value to patients. I believe that as a company with a long track record of achievements, we should strive to be both daring and responsible, conduct R&D while charged with a venturing spirit, and make steady progress toward launching products to the market and placing them in patients' hands.

Q What are the strengths of Kissei Pharmaceutical?

I believe we have three main strengths. The first is our human resources. The source of Kissei's strength is the solidarity that pushes us towards goals, driven by an all-for-one, one-for-all attitude that transcends departmental boundaries. We received an unexpected reminder of this solidarity in fiscal 2022, when responding to the termination of our licensing agreement with ObsEva SA for linzagolix (generic name), a gonadotropin-releasing hormone (GnRH) antagonist developed in-house. The out-licensed rights were returned to Kissei, and we had to proceed with everything in-house, including the clinical trials that had been underway in Europe and the United States, as well as handle our licensee (Theramex) and the authorities in Europe and the United States. Although we did not have much experience and knowledge in these kinds of dealings in an overseas context, every department came together, and the drug is scheduled to be launched in Europe as a result. I believe that we were able to respond to this unforeseen situation not only because of the capabilities of each department and individual but also because each department cooperated with one another to achieve this single goal, regardless of the scope of responsibility.

The second strength is our R&D capabilities. Our Research Division comprises over 200 researchers gathered at our research laboratory in Azumino City, Nagano Prefecture, where they work on drug discovery. This advantage allows for a quick turnover of our PDCA cycle, which involves compound synthesis, assessment, and feedback. In addition, we utilize a development system laid out as a matrix that places functions on a vertical axis and development pipelines on a horizontal axis, and while we have deep expertise in developing products, we also engage actively in discussions across projects, which creates fertile ground for many seeds of inspiration. The Clinical Development Division has set an ambitious goal of submitting New Drug Applications (NDAs) for six products and launching them over the course of "**PEGASUS**," as well as formulating and executing an efficient clinical plan that includes international joint clinical trials. To date, we have submitted five NDAs and launched three products. This practice of continually submitting applications and maintaining close communication with drug authorities has also enabled us to build up know-how and experience toward obtaining approval, which I believe is gaining Kissei more and more trust as a licensee among overseas companies.

The third strength is our abundant know-how in specialized areas. We have built a robust product lineup for each of these areas. In urology, we are the only pharmaceutical company in Japan that offers drugs to treat three conditions: overactive bladder (OAB), nocturia, and benign prostatic hyperplasia (BPH). Each of these drugs, Beova® for OAB, DESMOPRESSIN formulations and MINIRIN MELT® for nocturia, and Urief® for BPH, utilizes a different mechanism to improve these conditions. In renal diseases and dialysis and rare diseases, we are working steadily to build our lineup of drugs to treat pruritus in hemodialysis patients, such as difelikefalin (generic name), TAVNEOS®, and TAVALISSE®. Going forward, we will leverage our know-how in these key specialized areas to develop new drugs and continue to expand the range of products we sell.

Q What is your assessment of the progress of "**PEGASUS**"? Also, what should the Company focus on in particular?

We are promoting a growth strategy propelled by three arrows to hit the targets of our five-year medium-term management plan, "**PEGASUS**," launched in April 2020. The first arrow is the expansion of sales of existing mainstay products, focusing on our well-established areas. The second is the continual launch of new products, mainly in the rare diseases area. Finally, the third is the acquisition of new earnings overseas.

▶ Our Three-Arrow Growth Strategy

1. Expansion of sales of existing mainstay products, focusing on well-established areas
   Urology　Renal Diseases and Dialysis　Metabolism and Endocrinology
2. Continual launch of new products, mainly in rare diseases
3. Acquisition of new earnings overseas

In fiscal 2022, the third year of the plan, net sales increased 3.2%, to ¥67.4 billion, due to an increase in sales of pharmaceutical products in Japan and in co-promotion fees. However, we recorded an operating loss of ¥1.1 billion after expected revenue from technical fees for out-licensed products was deferred to the following fiscal year. On the other hand, profit attributable to owners of parent was ¥10.5 billion, due to a decrease in the gain on sale of investment securities. This marks an 18.5% decrease from the previous fiscal year. Taking a closer look at domestic sales, sales of mainstay products increased thanks to the launch of two new products, CAROGRA® and TAVNEOS®, and the completion of shipping adjustments for Beova®. Beova®, which is jointly marketed with KYORIN Pharmaceutical Co., Ltd., has been highly regarded for its high level of efficacy and safety, and many patients wished to continue receiving treatment. Beova® is administered to about 40% of patients beginning treatment for OAB,* with sales and the share of patients on a steady rise, owing to the efforts of our medical representatives to visit medical institutions and provide information on the drug. These trends put Beova® on track to becoming the most-prescribed treatment for OAB.

As for our domestic development pipeline, things are moving smoothly and on schedule. TAVALISSE® was launched in April 2023, and following behind it is difelikefalin, which currently has an NDA under review and is scheduled for launch in the second half of 2023. Although we temporarily withdrew the NDA for rovatirelin (generic name) to reconsider our development policy, other projects are going according to plan, such as oncolytic immunotherapy CG0070 (development code) and linzagolix, both of which are undergoing Phase III clinical trials in Japan, and KSP-0243 (development code), which is undergoing Phase II clinical trials. The acquisition of new earnings overseas—the third arrow—was knocked off course by the unexpected bankruptcy of the licensee for linzagolix, but, as I mentioned earlier, the entire company has been working as one to respond, and we are gradually getting back on the trajectory we originally envisioned, with prospects of launching in Europe and development in China underway. We will continue to look for new licensees in the United States and work toward global expansion.

I believe that, despite a decline in profits, fiscal 2022 was an overall positive, in that we pulled away from a period of stagnation and successfully built a foundation for regrowth, thanks to increased sales of mainstay products, steady progress in the development pipeline, and the launch of new drugs.

Looking at fiscal 2023, we launched TAVALISSE® in April, with plans to launch difelikefalin in the second half of the calendar year, representing our second arrow, the continual launch of new drugs. These launches are expected to increase domestic sales even further. As part of the third arrow, the acquisition of new earnings overseas, the European launch of linzagolix is moving as planned.

To strengthen our management base and promote sustainability initiatives further, in April 2023 we reorganized the SDGs Promotion Committee to the Sustainability Promotion Committee, which is chaired by a director. We will increase cooperation between this committee and the Board of Directors, get the Board to make an even stronger commitment to sustainability, and increase opportunities for the Company to convey its initiatives to an external audience.

To cultivate the next generation of human resources, we introduced a new human resource system in fiscal 2022 that encourages employees to show initiative. Previously, it took a certain number of years of employment for employees to receive a promotion, but under our new system promotions are based on ability, regardless of years worked, making it possible for those as young as their early 30s to reach manager status. At the same time, we have also established a self-assessment system for promotion that allows human resources who desire to grow to take on challenges. We intend to use these systems, in addition to the new training system introduced in fiscal 2023, to develop autonomous human resources that are in tune with themselves, their supervisors, and their company. In the previous fiscal year, I stated that I would like to reform our various personnel systems to allow each and every employee to realize self-growth and company growth. Now, I feel like these changes are coming to fruition and I would like us to keep enacting measures in the future.

Q What issues should Kissei Pharmaceutical target to spur regrowth over the medium to long term?

Our greatest challenge is expanding our development pipeline. We feel a great sense of concern as to whether it is too fragile to support our continued growth as a pharmaceutical company in the face of major changes in internal and external conditions. Although we are working to expand our pipeline by developing original products and in-licensing, drug discovery research, in particular, has become extremely sophisticated and specific, and conditions are such that we risk being left behind unless we utilize AI and other cutting-edge technologies from outside the Company. The competition for in-licensing is also growing more intense, making it difficult for us to acquire new in-licensed products unless the business development, R&D, and corporate strategy and planning wings can work as one to appeal to licensing companies with our track record and development capabilities.

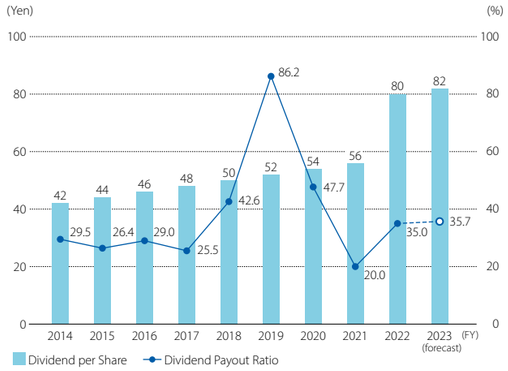
In April 2023, we began implementing the KISSEI DX-ZERO Project in regard to utilizing AI and other technologies, and under that banner we are formulating missions and creating a road map to promote DX in every organization within the Group. We must bear in mind that DX stands for "digital transformation"; therefore, we cannot simply inject AI and IT into existing work processes and call it "DX." Instead, we need to use the latest in AI and IT to transform these very processes. To this end, the KISSEI DX-ZERO Project is being spearheaded by department heads with a good understanding of business and operations. Drug discovery research is particularly difficult to carry out in its entirety through our resources alone, so we are concentrating on co-creation with partners that include academia and venture companies.

In addition, expansion of the development pipeline is the key to enhancing the corporate power of Kissei as a whole. A pharmaceutical company is held up by four major pillars: product research, development, manufacturing, and marketing. These four pillars, which take the form of departments, are themselves supported by indirect departments in charge of reliability assurance, general affairs, human resources, intellectual property, and public relations. Development pipelines run through these four pillars on a horizontal axis, and steady movement from R&D to obtaining approval, then to sales within these pipelines strengthens the organization of an entire company. Both our corporate and organizational strength are reinforced by many pipelines running horizontally through these four pillars. I believe that the ability to simultaneously and uninterruptedly move a great many pipelines is indicative of the corporate strength and growth potential of a pharmaceutical company. Over the course of "**PEGASUS**" to date, we have done just that—we have conducted R&D, obtained NDA approval, and brought products to market across multiple pipelines, building up drug development experience and enhancing our corporate strength along the way. We will leverage this corporate strength to create and acquire new pipelines, and by expanding our pipelines, we will increase corporate strength further.

Q Finally, what is your message to shareholders

We take the fact that our price-to-book ratio (PBR) is below 1.0 seriously and are proceeding with discussions on this point at Board meetings. We believe that one factor is the slump in business performance and recognize that our top priority is to generate a suitable amount of profit relative to the cost of capital. To make this happen, we will promote growth strategies and increase profits through our core business, while working to secure net income through the effective use of cross-shareholdings and other financial assets. As for profit distribution, our policy is to continue to pay stable dividends regardless of business performance, while allocating funds to capital investment and investment in R&D and DX in order to expand development pipelines and ensure a management foundation for the future. The annual dividend for fiscal 2022 was ¥80.0 per share, an increase for the 15th consecutive year. In fiscal 2023, we plan to increase the dividend by ¥2.0, to ¥82.0 per share. Furthermore, we will repurchase two million treasury shares valued at ¥6.0 billion during fiscal 2023, and cancel 2.5 million treasury shares in an effort to improve capital efficiency and enhance shareholder returns.

▶ Dividend per Share / Dividend Payout Ratio



I also believe that maintaining a dialogue with shareholders is extremely important. In fiscal 2022, we held 63 separate investor relations meetings, primarily with institutional investors, but we intend to provide more opportunities than ever for dialogue that will help investors understand the scenarios for regrowth. We will also take in the opinions and thoughts of investors and use them in our analysis of capital costs and profitability at Board meetings.

As we take on this challenge, we ask our shareholders for their continued understanding and support.

August 2023

Yasuo Takehana
President and Chief Operating Officer

Sustainability Management

Basic Stance on Sustainability

Kissei Pharmaceutical leverages its business activities to support the health of people around the world, resolve environmental and social issues, and promote environment conservation, drawing inspiration from its 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 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.

MESSAGE

Tetsu Takayama
Executive Managing Director in Charge of the Human Resources Department and General Administration Department

Kissei Pharmaceutical's Initiatives for a Sustainable Society

There is an increasing expectation and a growing need for companies to fulfill their corporate responsibilities and leverage their business activities to resolve social issues. This has manifested as a deepening interest in corporate activities that aim to realize a sustainable society, such as those directed toward the SDGs, disclosure of climate change countermeasures in line with the TCFD framework, and disclosure related to human capital.

This is in line with Kissei Pharmaceutical's Management Vision, "to be an R&D-oriented pharmaceutical company that contributes to the health of people around the world through innovative pharmaceutical products." To achieve this, we need to identify material issues that we must address for sustainable growth, create groundbreaking pharmaceutical products, redouble our environmental initiatives—whether this means finding ways to reduce greenhouse gases throughout the supply chain or otherwise—and create a comfortable workplace based on diversity and inclusion.

We will continue to increase engagement with stakeholders through responsible measures to combat these issues and through fitting disclosure, while striving to improve our value, continuously.

Sustainability Promotion System

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 to 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.48

Specifically, the Sustainability Promotion Committees formulates various policies for sustainability-related issues and promotes these policies in cooperation with related departments.

Process for Identifying Material Issues

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

(To be completed)

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
Identify social and internal issues, making reference to international guidelines*	Have the heads of 35 departments prioritize the issues via an in-Company survey after receiving SDG training	Narrow down the number of priority issues through dialogues with external experts regarding the survey results	Have the Sustainability Promotion Committee and the Board of Directors identify material issues, set KPIs, and promote activities	Formulate new medium-term management plans and revise material issues based on changes in the business environment and constructive dialogues with stakeholders

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

Initiatives Related to the Seven Categories of Material Issues

Kissei Pharmaceutical has identified 15 specific material issues, sorted into seven categories, and engaged in activities to address them as a high priority. In fiscal 2022, we promoted activities based on the KPIs for materiality set in fiscal 2021, with favorable progress overall. For details regarding fiscal 2022 activities, please refer to the following link: https://www.kissei.co.jp/sustainability/materiality/ (Japanese only)

Some KPIs have been revised to clarify the impact of activities further.

	Main SDGs related to the seven categories	Material issues (excerpt)	Key initiatives	KPIs
Material issues related to Kissei's business activities	**Development and provision of products useful to society** P.22	Development of innovative products (drugs, foods)	• Drug discovery initiatives and promotion of clinical development projects • Promotion of licensing activities and overseas development	• Number of items in the research and development pipeline and progress • Number of New Drug Applications and marketing authorization approvals • Number of countries where new drugs are launched via partnering*

	Steady supply of high-quality products P.32	Quality control and steady supply and procurement	• Formulation and implementation of the "Stable Supply Manual"
			• COVID-19-related countermeasures
			• Implementation of the Kissei Pharmaceutical Quality System
				• Appropriate inventory (by product)*
				• Implementation of management review and improvement to instructions
				• Progress toward developing a system to ensure a steady supply of high-quality pharmaceutical products
				• Product recalls
				  ・Zero recalls of pharmaceutical products
				  ・Complaint rate of 7.0 ppm (parts per million) or less for food products

	Communication with medical professionals and patients P.30, 42	Promote proper product usage (drugs, foods)	• Creation of a sales system for rare disease treatments • Promotion of activities to provide appropriate medical information	• Progress of activities for the Rare Diseases Project • Construction of an efficient and effective system to provide information utilizing digital tools
Material issues related to Kissei's management base	**Strengthening and enhancement of governance** P.44	Strengthen governance	• Formulation and implementation of the Kissei Basic Policy on Corporate Governance • Appointment of a female director • Increase in the number of outside directors	• Appropriate responses to Japan's revised Corporate Governance Code • Improvement of Board of Directors' functions through dialogue with stakeholders and evaluations of the effectiveness of the Board of Directors
	Creation of a fulfilling workplace environment P.36	Human resource cultivation	• Implementation of rank-based and job-specific training • Support for self-development • Establishment of an interview system for skill and career development	• Implementation of rank-based and job-specific training • Implementation of DX-based education for human resource development • Rate of participation in correspondence courses • Implementation of the Company's interview system for skill and career development

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

	Social contribution as a good corporate citizen P.43	Participate in social contribution activities	• Contribution to culture, the arts, and sports • Participation in local cleanup activities and offering of factory and research institute tours • Donations to child welfare facilities and assistance for natural disasters	• Number of sponsorships and donations that contribute to society and local communities • Status of social contribution activities by region*

* Revised in fiscal 2022

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

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

The Basic Policies of "**PEGASUS**"

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

1. Increase domestic sales

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

In the urology area, we are cultivating Beova® and MINIRIN MELT® to increase our presence in the market. In the renal diseases and dialysis area, we are working to expand sales of P-TOL® while taking steps toward the approval and launch of difelikefalin (generic name), after submitting an NDA in fiscal 2022. In the diabetes area, we are aiming to increase sales of Glubes® and MARIZEV®. We are also working to facilitate the smooth introduction of three new products into the market: CAROGRA® in the gastroenterology area, and TAVNEOS® and TAVALISSE® in the rare diseases area, with additional ongoing efforts to expand sales. Regarding development themes, CG0070 (development code) is undergoing Phase III clinical trials. In therapeutic and care foods, we are seeking to enhance sales under our established quality assurance system.

2. Strengthen earnings base overseas

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

We will establish linzagolix (generic name) as our new global product and fortify our overseas earnings base with newly discovered drugs as well as in-licensing and out-licensing initiatives. We will also secure overseas earnings for existing products in collaboration with partner companies.

3. Expand development pipeline

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

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

* A research method to design, synthesize, and evaluate compounds that includes a screening system for receptors and other treatment targets, synthesis of a large number of compounds to act on these targets, and acquisition of a large amount of data. This method ensures that compounds are well-suited for use in 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

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

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

		Fiscal 2018	Fiscal 2019	Fiscal 2020	Fiscal 2021	Fiscal 2022	Fiscal 2023	Fiscal 2024
Domestic	Urology	Beova® (overactive bladder)	MINIRIN MELT® 25 μg / 50 μg (nocturia due to nocturnal polyuria in males)	MINIRIN MELT® 60 μg / 120 μg / 240 μg (central diabetes insipidus (all versions), nocturnal enuresis resulting from decrease of urine osmolality or urine specific gravity (120 μg / 240 μg only))				
	Renal Diseases / Dialysis	P-TOL® Granules (hyperphosphatemia) Nalfurafine GE (pruritus in dialysis patients)	Darbepoetin Alfa BS Injection [JCR] (renal anemia)			Difelikefalin (MR13A9) (NDA in process) (pruritus in hemodialysis patients)		
	Diabetes		Glubes® OD (combination drug of rapid insulin secretagogue / postprandial hyperglycemic agent)	MARIZEV® (sustained selective DPP-4 inhibitor)				
	Gastroenterology					CAROGRA® (product launched) (ulcerative colitis)		
	Rare Diseases				Rovatirelin (KPS-0373) (NDA submitted) (spinocerebellar ataxia)	TAVNEOS®* (product launched) (microscopic polyangiitis and granulomatosis with polyangiitis)	TAVALISSE®* (product launched) (chronic idiopathic thrombocytopenic purpura) CG0070 (non-muscle-invasive bladder cancer)	
Overseas	Out-Licensing		Remogliflozin (type 2 diabetes mellitus / SGLT2 inhibitor) (launched in India by licensee)				Linzagolix (preparing for launch in Europe) (uterine fibroids)	

Notes:
1. Blue: Launched / Red: Designated as an intractable disease / * Designated as an orphan drug
2. Rovatirelin (spinocerebellar ataxia): NDA withdrawn, possibility of conducting additional clinical trials is being considered
3. For products launched during the medium-term management plan directly prior to "**PEGASUS**," please refer to page 28.

Under "**PEGASUS**," we will make investments in three directions. The first is sales, aimed at sales growth for strategically important products launched over the course of the previous medium-term management plan and the introduction of new products to be launched in the future. The second, R&D, is specifically aimed at advancing drug discovery research and development projects. The third direction for investments is in-licensing of development themes and products aimed at expanding our development pipeline and product lineup. As a result of our investment efforts, we launched MINIRIN MELT® and MARIZEV®, in April 2020. In addition, we plan to either launch or submit applications to launch six products for domestic sale over the five-year span of "**PEGASUS**." In fiscal 2022, we launched CAROGRA® and TAVNEOS®, and submitted an NDA and received approval for TAVALISSE®. In addition, we submitted an NDA for difelikefalin (generic name), a jointly developed treatment for uremic pruritus in hemodialysis patients.

Overseas, Kissei submitted an application for approval in Europe for linzagolix (generic name), a GnRH receptor antagonist discovered by Kissei, which was approved in June 2022. We are currently making preparations for launching the drug in fiscal 2023 via a licensee.

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

	Fiscal 2021	Fiscal 2022	Fiscal 2023
TAVNEOS®	NDA approved	Product launched	Product launched
CAROGRA®	NDA approved	Product launched	Product launched
Rovatirelin	NDA in process	NDA in process	NDA withdrawn*
TAVALISSE®	Phase III clinical trials	NDA in process	Product launched
Difelikefalin	Phase III clinical trials	NDA in process	NDA in process
CG0070	Global Phase III clinical trials (began drug treatments)	International joint Phase III clinical trials (drug treatment stage)	International joint Phase III clinical trials (drug treatment stage)

* Possibility of conducting additional clinical trials is being considered

Financial Strategy

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

R&D Investment

Kissei has also identified three material issues pertaining to its business activities under three categories: development and provision of products useful to society, steady supply of high-quality products, and communication with medical professionals and patients. We will continue to make investments to ensure that our business activities can help resolve these important social issues. R&D is critical to any pharmaceutical company. It is particularly important that we continue to expand our R&D pipeline to develop and provide new and useful drugs for patients worldwide. One of the basic policies of "**PEGASUS**" is to expand our pipeline through drug discovery research and in-licensing. Therefore, in addition to research aimed at creating innovative drug discovery themes, we will reinforce our development pipeline via in-licensing themes that mesh with our area strategies. We are making active investments in in-house drug discovery and in-licensing, both of which we have positioned as drivers for future growth.

Basic Policy on the Distribution of Profits

As a company listed on the Prime Market, we aim to secure a solid management base for the future while providing stable, consistent returns to shareholders. In fiscal 2022, the Company paid a full-year dividend of ¥80.0 per share, comprising an interim dividend of ¥40.0 per share and a year-end dividend of ¥40.0 per share, after taking a comprehensive look at the Company's past dividend payout ratio. In fiscal 2023, the Company plans to pay 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.

We will approach acquisition, disposal, and cancellation of treasury stock when it is deemed necessary in terms of business development, and after first giving consideration to increasing shareholder value. During a meeting of the Board of Directors held in May 2023, the decision was made to acquire and cancel treasury stock.

Investments, Dividends, and ROE

	Fiscal 2019	Fiscal 2020	Fiscal 2021	Fiscal 2022	Fiscal 2023 (forecast)
R&D expenses (millions of yen)	10,767	9,626	10,363	10,391	9,200
R&D expenses ratio (%)	17.0	13.9	15.9	15.4	12.3
Capital investment (millions of yen)	970	1,180	1,488	2,187	1,770
Cash dividends (yen)	52.0	54.0	56.0	80.0	82.0
Dividend payout ratio (%)	86.2	47.7	20.0	35.0	35.7
Treasury stock purchased (No. of shares)		¥1.3 billion (600,000 shares)			¥6.0 billion (2,000,000 shares)
Treasury stock canceled (No. of shares)					¥5.7 billion (2,500,000 shares)
ROE (%)	1.5	2.6	6.1	5.3	5.0 or higher

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

	Fiscal 2020 Results (First year of the plan)	Fiscal 2021 Results (Second year of the plan)	Fiscal 2022 Results (Third year of the plan)	Fiscal 2023 Forecast (Fourth year of the plan)	Fiscal 2024 Targets (Final year of the plan)
Consolidated net sales	¥69.0 billion	¥65.3 billion	¥67.4 billion	¥74.5 billion	¥87.0 billion or higher
Net sales for the Pharmaceutical Business	¥56.4 billion	¥54.1 billion	¥56.2 billion	¥62.5 billion	¥75.0 billion or higher
Pharmaceuticals*1	¥48.1 billion	¥45.7 billion	¥47.0 billion	¥51.5 billion	¥62.5 billion or higher
Therapeutic and care foods	¥3.7 billion	¥3.5 billion	¥3.4 billion	¥3.6 billion	¥4.5 billion or higher
Technical fees*2	¥0.8 billion	¥0.5 billion	¥1.0 billion	¥3.0 billion	¥8.0 billion or higher*4
Other*3	¥3.6 billion	¥4.2 billion	¥4.6 billion	¥4.4 billion	¥9.0 billion or higher
Consolidated operating profit (loss)	¥1.5 billion	¥(1.4 billion)	¥(1.1 billion)	¥4.2 billion	
R&D expenses	¥9.6 billion	¥10.3 billion	¥10.3 billion	¥9.2 billion	¥13.0 billion
ROE	2.6%	6.1%	5.3%	5.0% or higher	5.0% or higher

The Three Arrows of the Growth Strategy of "**PEGASUS**"

1. Expansion of sales of existing mainstay products, focusing on well-established areas
2. Continual launch of new products, mainly in rare diseases
3. Acquisition of new earnings overseas

*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

MESSAGE

DX Initiatives

All eyes are on digital transformation (DX) in light of the technological advances of the past few years. Kissei is no exception. We are making steady headway in updating the systems in areas that form the foundation of DX, namely collaboration and security. We are also preparing an environment that will improve existing operations while both creating and providing new value.

DX is not something achieved by computers; it is something achieved by people utilizing technology. We have framed DX as "digital technology as a means for transformation." Following this, we are planning and implementing several measures focused on people and their behavior, aiming to uncover and cultivate human resources who will bridge the gap between business-related issues and the right digital technology needed to address them.

Knowledge and technology are not the only factors that matter in DX—mindset is just as important. We reflect the mindset of an R&D-oriented pharmaceutical company within our DX policy, exemplified by the phrase "change does not guarantee success." In that spirit, we encourage all employees to cast off their fear of failure and take on challenges. Our annual budget for ICT-related spending is in excess of ¥2.0 billion, but this is an investment toward "a new Kissei Pharmaceutical, unbound by conventional thinking and methods." We believe that it is the responsibility of the Digital & ICT Strategy and Planning Department to promote DX that produces results that are worth the investment.

Chiaki Handa
Digital & ICT Strategy and Planning Department
DX Acceleration Manager

Main Products (As of August 2023)

Urology

		Results for fiscal 2022 (millions of yen)*1	Projected sales in fiscal 2023 (millions of yen)*1
Overactive Bladder Treatment Beova® 	**Active Ingredient:** Vibegron **Indications:** Urinary urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder **Month of release:** November 2018 (tablets) ● Joint development and marketing with KYORIN Pharmaceutical Co., Ltd.	11,795	16,200
DESMOPRESSIN Formulations MINIRIN MELT®, Etc. 	(MINIRIN MELT® OD tablets 25 μg/50 μg/60 μg/120 μg/240 μg, DESMOPRESSIN Intranasal,*2 DEMOPRESSIN 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	3,703*3	3,450*3
Dysuria Treatment Urief® 	**Active Ingredient:** Silodosin (*Japanese Pharmacopoeia*) **Indications:** Dysuria associated with benign prostatic hyperplasia **Month of release:** May 2006 (capsules*2), February 2009 (tablets), January 2016 (OD tablets) ● Joint development and marketing with Daiichi Sankyo Company, Limited	2,345	1,900

Renal Diseases and Dialysis

Hyperphosphatemia Treatment P-TOL® 	**Active Ingredient:** Sucroferric oxyhydroxide **Indications:** Improvement of hyperphosphatemia in patients with chronic kidney disease on dialysis **Month of release:** November 2015 (chewable tablets), November 2018 (granules)	5,665	5,800
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.	4,386	3,800
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.	3,055	2,300

Rare and Intractable Diseases

		Results for fiscal 2022 (millions of yen)*1	Projected sales in fiscal 2023 (millions of yen)*1
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)	1,029	3,200
Treatment for Chronic Idiopathic Thrombocytopenic Purpura TAVALISSE® 	**Active ingredient:** Fostamatinib sodium hydrate **Indications:** Chronic idiopathic thrombocytopenic purpura **Month of release:** April 2023 (tablets)	21	400
Treatment for Ulcerative Colitis CAROGRA® 	**Active ingredient:** Carotegrast methyl **Indications:** Moderate ulcerative colitis, limited to patients who had inadequate response to 5-aminosalicylic acid **Month of release:** May 2022 (tablets) ● Joint development with EA Pharma Co., Ltd., with co-promotion by both EA Pharma and Kissei	500	1,400

Metabolism and Endocrinology

Treatment for Diabetes Glubes® 	**Active ingredient:** Mitiglinide calcium hydrate (*Japanese Pharmacopoeia*), voglibose (*Japanese Pharmacopoeia*) **Indications:** Type 2 diabetes, limited to cases where a treatment with a combination of mitiglinide calcium hydrate and voglibose is deemed appropriate **Month of release:** July 2011 (combination tablets), June 2019 (combination OD tablets)	4,061	3,800
Treatment for Diabetes Glufast® 	**Active ingredient:** Mitiglinide calcium hydrate (*Japanese Pharmacopoeia*) **Indications:** Type 2 diabetes **Month of release:** May 2004 (tablets), June 2016 (OD tablets)		
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.	1,059	1,200

*1 Based on sales figures for fiscal 2022 announced in May 2023
*2 Currently not for sale
*3 Combined total for MINIRIN MELT®, DESMOPRESSIN Intranasal (fiscal 2022 only), DESMOPRESSIN Spray, and DESMOPRESSIN Injection

Financial and Non-Financial Highlights

Kissei Pharmaceutical Co., Ltd., and Its Subsidiaries

FY	2018	2019	2020	2021	2022	2022
	Millions of yen, except per share data					Thousands of U.S. dollars, except per share data
Financial Results						
Net Sales	¥ 72,297	¥ 63,234	¥ 69,044	¥ 65,381	**¥ 67,493**	**$ 505,414**
R&D Expenses	15,711	10,767	9,626	10,363	**10,391**	**77,812**
Operating Profit (Loss)	6,202	1,857	1,505	(1,402)	**(1,129)**	**(8,454)**
Profit Attributable to Owners of Parent	5,481	2,817	5,285	12,921	**10,528**	**73,838**
Financial Condition						
Total Liabilities and Net Assets	¥213,522	¥231,794	¥268,861	¥238,087	**¥221,200**	**$1,656,433**
Total Net Assets	182,707	192,970	219,953	202,180	**194,814**	**1,458,844**
Other Indicator						
Capital Investment	¥ 1,177	¥ 970	¥ 1,180	¥ 1,488	**¥ 2,187**	**$ 16,377**
Per Share (Yen and U.S. Dollars)						
Profit per Share	¥ 117.33	¥ 60.31	¥ 113.25	¥ 280.20	**¥ 228.31**	**$ 1.71**
Cash Dividends	50.0	52.0	54.0	56.0	**80.0**	**0.60**
Key Ratios (%)						
Operating Profit Ratio	8.6	2.9	2.2	(2.1)	**(1.7)**	
R&D Expenses Ratio	21.7	17.0	13.9	15.9	**15.4**	
Return on Assets (ROA)	2.6	1.2	2.0	5.4	**4.8**	
Return on Equity (ROE)	3.1	1.5	2.6	6.1	**5.3**	
Shareholders' Equity Ratio	85.4	83.0	81.6	84.6	**87.7**	
Dividend Payout Ratio	42.6	86.2	47.7	20.0	**35.0**	
Others						
Number of Employees	1,907	1,892	1,863	1,828	**1,795**	
Number of Shares Issued	51,811,185	51,811,185	51,811,185	51,811,185	**51,811,185**	

Note: Profit attributable to owners of parent per share is computed based on the weighted-average number of shares of common stock after subtracting the weighted-average number of shares of treasury stock for the fiscal year.

Kissei Pharmaceutical Co., Ltd.

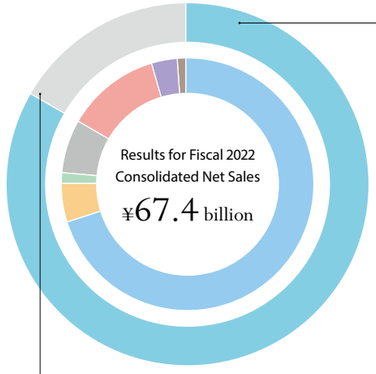
FY	2018	2019	2020	2021	2022	2022
Non-Financial Data						
Energy Used (kL)*1	8,239	8,010	7,821	7,990	**8,134**	
CO_2 Emissions (Tons)*2	17,818	17,065	16,297	15,999	**14,075**	
Amount of Waste Generated (Tons)	461	385	369	390	**395**	
Final Disposal Amount (Tons)*3	15	11	39	27	**17**	

*1 Calculation method has been adjusted for fiscal 2022 onward to reflect the ratio of gasoline to hybrid vehicles used by MRs. Figures for previous fiscal years have been retroactively adjusted to reflect this change.
*2 From fiscal 2022, the CO_2 emission factor for electricity has been changed from the base emission factor to an adjusted emission factor. Figures for previous fiscal years have been retroactively adjusted to reflect this change.
*3 The volume of residue produced after intermediate treatment is being reassessed following the adoption of an electronic manifest system in fiscal 2020.
Notes:
1. U.S. dollar amounts are converted at the rate of ¥133.54 = $1 USD, the approximate effective rate of exchange at March 31, 2023.
2. The Partial Amendments to Accounting Standard for Tax Effect Accounting (ASBJ Statement No. 28, issued February 16, 2018) have been applied from the start of fiscal 2018. Major management indicators from fiscal 2017 have been presented after retroactively applying these amended accounting standards.

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

The Kissei Group's Business

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



Pharmaceutical Business
¥56.2 billion 83.3% (percentage of consolidated net sales)

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

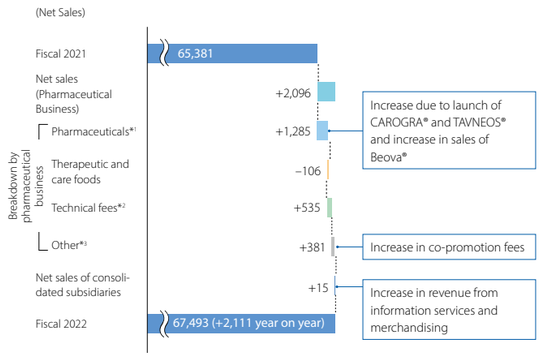
Furthermore, we are developing and marketing therapeutic and care foods (food for special dietary uses, etc.) to contribute to health through food.

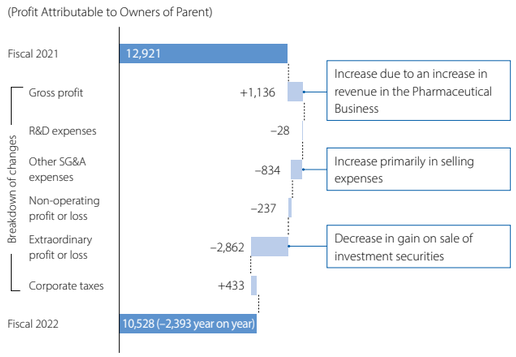
Breakdown of Business Results
- Pharmaceuticals*1 ¥47.0 billion — P.22–33
- Therapeutic and care foods (food for special dietary uses, etc.) ¥3.4 billion — P.34
- Technical fees*2 ¥1.0 billion
- Other*3 ¥4.6 billion

Other businesses ¥11.2 billion 16.7% (percentage of consolidated net sales) — P.35

Breakdown of Business Results
Information Services Business ¥8.2 billion Construction Business ¥2.3 billion
Merchandising Business ¥0.6 billion

Net Sales and Profit Attributable to Owners of Parent Compared with Fiscal 2021 (Millions of Yen)





Net sales for the Pharmaceutical Business in fiscal 2022 were ¥56,243 million, a year-on-year increase of 3.9%. The Company launched CAROGRA®, which was jointly developed with EA Pharma Co., Ltd., in May 2022, TAVNEOS® in June 2022, and TAVALISSE® in April 2023. In the midst of the COVID-19 pandemic, we promoted pharmaceutical information activities in a hybrid format that made effective use of a variety of digital tools as well as traditional in-person consultations. As a result, the introduction of these new products to the market went as planned, and sales increased for Beova® and Darbepoetin Alfa BS Injection [JCR], as did co-promotion fees. These increases, together with higher technical fees and export sales, contributed to the year-on-year increase in net sales.

Net sales for consolidated subsidiaries increased 0.1% year on year, to ¥11,249 million. As a result, consolidated net sales for the Group increased 3.2% year on year, to ¥67,493 million.

Regarding profit, increased selling, general and administrative expenses centering on R&D expenses could not be absorbed, resulting in an operating loss, in spite of the increase in net sales and a slight improvement in the cost of sales ratio. While ordinary profit increased, profit attributable to owners of parent decreased, despite a gain on sale of investment securities.

*1 Including active pharmaceutical ingredients (APIs) and bulk exports
*2 Includes supply to domestic sales partners and revenue from technical fees (contracting fees related to out-licensing, milestone payments, and running royalties)
*3 Total amount of revenue from supply to domestic sales partners and co-promotion fees

Feature
01 Introducing Newly Launched Orphan Drugs

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

Treatment for chronic idiopathic thrombocytopenic purpura

TAVALISSE®

In April 2023, Kissei launched TAVALISSE®, (generic name: fostamatinib,) a treatment for chronic idiopathic thrombocytopenic purpura (ITP).

The drug is an orally administered tyrosine kinase inhibitor discovered by United States-based Rigel Pharmaceuticals, Inc. Kissei acquired development and commercialization rights for the drug in Japan, China, South Korea, and Taiwan from Rigel Pharmaceuticals in October 2018.

TAVALISSE® suppresses platelet destruction by macrophages and the resulting drop in platelet count, improving the bleeding-related symptoms of chronic ITP. With a mechanism of action different from that of existing therapeutic agents, the drug is primed to become a new treatment option for chronic ITP patients who have had an insufficient response to steroids and other conventional treatments.

Japanese patients with chronic ITP participated in a domestic Phase III, placebo-controlled, double-blind, parallel-group, comparative study of the drug. All of the participants, 34 in total, had used and failed to respond to at least one of the standard ITP treatments or were intolerant to those treatments. During the double-blind test,*1 the drug or placebo was orally administered for 24 weeks to examine the efficacy and safety of this drug. The stable platelet response rate,*2 the primary endpoint, was significantly higher in the fostamatinib group than in the placebo group (36% in the fostamatinib group, 0% in the placebo group, p=0.030). Similarly, the secondary endpoint, overall response rate,*3 was also significantly higher for the fostmantinib group versus the placebo group (45% in the fostamatinib group, 0% in the placebo group, p=0.006). Most of the observed adverse events were mild or moderate in severity and could be managed through measures such as dose reduction or drug interruption. No new safety signals were identified in Japanese ITP patients.

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

In 2018, the drug was launched in the United States as a treatment for chronic ITP under the brand name TAVALISSE®, and has since been launched in Europe, Israel, and Canada. It is a designated orphan drug in the United States, Japan, and South Korea.

*1 Kuwana M., Ito T., Kowata S., Hatta Y., Fujimaki K., Naito K., et al. "Fostamatinib for the treatment of Japanese patients with primary immune thrombocytopenia: A phase 3, placebo-controlled, double-blind, parallel-group study." Br J Haematol. 2022; 200(6): 802-811.
https://onlinelibrary.wiley.com/doi/10.1111/bjh.18582
*2 Percentage of patients with a platelet count of 50,000/μl or higher at four or more of the six hospital visits from weeks 14 to 24
*3 Percentage of patients with platelet counts of 50000/μl or higher at one or more of the six hospital visits from weeks two to 12

Feature
02 Expanding Our Product Lineup in Renal Diseases and Dialysis

Treatment for pruritus in hemodialysis patients

Difelikefalin (generic name)

Difelikefalin is a kappa opioid receptor (KOR) agonist discovered by U.S.-based Cara Therapeutics, Inc. The drug is indicated for the improvement of pruritus in patients undergoing hemodialysis and is the first such treatment to be provided in an intravenous formulation that can be administered through the dialysis circuit. The expression mechanism of endogenous opioids is thought to be related to pruritus in hemodialysis patients. Difelikefalin selectively activates the KOR, a subtype of these opioid receptors, and is therefore expected to suppress pruritus.

In April 2013, Maruishi Pharmaceutical Co., Ltd., in-licensed the drug to Japan from Cara Therapeutics, and in March 2017, Kissei and Maruishi entered into a collaboration agreement for the development and sale of the drug. Joint development has been moving forward in Japan.

Pruritus is a common itching condition in the absence of obvious skin lesions that occurs when a patient of end-stage renal disease is undergoing hemodialysis. The long-lasting itching causes severe mental distress, which is reported to reduce quality of life (QOL) significantly and lead to poor sleep quality, depression, and an increased risk of death.

Kissei and Maruishi jointly conducted a domestic Phase III clinical trial for the drug. During the double-blind period, the primary endpoint, the change in the Numerical Rating Scale (NRS)*1 score for itching, and the secondary endpoint, the change in the Shiratori severity criteria score*2 for itching, showed significant improvement from the baseline in comparison with the placebo group. Good tolerability in terms of safety was also confirmed. Based on these results, Maruishi applied for manufacturing and marketing approval in September 2022.

Difelikefalin was launched in the United States in April 2022 and has since been launched in Europe.

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

Feature
03 Providing Orphan Drugs at an Early Stage

Treatment for non-muscle-invasive bladder cancer

CG0070 (development code)

CG0070 is a selectively replicative oncolytic immunotherapy based on a modified adenovirus type 5 backbone that contains a cancer-selective promoter and a granulocycte-macrophage colony-stimulating factor (GM-CSF) transgene, and destroys bladder tumor cells through their defective retinoblastoma (Rb) pathway. CG0070 was designed to work in two complementary ways. First, it replicates inside the tumor's cells with dysfunctional Rb pathways, causing tumor cell lysis and immunogenic cell death. Then, the rupture of the cancer cells can release tumor-derived antigens, along with the GM-CSF, which can stimulate a systemic anti-tumor immune response that involves the body's own white blood cells. In March 2020, Kissei acquired the exclusive development and marketing rights for the agent from CG Oncology, Inc., for 20 Asian countries and regions, such as Japan, South Korea, and Taiwan, with the exception of China.

Immunotherapy is a new treatment for tumor cells that involves infecting cancer cells with viruses known as oncolytic viruses, which are modified specifically to multiply in cancer cells without harming healthy cells, then destroy the cancer cells and grow in number. Some oncolytic viruses are expected to be effective not only in the direct destruction of cancer cells but also in activating an immunological response in the human body.

Bladder cancer is a malignant tumor that begins in the lining of the urothelium (transitional cells) of the bladder. The estimated number of patients with bladder cancer in Japan exceeds 20,000 a year, with men accounting for approximately 75% of cases. However, both men and women have a high percentage of bladder cancer in the 60-year-old age group.

Bladder cancer is largely divided into two groups, non-muscle-invasive bladder cancer (NMIBC) and muscle-invasive bladder cancer (MIBC). For NMIBC, especially for carcinoma in situ of the bladder, standard-of-care treatment is Bacillus Calmette-Guerin (BCG) therapy first. At present, radical cystectomy is indicated in most patients with NMIBC who failed BCG therapy or suffer a recurrence. Since preserving the bladder is ideal for maintaining the patient's quality of life, immunotherapy is being researched and developed as a new pharmacotherapy.

In advanced clinical studies, CG0070 has been shown to be a safe and efficacious agent in NMIBC following the failure of BCG therapy. The scientific rationale and clinical results to date of CG0070 make it a promising agent to be developed for a variety of solid tumor types to be used alone or in combination with immune checkpoint inhibitors.

Following in-licensing of the drug, Kissei has been conducting clinical trials in Japan as part of the BOND3 study, a global Phase III clinical trial led by CG Oncology, Inc., conducted across six countries but focused on the United States.

Treatment for spinocerebellar ataxia

Rovatirelin (generic name)

Rovatirelin is a derivative of a thyrotropin-releasing hormone (TRH) discovered by Shionogi & Co., Ltd. Rovatirelin activates the nervous system by promoting the release of acetylcholine and monoamine neurotransmitters such as dopamine after binding to TRH receptors distributed in the central nervous system, and is expected to improve the condition of patients with spinocerebellar ataxia. Kissei acquired the development and commercialization rights in Japan from Shionogi and developed it as an agent for spinocerebellar ataxia.

Kissei conducted a Phase III clinical trial for the drug for efficacy in treating spinocerebellar ataxia from 2013 to 2015, and another Phase III clinical trial from 2016 to 2018 based on the first trial. Although rovatirelin demonstrated safety and was well tolerated, no statistically significant improvement was observed in the total SARA*1 score, the primary endpoint for assessing ataxia in both trials, compared with a placebo group. On the other hand, a pooled analysis (post hoc analysis) that involved a detailed analysis of these trials, which included subgroup analysis by severity, revealed that patients with more severe conditions showed a statistically significant improvement in the change in total SARA score compared with the placebo-treated group. The results of this clinical trial were published online in the *Journal of Neurology, Neurosurgery & Psychiatry*.*2 An application for marketing approval was also submitted in December 2021 based on these results.

The application was temporarily withdrawn by Kissei in July 2023, after the Pharmaceuticals and Medical Devices Agency (PDMA) expressed the opinion that it cannot be approved based on the data submitted. Kissei is currently investigating the possibility of conducting additional clinical trials with the agency.

Spinocerebellar ataxia is a nerve degeneration disorder of unknown etiology in which symptoms such as ataxia appear owing to the degeneration of the cerebellum or spinal cord and has been designated as an intractable disease by the Ministry of Health, Labour and Welfare. Neuropathy is both irreversible and gradual, with treatments only capable of targeting symptoms. Patients' satisfaction with treatment is quite low, and drugs contribute little to their well-being.

We will make every effort to obtain marketing authorization approval for rovatirelin so that we can provide a new treatment to patients with spinocerebellar ataxia who are waiting for a new drug to help them.

*1 Scale for the assessment and rating of ataxia
*2 Nishizawa M., Onodera O., Hirakawa A. on behalf of the Rovatirelin Study Group, et al. "Effect of rovatirelin in patients with cerebellar ataxia: two randomized, double-blind, placebo-controlled Phase III trials." *Journal of Neurology, Neurosurgery & Psychiatry*, first published online: 14 January 2020. doi: 10.1136/ jnnp-2019-322168
https://jnnp.bmj.com/content/jnnp/91/3/254.full.pdf

Research and Development (R&D)

▶ Material issue related to Kissei's business activities

Development and provision of products useful to society

Drug Discovery R&D

Masahiro Hiratochi
Senior Director of Research Strategy and Planning Department, Research Division

In the Research Division, we are moving forward with highly competitive drug discovery R&D in order to discover original pharmaceutical products that share value with patients and other stakeholders. To do so, we conduct drug discovery along two axes: drug discovery concepts and compound discovery technology.

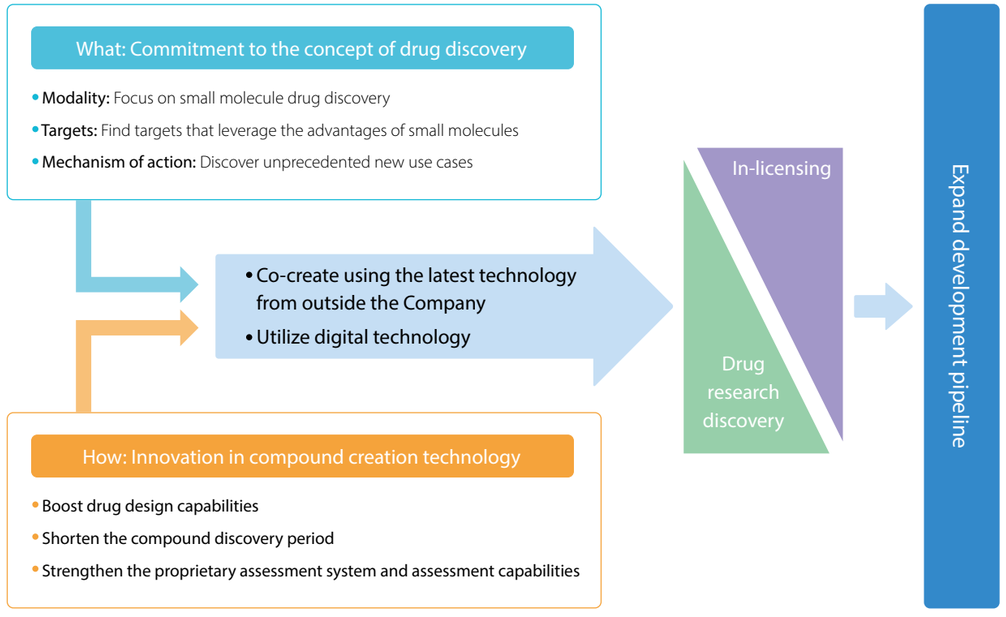
For drug discovery concepts, we are focusing our efforts on small molecules, since we can leverage our history of in-house small molecule drug discovery, a strength we have built up over time. We look for target molecules and their associated diseases that are particularly suited for small molecule treatments and position them as drug targets. In recent years, modalities have become more diverse, branching out to include biopharmaceuticals, nucleic acid medicines, and regenerative medicine. However, recent advances in science and technology have made it possible to apply small molecules to a wider range of target molecules, including ones that were previously difficult to approach. For this reason, I believe that small molecule drug discovery will remain a viable modality with a wide range of sustainable applications. We are currently focused on small molecule drug discovery research involving allosteric modulators. Allosteric modulators bind to target proteins at different sites than known ligands, which we expect will result in groundbreaking pharmacological effects that cannot be easily achieved through existing mechanisms of action. We intend to push the limits of small molecule drug discovery by focusing on these new possibilities and taking advantage of open innovation, while polishing our strengths in medical chemistry and remaining committed to this drug discovery concept, one that has value particularly because of the amazing things small molecules can achieve. Furthermore, as part of our commitment to drug discovery concepts, which are the launching point for drug discovery research, we are searching for target molecules that can unlock mechanisms of action that will bring with them unprecedented use cases. To support this effort, we have developed a proprietary system for analyzing external data and a database of genetic mutation diseases. In addition, we use AI to analyze genetic information and other forms of big data. With these tools, we are building an environment that fosters new knowledge and new insights that can prompt powerful drug discovery hypotheses and stimulate a constant stream of ideas. Furthermore, we will combine analyses of publicly available medical information and information from social media to help focus our efforts toward materializing original drug discovery ideas rooted in reliable science that can meet the unmet medical needs of medical professionals and patients.

Moving to the other axis, compound discovery technology, we have introduced AI into the in silico drug discovery technology that we have cultivated up to this point as part of our work to enforce our drug design capabilities and shorten the compound discovery period. We started research activities related to in silico drug discovery in the 1990s, which has sped up efficient searches for lead compounds by simulating the binding modes of small molecule agents. We will combine the use of this technology platform with AI to create compounds that synergize with small molecule drug discovery. AI can analyze the vast amount of accumulated data associated with compound structures, which can lead to new discoveries and methodologies. This, combined with wisdom and experience in medicinal chemistry, promotes innovation within the drug discovery process. The overall expectation is that these efforts will shorten the time needed to go from searching for compounds to selecting compounds as new drug candidates, and that drug discovery will become more productive. In addition to our drug design capabilities, we also prioritize improving the structure of our unique system for evaluating these compounds. We have developed a system that enhances the accuracy of clinical translation by utilizing biobanks, technology introduced from academia, genetically modified animals, and other methods in order to select appropriate target molecules and compounds that demonstrate efficacy in humans. From there, we assess the validity of evaluation results, bearing in mind human efficacy and clinical trial design. Furthermore, we are working on drug discovery research with a focus on structural biology. In the past, it was thought that changes in protein structure were not significant, functioning much like a lock and key. However, structural analysis of proteins has revealed that the structure of drug target proteins changes much more than expected, and that their movements are connected to their function. One of the strengths of small molecule drug discovery is the recognition of this protein movement, and when a small molecule agent is used to control this movement, it exhibits a characteristic pharmacological effect. To maximize the appeal of small molecules, we have integrated structural biology with our evaluation system to create a unique research process that combines speed and quality.

We also want to make AI and other rapidly advancing technologies an active part of the research process, so we are developing fundamental technologies and then cultivating data scientists and human resources with high DX literacy who will ultimately be tasked with implementing these technologies. The use of AI in drug discovery research is set to become a major trend, and I believe that it is essential to our research infrastructure that we grasp this trend by the horns, gain expertise, and find unique ways to put AI to work. When drug discovery targets and technologies turn out to be beyond our in-house technological base, we actively promote open innovation and approach the use of external technology and joint research with a flexible mindset. We also intend to introduce new drug discovery technologies through consortiums with academia and other activities.

With the in-house drug discovery we have conducted serving as our bedrock, we will use our commitment to the two axes of drug discovery—drug discovery concepts and compound discovery technology—to discover pharmaceutical products with value. To do this, we will build upon our existing technology base and ramp up efforts to build a base for AI and other new technologies to improve the probability of success and shorten the R&D period. Moreover, we will help expand the Company's development pipeline and carry on our tireless efforts to deliver high-quality, innovative pharmaceutical products to patients as soon as we can.

▶ Enhance Drug Discovery Research



Developing New Drugs

Takumitsu Yoshida
Director, Clinical Projects Management Department, Clinical Development Division

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. To fulfill this mission, the division is working swiftly to develop useful new drugs.

In 2021, we obtained domestic approval for TAVNEOS®, a treatment for microscopic polyangiitis and granulomatosis with polyangiitis, and in 2022 we obtained domestic approval for TAVALISSE®, a treatment for chronic idiopathic thrombocytopenic purpura. Both of these diseases are designated intractable diseases in Japan. In recent years, there have been growing problems with drug loss, which is when new and useful drug treatments are not released in Japan, and drug lag, which is when drug approval is delayed. One potential reason for these problems is that companies outside Japan are lowering the priority of new drug development in Japan due to the country's NHI drug pricing system, under which drug prices are set lower than in Europe and the United States and are subject to frequent price cuts. Since both TAVNEOS® and TAVALISSE® were in-licensed from overseas companies, we have been able to protect against possible drug lag or drug loss of these drugs in the future.

In order to obtain domestic approval for TAVNEOS®, we had to participate in global Phase III clinical trials that had already started in Europe and the United States and complete patient registration within the deadline. We were the last to participate in the trials, which made sticking to the trial schedule seem like an all-but-impossible task. However, thanks to the cooperation of the patients who participated in the trial, as well as medical institutions, and internal and external stakeholders, we were able to successfully complete patient registration and complete the trials. After confirming the efficacy of TAVNEOS®, the results of this study were published in the February 18, 2021, issue of *The New England Journal of Medicine*, one of the world's most authoritative medical journals. Japan also became the first country in the world to obtain approval for the drug, thanks to a prompt review of the NDA by Japanese regulatory authorities.

When TAVALISSE® was in-licensed, the drug was available on the U.S. market. To minimize the drug lag in Japan, we established an efficient domestic development plan using overseas test data after in-depth discussions with regulatory authorities, which consented to the plan. Following this step, patient registration for clinical trials was difficult due to the COVID-19 pandemic, but to ensure that we could quickly deliver the new drug to patients, the Company's Clinical Development Division found medical institutions with patients who could take part in the trial and added them as new participants. These efforts allowed us to complete clinical trials in a short period of time and obtain approval quickly.

Development of new drugs in continuation of these examples is progressing smoothly. CG0070 (development code), an oncolytic immunotherapy for bladder cancer, is our first foray into regenerative medicine. As with TAVNEOS® previously, this product is currently undergoing global Phase III clinical trials, which is the final stage of development, in order to obtain approval in Japan as soon as possible.

There still exist many unmet treatment needs, especially in cancer, in intractable and rare diseases. We will continue to strive for rapid new drug development in order to deliver useful new drugs to patients as rapidly as we can.

Yumi Ikezaki
Director of the Clinical Administration, Clinical Research Department, Clinical Development Division

One of the policies of the Clinical Research Department is to conduct efficient and reliable clinical trials. We work every day to accurately grasp changes in regulations and the environment that concern the development of pharmaceutical products for putting new drugs in the hands of patients swiftly.

Recent diversification and digitalization of clinical trials have led to a review of good clinical practice, which recommends more efficient monitoring with effective application of risk-based monitoring. In addition, "the concept of quality management" has been prepared as the comprehensive concept of quality control and quality assurance. In quality management systems for clinical trials, we should focus on activities essential to the clinical trial, and are recommended to ensure quality efficiently, while ensuring participants' protection and the reliability of the trial results.

The Clinical Administration of the Clinical Research Department collaborates with the other departments of the Clinical Development Division to conduct risk-based monitoring based on the concept of quality management. For example, when we prepare the protocol, we identify processes and data critical to participants' protection and the reliability of trial results, and try to avoid unnecessary complexity, procedures, and data collection of the protocol. For these critical processes and data, we identify and assess risks in detail. We try to take measures for particularly high risks.

As part of quality management, we also engage in quality control and monitoring that does not rely solely on visits to medical institutions. These efforts have become a useful means of ensuring quality even in situations where visits to medical institutions have been restricted due to COVID-19.

The Clinical Administration is also working to promote DX. In the development of pharmaceutical products, decentralized clinical trials (DCTs) are attracting attention, which do not rely on visits to medical institutions through the use of wearable devices and digital tools. A DCT is a means that could increase opportunities for patients to participate in clinical trials and is expected to result in increasing efficiency of clinical trials and the creation of innovative pharmaceutical products. So, we will continue to prepare for implementation of DCTs at Kissei.

We will continue to increase the efficiency of monitoring by making effective use of these risk-based activities and ensuring participants' protection and the reliability of clinical trial results. With Kissei's Management Philosophy of contributing to society through high-quality, innovative pharmaceutical products and serving society through our employees, we aim to bring new drugs to market early and continuously without forgetting to take on new challenges.

Intellectual Property Strategy

Tetsuji Ozawa
Manager of the Intellectual Property Section, Intellectual Property Department

It takes about nine to 16 years and a large amount of money to bring a new drug to market. Using a drug discovery strategy that focuses on small molecule drug discovery, Kissei has discovered groundbreaking compounds in its drug discovery research conducted in Japan and overseas, which we protect with tight-clad substance patents in order to secure a stable exclusivity period. To make progress in new drug development on the global stage, we need to select drug discovery themes likely to attract a lot of attention, look 10 years into the future, and acquire patents in appropriate countries. The Intellectual Property Department contributes to Kissei Pharmaceutical's global drug discovery by playing a role in these tasks, which includes working with researchers to select themes utilizing the intellectual property landscape, and by conducting market forecasts based on a variety of data.

More than only substances, the process for developing new drugs can yield new drug applications, dosages, salts and crystals, manufacturing methods, and formulations. Therefore, in addition to substance patents, we will acquire patents for these various original creations, protect the rights to new drugs diligently, and secure a competitive edge. We also conduct clearance searches from the beginning stages of research and implement risk management so as not to infringe on the intellectual property rights of others and to ensure that we can begin engaging in business at an early stage and maintain this business stably.

When promoting intellectual property strategies, the Intellectual Property Department appoints a person to handle each drug discovery theme. These people have a full understanding of their respective themes, which allows us to build a system that enables departments to work together in a timely manner to understand the various issues that occur when creating and utilizing intellectual property.

R&D Pipeline (As of July 2023)

New Drug Development (In-Company)

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

Note: NDA for Rovatirelin (spinocerebellar ataxia) withdrawn, possibility of conducting additional clinical trials is being considered

New Drug Development (Out-Licensing)

Generic name / Development code	Expected indications	Countries and regions	Development stage: Clinical trials under preparation	Phase I	Phase II	Phase III	Preparation to submit application	NDA in process	NDA approved	Partner company
Linzagolix	Uterine fibroids	Europe		■	■	■	■	■	■	Theramex HQ UK Limited
		China		■	■	■				Bio Genuine
		Taiwan		■	■	■	■			Synmosa Biopharma Corporation
	Endometriosis	Europe and the U.S.		■	■	■				Theramex HQ UK Limited
		China		■	■	■				Bio Genuine
Silodosin	Dysuria associated with benign prostatic hyperplasia	Vietnam, other countries		■	■	■	■	■		Eisai Co., Ltd.
Fostamatinib	Chronic idiopathic thrombocytopenic purpura	South Korea		■	■	■	■			JW Pharmaceutical
		China, other countries		■						Inmagene Biopharmaceuticals
KDT-3594	Parkinson's disease	China, other countries		■	■					Affamed Therapeutics Limited

Major R&D Projects

Treatment for uterine fibroids and endometriosis

Linzagolix (generic name)

(development code: KLH-2109)

Linzagolix is a novel, orally administered GnRH (gonadotropin-releasing hormone) receptor antagonist.

On November 30, 2022, Kissei Pharmaceutical terminated its licensing agreement with ObsEva SA, which granted the Swiss-based company exclusive worldwide rights on the drug, excluding Japan and some regions of Asia. Pursuant to this agreement, the sublicensing agreement between ObsEva and U.K.-based Theramex HQ UK Limited regarding the commercialization of this drug outside of North America and Asia was automatically taken over by Kissei upon termination of the agreement. This agreement was renewed in April 2023 after its terms were reviewed in light of the latest situation. Theramex is currently moving forward with preparations to launch the product in Europe during fiscal 2023.

Kissei will not undertake U.S. development of linzagolix and is instead looking into partnerships with other companies to handle this task. Furthermore, ObsEva withdrew its NDA for linzagolix for the indication of uterine fibroids in August 2022.

With respect to the out-licensing of linzagolix in Asia, the Company granted exclusive development and commercialization rights in China to China-based Bio Genuine in September 2021 and similar exclusive rights in Taiwan to Synmosa Biopharma Corporation of Taiwan in November 2022.

In Japan, a Phase II clinical trial for linzagolix as a treatment for endometriosis has been completed, and a Phase III clinical trial for uterine fibroids is currently underway.

Treatment for Parkinson's disease

KDT-3594

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

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

Treatment for ulcerative colitis

KSP-0243

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

Providing Drug Information

▶ Material issue related to Kissei's business activities

Communication with medical professionals and patients

Providing Drug Information

Akihide Nakata

General Manager of the Pharmaceuticals Promotion Department, Sales and Marketing Division

Providing Appropriate Pharmaceutical Information in the Medical Field

In May 2022, we launched CAROGRA® a treatment for ulcerative colitis, which we jointly developed with EA Pharma Co., Ltd., and in June 2022, we followed up with the launch of TAVNEOS®, a treatment for microscopic polyangiitis and granulomatosis with polyangiitis. Then, in April 2023, we launched TAVALISSE® Tablets as a treatment for chronic idiopathic thrombocytopenic purpura. Furthermore, in September 2022, we submitted an application in Japan for marketing approval for difelikefalin (generic name), a treatment for pruritis in hemodialysis patients,* and we are preparing for drug launch. We have also rapidly expanded the market for Beova®, a treatment for overactive bladder, after shipping adjustments were lifted in August 2022, and we are currently providing information to approximately 60,000 medical institutions.

Never before have we had such an overlap of new drugs coming to market. Although some medical institutions have tight restrictions on visitation due to the COVID-19 pandemic, which can make it difficult to distribute information in a typical manner, there is strong demand among medical professionals for information on new drug treatments. For this reason, we are working hard, every day, to enable doctors to write prescriptions that fit the condition of each of their patients, and to provide accurate information to ensure these drugs are used properly.

The gratitude we receive from medical professionals is a powerful reminder that our activities have real value for patients and medical professionals—it gives medical representatives (MRs) a strong sense of fulfillment.

Providing Information That Meets the Needs of Medical Professionals

The COVID-19 pandemic changed medical treatment in major ways, down to the way medical professionals think, and even today that way of thinking changes from moment to moment. Because of this, we continue to provide drug information through face-to-face meetings while also taking advantage of digital tools such as online lectures and providing details via email as part of our day-to-day work. Out of the everyday activities of an MR, I believe that providing information through face-to-face meetings is the method most likely to result in doctors beginning to prescribe the drug in question. This is especially true for new drugs.

Take, for example, our activities related to orphan drugs, which center on university hospitals. While we may need to hold remote meetings or online briefings helmed by the Rare Diseases Project—specifically the product manager in charge of the specific disease—for reasons of speed or expertise, some doctors may request to hear this information in person. For this reason, we are going forward with a hybrid form of information provision that can employ in-person visits and remote communication as the situation requires and according to the needs of medical personnel.

As the types of channels that medical professionals can utilize to access information become more diverse, we have also updated our website with content specifically for their use that offers clinical support, online lectures, and other functions that can enhance information that is useful in daily care.

This raises the question: "What, today, is the true value of having information provided by an MR?" An MR serves as the closest partner of medical professionals; they attach great importance to communication between people while making full use of digital tools to fulfill their quest to deliver appropriate drug information. As such people, they are fully committed to remaining mindful of the issues that concern medical professionals in order to help as many patients as they can.

Activities in Key Areas

We have positioned urology and renal diseases and dialysis as key areas and have accumulated a track record of activities aimed at being one of the top three companies selected by medical professionals in these areas. These activities, built up over many years, have been received positively based on questionnaires conducted by external organizations.

For urology, in particular, we provide appropriate treatment options for patients suffering from three conditions: Beova®, for the treatment of overactive bladder, MINIRIN MELT®, for the treatment of nocturia caused by nocturnal polyuria in males, and Urief® for the treatment of benign prostatic hyperplasia.

In renal diseases and dialysis, we have prepared a lineup of prescription drugs that can help improve patients' quality of life through medication adherence, such as P-TOL® for hyperphosphatemia, UPASITA® for secondary hyperparathyroidism, Darbepoetin Alfa BS Injection [JCR] for renal anemia, and MARIZEV® for diabetes. We are currently in the process of adding difelikefalin (generic name), which has an NDA in progress, to this lineup as a treatment for pruritus in hemodialysis patients.* It is crucial to communicate not only with doctors but also with pharmacists, nurses, technicians, and many other types of medical personnel. This is especially true at dialysis facilities. We will build relationships of trust with these people in a step-by-step process by providing information from the patient's perspective.

The efforts of MRs to provide information on the proper use of our products are truly key to realizing Kissei's Management Philosophy, to contribute to society through high-quality, innovative pharmaceutical products, and to serve society through our employees. Going forward, the Sales and Marketing Division will work together to build up the training necessary to deliver products that have been handed over from research, development, and production to medical professionals and patients.

* Expected indications

Rare Diseases Project

Natsuko Shichiri

Manager of the Rare Diseases Business Unit, Sales and Marketing

The Rare Diseases Project was established in April 2021 to strengthen the sales system for treatments of rare diseases and enable smooth introduction of these treatments to market. In addition to TAVNEOS®, a treatment for microscopic polyangiitis and granulomatosis with polyangiitis, we launched TAVALISSE® in April 2023, a treatment for chronic idiopathic thrombocytopenic purpura. The Rare Diseases Project plans promotion strategies, provides in-house education on the diseases and treatment methods, and provides information to specialists for these two products.

The scale of clinical trials for orphan drugs is typically small, meaning the amount of evidence of a drug's efficacy available at the time of approval is sparse. For this reason, the Rare Diseases Project collaborates with branch offices to provide information to specialists, confirm the status of patients receiving doses of the product, and promote post-marketing surveillance, all of which serve to build up evidence for the product. We also create opportunities such as academic seminars and lectures for doctors to share experiences of prescribing the drugs with other doctors, which provide a wide range of product knowledge and spread information on proper use.

TAVNEOS® is a selective C5a receptor antagonist, and TAVALISSE® is a tyrosine kinase inhibitor. Both are molecular-targeted drugs, giving them novel mechanisms of action that differ from existing treatments. Glucocorticoids (GCs) are widely used in the treatment of autoimmune diseases, and their potent immunosuppressive and anti-inflammatory effects contribute to improving the life prognosis of many patients. On the other hand, due to reports of side effects associated with the use of GCs, there has been a global trend in recent years to limit their dose and duration of use. Molecular-targeted drugs such as TAVNEOS® and TAVALISSE® are expected to revolutionize the current state of treatment for such autoimmune diseases.

In addition to launching TAVNEOS® and TAVALISSE®, over the course of "**PEGASUS**" we also plan to file an NDA and launch CG0070 (development code), an oncolytic immunotherapy for the treatment of non-muscle-invasive bladder cancer.

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

▶ Marketing System for Orphan Drugs

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

- Planning and developing marketing for rare disease treatments
- Building a system for providing information to specialists, confirming status of patients receiving the drug, and promoting post-marketing surveillance in collaboration with branch offices

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

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

Product name / Generic name / Development code	Development stage	Expected indications
TAVALISSE® / fostamatinib	April 2023: Drug launch	Chronic idiopathic thrombocytopenic purpura
TAVNEOS® / avacopan	June 2022: Drug launch	Microscopic polyangiitis and granulomatosis with polyangiitis
CG0070	Phase III clinical trials	Non-muscle-invasive bladder cancer

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

Production, Supply, and Reliability Assurance

▶ Material issue related to Kissei's business activities

Steady supply of high-quality products

Production and Supply

Mitsuaki Aizawa
Senior Director,
Manufacturing Planning,
Pharmaceutical
Manufacturing Division

As I reflect upon the COVID-19 pandemic, there are memories that remain fresh in my mind. One is the fervorous global effort to secure the ultimate countermeasure—a vaccine—which was approved with unprecedented speed; another is the united effort of Japan to protect its people and vaccinate one million people per day. Some of the vaccines needed to be transported and stored at low temperatures, drawing global attention to the idea of a steady supply of high-quality pharmaceuticals.

This is one of the Company's material issues, and one we focus on in the Production Division through our continuous future-facing efforts to improve supply and manufacturing systems for pharmaceutical products.

TAVNEOS® and TAVALISSE®, both launched over the course of "**PEGASUS**," are pharmaceutical products that meet unmet medical needs. Since these drugs have been newly positioned as treatments within medical guidelines, we are being particularly careful to ensure a steady supply is available. In addition to Japan, the drug substances and formulations created by Kissei are exported overseas, contributing to the health of patients around the world. Now, we are building domestic and overseas supply chains for linzagolix (generic name), positioned as our next pillar of earnings.

However, instability in the supply of generic drugs has broken down the supply balance among pharmaceutical companies, pushing us toward a society in which drugs are difficult to obtain. In response, we will work even harder than before to increase production efficiency and supply capacity so that our supply system can continue to meet the needs of the market.

We will also continue reviewing our organization and management system to enhance our ability to manage the supply chain, which is expected to become increasingly complex and sophisticated, and work to provide a stable supply of high-quality products.

Hiroaki Iriyama
Senior Director,
Production Engineering,
Pharmaceutical
Manufacturing Division

A scandal at the end of 2020 involving a maker of generic drugs set off a wave of instability in the supply of pharmaceutical products, with shipping suspensions and controls continuing to this very day. The Production Division manages every aspect of manufacturing, from bringing in raw materials to shipping out products, and we work day in, day out to fulfill our duty to provide patients with a steady supply of pharmaceutical products of an assured quality.

One of the policies for the division under "**PEGASUS**" is to build and stabilize production systems for new drugs and formulations. Under this banner, we launched TAVNEOS® and TAVALISSE®, new drugs in the field of rare diseases. When building a system of production for a new drug, it is crucial that a system's "product quality" can reliably reproduce "design quality," meaning that the products can fully demonstrate the same efficacy and safety as the drugs confirmed and verified at the R&D stage. For this reason, we worked closely with the Research Division to begin technology transfer at an early stage to make sure we had a full grasp of the technical information surrounding the new drugs. Using this information, we built a production system that can repeatedly manufacture high-quality products. Currently, we are working with related divisions on a project to launch linzagolix (generic name) in Europe, and we are pursuing quality that meets international standards.

We will continue manufacturing work that emphasizes quality and ensure a steady supply of high-quality pharmaceutical products in line with our Management Philosophy, to "contribute to society through high-quality, innovative pharmaceutical products" and "serve society through our employees."

Reliability Assurance

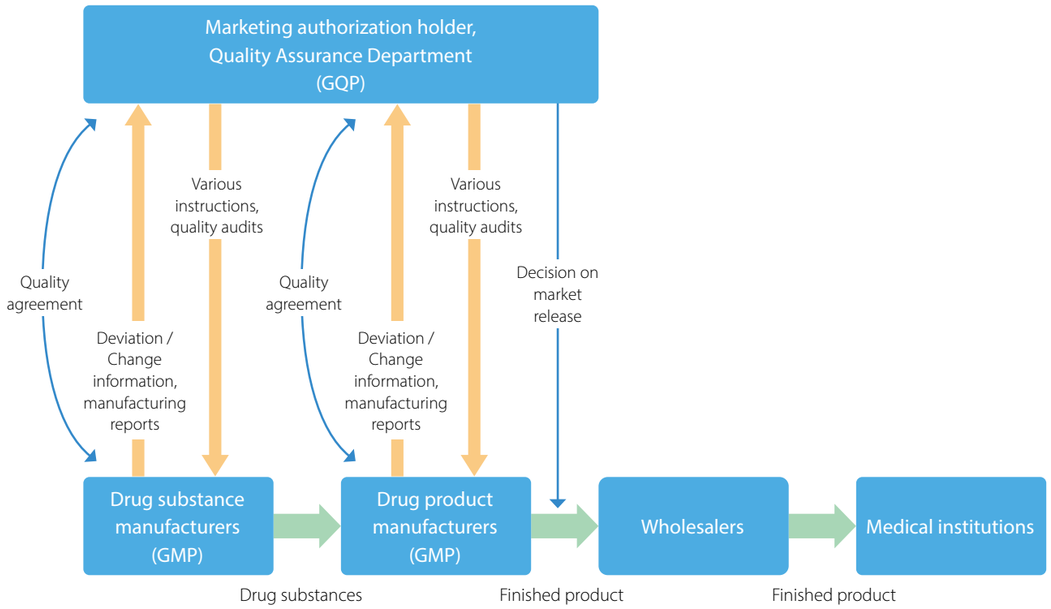
Koh Takeuchi
Senior Director,
Quality Assurance
Department, Quality,
Safety and Regulatory
Affairs Division

The Quality Assurance Department fulfills the stipulations for marketing authorization holders stated in the Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices by making appropriate market release decisions for pharmaceutical products manufactured in the factories of manufacturers and subcontractors inside and outside Japan, as well as those manufactured at the Company's Matsumoto Plant and Shiojiri Plant. In doing so, the department helps contribute to society through high-quality, innovative pharmaceutical products, one aspect of our Management Philosophy.

Pursuant to the Ministerial Ordinance on Standards for Quality Assurance for Drugs, Quasi-drugs, Cosmetics and Regenerative Medical Products (the GQP Ministerial Ordinance), we conclude quality agreements with manufacturers of drug substances and drug products, then work closely with these manufacturers to ensure that they produce high-quality products in a stable manner. At the same time, we periodically conduct quality audits of these manufacturers and manage any deviations that occur in manufacturing, quality testing, or other processes. When manufacturing-related changes occur, we assess their impact, determine whether the changes are acceptable, and, if necessary, coordinate with the Pharmaceutical Affairs Division to handle changes to manufacturing and marketing approval documents. We also confirm that there are no problems in the daily manufacture of drug substances and drug products based on the reports from each manufacturer, and then make decisions regarding market release.

Kissei is a medium-sized manufacturer and distributor of ethical pharmaceuticals, but I feel that the department's strengths, which lie in its light footwork and good cooperative ties with related departments, are a direct result of the Company's size. We will continue to work with related departments inside and outside the Company so that we can stably provide patients with high-quality pharmaceutical products.

▶ Flow of Drug Supply to the Market



Nutrition Division

▶ Material issue related to Kissei's business activities

Development and provision of products useful to society

Message from the General Manager

Yasumasa Mishima

Executive Officer,
General Manager,
Nutrition Division

Kissei established the therapeutic and care foods business in 1990, to develop and promote the sale of foods for special dietary uses. This business was tasked with supporting health through medicine and food, working hand in hand with the Pharmaceutical Business, which aims to fulfill Kissei Pharmaceutical's Management Philosophy, to contribute to society through high-quality, innovative pharmaceutical products. The KISSEI HEALTHY FOODS (KHF) brand embodies our determination to use food products to help raise the quality of life of elderly people, those who require nursing care, and people with kidney disease.

According to an investigation based on market research, the market for chewable, easy-to-swallow therapeutic foods is on the rise as the population grows older. As of fiscal 2021, the market was valued at an estimated ¥54.5 billion and ¥8.0 billion for foods made for people with kidney disease. Relative to competing manufacturers, we have the eighth-largest share of the overall market, at 4.1%, and the top share of foods for people with kidney disease, at 28.0%.

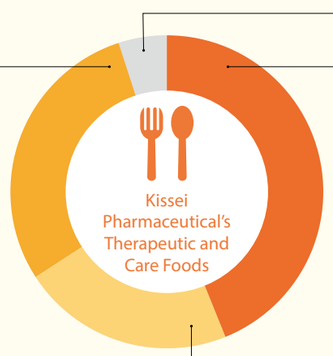
In fiscal 2022, therapeutic and care foods generated ¥3.4 billion in net sales, with 44% of net sales coming from foods for the elderly and those receiving nursing care, 29% from protein-controlled foods, 22% from energy supply foods, and 5% from other foods.

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

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

▶ Kissei Pharmaceutical's Therapeutic and Care Foods

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



Other Foods 5%

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

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

The Kissei Healthcare Net Shop

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

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

Other Businesses

▶ Material issue related to Kissei's business activities

Development and provision of products useful to society

The Kissei Group's Management Philosophy:

Make greater contributions to society by creating harmony among the Group's working parts

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

KISSEI COMTEC CO., LTD. (Information Services)

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

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

The company promotes the creation and provision of products and services that solve social issues to help achieve the SDGs. These include the creation of paperless solutions such as Smart Discussion, a system that can help save energy and resources by removing the need for paper from any kind of meeting. The company has also introduced teleworking and staggered working hours and support for paternity leave, as well as shorter working hours for employees with children who are yet to enter elementary school. These initiatives aim to enable diverse styles of working and help employees balance work and childcare.

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

HASHIBA TECHNOS CO., LTD. (Construction)

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

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

Description
- General construction services
- Factory and building management

Kissei Shoji Co., Ltd. (Merchandising)

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

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

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

Relationships with Our Employees

▶ Material issue related to Kissei's management base

Creation of a fulfilling workplace environment

Kissei's Approach to Human Capital

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, working styles, our human resource system, and other aspects, and have therefore introduced flexible workstyles in many departments. These include an elective-based human resource system that allows employees to choose a workstyle that matches their aptitudes and life plans as well as deemed working hour and flextime systems. 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

Kissei has set "the development of autonomous human resources" as its main vision for human resources, and has put in place the following three policies, through which we will develop autonomous and professional human resources with a high level of expertise, creativity, and excellence, who can accurately and promptly respond to changes in the business environment.

- The Company will provide an educational and learning environment that aims to simultaneously realize the growth of employees and the development of the Company.
- The Company will promote highly effective guidance and development by managers and systematic development of the next generation of employees.
- The Company will encourage self-development of employees and support self-motivated skill and career development.

Internal Environment Development Policy

Kissei has identified the "creation of a fulfilling workplace environment" as a material issue as part of its effort to create an environment that nurtures autonomous human resources. We believe that a fulfilling workplace environment is one where every employee feels that their work gives them a sense of satisfaction, accomplishment, mission, and growth. To make sure this is the case, we emphasize employee engagement and measure it regularly. Based on our analysis, we consider and implement new human resource-related measures and are working on the following initiatives:

- Operation of our dual-track human resource system
- Operation of our education system
- Promotion of diversity and inclusion and gender equality
- Promotion of health management

Employee Engagement Level

Kissei conducts the Human Resources Awareness Survey in order to understand the level of employee engagement.

The survey comprises questions in five categories—engagement, job satisfaction, goal management system, treatment of employees and career, and human resource system and work situation—as well as a question regarding overall satisfaction. We measure the degree of satisfaction for each question and degree of importance, meaning how important the subject of the question 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." Results of the surveys conducted before (2019) and during (2022) the period of "**PEGASUS**," the current five-year medium-term management plan, are shown in the table below.

▶ Results of the Human Resources Awareness Survey

Item	Questions regarding Engagement and Job Satisfaction	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 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

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

Cultivating the Next Generation

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

To this end, Kissei formulated and implemented its General Employers Action Plan based on the Act on Advancement of Measures to Support Raising Next-Generation Children,* with the first phase of the plan completed in 2008, the second phase completed in 2011, and the third phase completed in 2015. The efforts of each phase were evaluated and recognized in 2008, 2011, and 2015 with certification as a standards-compliant general business owner (Kurumin). Furthermore, at the end of the fourth phase in 2017, Kissei was granted special certification (Platinum Kurumin).

* Laws formulated in 2005 by national and local public entities and businesses to promote measures to support raising next-generation children. These measures are designed to create an environment in which children, who will be responsible for society in the coming generation, can be born and raised in a healthy manner.

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 among hires

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

▶ Diversity and Inclusion

Item	Fiscal 2022 results	Fiscal 2023 targets
Percentage of female employees taking childcare leave	100%	100%
Percentage of male employees taking childcare leave	80%	Maintain 80% or higher
Ratio of average length of employment for female employees to average length of employment for male employees	82.7%	Maintain 80% or higher
Percentage of employees with disabilities	2.45%	2.5% or higher

Promotion of Work–Life Balance

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

Occupational Health and Safety

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

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

Promoting Health Management

Kissei Pharmaceutical Health Declaration

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

Kissei Pharmaceutical Health Declaration

Established on April 1, 2017

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

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

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

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

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

Continuing the trend from fiscal 2022, in March 2023, Kissei was certified as a 2023 Organization with Outstanding Health & Productivity Management (Large Enterprise category).

Certification is granted based on the results of the annual Survey on Health and Productivity Management conducted by the Ministry of Economy, Trade and Industry. The Nippon Kenko Kaigi (Japan Health Council) reviews applicant companies' initiatives related to employee health from four perspectives: management philosophy and policy, organizational structure, systems and implementation of measures, and evaluation and improvement. The Nippon Kenko Kaigi then recognizes companies that are found to practice particularly excellent health management.

Main Issues and Targets Related to Health Management

▶ **1. Prevention of lifestyle-related diseases and other conditions in healthy people**

Target: Percentage of employees whose specific health guidance level improved in the medical examination for the following fiscal year

Most recent percentage*1	Target
44.0%	50%

*1 Fiscal 2022

▶ **2. Promotion of work–life balance and securing of personal time**

Target: 100% utilization of commemorative leave (three days per year) among employees

Most recent percentage*2	Target
98.4%	100%

*2 Fiscal 2022

Major Health Management Initiatives

- Formulation of the Kissei Pharmaceutical Health Declaration
- Medical testing exceeding legal requirements and subsidization of cancer screening and other testing costs in cooperation with the Kissei Group Health Insurance Society
- Promotion of specific health guidance and other health programs focused on preventing lifestyle-related diseases in collaboration with the Kissei Group Health Insurance Society
- Development of a mental health consultation system through outsourcing and other means, in addition to industrial physicians
- Implementation of no-overtime days and days to promote leaving work on time
- Creation of an environment that makes it easier to take annual paid leave and commemorative leave
- Provision of healthy menus in employee cafeterias
- Stress checks for all business establishments, including those with fewer than 50 employees
- Implementation of calisthenics in the workplace to establish exercise habits, holding of sporting events for improving health and physical fitness at each workplace, and subsidization of expenses for these events

▶ **Percentage of employees who took stress checks**

Fiscal 2020	Fiscal 2021	Fiscal 2022
97.2%	97.4%	93.9%

▶ **Percentage of annual paid leave and commemorative leave used*3**

	Fiscal 2020	Fiscal 2021	Fiscal 2022
Annual paid leave	55.4%	61.0%	65.9%
Commemorative leave	97.7%	98.4%	98.4%

*3 Percentage of days used out of total days granted

Health Management Promotion System

The director in charge of the Human Resources Department and the General Administration Department has been appointed as the general manager in charge of health promotion, and the Subcommittee for Health and Productivity Management has been established to further promote the drafting and implementation of measures, as well as the verification of their effects.

▶ **Subcommittee for Health and Productivity Management**

Relationship with the Environment

▶ Material issue related to Kissei's management base

Environmental initiatives

Environmental Management

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

Basic Environmental Policy

1. Basic Philosophy

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

2. Basic Policy

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

Environmental Management System

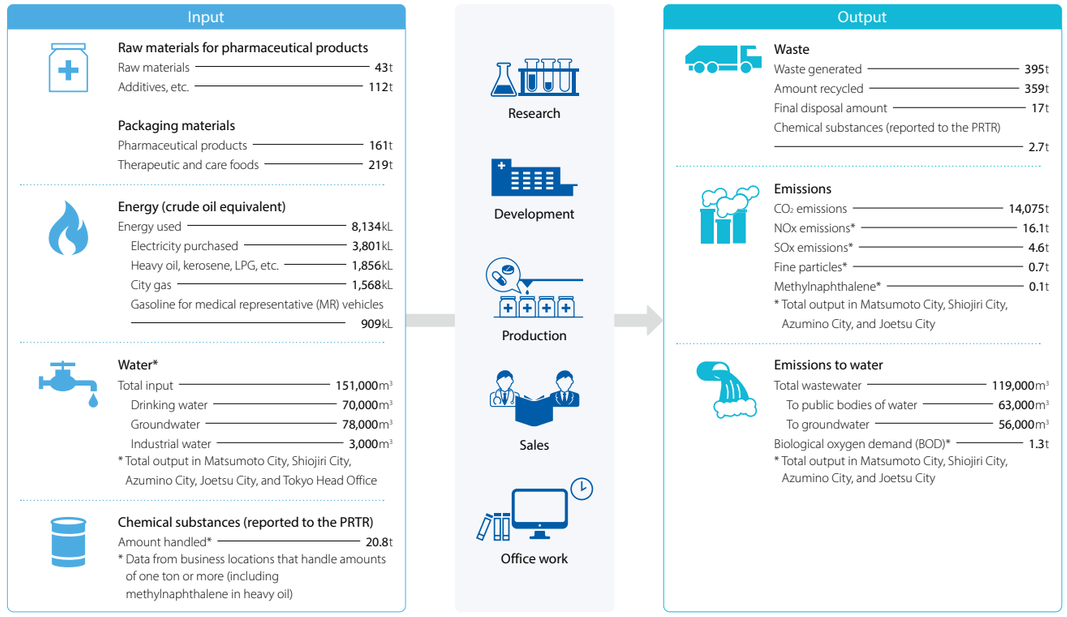
Kissei promotes environmental management based on the ISO 14001 standards for environmental management systems. Under the organizational structure of Kissei's environmental management system, the department manager of the General Administration Department serves as the person in charge of environmental management, and is therefore 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.

To promote environmentally friendly activities throughout the Company, the various plants and laboratories of Kissei Pharmaceutical acquired ISO 14001 certification between 2000 to 2007 and then transitioned to the ISO 14001: 2015 standard from 2017 to 2018.

In addition, Kissei Group companies KISSEI COMTEC CO., LTD., and HASHIBA TECHNOS CO., LTD., have also acquired ISO 14001 certification for their respective environmental management systems, with each company having established a system to promote environmental conservation activities, with efforts to reduce environmental impact.

The Environment and Kissei (Reducing Environmental Impact Companywide)

The figures below show the input of resources into Kissei Pharmaceutical for fiscal 2022, 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.



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

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

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

* Kissei Pharmaceutical endorsed the recommendations of the TCFD in June 2023.

Understanding the TCFD

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

1. Governance

Regarding environmental problems, Kissei engages in efforts aimed at realizing a sustainable society. In addition, the Sustainability Promotion Committee manages the planning and progress of a variety of measures, the content of which is managed and supervised by the Board of Directors. A cross-departmental TCFD Project Team was set up within the committee to conduct a specific investigation into major climate change-related issues and has identified, analyzed, and assessed business risks and opportunities.

2. Strategy

Regarding the impact of climate change on the Company's business, we created 1.5°C*2 and 4°C*3 climate change scenarios and identified risks and opportunities for both. These risks and opportunities were analyzed and assessed in terms of their financial impact and their likelihood of occurrence, and then possible measures were investigated and prioritized by the impact on our business strategy.

Although we have identified transition risks in the 1.5°C scenario, and immediate and long-term physical risks in the 4.0°C scenario, we are also working to increase resilience and reduce CO_2 emissions in pursuit of opportunities, such as cost reductions from the introduction of high-efficiency equipment as well as increased corporate value from active efforts to combat climate change, followed by disclosure of these efforts.

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

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

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

Results of Scenario Analysis

Classification		High-Priority Risks	Impact on the Company	Impact Level	Countermeasures	Business Risks
1.5°C Scenario	Transition Risks	Enhanced policies and regulations related to decarbonization	Addition of carbon pricing Company could incur an estimated cost of approximately ¥200 million due to carbon pricing (based on estimated CO_2 emissions in fiscal 2030 of 9,979 tons at a rate of US$130 per ton*4)	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 emission 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)	Intensification and increased frequency of natural disasters	Flooding could cause damage to key locations, leading to suspended operations and expenses to restore these operations, and could also affect the development pipeline and impact the steady supply of products	High	• Take appropriate measures to minimize damage to locations from floods and other disasters	Low
			Disasters could disrupt manufacturing due to damage incurred by suppliers, or hinder the steady supply of drugs by affecting the transportation network	High	• Maintain and improve the system for steady drug supply by keeping an inventory of drugs in conditions suited to their respective characteristics, and in decentralized locations • Reduce procurement risks by establishing multiple supply lines	Low
	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	Rising temperatures could lead to higher air-conditioning costs	Low	• Continue activities to instill the importance of saving energy among employees, and promote new activities • Introduce and shift to high-efficiency and energy-saving equipment	Low
		Water shortages	A lack of water resources could lead to restrictions on water use, thereby disrupting operations, while costs related to securing water resources could increase	Low	• Increase information collection related to water withdrawal in surrounding areas and construct an emergency response system that factors in the risk of acquiring water resources*5	Low

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

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

3. Risk Management

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

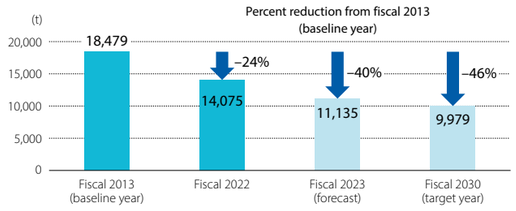
The Sustainability Promotion Committee will discuss and report on the management status of these risks to the Board of Directors, and will also report to the Risk Management Committee, an advisory body to the Board of Directors, to integrate and promote comprehensive Companywide risk management.

4. Metrics and Targets

We have set the utilization rate of renewable energy and reduction of CO_2 emissions as KPIs under "climate change countermeasures," a material issue for our management base.

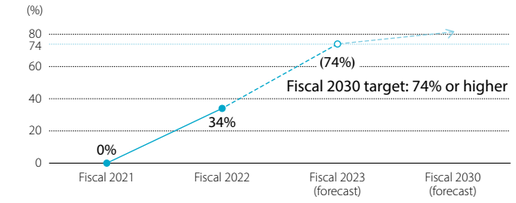
We have also set the following medium-term targets to contribute toward the government of Japan's 2050 Carbon Neutrality Declaration and its fiscal 2030 goal of a 46% reduction of greenhouse gas emissions compared with fiscal 2013 levels.

CO_2 Emissions (Scope 1 and 2)



Note: From fiscal 2022, the CO_2 emission factor for electricity has been changed from the base emission factor to an adjusted emission factor. Figures for previous fiscal years have been retroactively adjusted to reflect this change.

Ratio of Sustainable Energy Use and Medium-Term Goals



In April 2022, we started using Shinshu Green Electricity, CO_2-free electricity produced in Nagano Prefecture, at our head office and Matsumoto Plant and Shiojiri Plant. In fiscal 2022, approximately 34% of the electricity used in these plants was from renewable sources, reducing CO_2 emissions by an annual total of 2,280 tons.

In addition, from April 2023, we expanded the introduction of Shinshu Green Electricity to five additional locations: the Central Research Laboratory, the Pharmaceutical Laboratory, the Second Research Laboratory, the Nutritional Business Center, and the Tokai Hokuriku Branch. This change is expected to reduce annual CO_2 emissions by approximately 40% compared with fiscal 2013, and puts us on track to achieve our fiscal 2030 target ahead of schedule of total electricity consumption being 74% or more renewable energy. Going forward, we will continue to actively promote the use of renewable energy.

Shinshu Green Electricity Purchase Contract Certificate

Scope 3 Greenhouse Gas Emissions in the Supply Chain

In order to gain an understanding of the overall greenhouse gas emissions (CO_2 emissions) in the supply chain, we began calculating Scope 3 greenhouse gas emissions from fiscal 2022, 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. We will continue to calculate Scope 3 emissions and use these calculations in our work to reduce CO_2 emissions throughout the entire supply chain, including those outside the Company.

For details regarding Kissei's Scope 3 greenhouse gas emissions in the supply chain, please refer to the corporate website.
https://www.kissei.co.jp/sustainability/esg/ (Japanese only)

Relationships with Medical Professionals and Patients

▶ Material issue related to Kissei's business activities

Communication with medical professionals and patients

Collection and Appropriate Provision of Drug Information

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

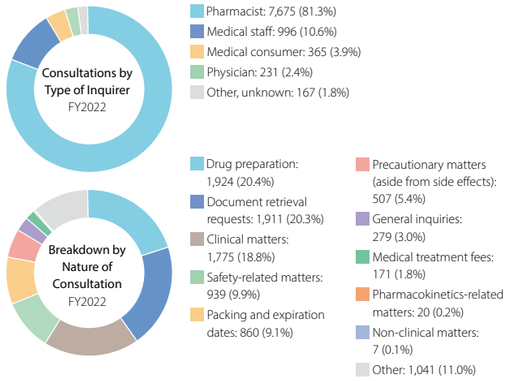
Furthermore, in September 2022, we updated KISSEI Medical Navi, a website for medical professionals, making it membership-based. This makes it possible to provide more detailed information and makes it easier for members to make reservations to participate in Company-hosted web lectures for doctors.

KISSEI Medical Navi
https://med.kissei.co.jp/ (Japanese only)

Product Customer Service Center

We have established the Product Customer Service Center to encourage the proper use of pharmaceutical products in a safe and effective manner, and we have responded to inquiries not only from healthcare professionals but also patients. In fiscal 2022, we responded to 9,434 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®.

▶ Consultations by Type of Inquirer and Nature of Consultation



Total inquiries in fiscal 2022: **9,434**

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

Patient-Oriented Information Websites

Kissei has established and operates patient-oriented information websites to communicate information to patients in its key fields of renal diseases and dialysis, urology, and rare and intractable diseases (sites in Japanese only).

The concept behind these sites is to help patients and their families enjoy living their daily 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 with each disease and their families.

In particular, the site dedicated to patients with ANCA-associated vasculitis provides medically accurate information in an easy-to-understand manner to address the questions and concerns that arise that are specific to rare diseases. The site provides checklists, a hospital search function, and information that can help patients undergoing treatment as well as people who have not been diagnosed.

Relationships with Local Communities

▶ Material issue related to Kissei's management base

Social contribution as a good corporate citizen

Contributions to Medical Treatments and Health

Kanzawa Medical Research Foundation

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

When the foundation was established, there was the expectation that the drop in birthrate and growth in life expectancy at that time would result in a declining birthrate and aging society phenomenon and become an important socioeconomic issue in the near future. From a medical perspective, it was believed that a highly significant part of solving this problem was the maintenance and promotion of women's health. Against this backdrop, the foundation promotes the development of healthcare and medical science by encouraging studies 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 subjected studies
(5) Other business necessary to achieve the purposes of the foundation

The total number of rewards and grants and the amount of money awarded to date (1997–2022) are shown in the following table.

	Total number	Total amount of money
Kanzawa Medical Award	24	¥71 million
Research grants	257	¥322 million
Overseas study grants	98	¥49 million

Number of Awards and Grants in Fiscal 2022

Kanzawa Medical Award

- Recipient: Associate Professor Hirota Yasushi
- Research Institution: The University of Tokyo Graduate School of Medicine, Department of Obstetrics and Gynecology
- Research Theme: Elucidation of the pathophysiology in implantation failure caused by uterine factors and development of new diagnostic and therapeutic tools

Research grants: 10 **Overseas study grants:** 4

Contributions to the Cultural Arts

Kissei Culture Hall (Nagano Prefectural Matsumoto Cultural Hall) Naming Rights

In July 2012, we acquired the naming rights for Nagano Prefectural Matsumoto Cultural Hall, located in Matsumoto City. The purpose for acquiring these rights is to contribute to culture and the arts through payment of the naming rights fee, to be used for maintenance and management of the facility.

The Kissei Culture Hall hosts a wide variety of events, such as the Seiji Ozawa Matsumoto Festival, concerts, and brass band performances, and is widely known as a base to support cultural and artistic activities in the region.

Seiji Ozawa Matsumoto Festival

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

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

Photo © Michiharu Okubo, 2023 OMF

Contributions to Sports and Culture

Support for the Matsumoto Yamaga Football Club

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

The Matsumoto Yamaga Football Club was formed in Matsumoto City in 1965 and is currently a member of the Japan Professional Football League (J-League). Kissei supports the club with a vision toward contributing to "town development," "human development," and "future development" through soccer, which brings vigor and vitality to local communities and supplies dreams and excitement to the community and its promising children.

Photo © Matsumoto Yamaga FC

List of Directors (As of June 22, 2023)

▶ Material issue related to Kissei's management base

Strengthening and enhancement of governance

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

Board of Directors

Mutsuo Kanzawa — Chairman and CEO

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

Yasuo Takehana — President and COO

1984 Joined the Company
2012 Director, General Manager of Research Division, Department Manager of Research Planning Department
2016 Managing Director, Department Manager of Corporate Strategy and Planning Department
2022 President and COO (current position)

Keiji Fukushima — Executive Vice President

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

Tetsu Takayama — Executive Managing Director

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

Takahide Kitahara — Managing Director

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

Yoshio Furihata — Director and Senior Adviser

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

Hiroshi Noake — Director

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

Keiji Miyazawa — Director

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

Shigetaka Shimizu — Outside Director (Independent)

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

Minoru Nomura — Outside Director (Independent)

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

Sayuri Uchikawa — Outside Director (Independent)

1973 Joined Marunouchi Typist School (currently Marunouchi College of Business)
1996 Principal of Marunouchi College of Business (current position)
2013 Outside Director at The Nagano Bank, Ltd. (current position)
2018 Chair of Shuoukai (incorporated educational institution) (current position)
2020 Outside Director at the Company (current position)

Yoshinori Otsuki — Outside Director (Independent)

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

Board of Corporate Auditors

Shinji Kikuchi — Corporate Auditor (Full-Time)

1988 Joined the Company
2011 Director of Drug Discovery Research Laboratory I
2012 Senior Director of Drug Discovery Research Department
2016 Director, General Manager of Research Division
2022 Corporate Auditor (full-time) (current position)

Masayuki Isaji — Corporate Auditor

1980 Joined the Company
2010 Director, Department Manager of Research Planning Department
2012 Managing Director, Department Manager of Corporate Strategy and Planning Department
2018 Corporate Auditor (full-time)
2023 Corporate Auditor (current position)

Kando Nakagawa — Outside Corporate Auditor (Independent)

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

Michio Iwabuchi — Outside Corporate Auditor (Independent)

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

Three Committees That Report Directly to 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 and revising in-house rules and manuals, designing training programs, implementing measures, and analyzing results of their implementation.

3. Sustainability Promotion Committee

This committee proposes various measures within sustainability activities, such as identifying material issues that Kissei should address as a priority, setting KPIs in activities, and confirming the status of progress. At the same time, the committee promotes these measures based on collaboration between related departments and regularly holds discussions with and reports to the Board of Directors.

▶ Director Skill Matrix

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

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

Messages from Outside Directors

Shigetaka Shimizu

Outside Director

I was appointed as outside director when Kissei adopted a governance structure, under which the chairman and chief executive officer (CEO) is given authority over all matters pertaining to management and the president and chief operating officer (COO) is responsible for all matters relating to business execution, for the purpose of further strengthening management capabilities by ensuring a stronger management system and high mobility. Since then, the governance system has grown more and more robust over the years as the number of outside directors increased to four, making up one-third of the Board of Directors, but there has been no deviation in the role expected of me. My role is to verify financial soundness and make comments based on the knowledge accumulated over years at a financial institution and experience gained through company management, with an awareness of stakeholders, including shareholders. Additionally, I communicate the effectiveness of the Board of Directors from an objective standpoint based on my involvement with other companies and experience as outside director at other companies.

When attending Board meetings, I make an effort to review materials sent prior to the meeting and to communicate with other directors and employees on a daily basis, such as directly asking the director, secretariat, or employee in charge about items that I do not fully understand or need to confirm. At Board meetings, we actively exchange opinions, such as by holding discussions without time constraints until all directors understand and agree and, depending on the agenda item, the chairperson may require the opinions of all members.

I recognize that Kissei will continue to further strengthen its governance system to ensure transparent and fair decision-making in line with the fundamental principles of the Corporate Governance Code and I will closely monitor the effectiveness and validity of such reinforcement.

Minoru Nomura

Outside Director

Even before I was appointed as outside director, I have been managing a comprehensive industrial manufacturer that integrates traditional technologies, represented by metal molds, die-casting, and forging (the founding business), with cutting-edge technologies, such as factory automation-related equipment and industrial robots, based on the philosophy of helping the world and pleasing people in business. While the companies manufacture completely different products, machinery, and pharmaceuticals, I believe that my management is in line with Kissei's philosophy of contributing to and serving society.

My role as outside director is to support management. This means that, when proposing management strategies and making decisions at Board meetings, I am not afraid to make comments objectively, not influenced by subjective interests or relationships, from the perspective of a third party, based on the experience and knowledge built up through my management, even when I am in the minority. I am particularly mindful of ensuring that I actively provide useful information to managers from an objective angle during discussions about new business opportunities and risks. Additionally, now that attention is focused on sustainability, I believe it is vital to monitor and gather information on global issues that cross industry boundaries, such as responding to climate change and diversity, and provide managers with appropriate information. Meanwhile, immediately following my appointment, I felt that there was little communication with outside directors and outside corporate auditors. However, to secure a forum for communication, a liaison meeting has been created for outside directors that corporate auditors can attend, allowing the free and easy exchange of opinions and plenty of communication. I think that the meeting is functional in a meaningful way.

Sayuri Uchikawa

Outside Director

A company in the Prime Market, namely a company that represents Japan's capital market, is required to have international corporate value. Surely, this means promoting a higher level of governance and corporate disclosure. Whether a company is seen as appealing by overseas investors, customers, shareholders, and business partners in Japan and by its employees means being open about not only its financial status but also issues it has and how to face them.

Under a 2022 survey by the Cabinet Office of Japan, over 60% of institutional investors replied that they considered the advancement of women when choosing companies to invest in. In May 2023, Japanese Prime Minister Kishida stated his aim to increase the number of female directors in Prime Market listed companies to over 30% by 2030. Realizing such a target in seven years that has barely progressed in 10 is not simply about achieving the numbers. It is essential to increase management roles by quickly creating companies that are easy for women to work at and plans under which women can aim to become directors.

For example, it is natural to think that parental leave is a significant life event for both men and women. There is an important relationship between a corporate culture that enables employees to continue working, regardless of gender, and both institutional investors and the companies young people choose to work at. The presence of role models that actively participate is appealing for young people and increases their expectations for the future.

There is an increasing number of female general managers in attendance at Kissei's Board meetings, and some offer suggestions from a management perspective. We are hoping to develop their successors. It will be difficult for this ratio of female directors to exceed the numerical target without the wisdom of people's diverse opinions.

I feel that discussions at Board meetings are beginning to create a path for all employees to play an active role, even with regard to Kissei's human resource system.

Yoshinori Otsuki

Outside Director

It has been one year since I was appointed as outside director. I always feel that Kissei employees are thoroughly aware of our compliance with the Corporate Governance Code, and social credibility is at the core of discussions by the Board of Directors. In labor–management negotiations about 2023 wage revisions, management decided to respond to employees who made restrained requests in light of the harsh business environment surrounding the pharmaceutical industry by exceeding their requests. The reasons for this were ensuring stable lifestyles for employees and investing in human resources, which symbolize Kissei's superior corporate culture. This response ensured a strong relationship of mutual trust between management and employees. I believe that forging these strong relationships of trust, which are a powerful aspect of Kissei-style management, is vital for the Company's development going forward.

The Tokyo Stock Exchange has enacted various measures with overseas investors in mind, such as establishing the Corporate Governance Code, restructuring its stock exchange market, and requesting that companies take action to realize management that is aware of capital costs and share prices. For a company whose mission is to contribute to the health of people around the world through the research and development of unique new medicines, I feel that being selected by overseas investors is an advantage for the Company's sustainability, while at the same time increasing demand for compliance with the Corporate Governance Code as a company listed on the Prime Market.

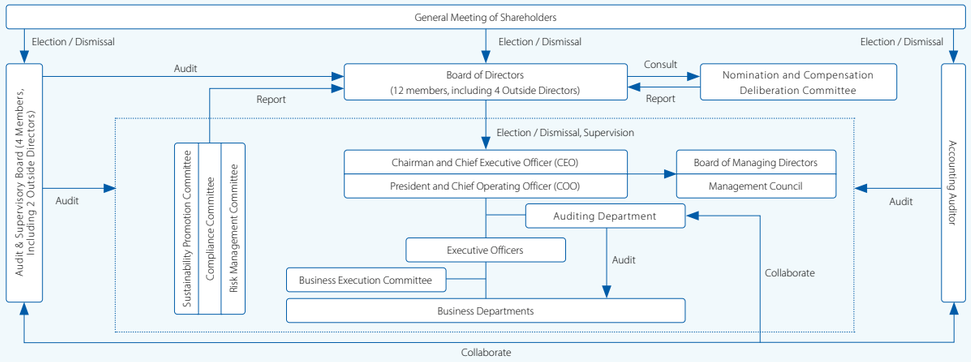
In Nikkei BP Consulting, Inc.'s global ranking of company longevity for 2022, over 50% of the companies founded over 100 years ago were Japanese. Additionally, it was analyzed that these long-lasting companies did not suffer damage from the COVID-19 pandemic. In 2026, Kissei will celebrate its 80th anniversary and this aligns with conditions to become a sustainable company at 100 years, and even 200 years. I will strive to fulfill the duties required of an outseide director so that Kissei will become a sustainable company by realizing corporate value and improved shareholder benefit through support for the happiness of employees and enhancement of local communities and society, which is the vital mission of business management.

Corporate Governance

Basic Approach

Kissei Pharmaceutical formulated the Kissei Basic Policy on Corporate Governance, considering strengthening and enhancing corporate governance to be an important management issue for increasing corporate value and achieving sustainable growth as a company with significance and value to society. Through implementation of the items stipulated in this policy, Kissei aims to comply with Japan's Corporate Governance Code, foster the trust of shareholders and other stakeholders, and develop as a sound and sustainable company that plays a necessary role in society.

Corporate Governance Bodies and Internal Control 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. The Board strives to increase the speed of decision-making and enhance the transparency of management. We also established the Nomination and Compensation Deliberation Committee as an advisory body to the Board of Directors, comprising outside directors (and outside Audit & Supervisory Board members in cases of selecting Audit & Supervisory Board members), the chief executive officer, and the chief operating officer in an effort to ensure the independence and objectivity of the Board of Directors and to ensure transparency of nomination and compensation processes. The Nomination and Compensation Deliberation Committee deliberates upon the appointment and dismissal of officers and proposes its recommendations to the Board of Directors. The committee deliberates on compensation levels for directors and proposes those recommendations to the Board as well. Mutsuo Kanzawa, who is the CEO, has taken on the role of chairman of 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, higher mobility, and greater management capabilities related to business execution entrusted to the Board of Directors. In addition, the CEO convenes the Board of Managing Directors, which consists of directors of managing director rank and above, to discuss and decide on pre-determined items for deliberation. 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 the rapid changes in the business environment, we also adopted an executive officer system in June 2022 with the aim of further strengthening corporate governance and building a more flexible business execution system.

Status of the Board of Directors

The details of specific issues discussed and decisions made by the Board of Directors include matters defined by laws and the articles of incorporation, matters related to organizations and systems, and matters related to acquisition and disposal of high-value assets, key human resource issues, and directors. The Board of Directors' meeting, chaired by CEO Mutsuo Kanzawa, convened 15 times in fiscal 2022.

In selecting directors, Kissei takes a number of factors into consideration, including their capacity to contribute to sustainable growth and enhanced corporate value in business execution, without being restricted by gender and other differences. Kissei's articles of incorporation stipulate that the Company shall have no more than 14 directors. Additionally, directors are appointed by resolutions at the General Meeting of Shareholders. These resolutions to appoint directors are approved by a majority of the votes of shareholders who attend the meeting, where shareholders holding one-third or more of the voting rights of shareholders entitled to vote are present.

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.

Risk Management

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 established the Risk Management Committee, which serves as an advisory body to the Board of Directors. Under the guidance of this committee, the Kissei Group put a management system in place to prevent the occurrence of possible risks and monitors its progress.

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 that we have licensed out the development and marketing rights for 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 application as its own. In addition, once a patent expires, Kissei faces price competition with generic products of the same composition. This competition could have a serious impact on the sales of existing drugs.
Unexpected Side Effects	Unexpected side effects undiscovered at the R&D stage sometimes appear after a drug has already been marketed. If unexpected side effects or serious adverse events occur, the use of a drug may be limited or sales of the drug may be terminated completely.
Product Quality	Although the Company strives to develop manufacturing and quality management systems in compliance with the latest laws, regulations, and guidelines, if a quality-related issue were to cause a drug to be recalled, there could be a negative impact on Kissei's operating results and financial position.
Intellectual Property Rights	If the Kissei Group is unable to appropriately protect its intellectual property, a third party may be able to use the Group's technology, which would undermine its competitive superiority in the market. Conversely, if the Group's business activities are with intellectual property rights owned by third parties, it may lead to associated disputes and damages or the suspension of said business activities.
Litigation	At present, there is no outstanding litigation affecting the Kissei Group's management. There is the possibility, however, that in the course of its business activities, the Group could face lawsuits in the future both at home and abroad regarding patents, product liability, the environment, labor matters, fair trade, or other issues.
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 or due to the interruption of supply chains caused by fires, floods, or accidents stemming from earthquakes, floods, or other natural disasters, or the effects of regional conflicts or pandemic outbreaks of new strains of influenza or other diseases. As a result, Kissei may experience losses in terms of time and money, which could negatively impact 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 records an impairment loss after looking at changes in quoted market prices for investment securities with a market price, or the net worth of companies with unlisted shares and no market price, and then taking a comprehensive account of its business plan.
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, which 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 2022.

Compliance

Compliance-Related Initiatives

Kissei Pharmaceutical developed the Kissei Code of Conduct for its corporate activities. In order to adhere to this code of conduct, ensure compliance with laws and regulations, maintain a high sense of ethics, and warrant the trust of society, we conduct corporate activities centered on compliance, with guidance from the Compliance Program Manual and the Kissei Pharmaceutical Code of Practice (Principles of Kissei Pharmaceutical's Corporate Activities for Medical Institutions and Healthcare Professionals). Kissei is a company that supports people's health and is involved in the research and development of pharmaceutical products. We will work in this role to build relationships of trust with all our stakeholders through ethics, transparency, and fairness and by being accountable for our corporate activities.

Compliance Promotion System

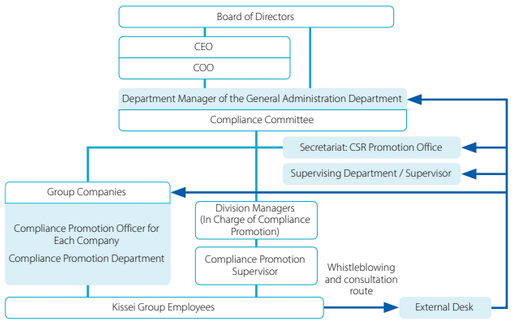
Kissei established the Compliance Committee to optimize compliance promotion, promote the Compliance Program, and serve as an advisory body to the Board of Directors. The committee is chaired by the department manager of the General Administration Department and is composed of managers from each division.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

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

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

Compliance Promotion System

: Whistleblowing and Consultation Desk



Whistleblowing and the Consultation System
Kissei Hotline

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

Compliance Promotion Activities

Continued compliance education and training is essential to firmly entrench the importance of observing the law and internal regulations as well as corporate ethics, and to ensure that all officers and employees fulfill their responsibility toward proper compliance.

Efforts to encourage greater employee understanding and awareness regarding compliance include regular messages from top management and the Company's Compliance Program Manual, which is distributed to every employee 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 that matches the stage in their careers. In addition, 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). Additional focus has been placed on the topic of harassment, an important issue for companies with the growing awareness of different forms of harassment in recent years.

Main Compliance Education and Training Implemented in Fiscal 2022

	Main Items Implemented
Companywide training	• Fiscal 2022 Compliance Status Questionnaire • Training over the course of one month dedicated to understanding of the Code of Practice (held annually) • Training regarding the establishment of a legal compliance system as required by the Pharmaceuticals and Medical Devices Act • Training regarding in-Company whistleblowing system
Rank-based training	• Training regarding the revised Act on the Protection of Personal Information • Training regarding the establishment of a legal compliance system in line with the revised Pharmaceuticals and Medical Devices Act • Training regarding proper promotion of labor management • Anger management training • Psychological safety in the workplace training • New employee education (Management Philosophy, Kissei Code of Conduct, etc.)
Departmental training	• Conducted compliance-related training/education a total of 1,214 times in 170 departments, including training/education related to the Compliance Program Manual, promotional and drug information provision activities, Fair Competition Code case studies, etc.

Compliance Status Questionnaire

Every year, we conduct the Compliance Status Questionnaire targeting all employees. This questionnaire allows employees to check their level of understanding, while allowing the Company to confirm whether proper compliance is being carried out and work toward even more thorough compliance practices. The response rate to the questionnaire has been high since it was introduced in 2005, increasing with each year. In fiscal 2022, the response rate remained high at 95.6%.

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.

Financial Review

Financial Position

Assets

For the fiscal year under review, ended March 31, 2023, total assets stood at ¥221,200 million, down ¥16,887 million from the previous consolidated fiscal year-end. Total current assets increased ¥1,299 million, to ¥100,641 million, mainly due to an increase in inventories, despite a decrease in cash and deposits and other accounts. Total non-current assets were down ¥18,186 million, to ¥120,558 million, mainly reflecting a decrease in investment securities.

Liabilities

Total liabilities amounted to ¥26,385 million at the fiscal year-end, down ¥9,521 million from the previous consolidated fiscal year-end. Total current liabilities stood at ¥14,957 million, down ¥3,786 million, mainly due to a decrease in income taxes payable and contract liabilities, despite an increase in notes and accounts payable. Total non-current liabilities were down ¥5,735 million, to ¥11,428 million, due to a decrease in deferred tax liabilities.

Shareholders' Equity

Total net assets amounted to ¥194,814 million at the consolidated fiscal year-end, a decrease of ¥7,365 million compared with the previous fiscal year-end. This decrease mainly reflects a decline in net valuation difference on available-for-sale securities.

As a result, the shareholders' equity ratio was 87.7%, up from 84.6% at the previous fiscal year-end.

Financial Results

Net sales for fiscal 2022 increased 3.2% year on year, to ¥67,493 million, with net sales of the Pharmaceutical Business, the Group's core business, up 3.9%, to ¥56,243 million. In May 2022, the Company launched CAROGRA®, a treatment for ulcerative colitis, which was jointly developed with EA Pharma Co., Ltd. In June 2022, it launched TAVNEOS®, a treatment for microscopic polyangiitis and granulomatosis with polyangiitis. Finally, in April 2023, it launched TAVALISSE® as a treatment for chronic idiopathic thrombocytopenic purpura. In the midst of the COVID-19 pandemic, we promoted pharmaceutical information activities in a hybrid format that made effective use of a variety of digital tools as well as traditional in-person consultations. As a result, the introduction of these new products to the market went as planned, and sales increased for Beova®, a treatment for overactive bladder, and Darbepoetin Alfa BS Injection [JCR] for the treatment of renal anemia, as did co-promotion fees. These increases, together with higher technical fees and export sales, contributed to the year-on-year increase in net sales. Net sales of the Information Services Business were ¥8,285 million, an increase of 7.0% year on year, net sales of the Construction Business were ¥2,343 million, a decrease of 20.5% year on year, and net sales of the Merchandising Business were ¥621 million, an increase of 14.3% year on year.

Regarding cost of sales, the cost of sales ratio decreased 0.2 percentage points. This improvement was due to increased income from technical fees and co-promotion fees as well as other factors within the Pharmaceutical Business, structural changes to other business, and other factors.

Regarding profit, increased selling, general and administrative expenses, particularly R&D expenses, could not be absorbed, resulting in the recording of an operating loss, in spite of the increase in net sales and a slight improvement in the cost of sales ratio. Operating loss improved by ¥273 million compared with the previous fiscal year; however, non-operating profit decreased by ¥237 million due to lower dividend income and gain on valuation of securities and other factors. As a result, ordinary profit increased ¥36 million, or 6.4% year on year, to ¥598 million.

Total extraordinary income decreased ¥2,862 due to a lower gain on sale of investment securities.

As a result of the above, profit before income taxes was down ¥2,826 million, or 17.1%, to ¥13,680 million, and profit attributable to owners of parent decreased ¥2,393 million, or 18.5% year on year, to ¥10,528 million.

Cash Flows

Cash and cash equivalents in fiscal 2022 amounted to ¥48,884 million, down ¥4,120 million, or 7.8%, year on year.

Cash Flows from Operating Activities

Net cash used in operating activities amounted to ¥6,679 million. This is largely a result of outflows such as an increase in inventories, a decrease in contract liabilities, and an increase in income taxes paid, and despite inflows such as an increase in trade payables.

Cash Flows from Investing Activities

Net cash provided by investing activities amounted to ¥6,001 million. This was largely due to inflows such as the gain on sale of investment securities and despite outflows such as purchase of long-term prepaid expenses.

Cash Flows from Financing Activities

Net cash used in financing activities amounted to ¥3,420 million, primarily as a result of dividends paid.

Consolidated Balance Sheet

KISSEI PHARMACEUTICAL CO., LTD. and its subsidiaries
At March 31, 2022 and 2023

	Millions of yen		Thousands of U.S. dollars
Assets	2022	**2023**	**2023**
Current Assets			
Cash and deposits	¥ 30,013	**¥ 25,893**	**$ 193,897**
Notes receivable - trade	233	**173**	**1,295**
Accounts receivable - trade	21,723	**21,910**	**164,071**
Contract assets	850	**696**	**5,212**
Securities	23,139	**23,706**	**177,520**
Merchandise and finished goods	10,491	**12,679**	**94,945**
Work in process	63	**129**	**966**
Raw materials and supplies	8,433	**9,990**	**74,809**
Other	4,392	**5,461**	**40,894**
Total current assets	99,342	**100,641**	**753,639**
Non-Current Assets			
Property, plant and equipment			
Buildings and structures	39,132	**39,026**	**292,242**
Accumulated depreciation	(30,525)	**(30,848)**	**(231,002)**
Buildings and structures, net	8,607	**8,177**	**61,233**
Land	12,611	**13,615**	**101,954**
Construction in progress	—	**27**	**202**
Other	16,469	**16,116**	**120,683**
Accumulated depreciation	(13,613)	**(13,357)**	**(100,022)**
Other, net	2,856	**2,758**	**20,653**
Total property, plant and equipment	24,074	**24,579**	**184,057**
Intangible Assets			
Software	1,179	**1,192**	**8,926**
Other	389	**314**	**2,351**
Total intangible assets	1,569	**1,507**	**11,285**
Investments and Other Assets			
Investment securities	96,631	**74,769**	**559,900**
Long-term loans receivable	3	**5**	**37**
Long-term prepaid expenses	12,480	**15,209**	**113,891**
Retirement benefit asset	2,460	**3,089**	**23,132**
Deferred tax assets	524	**433**	**3,242**
Other	1,024	**983**	**7,361**
Allowance for doubtful accounts	(23)	**(18)**	**(135)**
Total investments and other assets	113,101	**94,472**	**707,443**
Total non-current assets	138,745	**120,558**	**902,786**
Total assets	¥238,087	**¥221,200**	**$1,656,433**

	Millions of yen		Thousands of U.S. dollars
Liabilities	2022	**2023**	**2023**
Current Liabilities			
Notes and accounts payable - trade	¥ 4,104	**¥ 4,617**	**$ 34,574**
Short-term borrowings	1,640	**1,490**	**11,158**
Income taxes payable	3,497	**408**	**3,055**
Provision for bonuses	1,707	**1,670**	**12,506**
Provision for bonuses for directors (and other officers)	14	**9**	**67**
Provision for sales promotion expenses	137	**149**	**1,116**
Contract liabilities	2,696	**1,846**	**13,824**
Other	4,946	**4,764**	**35,675**
Total current liabilities	18,744	**14,957**	**112,004**
Non-Current Liabilities			
Deferred tax liabilities	16,259	**10,426**	**78,074**
Provision for retirement benefits for directors (and other officers)	181	**192**	**1,438**
Asset retirement obligations	138	**139**	**1,041**
Other	583	**669**	**5,010**
Total non-current liabilities	17,163	**11,428**	**85,577**
Total liabilities	35,907	**26,385**	**197,581**
Net Assets			
Shareholders' equity			
Share capital	24,356	**24,356**	**182,387**
Capital surplus	24,226	**24,226**	**181,414**
Retained earnings	118,183	**125,576**	**940,362**
Treasury shares	(12,912)	**(12,912)**	**(96,690)**
Total shareholders' equity	153,854	**161,246**	**1,207,473**
Accumulated other comprehensive income			
Valuation difference on available-for-sale securities	45,095	**30,393**	**227,595**
Remeasurements of defined benefit plans	2,435	**2,259**	**16,916**
Total accumulated other comprehensive income	47,531	**32,653**	**244,518**
Non-controlling interests	794	**914**	**6,844**
Total net assets	202,180	**194,814**	**1,458,844**
Total liabilities and net assets	¥238,087	**¥221,200**	**$1,656,433**

Consolidated Statement of Income and Consolidated Statement of Comprehensive Income

KISSEI PHARMACEUTICAL CO., LTD. and its subsidiaries
For the years ended March 31, 2022 and 2023

Consolidated Statement of Income

	Millions of yen		Thousands of U.S. dollars
	2022	2023	2023
Net Sales	¥65,381	**¥67,493**	**$505,414**
Cost of sales	34,143	**35,118**	**262,977**
Gross profit	31,238	**32,374**	**242,429**
Selling, General and Administrative Expenses	32,640	**33,503**	**250,884**
Operating loss	(1,402)	**(1,129)**	**(8,454)**
Non-Operating Income			
Interest income	42	**23**	**172**
Dividend income	1,544	**1,379**	**10,326**
Gain on sale of securities	—	**50**	**374**
Gain on valuation of securities	180	**65**	**487**
Foreign exchange gains	—	**186**	**1,393**
Other	325	**131**	**981**
Total non-operating income	2,092	**1,837**	**13,756**
Non-Operating Expenses			
Interest expenses	23	**20**	**150**
Foreign exchange losses	60	**—**	**—**
Provision of allowance for doubtful accounts	—	**15**	**112**
Other	44	**73**	**547**
Total non-operating expenses	127	**109**	**816**
Ordinary Profit	562	**598**	**4,478**
Extraordinary Income			
Gain on sale of non-current assets	0	**67**	**502**
Gain on sale of investment securities	16,601	**13,018**	**97,484**
Total extraordinary income	16,601	**13,086**	**97,993**
Extraordinary Losses			
Loss on sale of non-current assets	0	**—**	**—**
Loss on disposal of non-current assets	35	**4**	**30**
Loss on sale of investment securities	1	**0**	**0**
Loss on valuation of investment securities	619	**—**	**—**
Total extraordinary losses	656	**4**	**30**
Profit before income taxes	16,507	**13,680**	**102,441**
Income taxes - current	4,017	**2,113**	**15,823**
Income taxes - deferred	(542)	**932**	**6,979**
Total income taxes	3,475	**3,046**	**22,810**
Profit	13,032	**10,634**	**79,632**
Profit Attributable to Non-Controlling Interests	110	**105**	**786**
Profit Attributable to Owners of Parent	¥12,921	**¥10,528**	**$ 78,838**

Consolidated Statement of Comprehensive Income

	Millions of yen		Thousands of U.S. dollars
	2022	2023	2023
Profit	¥ 13,032	**¥ 10,634**	**$ 79,632**
Other Comprehensive Income			
Valuation difference on available-for-sale securities	(29,253)	**(14,688)**	**(109,990)**
Remeasurements of defined benefit plans, net of tax	2,456	**(174)**	**(1,303)**
Total other comprehensive income	(26,796)	**(14,863)**	**(111,300)**
Comprehensive Income	¥(13,764)	**¥ (4,229)**	**$ (31,668)**
Comprehensive income attributable to:			
Owners of parent	¥(13,920)	**¥ (4,349)**	**$ (32,567)**
Non-controlling interests	156	**120**	**899**

Consolidated Statement of Changes in Equity

KISSEI PHARMACEUTICAL CO., LTD. and its subsidiaries
For the years ended March 31, 2022 and 2023

	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, 2021	¥24,356	¥24,226	¥109,270	¥(12,911)	¥144,941	¥ 74,351	¥ 22	¥ 74,373	¥638	¥219,953
Cumulative effects of changes in accounting policies			(1,472)		(1,472)					(1,472)
Restated balance	24,356	24,226	107,798	(12,911)	143,469	74,351	22	74,373	638	218,481
Changes during period										
Dividends of surplus			(2,536)		(2,536)					(2,536)
Profit attributable to owners of parent			12,921		12,921					12,921
Purchase of treasury shares				(0)	(0)					(0)
Disposal of treasury shares		0		0	0					0
Net changes in items other than shareholders' equity						(29,255)	2,413	(26,842)	156	(26,686)
Total changes during period	—	0	10,385	(0)	10,385	(29,255)	2,413	(26,842)	156	(16,300)
Balance at March 31, 2022	24,356	24,226	118,183	(12,912)	153,854	45,095	2,435	47,531	794	202,180
Cumulative effects of changes in accounting policies					—					—
Restated balance	**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)**
Disposal 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**

	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, 2022	$182,387	$181,414	$885,001	$(96,690)	$1,152,119	$ 337,689	$18,234	$ 355,931	$5,946	$1,514,003
Cumulative effects of changes in accounting policies					—					—
Restated balance	**182,387**	**181,414**	**885,001**	**(96,690)**	**1,152,119**	**337,689**	**18,234**	**355,931**	**5,946**	**1,514,003**
Changes during period										
Dividends of surplus			**(23,476)**		**(23,476)**					**(23,476)**
Profit attributable to owners of parent			**78,838**		**78,838**					**78,838**
Purchase of treasury shares				**(0)**	**(0)**					**(0)**
Disposal of treasury shares					—					—
Net changes in items other than shareholders' equity						**(110,094)**	**(1,318)**	**(111,412)**	**899**	**(110,506)**
Total changes during period	—	—	**55,354**	**(0)**	**55,354**	**(110,094)**	**(1,318)**	**(111,412)**	**899**	**(55,152)**
Balance at March 31, 2023	**$182,387**	**$181,414**	**$940,362**	**$(96,690)**	**$1,207,473**	**$ 227,595**	**$16,916**	**$ 244,518**	**$6,844**	**$1,458,844**

Consolidated Statement of Cash Flows

KISSEI PHARMACEUTICAL CO., LTD. and its subsidiaries
For the years ended March 31, 2022 and 2023

	Millions of yen		Thousands of U.S. dollars
	2022	2023	2023
Cash flows from operating activities:			
Profit before income taxes	¥ 16,507	**¥ 13,680**	**$102,441**
Depreciation and amortization	3,730	**4,109**	**30,770**
Increase (decrease) in provisions	(431)	**(18)**	**(135)**
Decrease (increase) in retirement benefit asset	—	**(880)**	**(6,590)**
Increase (decrease) in retirement benefit liability	(161)	**—**	**—**
Interest and dividend income	(1,586)	**(1,402)**	**(10,499)**
Interest expenses	23	**20**	**150**
Loss (gain) on sale of securities	—	**(50)**	**(374)**
Loss (gain) on valuation of securities	(180)	**(65)**	**(487)**
Loss (gain) on sale of non-current assets	0	**(67)**	**(502)**
Loss on disposal of non-current assets	35	**4**	**30**
Loss (gain) on sale of investment securities	(16,600)	**(13,018)**	**(97,484)**
Loss (gain) on valuation of investment securities	619	**—**	**—**
Decrease (increase) in trade receivables and contract assets	250	**27**	**202**
Decrease (increase) in inventories	1,130	**(3,810)**	**(28,531)**
Decrease (increase) in other current assets	1,128	**(946)**	**(7,084)**
Increase (decrease) in trade payables	(3,804)	**513**	**3,842**
Increase (decrease) in contract liabilities	1,224	**(850)**	**(6,365)**
Increase (decrease) in other current liabilities	766	**466**	**3,490**
Increase (decrease) in other non-current liabilities	14	**(2)**	**(15)**
Other, net	(22)	**27**	**202**
Subtotal	2,644	**(2,262)**	**(16,939)**
Interest and dividends received	1,479	**1,302**	**9,750**
Interest paid	(23)	**(20)**	**(150)**
Income taxes paid	(2,567)	**(5,699)**	**(42,676)**
Net cash provided by (used in) operating activities	1,533	**(6,679)**	**(50,015)**
Cash flows from investing activities:			
Payments into time deposits	(75)	**(75)**	**(562)**
Proceeds from withdrawal of time deposits	75	**75**	**562**
Payments into investments in specified money trusts	—	**(800)**	**(5,991)**
Proceeds from withdrawal of investments in specified money trusts	97	**888**	**6,650**
Purchase of property, plant and equipment	(1,489)	**(2,103)**	**(15,748)**
Proceeds from sale of property, plant and equipment	23	**78**	**584**
Purchase of intangible assets	(430)	**(444)**	**(3,325)**
Purchase of investment securities	(5,682)	**(991)**	**(7,421)**
Proceeds from sale and redemption of investment securities	22,073	**14,022**	**105,002**
Loan advances	(3)	**(8)**	**(60)**
Proceeds from collection of loans receivable	25	**11**	**82**
Purchase of long-term prepaid expenses	(3,802)	**(4,688)**	**(35,106)**
Other, net	(34)	**35**	**262**
Net cash provided by (used in) investing activities	10,776	**6,001**	**44,938**
Cash flows from financing activities:			
Repayments of short-term borrowings	(90)	**(150)**	**(1,123)**
Repayments of long-term borrowings	(13)	**—**	**—**
Repayments of lease liabilities	(115)	**(133)**	**(996)**
Dividends paid	(2,536)	**(3,135)**	**(23,476)**
Purchase of treasury shares	(0)	**(0)**	**(0)**
Proceeds from sale of treasury shares	0	**—**	**—**
Net cash provided by (used in) financing activities	(2,756)	**(3,420)**	**(25,610)**
Effect of exchange rate change on cash and cash equivalents	4	**(21)**	**(157)**
Net increase (decrease) in cash and cash equivalents	9,557	**(4,120)**	**(30,852)**
Cash and cash equivalents at beginning of period	43,447	**53,004**	**396,915**
Cash and cash equivalents at end of period	¥ 53,004	**¥ 48,884**	**$366,063**

Corporate Information (As of March 31, 2023)

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: 1,359

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

Unconsolidated Subsidiaries

Kissei America, Inc.
400 Kelby Street, 16FL Fort Lee, NJ 07024, U.S.

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

Consolidated Subsidiaries

Kissei Shoji Co., Ltd.
1-1, Hiratahigashi 2-chome, Matsumoto, Nagano 399-0014, Japan
Established: April 1977
Number of employees: 36

KISSEI COMTEC CO., LTD.
KIC Building, 4010-10, Wada, Matsumoto, Nagano 390-1293, Japan
Established: April 1985
Number of employees: 333

HASHIBA TECHNOS CO., LTD.
1-1, Hiratahigashi 2-chome, Matsumoto, Nagano 399-0014, Japan
Established: January 1955
Number of employees: 67

Investor Information

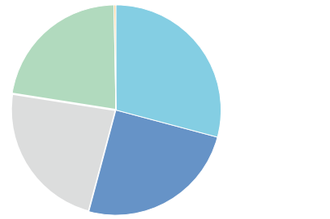
Stock Exchange Listing: Prime Market of the Tokyo Stock Exchange
Stock Code: 4547
Common Stock: Authorized: **227,000,000** shares Issued: **51,811,185** shares
Number of Shareholders: **4,326** (Increase of 340 compared with previous fiscal year-end)

Principal Shareholders

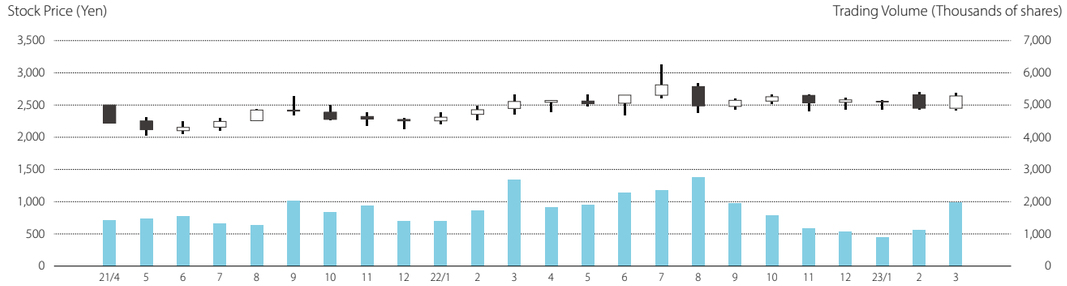
Name	Number of shares held (hundreds)	Voting rights (%)
The Master Trust Bank of Japan, Ltd. (Trust account)	39,881	8.6
Custody Bank of Japan, Ltd. (Trust account)	25,698	5.6
The Hachijuni Bank, Ltd.	23,004	5.0
The Dai-ichi Life Insurance Company, Limited	22,400	4.9
Kanzawa Limited	16,782	3.6
Mutsuo Kanzawa	15,423	3.3
Kissei Group Employee Stockholders Committee	13,278	2.9
Nabelin Co., Ltd.	12,223	2.7
THE NAGANO BANK, LTD.	11,260	2.4
NORTHERN TRUST CO. (AVFC) RE USL NON-TREATY CLIENTS ACCOUNT	11,076	2.4

Notes:
1. Kissei holds 5,695,618 shares of treasury stock but is not included in the above list of principal shareholders.
2. The calculation of voting rights percentages is based on total shares issued excluding treasury shares.

Composition of Shareholders by Category



Stock Price Range / Trading Volume



KISSEI PHARMACEUTICAL CO., LTD.

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

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