KISSEI

Looking Towards Tomorrow's Health

Annual Report 2020

For the fiscal year ended March 31, 2020

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Cover photo: The view of Dakesawa from Kamikochi (Azumi-kamikochi, Matsumoto, Nagano)

Cautionary Notice

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

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

Kissei's Value Creation Process

Management Philosophy

Contribute to society through high-quality, innovative pharmaceutical products
Serve society through our employees

— Management Vision —

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

— Kissei Code of Conduct —

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

Social Issues / External Environment

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

Kissei's Management Capital

Human Capital
Human resources with profound knowledge and technical skills

Intellectual Capital
Competitive intellectual property with a focus on small molecules

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

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

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

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

Business Activities

Five-Year Medium-Term Management Plan
"**PEGASUS**"
— Integrate our wisdom, soar to the new stage —

Pharmaceutical Business

Pharmaceuticals

Key Areas
- Urology
- Renal diseases and dialysis
- Diabetes
- Rare diseases

Research | Development | Production | Sales and marketing

Supply chain

Reliability assurance

Therapeutic and care foods

- Food for special dietary uses, etc.

Promotion of ESG

E (Environment)
- Initiatives related to environmental conservation

S (Social)
- Activities that contribute to local communities and society
- Employee-related initiatives

G (Governance)
- Corporate governance
- Compliance
- Risk management

Created Value

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

Social Value and Contributions to the SDGs Centered in SDG 3*
- Creation and provision of innovative drugs and medical treatment solutions
- Improved quality of life for patients and their families
- Stable supply of high-quality products
- Provision of appropriate drug and treatment-related information
- Provision of a motivating workplace for employees and opportunities to develop abilities
- Reduction of environmental impact
- Contribution to local communities

Create sustainable value through further accumulation and circulation of management capital

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

Letter from the CEO

Mutsuo Kanzawa
Chairman and Chief Executive Officer

We will contribute to people's health by further enhancing R&D for orphan and other new drugs, while promoting development of foods for the elderly and therapeutic and care foods, under the principle that a healthy diet leads to a healthy body.

Guided by its Management Philosophy, the Kissei Group aims to make significant contributions to society and drives Group companies to put their unique qualities toward engaging in business activities in Japan and overseas.

This philosophy, held by Kissei Pharmaceutical, which stands at the core of the Group, is to "contribute to society through high-quality, innovative pharmaceutical products" and "serve society through our employees." The history of Kissei Pharmaceutical began during the Second World War. After a Tokyo-based pharmaceutical manufacturer evacuated to Matsumoto City, Nagano Prefecture and set up in a health foods factory, they worked with local members of the pharmaceutical industry that had strong hopes for establishing a new pharmaceutical company in the area. With a great deal of cooperation from these local members, they founded the Tachibana Seikagaku Institute Co., Ltd. after the war, in 1946.

The late Kunio Kanzawa, fourth President of the Company, who sat on the Board of Directors in 1956 when our Management Philosophy was created, was a strong believer in the idea that a pharmaceutical company cannot exist without R&D. Based on that belief, he continuously preached that giving support to a company that invests in R&D to produce high-quality drugs is an idea common to both employees and shareholders. Though it was only a small company of 35 employees at the time, their track record shows they understood the mission of a pharmaceutical company, and were strongly united with a development-based attitude focused on drug discovery and development. This mind-set was stipulated as our Management Philosophy and has been passed down to present day.

In 1988, we were listed on the Tokyo Stock Exchange, making us literally a "public" institution within society. On the 50th anniversary of our founding in 1996, I took the opportunity to reaffirm our value to society—our very raison d'etre—to all employees, to develop innovative pharmaceutical products that will restore the health of patients around the world. As for our ideal corporate image, we maintain five aspirations as a company. We want to be a company with our employees and their families who we can entrust their dreams. We want to be a company that shareholders feel is a good investment. We want to be a company that pays their taxes fairly. We want to be a company that is good for the local community and the environment. Finally, we want to be a company that can contribute to society and support culture. To this very day, we remain united in our work and activities based on this manner of thinking.

Looking to the conditions that surround the ethical drug industry, new drug development is becoming more sophisticated, and the development risks are increasing, which will require months and years of major investments to address. In addition, countries are promoting a variety of policies to reign in growing medical expenses. That said, there remain several diseases for which there are no effective drug treatments, so the expectations for pharmaceutical companies to develop the drugs that will protect human life and health are stronger than ever before. We consider meeting these expectations a major mission, one that is a fundamental part of our Management Philosophy, and fully in line with the SDGs.

In April of this year, we embarked on our five-year medium-term management plan, "**PEGASUS**". One of the basic policies of this plan is to strengthen the management base to cope with changes in the business environment, and we are promoting ESG and SDGs-related efforts as well as strengthening our corporate governance system further as part of this policy. We will contribute to people's health by further enhancing R&D for orphan and other new drugs, while promoting development of foods for the elderly and therapeutic and care foods, under the principle that a healthy diet leads to a healthy body. We also strive to create a rewarding workplace that supports self-fulfillment and promote environmental conservation activities. Regarding corporate governance, at our General Meeting of Shareholders we appointed one new outside director, bringing the total number of outside directors to three. We believe this action, which is a move toward greater diversity, will serve to improve the oversight function of management.

This newly issued annual report provides a comprehensive summary of our value creation process and related efforts. Beyond financial information and our core medical and health fields, it includes non-financial information including our efforts to achieve the environmental, social, and economic aspects of the SDGs, be they activities related to reducing energy use, or creating a rewarding working environment, as well as our ESG-related efforts.

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

Mutsuo Kanzawa
Chairman and Chief Executive Officer

COO Interview

Yoshio Furihata
President and Chief Operating Officer

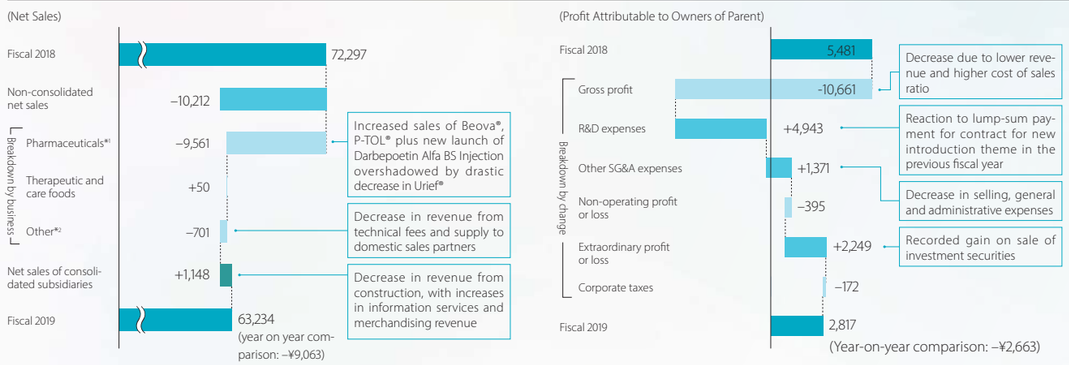
Q Please tell us about fiscal 2019 in terms of Kissei Pharmaceutical's financial performance and as a year overall.

After the December 2018 expiration of the patent for Urief® (Japanese product name), a Kissei-discovered drug for the treatment of dysuria associated with benign prostatic hyperplasia, we have gone on to cultivate new products to serve as pillars of revenue, we have promoted R&D efforts, and worked toward deriving development themes and product in-licensing. Sales increased of Beova®, a treatment for an overactive bladder, as did sales of P-TOL®, a treatment for hyperphosphatemia. Another boost to net sales was the November 2019 launch of a biosimilar of Darbepoetin Alfa, a treatment for renal anemia. However, due to the patent expiration of Urief®, net sales for Kissei Pharmaceutical in fiscal 2019 decreased ¥10.2 billion year on year, to ¥51.3 billion.

Net sales for consolidated subsidiaries increased ¥1.1billion due to increased revenue in the information services and merchandising industries, despite a decrease in revenue in the construction industry. Net sales for the Group totaled ¥63.2 billion, a year-on-year decrease of ¥9.0 billion.

The COVID-19 pandemic of 2020 is having a major impact on the global economy. In order to fulfill our responsibilities as a pharmaceutical company, we are committed to preventing the spread of the infection among employees so that we can maintain a steady supply of drugs, provide ongoing information, and collect safety information. To this point, the negative impact of COVID-19 has been minimal, but there have been slight delays on promotional efforts for new products due to restrictions on visits to medical institutions. With that said, sales of Darbepoetin Alfa BS Injection and other new products released last in fiscal 2019 exceeded original projections. As for the supply chain, we are taking steps to secure inventory and establish multiple supply lines from a long-term perspective, factoring in the risk of increased infections in the future. We also have enough cash on hand to continue business activities and invest in new projects of interest; therefore, I believe that the short-term impact of COVID-19 will be limited in terms of financial position, operating results, and cash flow.

Net Sales and Profit Attributable to Owners of Parent Compared to Fiscal 2018 (millions of yen)



*1 Includes drug substance and bulk exports *2 Includes supply to domestic sales partners

Q Please tell us about the reasons behind the premature end of the previous five-year medium-term management plan (hereinafter "the previous medium-term plan") and any challenges that have appeared.

The previous medium-term plan, which covered the five-year period from fiscal 2017 to fiscal 2021, took active steps toward making alliances and other actions that would lead to drug discovery and expanding our portfolio. This led to developments in themes within the area of rare diseases, which was not part of the previous medium-term plan when it was first formulated. These include the acquisition of exclusive development and marketing rights of Avacopan (generic name), a selective complement C5a receptor antagonist, of small molecule tyrosine kinase inhibitor Fostamatinib (generic name), and of oncolytic viral therapy CG0070 (development code). In terms of sales, our efforts under the plan also led to the acquisition of domestic marketing rights of MINIRIN MELT® OD Tablets 25μg and 50μg for the treatment of nocturia due to nocturnal polyuria in males, MINIRIN MELT® OD Tablets 60μg, 120μg, and 240μg and DESMOPRESSIN formulations for treatment of nocturnal enuresis, and central insipidus, and MARIZEV®, a treatment for diabetes. With the introduction of so many development themes and products, over the past few years, profits deviated from projections put forth in the previous medium-term plan. Furthermore, the launch of Fostamatinib, a rare disease treatment, in the United States followed by Europe, as well as positive results for global phase III clinical trials of Avacopan (which included Japan) increased the possibility of these drugs acquiring approval in Japan. This was significant in that it became necessary to investigate and establish a promotional system for rare disease treatments.

This, in turn, made it necessary to revise our plans, as our path forward deviated from the previous medium-term plan both in terms of qualitative factors such as our R&D pipeline and promotional system, and quantitative factors such as operating income. Therefore, we formulated a new five-year medium-term management plan, "**PEGASUS**" (hereinafter "new medium-term plan").

Some key challenges coming out of the previous medium-term plan are seeing how quickly our product lineup under the new plan can permeate the market as Kissei products, and how quickly we can introduce products under in-licensed development themes to market based on overseas data. And, while it is true that the drugs in the rare diseases area of our business could be categorized as drugs within urology and renal diseases and dialysis areas, our particular areas of expertise, we need to develop ways to provide information on these drugs different from the field of primary care, which is why we will set up a promotional system specific to treatments for rare diseases.

Q Please tell about "**PEGASUS**", the new medium-term plan.

Taking note of the challenges I mentioned earlier, we have established four basic policies along with basic strategies. The first policy of the plan is to increase domestic sales. We intend to expand sales of new products in the existing key areas of urology, renal diseases and dialysis, and diabetes. We will introduce multiple new drugs in the rare diseases area as well.

The second policy is to strengthen our earnings base overseas. We have out-licensed Linzagolix (generic name), a treatment for endometriosis discovered by Kissei, to Swiss company ObsEva SA, which will develop the drug and launch it in Europe and the United States, securing overseas revenue in the process. In addition, we will promote out licensing of development and sales rights to countries in Asia outside of Japan for products introduced by the Company.

The third policy is to expand our development pipeline. Putting our cultivated know-how to use, we will focus our R&D efforts on small molecules. In addition, we will reduce risks as much as possible by targeting late-stage development projects with clinical trial data in Europe and the United States. Avacopan and Fostamatinib, both drugs with indications for intractable diseases, have been designated as orphan drugs based on a number of patients and medical need and therefore eligible for benefits under the orphan drug/medical device system. The many benefits of this system include advice and guidance from the Pharmaceuticals and Medical Devices Agency (PMDA) at the development stage as well as subsidies for development expenses, priority review, and an extended period of exclusive sales, all of which will help ensure development and sales.

The fourth policy is to strengthen the management base to cope with the changes in the business environment. This refers to further strengthening our corporate governance system, developing the next generation of personnel, and promoting ESG and SDGs-related initiatives. These four basic policies and their related strategies will be the foundation upon which we implement "**PEGASUS**".

Numerical targets for fiscal 2024, the final year of the plan, are consolidated net sales ¥87.0 billion or higher, consolidated operating income of ¥9.0 billion or higher, ROE of 5.0% or higher, and R&D expenses of ¥13.0 billion. During the first half of the new medium-term plan, we will boost sales of new products released during the previous medium-term plan, and for products that were released in April 2020 due to a transfer of marketing and distribution duties to Kissei. During the second half, we will apply for approval and then release projects currently under development. The numerical targets for the final fiscal year of the plan we calculated with under the premise that these projects will lead to the launch of multiple new products (for more details, refer to the section New Five-Year Medium-Term Management Plan "**PEGASUS**" on page 14).

The long-term impact of COVID-19 on the Company is difficult to predict accurately, as it depends on whether the infection will continue to spread, and to what degree. The impact of COVID-19 was not factored into the future outlook of fiscal 2020 when financial results were announced in May 2020, nor was it factored into to the new medium-term plan. If the socio-economic impact of the infection grows more serious and lasts for a long period of time, it may affect the Group's consolidated business results. If such a thing occurs, we will assess the situation and, if it is deemed necessary, we will review sales and production schedules and implement a rolling plan.

To fulfill the goals of the new medium-term plan, we are focusing investments in three directions over its course. The first direction is toward sales, and is aimed at market growth for strategically important products. The second direction is toward R&D, specifically investment in development projects and drug discovery research scheduled to start the new medium-term management plan. The third direction is toward in-licensing, which refers to investments in development themes and introducing products aimed at further enhancing our portfolio of products and promoting stable long-term growth.

As far as shareholder returns go, our main goal is to provide stable dividends to shareholders. To support our shareholders and investors, we increased dividends by ¥2.0 per share in the previous fiscal year, marking our 12th consecutive year of stable increases. Although we plan on recording losses on operating income and ordinary income in fiscal 2020, we have secured net income by effectively utilizing financial assets and recording gains on sales of investment securities. This will allow us to raise dividends in fiscal 2020 by ¥2.0 once more, allowing for a full-year cash dividend of ¥54.0 per share, including an interim dividend of ¥27.0 per share.

There is the possibility that we may invest in projects or in-licensing should we find a suitable target, which may cause a temporary decrease in cash and deposits or short-term securities. In that, we will make adjustments within our overall financial assets.

Central Research Laboratories / Pharmaceutical Laboratories

Q Please tell about specific measures you are taking in fiscal 2020.

Regarding domestic drug sales, a crucial question is just how quickly can we cultivate our group of new products such as Beova®, which was released to market during the previous medium-term plan. This same question applies to MINIRIN MELT® and MARIZEV®, after taking over marketing duties for these products in April 2020. We also expect the market to expand for Beova® and Darbepoetin Alfa BS Injection JCR thanks to promotions that took place during the previous medium-term plan. As for COVID-19-related measures for sales of products for which we have assumed marketing duties, we will work to disseminate these products through the market over time via in-person promotions and online and other digital promotional methods. There is the belief that COVID-19 will negatively impact medical representative (MR)-based promotions over the long term, and that difficulties meeting with medical personnel face-to-face will continue. Therefore, in June 2020 we set up a new detail system as part of our Company website aimed at providing product information to these medical personnel.

We are also making adjustments to shipping of Beova®. In December 2019, limits on prescription intervals for the drug were lifted, prompting prescriptions that greatly exceed the forecasts on quantity submitted to authorities when calculating drug prices. Therefore, we are working with suppliers to develop a system with increased production.

As for the development pipeline, we are making applications for in-licensing through effective use of overseas data. For out-licensing, we are using Chemistry, Manufacturing and Control (CMC) data from Japan, as well as non-clinical and clinical data to prepare applications for Europe and the United States.

We have focused our drug discovery research on small molecules, which has yielded interesting compounds. We are collecting data in order to ensure an early start for clinical trials.

Q Please tell us about Kissei's strengths in the urology and renal diseases and dialysis areas. Also, please tell us about what you consider important toward building a promotional system for the rare diseases area.

We have been in the urology field since 1983. We licensed, developed, and sold the drug Terodiline (generic name), a treatment for frequent urination and incontinence, from a Swedish company. From there, we embarked of four projects in the urology field: Urief® a treatment for dysuria associated with benign prostatic hyperplasia, KUL a treatment for urinary stones, KUC to treat an overactive bladder, and KUX, a treatment for gout and hyperuricemia. KUL, KUC, and KUX were dropped at the clinical stage, but Urief® went on to become a global product. During the period, we also built relationships of trust with several doctors, pharmacists, and other medical personnel, patients, and contract research organizations (CROs), many of these relationships existing to this day.

Since starting clinical trials in the renal diseases and dialysis field in 1987, we have released six products to the market. In the renal and dialysis field, maintaining good relations with doctors is a given, but it is important to do the same with technicians, nurses, and dieticians as well. Moreover, there are several organizations working in local medical communities, so a good relationship with these organizations is important as well. We have been working for over 30 years to become a company with the trust over everyone involved in renal and dialysis treatment, which is where we are now.

I believe that there is no magic bullet when it comes to building a relationship of trust. In clinical trials, we collect reliable data in accordance with good clinical practice (GCP) and with the cooperation of medical personnel and patients. After the drug launch, this data is communicated accurately and clearly. Since massive amounts of data accumulate under clinical practices, it is possible to gather and analyze market data in an appropriate manner as well. This data is communicated accurately and clearly as well. This is a process that happens time and time again, and there is nothing inherently special about it. However, when a company continually engages in this rather typical practice over several years, it becomes a company with a great deal of trust. We are committed to building even stronger trust relationships going forward.

In March 2020, we entered into a licensing agreement for CG0070, a drug for bladder cancer, as part of a development

theme targeting the urinary system. Development is also moving forward for Avacopan, a drug treatment for vasculitis. Vasculitis can appear throughout the entire body, but it typically affects the kidneys; therefore, treatment is administered by a kidney specialist. The urology and renal and dialysis are important for the Company, but CG0070 and Avacopan are themes within these respective fields while also being treatments for rare diseases, so it is not true to say that we have no experience in the area of rare diseases. In the future, we will need to establish a specific promotional system for treatments of rare diseases, but we will draw on our base of knowledge and experience in urology and renal diseases and dialysis to do so.

Q Please give us your earnest opinion on the current state of corporate governance, any issues you are aware of, and future countermeasures you intend to take.

We believe that our current governance system is sufficient for the responsible execution of duties, and fulfills its function properly as something that should enable for efficient and prompt management. As of June 2020, our governance system includes three outside directors. The newly appointed outside director, a woman, has served as chairperson of an education institution and principal of a business college, and we believe the experience and knowledge she has gained from many years in education and as a manager make her appropriate for the role.

Compliance has become increasingly important for pharmaceutical companies in recent years. We believe that compliance is the most important aspect of our business, and we are putting the utmost effort into creating a system that can guarantee reliability. This will require that every single employee performs his or her duties while being mindful of the patients who will benefit.

Q Please tell us what you think is important for retaining human resources and improving their capabilities.

Along with strategy and tactics, a key factor in the growth of a company is its corporate culture. It has truly taken a great deal of time for us to create a corporate culture that reflects our philosophy and beliefs while encouraging employees to work toward a common goal. We pride ourselves on this corporate culture, which is disciplined, caring, and has a strong sense of mutual cooperation among our employees to achieve their goals.

The Company was born in Nagano Prefecture in 1946. We have stayed in step with the culture of Nagano with no intention of being led astray. We are currently working to expand globally, but many of our employees have a strong affection for the Company and the region and that has helped foster our corporate culture.

We are not a company with a large number of employees, but we are one where each and every one of us is free to state their opinion, and to be frank and tenacious in our actions in pursuit of the same goal. In order to realize our ambitions with limited human resources we are taking steps to create a culture that unites us in the desire to increase the corporate value of our Company. On top of that, we are promoting on-the-job training with lecture-based personnel training, MR training, English education, education on laws and guidelines, as well as position-based education and training.

Q Please tell us your thoughts on coexistence and shared prosperity with the environment and local communities.

As a company involved in life sciences, we must engage in business activities that take the global environment into consideration. Therefore, we are actively working to reduce the environmental impact and effectively use resources in various aspects of these activities. One of the roles companies play in the local community is to make progress alongside them and address any issues along the way. A company can only ever sustain its business when the local communities have sustainability as well. Companies and the community are like two wheels on a bicycle—one cannot move forward without the other. When a pollution problem appeared in a river near our head office, nearby companies banded together with neighborhood associations and local authorities to begin purification efforts. These continued efforts toward river and environmental conservation, spanning the course of about 50 years, is one case of the Company's continued contributions to the community.

We have established ties with the community from a variety of perspectives. From the perspective of medical treatment, we are involved in joint drug discovery research with the Shinshu University School of Medicine. In terms of culture, we sponsor music festivals such as the Seiji Ozawa Matsumoto festival and support sports by sponsoring the Matsumoto Marathon and uniforms for the J-League soccer team Matsumoto Yamaga F.C. We also acquired naming rights for the Nagano Prefecture Matsumoto City Cultural Center. Furthermore, since the current medical care wis moving toward a comprehensive integrated care system, clinical development and product promotion cannot be done without the cooperation of the people in each region. Therefore, we would like to promote coexistence with local communities not only in Nagano Prefecture, but with communities around branches nationwide.

Q Please tell us your message to stakeholders as it relates to creating corporate value over the long term.

SDG 3 of the Sustainable Development Goals (SDGs) is "ensure healthy lives and promote well-being for all ages." The appearance of COVID-19 has reaffirmed in all of us the need for vaccines and treatments. Maintaining good health is not only important to improve the quality of life (QOL) of each patient, but also to maintain our systems for providing medical care and universal health insurance and avoiding medical care collapse. Good health has also been shown to be important for sustaining economic activity.

While we do not develop treatments for infectious diseases, we are taking steps to develop drugs in the area of lifestyle-related diseases with advantages over existing drugs. We are also developing new drugs in the rare diseases area that fulfill unmet medical needs, targeting diseases that as of yet have few treatments or none at all. In drug discovery research, we are taking on challenges in areas that call for new drugs.

With the spirit to help patients, we will continue to research, develop, produce, and sell drugs that help patients. As a first step, we will do our utmost to deliver late-stage projects currently under development to patients as soon as possible.

We appreciate all of your continued understanding and support in these matters

Yoshio Furihata
President and Chief Operating Officer

Financial and Non-Financial Highlights

Kissei Pharmaceutical Co., Ltd. and its subsidiaries	Millions of yen, except per share data					Thousands of U.S. dollars, except per share data
FY	2015	2016	2017	2018	**2019**	**2019**
Financial Results						
Net Sales	¥ 71,294	¥ 71,706	¥ 74,009	¥ 72,297	**¥ 63,234**	**$ 580,128**
R&D Expenses	14,106	13,877	14,179	15,711	**10,767**	**98,780**
Operating Income	10,274	8,491	9,887	6,202	**1,857**	**17,037**
Profit Attributable to Owners of Parent	8,165	7,726	9,045	5,481	**2,817**	**25,844**
Financial Condition						
Total Assets	¥193,345	¥186,801	¥210,821	¥213,522	**¥231,794**	**$2,126,550**
Total Net Assets	158,125	157,783	176,092	182,707	**192,970**	**1,770,367**
Other Indicator						
Capital Investment	¥ 1,942	¥ 1,477	¥ 1,989	¥ 1,177	**¥ 970**	**$ 8,899**
Per Share (Yen and U.S. Dollars)						
Profit Attributable to Owners of Parent	¥ 166.89	¥ 158.74	¥ 188.26	¥ 117.33	**¥ 60.31**	**$ 0.55**
Cash Dividends	44.0	46.0	48.0	50.0	**52.0**	**0.48**
Key Ratios (%)						
Operating Income Ratio	14.4	11.8	13.4	8.6	**2.9**	
R&D Expenses Ratio	19.8	19.4	19.2	21.7	**17.0**	
Return on Assets (ROA)	4.4	4.1	4.3	2.6	**1.2**	
Return on Equity (ROE)	5.3	4.9	5.4	3.1	**1.5**	
Shareholders' Equity Ratio	81.6	84.3	83.3	85.4	**83.0**	
Dividend Payout Ratio	26.4	29.0	25.5	42.6	**86.2**	
Others						
Number of Employees	1,908	1,905	1,903	1,907	**1,892**	
Number of Shares Issued	54,311,185	54,311,185	51,811,185	51,811,185	**51,811,185**	

Kissei Pharmaceutical Co., Ltd.

FY	2015	2016	2017	2018	**2019**
Non-Financial Data					
Energy Used (kL)	9,281	8,945	8,694	8,489	**8,257**
CO_2 Emissions (tons)	20,695	19,701	19,162	18,516	**17,767**
Amount of Waste Generated (tons)	398	366	424	461	**385**
Final Disposal Amount (tons)	14	13	12	15	**11**

Notes:
1. U.S. dollar amounts are converted at the rate of ¥109 = $1 USD, the approximate effective rate of exchange at March 31, 2020.
2. Profit attributable to owners of parent per share is computed based on the weighted-average number of shares of common stock after subtracting the weighted-average number of shares of treasury stock for the fiscal year.
3. The Partial Amendments to Accounting Standard for Tax Effect Accounting (ASBJ Statement No. 28, issued February 16, 2018) have been applied from the start of fiscal 2018. Major management indicators from fiscal 2017 have been presented after retroactively applying these amended accounting standards.

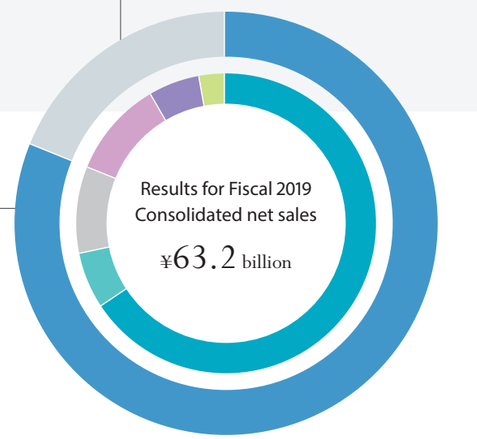
The Kissei Group's Business

The Kissei Group comprises Kissei Pharmaceutical Co., Ltd., three consolidated subsidiaries in Japan, one non-consolidated subsidiary in Japan, and one non-consolidated subsidiary overseas for a total of six companies. The main focus of the Kissei Group is the pharmaceutical business, but it is also engaged in the purchasing and sale of related materials, as well as system development and information processing, construction contracting, equipment and facility management, information gathering and development support, and other services.

Pharmaceutical Business
¥51.3 billion 81.1% (percentage of consolidated net sales)

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

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



Pharmaceutical Business Breakdown

■ Pharmaceuticals*1 ¥41.3 billion

■ Other*2 ¥6.0 billion

■ Therapeutic and Care Foods (Food for special dietary uses, etc.) ¥3.8 billion

Other Businesses Breakdown

■ Information Services Business ¥6.6 billion

■ Construction Business ¥3.6 billion

■ Merchandising Business ¥1.6 billion

*1 Including active pharmaceutical ingredients (API) and bulk exports
*2 Includes supply to domestic sales partners, revenue from technical fees, and co-promotion fees

Pharmaceuticals

As part of our new five-year medium-term management plan, "**PEGASUS**", we have positioned urology, renal disease and dialysis, diabetes, and rare diseases as key areas, and are making focused investments of management resources in these areas to overcome the Urief® patent cliff and ensure stable future growth. In fiscal 2019, we launched Darbepoetin Alfa BS Injection [JCR] in the renal diseases and dialysis area. In fiscal 2020, we acquired marketing and distribution rights for MINIRIN MELT® and other DESMOPRESSIN formulations as part of the urology area and began product sales. In the same fiscal year, we acquired distribution rights and began sales of MARIZEV® in the diabetes field.

Main Products

		Results for fiscal 2019 (millions of yen)	Projected sales for fiscal 2020*1 (millions of yen)
Urology			
Overactive Bladder Treatment Beova®	**Active ingredient:** Vibegron **Indications:** Urinary urgency, urinary frequency and urge urinary incontinence associated with overactive bladder **Month of release:** November 2018 (tablet) ■ Joint development and marketing with KYORIN Pharmaceutical Co., Ltd.	3,185	5,900
DESMOPRESSIN Formulations MINIRIN MELT®, etc.	(Overview of MINIRIN MELT® OD Tablets 25μg/50μg/60μg/120μg/240μg) **Active ingredient:** Desmopressin acetate hydrate **Indications:** Nocturia due to nocturnal polyuria in males (OD tablets 25μg/50μg) Central diabetes insipidus (OD tablets 60μg/120μg/240μg) Nocturnal enuresis resulted from decrease of urine osmolality or urine specific gravity (OD tablets 120μg/240μg) **Month of release:** April 2020 (OD tablets) ■ Marketing and distribution operations transferred from Ferring Pharmaceutical Co., Ltd., with co-promotion by both Ferring and Kissei	—	4,400*2
Dysuria Treatment Urief®	**Active ingredient:** Silodosin (Japanese Pharmacopoeia) **Indications:** Dysuria associated with benign prostatic hyperplasia **Month of release:** May 2006 (capsules*3), February 2009 (tablets), January 2016 (OD tablets) ■ Joint development and marketing with Daiichi Sankyo Company, Limited	5,857	3,700
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)	5,752	6,600
Treatment for Renal Anemia Epoetin Alfa BS Injection [JCR]	**Active ingredient:** Epoetin kappa (genetical recombination) [epoetin alfa biosimilar 1] **Indications:** 1. Renal anemia on dialysis 2. Immature infant anemia **Month of release:** May 2010 (syringe), June 2010 (vial) ■ Joint development with JCR Pharmaceuticals Co., Ltd.	5,520	3,500
Treatment for Renal Anemia Darbepoetin Alfa BS Injection [JCR]	**Active ingredient:** Darbepoetin Alfa (Genetical Recombination) [Darbepoetin Alfa Biosimilar 1] **Indications:** Renal anemia **Month of release:** November 2019 (syringe) ■ Joint development with JCR Pharmaceuticals Co., Ltd.	812	2,700
Diabetes			
Treatment for Diabetes Glubes®	**Active ingredient:** Mitiglinide calcium hydrate (Japanese Pharmacopoeia), Voglibose (Japanese Pharmacopoeia) **Indications:** Type 2 diabetes, limited to cases where a treatment with a combination of mitiglinide calcium hydrate and voglibose is deemed appropriate **Month of release:** July 2011 (combination tablet), June 2019 (combination OD tablet)	4,501	4,700
Treatment for Diabetes Glufast®	**Active ingredient:** Mitiglinide calcium hydrate (Japanese Pharmacopoeia) **Indications:** Type 2 diabetes **Month of release:** May 2004 (tablet), June 2016 (OD tablets) ■ Joint marketing with Takeda Pharmaceutical Company, Limited (tablets only)	1,406	1,100
Treatment for Diabetes MARIZEV®	**Active ingredient:** Omarigliptin **Indications:** Type 2 diabetes **Month of release by the Company:** April 2020 (tablet) ■ Distribution operations transferred from MSD K.K.	—	2,000

*1 Based on figures from financial results for fiscal 2019 announced in May 2020.
*2 Combined total for MINIRIN MELT® OD Tablets 25μg/50μg/60μg/120μg/240μg, DESMOPRESSIN Intranasal 0.01% Kyowa, DESMOPRESSIN Spray 2.5 Kyowa, DESMOPRESSIN Spray 10 Kyowa, and DESMOPRESSIN Injection 4 Kyowa
*3 Currently not for sale.

Therapeutic and Care Foods

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

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

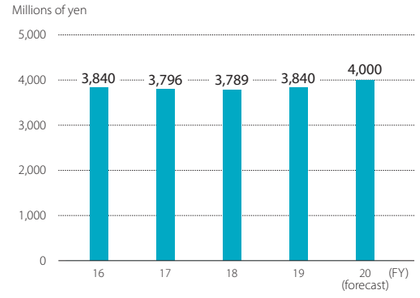
Main Products

■ **Protein controlled foods**
• Yume Gohan Series • Yume Series
• Yume No Shokutaku Series • Genta Series

■ **Foods for patients undergoing long-term care and the elderly**
• Viscosity-modified foods • Yawaraka Cup Series
• Yawaraka Ai Dish • Okayu care through

■ **Energy supply foods**
• Agarori Series • Macton Series

Net Sales (Therapeutic and Care Foods)



In light of changing business conditions in Japan and overseas, Kissei Pharmaceutical is conducting business activities following a new management strategy in order to achieve sustainable growth as an R&D-oriented company. We have ended our previous five-year medium term management plan after three years, and embarked on a new five-year medium-term management plan, “**PEGASUS**”, from April 2020 and are making efforts under the following four policies.

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

New Products Launched During Previous Medium-Term Management Plan / Products Scheduled to Be Launched or Filed for Approval during “PEGASUS”

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

Note: Blue: Launched Red: Designated as an intractable disease * Designated as an orphan drug

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

Performance Outlook

	Performance in Fiscal 2019	Targets for Final Year (Fiscal 2024)
Consolidated net sales	¥63.2 billion	¥87.0 billion or higher
Non-consolidated net sales	¥51.3 billion	¥75.0 billion or higher
Pharmaceuticals*1	¥41.3 billion	¥62.5 billion or higher
Therapeutic and care foods	¥3.8 billion	¥4.5 billion or higher
Others*2	¥6.0 billion	¥8.0 billion or higher
Consolidated operating income	¥1.8 billion	¥9.0 billion or higher
R&D investment	¥10.7 billion	¥13.0 billion
ROE	1.5%	5.0% or higher

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

*1 Including active pharmaceutical ingredients (API) and bulk exports
*2 Supply to domestic sales partners + royalty revenue + co-promotion fees

1. Increase domestic sales

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

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

2. Strengthen earnings base overseas

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

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

3. Expand development pipeline

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

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

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

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

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

Basic Policy

As an R&D-oriented pharmaceutical company, Kissei aims to develop and provide a steady stream of new drugs through drug discovery research and in-licensing of development themes in key areas. The driving force behind the Company's R&D efforts is the desire to help patients who are suffering from illnesses and contribute to the health of people around the world.

One of the basic policies highlighted in "**PEGASUS**", our new five-year medium-term management plan, is expanding the development pipeline. Therefore, we are working to promote R&D focused on small molecules, and in-licensing in accordance with therapeutic area strategy.

Initiatives in Drug Discovery Research

We concentrate our resources with regard to drug discovery research on medicinal chemistry, one of our strengths. Our research, which is focused on small molecules, is aimed at identifying innovative drug discovery targets that address medical needs, have competitive advantages, and have high probability of successful development.

The Research Division is composed of the Drug Discovery Strategy, which was established in April 2019 and is responsible for discovering new drug discovery themes and managing theme proposals, and the Drug Discovery Research Laboratory, which is responsible for managing the progress of drug discovery themes. By clearly delegating these responsibilities, we are better able to create new, highly original development themes that will drive the Company in the future. These two functions maintain a cooperative relationship with each other and a cross-sectional relationship with project teams from other specialized laboratories, which increases the mutual quality of the compounds produced, and allows us to allocate appropriate funds and research according to project priority and proceed with prompt drug discovery research. On the other hand, animal testing is an indispensable part of drug discovery research. To ensure that appropriate animal testing is conducted from the perspective of animal welfare, we have determined guidelines for animal experimentation, and each test is conducted after being screened by the Animal Testing Committee at each research institute. In March 2015, our Safety Research Laboratories received full accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International), indicating that this facility is operating at a level that meets international standards for humane experimental animal testing. In 2018, we renewed our full certification to properly breed, protect, and manage animals in accordance with international standards, with objective proof that we are engaged in these efforts properly.

We believe that open innovation is essential to discovering drug discovery seeds, acquiring new research themes, introducing new technology, and harnessing various modalities. Joining various types of consortiums and establishing strategic connection will evolve our research and, in doing so, lead to creative drug discovery.

AAALAC Certification

Promotion of Clinical Trials

R&D projects still under clinical development are moving forward according to our development plans, and we aim for early and continuous launch of new products to the market. Multiple projects in the development stage in the rare disease area are moving forward, with the location of clinical trials expanding beyond Japan to the United States, Europe, and Asia. In addition to small molecule compounds, we will develop new modalities such as regenerative medicine. Instead of relying solely on the knowledge and experience we have acquired thus far, we will also utilize new ideas to actively promote initiatives and handle clinical trials.

By making full use of the roles and function of each organization and facilitating open communication and collaboration, we conduct effective and highly reliable clinical trials mindful of the target product profile each project is aimed for, with the goal of expanding our product portfolio and both building a data package for new drug applications and acquiring approval of the drug under trial as soon as possible.

Clinical trials are conducted in accordance with the regulations put forth in the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines. They are conducted according to a trial plan reviewed and approved for scientific and ethical validity by a Review Committee established by the Company and the medical institution conducting the trial. We obtain informed consent from participating subjects, with maximum consideration given to subjects' human rights and welfare. In addition, new safety information obtained during clinical trials is promptly reported to the conducting medical institutions and regulatory authorities in accordance with GCP and regulatory requirements, and we are doing our utmost to ensure the safety of the subjects.

Status of Main Research and Development Activities

The features and progress of the main R&D projects we are pursuing are as follows.

Treatment for spinocerebellar ataxia **Rovatirelin** (generic name, development code KPS-0373)	Rovatirelin is an orally administered thyrotropin-releasing hormone (TRH) derivative discovered by Shionogi & Co., Ltd. Kissei conducted an initial phase III clinical trial as a treatment for spinocerebellar ataxia from 2013–2015. Based on the results, we conducted an additional phase III clinical trial starting from 2016–2018; the primary endpoint of these trials was the mean change from baseline in total SARA*1 score for the assessment of ataxia. However, there was no statistically significant difference from the placebo-controlled group. We have conducted detailed analysis based on the results of the two phase III clinical trials, including subgroup analysis based on the severity of results. This pooled, post-hoc analysis shows statistically significant improvement in the SARA score compared to a placebo in patients with more severe degrees of ataxia. This matter is currently being discussed with Japan's Pharmaceuticals and Medical Devices Agency (PMDA). In January 2020, the results of the pooled analysis of the two phase III clinical trials were published*2 of the medical journal "Journal of Neurology, Neurosurgery, and Psychiatry." *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 3 trials. Journal of Neurology, Neurosurgery & Psychiatry Published Online First: 14 January 2020. Doi:10.1136/jnnp-2019-322168
Selective complement C5a receptor antagonist **Avacopan** (generic name, development code: CCX168)	Avacopan is an orally administered drug developed by U.S.-based ChemoCentryx, Inc. for the treatment of rare-kidney diseases. Kissei participated in an international phase III ADVOCATE trial of Avacopan for the treatment of patients with anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV) conducted by ChemoCentryx. The ADVOCATE trial was a global double-blind phase-III trial of 331 patients with AAV in 20 countries that compared Avacopan to glucocorticoids, the current standard of care, as an active control.. Its primary endpoints were remission of the disease at 26 weeks and sustained remission at 52 weeks, assessed by the Birmingham Vasculitis Activity Score (BVAS). The study met both of its primary endpoints; the Avacopan treatment group has demonstrated statistically significant non-inferiority compared to the current standard of care (glucocorticoids) group at 26 weeks. Furthermore, the Avacopan treatment group achieved statistically significant superiority to the standard of care group at week 52. In addition, the safety of the Avacopan group was favorable compared to the standard of care group. We are working closely with our licenser, Swiss-based Vifor Fresenius Medical Care Renal Pharma Ltd., in order to submit a new drug application in Japan. In March 2019, the drug received orphan drug designation for microscopic polyangiitis (MPA) and granulomatosis with polyangiitis (GPA), two forms of AAV. In July 2020, ChemoCentryx submitted a New Drug Application to the U.S. Food and Drug Administration for Avacopan for the treatment of patients with AAV.
Tyrosine kinase inhibitor **Fostamatinib** (generic name, development code: R788)	Fostamatinib is an orally available small molecule compound developed by U.S.-based Rigel Pharmaceuticals, Inc. (hereinafter "Rigel"). In October 2018, Kissei acquired exclusive development and marketing rights for the drug in Japan, China, Korea, and Taiwan. In September 2019, Kissei initiated a phase III clinical study of Fostamatinib for chronic idiopathic thrombocytopenic purpura (chronic ITP) in Japan. In this trial, the efficacy and safety of orally administered Fostamatinib will be assessed by comparing with a placebo in randomized, double-blind methods in patients with chronic ITP. Chronic ITP causes serious bleeding events and bruising due to a decrease in platelet count despite the absence of other obvious illnesses or medications that cause thrombocytopenia. Fostamatinib is an inhibitor of SYK, a spleen-associated tyrosine kinase, and suppresses phagocytosis by macrophages. Therefore, it is expected to improve the thrombocytopenia and bleeding symptoms associated with chronic ITP. In February 2020, Fostamatinib was designated an orphan drug for the treatment of chronic ITP in Japan. In the United States, it was granted an orphan drug designation in August 2015 and was launched by Rigel in May 2018. Regarding sales in Europe, in July 2020 Rigel released Fostamatinib in Germany and the United Kingdom via a collaborative partner in Europe.
Treatment for uremic pruritus in hemodialysis patients **Difelikefalin** (generic name, development code: MR13A9)	Difelikefalin is a kappa opioid receptor agonist discovered by U.S.-based Cara Therapeutics, Inc. In Japan, Kissei and Maruishi Pharmaceutical Co., Ltd., completed a late-stage phase II clinical study of Difelikefalin for uremic pruritus in hemodialysis patients and met the primary endpoint. Currently, we plan to initiate phase III clinical study. As an intravenous injection formulation administered during dialysis through the dialysis circuit, Difelikefalin is expected to become a new option for patients with uremic pruritus and to make a great contribution to their convenience and drug compliance.

In-Licensing Initiatives

In order to expand our product portfolio, we make active efforts to license promising products and late-stage development themes, in addition to drug discovery research. In order to minimize domestic development risks for development themes, we target projects in the later stages of development that have available clinical trial data in the United States and Europe. We will also acquire marketing rights for products matching our business area strategy, thereby enhancing our presence in those business areas.

R&D Pipeline (as of August 2020)

In-House

Development Code (Generic Name)	Expected Indications	Category	Development Classification	Stage: Phase I	Phase II	Phase III	NDA filed	Remarks
Renal Diseases and Dialysis								
MR13A9 (Difelikefalin)	Uremic pruritus in dialysis patients	Kappa opioid receptor agonist	In-licensed / Co-development with Maruishi Pharmaceutical (Japan)					
Rare Diseases								
KPS-0373 (Rovatirelin)	Spinocerebellar ataxia	TRH receptor agonist	In-licensed / Shionogi (Japan)					Phase III clinical trials complete In discussions with PMDA
CCX168 (Avacopan)	Microscopic polyangiitis, granulomatosis with polyangiitis	Selective complement C5a receptor antagonist	In-licensed / Vifor-Fresenius Medical Care Renal Pharma (Switzerland)					Phase III clinical trials complete
AJM300 (Carotegrast Methyl)	Ulcerative colitis	Alpha 4 integrin receptor antagonist	In-licensed / Co-development with EA Pharma (Japan)					
R788 (Fostamatinib)	Chronic idiopathic thrombocytopenic purpura	Tyrosine kinase inhibitor	In-licensed / Rigel Pharmaceuticals (U.S.)					
Other								
KLH-2109 (Linzagolix)	Endometriosis	GnRH receptor antagonist	Kissei					
KDT-3594	Parkinson's disease	Dopamine receptor agonist	Kissei					

Out-Licensing (for drugs discovered by Kissei)

Development Code (Generic Name)	Expected Indications	Category	Territory	Stage: Phase I	Phase II	Phase III	NDA filed	Development Company
Silodosin	Dysuria associated with benign prostatic hyperplasia	Alpha 1A-adorenoreceptor antagonist	ASEAN, India, Sri Lanka*1					Eisai (Japan)
Mitiglinide	Type 2 diabetes mellitus	Rapid-acting insulin secretagogue	ASEAN *2					Eisai (Japan)
KLH-2109 (Linzagolix)	Uterine fibroids	GnRH receptor antagonist	Worldwide, excluding some countries in Asia such as Japan					ObsEva SA (Switzerland)
KLH-2109 (Linzagolix)	Endometriosis	GnRH receptor antagonist	Worldwide, excluding some countries in Asia such as Japan					ObsEva SA (Switzerland)
Bedoradrine	Acute exacerbation of asthma	Beta 2 adrenergic receptor agonist	Worldwide, except for Japan					MediciNova (U.S.)

*1 NDA in two ASEAN countries *2 NDA in Vietnam

Topic

In-Licensing for CG0070, a Medical Product for Bladder Cancer

In March 2020, Kissei entered into a licensing agreement with CG Oncology, Inc., a company based in California, U.S.A., for its oncolytic viral therapy drug CG0070, which is under development for the treatment of bladder cancer for 20 Asian countries other than China, such as Japan, South Korea, and Taiwan.

Bladder cancer is a malignant tumor that typically begins in the lining of the urothelium (transitional cell) of the bladder. The estimated number of patients with bladder cancer in Japan exceeds 20,000 a year, and approximately 75% are men. Both men and women have a high percentage of bladder cancer from 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 is Bacillus Calmette-Guerin (BCG) therapy first. Currently, in most patients with NMIBC who failed BCG therapy or are recurrent, radical cystectomy is indicated. Preservation of the bladder is also desired to maintain the patient's quality of life, and viral therapy is being researched and developed as new pharmacotherapies.

Oncolytic viral therapy is a new treatment for tumor cells that infect cancer cells with viruses that have been modified to specifically multiply in cancer cells without harming healthy cells, and then destroy the cancer cells. These viruses are called oncolytic viruses. 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.

CG0070, a selectively replicative oncolytic immunotherapy based on a modified adenovirus type 5 backbone that contains a cancer-selective promoter and a GM-CSF transgene, 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 GM-CSF, which can stimulate a systemic anti-tumor immune response that involves the body's own white blood cells.

In previous clinical studies, CG0070 has been shown to be a safe and efficacious agent in NMIBC following BCG failure. 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.

Takuya Morisaki

Medicinal Chemistry
Research Group
Chemistry Research Lab.,
Research Division

Researcher's Voice

The medicinal chemistry research group I belong to is part of the department that bears responsibility as the core for generating compounds for new drug discovery. They say that, in recent years, this is a new drug candidate that has a success rate of one in 25,000, but we work closely with several related departments to synthesize compounds.

Personally, I was drawn to Kissei's belief that a pharmaceutical company cannot exist without R&D. I am in my second year as a medicinal chemist, and I entered the Company to realize my "pharma dream" of working amid the natural beauty of Azumino and conducting innovative R&D to discover a revolutionary new drug, and with that one new drug saving the lives of many patients. Kissei's researchers have an image of being singularly devoted to research and development, but we also place a great deal of importance on research activities that comply with laws and regulations and show consideration for the environment, including strict management of reagents necessary for research and any waste produced through research, reducing waste and energy consumption, and introducing efficient, low-cost systems. I also feel that the cleanup activities around the research lab and the contributions and exchanges with the local community we make through the summer festival at the Central Research Laboratories are essential activities for a company that wants to be trusted and needed by society.

Promoting Overseas Development

Kissei's basic strategy for overseas expansion is to obtain profits from supplying drug substances and royalty income by out-licensing our original products. We will establish Linzagolix as a new global product and successor to Silodosin, whose substance patent has expired, and strengthen our overseas earnings base by licensing out new products.

Out-Licensing of Silodosin

Silodosin has been sold in Japan by Kissei since May 2006 under the brand name of Urief®. It is a therapeutic drug for the treatment of dysuria associated with benign prostatic hyperplasia, and has earned a strong reputation around the world for its superior ability to relieve symptoms shortly after administration. Due to our active efforts to license the drug out to pharmaceutical companies overseas, in April 2009 it was launched in the United States by licensing partner Watson Pharmaceuticals, Inc. (currently AbbVie Inc.) under the brand name RAPAFLO®. Furthermore, it was introduced in Germany in June 2010 under the brand name UROREC® by licensing partner Recordati S.p.A., of Italy, which has been granted licensing rights from Kissei to develop and sell the drug in 84 countries and regions such as Europe, the Middle East, Africa, and Oceania. In April 2013, our licensing partner in China, Daiichi Sankyo, Limited (Japan) began selling the drug in China under the name URIEF® through a local subsidiary. Moreover, it has been launched in several other Asian countries through licensing partners in each respective country.

Although the patent for Silodosin expired in the United States in December 2018 and the data protection period in Europe expired in January 2020, as of August 2020 it is still sold in 58 countries and regions around the world, and is helping improve patients' quality of life.

Promoting Development of Linzagolix (Generic Name, Development Code: KLH-2109/OBE2109) in Europe and North America

Kissei promotes out-licensing of new drugs and aims to build future overseas earnings bases to succeed Silodosin. In November 2015, Kissei granted exclusive rights to Swiss-based ObsEva SA to develop and commercialize the novel drug candidate Linzagolix (generic name, development code: KLH-2109), a gonadotropin-releasing hormone (GnRH) antagonist discovered by Kissei, to all regions worldwide excluding some countries in Asia such as Japan. Kissei will receive milestone payments from ObsEva as development moves forward as well as royalties upon launch. In addition, Kissei will supply drug substances to ObsEva.

Linzagolix is a new orally administrable GnRH antagonist. It acts by antagonizing GnRH at the GnRH receptor located in the pituitary gland, thereby suppressing the secretion of gonadotropin, a gonadotropic hormone.

Licensee company ObsEva is a clinical-stage biopharmaceutical company that specializes in the development of new drugs in the field of obstetrics and gynecology. ObsEva is pursuing development of this drug (overseas development code: OBE2109) for European and North American markets. This candidate is currently under two phase III clinical trials (EDELWEISS 2, EDELWEISS 3) for endometriosis as well as two phase III trials (PRIMROSE 1, PRIMROSE 2) for uterine fibroids.

In December 2019, ObsEva announced the results of the 24-week interim analysis for PRIMROSE 2. In July 2020, it announced the results of the 24-week interim analysis of PRIMROSE 1 and the 52-week results for PRIMROSE 2.

PRIMROSE 1 has been conducted in the United States with 526 patients, and PRIMROSE 2 has been conducted in the United States and the EU with 535 patients. The efficacy of Linzagolix 100mg or 200mg once daily, or each dose with add-back therapy (ABT), has been compared to a placebo. The primary endpoint is the "responder rate at 24 weeks of menstrual blood loss of ≤ 80 mL and a ≤ 50% reduction from baseline".

In PRIMROSE 1, the responder rate of the 24-week primary endpoint was 56.4% (P=0.003) and 75.5% (P<0.001) for 100mg without ABT and 200mg with ABT, respectively. Each showed statistically significant improvement in comparison to the placebo, and each showed improvement in clinically important secondary endpoints such as reduction in pain, improvement of anemia, and quality of life. In safety results, the incidence of adverse events were similar in the Linzagolix and placebo arms. The incidence rate of adverse events >5% were headache and hot flushes. The BMD loss at the lumbar spine from baseline to week-24 was a minimal mean percentage change.

In PRIMROSE 2, the responder rate of the 24-week primary endpoint was 56.7% (P<0.001) and 93.9% (P<0.001) for 100mg without ABT and 200mg with ABT, respectively. Each showed statistically significant improvement in comparison to the placebo, and each showed improvement in clinically important secondary endpoints such as reduction in pain, improvement of anemia, and quality of life. The effect of the responder rate of PRIMROSE 2 at week-52 long-term treatment was 53.2% and 91.6% for 100mg without ABT and 200mg with ABT, respectively. The efficacy of Linzagolix has been sustained from the 24-week results. Adverse events of incidence rate of >5% were headache, hot flush, and anemia. A smaller incremental change in BMD loss at the lumbar spine was observed at week-52 compared to week-24. These results demonstrated that it is well tolerated.

The overall responder rate for primary endpoint at week-24 of the pooled data from the two phase III studies ware 56.6% and 84.7% for 100mg without ABT and 200mg with ABT. This supports that Linzagolix has a profile with a potential to become the best-in-class as the GnRH antagonists and offers a unique treatment option that does not require ABT.

With the results of the two studies, ObsEva will be submitting for regulatory approval to the EU in 2020 Q4 and US in the first half of 2021 for uterine fibroid. In addition, patient screening has resumed for the clinical trials EDELWEISS 2 and 3 of Linzagolix for the treatment of endometriosis after being put on temporary hold due to COVID-19.

Going forward, we will promote international expansion by licensing our original product, Linzagolix, and contribute to the health of people around the world.

Progress of Overseas Development of Linzagolix by ObsEva

Phase I Clinical Trial	Phase II Clinical Trial	Phase III Clinical Trial	Market Scale	
Uterine Fibroids—Phase III PRIMROSE 2 EU and United States			Number of patients (United States): up to 4 million	Primary endpoints for 24 weeks reached in December 2019 52-week results announced in July 2020
Uterine Fibroids—Phase III PRIMROSE 1 United States				Primary endpoints for 24 weeks reached in July 2020
				Application in Europe planned for fourth quarter of 2020 Application in United States planned for first half of 2021
Endometriosis—Phase III EDELWEISS 2 United States			Number of Patients (United States): up to 5 million	Phase III clinical trial started in May 2019
Endometriosis—Phase III EDELWEISS 3 EU and United States				
Endometriosis—Late-stage phase II EDELWEISS				Late-stage phase II clinical trial results scheduled for 2018/2019

Materials published by ObsEva SA

Providing Drug Information

Report for Fiscal 2019 and Plan for Fiscal 2020

Kissei Pharmaceutical is engaged in activities to provide drug information, having positioned urology, renal diseases and dialysis, and diabetes as three key marketing areas.

In the urology field, we have expanded our product lineup, which contributes to patients' quality of life by providing multiple treatment options. In addition to Urief® for the treatment of dysuria associated with benign prostatic hyperplasia, we also released Beova® for the treatment of overactive bladder in November 2018. Furthermore, MINIRIN MELT® OD Tablets 25μg and 50μg for the treatment of nocturia due to nocturnal polyuria in males was released by Ferring Pharmaceuticals Co., Ltd. in September 2019 after entering into a co-promotion agreement with the Company. In renal diseases and dialysis, we provide hyperphosphatemia treatment P-TOL® in addition to Darbepoetin Alfa BS injection [JCR], a treatment for renal anemia, a new product launched in November 2019. We have taken steps to provide medical personnel in the renal diseases and dialysis field with information on both drugs and therapeutic food products by increasing our involvement on our therapeutic and care foods business.

Regarding the urology field in fiscal 2020, we acquired domestic marketing rights for MINIRIN MELT® OD Tablets 25μg and 50μg as well as MINIRIN MELT® OD Tablets 60μg, 120μg, and 240μg and DESMOPRESSIN formulations for treatment of nocturnal enuresis and central diabetes insipidus, which began sales in April 2020. After May 2020, revisions in the Clinical Guidelines for Nocturia 2nd Edition, MINIRIN MELT® OD Tablets 25μg and 50μg were positioned as grade A recommended treatments for nocturia due to nocturnal polyuria in males. Going forward, we will continue to improve the quality of life in these patients. In the diabetes area, we acquired marketing rights and began sales of diabetes treatment MARIZEV® in April 2020. We will continue work to maximize the presence of Glufast® and Glubes® within the diabetes field as well as our efforts to meet the needs of patients and medical professionals.

Looking toward the future, we will need to respond to the diversifying needs of stakeholders as the medical care provision system changes by area in light of the move toward a community-based integrated healthcare system aimed at 2025. Moreover, we must also provide information with high added value amid major changes in the environment, including the appearance of sales information provision activity guidelines, work-style reforms, and the spread of COVID-19.

In October 2018, the Sales and Marketing Division established Area Strategy Offices at 10 branches nationwide to improve medical care in their respective jurisdictions and to establish a system that can respond to market trends. Under this system, and in compliance with sales information provision activity guidelines, we will enhance the knowledge and skills of each medical representative, increase the detail of information provided, and combine "real" activities (providing information by in-person visits), with "digital" activities (providing information via email or online methods). In doing so, we will provide information effectively and efficiently.

Information website for medical professionals

Production, Supply, and Reliability Assurance

Production System

Kissei has two plants for manufacturing pharmaceutical products, located in Matsumoto City and Shiojiri City in Nagano Prefecture. These plants are responsible for the entire manufacturing process, from procuring raw materials to shipping marketed products. Several products are concurrently outsourced to external parties, aimed at providing a stable supply of Kissei drugs to the market.

The Matsumoto Plants serve primarily as pharmaceutical formulation plants, focusing on drug formulation and the manufacture of the Company's high-quality drugs, including key strategic products such as Urief® and P-TOL®. In addition, we are actively taking steps to incorporate innovative formulation technology in collaboration with the research laboratory, and are working to add new dosage forms to make the formulation easier to intake from the perspective of the patient.

The Shiojiri Plants specialize in packaging for the drugs formulated at the Matsumoto Plants and other locations. After being subjected to thorough inspection, these packaged products are shipped to domestic distribution centers.

Matsumoto Plants

Shiojiri Plants

Stable Supply System

Because pharmaceutical products are life-related products, it is important to maintain and operate a continuous supply system. Therefore, we have established a supply chain management system that spans from the procurement of main components and other raw materials to drug manufacturing, inventory storage, and delivery. Procurement of raw materials can be fraught with unstable factors such as discontinued production stemming from reorganization of manufacturers and unprofitability. Based on these factors, we implement measures to ensure stable procurement which include purchasing from multiple manufacturers and maintaining proper amounts of stock in accordance with risk.

We have also determined a business continuity plan so that even in the unlikely event of a major earthquake or other natural disaster, we have enough of our product in stock based on the amount of time it would take to restart operations at our plants. The amount of stock is determined based on the specific characteristics of each drug—for instance, we maintain an increased stock of drugs for emergency purposes and drugs of high importance. Furthermore, our stock storage centers are spread across multiple locations in Japan. These safeguards are part of our established supply system to ensure that the provision of pharmaceutical products is not cut off. To further ensure continued implementation of these operations, we have formalized them in a stable supply manual, and changes are made to supply operations if deemed necessary as a result of regular self-checks. Even in situations like the COVID-19 outbreak, the system we have in place will ensure stable plant and product supply operations.

In addition, we are committed to maintaining quality when storing and delivering drugs and aim to provide our drugs to patients safely. We are also committed to measures against counterfeit drugs and strive to ensure traceability and prevent the influx of counterfeits. Furthermore, we are devising drug packaging that will act as a countermeasure to counterfeit drugs as well.

Production, Supply, and
Reliability Assurance

Quality Assurance System

Working under Kissei's Management Philosophy, to "contribute to society through high-quality, innovative pharmaceutical products," our pharmaceutical products are manufactured with a rigorous manufacturing and quality control system in compliance with the Good Manufacturing Practice (GMP) system, to provide a stable supply of high-quality pharmaceutical products to patients.

Each factory maintains an appropriate GMP system by conducting periodic quality audits, and the manufactured pharmaceutical products are shipped only after overall judgment of quality, efficacy, and safety.

Kissei also operates the Kissei Pharmaceutical Quality System (KPQS) to continuously improve the quality and stable supply of pharmaceutical products throughout their life cycles. Under the Kissei Quality Policy, we implement the appropriate management of change and deviation, and subsequent corrective and preventive actions at each plant. We have also established procedures for the handling of information on product quality from the market and ensuring continuous improvement of quality, and have also organized a change management system to make appropriate decisions in compliance with pharmaceutical regulations. Furthermore, pharmaceutical products are subject to periodic monitoring for quality, and these quality assurance activities are regularly reviewed by senior management to continuously improve pharmaceutical quality.

Kissei has a system in place that includes a product recall procedure to ensure measures are taken promptly when a problem concerning product safety, efficacy, or quality is suspected.

The Basic Philosophy of the Kissei Quality Policy

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

Safety Information Management System

Safety information up to drug approval and sale is collected from clinical trials conducted under controlled conditions. In order for patients to use drugs appropriately, it is necessary to continue to collect and confirm information on safety and efficacy after product launch.

We have established a Safety Management Control Department at our head offices in Tokyo and Matsumoto and are promoting safety monitoring activities in cooperation with safety management implementation departments at our branches and other business locations. Medical representatives engage in activities and post-marketing surveillance in order to collect a wide variety of information on the efficacy and safety of our products, which is then exchanged with consulting doctors for close consideration. We adhere to pharmaceutical regulations, which include reporting adverse drug reactions to regulatory authorities. In addition, if we determine that it is necessary to provide information on new safety measures and proper use of products, we will promptly inform healthcare professionals and patients. Furthermore, medical representatives carry mobile PCs equipped with the Kissei-developed Safety Information Provision System when engaging in information provision activities, which allows them to provide information on-demand at medical sites.

Regarding drugs that are launched overseas, we have concluded agreements with overseas partner companies to share safety information and are engaged in safety monitoring activities to make sure that patients can use drugs safely, not only in Japan, but also around the world.

CSR

CSR Management

Based on its Management Philosophy and vision, the Kissei Group has used its pharmaceutical products to contribute to the health of its customers for many years in addition to conducting a variety of initiatives as a good corporate citizen and deepening its relationships of trust with each and every stakeholder. We are pushing ahead with CSR management as part of efforts to expand our business activities and our goal for continuous growth as a company that is truly needed by society.

Initiatives Related to the SDGs

In response to the Sustainable Development Goals (SDGs), adopted by members of the United Nations in 2015, Nagano Prefecture established the Nagano Prefecture SDG-Promoting Companies Registration System in April 2019. Kissei Pharmaceutical registered to this system in July of that same year.

Working under our Management Philosophy, and with compliance as our foundation, we believe it is our duty as an R&D-oriented company to both provide new value and give to society by contributing to the health of people around the world through the creation and provision of innovative pharmaceutical products and medical solutions. At the same time, we will actively promote corporate activities that balance environmental, social, and economic aspects and contribute to the achievement of the SDGs, health-related and otherwise.

Our Relationship with Patients

Collection and Appropriate Provision of Drug Information

Drug information obtained from the point of approval until sale 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 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 begin sales of new drugs, we systematically collect information on safety and efficacy by conducting post-marketing surveillance and post-marketing clinical trials targeting hundreds to thousands of patients. If we determine that it is necessary to provide information on new safety measures and proper usage based on the information collected, we will promptly inform medical professionals and patients.

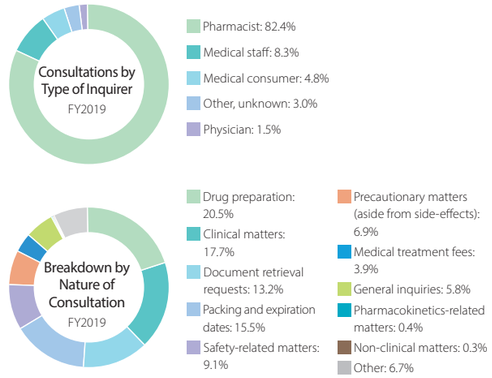
Product Customer Service Desk

We have established the Product Customer Service center to encourage proper use of pharmaceutical products in a safe and effective manner, and have responded to inquiries not only from healthcare professionals, but patients as well. In fiscal 2019, we responded to 11,286 such inquiries. In addition, we are working to build a dedicated phone line for SAVENE®, a treatment for anthracycline extravasation, and RECTABUL®, Japan's first injectable foam treatment for ulcerative colitis in anticipation of urgent inquiries and to facilitate easy consultation.

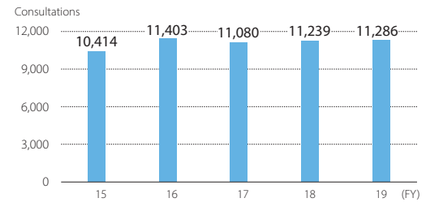
Patient-Oriented Information Website

To help patients undergoing dialysis or suffering from urinary symptoms enjoy their lives and stay upbeat, we operate an information website accessible through our corporate website that can be used by these patients and their families.

Consultations by Type of Inquirer and Nature of Consultation



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



Relationships with Society

Contributions to Medical Treatments and Health

Kanzawa Medical Research Foundation

Kanzawa Medical Research Foundation was established in 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 growing life expectancy of the time would result in a declining birthrate and aging society phenomenon and become an important socio-economic issue in the near future. From the 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 development of healthcare and medical science by encouraging studies (hereinafter referred to as subjected studies) from various angles on causes, prevention, diagnoses, therapies, etc. of various diseases occurred in women of reproductive age with a focus on perinatal period and elderly/senile women, thereby contributing to the enhancement of the people's health and welfare.

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

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

The total number of rewards and grants and the amount of money awarded to date so far (1997–2019) are shown on the following table.

	Total number	Total amount of money
Kanzawa Medical Award	21	¥62 million
Research Grants	227	¥262 million
Overseas Study Grants	86	¥43 million

Rewards and Grants Awarded 2019

Kanzawa Medical Award
Recipient: Associate Professor Hiroaki Kajiyama
Research Institution: Department of Obstetrics and Gynecology, Graduate School of Medicine, Nagoya University
Research Theme: Interdisciplinary study on fertility-sparing surgery in young patients with ovarian cancer: From molecular biology to epidemiology aiming for overcoming occult peritoneal metastasis
Research Grants: 10 **Overseas Study Grants: 4**

Joint Research Courses with the Shinshu University School of Medicine

Since April 1, 2012, we have collaborated with the Shinshu University School of Medicine to conduct a drug discovery science course with the goals of raising the level of the field, cultivating human resources who will be responsible for drug discovery science in the future, and to promote science and technology.

Period of establishment: April 1, 2012–March 31, 2021
Faculty and researchers: one professor, one specially appointed professor, one assistant professor, two researchers

Initiatives Related to COVID-19

In response to a request from the Japan Business Federation, we provided 1,000 DS2 masks and donated a total of ¥20 million to support medical professionals in Matsumoto City, Shiojiri City, and Azumino City, Nagano Prefecture, where our head offices, plants, and laboratories are located.

Contributions to Culture and Sports

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 being 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 Pharmaceutical supported the festival since its first iteration with a directorship in the Saito Kinen Foundation since its inception.

Opera Eugene Onegin by Tchaikovsky © Michiharu Okubo

Support for the Matsumoto Yamaga Football Club

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

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

© Matsumoto Yamaga FC

Relationships with Our Employees

Our Stance on Human Resources

We are taking steps to cultivate human resources and create an environment where our diverse employees can display their skills to their utmost based on the stance that intellectual stimulation results from mutual respect for a variety of mind-sets and values, inciting creativity and dynamism in the Company. As part of our continued efforts to create a working environment that encompasses employment, labor conditions, and human resources management, we have adopted a multiselective human resources system which gives consideration to our employees' aptitudes and life plans. In addition, we are also introducing multiple flexible working styles to our departments, such as flextime and deemed working hours, in order to allow a variety of personnel to work to their fullest capability. We are also working to introduce a post-retirement re-employment system as a way to allow many people to utilize the experience, skill, and knowledge they have acquired over their careers after they retire.

Cultivating Human Resources

The Kissei Group has set "enabling employees to demonstrate their strengths to the utmost degree as both an individual and a part of an organization" as the objective of its Vision for Human Resources Cultivation. To achieve this vision, we are organically developing measures to help cultivate each type of human resource in a continuous and systematic manner over the medium to long term.

Vision for Human Resources Cultivation

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

Cultivating the Next Generation

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

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

Promoting the Success of Women

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

Major Initiatives

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

Promoting Work-Life Balance

To promote the usage of annual paid leave, Kissei Pharmaceutical has established a systematic paid leave usage system, which covers an annual Company-wide leave period of two days and a leave period of three days for commemorative occasions such as wedding anniversaries and birthdays. To reduce overtime work, head offices and laboratories have set every Wednesday and salary payment days as "no-overtime" days, while sales branches and offices promote days without outcalls 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 work-life balance.

Occupational Health and Safety

In addition to complying with the Environment Basic Act, 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 to ensure a safe, secure, and reliable workplace environment for its employees.

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

Enactment of the Kissei Pharmaceutical Health Declaration

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

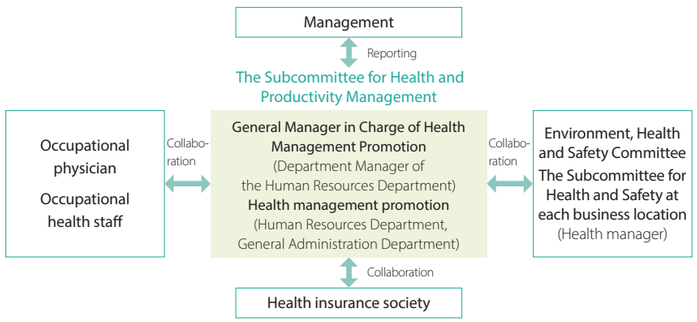
Recognized under the 2020 Certified Health & Productivity Management Outstanding Organizations Recognition Program (Large Enterprise Category)

Kissei Pharmaceutical makes efforts to promote health management with the goal of creating a workplace where Kissei works closely with the Kissei Group Health Insurance Society while making efforts to maintain and improve the health of employees and their families and to promote health management, the goal of which is to establish a workplace both healthy and vital, where employees can put their abilities on full display with a feeling of purpose and drive. In recognition of these efforts, Kissei Pharmaceutical was certified as a 2020 Organization with Outstanding Health & Productivity Management (Large Enterprise Category) in March 2020.

2020 健康経営優良法人 Health and productivity

Health Management Promotion System

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



Major Health Management Initiatives

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

Kissei Health Declaration

Enacted on April 1, 2017

We will contribute to the health and medical care of people around the world by providing ethical drugs and other high-quality, innovative pharmaceutical products. (From the Kissei Code of Conduct)
To that end, each and every employee must be healthy both in mind and body.

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

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

Environmental Initiatives

Environmental Management

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

Basic Environmental Policy

1. Basic Philosophy

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

2. Basic Policy

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

Environmental Management System

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

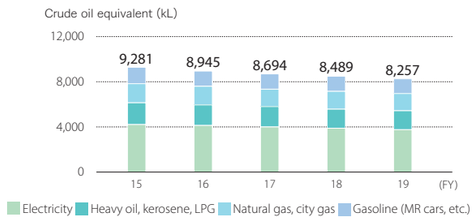
ISO 14001 Certification Status

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

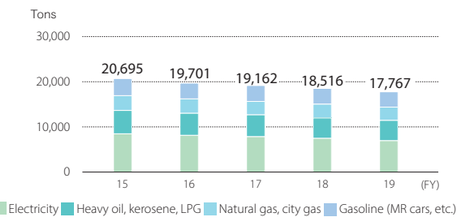
Group Company	Month of Acquisition	Transition to 2015 Standard
KISSEI COMTEC CO., LTD.	June 2002	November 2017
HASHIBA TECHNOS CO., LTD.		
Head Office	February 2002	February 2018
Facility Management Headquarters (shared with Kissei Pharmaceutical)	September 2000	September 2018

Results of Environmental Conservation Activities

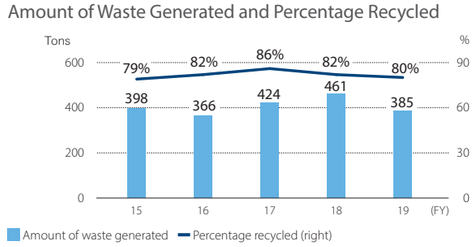
Trend in Energy Usage



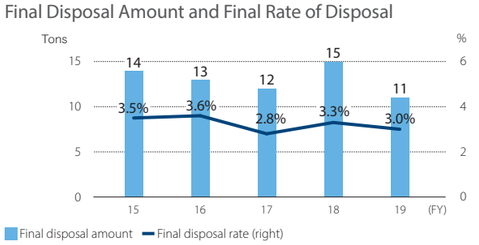
CO_2 Emissions



Amount of Waste Generated and Percentage Recycled



Final Disposal Amount and Final Rate of Disposal



List of Directors (as of June 26, 2020)

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

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

Board of Directors

Mutsuo Kanzawa — Chairman and CEO

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

Yoshio Furihata — President and COO

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

Hiroe Sato — Executive Vice President

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

Keiji Fukushima — Executive Managing Director

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

Yasuo Takehana — Managing Director

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

Tetsu Takayama — Managing Director

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

Masaki Morozumi — Director and Senior Adviser

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

Shinji Kikuchi — Director

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

Takahide Kitahara — Director

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

Minoru Nomura — Outside Director (independent)

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

Eiichi Matsushita — Director

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

Suminori Sagara — Director

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

Shigetaka Shimizu — Outside Director (independent)

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

Sayuri Uchikawa — Outside Director (independent)

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

Board of Corporate Auditors

Masayuki Isaji — Corporate Auditor (full-time)

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

Kando Nakagawa — Outside Corporate Auditor (independent)

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

Makoto Yonekubo — Corporate Auditor

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

Michio Iwabuchi — Outside Corporate Auditor (independent)

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

Our Basic Approach to Corporate Governance

Kissei aims to improve its corporate value and realize sustainable growth as a company with a clear raison d'être. At the same time, the Company positions the enhancement and reinforcement of corporate governance as a core management issue in order to maintain a positive relationship with all of its stakeholders, including shareholders and other investors, customers, local communities, business partners, and employees, as well as to fulfill its social responsibility. As such, the Company established the Kissei Basic Policy on Corporate Governance in October 2015. This policy was revised in November 2018 in response to revisions made to the Corporate Governance Code in June 2018. By practicing corporate governance in line with our basic policy, we aim to address the Corporate Governance Code in a proper manner while building trust with shareholders and other stakeholders, and to become a sound and sustainable company needed by society.

Overview of Bodies

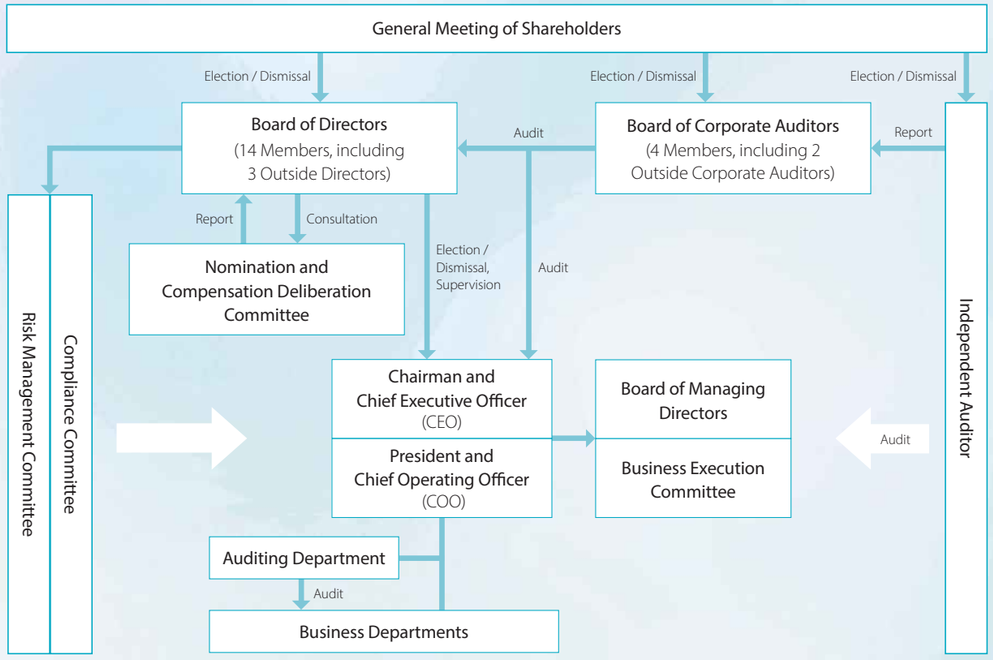
Kissei's Board of Directors sets basic strategies for Kissei and makes decisions on all important matters while also providing oversight of business execution. The Board of Directors strives to make prompt business decisions and increase the transparency of operations.

The Company employs a corporate governance management system under which the Board Chairman serves as chief executive officer (CEO), given authority over all matters pertaining to management, and the president serves as chief operating officer (COO), responsible for all matters related to business execution. This system delegates certain business execution responsibilities from the Board of Directors, and it was instituted with the aim of strengthening management systems and allowing for management to be conducted more flexibly. In addition, the CEO is responsible for convening meetings of the Board of Managing Directors, which consists of managing directors and directors of a higher rank and is responsible for discussing and ruling on items from a predetermined agenda. Furthermore, the Business Execution Committee has been established as an advisory committee to the COO to aid the COO in decision making and to assist in examining the management matters to be proposed or reported to the Board of Directors.

The Company has adopted a corporate auditor system. This system was deemed rational as the corporate auditors together with the appointed outside directors effectively facilitate improvements in the functionality of the Board of Directors while strengthening management oversight functions.

The Company has 2 internal and 2 outside corporate auditors. Corporate auditors attend meetings of the Board of Directors and actively state opinions. One outside corporate auditor is a licensed attorney and the other is a certified public accountant. Consequently, they are able to conduct audits from a specialist perspective. Moreover, 3 outside directors and 2 outside corporate auditors are designated independent officers in accordance with regulations of the Tokyo Stock Exchange, to which they report.

Corporate Governance Bodies and Internal Control System



Nomination and Compensation Deliberation Committee

The Company established the Nomination and Compensation Deliberation Committee as an advisory body to the Board of Directors in order to ensure the independence and objectivity of the Board of Directors in its deliberations as well as the transparency of the deliberation process. This committee holds meetings where it engages in discussions on director and corporate auditor candidates for appointment or dismissal as well as levels of director compensation and makes proposals to the Board of Directors.

Analysis and Evaluation of the Effectiveness of the Board of Directors as a Whole

In an effort to maintain and improve effectiveness, all directors and auditors perform self-evaluations once a year, which are shared with the Board along with results of the analysis and evaluation of the effectiveness of the entire Board of Directors.

The evaluation focuses on eight different areas: (1) establishment of roles for the Board of Directors, directors, and auditors; (2) organizational frameworks for the Company as a whole; (3) content of proposals made by Board members and corresponding deliberation times; (4) information that should be pursued by the Board; (5) leadership shown by the Chairman of the Board; (6) directors' skills; (7) diversity of Board of Directors members; and (8) performance of the Board of Directors and directors.

In fiscal 2019, the Board was evaluated as being sufficiently effective, displaying effectiveness in decision-making, business execution, and supervisory functions. As we move forward, we will continue to work toward full functionality and improved effectiveness of the Board of Directors based on the results of this year's evaluation.

Internal Control System and Risk Management Structure

Kissei operates under the Management Philosophy of "contribute to society through high-quality, innovative pharmaceutical products" and "serve society through our employees." The Kissei Code of Conduct guides employee conduct, with the aim of upholding high ethical standards in R&D, manufacturing, and sales activities, all of which are fundamental to our business as a company involved in life sciences. In addition, Kissei has established the Compliance Committee to provide advice to the Board of Directors to help ensure that all laws and regulations are followed both in letter and spirit. The Company's Compliance Program is conducted on a regular basis, and as part of this program Kissei Pharmaceutical's Compliance Program Manual is continually updated with employees receiving regular instruction on compliance related issues.

Kissei also created the Kissei Basic Policy on Internal Controls, in which every employee is trained. Based on this policy, in addition to maintaining all Company rules, the Risk Management Committee—which is an advisory body to the Board of Directors—was established, and risk management and other internal systems are consequently promoted.

Audits

Kissei has established the Auditing Department, an independent body that reports directly to the Chief Operating Officer (COO). This 5-member body conducts internal audits for each department and all internal systems in Kissei based on the annual auditing plan, ensuring that all departments are carrying out business activities in an appropriate manner.

The Board of Corporate Auditors and the Auditing Department discuss the auditing systems and auditing plan at the beginning of each fiscal year. In addition, they meet every month to exchange opinions on the status of the audits being conducted.

Furthermore, 2 certified public accountants belonging to Ernst & Young ShinNihon LLC provide the Company with accounting services. An additional 13 certified public accountants and 9 other audit personnel provide assistance in the auditing of the Company.

Kissei regularly undergoes outside auditing by an independent auditor. The independent auditor engages in discussions with members of the Board of Directors, finance officers, the Auditing Department, and the Board of Corporate Auditors, which aids the strengthening and maintenance of the corporate governance structure. In addition, the Tripartite Auditing Council convenes periodically, providing an opportunity for corporate auditors, the Auditing Department, and the independent auditor to work together to make joint audit engagements more effective.

Policies for Determining Director Compensation Amounts and Calculation Methods

Director compensation comprises a base salary and a bonus; the policy for determining the amount/calculation method is explained hereafter.

Base salary is determined by director rank (position) as a member of the Board, and also includes an additional amount based on individual experience and Company performance.

Bonus is determined by director rank within the Board, and takes into account the Company's performance for the period, with similar consideration given toward the amount of compensation according to position.

Cross-Shareholdings

Kissei's basic policy is to maintain no cross-shareholdings unless it is deemed they will contribute to the Group's business stability and improve corporate value through the development and strengthening of business relationships and alliances. At the end of March 2020, the Board of Directors conducted both a quantitative and qualitative appraisal of the Company's cross-shareholdings. The quantitative factors included related revenue, such as dividends and transaction earnings, the impact of impairment probability, and stock price fluctuations on Company equity, in addition to a qualitative examination of holding necessity. After this appraisal, it was determined that all cross-shareholdings were consistent with the Company's basic policy.

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

	Millions of yen					
		Totals by compensation type				Number of applicable officers
Classification	Total compensation	Base compensation	Stock options	Bonuses	Retirement benefits	
Directors (excluding outside directors)	303	296	—	6	—	12
Corporate auditors (excluding outside corporate auditors)	27	26	—	1	—	2
Outside officers	25	25	—	0	—	4

Interview with Newly Appointed Outside Director and Outside Auditor

Q Please tell us about your careers up to this point. Also, based on your experience, what do you believe is expected of you at Kissei Pharmaceutical, and what role would you like to play in the Company?

Director Uchikawa

After graduating from university, I joined a typist school that was managed by my mother. In 1976, that school became a business college, and I served as vice-principal until 1996, when I was appointed as principal. To date, we have been involved in the education of people spanning a wide age range, from elementary students upward. This includes exchange students as well. Furthermore, in 2013 I became an outside director for The Nagano Bank, Ltd., and in 2018 the business college became an incorporated educational institution, and I was appointed as chair.

As an outside director I believe there are three expectations placed upon me. First is to convey how Kissei Pharmaceutical is seen from outside the Company from an objective vantage point. Second, while I am not too familiar with the pharmaceutical industry, I believe I should reflect diverse management values by participating in management as the only female director. And, third, I believe that with my many years in the education industry, which has brought into contact with many diverse ways of thinking in the field, that I can be expected to use my experience for the management of the Company.

Corporate Auditor Iwabuchi

After graduating from university, I joined an audit corporation, registered as a certified public accountant, and conducted audit work for companies. Having gained experience in the CPA field in this audit corporation, now I am working independently, auditing the accounts of various organizations and serving as an outside director for a construction machinery manufacturer in Nagano Prefecture and as an outside corporate auditor for the joint holding company of two wholesale companies.

I believe the Company will want to make use of my experience in positions outside of the corporate sphere to perform audits as a financial and accounting expert, while judging whether there are discrepancies between the mindset of the common sense and that of Kissei Pharmaceutical.

Q What issues do you see concerning Kissei Pharmaceutical?

Director Uchikawa

First and foremost, as a listed company, Kissei needs to earn profits and return these profits to shareholders. On the other hand, in order for the Company to survive, it must also promote ESG management further. This includes efforts toward environmental conservation activities social contribution, both of which contribute to a sustainable society. In particular, with the spread of COVID-19 affecting the entire medical industry, I think stakeholders are paying close attention to how Kissei will contribute to society.

Corporate Auditor Iwabuchi

As medical cost control measures—which include a push for the use of generic drugs—continued to be strongly promoted, we can expect the success rate of new drug development to decline and the business conditions for drug manufacturers to become more challenging. In drastically changing external conditions such as these, I believe it is necessary to carefully audit how directors manage operations and where there is an appropriate management system that is conscious of the Company's stakeholders in place.

Financial Review

Financial Position

▪ Assets

For the fiscal year under review, ended March 31, 2020, total assets stood at ¥231,794 million, up ¥18,272 million from the previous fiscal year-end. Total current assets increased ¥894 million, to ¥96,677 million, due to an increase in cash on hand and in banks and in marketable securities, which offset a decrease in notes and accounts receivable and in inventories. Total non-current assets were up ¥17,378 million, to ¥135,117 million, mainly reflecting an increase in investments in securities.

▪ Liabilities

Total liabilities amounted to ¥38,824 million at the fiscal year-end, up ¥8,009 million from the previous fiscal year-end. Total current liabilities stood at ¥17,024 million, up ¥3,222 million, mainly due to an increase in trade notes and accounts payable listed under "other current liabilities." Total long-term liabilities were up ¥4,787 million, to ¥21,800 million, due to an increase in deferred tax liabilities and net defined benefit liabilities.

▪ Shareholders' Equity

Total net assets amounted to ¥192,970 million at the fiscal year-end, an increase of ¥10,262 million compared with the previous fiscal year-end. This increase mainly reflected an increase in retained earnings and net unrealized holding gains on securities, in addition to other factors.

As a result, the shareholders' equity ratio was 83.0%, down from 85.4% at the previous fiscal year-end.

Financial Results

Net sales for the fiscal year ended March 31, 2020 decreased 12.5% year on year, to ¥63,234 million. Accounting for the majority of net sales, the segment sales of the Kissei Group's core pharmaceutical business were down ¥10,212 million, or 16.6%, to ¥51,308 million. Due to active efforts to share information for our key products, net sales increased for products including of Beova®, a treatment for overactive bladder, P-TOL® Chewable Tablet, and P-TOL® Granules, treatments for hyperphosphatemia, and Glubes® Combination Tablet and Glubes® Combination OD Tablet (released in June 2019), treatments for diabetes. However, this was not sufficient to offset the decrease in sales resulting from the launch of generic versions of Urief® Tablet and Urief® OD Tablet, treatments of dysuria associated with benign prostatic hyperplasia. In addition, Darbepoetin Alfa BS Injection [JCR], a treatment for renal anemia jointly developed by JCR Pharmaceuticals Co., Ltd., was launched in November 2019.

In addition, net sales for information services increased 19.9% year on year, to ¥6,631 million, net sales for construction decreased 6.5% year on year, to ¥3,610 million, and net sales for merchandising increased 21.9% year on year, to ¥1,684 million.

The cost of sales ratio was up 7.8 percentage points. As a result, gross profit decreased ¥10,661 million, or 23.4% year on year, to ¥34,905 million.

In selling, general and administrative expenses, R&D expenses decreased. As a result of this and other factors, operating income decreased ¥4,345 million, or 70.1%, to ¥1,857 million.

In non-operating income or loss, expenses increased ¥395 million year or year, due to recording a loss on valuation of securities. As a result, ordinary income decreased 66.1% year on year, or ¥4,740 million, to ¥2,429 million.

Extraordinary income or loss increased ¥2,249 million due to an increased gain on sales of investment securities.

As a result of the above, profit before income taxes and non-controlling interests was down ¥2,491 million, or 35.0% year on year, to ¥4,630 million, and profit attributable to owners of parent decreased ¥2,663 million, or 48.6% year on year, to ¥2,817 million.

Basic Policy on the Distribution of Profits / Dividends

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

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

In the fiscal year under review, the Group made the decision to pay an interim cash dividend of ¥26.0 per share and a year-end cash dividend of ¥26.0 per share, giving a full-year cash dividend of ¥52.0 per share.

For the coming fiscal year, the Group plans to pay an interim cash dividend of ¥27.0 per share and a year-end cash dividend of ¥27.0 per share, giving a full-year cash dividend of ¥54.0 per share. Internal funds are maintained to respond to expected changes in government policy, system reforms, and the challenges of increasing globalization. At the same time, Kissei will actively invest in R&D to develop drugs that patients need. Kissei believes this policy will not only contribute to future profits but also enable Kissei to distribute profits to its shareholders appropriately.

Risk Factors

The following are the most significant risks which could potentially affect the Kissei Group's operating results and financial position. Forward-looking statements are based on the judgments the Kissei Group has made from the consolidated financial statements for fiscal 2019.

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

1 R&D

The process of developing pharmaceuticals—from the R&D stage to approval and sales—requires large investments of both time and funds. Kissei estimates its medium- to long-term business performance based on an anticipated drug discovery schedule that which 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 guarantee neither that a new drug undergoing development or an additional indication will have its intended benefit nor predict when or if the drug will be approved.

2 Medical System Reform

The prices of pharmaceuticals in Japan are set based on the government's NHI drug prices and are revised on a regular basis. There may be drastic reforms of medical and pharmaceutical administrative systems that go beyond Kissei's expectations, including revisions to Japan's health insurance system, such as the introduction of diagnosis procedure combinations or the promotion of generic drugs, which would negatively impact Kissei's operating results and financial position.

3 Competition with Other Companies' Products

The Kissei Group faces competition from companies selling products with the same application as its own. In addition, once a patent expires, Kissei faces price competition with generic products of the same composition. This competition could have a serious impact on the sales of existing drugs.

4 Unexpected Side Effects

Unexpected side effects undiscovered at the R&D stage sometimes appear after a drug has already been marketed. If unexpected side effects or serious adverse events occur, the use of a drug may be limited, or sales of the drug may be terminated completely.

5 Manufacturing and Procurement

Malfunctions with production equipment or the inability to procure raw materials in a timely fashion could delay or shut down drug manufacturing. In addition, if a quality problem causes a drug to be recalled, or if shipments have to be adjusted because supply cannot keep up with demand, there could be a negative impact on Kissei's operating results and financial position.

6 Intellectual Property Rights

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

7 Litigation

At present, there is no outstanding litigation affecting the Kissei Group's management. There is the possibility, however, that in the course of its business activities, the Kissei Group could face lawsuits in the future both at home and abroad regarding patents, product liability, environment, labor matters, fair trade, or other issues.

8 Environmental Conservation

Pharmaceutical chemical substances used in research and manufacturing processing could have an impact on the environment. Every department and work site in the Kissei Group is working diligently to follow stringent substance management rules to protect the environment. However, if chemical substances were found to have polluted areas around a work site, legal action may be taken against the work site, and Kissei may be faced with large costs to restore the environment, which would negatively impact Kissei's operating results and financial position.

9 Information Security Management

Business may be hindered by cyberattacks on the various information systems used by the Group. The Kissei Group is paying close attention to the need to protect information by establishing strict rules for the management of personal and confidential information as well as providing education on this issue to employees. However, there is the possibility that an unexpected incident occurs in which information is improperly disclosed. In such an event, the Kissei Group's image may be tarnished, which could negatively impact Kissei's operating results and financial position.

10 Large-Scale Disasters and Pandemics

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

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

11 Assets under Possession

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

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

Consolidated Balance Sheets

Kissei Pharmaceutical Co., Ltd. and its subsidiaries
At March 31, 2019 and 2020

Assets	Millions of yen 2019	Millions of yen 2020	Thousands of U.S. dollars (Note 03) 2020
Current Assets:			
Cash on hand and in banks (Notes 04 and 05)	¥ 26,325	**¥ 36,329**	**$ 333,294**
Notes and accounts receivable (Note 05)	26,963	**19,462**	**178,550**
Marketable securities (Notes 04, 05 and 06)	23,039	**23,342**	**214,147**
Inventories (Note 07)	13,965	**13,439**	**123,294**
Other current assets	5,491	**4,103**	**37,642**
Allowance for doubtful accounts	(1)	**—**	**—**
Total current assets	95,782	**96,677**	**886,945**
Property, Plant and Equipment:			
Buildings and structures (Note 12)	38,691	**38,746**	**355,468**
Less: accumulated depreciation	(28,754)	**(29,347)**	**(269,239)**
Buildings and structures, net	9,937	**9,398**	**86,220**
Land (Note 12)	12,716	**12,622**	**115,798**
Construction in progress	—	**1**	**9**
Other	16,088	**16,601**	**152,303**
Less: accumulated depreciation	(13,238)	**(14,018)**	**(128,606)**
Other, net	2,849	**2,582**	**23,688**
Total property, plant and equipment	25,503	**24,605**	**225,734**
Intangible Assets:			
Software for internal use	907	**975**	**8,945**
Other	612	**536**	**4,917**
Total intangible assets	1,519	**1,511**	**13,862**
Investments and Other Assets:			
Investment securities (Notes 05 and 06)	86,958	**105,158**	**964,752**
Long-term loans receivable	118	**36**	**330**
Long-term prepaid expenses	1,999	**2,103**	**19,294**
Deferred tax assets (Note 09)	644	**677**	**6,211**
Other	1,046	**1,060**	**9,725**
Allowance for doubtful accounts	(50)	**(36)**	**(330)**
Total investments and other assets	90,716	**108,999**	**999,991**
Total assets	¥213,522	**¥231,794**	**$2,126,550**

The accompanying notes are an integral part of these statements.

Liabilities and Net Assets	Millions of yen 2019	Millions of yen 2020	Thousands of U.S. dollars (Note 03) 2020
Current Liabilities:			
Notes and accounts payable	¥ 4,347	**¥ 5,237**	**$ 48,046**
Short-term bank loans (Note 08)	1,730	**1,730**	**15,872**
Current portion of long-term debt (Note 08)	34	**16**	**147**
Income taxes payable	465	**196**	**1,798**
Accrued bonuses to employees	1,971	**1,858**	**17,046**
Accrued bonuses to directors and corporate auditors	18	**8**	**73**
Reserve for sales returns	17	**6**	**55**
Reserve for sales rebates	294	**273**	**2,505**
Reserve for sales promotion expenses	166	**163**	**1,495**
Other current liabilities	4,756	**7,532**	**69,101**
Total current liabilities	13,801	**17,024**	**156,183**
Long-Term Liabilities:			
Long-term debt (Note 08)	1,930	**13**	**119**
Deferred tax liabilities (Note 09)	11,388	**17,191**	**157,716**
Net defined benefit liability (Note 10)	2,750	**3,572**	**32,771**
Accrued retirement benefits to directors and corporate auditors	157	**175**	**1,606**
Asset retirement obligations	116	**117**	**1,073**
Other long-term liabilities	668	**729**	**6,688**
Total long-term liabilities	17,013	**21,800**	**200,000**
Total liabilities	30,814	**38,824**	**356,183**
Net Assets:			
Shareholders' equity:			
Common stock:			
Authorized: 227,000,000 shares			
Issued: 51,811,185 shares	24,356	**24,356**	**223,450**
Additional paid-in capital	24,226	**24,226**	**222,257**
Retained earnings	106,026	**106,461**	**976,706**
Treasury stock (5,094,806 shares and 5,095,024 shares at March 31, 2019 and 2020, respectively)	(11,607)	**(11,608)**	**(106,495)**
Total shareholders' equity	143,001	**143,435**	**1,315,917**
Accumulated other comprehensive income:			
Unrealized holding gains on securities	40,326	**50,706**	**465,193**
Retirement benefits liability adjustments	(1,065)	**(1,676)**	**(15,376)**
Total accumulated other comprehensive income	39,261	**49,029**	**449,807**
Non-controlling interests	444	**504**	**4,624**
Total net assets	182,707	**192,970**	**1,770,367**
Total liabilities and net assets	¥213,522	**¥231,794**	**$2,126,550**

Consolidated Statements of Income and Consolidated Statements of Comprehensive Income

Kissei Pharmaceutical Co., Ltd. and its subsidiaries
For the years ended March 31, 2019 and 2020

Consolidated Statements of Income

	Millions of yen		Thousands of U.S. dollars (Note 03)
	2019	2020	2020
Net Sales	¥72,297	**¥63,234**	**$580,128**
Cost of Sales	26,731	**28,329**	**259,899**
Gross profit	45,566	**34,905**	**320,229**
Selling, General and Administrative Expenses (Note 15)	39,363	**33,048**	**303,193**
Operating income	6,202	**1,857**	**17,037**
Other Income (Expenses):			
Interest and dividend income	1,112	**1,227**	**11,257**
Interest expense	(23)	**(23)**	**(211)**
Gain on sales of investment securities	3	**2,236**	**20,514**
Gain on sales and loss on disposal of property, plant and equipment, net	(2)	**(35)**	**(321)**
Gain (loss) on valuation of securities	(176)	**(803)**	**(7,367)**
Impairment loss	(49)	**—**	**—**
Foreign exchange gain (loss)	(38)	**51**	**468**
Other, net	92	**119**	**1,092**
Total other income (expenses)	918	**2,773**	**25,440**
Profit before income taxes and non-controlling interests	7,121	**4,630**	**42,477**
Income Taxes (Note 09)**:**			
Current	1,634	**390**	**3,578**
Deferred	(47)	**1,351**	**12,394**
	1,586	**1,741**	**15,972**
Profit	5,535	**2,888**	**26,495**
Profit Attributable to Non-Controlling Interests	54	**71**	**651**
Profit Attributable to Owners of Parent (Note 16)	¥ 5,481	**¥ 2,817**	**$ 25,844**

The accompanying notes are an integral part of these statements.

Consolidated Statements of Comprehensive Income

	Millions of yen		Thousands of U.S. dollars (Note 03)
	2019	2020	2020
Profit	¥5,535	**¥ 2,888**	**$ 26,495**
Other Comprehensive Income:			
Unrealized holding gains on securities	3,578	**10,379**	**95,220**
Retirement benefits liability adjustments	(209)	**(622)**	**(5,706)**
Total other comprehensive income (Note 11)	3,368	**9,757**	**89,514**
Comprehensive Income	¥8,903	**¥12,646**	**$116,018**
Comprehensive income attributable to:			
Owners of Parent	¥8,850	**¥12,585**	**$115,459**
Non-controlling interests	53	**60**	**550**

The accompanying notes are an integral part of these statements.

Consolidated Statements of Changes in Net Assets

Kissei Pharmaceutical Co., Ltd. and its subsidiaries
For the years ended March 31, 2019 and 2020

Millions of yen

	Shareholders' equity					Accumulated other comprehensive income			
	Number of shares of common stock	Common stock	Additional paid-in capital	Retained earnings	Treasury stock	Unrealized holding gains on securities	Retirement benefits liability adjustments	Non-controlling interests	Total net assets
Balance at April 1, 2018	51,811,185	¥24,356	¥24,226	¥102,834	¥(11,607)	¥36,752	¥ (859)	¥390	¥176,092
Profit attributable to owners of parent for the year	—	—	—	5,481	—	—	—	—	5,481
Cash dividends paid	—	—	—	(2,289)	—	—	—	—	(2,289)
Treasury stock purchased (93 shares)	—	—	—	—	(0)	—	—	—	(0)
Net changes in items other than those in shareholders' equity	—	—	—	—	—	3,574	(205)	53	3,422
Balance at April 1, 2019	51,811,185	¥24,356	¥24,226	¥106,026	¥(11,607)	¥40,326	¥(1,065)	¥444	¥182,707
Profit attributable to owners of parent for the year	**—**	**—**	**—**	**2,817**	**—**	**—**	**—**	**—**	**2,817**
Cash dividends paid	**—**	**—**	**—**	**(2,382)**	**—**	**—**	**—**	**—**	**(2,382)**
Treasury stock purchased (270 shares)	**—**	**—**	**—**	**—**	**(0)**	**—**	**—**	**—**	**(0)**
Disposal of treasury stock (52 shares)	**—**	**—**	**0**	**—**	**0**	**—**	**—**	**—**	**0**
Net changes in items other than those in shareholders' equity	**—**	**—**	**—**	**—**	**—**	**10,379**	**(611)**	**60**	**9,828**
Balance at March 31, 2020	**51,811,185**	**¥24,356**	**¥24,226**	**¥106,461**	**¥(11,608)**	**¥50,706**	**¥(1,676)**	**¥504**	**¥192,970**

Thousands of U.S. dollars (Note 03)

	Shareholders' equity					Accumulated other comprehensive income			
	Number of shares of common stock	Common stock	Additional paid-in capital	Retained earnings	Treasury stock	Unrealized holding gains on securities	Retirement benefits liability adjustments	Non-controlling interests	Total net assets
Balance at April 1, 2019	51,811,185	$223,450	$222,257	$972,716	$(106,486)	$369,963	$ (9,771)	$4,073	$1,676,211
Profit attributable to owners of parent for the year	**—**	**—**	**—**	**25,844**	**—**	**—**	**—**	**—**	**25,844**
Cash dividends paid	**—**	**—**	**—**	**(21,853)**	**—**	**—**	**—**	**—**	**(21,853)**
Treasury stock purchased (270 shares)	**—**	**—**	**—**	**—**	**(0)**	**—**	**—**	**—**	**(0)**
Disposal of treasury stock (52 shares)	**—**	**—**	**0**	**—**	**0**	**—**	**—**	**—**	**0**
Net changes in items other than those in shareholders' equity	**—**	**—**	**—**	**—**	**—**	**95,220**	**(5,606)**	**550**	**90,165**
Balance at March 31, 2020	**51,811,185**	**$223,450**	**$222,257**	**$976,706**	**$(106,495)**	**$465,193**	**$(15,376)**	**$4,624**	**$1,770,367**

The accompanying notes are an integral part of these statements.

Consolidated Statements of Cash Flows

Kissei Pharmaceutical Co., Ltd. and its subsidiaries
For the years ended March 31, 2019 and 2020

	Millions of yen		Thousands of U.S. dollars (Note 03)
	2019	2020	2020
Cash Flows from Operating Activities:			
Profit before income taxes and non-controlling interests	¥ 7,121	**¥ 4,630**	**$ 42,477**
Depreciation and amortization	2,607	**2,562**	**23,505**
Increase (decrease) in allowance reserves	(397)	**(140)**	**(1,284)**
Decrease in net defined benefit liability	(2,174)	**(73)**	**(670)**
Impairment loss	49	**—**	**—**
Interest and dividend income	(1,112)	**(1,227)**	**(11,257)**
Interest expense	23	**23**	**211**
Foreign exchange (gain) loss	(1)	**0**	**0**
(Gain) loss on valuation of securities	176	**803**	**7,367**
(Gain) loss on sales of property, plant and equipment	(1)	**(27)**	**(248)**
(Gain) loss on sales of investment securities	(3)	**(2,236)**	**(20,514)**
Loss on disposal of property, plant and equipment	3	**62**	**569**
(Increase) decrease in notes and accounts receivable	1,910	**7,500**	**68,807**
(Increase) decrease in inventories	1,968	**525**	**4,817**
(Increase) decrease in other current assets	16	**599**	**5,495**
Increase (decrease) in notes and accounts payable	(546)	**890**	**8,165**
Increase (decrease) in other current liabilities	(219)	**(5)**	**(46)**
Increase (decrease) in other long-term liabilities	3	**0**	**0**
Other	(31)	**8**	**73**
Subtotal	9,391	**13,896**	**127,486**
Receipt of interest and dividends	995	**1,110**	**10,183**
Payment of interest	(23)	**(23)**	**(211)**
Payment of income taxes	(4,017)	**(1,048)**	**(9,615)**
Net cash provided by operating activities	6,346	**13,934**	**127,835**
Cash Flows from Investing Activities:			
Time deposits received	75	**76**	**697**
Time deposits paid	(74)	**(75)**	**(688)**
Reduction of investments in specified trusts	80	**97**	**890**
Acquisition of property, plant and equipment	(1,093)	**(879)**	**(8,064)**
Proceeds from sales of property, plant and equipment	152	**70**	**642**
Acquisition of intangible assets	(240)	**(423)**	**(3,881)**
Acquisition of investment securities	(406)	**(689)**	**(6,321)**
Proceeds from sales of investment securities	126	**2,755**	**25,275**
Payments for loans	(71)	**(76)**	**(697)**
Collection of loans	72	**168**	**1,541**
Long-term advance payment costs	(682)	**(503)**	**(4,615)**
Other	(25)	**(30)**	**(275)**
Net cash provided by (used in) investing activities	(2,087)	**490**	**4,495**
Cash Flows from Financing Activities:			
Long-term debt received	91	**—**	**—**
Repayment of long-term debt	(30)	**(1,934)**	**(17,743)**
Repayment of finance lease obligation	(77)	**(101)**	**(927)**
Cash dividends paid	(2,289)	**(2,382)**	**(21,853)**
Treasury stock purchased	(0)	**(0)**	**(0)**
Proceeds from sale of treasury stock	—	**0**	**0**
Net cash provided by (used in) financing activities	(2,306)	**(4,419)**	**(40,541)**
Effect of Exchange Rate Changes on Cash and Cash Equivalents	1	**(0)**	**(0)**
Increase (Decrease) in Cash and Cash Equivalents	1,954	**10,004**	**91,780**
Cash and Cash Equivalents at Beginning of Year (Note 04)	47,360	**49,315**	**452,431**
Cash and Cash Equivalents at End of Year (Note 04)	¥49,315	**¥59,319**	**$544,211**

The accompanying notes are an integral part of these statements.

Notes to the Consolidated Financial Statements

Kissei Pharmaceutical Co., Ltd. and its subsidiaries

Note 01 Basis of Presenting the Consolidated Financial Statements

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

Note 02 Summary of Significant Accounting Policies

(1) Scope of Consolidation

The number of subsidiaries the Company had for the years ended March 31, 2019 and 2020 were four and five, respectively, of which three were consolidated in the respective years. Those subsidiaries are listed below:

Name of subsidiaries	% of voting rights owned	Paid-in capital, millions of yen
Kissei Shoji Co., Ltd.	**100%**	**¥ 50**
Kissei Comtec Co., Ltd.	**83%**	**¥334**
Hashiba Technos Co., Ltd.	**100%**	**¥ 45**

(2) Consolidation and Elimination

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

(3) Investments in Unconsolidated Subsidiaries

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

(4) Valuation of Securities

Held-to-maturity debt securities are carried at amortized cost.

Marketable securities classified as other securities are carried at fair value as of the balance sheet date with changes in unrealized holding gain or loss, net of the applicable income taxes, included directly in net assets. The cost of securities sold is primarily determined by the moving average method.

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

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

(5) Inventory Valuation

Inventories are mainly valued at cost using the gross average method (the amount on the balance sheet is reduced to reflect decreased profitability).

(6) Method of Depreciation of Significant Depreciable Assets

(i) Property, plant and equipment (excluding lease assets)

Depreciation is computed using the declining-balance method at rates based on the estimated useful lives of the assets. The range of useful lives is principally from 3 to 50 years for buildings and structures.

Depreciation for buildings acquired on or after April 1, 1998 (excluding facilities attached to buildings) and for both facilities attached to buildings and other non-building structures acquired on or after April 1, 2016 is computed using the straight-line method.

(ii) Intangible assets (excluding lease assets)

Depreciation is computed using the straight-line method.

Software costs for internal use are amortized over their expected useful lives (mainly 5 years) on a straight-line basis.

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

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

(7) Accounting for Consumption Tax

Consumption tax is imposed at the flat rate of 10% on all domestic consumption of goods and services (with certain exemptions).

Consumption tax withheld upon sale and consumption tax paid by the Companies on their purchases of goods and services are not included in the respective revenue and cost or expenses in the accompanying consolidated statements of income.

(8) Foreign Currency Translation

Receivables and payables denominated in foreign currencies are translated into yen at the rates of exchange in effect at the balance sheet date, and differences arising from the translation are included in the consolidated statements of income.

Investments in unconsolidated subsidiaries denominated in foreign currencies are translated at the historical exchange rates prevailing at the time such transactions were made.

(9) Income Taxes

Income taxes of the Companies consist of corporate income tax, local inhabitants taxes, and enterprise tax.

The asset and liability approach is used to recognize deferred tax assets and liabilities in respect of temporary differences between the carrying amounts and the basis of assets and liabilities.

(10) Allowances, Accrued Bonuses to Employees and Reserves for Certain Expenses

(i) Allowance for doubtful accounts

The Companies provide an "Allowance for doubtful accounts" based on the percentage of their historical bad debt loss incurred against the balance of total receivables in addition to the amount of uncollectable receivables estimated on an individual basis.

(ii) Accrued bonuses to employees

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

(iii) Accrued bonuses to directors and corporate auditors

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

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

(11) Accounting Method for Retirement Benefits
Accrued retirement benefits and prepaid pension cost for employees have been recorded mainly at the amount calculated based on the retirement benefit obligation and the fair value of the plan assets as of the balance sheet date.
(i) Allocation of expected benefit payments
When calculating the retirement benefit obligation, the benefit formula method is used to allocate expected benefit payments to the period.
(ii) Actuarial differences and prior service cost
Prior service cost is amortized through the straight-line method over a term that does not exceed the average remaining service period of employees who are expected to receive benefits under the plans (10 years).

Net actuarial gains or losses are amortized from the following year through the straight-line method over a term that does not exceed the average remaining service period of employees who are expected to receive benefits under the plans (10 years).
(iii) Accounting treatment for unrecognized actuarial gains and losses and unrecognized prior service cost
Unrecognized actuarial gains and losses and unrecognized prior service cost are adjusted for tax effects and then recorded in retirement benefits liability adjustments under accumulated other comprehensive income in the net assets portion of the consolidated balance sheets.

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

(13) Profit and Dividends per Share
Profit attributable to owners of the parent per share is based upon the weighted-average number of shares of common stock outstanding during each fiscal year.

Cash dividends per share shown for each year in the accompanying consolidated statements of changes in net assets represent dividends approved or declared as applicable to the respective years.

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

(15) Accounting Standards Issued but Not Yet Effective
"Accounting Standard and Implementation Guidance on Revenue Recognition"

On March 31, 2020 the ASBJ issued "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29) and "Implementation Guidance on Accounting Standard for Revenue Recognition" (ASBJ Guidance No. 30).
(i) Overview
This is a comprehensive accounting standard for revenue recognition. Specifically, the accounting standard establishes the following five-step model that will apply to revenue from customers:
1. Identify the contract(s) with a customer
2. Identify the performance obligations in the contract
3. Determine the transaction price
4. Allocate the transaction price to the performance obligations in the contract
5. Recognize revenue when (or as) the entity satisfies a performance obligation

(ii) Scheduled date of adoption
The Companies expect to adopt the accounting standard and implementation guidance from the beginning of the fiscal year ending March 31, 2022.
(iii) Impact of the adoption of accounting standard and implementation guidance
The Companies are currently evaluating the effect of the adoption of this accounting standard and implementation guidance on its consolidated financial statements.

(16) Additional Information
The Companies have made accounting estimates (mainly regarding recoverability of deferred tax assets, etc.) with the assumption that COVID-19 will continue to impact social and economic activities for some time into the future. These assumptions have been reflected in the Companies' accounting process. The Companies also anticipate the impact of COVID-19 to affect the following fiscal year as well, but the present belief is that its impact on the Companies' financial position, operating results, and cash flows will be limited.

Note 03 United States Dollar Amounts

The accompanying consolidated financial statements are expressed in yen, and solely for the convenience of the reader, have been translated into U.S. dollars at the rate of ¥109=U.S.$1, the approximate rate of exchange prevailing at March 31, 2020. This translation should not be construed as a representation that all amounts shown could be converted into U.S. dollars at such a rate.

Note 04 Cash and Cash Equivalents

Cash and cash equivalents at March 31, 2019 and 2020 are as follows:

		Millions of yen	Thousands of U.S. dollars
	2019	**2020**	**2020**
Cash on hand and in banks	¥26,325	**¥36,329**	**$333,294**
Marketable securities	23,039	**23,342**	**214,147**
Time deposits with original maturities of over three months	(50)	**(48)**	**(440)**
Claims with redemption period exceeding three months, etc.	—	**(302)**	**(2,771)**
Cash and cash equivalents	¥49,315	**¥59,319**	**$544,211**

Note 05 Financial Instruments

Overview
(1) Policy for financial instruments
The Companies manage temporary cash surpluses through low-risk financial assets. Further, the Companies raise short-term capital through bank borrowings. The Companies use derivatives for the purpose of reducing risk arising from fluctuations in foreign currency exchange rates and do not enter into derivatives for speculative purposes.
(2) Types of financial instruments and related risk
Trade receivables—notes and accounts receivable—are exposed to credit risk in relation to customers. In accordance with the internal policies for managing credit risk of the Companies arising from receivables, each related division monitors credit worthiness of their main customers periodically, and monitors due dates and outstanding balances by individual customer.

Marketable securities and investment securities are exposed to market risk. Those securities are composed of mainly the shares of common stock of other companies with which the Companies have business relationships. The market value of these securities is periodically reported to the Board of Directors.
(3) Supplementary explanation of the estimated fair value of financial instruments
The fair value of financial instruments is based on their quoted market price, if available. When there is no quoted market price available, fair value is reasonably estimated. Since various assumptions and factors are reflected in estimating the fair value, different assumptions and factors could result in a different fair value.

Estimated Fair Value of Financial Instruments
Carrying value of financial instruments on the consolidated balance sheets as of March 31, 2019 and 2020 and unrealized gains (losses) are shown in the following tables. The following does not include financial instruments for which it is extremely difficult to determine the fair value.
(Please refer to *2 in the following.)

	Millions of yen		
As of March 31, 2019	Carrying value	Estimated fair value	Unrealized gains (losses)
Assets:			
Cash on hand and in banks	¥ 26,325	¥ 26,325	¥—
Notes and accounts receivable	26,963	26,963	—
Marketable securities and investment securities	108,242	108,242	—
Total	¥161,531	¥161,531	¥—
Derivatives	¥ —	¥ —	¥—

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

As of March 31, 2020	Thousands of U.S. dollars		
	Carrying value	Estimated fair value	Unrealized gains (losses)
Assets:			
Cash on hand and in banks	**$ 333,294**	**$ 333,294**	**$—**
Notes and accounts receivable	**178,550**	**178,550**	**—**
Marketable securities and investment securities	**1,129,183**	**1,129,183**	**—**
Total	**$1,641,028**	**$1,641,028**	**$—**
Derivatives	**$ —**	**$ —**	**$—**

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

Cash on hand and in banks and notes and accounts receivable

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

Marketable securities and investment securities

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

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

	Millions of yen		Thousands of U.S. dollars
	2019	**2020**	**2020**
Unlisted stocks	¥1,270	**¥4,529**	**$41,550**
Investments in partnerships	17	**—**	**—**
Investments in unconsolidated subsidiaries	467	**889**	**8,156**

Because no quoted market price is available and it is extremely difficult to determine the fair value, the above financial instruments are not included in "Marketable securities and investment securities."

*3: Redemption schedules for receivables and marketable securities with maturities at March 31, 2019 and 2020 are as follows:

As of March 31, 2019	Millions of yen			
	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
Assets:				
Cash on hand and in banks	¥26,325	¥ —	¥ —	¥ —
Notes and accounts receivable	26,963	—	—	—
Marketable securities and investment securities	23,040	1,866	2,468	1,000
Total	¥76,328	¥1,866	¥2,468	¥1,000

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

As of March 31, 2020	Thousands of U.S. dollars			
	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
Assets:				
Cash on hand and in banks	**$333,294**	**$ —**	**$ —**	**$ —**
Notes and accounts receivable	**178,550**	**—**	**—**	**—**
Marketable securities and investment securities	**214,202**	**17,927**	**20,743**	**9,174**
Total	**$726,046**	**$17,927**	**$20,743**	**$9,174**

Note 06 Securities

Trading Securities

Unrealized losses for trading securities for the years ended March 31, 2020 and 2019 are ¥803 million ($7,367 thousand) and ¥176 million, respectively.

Other Securities

The acquisition cost, carrying amount, and gross unrealized holding gains and losses for securities with fair value by security type at March 31, 2019 and 2020 are as follows:

	Millions of yen			
	2019			
	Acquisition cost	Carrying amount	Gross unrealized holding gains	Gross unrealized holding losses
Equity securities	¥18,213	¥ 75,396	¥57,633	¥450
Corporate debt securities	1,350	1,362	14	1
Other	30,928	31,482	733	179
Total	¥50,493	¥108,242	¥58,381	¥632

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

	Thousands of U.S. dollars			
	2020			
	Acquisition cost	Carrying amount	Gross unrealized holding gains	Gross unrealized holding losses
Equity securities	**$162,734**	**$ 832,624**	**$677,284**	**$ 7,394**
Corporate debt securities	**14,220**	**13,936**	**18**	**294**
Other	**283,450**	**282,615**	**3,303**	**4,147**
Total	**$460,413**	**$1,129,183**	**$680,615**	**$11,844**

Unlisted stocks are not included in the preceding tables because there were no quoted market prices available and it is extremely difficult to determine the fair value.

Sales proceeds of securities classified as other securities and the gross realized gains and losses for the years ended March 31, 2019 and 2020 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2019	**2020**	**2020**
Sales proceeds	¥16	**¥2,731**	**$25,055**
Gross realized gains	3	**2,236**	**20,514**
Gross realized losses	—	**—**	**—**

Note 07 Inventories

Inventories at March 31, 2019 and 2020 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2019	**2020**	**2020**
Merchandise	¥ 2,013	**¥ 2,880**	**$ 26,422**
Finished goods	2,740	**2,712**	**24,881**
Work-in-process	1,950	**1,956**	**17,945**
Raw materials	7,131	**5,797**	**53,183**
Supplies	128	**93**	**853**
Total	¥13,965	**¥13,439**	**$123,294**

Note 08 Summary of Loans and Debt

Classification	Balance at beginning of fiscal year (millions of yen)	Balance at end of fiscal year (millions of yen)	Balance at end of fiscal year (Thousands of U.S. dollars)	Average interest rate (%)	Repayment period
Short-term loans	¥1,730	¥1,730	$15,872	1.09	—
Current portion of long-term debt payable	34	16	147	0.28	—
Current portion of lease obligations	110	136	1,248	—	—
Long-term debt (excluding current portion)	1,930	13	119	0.28	April 2021–January 2022
Lease obligations (excluding current portion)	271	373	3,422	—	April 2021–February 2027
Total	¥4,077	¥2,269	$20,817	—	—

*1. Figures under average interest rate refer to weighted-average interest rate applied to the balance at the end of fiscal year.
*2. Average interest rate for lease obligations is not stated because lease obligations appear in the consolidated balance sheets as total amounts before deductions of interest equivalents included in lease payments.
*3. Long-term debt and lease obligations (excluding current portion) payable within five years of the end of the fiscal year are as follows:

Classification	Over one year, within two years (millions of yen)	Over two years, within three years (millions of yen)	Over three years, within four years (millions of yen)	Over four years, within five years (millions of yen)
Long-term debt	¥ 13	¥—	¥—	¥—
Lease obligations	¥116	¥93	¥58	¥49

Classification	Over one year, within two years (Thousands of U.S. dollars)	Over two years, within three years (Thousands of U.S. dollars)	Over three years, within four years (Thousands of U.S. dollars)	Over four years, within five years (Thousands of U.S. dollars)
Long-term debt	$ 119	$ —	$ —	$ —
Lease obligations	$1,064	$853	$532	$450

Note 09 Income Taxes

Deferred tax assets and liabilities at March 31, 2019 and 2020 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2019	**2020**	**2020**
Deferred Tax Assets:			
Prepaid research and development expenses	¥ 3,545	**¥ 2,596**	**$ 23,817**
Net defined benefit liability	1,438	**1,588**	**14,569**
Inventory assets	626	**661**	**6,064**
Accrued bonuses to employees	601	**566**	**5,193**
Write-down of securities	438	**440**	**4,037**
Payment of retirement benefits to directors and corporate auditors	155	**161**	**1,477**
Impairment loss	150	**149**	**1,367**
Reserve for sales rebates	89	**83**	**761**
Accrued enterprise tax	90	**68**	**624**
Other	745	**818**	**7,505**
Total gross deferred tax assets	7,882	**7,136**	**65,468**
Valuation allowance	(1,059)	**(1,390)**	**(12,752)**
Total deferred tax assets	¥ 6,822	**¥ 5,746**	**$ 52,716**
Deferred Tax Liabilities:			
Unrealized holding gains on securities	¥(17,430)	**¥(22,123)**	**$(202,963)**
Other	(137)	**(136)**	**(1,248)**
Total deferred tax liabilities	(17,567)	**(22,260)**	**(204,220)**
Deferred tax assets (liabilities), net	¥(10,744)	**¥(16,514)**	**$(151,505)**

Reconciliation of the effective statutory tax rate and the actual tax rate for the years ended March 31, 2019 and 2020 is as follows:

	2019	**2020**
Effective statutory tax rate	30.5%	**30.5%**
Adjustments:		
Entertainment expenses and other non-deductibles	1.0	**1.1**
Dividend income not taxable	(1.0)	**(1.8)**
Tax benefits due to research and development expenses	(9.1)	**(1.4)**
Per capital levy of local inhabitants taxes	1.2	**1.8**
Valuation allowance	(0.6)	**7.1**
Other	0.3	**0.3**
Actual tax rate	22.3%	**37.6%**

Note 10 Funded Defined Benefit Plans

General Outline of Retirement Benefit Plans Implemented

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

For the years ended March 31, 2019 and 2020

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

	Millions of yen		Thousands of U.S. dollars
	2019	**2020**	**2020**
Defined benefit obligation at beginning of period	¥21,511	**¥22,269**	**$204,303**
Service cost	863	**880**	**8,073**
Interest cost	61	**53**	**486**
Actuarial gains and losses incurred this period	367	**213**	**1,954**
Retirement benefits paid	(534)	**(662)**	**(6,073)**
Defined benefit obligation at end of period	¥22,269	**¥22,754**	**$208,752**

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

	Millions of yen		Thousands of U.S. dollars
	2019	**2020**	**2020**
Plan assets at beginning of period	¥16,887	**¥19,518**	**$179,064**
Expected return on plan assets	422	**487**	**4,468**
Actuarial gains and losses incurred this period	(188)	**(864)**	**(7,927)**
Employer contribution	1,031	**702**	**6,440**
Retirement benefits paid	(534)	**(662)**	**(6,073)**
Establishment of employee retirement benefit trust	1,900	**—**	**—**
Plan assets at end of period	¥19,518	**¥19,181**	**$175,972**

(iii) Reconciliation of defined benefit obligation and plan assets with net defined benefit liability and asset reflected on the consolidated balance sheets

	Millions of yen		Thousands of U.S. dollars
	2019	**2020**	**2020**
Defined benefit obligation for funded plan	¥ 22,269	**¥ 22,754**	**$ 208,752**
Plan assets	(19,518)	**(19,181)**	**(175,972)**
Net amount of defined benefit liability and asset on the consolidated balance sheets	¥ 2,750	**¥ 3,572**	**$ 32,771**
Defined benefit liability	2,750	**3,572**	**32,771**
Net amount of defined benefit liability and asset on the consolidated balance sheets	¥ 2,750	**¥ 3,572**	**$ 32,771**

(iv) The components of retirement benefit expense

	Millions of yen		Thousands of U.S. dollars
	2019	2020	2020
Service cost	¥ 863	¥ 880	$ 8,073
Interest cost	61	53	486
Expected return on plan assets	(422)	(487)	(4,468)
Amortization of actuarial gains and losses	508	437	4,009
Amortization of prior service cost	(255)	(255)	(2,339)
Other	50	62	569
Retirement benefit expense	¥ 807	¥ 690	$ 6,330

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

	Millions of yen		Thousands of U.S. dollars
	2019	2020	2020
Prior service cost	¥(255)	¥(255)	$(2,339)
Actuarial gains and losses	(46)	(640)	(5,872)
Total	¥(301)	¥(895)	$(8,211)

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

	Millions of yen		Thousands of U.S. dollars
	2019	2020	2020
Unrecognized prior service cost	¥(1,275)	¥(1,020)	$ (9,358)
Unrecognized actuarial gains and losses	2,845	3,485	31,972
Total	¥ 1,569	¥ 2,464	$22,606

(vii) Plan assets information

Breakdown of plan assets

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

	2019	2020
Debt securities	18%	21%
Equity securities	25	21
Cash on hand and in banks	11	2
General accounts	46	47
Other	0	8
Total	100%	100%

* Total pension assets include a retirement benefit trust established as part of the Company's defined benefit corporate pension plans. The proportion of pension assets in trust was 9.7% for the year ended March 31, 2019 and 8.0% for the fiscal year under review.

The expected return on assets has been estimated based on the anticipated allocation to each asset class and the expected long-term returns on assets held in each category.

(viii) Assumptions used in accounting for the above plans (discount rate is displayed as a weighted average)

	2019	2020
Discount rate	0.4%	0.3%
Expected rate of return on plan assets	2.5%	2.5%

Note 11 Other Comprehensive Income

Reconciling items with income tax effect relating to other comprehensive income for the years ended March 31, 2019 and 2020 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2019	2020	2020
Unrealized holding gains on securities:			
Amount recognized in the year	¥ 5,201	¥17,308	$158,789
Amount of recycling	(3)	(2,236)	(20,514)
Before income tax effect adjustment	5,198	15,071	138,266
Amount of income tax effect	(1,620)	(4,691)	(43,037)
Unrealized holding gains on securities	3,578	10,379	95,220
Retirement benefits liability adjustments:			
Amount recognized in the year	(555)	(1,077)	(9,881)
Amount of recycling	253	182	1,670
Before income tax effect adjustment	(301)	(895)	(8,211)
Amount of income tax effect	92	273	2,505
Retirement benefits liability adjustments	(209)	(622)	(5,706)
Total other comprehensive income	¥ 3,368	¥ 9,757	$ 89,514

Note 12 Government Grants

For the years ended March 31, 2019 and 2020

Government grants of ¥798 million ($7,321 thousand) for buildings and ¥113 million ($1,037 thousand) for land are deducted in calculating the carrying amounts of these assets.

Note 13 Segment Information

(1) Overview of Reportable Segments

The Reportable segments of the Companies are components for which discrete financial information is available and whose operating results are regularly reviewed by the Board of Directors to make decisions about resource allocation and to assess their performance.

(2) Method of Calculating Sales and Profit (Loss), Identifiable Assets / Liabilities, and Other Items by Reportable Segment

The accounting procedure for Reportable segments is the same as that described in Note 02 Summary of Significant Accounting Policies.

Segment profit is calculated based on operating income.

Intersegment sales are recognized based on the price in an arm's-length transaction.

(3) Change in Reportable Segments

During the financial year ended March 31, 2020, reportable segments for information solution services, Construction subcontracting and Sales of materials and other goods, which had previously included in other segment, were separately represented in light of their quantitative importance.

In this connection, segment information for the comparative year has been reclassified.

(4) Information on Sales and Profit (Loss), Identifiable Assets / Liabilities, and Other Items by Reportable Segment

	Millions of yen				
	Reportable segments				
As of March 31, 2019	Pharmaceuticals	Information solution services	Construction subcontracting	Sales of materials and other goods	Total
Net sales:					
Sales to third parties	¥ 61,520	¥5,532	¥3,862	¥1,381	¥ 72,297
Intersegment sales and transfers	—	1,694	1,342	1,610	4,647
Total	¥ 61,520	¥7,226	¥5,205	¥2,992	¥ 76,944
Segment profit	¥ 5,487	¥ 405	¥ 176	¥ 41	¥ 6,110
Segment assets	¥203,818	¥5,938	¥3,189	¥2,547	¥215,494
Other items:					
Depreciation*	¥ 2,357	¥ 350	¥ 29	¥ 28	¥ 2,765
Increase of property, plant and equipment and intangible assets*	1,899	299	9	15	2,224

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

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

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

As of March 31, 2020	Thousands of U.S. dollars				
	Reportable segments				
	Pharmaceuticals	Information solution services	Construction subcontracting	Sales of materials and other goods	Total
Net sales:					
Sales to third parties	$ 470,716	$60,835	$33,119	$15,450	$ 580,128
Intersegment sales and transfers	—	17,000	10,046	11,083	38,138
Total	$ 470,716	$77,835	$43,174	$26,532	$ 618,275
Segment profit	$ 8,248	$ 4,982	$ 2,523	$ 266	$ 16,018
Segment assets	$2,030,394	$59,771	$29,890	$22,982	$2,143,055
Other items:					
Depreciation*	$ 21,028	$ 3,284	$ 266	$ 248	$ 24,844
Increase of property, plant and equipment and intangible assets*	14,349	3,697	92	18	18,165

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

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

(i) Major items for adjustments

	Millions of yen		Thousands of U.S. dollars
	2019	2020	2020
Net sales:			
Total of reportable segments	¥ 76,944	¥ 67,392	$ 618,275
Elimination of intersegment transactions	(4,647)	(4,157)	(38,138)
Reported on consolidated financial statements	¥ 72,297	¥ 63,234	$ 580,128
Segment profit:			
Total of reportable segments	¥ 6,110	¥ 1,746	$ 16,018
Elimination of intersegment transactions	69	71	651
Adjustments to depreciable assets	56	5	46
Other adjustments	(33)	32	294
Reported on consolidated financial statements	¥ 6,202	¥ 1,857	$ 17,037
Segment assets:			
Total of reportable segments	¥215,494	¥233,593	$2,143,055
Elimination of intersegment transactions	(1,972)	(1,798)	(16,495)
Reported on consolidated financial statements	¥213,522	¥231,794	$2,126,550

(ii) Other items for adjustments

	Millions of yen		Thousands of U.S. dollars
	2019	2020	2020
Depreciation:			
Total of reportable segments	¥2,765	¥2,708	$24,844
Adjustments	(157)	(145)	(1,330)
Reported on consolidated financial statements	¥2,607	¥2,562	$23,504
Increase of property, plant and equipment and intangible assets:			
Total of reportable segments	¥2,224	¥1,980	$18,165
Adjustments	(102)	(82)	(752)
Reported on consolidated financial statements	¥2,122	¥1,897	$17,404

(6) Related Information

(i) Product and service information

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

(ii) Geographical information

(1) Net sales

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

(2) Property, plant and equipment

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

(iii) Major customer information

	Millions of yen		Thousands of U.S. dollars
	2019	2020	2020
Alfresa Corporation	¥11,612	¥9,714	$89,119
SUZUKEN CO., LTD.	10,053	7,655	70,229
MEDICEO CORPORATION	7,737	6,569	60,266

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

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

For the year ended March 31, 2019

	Millions of yen				
	Reportable segment				
	Pharmaceuticals	Information solution services	Construction subcontracting	Sales of materials and other goods	Total
Impairment loss	¥49	¥—	¥—	¥—	¥49

For the year ended March 31, 2020

No corresponding items.

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

For the years ended March 31, 2019 and 2020

No corresponding items.

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

For the years ended March 31, 2019 and 2020

No corresponding items.

Note 14 Related Party Transactions

(1) Transaction with Companies in which Executives and Their Close Relations Own a Majority of Voting Rights, etc.

For the years ended March 31, 2019 and 2020

No corresponding items.

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

For the years ended March 31, 2019 and 2020

No corresponding items.

Note 15 Selling, General and Administrative Expenses

Selling, general and administrative expenses for the years ended March 31, 2019 and 2020 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2019	**2020**	**2020**
Payroll costs	¥ 9,245	**¥ 8,913**	**$ 81,771**
Research and development expenses	15,711	**10,767**	**98,780**
Depreciation	909	**985**	**9,037**
Other	13,497	**12,381**	**113,587**
Total	¥39,363	**¥33,048**	**$303,193**

Note 16 Amounts Per Share

Amounts per share as of March 31, 2019 and 2020 and for the years then ended are as follows:

	Yen		U.S. dollars
	2019	**2020**	**2020**
Net assets	¥3,901.49	**¥4,119.89**	**$37.80**
Profit attributable to owners of parent	117.33	**60.31**	**0.55**
Cash dividends	50.0	**52.0**	**0.48**

Diluted profit attributable to owners of parent per share is not presented because there are no dilutive potential of shares of common stock.

Net assets per share are computed based on the net assets excluding non-controlling interests and the number of common stock outstanding at the year–end.

Profit attributable to owners of parent per share is computed based on the profit attributable to owners of parent and the average number of shares of common stock outstanding during the year.

Cash dividends per share represent the cash dividends proposed by the Board of Directors together with the interim cash dividends paid.

Note 17 Subsequent Events

No corresponding items.

Independent Auditor's Report

The Board of Directors
Kissei Pharmaceutical Co., Ltd.

Opinion

We have audited the accompanying consolidated financial statements of Kissei Pharmaceutical Co., Ltd. and its consolidated subsidiaries (the Group), which comprise the consolidated balance sheet as at March 31, 2020, and the consolidated statements of income, comprehensive income, changes in net assets, and cash flows for the year then ended, and notes to the consolidated financial statements.

In our opinion, the accompanying consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Group as at March 31, 2020, and its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with accounting principles generally accepted in Japan.

Basis for Opinion

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

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

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

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

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

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

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

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

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

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

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

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

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

Convenience Translation

The U.S. dollar amounts in the accompanying consolidated financial statements with respect to the year ended March 31, 2020 are presented solely for convenience. Our audit also included the translation of Japanese yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made on the basis described in Note 03 to the consolidated financial statements.

Ernst & Young ShinNihon LLC
Matsumoto, Japan

June 26, 2020

山中榮

Takashi Yamanaka
Designated Engagement Partner
Certified Public Accountant

富田哲也

Tetsuya Tomita
Designated Engagement Partner
Certified Public Accountant

Corporate Information

As of March 31, 2020

Corporate Data

Head office

Company Name

KISSEI PHARMACEUTICAL CO., LTD.

Established

August 9, 1946

Capital

¥24,356 million

Number of Employees

1,479 (Non-consolidated)

URL

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

Major Business Locations / Consolidated Subsidiaries

Headquarters

Head Office
19-48, Yoshino, Matsumoto, Nagano 399-8710, Japan
+81-263-25-9081

Tokyo Head Office
8-9, Nihonbashi-Muromachi 1-chome, Chuo-ku,
Tokyo 103-0022, Japan
+81-3-3279-2761

Tokyo Head Office (Koishikawa)
1-3, Koishikawa 3-chome, Bunkyo-ku, Tokyo 112-0002, Japan
+81-3-5684-3530

Laboratories

Central Research Laboratories
Pharmaceutical Laboratories
4365-1, Hotaka-kashiwabara, Azumino, Nagano 399-8304, Japan

Safety Research Laboratories
2320-1, Hotaka-maki, Azumino, Nagano 399-8305, Japan

Joetsu Chemical Laboratories
197-5, Kamikichi, Kubiki-ku, Joetsu, Niigata 942-0145, Japan

Plants

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

Shiojiri Plants
9637-5, Kataoka, Shiojiri, Nagano 399-0711, Japan

Centers

Nutritional Business Center
9637-6, Kataoka, Shiojiri, Nagano 399-0711, Japan

Information Center
4010-10, Wada, Matsumoto, Nagano 390-1293, Japan

Subsidiaries

▶ Consolidated Subsidiaries

Kissei Shoji Co., Ltd.
1-1, Hiratahigashi 2-chome, Matsumoto, Nagano 399-0014, Japan

KISSEI COMTEC CO., LTD.
4010-10, Wada, Matsumoto, Nagano 390-1293, Japan

HASHIBA TECHNOS CO., LTD.
1-1, Hiratahigashi 2-chome, Matsumoto, Nagano 399-0014, Japan

▶ Unconsolidated Subsidiaries

Kissei America, Inc.
400 Kelby Street, 16FL Fort Lee, NJ 07024, USA
+1-201-363-4630

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

Investor Information

As of March 31, 2020

Stock Exchange Listing

Tokyo

Stock Code

4547

Common Stock

Authorized
227,000,000 shares

Issued
51,811,185 shares

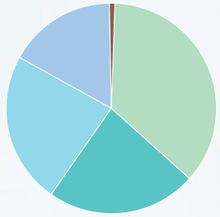
Number of Shareholders
3,346
(Year-on-year change: 5 increase)

Principal Shareholders

	Number of shares held (hundreds)	Voting rights (%)
The Dai-ichi Life Insurance Company, Limited	32,000	6.8
Japan Trustee Services Bank, Ltd. (Trust account)	29,459	6.3
The Hachijuni Bank, Ltd.	23,333	5.0
The Master Trust Bank of Japan, Ltd. (Trust account)	22,983	4.9
Mizuho Bank, Ltd.	18,334	3.9
Kanzawa Limited	16,782	3.6
Mutsuo Kanzawa	15,416	3.3
Kissei Group Employee Stockholders Committee	12,294	2.6
Nabelin Co., Ltd.	12,223	2.6
THE NAGANO BANK, LTD.	11,260	2.4

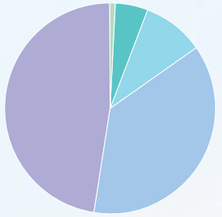
Note: 1. Kissei holds 5,095,024 shares of treasury stock but is not included in the above list of principal shareholders.
2. The calculation of voting rights percentages is based on total shares issued excluding treasury stock.

Composition of Shareholders by Category



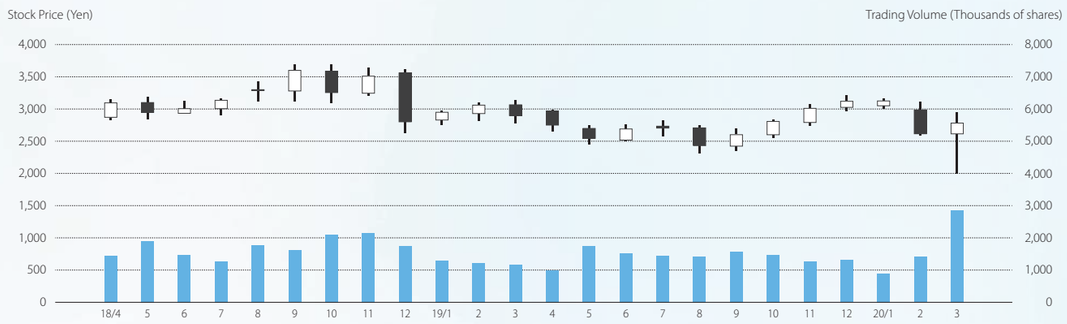
- Securities companies: 25/ 4,681 hundred shares (1.0%)
- Financial institutions: 47/ 187,013 hundred shares (36.1%)
- Individuals and others: 2,868/ 119,934 hundred shares (23.1%)
- Other companies: 172/ 121,358 hundred shares (23.4%)
- Non-Japanese institutions and individuals: 234/85,124 hundred shares (16.4%)

Composition of Shareholders by Number of Shares Held



- 1–99 shares: 192/ 38 hundred shares (0.0%)
- 100–999 shares: 1,783/ 4,658 hundred shares (0.9%)
- 1,000–9,999 shares: 1,140/ 26,167 hundred shares (5.1%)
- 10,000–99,999 shares: 161/ 48,860 hundred shares (9.4%)
- 100,000–999,999 shares: 59/ 193,348 hundred shares (37.3%)
- 1,000,000 and over shares: 11/ 245,038 hundred shares (47.3%)

Stock Price Range / Trading Volume



KISSEI PHARMACEUTICAL CO., LTD.

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

VEGETABLE OIL INK

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Printed in Japan