

CORPORATE REPORT 2020



KAKEN PHARMACEUTICAL CO., LTD.

"Bringing Smiles to Everyone" — This is the hope of KAKEN.

Bringing Smiles to Everyone

KAKEN helps improve the quality of life of patients by serving as many people as possible to return smiles of happiness to their faces, through supplying superior pharmaceuticals. In this endeavor, we always strive to become “the best,” rather than pursuing the scale of business. We aspire to be, and to remain, a company that can create “joys” for patients, the Company itself and our employees. We also hope to contribute to society by demonstrating KAKEN’s distinctive and vigorous presence.

Corporate Philosophy

KAKEN helps improve the quality of life of patients by serving as many people as possible to return smiles of happiness to their faces, through supplying superior pharmaceuticals.

Business Philosophy

KAKEN “Three Joys”

“Joy for patients”

We strive to create and supply efficacious drugs that satisfy the needs of patients and medical professionals.

“Joy as a company”

We recognize our social responsibility as a pharmaceutical company, engage in all activities with high ethical standards, and aspire to earn society’s trust.

“Joy for employees”

Our objective is to become a company with vitality and presence whose employees enjoy and take pride in their work.

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Editorial Policy

This Report has been edited with a basic objective of helping our various stakeholders (including shareholders and investors) to understand the management foundation and strengths that KAKEN has built to date, as well as the sustainable growth KAKEN aspires to achieve through creation of corporate value in the future, in reference to the disclosure framework provided by the International Integrated Reporting Council (IIRC).

Reporting Period: From April 1, 2019 to March 31, 2020

Precautions

This Report contains forward-looking statements on the Group’s business. They are projections based on currently available information and may differ from the actual results due to a variety of factors in the future. In addition, although this Report includes information related to pharmaceuticals (including those under development), these statements are not intended to be advertisements or medical advice.

Greetings



Since the incorporation of KAKEN in 1948, we have been providing a number of drugs to medical front lines and contributed to improving the quality of life of patients. Guided by KAKEN's business philosophy of "three joys," namely, "joy for patients," "joy as a company," and "joy for employees," we aim to become a company that meets the trust and expectations of our stakeholders by addressing social issues, primarily focusing on the medical field.

In recent years, the business environment surrounding the pharmaceutical industry in Japan has been undergoing drastic changes due to various factors such as new regulations and systems, and pharmaceutical companies are increasingly being required to continue to generate innovative new drugs while further improving efficiency as they struggle for survival.

In this environment, we will focus on developing human resources in order to maximize our organizational strength through the growth of each and every employee. We will further accelerate our evolution as an R&D-oriented company to increase our corporate value for the smiles of all people.

From June 2020, we have established a new management structure under which Tetsuo Onuma serves as Chairman and Representative Director and Hiroyuki Horiuchi serves as President and Representative Director. We look forward to the continued support of all of our stakeholders.

Tetsuo Onuma

Chairman and Representative Director

Hiroyuki Horiuchi

President and Representative Director

History of KAKEN

The origin of Kaken Pharmaceutical Co., Ltd., can be traced back to the Institute of Physical and Chemical Research (Riken), which was established in 1917. In 1948, the Company started its business by manufacturing and marketing penicillin utilizing Riken's proprietary technologies. Since then to date, KAKEN has been providing a wide variety of drugs as an R&D-oriented pharmaceutical company.

Business-related events

1948 The Institute of Physical and Chemical Research reorganized into a stock company Kagaku-Kenkyusho (first president: Yoshio Nishina)

1952 Kagaku-Kenkyusho was renamed Kaken Chemicals

1961 Kaken Chemicals was listed on the Second Section of the Tokyo Stock Exchange

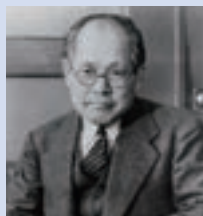
1962 Kaken Chemicals was listed on the First Section of the Tokyo Stock Exchange

1963 Construction of Shizuoka Factory (Fujieda City) was completed

1965 Received the 11th Okochi Memorial Prize

1966 Business offices (present branches) were established in major cities throughout Japan

1971 Received the 17th Okochi Memorial Prize



1982 Kaken Chemicals merged with Kakenyaku-Kako to form Kaken Pharmaceutical Co., Ltd.

1988 Kaken Pharma Co., Ltd. was established

1991 Temporarily moved the head office to Urayasu City, Chiba due to the Honkomagome Redevelopment Project

1998 Bunkyo Green Court was completed
Moved the head office to its center office

2000 Shiga Factory was closed and its operation was integrated with the Shizuoka Factory
Recognized as the winner of the FY 2000 3Rs (Reduce, Reuse, and Recycle) Promotion Merit Award, and awarded the Minister of Health and Welfare Prize

1948 → 1980

New product launches

1948 Began production of **Penicillin KAKEN**



1950 Streptomycin KAKEN was launched

1953 **Athletan (anti-trichophyton agent)** was launched



1987 **Artz (anti-osteoarthritis agent)** was launched



1988 Adofeed (pain- and inflammation-relieving plaster) was launched

1989 Ebrantil ($\alpha 1$ blocker to treat dysuria and hypertension) was launched

1992 Procylin (oral-use prostaglandin I₂ analog) was launched, Mentax (anti-trichophyton agent) was launched

1998 **Seprafilm (absorbable adhesion barrier)** was launched



The Institute of Physical and Chemical
Research, Building No. 1



- 2001** ISO14001 certification obtained at the Shizuoka site
- 2005** Concluded a license agreement regarding worldwide rights for bFGF
- 2006** Antifungal compound KP-103 was out-licensed for Europe and the United States
- 2012** Exclusive distribution rights were acquired for SI-6603 (lumbar disc herniation treatment agent) in the Japanese market
- 2015** Exclusive rights were acquired for development, manufacture, and distribution of BBI-4000 (primary axillary hyperhidrosis treatment agent) in Japan and other Asian countries
- 2016** Exclusive rights to develop and distribute Nexobrid (burn wound eschar-specific removal agent) in Japan were acquired
Clenafin (topical onychomycosis treatment agent) was out-licensed for Korea
- 2017** Launched collaborative research with Numab Therapeutics AG to develop a new antibody drug
Clenafin (topical onychomycosis treatment agent) was out-licensed for Taiwan
- 2018** KP-470, a new compound for psoriasis, was out-licensed
Clenafin (topical onychomycosis treatment agent) was out-licensed for Hong Kong and Macau
- 2019** Exclusive rights to distribute Lenabasum (systemic sclerosis and dermatomyositis treatment agent) in Japan were acquired
Clenafin (topical onychomycosis treatment agent) was out-licensed for China
Exclusive rights to develop and distribute Ivermectin lotion, 0.5% (head lice treatment agent) in Japan were acquired
- 2020** Ecclock Gel 5% approved in Japan for the treatment of primary axillary hyperhidrosis

→ 2001 →

- 2001** **Fiblast Spray (wound-healing agent)** was launched



- 2005** GHRP KAKEN 100 Injection (diagnostic agent for growth hormone deficiency) was launched
- 2007** Berasus LA Tablet 60μg (pulmonary arterial hypertension treatment agent) was launched
- 2011** Lipidil Tablet (anti-hyperlipidemia agent) was launched

- 2014** **Clenafin (topical onychomycosis treatment agent)** was launched



- 2016** **Regroth (medicinal product for periodontal regeneration)** was launched



- 2018** **Hernicore (lumbar disc herniation treatment agent)** was launched



KAKEN's Value-creating Process

Corporate Philosophy

KAKEN helps improve the quality of life of patients by serving as

Social Issues

Aging
populationUnmet
medical
needsGrowing
medical
expensesIn-house
Drug Discovery

Main discovery research focus

Immune system
(Inflammatory skin diseases, allergic diseases, rheumatism, etc.)

Nervous system
(Neuropathic pain, etc.)

Infectious diseases
(Deep mycosis, etc.)

Source of
competitivenessProactive
partnering strategy

**Expansion of products both
under development and
marketed**

**Global expansion of
in-house developed
products**

Therapeutic
Franchises*

Dermatology
Orthopedics
Other Fields
(collagen disease, etc.)

* In-licensing of products under development and distribution rights, maximizing value of existing products, etc.

KAKEN's
Business

Pharmaceuticals Segment
(Pharmaceuticals/Medical
Devices and Agrochemicals)

Real Estate Segment

Pharmaceuticals Segment

Pharmaceuticals/Medical Devices

See p. 15 for more details ▶

KAKEN specializes in the therapeutic areas of dermatology and orthopedics. In the dermatology field, we market products such as Clenafin, a topical treatment for onychomycosis, and Fiblast Spray, a wound-healing agent. In the orthopedics field, we market Artz, an anti-osteoarthritis agent, and Hemicore, a product to treat lumbar disc herniation, and others. All these products are widely used in medicine.

Agrochemicals

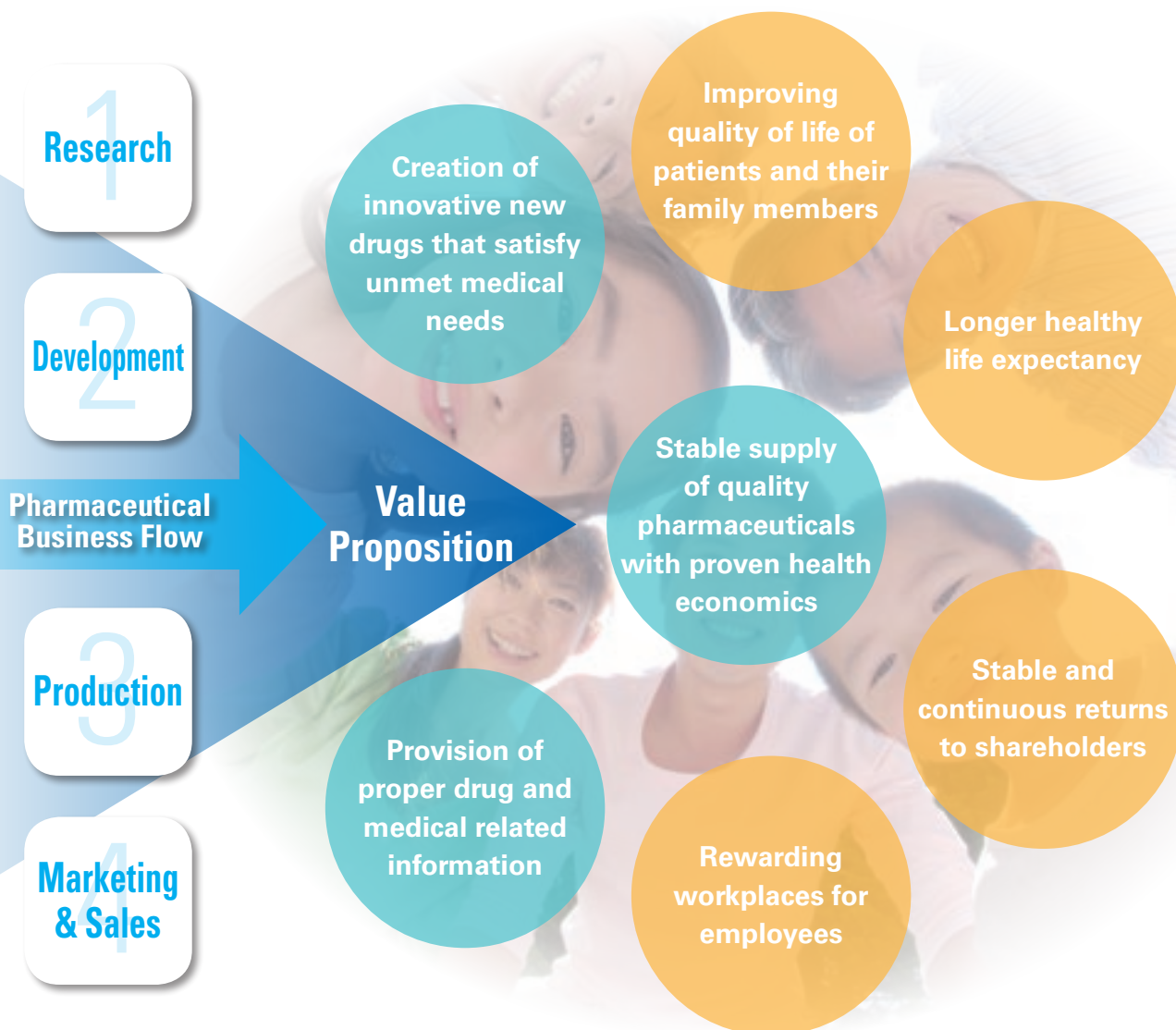
See p. 25 for more details ▶

KAKEN contributes to the safety and reliability of food production through its operations ranging from research and development to the manufacture and distribution of highly safe agrochemicals, feed additives, and drugs for animals with reduced burden on humans, animals and the environment.

As for agrochemicals, the Company primarily sells Polyoxins, a group of agricultural fungicides, and Pentoxazone, a rice herbicide, both in Japan and overseas.

As for feed additives and drugs for animals, the Company sells Salinomycin, an anticoccidial antibiotic for chickens, and Uroston, a drug for cattle, among others.

many people as possible to return smiles of happiness to their faces, through supplying superior pharmaceuticals.

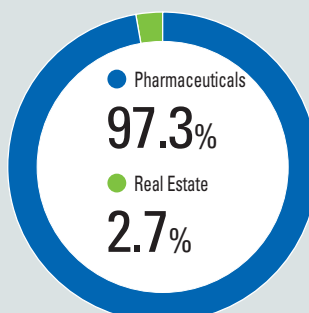


Real Estate Segment

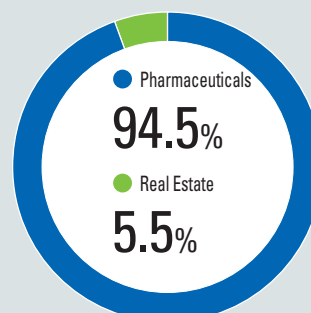
In the real estate segment, the majority of revenue comes from rent related to Bunkyo Green Court, a commercial complex built through redevelopment of land succeeded from the former Institute of Physical and Chemical Research. This source of stable revenue supports the Pharmaceuticals segment, the Company's core business.



Net sales ratio



Operating profit ratio



KAKEN's Priority Issues

The KAKEN Group delivers value to society and contributes to achieving a sustainable society by practicing our Corporate Philosophy: "KAKEN helps improve the quality of life of patients by serving as many people as possible to return smiles of happiness to their faces, through supplying superior

Process of Identifying Priority Issues

The Corporate Planning & Coordination Department and the General Affairs Department first identified the priority issues to be addressed through the Company's business activities, and extracted social issues by taking into account, among other factors, the status of our business, management plans, GRI Standards, and ISO26000.



The extracted social issues were mapped out based on two axes: "relevance to KAKEN's business" and "impact on stakeholders," and items with a high degree of importance were narrowed down. Based on the results of the above process, we selected priority issues by taking into account KAKEN's management philosophy, and listed up "associated risks and opportunities" and "main initiatives."

Priority Issues

Business Philosophy Three Joys	Priority Issues	
"Joy for patients" We strive to create and offer efficacious drugs that satisfy the needs of patients and medical professionals.	① Contributing to medical solution <ul style="list-style-type: none"> • Creation of innovative new drugs that satisfy unmet medical needs • Provision of pharmaceuticals with proven health economics • Partnerships with domestic and overseas companies, etc. 	
	② Fulfilling responsibilities as a pharmaceutical company <ul style="list-style-type: none"> • Stable supply of high-quality pharmaceuticals with proven safety • Activities to deliver appropriate information • Intellectual property strategies 	
"Joy as a company" We recognize our social responsibility as a pharmaceutical company, engage in all activities with high ethical standards, and aspire to earn society's trust.	③ Strengthening corporate governance <ul style="list-style-type: none"> • Strengthening relationships with stakeholders • Promotion of compliance • Risk management to ensure business continuity 	
	④ Consideration for the environment <ul style="list-style-type: none"> • Proper management of waste and wastewater • Efficient use of water and resources • Reduction of CO₂ emissions • Supply of environmentally-friendly agrochemicals 	
"Joy for employees" Our objective is to become a company with vitality and presence whose employees enjoy and take pride in their work.	⑤ Creating fulfilling workplaces <ul style="list-style-type: none"> • Generating and maintaining employment opportunities • Work-style reform and improved productivity • Employees' health, occupational safety and welfare • Diversity • Development of the next-generation human resources • Respect for human rights 	

pharmaceuticals.” We believe that this will lead to the sustainable growth of the Company. In order to set out the challenges and initiatives in achieving this objective, we have identified priority issues related to KAKEN’s future value creation.



	Associated Risks and Opportunities (Risks: ▲, Opportunities: ●)	Main Initiatives
	<ul style="list-style-type: none"> ▲ Insufficient development pipeline ▲ Changes in healthcare policy and market trends ● Fulfillment of unmet medical needs ● Contribution to society and improvement of the Company's presence through development of innovative drugs 	<ul style="list-style-type: none"> ● Focus management resources on R&D ● Promote alliances with overseas companies (in-licensing of products under development, out-licensing of in-house products, joint research, etc.)
	<ul style="list-style-type: none"> ▲ Decline in corporate value due to disruption in supply of pharmaceuticals ▲ Business impact from intellectual property risks ▲ Suspension of sales due to inappropriate activities ● Maximization of product value through stable supply and provision of useful information 	<ul style="list-style-type: none"> ● Maintain the GMP (Good Manufacturing Practice) level that meets domestic and international standards ● Generate evidence to improve product value, thus contributing to better medical treatment ● Utilize digital tools to establish efficient systems for delivering product information ● Global intellectual property strategies
	<ul style="list-style-type: none"> ▲ Decline in trust of stakeholders ▲ Disruption in supply chain ▲ Increased risk of violations of laws and regulations, misconduct, etc. ● Earning trust of stakeholders 	<ul style="list-style-type: none"> ● Strengthen governance framework ● Appropriate and timely information disclosure and dialogue ● Training and education on compliance, risk, and relevant laws and regulations ● Contribute to local communities (participation in local beautification initiatives, disaster relief support, etc.) ● Develop/update disaster and pandemic response plans
	<ul style="list-style-type: none"> ▲ Disruption in production due to water/resource depletion, etc. ▲ Decline in trust of society due to insufficient efforts ● Cost reductions from energy conservation initiatives ● Contribution to the world's food safety 	<ul style="list-style-type: none"> ● Roll out environmental management system ● Maintain ISO14001 certification (Shizuoka Factory) ● Continue CO₂ emission reduction initiatives ● R&D of environmentally-friendly agrochemicals
	<ul style="list-style-type: none"> ▲ Outflow of personnel ▲ Labor-related problems ▲ Decline in productivity ● Corporate growth from increased employee fulfillment and motivation ● Hiring and retention of talented personnel 	<ul style="list-style-type: none"> ● Work-style reform (digitalization of work processes, etc.) ● Appointment of female directors ● Enhance employment systems for employees with disabilities and senior staff ● Promote employees' disease prevention and mental health care ● Training programs, self-development support, and discrimination/harassment prevention

Medium-Term Business Plan 2021

Under the three-year Medium-Term Business Plan that started in 2019, we have set as our primary objective “establishment of growth foundations” that will allow us to survive through the difficult times, rather than being merely concerned about numerical management targets during the said period. KAKEN is focusing on the following four measures under this business plan.

1	Set enhancement of the R&D pipeline as our foremost priority, and allocate maximum management resources to this task.
2	Work on overseas expansion of Clenafin, as well as overseas expansion and additional indications of new products, thus maximizing the value of these products.
3	Aim to achieve consolidated net sales of ¥94.5 billion, through higher productivity from strengthening and optimizing the marketing base.
4	Improve the productivity of all employees through human resource development and training, in order to develop employees with distinctive capabilities, while endeavoring to streamline our organization and achieve appropriate staffing.

Numerical management targets for FY2021

Item	Numerical target (consolidated)
Net sales	¥94.5 billion
Operating profit	¥25.0 billion
ROE	12% or more

1 Enhance the R&D pipeline

Expansion and integration of the in-house drug discovery foundations

Enlarge technological foundations in the three priority areas

Immune system
Inflammatory skin diseases, allergic diseases, rheumatism, etc.

Nervous system
Neuropathic pain, etc.

Infectious diseases
Deep mycosis, etc.

Three year vision for the R&D pipeline

	At outset of plan (April 2019)	By FY2021 (planned)
Product launch or NDA application		● BBI-4000 ● KMW-1 ● Lenabasum
Clinical trial stage	Phase III: BBI-4000/KMW-1/Lenabasum (Corbus Pharmaceuticals Holdings, Inc.) Phase I: KP-607 Preparing for Phase I: KAR (Ivermectin) Exploratory clinical trials (Canada): KP-470 (Bausch Health Companies Inc.)	● KAR (Ivermectin) ● KP-607 ● KP-470 (In-house development in Japan) ● Accelerate R&D of compounds from in-house research ● In-licensing of products under development

2 Maximize the value of Clenafin and new products

Maximize the value of Clenafin through overseas expansion

Clenafin

East Asia: Strengthen and promote alliance with partner in each country
The United States and Canada: Distributed by the licensee, Bausch Health Companies Inc.

Outside of North America: Have license returned from Bausch Health Companies Inc. ▶ Consider new partners



Maximize the value of new products through overseas expansion and additional indications

Regroth

With a view to overseas expansion, integrate actual marketing data in Japan and analyze market opportunities

Products under development in Phase III

Consider measures for maximizing value

Lenabasum (for systemic sclerosis and dermatomyositis) → Expand to other intractable diseases, etc.

3 Strengthen and optimize marketing base

Grow sales by utilizing the marketing base

Post-marketing drug development

- Grow Regroth and Hernicore
- Strengthen our presence in dermatology and plastic surgery in preparation for the launch of BBI-4000 and KMW-1
- Actively in-license distribution rights for products that can have synergy with our marketing base

Grow core products

- Strengthen promotion of Clenafin, Artz, Seprafilm and others

Strengthen marketing base

- Allocate staff and structure organizations in accordance with product characteristics and therapeutic areas, in response to changes in the market and regulations
- Disseminate product evidence through academic conferences and study group activities

4 Develop our human resources and reform operations for improved productivity

Human resource development and training

- Improve the productivity of all employees and foster employees with distinctive capabilities
- Promote management that develops potential of individual employees to take full advantage of their strengths
- Develop human resources capable of delivering results on a global level

Reforms in operation and organization

- Assignment of right people in right positions, optimization of organizations, and improvement of operational efficiency including IT environment
- Improve the working environment through work-style reforms, etc. that enable all employees to show optimal performance
- Reduce manufacturing costs through well planned and efficient capital investments

Products in Late Development Phases (as of September 2020)

BBI-4000

(primary axillary hyperhidrosis treatment product)

* Approved for manufacture and sale as "ECCLOCK Gel 5%" on September 25, 2020

Primary axillary hyperhidrosis is a disease that causes profuse sweating from the armpits even without factors such as heat or mental stress. BBI-4000 is a topical product that inhibits sweating by blocking the action of acetylcholine, a neurotransmitter believed to cause the sweat glands to produce perspiration.

KMW-1

(eschar-specific removal product)

A topical enzyme formulation that removes eschar (necrotic tissue caused by burns). KMW-1 is marketed as NexoBrid outside of Japan, and is anticipated to reduce the burden on medical professionals and patients due to its ability to remove necrotic tissue more easily and selectively than surgical excision, without causing damage to healthy tissue.

Lenabasum

(systemic sclerosis and dermatomyositis treatment product)

Lenabasum induces the production of mediators with inflammation-resolving properties, returning the inflammatory state to normal without immunosuppression. It also prevents tissue fibrosis by acting directly on fibroblasts and inhibiting the production of extracellular matrix.



Q1

Could you start by telling us about the profile of yourself and your ambitions as President?

A1

We aim to build a “bottom-up” style company where employees play a central role in our growth, and I intend to lead these efforts.

I am originally from Osaka and have spent 36 years exclusively in sales since joining the company in 1984. Having served as general manager of the Hiroshima and Osaka sales branches, I moved to the head office and, after being appointed as Director, was responsible for overseeing the Marketing & Sales Division. My sales career, where I was assigned to university and major hospitals, gave me opportunities to collaborate with the R&D Division. I believe this experience helped me develop a company-wide perspective, rather than solely focusing on sales.

The business environment surrounding the pharmaceutical industry in Japan has undergone major shifts in recent years. In particular, government policies designed to keep down drug costs by lowering reimbursement prices and promoting the use of generic drugs have had a severe impact on our business. In addition, the global COVID-19 pandemic since the start of 2020 has had a negative influence on our business activities.

Amid these shifts in the business environment arisen from a range of factors including regulations and

systems, rather than reacting to them, we must take proactive actions to pioneer new growth opportunities and achieve breakthroughs. To do this, we need to create a “bottom-up” style company that does not rely on top-down leadership. It is each and every one of our employees that will drive the company's sustainable growth. As President, I will play a leading role in encouraging and fostering this culture, while always striving to make right and speedy management decisions.

I recognize that human resource strategy is the highest priority task for the company going forward. Improving the skills of our employees across the company will help drive innovation, create new value, and build stronger relationship of trust with society. These efforts will ultimately serve to “help improve the quality of life of patients” as set out in our Corporate Philosophy. We aim to become a company with a strong presence that is needed and valued by society, and to realize “joy for patients,” “joy as a company,” and “joy for employees” as set forth in our Business Philosophy. This is my personal mission as President.

We will take proactive actions toward anticipated changes and pioneer new growth opportunities.

Hiroyuki Horiuchi

President and Representative Director

Q2

Please provide a general overview of the company's efforts and results, by looking back on the business conditions in FY2019.

A2

Revenue declined due to our mainstay products being impacted by NHI drug price revisions and competing products. With regard to income, profit increased owing to lower research and development expenses.

Looking at our consolidated business results for FY2019, while net sales decreased from the previous period to ¥89,232 million (down 5.2% year on year), on the profit side, operating profit amounted to ¥26,512 million (up 7.8% year on year), ordinary profit amounted to ¥26,946 million (up 7.9% year on year), and profit attributable to owners of parent amounted to ¥19,370 million (up 9.0% year on year), against our initial projections of a decrease in profit.

The main factor for the decline in revenue was decreased sales of our mainstay products such as Artz, an anti-osteoarthritis agent, and Seprafilm, an absorbable adhesion barrier, due to the impact of NHI drug price revisions and competing products, including generics. Sales outside Japan were lower year on year. Sales of Clenafin, a topical onychomycosis treatment product, were flat year on year.

Looking at profit, although cost reductions showed results, the increase was primarily because of lower research and development expenses due to a reduction in experimental research costs.

In our development pipeline, a new drug application for primary axillary hyperhidrosis treatment agent BBI-4000 has been submitted. Topical onychomycosis treatment agent KP-607, which we developed in-house as a successor to Clenafin, is now in Phase II clinical development. Head lice treatment agent KAR (Ivermectin) progressed to Phase I. KMW-1, a burn wound eschar-specific removal agent is in Phase III clinical development.

In the last part of FY2019, due to the COVID-19 pandemic we refrained from visits to medical institutions for the purpose of providing drug information. It appears that patients being reluctant to visit medical institutions due to the COVID-19 pandemic have also had some impact on pharmaceutical sales. As these developments occurred from the fourth quarter, the impact on FY2019 results was limited. There is a risk that this impact will become more pronounced in our FY2020 results.

President's Message

Q3

Please update us on the status of the growth strategy set out in Medium-Term Business Plan 2021.

A3

We are making steady progress on efforts in each of the four key measures and developing a foothold for our sustained growth.

In FY2019, we launched “Medium-Term Business Plan 2021,” our new three-year plan. The basic policy of the Plan is “establishment of foundations for sustainable growth,” and under this Plan we aim to achieve net sales of ¥94.5 billion, operating profit of ¥25.0 billion, and an ROE of 12% or higher as the numerical management targets for consolidated FY2021, which is the final year of the Plan. The Plan will focus on four priority measures, namely to “enhance the R&D pipeline,” to “maximize the value of Clenafin and new products,” to “strengthen and optimize marketing base,” and to “develop our human resources and reform operations for improved productivity,” and we are implementing our growth strategy in order to achieve each of these priority measures.

In the first year of the Plan, we made steady progress of our R&D pipeline, including filing for approval of BBI-4000. However, we were unable to expand our development pipeline through in-licensing. We will continue to focus on progressing products in late-stage development to new drug application and launch them

as quickly as possible, while further strengthening the development of novel in-house products as well as in-licensing.

In March 2020, we commenced sales of out-licensed Clenafin in Hong Kong (overseas trade name: Jublia), further expanding our foothold for sales expansion in East Asia. As for our new products, Hernicore, a lumbar disc herniation treatment agent launched in FY2018, has been making steady inroads into the market.

With regard to our marketing base, we are working to improve operational efficiency by introducing new ICT tools and digital technology, while working on optimal allocation of human resources. The impacts of the COVID-19 pandemic on sales activities have made it necessary to further accelerate efforts in these areas.

As I mentioned when outlining my ambitions earlier, I believe that human resource strategy is our highest priority task, and I intend to steadily strengthen our human resource development over the three years of the Plan. We are currently working on a company-wide level to achieve this, primarily through promoting job rotations.



Medium-Term Business Plan 2021

Establishment of growth foundations to overcome challenging times

1

Enhance the R&D pipeline

2

Maximize the value of Clenafin and new products

3

Strengthen and optimize marketing base

4

Develop our human resources and reform operations for improved productivity

As for the consolidated results of FY2020, the Plan's second year, we anticipate a decline in net sales due to the NHI drug price revisions, and an increase in research and development expenses, projecting net sales of ¥82.9 billion (down 7.1% year on year), operating profit of ¥20.8 billion (down 21.5% year on year), ordinary

income of ¥21.2 billion (down 21.3% year on year), and net income attributable to owners of parent of ¥15.0 billion (down 22.6% year on year). As it is currently difficult to assess the effect of the COVID-19 pandemic on our business activities over the full year, we have not factored the impact of COVID-19 into our initial forecast.

Q4

Please tell us about your approach to ESG management, and your message to stakeholders.

A4

We have identified the priority tasks that we aim to address through our business activities. We will clarify their relationship with our Business Philosophy, and are working to implement measures.

Promoting environmental, social and governance (ESG) management is critical for KAKEN to achieve sustainable improvement of its corporate value and continue to survive in society. At the same time, we recognize the need to address the SDGs (United Nations Sustainable Development Goals for 2030), from the viewpoint of aiming to be a company that grows together with society and the environment and solving social issues through our business activities.

We have always been taking pride in contributing to people's health and happiness through providing pharmaceutical products and in being engaged in business activities serving public and social interests. We have identified new priority issues to address through our business activities and clarified their relationship with our Business Philosophy. These are comprised of five items, namely, (1) Contributing to medical solution and (2) Fulfilling responsibilities as a pharmaceutical company, for creating joy for patients; (3) Strengthening corporate governance and (4) Consideration for the environment, for creating joy as a company; and (5) Creating fulfilling workplaces, for

creating joy for employees (see p7-8 for further details).

While all of these tasks need to be addressed in conformity with KAKEN's unique value generation process, with regard to the task of strengthening corporate governance, in particular, we will maintain management transparency and soundness by proactively introducing external perspectives, such as increased number of Outside Directors and establishment of the Nomination and Compensation Committee, and thus build a governance structure that will help increase our corporate value.

At KAKEN, always conscious of the "patient-first" principle, we are committed to supporting medical professionals and contributing to people's health and happiness by providing excellent pharmaceutical products. To repay our shareholders for their support, we will further enhance the return of profits to shareholders, while striving to make KAKEN a rewarding and fulfilling workplace for our employees. We will continue striving toward our goal of making KAKEN a company that brings smiles to all of our stakeholders.

(July 2020, at KAKEN'S Head Office)

Value Chain and Four Divisions

We have an established system to deliver new pharmaceuticals with proven safety and efficacy, confirmed through stringent processes including basic research, various studies, reviews and approvals from Japanese Government.



As a pharmaceutical manufacturer, KAKEN utilizes the technologies it has developed throughout its long history as well as its distinguished R&D staff to advance research and development activities to continually develop new drugs.

The Drug Research Centers in Kyoto and Shizuoka and the CMC Center in Shizuoka advance drug discovery research through collaborative, coordinated efforts. The Drug Research Centers synthesize candidate compounds for creating new pharmaceuticals and evaluates their pharmacological effects, pharmacokinetics, and safety by using animals and cell cultures. The CMC Center develops manufacturing processes for candidate compounds, designs formulations, conducts studies aimed at actual production, establishes specifications and testing methods, and carries out stability tests.

The Clinical Development Department confirms the efficacy and safety of in-house or in-licensed candidate compounds on human subjects through clinical trials. The Company conducts not only independent clinical trials, but also joint clinical trials with other companies (including joint global clinical trials). The R&D Quality Assurance Department manages the reliability of test plans and reports for the research divisions and clinical development divisions. These clinical development-related divisions mutually cooperate with the research divisions in an effort to conduct clinical trials at the earliest possible time.

The Company strenuously works to expand the development pipeline through promotion of joint research with other companies and research institutions as well as in-licensing activities.



The Regulatory Affairs Division consists of three departments: the Quality Assurance Department, the Pharmacovigilance Department and the Regulatory Affairs Department. The division files various applications with the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA), and responds to reviews and investigations related thereto, in accordance with stipulated regulations for development and marketing of pharmaceuticals, by working closely with the R&D Division. The division also holds responsibility as marketing authorization holder of pharmaceuticals, by determining the market release of pharmaceuticals based on confirmation that they are manufactured in accordance with approved methods and procedures, and by confirming that there are no issues with the safety information obtained from sales divisions, etc.

The Quality Assurance Department works to assure quality by periodical quality audits on manufacturing sites and the collection and investigation of complaints. The Pharmacovigilance Department collects and evaluates safety management information, takes necessary safety measures, reflects them into the package inserts and otherwise promotes the proper use of pharmaceuticals. All of these efforts are made with the aim of maintaining the quality, efficacy and safety of pharmaceuticals. The Regulatory Affairs Department is responsible for application for the approval of pharmaceuticals, in addition to maintaining approvals and licenses of marketing authorization, application for listing in the National Health Insurance (NHI) Drug Price List, and the preparation of product information materials.



Production

Production Division

The Production Division makes efforts to provide high quality pharmaceuticals, etc., in a stable manner. In particular, we maintain a high level of quality and supply products stably to consistently deliver products to patients and medical professionals with guaranteed efficacy and safety. In addition, we are working to improve the GMP (Good Manufacturing Practice) level of each employee. The quality of our products meets global standards, and they also pass on-site inspections by relevant authorities of the United States and Asian countries.

In order to respond to recent significant changes in the environment surrounding the pharmaceutical industry, we also aim to strengthen our efficient production and quality assurance systems. We built a new factory for topical medicine in 2016 to start the efficient production of Clenafin, which is a topical

onychomycosis treatment product. On the other hand, we are outsourcing the manufacture of agrochemical ingredients and are downsizing the fermentation production line which has been operating since our plant was established. Furthermore, a new quality control building was completed in 2018 with a view to improving the test environment and enhancing our quality control system.

The Production Division continues its production activities with a focus on improving quality, maximizing product value and enhancing cost performance by making appropriate investments in facilities using a risk-based approach, establishing a supply system for developing international markets, and responding appropriately to domestic and overseas regulations.



Marketing & sales

Marketing & Sales Division

In order to ensure that the prescription drugs and medical devices sold by the Company are properly used, we provide medical information mainly through three of our units, namely, Sales & Marketing, Science, and Sales Promotion. At Sales & Marketing unit, medical representatives (MRs) provide medical professionals with proper usage information. While providing information, they also concurrently collect information related to product safety and suggestions for product improvement and share the information within the Company. Such efforts lead to information provision and product improvement that meet the needs of medical practices. In recent years, provision of high value-added information is being required within a limited amount of time, due to the introduction of the Guidelines for the Improvement of Commercial Transaction Practices of Ethical Drugs for Manufacturers, Wholesalers, and Medical Institutions/ Pharmacies, work-style reforms of medical professionals, and the spread of the COVID-19 pandemic. In response to the rapidly changing

environment, we are working to improve the quality and speed of our information provision by utilizing digital tools in addition to face-to-face meetings, providing web lectures, introducing IT systems for sales support, and restructuring our sales organizations. MRs need to have not only knowledge of the products themselves, but also highly-technical knowledge such as related medical information. For this reason, each and every one of the MRs devotes themselves to acquiring new knowledge on a daily basis, undergoing employee education and training with support from Science unit. Sales Promotion unit is in charge of product distribution, delivering to medical institutions via pharmaceutical and medical-device wholesalers.

Going forward, the Company is committed to undertaking higher-quality information provision activities so as to gain an even stronger presence in the fields of dermatology and orthopedics, where its mainstay products are promoted, and become a company essential for regional healthcare.



We are conducting R&D with clear goals in order to provide patients with easy-to-use, distinctive new drugs that meet unmet medical needs.

Masanao Shimano

Corporate Officer
Chief Officer of R&D Division

We are striving to develop innovative new pharmaceuticals based on the accumulated technologies and our firm resolve.

KAKEN upholds its Corporate Philosophy to “help improve the quality of life for patients by serving as many people as possible to return smiles of happiness to their faces, through supplying superior pharmaceuticals.” The key element to that end is KAKEN's research and development. With the objective of bringing smiles of happiness to the faces of as many patients as possible, the Company engages in research and development activities in an effort to continually develop innovative new drugs that meet unmet medical needs, based on the technologies it has fostered over many years as a pharmaceutical manufacturer and its firm resolve.

The Company focuses its investments and human resources in research and development themes within fields where its experience, technologies and foundations can best be utilized: namely, the immune system field, the nervous system field, and the infectious diseases field. The Company's R&D staff predicts future needs and explores any latent needs that may lie behind existing drugs, and generates and promotes research projects by searching for and optimizing target sites and methods of administration in order to develop easy-to-use, distinctive new drugs.

KAKEN's drug discovery research is conducted at the Drug Research Centers in Kyoto and Shizuoka as well as the CMC Center in Shizuoka. The Company has introduced state-of-the-art equipment and technologies

to effectively advance its drug discovery research that requires a long and strict research processes. The success of research activities primarily depends on the expertise of research personnel. Since the manpower, research and development expenses, and time allocated can generate several times the value invested depending on the abilities of the R&D staff entrusted with these resources, we actively engage in human resource development within and outside the company. In particular, each department's leaders and project managers responsible for propelling research projects and making appropriate decisions in a timely manner hold the key to research direction and success, and accordingly we are working to develop personnel with these capabilities. As part of these efforts, we dispatch researchers to research institutions in Japan and overseas to further enhance their expertise, and also strive to introduce state-of-the-art technologies and knowledge.

KP-607, which is developed through in-house discovery, is currently under the phase of clinical trials. KP-607, the successor to Clenafin, an onychomycosis drug launched in 2014, has completed the Phase I stage (clinical pharmacological trial) and advanced to the Phase II stage (exploratory trial) in FY2020. With a number of themes that progressed into the preclinical stage or the new drug discovery stage, the Company is strenuously working on research and development activities.

Status of products under development (as of the end of June 2020)

Development code	Indication	Development stage				
		Phase I	Phase II	Phase III	Application	Approval
BBI-4000*	Primary axillary hyperhidrosis	Phase III			Under application	
KMW-1	Removal of eschar	Phase III				
KAR (Ivermectin)	Head lice	Phase III preparation				
KP-607	Onychomycosis	Phase II				

* BBI-4000 was approved for manufacture and sale as “ECCLOCK Gel 5%” on September 25, 2020.

KAKEN is propelling joint research, together with research institutions and companies in Japan and overseas, and in- and out-licensing of products under development.

Enhancement of our development pipeline is essential to ensure the continued launch of new drugs. To this end, we actively conduct joint research and development, as well as in-licensing of products under development, with domestic and overseas pharmaceutical companies and research institutions, in parallel with in-house drug discovery.

In FY2019, BBI-4000 (indication: primary axillary hyperhidrosis; in-licensed from Brickell Biotech, Inc. in the United States) completed Phase III trial (confirmatory trial), and is currently awaiting approval for manufacture and sale. Meanwhile, Phase III trial of KMW-1 (indication: removal of eschar; in-licensed from MediWound Ltd. in Israel) is currently progressing on schedule. In addition, Ivermectin lotion, 0.5% (indication: head lice infestation) which was in-licensed from Arbor Pharmaceuticals, LLC. in the United States in FY2018 has begun clinical trial, and Lenabasum (indication: systemic sclerosis and dermatomyositis),

which was in-licensed from Corbus Pharmaceuticals Holdings, Inc. in the United States, is currently in Phase III clinical trial. As for discovery research themes, the Company concluded a collaborative research agreement for the identification of a multispecific antibody candidate for development in inflammatory diseases with Numab Therapeutics AG in Switzerland, which has a multispecific antibody technology platform.

We also utilize outsourcing to conduct efficient R&D, and in recent years, we have expanded and integrated our R&D infrastructure to challenge new research fields.

To accelerate our R&D and deliver easy-to-use and distinctive new drugs to patients as quickly as possible, we make swift decisions and advance our research projects continually while valuing the creativity and scientific judgment of our R&D team. Going forward, we will expand our development pipeline to continuously provide new drugs.

Pick up Drug Research Centers

The Drug Research Centers are comprised of the Chemistry Department, Pharmacology Department, Pharmacokinetics and Safety Department, and Research Planning and Collaboration Department, and strive to discover effective, world-leading medications based on our management philosophy of "creating joy for patients." By concentrating our limited resources in the immune system field, the nervous system field, and the infectious diseases field, we aim to further expand our research base and enhance our development pipeline.

Although competition in the immune system and the nervous system fields is fierce on a global scale, we are proceeding with our drug discovery research by concentrating on themes with high originality, while focusing on diseases with future unmet medical needs such as inflammatory skin diseases and neuropathic pain.

In the infectious diseases field, we have consistently conducted R&D into antifungal agents since the Company's foundation. KP-607, an in-house drug that was developed as a successor to Clenafin, an onychomycosis treatment, is currently in the Phase II stage. We are currently focusing on the discovery of drugs for deep fungal infections - a field in which the Company's R&D know-how can be directly applied, and where unmet medical needs remain.

To complement the in-house drug discovery, we are actively searching for external seeds and



Hironobu Ogura
Chief of Drug Research Centers
(currently CMC Center)

new drug discovery technologies both within Japan and overseas to promote in-licensing and joint research. Furthermore, we are working to accelerate and improve the success rate of the approval process by capitalizing on joint development and outsourcing. We are steadily conducting non-clinical trials of KP-607, our in-house drug, and in-licensed products including BBI-4000, KMW-1, Lenabasum and KAR, and proceeding with regulatory filing with the aim of gaining rapid approval in Japan and overseas.

In our work environment, any member, including junior researchers, is able to propose new research themes and take initiatives to lead these projects. With an eye to the future, we are also working to explore new disease fields and modalities other than small molecule compounds. We are convinced that the sense of mission and passion of each and every member of the team will consistently lead to "creating joy for patients."



As professionals who reliably meet the medical needs of our stakeholders, we are firmly focused on post-marketing drug development.

Hiroshi Miyama

General Manager of Medical Affairs Department, R&D Division

Our mission is to meet unmet medical needs and provide the optimal medical treatment to medical professionals and patients.

The Medical Affairs Department is a new unit in only its second year, tasked with the important mission of delivering new benefits to medical professionals and patients by generating high-quality evidence and communicating appropriate information in order to satisfy medical needs not currently met by conventional treatments (unmet medical needs).

To accurately identify unmet medical needs in real time, in addition to conducting medical journal surveys, we also share information through medical and scientific information exchanges with external medical experts as well as planning and holding advisory board meetings. Some of these medical needs provide hints that can lead to improved formulations or additional indications. To respond to the unmet medical needs and clinical questions that we have identified through this information sharing process, we then develop a medical strategy (medical plan) for maximizing the medical value that our drugs provide to medical professionals and patients. Medical plans include specific details regarding the planning and

implementation of clinical studies and observational studies of the Company's pharmaceuticals, research support, non-clinical research, and various data analyses, and aim to generate evidence that helps provide scientific answers to the needs in question. Based on the evidence generated, we believe it is our role to provide information and support to medical professionals through publication of academic papers as well as conference presentations, and to communicate appropriate information to patients for raising awareness of diseases.

As stated above, in order to meet the unmet medical needs, we repeat and implement a series of processes to identify the unmet medical needs, prepare medical plans, generate evidence, and implement information provision and communication. I believe that these processes will translate into increasing the value as pharmaceuticals that are truly beneficial to patients and proceeding with the so-called "drug fostering," and that this will in turn lead to the provision of the optimal medicine.

Through the mission of the Medical Affairs, we work to deliver the true value of innovative in-house developed and marketed drugs.

KAKEN's excellent R&D capabilities are exemplified by the following products: Clenafin, the first topical treatment for onychomycosis launched in Japan; Fibblast Spray, the world's first basic fibroblast growth factor (bFGF) spray-on drug for the treatment of pressure ulcers and other skin ulcers; and Regroth Dental Kit, the world's first medicinal product for periodontal regeneration, featuring the same active ingredient of bFGF. These are innovative drugs developed in-house by KAKEN that satisfy unmet medical needs. In the orthopedic field, we offer Hernicore, a treatment for lumbar disc herniation that serves as an intermediate between conservative and surgical treatment,

contributing to patient benefits.

To continue developing these innovative drugs and fostering them, it is important that we continue striving to identify and respond to unmet medical needs.

While maintaining a strong sense of professional awareness, KAKEN's Medical Affairs Department makes serious efforts to identify the unmet medical needs related to these drugs and appropriately provides information on their efficacy and safety from a scientific point of view. By doing so, we will fulfil the needs of medical professionals and patients and continue to deliver the true value of innovative in-house developed and marketed drugs.



The virtuous cycle between in- and out-licensing activities, utilizing our strong presence in the therapeutic areas, and strengthening our alliance activities with our partner companies - this contributes to the sustainable growth of the Company.

Motonori Miyakawa, Ph.D.

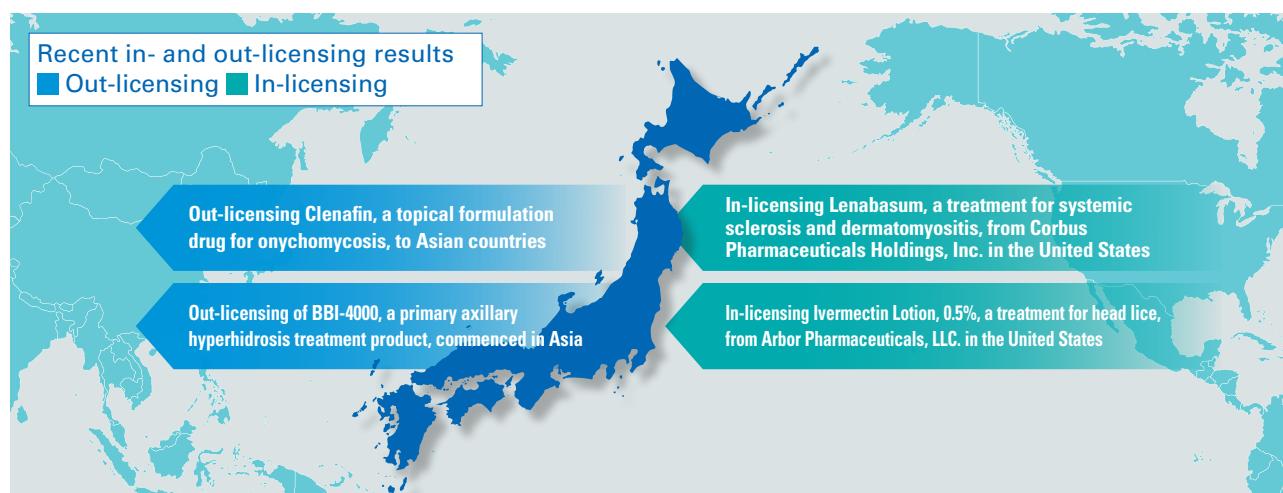
General Manager of Business Development Department

The recent in- and out-licensing activities have increased the Company's presence in the pharmaceutical industry, and has contributed to building relationships with new partner companies.

The Business Development Department has consistently worked on the in- and out-licensing activities and the subsequent alliance management with our partner companies. The absorbable adhesion barrier Seprafilm is the in-licensed product from an overseas company. The in-licensing activity of basic fibroblast growth factor (bFGF) led to the development and launch of such unique products as Fiblast Spray, a wound-healing product, and Regroth Dental Kit, a medicinal product for periodontal regeneration. In out-licensing, we out-licensed Clenafin, a topical formulation drug for onychomycosis, to Dow Pharmaceutical Sciences, Inc. (DPSI; currently Bausch Health Companies Inc.), a U.S. startup company specialized in development of topical formulations, at the preclinical stage. As a result of synergy between our strengths in antifungal research and DPSI's drug formulation technologies and development capabilities in dermatological therapeutic area, Clenafin obtained approval through the global study and launched simultaneously in Japan and the United States. To deliver Clenafin to the patients with onychomycosis around the world, we have to date out-licensed Clenafin to partner companies in Asian countries, while working on further increasing its geographical scope.

Because of the success of Clenafin, the Company has greatly improved its global recognition and presence in the dermatology area. In recent years, the Company has entered into in-licensing agreements with such U.S.-based specialty firms as Corbus Pharmaceuticals Holdings, Inc. (Lenabasum: systemic sclerosis and dermatomyositis treatment product; global Phase III study is ongoing), and Arbor Pharmaceuticals, LLC. (Ivermectin Lotion 0.5% treatment for head lice; in Phase I in Japan). We expect these achievements to have positive effects on sales and co-promotion partnerships in the future. A good example is BBI-4000, a treatment for primary axillary hyperhidrosis. We began out-licensing activities for this product in major Asian countries, and have already received a number of inquiries from pharmaceutical companies in each country. We are continuing our efforts to strengthen the capabilities of our team to further develop this virtuous cycle of partnerships.

We will continue to seek in- and out-licensing opportunities for new products that contribute to sustainable growth of the Company, and strive to strengthen our relationships with existing partner companies.



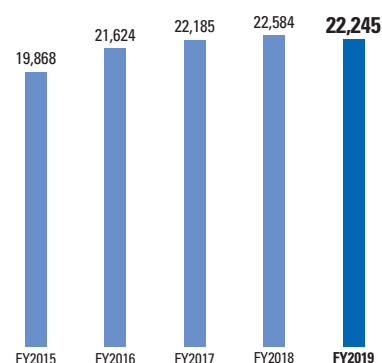
Overview of Major Products

KAKEN provides highly competitive drugs in the global market, focusing on the orthopedic and dermatological therapeutic areas.

Clenafin [topical onychomycosis treatment agent]



Sales (Millions of yen)

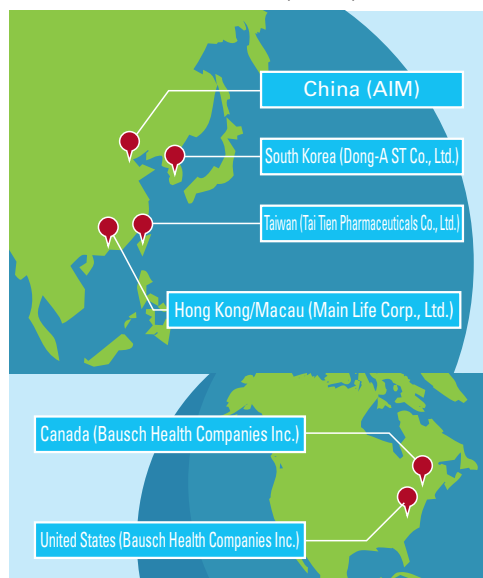


Launched in Japan in September 2014, Clenafin is the country's first topical treatment for onychomycosis. This drug contains efinaconazole, which was discovered by KAKEN, as its active ingredient. Possessing high antifungal activity against the causative fungus for the infection of onychomycosis, and excellent nail permeability as it has low affinity for keratin, which is the major component of nails, Clenafin has proven effective in treating onychomycosis through a once-daily application to the infected nails.

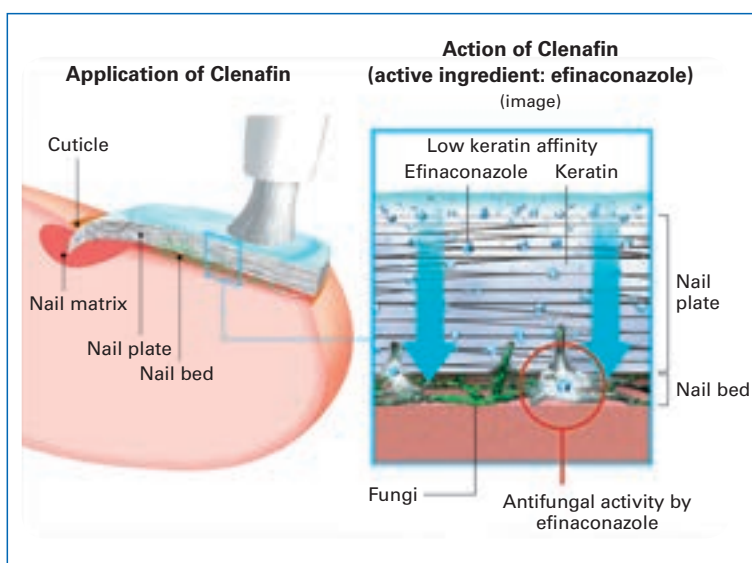
Clenafin comes packaged in a bottle with a connected brush, making it easy to apply the drug across the surface of nails. As a new therapeutic option for onychomycosis, Clenafin is used at many medical institutions, primarily by dermatologists.

Outside Japan, Clenafin is marketed by licensee companies in respective regions. It has been marketed under the trade name Jublia since 2014 in the United States and Canada, since 2017 in South Korea, since 2018 in Taiwan, and since 2020 in Hong Kong and Macau. In China, where it was licensed in 2019, the licensee company is now working toward launch.

Global launches of Clenafin (Jublia)



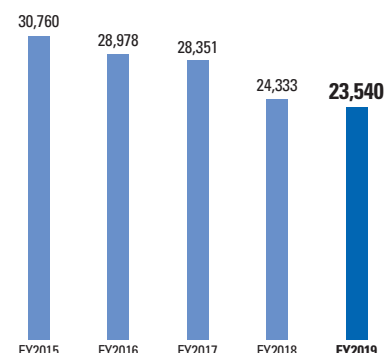
Mechanism of Action of Clenafin



Artz [anti-osteoarthritis agent]



Sales (Millions of yen)



Artz is an anti-osteoarthritis agent. Its active ingredient is purified sodium hyaluronate extracted from fresh chicken combs, and it has viscoelastic, water-retentive, and lubricating properties. Seikagaku Corporation holds the license to manufacture and distribute the drug.

Artz exhibits pharmacological effects, including suppression of cartilage degeneration, pain suppression, improvement in range of joint motion, prevention of tendon adhesion, improvement of lubrication, suppression of synovial membrane inflammation, and improvement in properties of pathological synovial fluid. Possessing

such efficacy, Artz was launched in 1987 as the world's first hyaluronic drug indicated to treat osteoarthritis in the knee by intra-articular injection. Later in 1989, an indication for shoulder periarthritis was added. In 2005, an indication for knee joint pain in rheumatoid arthritis was added.

In 1992, Artz Dispo, a kit product with disposable pre-filled syringe, was launched mainly to make injection procedures simpler and faster as well as to reduce the infection risk. Since then, its formulation has been improved to meet various needs.

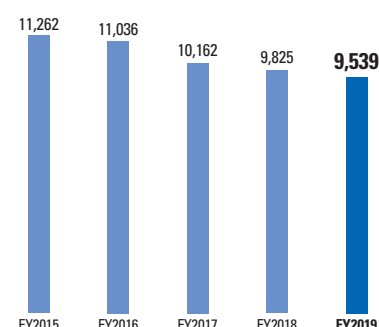
Seprafilm [absorbable adhesion barrier]

Developed by Genzyme Corporation of the United States (presently Sanofi K.K.), Seprafilm is a semitransparent film-type absorbable adhesion barrier. It was approved by the U.S. FDA in 1996, and it is now used globally. In Japan, Seprafilm has been used for over 20 years since its launch in the market in 1998.

Seprafilm transforms into a hydrated gel within 24 to 48 hours after being applied to tissue that has been damaged by surgery. It then remains in place for approximately seven days, preventing adhesion by forming a physical barrier between the damaged tissue and the healthy tissue surrounding it. Owing to its firm contact with wet tissues, there is no need for sutural attachment. In addition, surgical removal is unnecessary because Seprafilm is a bioabsorbable material composed mainly of sodium hyaluronate and



Sales (Millions of yen)



carboxymethyl cellulose, both of which have long been used as pharmaceutical and food additives. Furthermore, it has been proved not to hinder the normal process of wound healing.

To suit market needs, new types have been added and there are now four types of Seprafilm available. Thus allowing surgeon can select one depending on usage.

Overview of Major Products

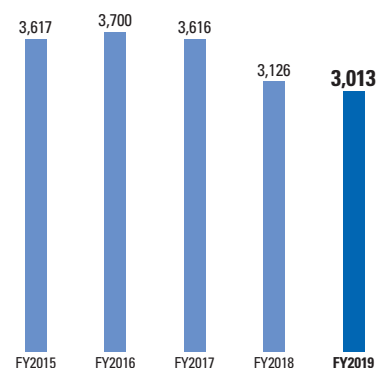
Fiblast [wound-healing agent]

Fiblast is a spray-on drug for the treatment of pressure ulcers and other skin ulcers containing the active ingredient trafermin, which is a recombinant human bFGF (basic fibroblast growth factor). It facilitates wound healing mainly by promoting angiogenesis and granulation formation.

Following the discovery of bFGF in 1974, the entire DNA sequence of the human bFGF gene was mapped by Scios Inc. of the United States in 1986. As recombinant bFGF became available, dramatic advances in basic and clinical application research demonstrated that bFGF promotes the migration and proliferation of various cells mediating wound repair.



Sales (Millions of yen)



KAKEN signed a licensing agreement with Scios in 1988 and began research and development activities in 1989. The safety and efficacy of Fiblast for pressure ulcers and other skin ulcers (burn and leg ulcers) were demonstrated in clinical trials. In 2001, Fiblast was launched as the world's first human bFGF preparation in Japan.

Regroth [medicinal product for periodontal regeneration]

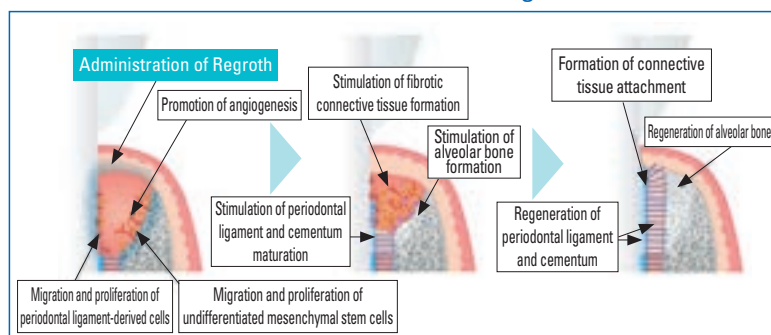
FY2019 Sales: **¥683 million**

Regroth is the world's first medicinal product for periodontal regeneration. Its active ingredient is trafermin, a recombinant human bFGF (basic fibroblast growth factor). In addition to the wound-healing effects on various cells demonstrated by Fiblast, which was launched in 2001, bFGF was shown to promote the proliferation of undifferentiated mesenchymal stem cells and periodontal ligament-derived cells as well as facilitate angiogenesis when administered to periodontal tissue defects, demonstrating promotion of periodontal tissue regeneration.

Recognizing that bFGF could become a drug to regenerate periodontal tissue damage caused by periodontitis, KAKEN pursued development and conducted five clinical trials in Japan targeting approximately 1,000 periodontitis patients undergoing periodontal flap surgery. The results confirmed the efficacy and safety in periodontal tissue regeneration, including augmented alveolar bone, leading to the launch of Regroth in Japan in December 2016.



Mechanism of Action of Regroth



Hernicore [lumbar disc herniation treatment agent]

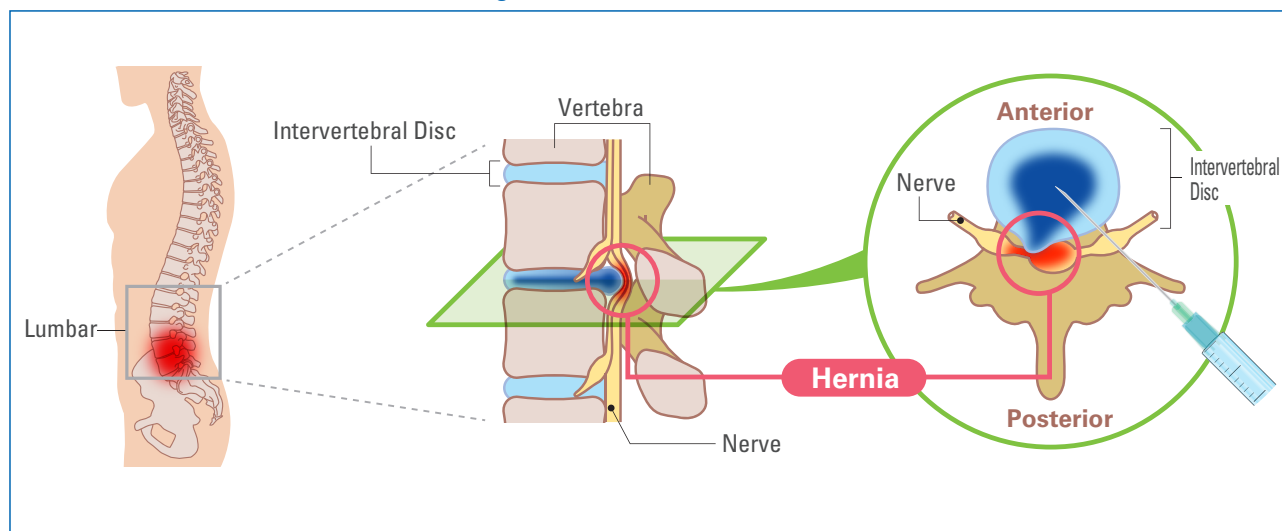
FY2019 Sales: **¥381 million**

Hernicore is a new lumbar disc herniation treatment agent with condoliase, which was approved in Japan ahead of the rest of the world, as the active ingredient.

Condoliase specifically dissolves glycosaminoglycans, a waterretaining component within the nucleus pulposus of the intervertebral disc, without dissolving protein. Therefore, Seikagaku Corporation, the manufacturer and distributor of Hernicore, conjectured that there was low risk of condoliase causing significant injury to nerve tissues around the intervertebral discs, and began developing a new drug for enzyme injection therapy. In Japan, after confirmation of the efficacy and tolerability in domestic clinical trials, approval was obtained for the indication of Hernicore in the treatment of lumbar disc herniation by prolapse of the posterior longitudinal ligament for which sufficient improvement cannot be obtained through conservative treatment, and the product was launched by KAKEN in August 2018.



Image of Hernicore Administration



Other products

Adofeed	Pain- and inflammation-relieving plaster
Ebrantil	α 1 blocker to treat dysuria and hypertension
Procylin	Oral-use prostaglandin I ₂ analog
Mentax	Anti-trichophyton agent
Lipidil	Anti-hyperlipidemia agent
Loxoprofen Na Tape	Pain-relieving and anti-inflammatory plaster

Agrochemicals

Towards sustainable agriculture that can be operated in harmony with nature, KAKEN supports agriculture in an effort to contribute to food safety and security by offering eco-friendly, low residue products that have a low impact on humans, animals and the environment.



Business features

We conduct an integrated operation for agrochemicals, feed additives, and drugs for animals, covering from research and development to marketing. As for agrochemicals, we develop and market focusing on our original products including fungicide, Polyoxin and rice herbicide, Pentoxazone for paddy fields both in and outside Japan. Polyoxin, a substance produced using a fermentation process, exhibits the characteristic mechanism of action known as chitin synthesis inhibition. As fungicides with a high level of safety for humans and animals and a low risk to the environment, they have long been well accepted by farmers both in

and outside Japan since its registration as an agrochemical in Japan in 1967. Pentoxazone has excellent herbicidal effects on some annual weeds in paddy fields, and is even effective on weeds resistant to some herbicides, making it an indispensable active ingredient for paddy rice production. Furthermore, we are working to expand our product lineup by introducing and developing Metamifop, a rice herbicide for paddy fields.

Regarding feed additives and drugs for animals, we contribute to livestock farmers by marketing Salinomycin, an anti-coccidial feed additive for chickens, and Uroston, a drug for cattle.

Herbicides

Pentoxazone

Synthesized at the Sagami Chemical Research Institute and developed by KAKEN, Pentoxazone is an oxazolidinedione-type rice herbicide for paddy fields. Since its registration as an agrochemical in 1997, it has been widely used as a rice herbicide for paddy field.

Pentoxazone is very safe for paddy rice plants, and it offers a broad application timing, including before, after and simultaneously during rice transplanting. Furthermore, Pentoxazone is an environmentally friendly agrochemical having a low risk of the herbicide runoff in the environment that occurs after a treatment because of its high soil adsorption and low water solubility. It is marketed in Japan and South Korea.



Metamifop

Metamifop is a rice herbicide for paddy fields which we have in-licensed from Farm Hannong of South Korea. We launched TODOME MF granules and emulsion in 2018, SHIAGE MF granules in 2019, and TODOMEBAS MF solution in 2020.

Metamifop is highly effective against many weeds of the *Gramineae* family, including barnyard grass at high foliar ages, and is very safe for paddy rice. It is expected to serve for more efficient weed control in paddy fields.





Fungicides

Polyoxins

Discovered by the Institute of Physical and Chemical Research in 1961, Polyoxins are substances derived from fermentation culture of *Streptomyces cacaoi* var. *asoensis*, an actinomycete isolated from soil collected from the Aso district of Kumamoto, Japan. Polyoxins are commercially available in two product types: Polyoxin AL based on a Polyoxin complex as the active ingredient, and Polyoxin Z based on Polyoxin D zinc salt as the active ingredient. Polyoxins are highly safe for both humans and animals and it has been confirmed that they are readily biodegraded in the environment by soil microorganisms, making them environmentally-friendly pesticides with no risk of long-term residues. Polyoxin AL exhibits a broad antifungal activity against diseases caused by filamentous fungi on vegetables, fruit trees, flower plants, and the like, and it has been approved for expanded use for spider mites and thrips (molting inhibitor). Polyoxin Z is widely used for the prevention of not only diseases of turf, vegetable and fruit trees, but also diseases of nut trees.

Polyoxins are marketed in 16 countries, mainly South Korea, China, and in North America. In particular, due to its high level of safety, Polyoxin Z is exempted from setting maximum residue level (MRL) in countries such as United States, Canada, and New Zealand.



Feed additives

Salinomycin

Salinomycin, a feed additive discovered and developed by KAKEN in 1968, is a polyether antibiotic obtained from a culture solution of *Streptomyces albus*, a strain of actinomycete. Salinomycin is contributory to poultry production as an agent for preventing chicken coccidiosis.

Drugs for animals

Uroston

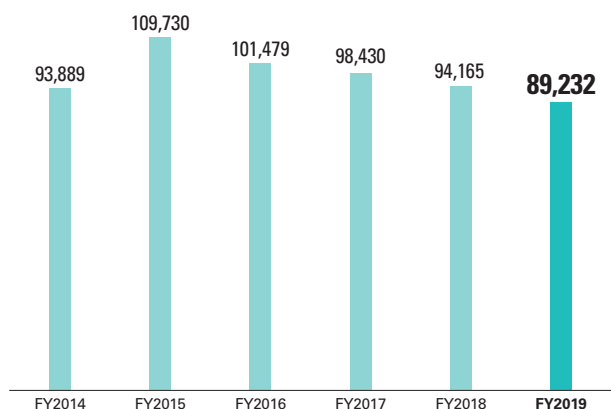
Uroston, an herbal medicine mainly consisting of extracts from naturally occurring *Quercus Salicina Blume*, serves to prevent and treat bovine urolithiasis. It promotes the dissolution of phosphate urinary calculus as well as prevents bovine urinary calculus and facilitates excretion through effects of calculus formation suppression, urinary pH reduction, anti-inflammatory activity, and diuresis.



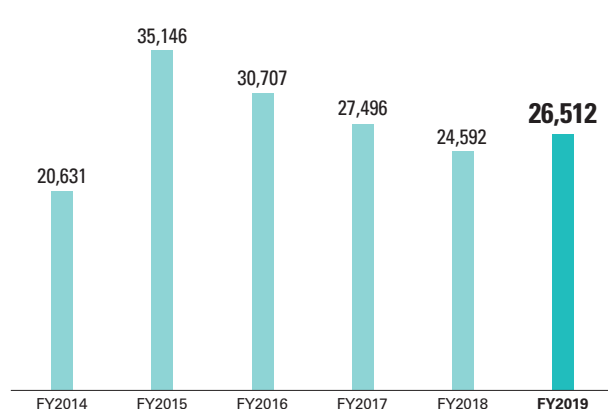
Financial and Non-Financial Highlights

Financial Highlights

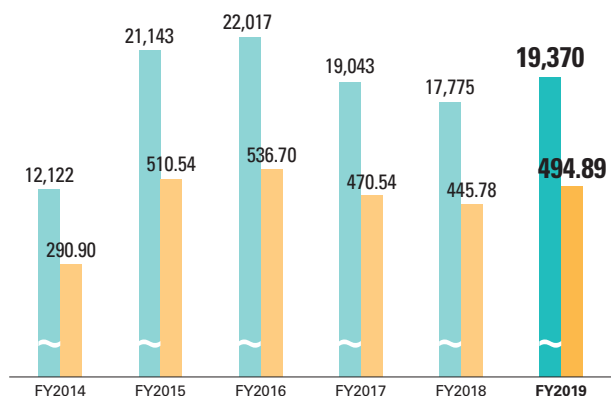
Net sales (Millions of yen)



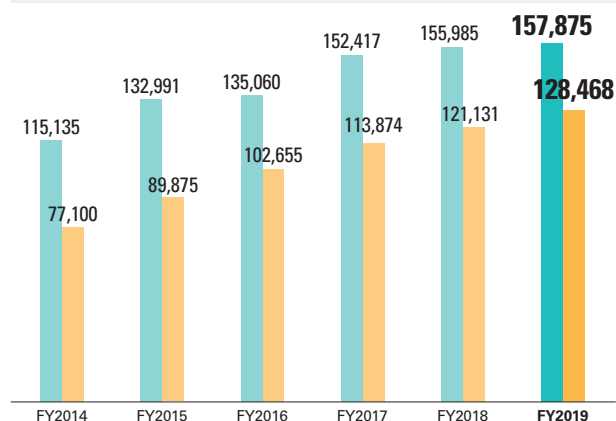
Operating profit (Millions of yen)



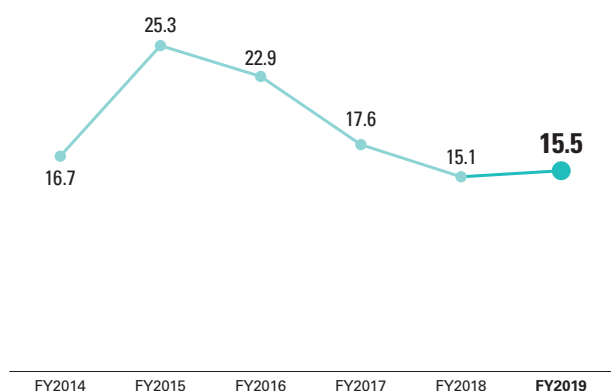
■ Profit attributable to owners of parent (Millions of yen)
■ Profit per share (Basic) (Yen)



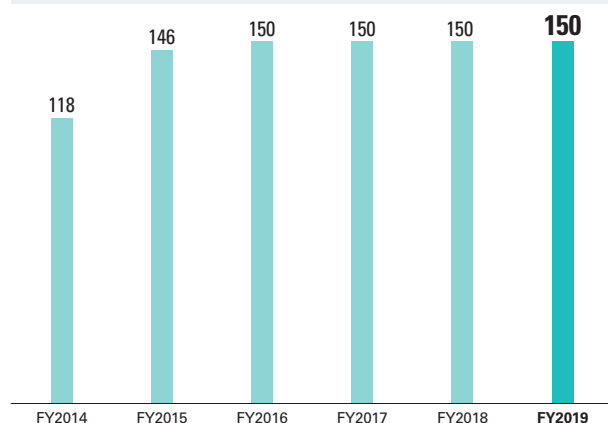
■ Total assets (Millions of yen)
■ Net assets (Millions of yen)



ROE (%)



Dividends per share (Yen)

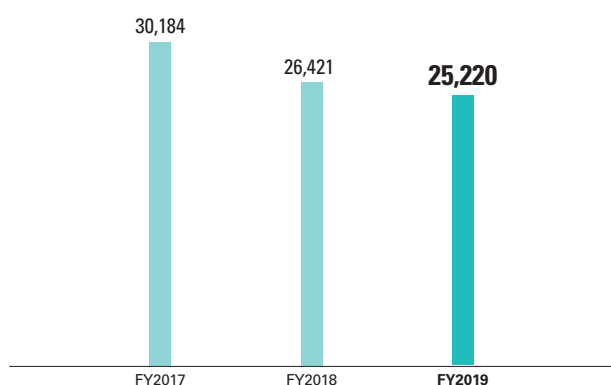


* The Company implemented a one-for-two reverse stock split on October 1, 2015. Dividends paid for the interim period of FY2015 or earlier are calculated on a post-reverse-stock-split basis.

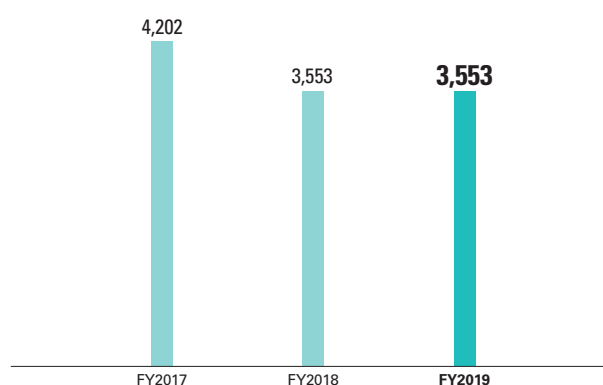
Non-Financial Highlights

Environment-related Society-related

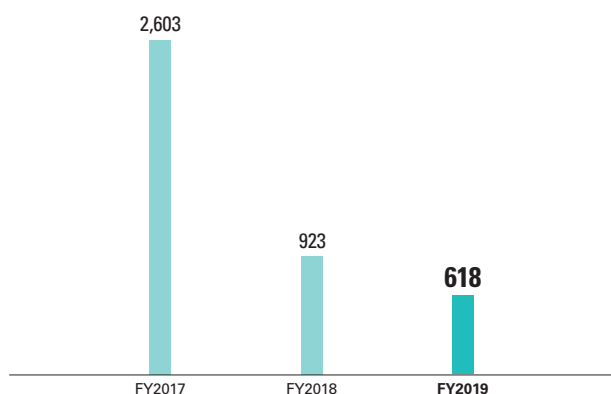
Electricity consumption (1,000 kWh)



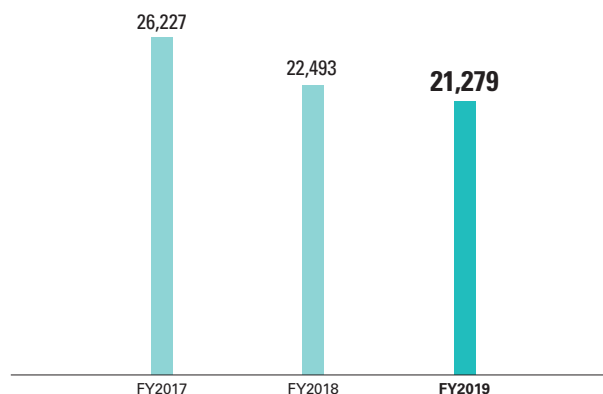
Water consumption at the Shizuoka site and the Drug Research Center in Kyoto (1,000 tons)



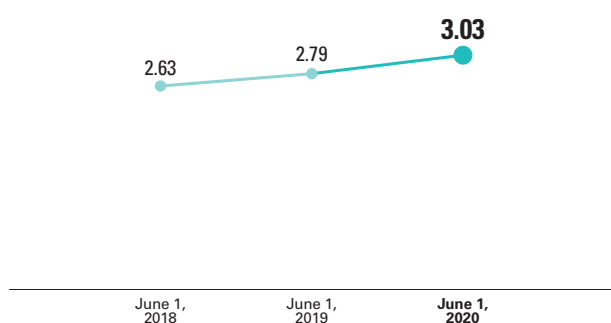
Waste produced at the Shizuoka site and the Drug Research Center in Kyoto (tons)



CO₂ emissions (t-CO₂)



Ratio of employees with disabilities* (%)

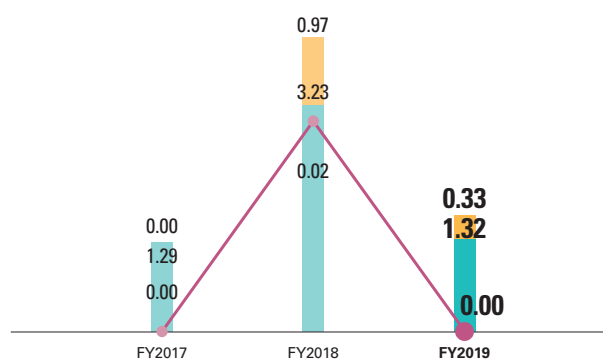


* Legal employment rate from 2018-2020 was 2.2%.

Frequency rate of occupational accidents*1 (%)

Lost-time accidents Accidents not requiring leave from service

Severity rate*2 (%)



*1 Frequency rate = Number of deaths and injuries from occupational accidents/total number of working hours * 1,000,000

*2 Severity rate = Number of workdays lost/total number of working hours * 1,000

Corporate Governance



Message from the Chairperson of the Board

In our continued efforts to strengthen corporate governance, in 2018, we established the Nomination and Compensation Committee, whose majority are Outside Directors. In 2019, we appointed a female Outside Director, increasing the number of Outside Directors to three, and introduced a stock compensation plan for officers.

I believe that my most important role as Chairperson of the Board is to utilize Outside Directors' wealth of knowledge and experience in order to strengthen KAKEN's corporate governance. I will further improve the quality of discussions at the Board, which is at the center of our corporate governance, by ensuring that our Outside Directors are provided with sufficient explanations and information in advance of discussions, by encouraging them to raise issues that are difficult to recognize from an internal perspective, and by drawing on their earnest suggestions and guidance.

I will continue to draw on the opinions from our stakeholders, endeavor to build a management system, including an effective Board of Directors, in order to fulfill the trust placed in us, and further strengthen corporate governance that contributes to sustainable growth and increased corporate value.

Tetsuo Onuma

Chairman and Representative Director
(Chairperson of the Board of Directors)

Basic approach to corporate governance

KAKEN's business philosophy is centered on the three joys of "creating joy for patients," "creating joy as a company," and "creating joy for employees." "Creating joy as a company," one of the three joys, is based on the principle that "KAKEN aims to be a company that recognizes its social responsibility as a pharmaceutical company, engages in all activities with high ethical standards, and aspires to earn society's trust." Accordingly, the tasks of "enhancing corporate governance" and "ensuring the transparency of management and providing our stakeholders with proper explanations of the Company's activities," are placed among our top management priorities.

Corporate governance system

KAKEN has elected to structure its corporate governance system with an Audit & Supervisory Board System by taking into consideration the scale of our business, our management monitoring functions and other circumstances. Four Audit & Supervisory Board Members, including two Outside Audit & Supervisory Board Members, attend all important meetings, including Board of Directors meetings, and express their opinions at such meetings. In particular, Outside Audit & Supervisory Board Members provide their opinions from a neutral standpoint. In view of the above, KAKEN considers its management monitoring functions to be fully functional under its current auditing system.

In addition, KAKEN has adopted the Executive Officer System to speed up decision making and to clarify the functions of the oversight and execution of the business.

Board of Directors meetings are regularly held once a month, and extraordinary meetings are held when necessary. Three of the Directors are Outside Directors. Furthermore, Audit & Supervisory Board Members, including Outside Audit & Supervisory Board Members, and Corporate Officers attend Board of Directors meetings. In this way, the Board of Directors ensures the thorough implementation of the management policy and the fairness and transparency of its decision making.

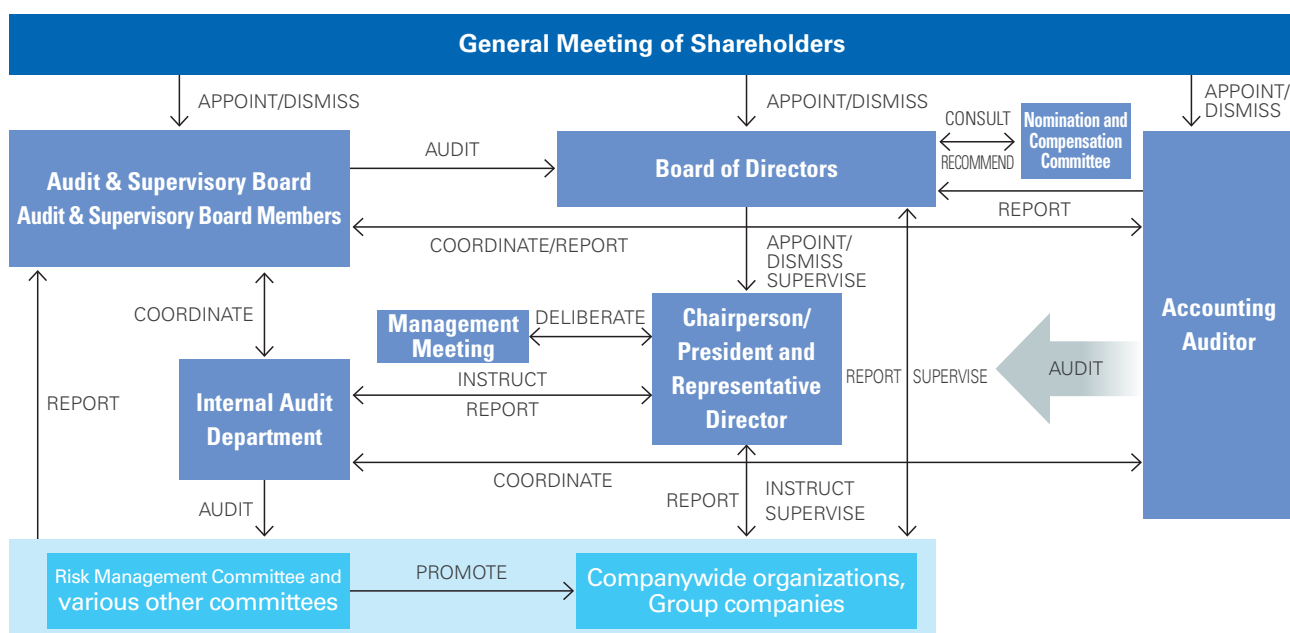
Overview of the corporate governance system

Structure of organization	A company with an Audit & Supervisory Board
Term of office of Directors stipulated in Articles of Incorporation	One year
Number of Outside Directors	3
Number of Independent Directors	3

Board of Directors

The Board of Directors consists of nine Directors, three of whom are Outside Directors. The Chairman and Representative Director serves as the Chairperson of the Board. Board of Directors meetings are normally held on a monthly basis, and extraordinary meetings are held when necessary. As a management decision-making body, the Board of Directors adopts resolutions on matters to be deliberated at the Board of Directors meetings as stipulated by laws and regulations, the Articles of Incorporation, etc., discusses other important management issues and receives reports on the status of business execution as and when necessary.

Corporate governance system



Corporate Governance

Audit & Supervisory Board Members and the Audit & Supervisory Board

KAKEN has elected to structure its corporate governance system with an Audit & Supervisory Board System and has four Audit & Supervisory Board Members, including two standing Audit & Supervisory Board Members and two Outside Audit & Supervisory Board Members. In addition, KAKEN has appointed one Substitute Outside Audit & Supervisory Board Member. Although no staff reporting to Audit & Supervisory Board Members has been currently assigned, the General Affairs Department assists the Audit & Supervisory Board Members and the Audit & Supervisory Board.

Audit & Supervisory Board Members attend important meetings, including Board of Directors meetings, and audit the execution of duties by the Board of Directors. In this way, they work to ensure fairness and transparency of management decision making and execution.

Audit & Supervisory Board meetings are held once a month on a periodic basis.

The Audit & Supervisory Board holds scheduled meetings with the Accounting Auditor to have proactive discussions and information exchange, among other purposes, and thereby works to create a system where fair audits are implemented.

Outside Directors and Outside Audit & Supervisory Board Members

The Company has appointed three Outside Directors and two Outside Audit & Supervisory Board Members.

The role of Outside Directors is to provide advice and supervision, based on their expertise, to achieve company's sustainable growth by directly engaging in decision making of the Board of Directors, as well as to appropriately reflect the opinions of stakeholders, including minority shareholders, to Board of Directors meetings from a neutral and independent standpoint.

The role of Outside Audit & Supervisory Board Members is to strengthen the auditing function and ensure the transparency and objectivity of management by auditing the execution of duties by Directors based on their expertise and from a neutral and

independent standpoint.

The Company has not set criteria, etc., for appointing Outside Directors and Outside Audit & Supervisory Board Members. However, in appointing them, the Company pays due consideration to their independence from the Company so that the neutrality of their role will not be impaired. There is no special interest between the Company and any of the Outside Directors and Outside Audit & Supervisory Board Members.

Evaluation of effectiveness of the Board of Directors

In FY2019, Board of Directors meetings were held 16 times (12 scheduled meetings and four extraordinary meetings). Directors and Audit & Supervisory Board Members attended the extraordinary Board of Directors meetings, and Corporate Officers also attended the scheduled Board of Directors meetings. They had multifaceted deliberations based on their expertise and experience, and made management decisions in a timely and appropriate manner. Specifically, Outside Directors and Outside Audit & Supervisory Board Members provided a wide range of opinions and questions without being constrained by internal norms. Taking into account this situation and also in reference to the self-evaluation based on questionnaire surveys conducted for each Director as well as interviews with the Chairperson of the Board, the Board of Directors evaluates its effectiveness as being ensured.

Nomination and Compensation Committee

The majority of the Nomination and Compensation Committee Members are Outside Directors and the Committee serves as an advisory body to the Board of Directors and deliberates on the nomination of Directors, Audit & Supervisory Board Members and other members and the compensation of Directors and other members, and provides advice and recommendations to the Board of Directors. Nomination and Compensation Committee meetings shall be held 2 to 4 times a year and further meetings shall be held on an as-needed basis. All committee members attended all four meetings held in FY2019.

Outside Directors or Outside Audit & Supervisory Board Members

Name	Major activities
Director Eiki Enomoto	Mr. Eiki Enomoto attended all 16 Board of Directors meetings held during the fiscal year under review and provided comments as necessary based on his experience gained through engaging in corporate legal work and expert perspective as an attorney at law.
Director Kiyoko Kamibepu	Ms. Kiyoko Kamibepu attended 11 of the 13 meetings of the Board of Directors held after her appointment as an Outside Director, and provided comments as necessary based on her extensive professional expertise, experience and insights as a Doctor of Health Science and a Professor of Graduate School.
New appointment Director Shoichiro Takagi	Based on his experience, achievements and insights gained from being involved in management at multiple companies including a pharmaceutical company, Mr. Shoichiro Takagi was elected as Director at the 100th Ordinary General Meeting of Shareholders held on June 26, 2020.
Audit & Supervisory Board Member Kazuo Hara	Mr. Kazuo Hara attended all 16 Board of Directors meetings and all 13 Audit & Supervisory Board meetings held during the fiscal year under review and asked questions and provided opinions as necessary as he has in-depth knowledge of and extensive experience in tax affairs and accounting as a certified public tax accountant.
Audit & Supervisory Board Member Hirotoishi Endo	Mr. Hirotoishi Endo attended all 13 Board of Directors meetings and all 10 Audit & Supervisory Board meetings held after his appointment as an Outside Audit & Supervisory Board Member and asked questions and provided opinions as necessary based on his extensive experience in the financial industry and his achievements and insights as a corporate manager.

Officer Compensation

In an effort to provide an incentive to contribute toward the sustainable growth of KAKEN, the compensation for the Company's officers comprises basic compensation, bonus and stock compensation, which are determined by comprehensively taking into consideration the Company's medium- to long-term performance as well as past payment amounts, in addition to the responsibilities of the officers.

The basic compensation is a fixed monthly compensation and the amount of basic compensation is set within the amount approved by the General Meeting of Shareholders. The bonus is linked with short-term performance and calculated based on comparisons of the consolidated operating profit and the consolidated profit of each fiscal year with those of the previous fiscal year. As for stock compensation, Board Benefit Trust (BBT) has been introduced as a Performance-Linked Stock Compensation Plan. The stock compensation is calculated by using coefficients obtained by prorating the achievement of those such as consolidated net sales, consolidated operating income and consolidated ROE in the mid-term management plan in accordance with the Rules for Share-based Remuneration for Officers, and is linked with medium- and long-term performance, which provides stock and other benefits at the time of retirement, and is intended to contribute to increased

corporate value and sustainable growth. However, bonuses and stock compensation are not paid to Outside Directors and Audit & Supervisory Board Members, as they are responsible for the functions of supervision and oversight over management, from an independent standpoint.

Compensation for Directors is determined by the Board of Directors upon deliberation by the Nomination and Compensation Committee whose majority of members are Outside Directors. In FY2019, the Nomination and Compensation Committee meeting was held in March 2020 regarding the Directors' compensation to deliberate the draft of basic compensation and performance-linked compensation for each individual in accordance with the above criteria. The compensation for Audit & Supervisory Board Members is determined by discussion among the Audit & Supervisory Board Members.

It was resolved at the 87th Ordinary General Meeting of Shareholders held on June 28, 2007 that the annual basic compensation for Directors and Audit & Supervisory Board Members shall be ¥330 million or less and ¥70 million or less, respectively. With respect to Performance-Linked Stock Compensation, it was resolved at the 99th Ordinary General Meeting of Shareholders held on June 27, 2019 that the maximum amount to be contributed to the trust (covering three fiscal years) shall be ¥141 million for Directors.

Total amounts of compensation, etc., total amounts of compensation, etc. by type, and the number of officers paid, by officer category in FY2019

Officer category	Total amounts of compensation, etc. (millions of yen)	Total amounts of compensation, etc. by type (millions of yen)			Number of officers paid
		Basic Compensation	Bonus	Stock Compensation	
Directors (Excluding Outside Directors)	322	199	93	29	5
Audit & Supervisory Board Members (Excluding Outside Audit & Supervisory Board Members)	48	48	—	—	2
Outside Officers	35	35	—	—	6

* Stock compensation represents a provision for share-based remuneration for directors in FY2019.

Outside Director's Message

I hope KAKEN will build an accessible, flexible and strong management structure that is aligned with internal vectors.

Looking back on FY2019 at KAKEN from my perspective as Outside Director, although the company continued to face pressure from NHI drug price revisions and competing products, and sales activities were impacted by the spread of the COVID-19 pandemic from the beginning of 2020, I believe that we could mitigate risks related to compliance, governance and legal disputes, the areas where we conduct monitoring and offer recommendations from an external perspective.

Meanwhile, candidate Directors were selected upon involvement and advice of the Nomination and Compensation Committee, which serves as an advisory body to the Board of Directors, and in June this year, the company launched a new management team headed by Mr. Horiuchi, new President. In recent years, the company has proceeded with activities such as appointing younger Corporate Officers with a view to fostering candidates for next generation management members. So, I respect the company's efforts in making a good start with a new management team at an appropriate timing.

Newly-appointed President, Mr. Horiuchi, has outlined a vision for achieving growth through the efforts of all employees, by leveraging their capabilities on the business front line, and he is keenly aware that alignment of internal vectors is essential in the current era. I hope that all officers and employees work together under the leadership of the new President to build an accessible, flexible and strong management structure.

We outside directors have also welcomed Mr. Shoichiro Takagi as a new Outside Director with a wealth of experience in corporate management in the pharmaceutical industry. Having been supplemented with his expert insight, we will enhance KAKEN's management transparency more than ever before, and conduct and provide monitoring and recommendations that will contribute to the improvement of its corporate value.



Eiki Enomoto
Director (Outside)

Members of the Management Team

Directors



Tetsuo Onuma
Chairman and
Representative Director

April 1974 Joined the Company
April 2002 General Manager of
Marketing Planning &
Coordination Department of
the Company
July 2004 Corporate Officer of the
Company
June 2005 Director of the Company
April 2007 Chief Officer of Marketing &
Sales Division of the
Company
June 2007 Managing Director of the
Company
June 2011 President and Representative
Director of the Company
June 2020 Chairman and Representative
Director of the Company (to
present)



Hiroyuki Horiuchi
President and
Representative Director

April 1984 Joined the Company
October 2010 General Manager of Hiroshima
Branch of the Company
April 2014 General Manager of Osaka
Branch of the Company
July 2015 Corporate Officer of the
Company
April 2016 General Manager of
Marketing & Sales
Department of the Company
June 2016 Director of the Company
April 2017 Chief Officer of Marketing &
Sales Division of the
Company (to present)
June 2018 Managing Director of the
Company
June 2020 President and Representative
Director of the Company (to
present)



Fumihiro Watanabe
Director

April 1984 Joined Toho Mutual Life
Insurance Company
April 2000 Joined the Company
April 2007 General Manager of
Accounting & Finance Depart-
ment of the Company
April 2013 General Manager of General
Affairs Department of the
Company
July 2013 Corporate Officer of the
Company
June 2016 Director of the Company (to
present)



Yoshio Tanabe
Director

April 1978 Joined the Ministry of Foreign
Affairs of Japan
October 1989 Joined McKinsey & Company,
Inc., Japan
June 2001 Operating Officer of Otsuka
Pharmaceutical Co., Ltd.
April 2009 President and Representative
Director of TOKUHON
Corporation
September 2014 Partner of KIZASHI
Corporation
June 2016 Director of the Company (to
present)
September 2017 Representative Director of
Medical Opinion Co., Ltd.



Masahiro Matsuura
Director

April 1994 Joined the Company
April 2016 General Manager of
Corporate Planning &
Coordination Department of
the Company
July 2018 Corporate Officer of the
Company
June 2020 Director of the Company (to
present)



Minoru Ohta
Director

April 1982 Joined The Norinchukin Bank
June 2007 General Manager of Nagoya
Branch, The Norinchukin Bank
July 2009 General Manager of JA Bank
System Management
Division, The Norinchukin
Bank
June 2010 Representative Director and
President of Kyodo Housing
Loan Co., Ltd.
June 2012 Managing Director of The
Norinchukin Bank
June 2014 Advisor of Norinchukin
Research Institute Co., Ltd.
August 2014 Managing Director of Central
Union of Agricultural
Cooperatives
August 2017 Representative Director and
President of Nocu Business
Support, Co., Ltd.
June 2020 Director of the Company (to
present)



Eiki Enomoto
Outside Director

April 1999 Registered as attorney at law
(Dai-ichi Tokyo Bar
Association)
June 2005 Outside Auditor, ZENRIN CO.,
LTD.
August 2009 Established Ishii & Enomoto
Law Office Partner of Ishii &
Enomoto Law Office
April 2014 Auditor of Dai-ichi Tokyo Bar
Association
June 2014 Director of the Company (to
present)
April 2018 Professor of The Legal
Training and Research
Institute, The Supreme Court
of Japan (to present)
January 2019 Established Enomoto &
Fujimoto Law Office Partner
of Enomoto & Fujimoto Law
Office (to present)



Kiyoko Kamibepu,
Ph.D., RN, FAAN
Outside Director

April 2001 Associate Professor of Nihon-
bashi Gakkan University
(currently Kaichi International
University)
April 2002 Associate Professor of
Division of Health Sciences
and Nursing, Graduate School
of Medicine, the University of
Tokyo
December 2012 Professor of Division of
Health Sciences and Nursing,
Graduate School of Medicine,
the University of Tokyo (to
present)
April 2017 Department Director of
Division of Health Sciences
and Nursing, Graduate School
of Medicine, the University of
Tokyo (to present)
June 2019 Director of the Company (to
present)



Shoichiro Takagi
Outside Director

April 1983 Joined the Japan Tobacco
and Salt Public Corporation
(currently Japan Tobacco Inc.)
November 2002 Representative Director and
President of Ipinshang
Foods Corporation
March 2007 Representative Director and
President of Saint-Germain
Co., Ltd.
June 2011 Member of the Board,
Director, Deputy Leader of
Pharmaceutical Marketing &
Promotion Group, TORII
PHARMACEUTICAL CO., LTD.
June 2013 Representative Director,
President and Chief Executive
Officer of TORII PHARMA-
CEUTICAL CO., LTD.
March 2019 Part-time Advisor of
Pharmaceutical Business,
Japan Tobacco Inc.
June 2020 Director of the Company (to
present)

Audit & Supervisory Board Members



Atsutada Iwamoto
Audit & Supervisory Board
Member (Standing)

April 1979 Joined the Company
April 2008 General Manager of Osaka
Branch II of the Company
July 2011 General Manager of
Purchasing Department of the
Company
June 2015 Audit & Supervisory Board
Member of the Company (to
present)



Naomi Doi
Audit & Supervisory Board
Member (Standing)

April 1990 Joined the Company
April 2010 General Manager of R&D
Administration Center of the
Company
April 2012 General Manager of R&D
Quality Assurance
Department of the Company
June 2018 Audit & Supervisory Board
Member of the Company (to
present)



Kazuo Hara
Outside Audit & Supervisory
Board Member

April 1968 Joined Fukuoka Regional
Taxation Bureau
July 1986 Commissioner's Secretariat of
the National Tax Agency
July 2007 Vice President of the National
Tax College
July 2008 Regional Commissioner of
Kumamoto Regional Taxation
Bureau
September 2009 Registered as certified public
tax accountant
June 2015 Audit & Supervisory Board
Member of the Company (to
present)
March 2016 Outside Director (Audit and
Supervisory Committee Mem-
ber) of Toagosei Co., Ltd.



Hirotoshi Endo
Outside Audit & Supervisory
Board Member

April 1978 Joined The Yasuda Mutual
Life Insurance Company
(currently Meiji Yasuda Life
Insurance Company)
April 2009 Managing Executive Officer
of Meiji Yasuda Life
Insurance Company
April 2012 Senior Managing Executive
Officer of Meiji Yasuda Life
Insurance Company
April 2014 President and Representative
Director of Meiji Yasuda
General Insurance Co., Ltd.
April 2018 Corporate Auditor of Meiji
Yasuda Trading Co., Ltd.
June 2019 Audit & Supervisory Board
Member of the Company (to
present)

Corporate Officers

Norihide Oizumi

Chief Officer of Production
Division, General Manager
of Shizuoka Factory

Naoyuki Ishida

General Manager of
Human Resources
Department

Masashi Suzudo

General Manager of
Corporate Planning &
Coordination Department

Hirofumi Fujii

General Manager of Kanto
Branch and Kanto Branch II

Masanao Shimano

Chief Officer of R&D
Division

Compliance

Basic approach and system to promote compliance

KAKEN believes that compliance-based management is a fundamental element in earning the trust of society and promoting the healthy development of the company. KAKEN promotes compliance-based management based on this principle.

KAKEN has appointed a Compliance Officer who is in charge of promoting compliance-related initiatives on a company-wide basis and established a compliance group in the Legal Affairs & Intellectual Property Department, which serves as a department responsible for promoting compliance.

Activities to promote compliance

In April 2002, the Company formulated KAKEN's Activity Principles and Guidelines as a basis for making decisions and taking actions in the performance of duties by executives and employees, and KAKEN's Code of Conduct as a guideline to be followed by executives and employees, both toward the achievement of the Corporate Philosophy and Business Philosophy. We hung panels displaying "KAKEN's Activity Principles and Guidelines" on the wall at the most easy-to-see location of each office, branch, sales office, and subsidiary to help officers and employees of the Company and its subsidiaries practice compliance, whereby the Company endeavors to promote compliance-based corporate activities.

In addition, the Company strives to practice compliance at all times through measures including distribution of Compliance Check Cards to all executives and employees, and those of subsidiaries, posting of the Compliance Guidebook on the in-house intranet, and encouraging executives and employees to use them in verifying their own activities, etc. KAKEN's Activity Principles and Guidelines and Code of Conduct are disclosed on the Company's website.

As part of its efforts to promote compliance, KAKEN provides compliance education through comprehensive training for newly hired employees, lectures for newly appointed office managers, etc., and distributes messages from the Compliance Officer and provides related information on the in-house intranet as appropriate to improve compliance awareness.

Compliance Hotline and whistleblowing contact desk

The Company has put in place the Compliance Hotline for employees to directly report to or consult with the Compliance Officer and the General Manager of the Legal Affairs & Intellectual Property Department, should such employee become aware of any actual or potential compliance violation inside or outside the Company.

In addition to the internal contact desk, the Company has also established in April 2006 a system for employees to report to, notify

or consult with an external legal counsel as a whistleblowing contact desk.

Whether the contact is made via the Compliance Hotline or the whistleblowing contact desk, in either case, the related parties are bound by confidentiality obligations under internal regulations, and the privacy and confidentiality of the whistleblower are strictly maintained.

Ethical considerations in animal testing

In developing pharmaceuticals and agrochemicals, animal testing is indispensable for verifying the safety and effectiveness of the drugs.

The Company has formulated its internal regulations by fully reflecting the purposes of "the Act on the Welfare and Management of Animals," "the Standards relating to the Care and Keeping and Reducing Pain of Laboratory Animals," and "the Basic Policies for the Conduct of Animal Experiments in Research Institutions under the Jurisdiction of the Ministry of Health, Labour, and Welfare," and giving full consideration to the utilization of alternatives to animal testing (Replacement), the reduction of the number of animals used (Reduction), and the mitigation of pain (Refinement).

In conducting animal tests, the Company complies with relevant laws and regulations and internal regulations, gives due

consideration to animal welfare, and carries out examinations by the Animal Testing Committee to ensure that the tests are appropriately carried out from a scientific point of view.

Self-inspection and self-assessment on the status of animal testing are carried out every year to verify the appropriateness of the tests.

In addition, the Company's initiatives for animal testing have been assessed by an external party as being appropriately carried out in accordance with the policies of the Ministry of Health, Labour and Welfare. KAKEN received the Accreditation of Animal Experimentation Facilities by the Japan Health Sciences Foundation in January 2019 for the third time.

Risk Management

Basic approach and system to promote risk management

KAKEN engages in risk management initiatives with the aim of fulfilling its social responsibility and contributing to sustainable corporate value improvement by appropriately managing risks that could hinder the realization of the Corporate Philosophy and the achievement of the business plan.

Overview of the risk management system

- Regulations and other systems concerning the loss risk management
 - Regulations and other systems concerning the loss risk management of subsidiaries
1. The Company establishes a system to identify and manage risks that the KAKEN Group is exposed to under which a Risk Management Officer is appointed and the Corporate Planning & Coordination Department is designated as the responsible department.
 2. The Company classifies risks and manages them by designating the responsible departments, respectively.
 3. The Board of Directors makes management decisions on the handling of material risks from the perspective of the KAKEN Group's management, and such risks are managed by the responsible departments.

4. The Internal Audit Department audits the status of risk management at the KAKEN Group and reports the results to the President, the Board of Directors and the Audit & Supervisory Board.

The Company has formulated the Regulations for Risk Management and carries out risk management activities such as identifying risks, taking countermeasures, providing education, etc., for each division and department. At the same time, the Risk Management Committee is organized with the Risk Management Officer appointed by the Board of Directors serving as the chair. In such ways, the Company has established a system to manage risks on a company-wide basis. Important matters deliberated at the Risk Management Committee meetings are submitted for approval or reported to the Board of Directors.

Major risks

Major risks recognized by the management as those that materially affect the financial status, business performance and cash flows of consolidated companies are as follows.

The forward-looking statements contained herein reflect the judgment of the KAKEN Group (KAKEN and its consolidated subsidiaries) as of the end of the consolidated fiscal year under review.

Major risks	Status of major risks
Risks related to legal regulations and administrative developments such as policies to curtail public healthcare expenditure	The pharmaceutical business in Japan is subject to various regulations under the pharmaceutical administration. In addition, various medical system reforms are underway as part of policies to curtail public healthcare expenditure, such as revisions of the drug price standards and measures to promote the use of generic drugs. Depending on the revisions of these related laws and regulations and the developments in the administrative policies related to medical system and health insurance, they could materially affect the Group's business performance and financial status.
Risks related to new drug development	Considerable financial investment and development periods of more than 10 years are required for the research and development of drugs; however, the probability of these efforts coming to fruition as a new product or technology is not high. The Company carefully develops new drugs while taking the efficacy and safety of a particular drug into full consideration, and it is possible that the development could be halted before its completion if the expected efficacy cannot be proven or a safety issue is identified. In such case, it could materially affect the Group's business performance and financial status.
Risks related to the side effects	Pharmaceutical products are approved and marketed only after sufficient safety tests and thorough review; however, only a limited number of patients are subject to the trial administration of the experimental drug for clinical trials undertaken in the development stage. In order to supplement these clinical trials, post-marketing surveillance is conducted after the product is launched onto the market. If unexpected side effects are identified in post-marketing surveillance, we may be compelled to recall the product or discontinue its sales. In such case, it could materially affect the Group's business performance and financial status.
Risks due to competition	The pharmaceutical industry is very competitive. Sales competition with competing products which have the similar efficacy and effect and generic products launched after the patents expire may result in declines in sales of our products, which could materially affect the Group's business performance and financial status.
Risks related to intellectual property rights	The Group manages its intellectual property properly and takes precautions against infringement by third parties. If a third party infringes our intellectual property right, we may file a lawsuit against the third party to protect such right. Depending on the litigation outcome, it could materially affect the Group's business performance and financial status. We also pay close attention to ensure that the Group's projects do not infringe the intellectual property rights of any third party. However, in the event that we infringe the intellectual property right of a third party, it may result in a dispute and subsequent compensation for damages and cancellation of such project, which could materially affect the Group's business performance and financial status.
Risks related to litigation	As a company conducting business activities on a continuing basis in both Japan and abroad, we are at a risk of litigation instituted for side effects of our pharmaceutical products and issues concerning product liability, labor, environment, and fair trade. In such case, it could materially affect the Group's business performance and financial status.
Risks related to delay or interruption of product supply	Delay or interruption of product supply due to problems with the manufacturing facilities of the Company or its suppliers and delays in the procurement of raw materials, or product recall due to a quality problem could materially affect the Group's business performance and financial status.
Risks related to IT security and information management	The Group uses various information systems; therefore, our business operation may be hampered by system failures, computer viruses, and cyber-attacks, and other factors. If confidential information including personal information in our possession is leaked to any third party, the Group would face compensation for damages, administrative actions, and loss of social credibility. These events could materially affect the Group's business performance and financial status.
Risks related to large-scale disasters	If natural disasters such as earthquakes and typhoons, accidents such as fires, or pandemics occur and cause extensive damage to the Group's offices and business partners, resulting in disruption of business activities or considerable expense being required to repair facilities damaged by such disaster, it could materially affect the Group's business performance and financial status.
Risks associated with the spread of COVID-19	The spread of COVID-19 has a diverse range of influences. For instance, patients tend to refrain from visiting medical institutions, and activities of medical representatives to provide information are minimized. These changes could materially affect the Group's business performance and financial status. In addition, even after the spread of COVID-19 is curbed or contained, it may continue to have an impact for an extended period of time.

Environment Initiatives for Environmental Protection

The Shizuoka site and the Drug Research Center in Kyoto work to comply with laws and regulations by establishing strict internal standards, discharging wastewater after appropriate treatment, and periodically measuring the environmental impact.

Conservation of water quality

The Shizuoka site separates wastewater from production activities into organic wastewater and other wastewater. Organic wastewater then undergoes treatment using active sludge, after which it is mixed with other wastewater and subsequently discharged into rivers. To further its efforts to prevent water pollution, the site concluded an agreement with Fujieda City, Shizuoka Prefecture, regarding pollution prevention in 1976, periodically measures its

Shizuoka site (agreement on pollution control with Fujieda City)

	Agreed values for pollution control	Results (average)
pH	6.0-8.5	7.5
BOD (mg/L)	Average: 35; maximum: 45	2.1
SS (mg/L)	Average: 45; maximum: 65	2.0
Emissions (m ³)	20,000 or less	5,991

Efficient use of water resources

Our Shizuoka site, which has a factory in its premises, is striving to use water resources efficiently. There are concerns that water resources may become insufficient due to the effects of climate change hereafter. We will promote the efficient use of water from the viewpoint of business continuity for the future.

Conservation of air quality

In order to reduce emissions of carbon dioxide (CO₂), sulfur oxide (SO_x), etc., city gas fired boilers were installed to replace the previous boilers at the Shizuoka site and the Drug Research Center in Kyoto in FY2006 and FY2007, respectively. As a result, both of the factories have continued to boast zero emissions of SO_x since then. In addition, smoke

Chemical substance management

Both the Shizuoka site and the Drug Research Center in Kyoto are managing chemical substances on a voluntary basis. In order to reduce exposure to potential risks from using harmful chemical substances, the Company considers possible revisions to its processes for manufacturing and analyzing pharmaceuticals, and it is working to reduce the amount of solvents used and switch to less harmful substances. In addition, the Company has established internal regulations for handling harmful chemical substances, placing them under reliable management, to prevent accidents and environmental pollution at all stages of handling these chemicals, from purchasing to use and then disposal. The Company also manages chemical substances in an integrated manner together with reagents. Safety data sheets (SDSs) regarding the usage of such substances are kept up to date to ensure readiness for emergencies.

The Shizuoka site and the Drug Research Center in Kyoto monitor the status of use of chemical substances subject to the Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the

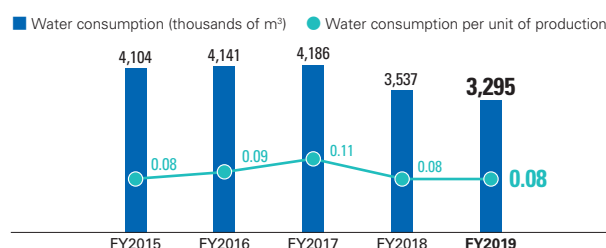
environmental impact and is practicing strict compliance with laws and regulations.

The Drug Research Center in Kyoto treats organic wastewater using active sludge and then mixes it with wastewater from other systems before discharging it into public sewers. When discharging such wastewater, the Drug Research Center adheres to its own internal standards, which are stricter than the standards of Kyoto City, and periodically measures its emissions and reports the findings.

Drug Research Center in Kyoto (internal standards for the Drug Research Center in Kyoto)

	Internal standard values	Results (average)
pH	5.8-8.6	6.7
BOD (mg/L)	1,500 or less	54.4
SS (mg/L)	1,500 or less	85.9

Water consumption and consumption per unit of production at Shizuoka site

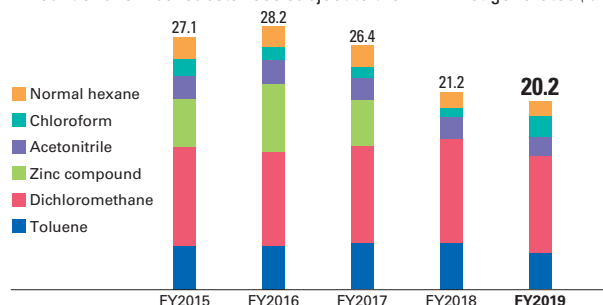


* Water consumption per unit of production: water consumption (thousands of m³) / plant production amount (millions of yen)

dust emission levels, which are measured twice a year at both sites, are always significantly lower than the standard levels. Going forward, both the Shizuoka site and the Drug Research Center in Kyoto will continue strengthening environmental management procedures to better prevent air pollution.

Environment and Promotion of Improvements to the Management Thereof (the "PRTR Act") by, for example, using the network within the sites. They also strive to reduce the amount of such substances used, consider alternative substances, and ensure that they are handled appropriately.

Amount of chemical substances subject to the PRTR Act generated (tons)



Waste reduction and recycling

The production of waste cannot be avoided in the business activities of manufacturing products from raw materials. However, the development of a recycling-based society requires that the production of waste for final disposal be reduced to the greatest extent possible. To this end, the Shizuoka site and the Drug Research Center in Kyoto act in accordance with the Basic Act on Establishing a Sound Material-Cycle Society and is actively practicing the 4Rs (Refuse, Reduce, Reuse, Recycle).

In FY2019, the total amount of waste produced by the Shizuoka site was 584 tons. Of this, 38% was sludge produced during the treatment of wastewater and residual materials from fermentation processes (animal and plant residues). The entire volume of this sludge and residual materials produced in the year under review was used for composting, etc. We are also working to recycle other wastes and collected 35 tons (account for 10% of the total amount of other wastes) as valuable materials.

Reduction of CO₂ emissions and energy saving

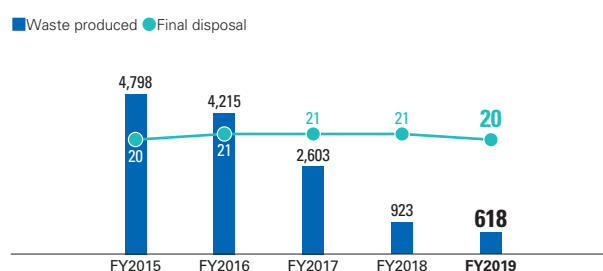
As the reduction of CO₂ emissions is necessary for the mitigation of global warming, the Shizuoka site is systematically pushing forward with its measures to this end and carrying out ongoing energy saving activities such as the introduction of highly-efficient equipment.

The Drug Research Center in Kyoto has worked on various measures to reduce electricity consumption such as the promotion of air-conditioning temperature control, the reduction of unnecessary lighting, the implementation of measures to prevent people from forgetting to turn off lights, and the transition from fluorescent lights to LED lights under a three-year plan starting from FY2014. As a result of these efforts, the site's electricity consumption has been reduced almost as planned on a continuous basis.

Lights of office divisions of the Head Office and branches are gradually being replaced with LED lights, starting with sites where they are readily replaceable. In addition, motion sensor lighting is installed in restrooms, fire escapes, etc., of some of the branch office buildings, to reduce excess power use by turning off or dimming the lights when nobody is present.

The amount of final landfill was 16 tons. Going forward, the Company will continue to advance activities promoting the reduction and recycling of waste.

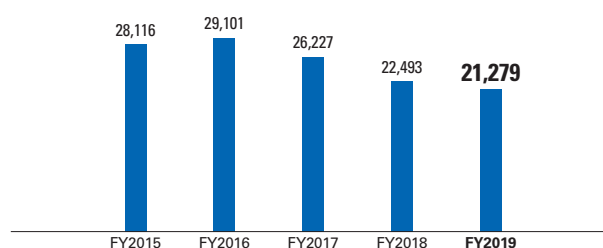
Amounts of waste produced and final disposal at the Shizuoka site and the Drug Research Center in Kyoto (tons)



Heat pumps are installed and used in the air-conditioning system, etc. of the buildings, enabling the efficient use of energy by utilizing heat in the air. In branch office buildings, the air-conditioning system allows for separate control for each divided section of a room, and employees are encouraged to give consideration to energy saving at all times in their day-to-day duties.

Going forward, KAKEN is committed to continuing to adopt highly-efficient facilities with the aim of achieving further energy saving.

CO₂ emissions (t-CO₂)



CO₂ reduction target of the Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ) and the Company

CO₂ reduction target of FPMAJ and the Company

Reduce CO₂ emissions in FY2020 by 23% compared to CO₂ emissions in FY2005

We are participating in the Implementation Scheme for a Low Carbon Society formulated by the Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ) based on a request by Keidanren. We have set the same target as FPMAJ, and we aim to contribute to the achievement of this target.

Environmental action plan

The Shizuoka site and the Drug Research Center in Kyoto aim to carry out eco-friendly corporate activities and promote environmental activities by setting targets for each fiscal year based on a medium-term perspective.

The Shizuoka site acquired ISO14001 (International Environmental Standard) certification in August 2001 and is conducting sustained environmental conservation activities.

Activity report for FY2019 and activity targets for FY2020 of the Shizuoka site

Environmental policy	FY2019		FY2020 target
	Target	Result	
Energy saving	Reduce CO ₂ emissions by 1% by the end of FY2019 compared with the benchmark CO ₂ emissions of 17,600 t-CO ₂ .	Succeeded in reducing CO ₂ emissions by 1,465 t (8.3%) as of the end of FY2019 compared with the benchmark CO ₂ emissions of 17,600 t-CO ₂ .	Reduce CO ₂ emissions by 2% by the end of FY2020 compared with the benchmark CO ₂ emissions of 17,600 t-CO ₂ .
Management of chemical substances	Ensure proper usage and ascertain the used amount of chemical substances.	Identified the amount of reagents purchased and purchased the reagents in the minimum necessary amount. Carried out drills for accidental leak at all sites.	Ensure proper usage and ascertain the used amount of chemical substances.
Reduction of waste	Reduce the amount of incinerated waste by 1% (0.4 t) from FY2013-FY2017 average (43.4 t) by the end of FY2019.	Achieved the target by reducing the amount of waste by 37% (16.0 t), compared to the initial target of reducing 1% (0.4 t).	Reduce the amount of incinerated waste by 2% (0.9 t) from FY2013-FY2017 average (43.4 t) by the end of FY2020.
Eco-friendly product development	Develop eco-friendly products and improve manufacturing and analysis technologies.	Reduced the amount of organic solvents used in manufacturing and analysis processes, improved the manufacturing method, and provided support to manufacturing contractors.	Develop eco-friendly products and improve manufacturing and analysis technologies.
Proactive participation in environmental protection activities in local communities	Proactively participate in environment-related external organizations. Promote interchange with local residents.	Participated in environment-related organizations and exchanged information. (17 times in total) Participated in cleaning and river beautification activities carried out around the site. (April 23/October 16) Held an environmental report meeting for local residents. (November 27)	Proactively participate in environment-related external organizations. Promote interchange with local residents.

Activity report for FY2019 and activity targets for FY2020 of the Drug Research Center in Kyoto

Environmental policy	FY2019		FY2020 target
	Target	Result	
Management of crude oil-equivalent energy usage	Maintain and manage crude oil-equivalent energy usage results of FY2018.	Compared to approximately 1,128 kℓ in FY2018, it decreased by approximately 3.8% to approximately 1,085 kℓ in FY2019. This is largely due to a review of the way the absorption chillers operate (now, only one unit is operated at night). An "A" rating with an achievement degree of 104.0%.	Maintain and manage crude oil-equivalent energy usage results of FY2019.
Proper management of chemical substances	Implement concrete measures planned at each department. (24 times during the year)	The site planned to carry out measures 24 times a year, and measures were implemented just as planned, resulting in an "A" rating with an achievement degree of 100%.	Implement concrete measures planned at each department. (24 times during the year)
Reduction of general waste	Maintain and manage the total volume discharged relative to the data in FY2018.	Compared to 1,027 kg in FY2018, it was 649 kg in FY2019, resulting in an "A" rating with an achievement degree of 158.2%.	Maintain and manage the total volume discharged relative to the data in FY2018.
Harmony with the environment	<ul style="list-style-type: none"> Cleaning activities around the site: 12 times during the year Cleaning activities of the Shinomiya River: twice during the year 	Performed cleaning activities around the site 12 times with a monthly rotating schedule, as well as river cleaning activities once each in spring and fall, a total of 14 times, resulting in an "A" rating with an achievement degree of 100%.	<ul style="list-style-type: none"> Cleaning activities around the site: 10 times during the year Cleaning activities of the Shinomiya River: once during the year <p>* In FY2020, cleaning activities around the site in April and May and cleaning activities of the Shinomiya River in May were canceled due to the effects of the COVID-19 pandemic.</p>
Preferential selection of environmentally conscious goods	More than 120 goods during the year	<ul style="list-style-type: none"> Procured green goods: Purchased 122 items Replaced equipment using CFC with CFC-free freezer: 2 models 124 items, resulting in an "A" rating with an achievement degree of 103.3%. 	More than 120 goods during the year

Compatibility evaluation criteria: achievement level "A": good (95% or higher achieved); "B" slightly insufficient (95%-80%); "C" unsatisfactory (less than 80%)

Environment-related qualifications

The Shizuoka site and the Drug Research Center in Kyoto encourage the acquisition of various public qualifications necessary for environmental management. The number of employees with qualifications is as indicated below. (As of April 1, 2020)

Qualification	Number of employees
Poisonous and deleterious substance handler	35
Operations chief of specified chemical substances, etc.	66
Operations chief of organic solvents	80
Air pollution control manager	6
Water pollution control manager	9
Intermediate industrial waste treatment facility engineering manager	2

Qualification	Number of employees
Specially controlled industrial waste manager	9
Hazardous material engineer	159
Qualified person for energy management	5
High pressure gas production safety technical manager	20
Boiler expert	19

KAKEN places great importance on employees' health, safety and hygiene and human rights, and promotes the creation of a working environment in which our employees can work with without worry. We also focus on human resource development and education, and work on creating an environment where each and every one of our employees can grow and fully demonstrate their abilities.



Working Environment/ Human Resources Utilization

In order to create a working environment in which all employees can be highly motivated in doing their work, we believe it is important to respond flexibly to the "new working styles" in light of legal reforms and to constantly evolve them.

Support for childcare and nursing care

We have established various systems such as systems for taking leave of absence and days off, or working shorter hours based on the Regulations for Childcare Leave and the Regulations for Nursing Care Leave, so that even employees, who have difficulty in working under normal conditions due to childcare or nursing care, can continue to work without worry.

Employment of elderly workers

The Company has introduced the "Senior Staff Program" for the post-retirement reemployment of employees who reach the mandatory retirement age of 60. This system has enabled them to play an active role in their respective workplaces by effectively utilizing their experience, expertise and skills accumulated over many years even after their retiring age.

Employment of persons with disabilities

As part of its corporate responsibility, the Company proactively engages in efforts to hire persons with disabilities. The Company maintains employment that exceeds the statutory employment rate by enhancing its support system to ensure such workers receive appropriate support in the workplace.



Employee health management

As for employee health management, the Company provides regularly scheduled health checkups in the spring and lifestyle disease medical examinations (complete medical checkup/brain checkup) in the fall every year. In cooperation with industrial physicians, nurses and medical examination centers, the Company conducts the follow-up procedures for employees whose checkups revealed health problems, based on the results of such checkups. The Company also cooperates proactively with the specified health checkups and health guidance provided by the health insurance association, in order to prevent diseases and maintain and improve the health of our employees.

In terms of mental health measures, we have introduced a program in partnership with an outside organization for the purpose of preventing, detecting and responding to mental health problems at an early stage. In addition to stress checks required by law (once per year), we offer simple stress checks that employees can perform voluntarily and a wide range of learning content including a variety of e-learning programs, in order to support employees' mental health measures.

Particularly, the Shizuoka site has appointed a person in charge of promoting mental health measures at each workplace and held roundtable meetings attended by health supervisors and thus is actively engaged in the improvement of working environment. The site has also set up a month in which employees are intensively engaged in walking in the spring and conducts a physical fitness test as a health campaign in the fall to maintain and improve the health of its employees. The Company will actively work on the management of physical and mental health of employees in cooperation with industrial physicians while utilizing the external consultation desk at the health insurance association and counseling services.



Occupational safety and health

Based on the Regulations for Safety and Health Management, which aims to prevent occupational accidents and diseases from occurring and to create a comfortable working environment, the Company holds the Safety and Health Committee meetings on a monthly basis at each office. The Company works to eliminate occupational accidents by implementing safety inspections and remedial measures at each facility and operational environment. We also actively work on the improvement of work environment by conducting regular questionnaire surveys of our employees.

At the Shizuoka site, health supervisors actively work on ensuring occupational health and safety by various efforts such as holding regular meetings, formulating annual health plans, conducting workplace inspections, and observing the work environment. Furthermore, in conjunction with the safety and health week, various lectures are held jointly with the health insurance association, and activities to promote the awareness of safety and physical and mental health issues are being conducted.



Creation of a
workplace free
from discrimination
and harassment

The Company is obligated to provide all employees with equal employment opportunities based on employment agreements and a comfortable working environment that is free from unfair discrimination, abuse of authority, sexual harassment, pregnancy discrimination, etc.

The Company works to enhance awareness of the prevention of discrimination and harassment among all employees through means such as the Rules of Employment, Regulations for Rewards and Punishments, Compliance Guidebook, information meetings for employees in managerial positions, and postings and education, etc. through the utilization of the in-house intranet, and keeps employees informed of the internal consultation channels.



Training programs
and
self-development
support

Human resource development is a fundamental part of the corporate management, and the growth of each employee leads to the sustainable growth of our Company. We work on human resources development based on our basic policy of developing employees with a presence, who will bear the future of the Company.

The Company provides comprehensive education and training by employment year and position, in order to foster employees who can make the most of their abilities and achieve results at each stage of their career while gaining experience as members of society. This is also for the purpose of fostering human resources who can practice the Company's Corporate Philosophy: "KAKEN helps improve the quality of life for patients by serving as many people as possible to return smiles of happiness to their faces, through supplying superior pharmaceuticals."

Approach of education and training

- (1) The purpose of training and education is to foster employees who can accurately grasp the current state of the Company and the changes in the industry environment, discern what is best for the Company, and think and act on their own based on their new ideas and creativity.
- (2) By positioning the human resources development for mid-career and young employees as one of our priority issues, we work on human resources development by actively utilizing on-the-job training in the workplace as well as external training by outside expert lecturers.
- (3) We utilize internal and external training programs for implementing the next-generation training to foster next generation leaders and the management training for managers.

Training by position

Training for newly hired employees	Basic training for working adults
3rd year training	Training by employment year
4th year training	
8th year training	
Training to foster next-term leaders	Next-generation training
Training for new team leaders	Career training
Training for new managers	

Self-development support

Support for correspondence
courses for self-development
(For all employees)

In addition to the development of employees' abilities through various training programs, we support employees' self-development efforts in taking correspondence courses for improving individual work skills or acquiring necessary language skills, among other objectives.

Quality assurance policy

KAKEN is committed to realizing its Corporate Philosophy and the management policy and supplying superior pharmaceuticals. To do just that, KAKEN will carry out the following activities in deep recognition of the fact that it is engaged in the pharmaceuticals industry, in pursuit of higher ethical standards and with primary and permanent emphasis on quality during the course of activities including drug discovery, exploratory research, development, clinical trials, manufacture, post-marketing surveillance, the provision of pharmaceutical information, etc.

- 1 KAKEN will establish a pharmaceuticals quality system that covers all the products sold by KAKEN in recognition that product quality assurance is one of the most important issues related to management responsibility.**
- 2 KAKEN will provide a warranty on product quality in response to demands of customers and society.**
- 3 In order to supply patients with superior pharmaceuticals, KAKEN makes it a basic rule to not only comply with laws related to the securing of the quality, effectiveness and safety of pharmaceuticals, medical devices, etc., as well as other relevant laws and regulations, in addition to good laboratory practice (GLP), good clinical practice (GCP), good manufacturing practice (GMP), good quality practice (GQP), good vigilance practice (GVP), etc., but also to assume responsibility for its own behavior.**
- 4 KAKEN aims to establish a quality assurance system that promotes not only conformance with the standards and specifications required by regulatory authorities, but also continuous improvements that take the technological standards of the times into account.**



Product quality assurance

KAKEN helps improve the quality of life of patients by serving as many people as possible to return smiles of happiness to their faces, through supplying superior pharmaceuticals. To that end, KAKEN believes that it is absolutely essential to possess a quality assurance system in which both its Head Office (a manufacturer and distributor of pharmaceuticals) and its factory (a manufacturer of pharmaceuticals) fulfill their respective responsibilities and maintain close coordination. At KAKEN's factory, competencies and appropriateness of each manufacturing process and facility is evaluated to ensure that manufacturing practices and quality are suitably managed.

The Quality Assurance Department of the Head Office evaluates and confirms these activities, believed to result in the creation of a more stringent quality assurance system. Such collaborative activities have not been limited to the departments in charge of quality, but have been expanded to the R&D Division, the Production Division and the Marketing & Sales Division to guarantee the utmost quality throughout all stages of a product's lifecycle.



Safety assurance for pharmaceuticals after launch

Pharmaceuticals receive marketing approval after undergoing evaluations based on the results of clinical trials, which have a limited scope in regard to such considerations as patient age, gender, complications and drugs taken simultaneously. After drugs are launched, they are used by a wider range of patients, and this can result in the occurrence of unexpected side effects. For this reason, the Company is required to take actions based on a consistent risk management plan to continue collecting information and take necessary measures.

With the establishment of the Pharmacovigilance Department, the Company strives to minimize the safety risks of patients by collecting and evaluating data regarding the safety of the pharmaceuticals throughout phases ranging from development to post marketing and providing medical practitioners with information regarding proper usage methods.



Pharmaceuticals Information Service Office

Correct information is essential for the proper usage of prescription drugs.

The Company provides and collects proper-usage information pertaining to its pharmaceuticals mainly through MR (medical representative) activities; however, it also proactively provides and collects information through the Pharmaceuticals Information Service Office, a consultation desk related to pharmaceuticals, and via the website.

The office promptly and accurately informs customers of proper-usage information of pharmaceuticals and reports valuable opinions and suggestions on pharmaceutical formulations, etc., to relevant departments within the Company, and thereby works to improve pharmaceutical formulations, enhance product information and feed them back to customers.

Most of the inquiries the Company receives are by phone; however, the Company has set up an inquiry form on its website to receive inquiries online, even outside office hours with the aim of enhancing convenience for customers.

With the aim of deepening engagement with local communities as a good corporate citizen, each and every one of our employees gives consideration to how they can contribute to society and is proactively engaged in environmental issues familiar to them. In addition, initiatives are undertaken at the Head Office to improve awareness of disaster prevention and strengthen safety measures through the provision of the standard first aid course and various other drills.

Regional activities of the Shizuoka site

River beautification activities

The Shizuoka site has benefited from the waters of the Oi River, a first-class river in Japan. The site works to protect the environment of the Oi River through river beautification activities undertaken every April. While the activities are carried out as part of the site's efforts to contribute to society, they also provide a venue to foster friendly relationships with newly hired employees. In addition, the site participates in the cleaning and beautification activities hosted by the Fujieda City Environmental Protection Joint Committee together with other corporations.

Environmental report meetings

The Shizuoka site holds environmental report meetings every year. Reports are made on various measurement results, the status of employee education and other activities undertaken for the purpose of adherence with laws and regulations, so as to promote better understanding of the Company's environmental initiatives.

Fujieda City Science Education Support Project

The Fujieda City Science Education Support Project is a project jointly planned by Fujieda City and private companies to help children's learning by utilizing corporate activities to make classes more attractive. The project, which is intended for junior high school science teachers, was held at the Shizuoka site in FY2019. Under the topic entitled, "Pesticides Training Course," we offered a lecture on the role of pesticides and a mechanism to ensure safety, with the cooperation of the Agrochemical & Animal Health Products Department.



Regional activities of the Drug Research Center in Kyoto



Regional environment beautification activities

The Drug Research Center in Kyoto participates in the beautification campaign for the Lake Biwa-Yodo River water system as a member of the Yamashina Beautification Promotion Corporate Council. A cleaning activity of Shinomiya River, which runs beside the site, is held every May and October, and this is one of the leading activities for the Lake Biwa-Yodo River water system. In addition, the site has set cleaning activities around the site as its environmental improvement target and conducts the cleaning activities every month since October 2004. From 9:00 a.m. of around the 15th of each month, several employees work in groups to clean the roads around the site, wearing a bib with our company name of KAKEN.

Firefighting and disaster prevention drills and regional agreements for disaster prevention and cooperation

The Head Office provides a standard first aid course every September with the cooperation of the Tokyo Disaster Prevention & Emergency Medical Service Association and the Hongo Fire Station, and was awarded the Certificate of the Excellent Completion of a First-Aid Course from the Tokyo Fire Department in recognition of its active involvement in life-saving training.

In addition, firefighting and disaster prevention drills are carried out at each office every November in conjunction with the Autumn Nationwide Fire Prevention Campaign, so as to heighten awareness of fire and disaster prevention and enhance safety measures. The Drug Research Center in Kyoto has concluded regional agreements for disaster prevention, focused on human cooperation in the event of a disaster, with two neighboring school districts based on the lessons learned from the Great Hanshin-Awaji Earthquake.

Consolidated Five-Year Summary

	MILLIONS OF YEN					THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2018	2017	2016	2020
FOR THE YEARS ENDED MARCH 31						
Net sales	¥89,232	¥94,165	¥98,430	¥101,479	¥109,730	\$826,222
Operating profit	26,512	24,592	27,496	30,707	35,146	245,481
Profit attributable to owners of parent	19,370	17,775	19,043	22,017	21,143	179,352
AT MARCH 31						
Total net assets	128,468	121,131	113,874	102,655	89,875	1,189,519
Total assets	157,875	155,985	152,417	135,060	132,991	1,461,806
PER SHARE DATA						
	YEN					U.S. DOLLARS (NOTE 1)
Profit (Basic)	¥494.89	¥445.78	¥470.54	¥536.70	¥510.54	\$4.582
Cash dividends (Non-Consolidated)	150.00	150.00	150.00	150.00	—	1.389
RATIOS						
	%					
ROE	15.5	15.1	17.6	22.9	25.3	
Capital adequacy ratio	81.4	77.7	74.7	76.0	67.6	

Notes: 1. U.S. dollar amounts are translated, for convenience only, at the rate of ¥108 = U.S.\$1.00, effective on March 31, 2020.

2. The Company conducted a 1-for-2 share consolidation on October 1, 2015. Profit per share has been calculated assuming that the share consolidation was conducted at the beginning of the year ended March 31, 2015.

3. The Company conducted a 1-for-2 share consolidation on October 1, 2015. Dividends per share figures up to the year ended March 31, 2015, are presented at the values prior to the share consolidation and dividends per share for the year ended March 31, 2016, is presented as “—.” When calculated assuming that the share consolidation was conducted at the beginning of the year ended March 31, 2015, the interim dividend was ¥68.00 per share and the total dividend payment per share was ¥146.00 (including a commemorative dividend of ¥10.00 per share) in the year ended March 31, 2016.

4. The Company has introduced the Board Benefit Trust (BBT) from the year ended March 31, 2020. The Company's shares held by the BBT, which are recorded as the treasury stock in shareholders' equity, are included in the treasury stock to be deducted when calculating the weighted average number of shares for computation of profit per share.

Management Discussion and Analysis

Operating Performance

Consolidated net sales were down 5.2% year on year, to ¥89,232 million.

With regard to income, although net sales decreased, operating profit increased 7.8% year on year, to ¥26,512 million, as a result of a decline in selling, general and administrative expenses. Selling, general and administrative expenses declined primarily because research and development costs decreased 37.5% year on year, to ¥6,418 million. Ordinary profit increased 7.9% year on year, to ¥26,946 million, and profit attributable to owners of parent was up 9.0% year on year, to ¥19,370 million.

Segment Information

Pharmaceuticals

In pharmaceuticals and medical devices, overall sales were down, mainly due to a decline in sales of Artz, an anti-osteoarthritis drug, and Lipidil, an anti-hyperlipemia product, as well as a decrease in net sales from overseas, in spite of sales of Clenafin, a topical treatment for onychomycosis, remaining largely at the same level as the previous year.

This decline was largely attributable to the impact of competing products, including generic drugs, as well as NHI drug price revisions.

Sales of agrochemicals decreased.

As a result of the above, net sales in the pharmaceuticals segment decreased 5.4% year on year, to ¥86,853 million, and segment income* was up 8.4%, to ¥25,048 million.

Net sales from overseas decreased 11.1% year on year, to ¥8,012 million.

Real Estate

In the real estate segment, the majority of revenues are generated through rent fees related to the Bunkyo Green Court commercial facility. Net sales for the real estate segment were up 0.8% year on year, to ¥2,378 million, and segment income* decreased 0.8% year on year, to ¥1,463 million.

* Segment income is based on operating profit.

Financial Position

Total assets were ¥157,875 million as of March 31, 2020, up ¥1,889 million from the previous fiscal year-end, primarily due to an increase in cash and deposits.

Total liabilities were ¥29,406 million, down ¥5,447 million, largely as a result of a decrease in notes and accounts payable-trade.

Net assets totaled ¥128,468, a rise of ¥7,337 million, mainly following higher retained earnings.

The capital adequacy ratio stood at 81.4%.

Cash Flows

Cash and cash equivalents as of March 31, 2020, totalled ¥73,322 million, an increase of 14,766 million compared with the previous fiscal year-end.

(Cash flows from operating activities)

Net cash provided by operating activities was ¥27,468 million, an increase of ¥6,339 million year on year, due to factors including a decrease in notes and accounts receivable-trade.

(Cash flows from investing activities)

Net cash used in investing activities stood at ¥2,528 million, a decrease of ¥3,215 million year on year, primarily as a result of a decrease in purchase of long-term prepaid expenses.

(Cash flows from financing activities)

Net cash used in financing activities totaled ¥10,173 million, an increase of ¥649 million year on year, largely due to an increase in purchase of treasury stock.

Business Risks

Among the matters concerning the status of business, the status of accounting, etc. described in the securities reports, the major risks recognized by management as potentially having a significant impact on the financial position, operating results, and cash flows of consolidated companies are as follows.

The forward-looking statements contained herein reflect the judgment of the KAKEN Group (KAKEN and its consolidated subsidiaries) as of the end of the consolidated fiscal year under review.

(1) Risks related to legal regulations and administrative developments such as policies to curtail public healthcare expenditure

The pharmaceutical business in Japan is subject to various regulations under the pharmaceutical administration. In addition, various medical system reforms are underway as part of policies to curtail public healthcare expenditure, such as revisions of the drug price standards and measures to promote the use of generic drugs. Depending on the revisions of these related laws and regulations and the developments in the administrative policies related to medical system and health insurance, they could materially affect the Group's business performance and financial status.

(2) Risks related to new drug development

Considerable financial investment and development periods of more than 10 years are required for the research and development of drugs; however, the probability of these efforts coming to fruition as a new product or technology is not high. The Company carefully develops new drugs while taking the efficacy and safety of a particular drug into full consideration, and it is possible that the development could be halted before its completion if the expected efficacy cannot be proven or a safety issue is identified. In such case, it could materially affect the Group's business performance and financial status.

(3) Risks related to the side effects

Pharmaceutical products are approved and marketed only after sufficient safety tests and thorough review; however, only a limited number of patients are subject to the trial administration of the experimental drug for clinical trials undertaken in the development stage. In order to supplement these clinical trials, post-marketing surveillance is conducted after the product is launched onto the market. If unexpected side effects are identified in post-marketing surveillance, we may be compelled to recall the product or discontinue its sales. In such case, it could materially affect the Group's business performance and financial status.

(4) Risks due to competition

The pharmaceutical industry is very competitive. Sales competition with competing products which have the similar efficacy and effect and generic products launched after the patents expire may result in declines in sales of our products, which could materially affect the Group's business performance and financial status.

(5) Risks related to intellectual property rights

The Group manages its intellectual property properly and takes precautions against infringement by third parties. If a third party infringes our intellectual property right, we may file a lawsuit against the third party to protect such right. Depending on the litigation outcome, it could materially affect the Group's business performance and financial status. We also pay close attention to ensure that the Group's projects do not infringe the intellectual property rights of any third party. However, in the event that we infringe the intellectual property right of a third party, it may result in a dispute and subsequent compensation for damages and cancellation of such project, which could materially affect the Group's business performance and financial status.

(6) Risks related to litigation

As a company conducting business activities on a continuing basis in both Japan and abroad, we are at a risk of litigation instituted for side effects of our pharmaceutical products and issues concerning product liability, labor, environment, and fair trade. In such case, it could materially affect the Group's business performance and financial status.

(7) Risks related to delay or interruption of product supply

Delay or interruption of product supply due to problems with the manufacturing facilities of the Company or its suppliers and delays in the procurement of raw materials, or product recall due to a quality problem could materially affect the Group's business performance and financial status.

(8) Risks related to IT security and information management

The Group uses various information systems; therefore, our business operation may be hampered by system failures, computer viruses, and cyber-attacks, and other factors. If confidential information including personal

information in our possession is leaked to any third party, the Group would face compensation for damages, administrative actions, and loss of social credibility. These events could materially affect the Group's business performance and financial status.

(9) Risks related to large-scale disasters

If natural disasters such as earthquakes and typhoons, accidents such as fires, or pandemics occur and cause extensive damage to the Group's offices and business partners, resulting in disruption of business activities or considerable expense being required to repair facilities damaged by such disaster, it could materially affect the Group's business performance and financial status.

(10) Risks associated with the spread of COVID-19

The spread of COVID-19 has a diverse range of influences. For instance, patients tend to refrain from visiting medical institutions, and activities of medical representatives to provide information are minimized. These changes could materially affect the Group's business performance and financial status. In addition, even after the spread of COVID-19 is curbed or contained, it may continue to have an impact for an extended period of time.

Shareholder Returns

The Company considers continuous return of profits to shareholders to be an important management objective. In the pharmaceuticals industry, where business risks are higher than in other industries, companies are required to maintain an adequate capital base. However, the Company has adopted a flexible dividend policy for payment commensurate with its level of performance, considering the balance with shareholder returns.

The Company's basic policy is to distribute surplus twice a year as interim dividend and year-end dividend, which are determined respectively by the Board of Directors and the general meeting of shareholders.

Based on the basic policy above, the annual dividend for the fiscal year under review will be ¥150, consisting of an interim dividend of ¥75 per share and a year-end dividend of ¥75 per share.

The Company will invest retained earnings intensively in research and development and marketing base establishment, and will seek to maximize its corporate value.

Consolidated Balance Sheets

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiary
As of March 31, 2020 and 2019

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
ASSETS			
CURRENT ASSETS:			
Cash and deposits (Notes 3 and 9)	¥ 59,722	¥ 46,956	\$ 552,981
Marketable securities (Notes 3, 4 and 9)	13,599	11,599	125,917
Receivables:			
Notes and accounts receivable-trade (Note 9)	21,800	30,340	201,852
Accounts receivable-other	641	828	5,935
	22,441	31,168	207,787
Inventories (Note 5)	12,275	13,721	113,657
Other	297	285	2,750
Allowance for doubtful accounts	(0)	(0)	(0)
Total current assets	108,336	103,731	1,003,111
PROPERTY, PLANT AND EQUIPMENT (Notes 6, 7 and 8):			
Buildings and structures	41,821	41,668	387,231
Machinery, equipment and vehicles	15,542	15,345	143,907
Tools, furniture and fixtures	7,393	7,380	68,454
	64,757	64,394	599,602
Accumulated depreciation	(43,882)	(42,483)	(406,315)
	20,875	21,911	193,287
Land	4,324	4,324	40,037
Construction in progress	317	166	2,935
Total property, plant and equipment	25,518	26,402	236,278
INVESTMENTS AND OTHER ASSETS:			
Investment securities (Notes 4 and 9)	15,036	17,068	139,222
Intangible assets	414	551	3,833
Deferred tax assets (Note 16)	3,229	2,934	29,898
Long-term prepaid expenses	4,450	4,610	41,204
Other assets	888	685	8,222
Total investments and other assets	24,020	25,851	222,407
TOTAL ASSETS	¥157,875	¥155,985	\$1,461,806

See accompanying Notes to the Consolidated Financial Statements.

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
LIABILITIES AND NET ASSETS			
CURRENT LIABILITIES:			
Short-term bank loans (Notes 6 and 9)	¥ 3,850	¥ 3,875	\$ 35,648
Payables:			
Notes and accounts payable–trade (Note 9)	7,720	10,729	71,481
Accounts payable–other	2,803	3,639	25,954
Electronically recorded obligations–operating (Note 9)	962	1,529	8,907
	11,485	15,899	106,343
Accrued expenses	535	427	4,954
Provision for bonuses	1,175	1,236	10,880
Provision for sales returns	4	7	37
Provision for sales rebates	312	314	2,889
Income taxes payable (Note 16)	2,904	4,042	26,889
Other	1,386	1,777	12,833
Total current liabilities	21,655	27,580	200,509
NON-CURRENT LIABILITIES:			
Provision for share-based remuneration	47	—	435
Net defined benefit liability (Note 10)	7,303	6,642	67,620
Other	400	631	3,704
Total non-current liabilities	7,750	7,274	71,759
NET ASSETS:			
Shareholders' equity (Note 11):			
Common stock			
Authorized: 193,000,000 shares as of March 31, 2020 and 2019			
Issued: 45,939,730 shares as of March 31, 2020 and 48,439,730 shares as of March 31, 2019	23,853	23,853	220,861
Capital surplus	11,406	11,408	105,611
Retained earnings	114,869	109,057	1,063,602
Treasury stock, at cost: 7,022,576 shares as of March 31, 2020 and 8,721,768 shares as of March 31, 2019	(23,373)	(26,782)	(216,417)
Total shareholders' equity	126,756	117,536	1,173,667
Accumulated other comprehensive income:			
Net unrealized holding gain on securities	3,116	4,524	28,852
Remeasurements of defined benefit plans	(1,404)	(930)	(13,000)
Total accumulated other comprehensive income	1,712	3,594	15,852
Total net assets	128,468	121,131	1,189,519
TOTAL LIABILITIES AND NET ASSETS	¥157,875	¥155,985	\$1,461,806

See accompanying Notes to the Consolidated Financial Statements.

Consolidated Statements of Income

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiary
For the years ended March 31, 2020 and 2019

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
NET SALES	¥89,232	¥94,165	\$826,222
COST OF SALES	38,750	40,363	358,796
Gross profit	50,481	53,802	467,417
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (Note 12)	23,969	29,209	221,935
OPERATING PROFIT	26,512	24,592	245,481
OTHER INCOME (EXPENSES):			
Interest and dividends income	393	351	3,639
Interest expenses	(17)	(17)	(157)
Foreign exchange losses	(50)	(39)	(463)
Loss on cancellation of insurance policies	(25)	—	(231)
Gain on sales of non-current assets (Note 13)	4	—	37
Loss on retirement of non-current assets (Note 14)	(68)	(44)	(630)
Gain on sales of investment securities	3	0	28
Impairment loss (Note 15)	(287)	—	(2,657)
Loss on sale of golf club membership	(6)	(4)	(56)
Other, net	135	85	1,250
	80	330	741
PROFIT BEFORE INCOME TAXES	26,592	24,922	246,222
INCOME TAXES (Note 16):			
Current	6,686	8,022	61,907
Deferred	535	(874)	4,954
	7,222	7,147	66,870
PROFIT	19,370	17,775	179,352
PROFIT ATTRIBUTABLE TO OWNERS OF PARENT	¥19,370	¥17,775	\$179,352

	YEN		U.S. DOLLARS (NOTE 1)
	2020	2019	2020
PER SHARE DATA:			
Profit (Note 18):			
Basic	¥494.89	¥445.78	\$4.58
Diluted	—	—	—
Cash dividends applicable to the year (Note 11)	¥150.00	¥150.00	\$1.39

See accompanying Notes to the Consolidated Financial Statements.

Consolidated Statements of Comprehensive Income

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiary
For the years ended March 31, 2020 and 2019

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
PROFIT	¥19,370	¥17,775	\$179,352
OTHER COMPREHENSIVE INCOME (LOSS) (Note 19):			
Net unrealized holding gain (loss) on securities	(1,408)	(985)	(13,037)
Remeasurements of defined benefit plans	(473)	(6)	(4,380)
Total other comprehensive income (loss)	(1,882)	(992)	(17,426)
COMPREHENSIVE INCOME	17,487	16,782	161,917
Total comprehensive income attributable to:			
Owners of parent	¥17,487	¥16,782	\$161,917

See accompanying Notes to the Consolidated Financial Statements.

Consolidated Statements of Changes in Net Assets

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiary
For the years ended March 31, 2020 and 2019

MILLIONS OF YEN

	SHAREHOLDERS' EQUITY					ACCUMULATED OTHER COMPREHENSIVE INCOME			TOTAL NET ASSETS
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total	Net unrealized holding gain on securities	Remeasurements of defined benefit plans	Total	
BALANCE—March 31, 2018	¥23,853	¥11,408	¥ 97,284	¥(23,259)	¥109,287	¥ 5,510	¥ (923)	¥ 4,587	¥113,874
Changes during the year:									
Cash dividends			(6,002)		(6,002)				(6,002)
Profit attributable to owners of parent			17,775		17,775				17,775
Purchase of treasury stock				(3,523)	(3,523)				(3,523)
Other, net						(985)	(6)	(992)	(992)
Total changes during the year	—	—	11,772	(3,523)	8,249	(985)	(6)	(992)	7,256
BALANCE—March 31, 2019	¥23,853	¥11,408	¥109,057	¥(26,782)	¥117,536	¥ 4,524	¥ (930)	¥ 3,594	¥121,131
Changes during the year:									
Cash dividends			(5,897)		(5,897)				(5,897)
Profit attributable to owners of parent			19,370		19,370				19,370
Purchase of treasury stock			88	(4,341)	(4,252)				(4,252)
Cancellation of treasury stock		(1)	(7,748)	7,750	—				—
Other, net						(1,408)	(473)	(1,882)	(1,882)
Total changes during the year	—	(1)	5,812	3,408	9,219	(1,408)	(473)	(1,882)	7,337
BALANCE—March 31, 2020	¥23,853	¥11,406	¥114,869	¥(23,373)	¥126,756	¥ 3,116	¥(1,404)	¥ 1,712	¥128,468

THOUSANDS OF U.S. DOLLARS (NOTE 1)

	SHAREHOLDERS' EQUITY					ACCUMULATED OTHER COMPREHENSIVE INCOME			TOTAL NET ASSETS
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total	Net unrealized holding gain on securities	Remeasurements of defined benefit plans	Total	
BALANCE—March 31, 2019	\$220,861	\$105,630	\$1,009,787	\$(247,981)	\$1,088,296	\$ 41,889	\$ (8,611)	\$ 33,278	\$1,121,583
Changes during the year:									
Cash dividends			(54,602)		(54,602)				(54,602)
Profit attributable to owners of parent			179,352		179,352				179,352
Purchase of treasury stock			815	(40,194)	(39,370)				(39,370)
Cancellation of treasury stock		(9)	(71,741)	71,759	—				—
Other, net						(13,037)	(4,380)	(17,426)	(17,426)
Total changes during the year	—	(9)	53,815	31,556	85,361	(13,037)	(4,380)	(17,426)	67,935
BALANCE—March 31, 2020	\$220,861	\$105,611	\$1,063,602	\$(216,417)	\$1,173,667	\$ 28,852	\$(13,000)	\$ 15,852	\$1,189,519

See accompanying Notes to the Consolidated Financial Statements.

Consolidated Statements of Cash Flows

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiary
For the years ended March 31, 2020 and 2019

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
CASH FLOWS FROM OPERATING ACTIVITIES:			
Profit before income taxes	¥ 26,592	¥24,922	\$246,222
Adjustments for:			
Depreciation	2,312	2,153	21,407
Impairment loss	287	—	2,657
Amortization of long-term prepaid expenses	449	446	4,157
Increase (decrease) in net defined benefit liability	(22)	(154)	(204)
Interest and dividends income	(393)	(351)	(3,639)
Interest expenses	17	17	157
Loss on retirement of non-current assets	61	43	565
Decrease (increase) in notes and accounts receivable-trade	8,539	2,975	79,065
Decrease (increase) in inventories	1,446	2,930	13,389
Increase (decrease) in trade payables	(3,576)	(1,193)	(33,111)
Other, net	(813)	(1,928)	(7,528)
Subtotal	34,900	29,861	323,148
Interest and dividends income received	393	351	3,639
Interest expenses paid	(17)	(17)	(157)
Income taxes (paid) refund, net	(7,807)	(9,065)	(72,287)
Net cash provided by (used in) operating activities	27,468	21,129	254,333
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property, plant and equipment	(2,159)	(1,908)	(19,991)
Purchase of intangible assets	(43)	(220)	(398)
Purchase of investment securities	—	(1)	—
Purchase of long-term prepaid expenses	(400)	(3,661)	(3,704)
Other, net	75	47	694
Net cash provided by (used in) investing activities	(2,528)	(5,744)	(23,407)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Net decrease (increase) in short-term bank loans	(25)	—	(231)
Net decrease (increase) in treasury stock	(4,252)	(3,523)	(39,370)
Cash dividends paid	(5,896)	(6,001)	(54,593)
Net cash provided by (used in) financing activities	(10,173)	(9,524)	(94,194)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	14,766	5,860	136,722
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	58,555	52,694	542,176
CASH AND CASH EQUIVALENTS AT END OF YEAR (Note 3)	¥ 73,322	¥58,555	\$678,907

See accompanying Notes to the Consolidated Financial Statements.

Notes to the Consolidated Financial Statements

1. Basis of Presenting Consolidated Financial Statements

The accompanying consolidated financial statements of KAKEN PHARMACEUTICAL CO., LTD. (the "Company") and its consolidated subsidiary (collectively the "Group") are prepared on the basis of the accounting principles generally accepted in Japan, which are different in certain respects as to the 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.

In preparing these consolidated financial statements, certain reclassifications and rearrangements have been made to the consolidated financial statements issued domestically in order to present them in a form which is more familiar to readers outside Japan. In addition, certain reclassifications have been made to the 2019 financial statements to conform to the classifications used in 2020.

As permitted by the Financial Instruments and Exchange Act of Japan, amounts of less than one million yen have been omitted. As a result, the totals shown in the accompanying consolidated financial statements (both in yen and U.S. dollars) do not necessarily agree with the sum of the individual amounts.

The U.S. dollar amounts in the accompanying consolidated financial statements have been translated from Japanese yen amounts solely for convenience of readers outside of Japan at ¥108= U.S.\$1.00, the approximate rate of exchange prevailing on March 31, 2020. This translation should not be construed as a representation that Japanese yen amounts have been, could have been, or could in the future be, converted into U.S. dollars at the above or any other rate.

2. Summary of Significant Accounting Policies

(a) Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its subsidiary. For the years ended March 31, 2020 and 2019, the Company had one consolidated subsidiary as follows:

KAKEN PHARMA CO., LTD.

For the years ended March 31, 2020 and 2019, there was no affiliate accounted for using the equity method.

All significant intercompany transactions, account balances and unrealized profits or losses among the Group have been eliminated in consolidation.

(b) Cash and Cash Equivalents

Cash and cash equivalents in the consolidated statements of cash flows are comprised of cash on hand, bank deposits which are able to be withdrawn within three months, and short-term investments with original maturity of three months or less and are considered to have minimal risk from market fluctuations.

(c) Marketable and Investment Securities

Securities are classified into one of the following three categories: (1) Trading, (2) Held-to-maturity debt securities, and (3) Available-for-sale securities. Trading securities are recorded at market value with unrealized gains or losses recognized in the current year's earnings. Held-to-maturity debt securities are carried at amortized cost. Available-for-sale securities are expected to be sold in future and those whose fair values are readily determinable are carried at fair value and the related unrealized gains or losses, net of taxes, are included as a component of "Accumulated other comprehensive income" under net assets. Available-for-sale securities without market quotations are stated at cost determined by the moving average method.

(d) Inventories

Inventories are stated at the lower of cost determined by the gross average method, or net selling value, which is defined as the selling price less additional estimated manufacturing costs and estimated direct selling expenses.

(e) Property, Plant and Equipment

Depreciation is computed using the straight-line method.

The range of useful lives is 3 to 60 years for buildings and structures, and 2 to 8 years for machinery, equipment and vehicles.

(f) Intangible Assets

Software for internal use is amortized over the estimated useful life (5 years) using the straight-line method.

(g) Long-Term Prepaid Expenses

Depreciation is computed using the straight-line method.

(h) Allowance for Doubtful Accounts

To cover losses due to bad debt, allowance for doubtful accounts is provided at the amount determined based on the historical write-off rate for ordinary receivables and the estimated uncollectible amount determined based on the analysis of individual recoverability for specific doubtful receivables such as debt with a possibility of default.

(i) Provision for Bonuses

Provision for bonuses to directors and employees is provided at the amount estimated as of the balance sheet date.

(j) Provision for Sales Returns

In order to cover losses on sales returns after the balance sheet date, provision for sales returns is provided at the total amount of gross profits on estimated sales returns and losses on disposal of returned inventories.

(k) Provision for Sales Rebates

In order to cover expected sales rebates after sales, provision for sales rebates is provided at an amount calculated by multiplying the balance of trade receivables as of the balance sheet date by the estimated sales rebate rates.

(l) Provision for Share-Based Remuneration

In order to prepare for the granting of the Company's stock to directors and corporate officers pursuant to the rules on share distribution to officers, provision for share-based remuneration is recorded at an estimated amount of share-based remuneration obligations as of the balance sheet date.

(m) Retirement and Pension Plan

The Company applies the benefit formula basis as the attribution method for estimated retirement benefits.

Unrecognized prior service cost is amortized on a straight-line basis over a period within the average remaining years of service of the employees (10 years) from the year in which it arises. Unrecognized actuarial gain or loss is amortized on a straight-line basis over a period within the average remaining years of service of the employees (10 years) from the year following the year in which it arises.

(n) Income Taxes

Income taxes—deferred are determined using the asset and liability approach, where deferred tax assets and liabilities are recognized for temporary differences between the tax basis of assets and liabilities and their reported amount in the consolidated financial statements.

(o) Consumption Taxes

Consumption taxes withheld and consumption taxes paid are excluded from revenues and expenses in the accompanying consolidated statements of income. The net balance of consumption taxes withheld and consumption taxes paid is included in current liabilities of the consolidated balance sheets as of the end of the fiscal year.

(p) Derivative Financial Instruments and Hedge Accounting

Derivative instruments, which include forward foreign exchange contracts, are used as a part of the Company's risk management of foreign currency risk exposure of its financial assets and liabilities.

Forward foreign exchange contract:

The Company enters into forward foreign exchange contracts to limit risk exposure, affected by changes in foreign currency exchange rates, on trade receivables and trade payables and cash flows generated from forecasted transactions denominated in foreign currencies. For forward foreign exchange contracts which are designated and are effective as hedges of such foreign currency risk on existing assets and liabilities, the Company adopted the accounting method whereby foreign currency denominated assets and liabilities are measured at the contract rate of the respective forward foreign exchange contract. With respect to such contracts for forecasted transactions, the contracts are marked-to-market and the unrealized gains/losses are deferred in the balance sheet to be released to income when the exchange gains/losses on the hedged items or transactions are recognized.

Hedge accounting:

Hedging instruments and hedged items, hedging policy, method for assessment of hedge effectiveness, and other matters related to hedge accounting are as follows:

(1) Hedging instruments and hedged items

Hedging instrument: Forward foreign exchange contract

Hedged items: Foreign currency denominated receivables and payables, and forecasted foreign currency denominated transactions

(2) Hedging policy

Hedging instruments are used within the amounts of foreign currency denominated transactions, and the Company makes it a policy not to use derivatives for speculative purposes.

(3) Method for assessment of hedge effectiveness

Since material terms related to hedged items and hedging instruments are substantially identical, and the market fluctuations is expected to be completely offset continuously at the time of and after the inception of the related hedge, assessment of hedging effectiveness is omitted.

Assessment of effectiveness is omitted also for the forward foreign exchange contracts, under which the hedged items are translated using the forward contract rates.

(q) Appropriations of Retained Earnings

Appropriations of retained earnings at each year-end are reflected in the consolidated financial statements for the following year upon shareholders' approval.

(r) Shareholders' Equity

Japanese companies are subject to the Companies Act of Japan (the "Act"). The Act provides that an amount equal to 10% of the amount to be disbursed as distributions of capital surplus (other than the capital reserve) and retained earnings (other than the legal reserve) be transferred to the capital reserve and the legal reserve, respectively, until the sum of the capital reserve and legal reserve equals 25% of the stated capital. Such distributions can be made at any time by resolution of the shareholders or by the Board of Directors if certain conditions are met. The above-mentioned legal reserve is included in retained earnings in the accompanying consolidated balance sheets.

(s) Dividends per Share

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

(t) New Accounting Standards Not Yet Applied**Accounting Standard for Revenue Recognition**

"Accounting Standard for Revenue Recognition" (Accounting Standards Board of Japan ("ASBJ") Statement No. 29, revised on March 31, 2020)

"Implementation Guidance on Accounting Standard for Revenue Recognition" (ASBJ Guidance No. 30, revised on March 31, 2020)

(1) Overview

ASBJ has developed a comprehensive accounting standard for revenue recognition and issued it with implementation guidance. Revenue is recognized by applying the following five steps:

- Step 1: Identify the contract(s) with a customer.
- Step 2: Identify the performance obligations in the contract.
- Step 3: Determine the transaction price.
- Step 4: Allocate the transaction price to the performance obligations in the contract.
- Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation.

(2) Scheduled date of application

The Standard and Implementation Guidance are scheduled to be applied from the beginning of the year ending March 31, 2022.

(3) Effect of applying the accounting standard and guidance

The Company is currently evaluating the effect of applying the accounting standard and guidance.

Accounting Standards for Fair Value Measurement, etc.

"Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 30, issued on July 4, 2019)

"Implementation Guidance on Accounting Standard for Fair Value Measurement" (ASBJ Guidance No. 31, issued on July 4, 2019)

"Accounting Standard for Measurement of Inventories" (ASBJ Statement No. 9, revised on July 4, 2019)

"Accounting Standard for Financial Instruments" (ASBJ Statement No. 10, revised on July 4, 2019)

"Implementation Guidance on Disclosures about Fair Value of Financial Instruments" (ASBJ Guidance No. 19, revised on March 31, 2020)

(1) Overview

In order to enhance comparability with requirements under international accounting standards, "Accounting Standard for Fair Value Measurement" and "Implementation Guidance on Accounting Standard for Fair Value Measurement" (hereinafter collectively "Fair Value Measurement Accounting Standards, etc.") have been developed and guidance on fair value measurement, etc. has been provided. Fair Value Measurement Accounting Standards, etc. will be applied to the fair value of the following items:

- Financial instruments as defined in "Accounting Standard for Financial Instruments"
- Inventories held for trading purpose as defined in "Accounting Standard for Measurement of Inventories"

In addition, "Implementation Guidance on Disclosures about Fair Value of Financial Instruments" was revised and notes disclosure requirements as to the breakdown of fair values for financial instruments by the level of fair value hierarchy, etc. were provided.

(2) Scheduled date of application

Fair Value Accounting Standards, etc. are scheduled to be applied from the beginning of the year ending March 31, 2022.

(3) Effect of applying the accounting standards and guidances

The Company is currently evaluating the effect of applying the accounting standards and guidances.

Accounting Standard for Accounting Policy Disclosures, Accounting Changes and Error Corrections

"Accounting Standard for Accounting Policy Disclosures, Accounting Changes and Error Corrections" (ASBJ Statement No. 24, revised on March 31, 2020)

(1) Overview

This accounting standard intends to show the outline of accounting principles and procedures in case that the provisions of the relevant accounting standards are not clearly defined.

(2) Scheduled date of application

The Standard is scheduled to be applied from the end of the year ending March 31, 2021.

Accounting Standard for Disclosure of Accounting Estimates

"Accounting Standard for Disclosure of Accounting Estimates" (ASBJ Statement No. 31, issued on March 31, 2020)

(1) Overview

The Standard aims to disclose information that will facilitate the understanding of the users of the financial statements, regarding items of accounting estimates used in the financial statements for the current fiscal year that have risk of significant impact on the financial statements for the following fiscal year.

(2) Scheduled date of application

The Standard is scheduled to be applied from the end of the year ending March 31, 2021.

(u) Changes in Presentation**Changes in presentation of the consolidated statements of income**

"Loss on cancellation of leases," which was independently presented for the year ended March 31, 2019, has been included in "Other, net" under "Other income (expenses)" for the year ended March 31, 2020, due to the decreased materiality. To reflect the changes in presentation, the consolidated statement of income for the year ended March 31, 2019 has been restated.

As a result, "Loss on cancellation of leases" of ¥10 million and "Other, net" of ¥17 million has been reclassified into "Other, net" of ¥27 million under "Other income (expenses)" in the consolidated statement of income for the year ended March 31, 2019.

(v) Additional Information**Introduction of Board Benefits Trust ("BBT")**

The Company, based on the resolution of the 99th ordinary general meeting of shareholders held on June 27, 2019, has newly introduced a Performance-Linked Share-Based Remuneration Plan (Board Benefit Trust (BBT)) (hereinafter "the Plan") for the directors (excluding outside directors) and corporate officers (hereinafter collectively "directors, etc.") from the year ended March 31, 2020, with the aim to enhance their awareness of improving medium- to long-term performances and contributing to an increase of corporate value.

The Company adopted the gross method to account for the Plan, in accordance with "Practical Solution on Transactions of Delivering the Company's Own Stock to Employees etc. through Trusts" (ASBJ Practical Issue Task Force (PITF) No. 30, issued on March 26, 2015).

(1) Overview of the transaction

The Plan is a share-based remuneration plan whereby shares in the Company are acquired through a trust using funds contributed by the Company (hereinafter, such trust established pursuant to the Plan, the "Trust"), and the Company's shares and cash equivalents of such shares at their market value (hereinafter "the Company's shares, etc.") are granted through the Trust to the directors, etc. pursuant to the rules on share distribution to officers established by the Company.

The directors, etc. will receive the Company's shares, etc., in principle, upon their retirement.

(2) The Company's shares remaining in the Trust

The Company's shares remaining in the Trust are recorded as "Treasury stock" under net assets at the carrying amount in the Trust (except for incidental costs). As of March 31, 2020, the carrying amount and the number of shares of the treasury stock were ¥224 million (\$2,074 thousand) and 41,100 shares, respectively.

Accounting Estimates Associated with the Spread of the Novel Coronavirus (COVID-19) Infection

The spread of COVID-19 infection is having various effects on the pharmaceutical industry including scaled-back health checkups at medical institutions and restrictions over information sharing activities. If period to cessation of COVID-19 infection is prolonged, the supply system of pharmaceuticals as well as research and development activities may also incur negative impacts, which may persist and repeat.

The management considers it does not have significant impact on accounting estimates for the year ended March 31, 2020 although there have been certain impact on the business activities of the Group.

3. Cash and Cash Equivalents

Cash and deposits and marketable securities are reconciled to cash and cash equivalents on the consolidated statements of cash flows as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
Cash and deposits	¥59,722	¥46,956	\$552,981
Marketable securities	13,599	11,599	125,917
Subtotal	¥73,322	¥58,555	\$678,907
Time deposits due after three months	—	—	—
Marketable securities due after three months	—	—	—
Cash and cash equivalents	¥73,322	¥58,555	\$678,907

4. Marketable and Investment Securities

The carrying amounts and fair values of held-to-maturity debt securities are as follows:

	MILLIONS OF YEN					
	Carrying amount	Fair value	Unrealized gain (loss)	Carrying amount	Fair value	Unrealized gain (loss)
	2020			2019		
Fair values exceeding carrying amounts	¥ —	¥ —	¥—	¥ —	¥ —	¥—
Fair values not exceeding carrying amounts	10,999	10,999	—	9,999	9,999	—
Total	¥10,999	¥10,999	¥—	¥9,999	¥9,999	¥—

	THOUSANDS OF U.S. DOLLARS (NOTE 1)		
	Carrying amount	Fair value	Unrealized gain (loss)
	2020		
Fair values exceeding carrying amounts	\$ —	\$ —	\$—
Fair values not exceeding carrying amounts	101,843	101,843	—
Total	\$101,843	\$101,843	\$—

The aggregate fair values (carrying amounts) and acquisition costs of available-for-sale securities are as follows:

	MILLIONS OF YEN					
	Fair value	Acquisition cost	Unrealized gain (loss)	Fair value	Acquisition cost	Unrealized gain (loss)
	2020			2019		
Carrying amounts exceeding acquisition costs						
Equity securities	¥12,939	¥ 8,073	¥4,866	¥16,547	¥ 9,990	¥6,557
Other	—	—	—	—	—	—
Subtotal	12,939	8,073	4,866	16,547	9,990	6,557
Carrying amounts not exceeding acquisition costs						
Equity securities	2,039	2,414	(374)	463	498	(35)
Other	2,600	2,600	—	1,600	1,600	—
Subtotal	4,639	5,014	(374)	2,063	2,098	(35)
Total	¥17,579	¥13,087	¥4,491	¥18,610	¥12,089	¥6,521

THOUSANDS OF U.S. DOLLARS (NOTE 1)

	Fair value	Acquisition cost	Unrealized gain (loss)
	2020		
Carrying amounts exceeding acquisition costs			
Equity securities	\$119,806	\$ 74,750	\$45,056
Other	—	—	—
Subtotal	119,806	74,750	45,056
Carrying amounts not exceeding acquisition costs			
Equity securities	18,880	22,352	(3,463)
Other	24,074	24,074	—
Subtotal	42,954	46,426	(3,463)
Total	\$162,769	\$121,176	\$41,583

Available-for-sale securities sold for the years ended March 31, 2020 and 2019 are summarized as follows:

MILLIONS OF YEN

	Proceeds	Gain	Loss	Proceeds	Gain	Loss
	2020			2019		
Equity securities	¥5	¥3	¥—	¥0	¥0	¥—
Total	¥5	¥3	¥—	¥0	¥0	¥—

THOUSANDS OF U.S. DOLLARS (NOTE 1)

	Proceeds	Gain	Loss
	2020		
Equity securities	\$46	\$28	\$—
Total	\$46	\$28	\$—

5. Inventories

Inventories as of March 31, 2020 and 2019, comprised the following:

MILLIONS OF YEN

THOUSANDS OF U.S. DOLLARS (NOTE 1)

	2020	2019	2020
Merchandise and finished products	¥ 4,762	¥ 6,113	\$ 44,093
Work in process	2,829	2,647	26,194
Raw materials and supplies	4,683	4,959	43,361
Total	¥12,275	¥13,721	\$113,657

6. Short-term Bank Loans and Pledged Assets

(a) Short-term bank loans

Short-term bank loans outstanding as of March 31, 2020 and 2019, amounting to ¥3,850 million (\$35,648 thousand) and ¥3,875 million, respectively, consisted mainly of bank overdrafts. The weighted-average interest rates applicable to short-term bank loans as of March 31, 2020 and 2019 were 0.45%.

(b) Pledged assets

As of March 31, 2020 and 2019, assets pledged as collateral for certain short-term bank loans are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
Assets pledged:			
Buildings and structures	¥6,114	¥ 6,311	\$56,611
Machinery, equipment and vehicles	2,730	3,084	25,278
Tools, furniture and fixtures	806	785	7,463
Land	117	117	1,083
Total	¥9,769	¥10,298	\$90,454
Liabilities secured:			
Short-term bank loans	¥1,400	¥ 1,400	\$12,963
Total	¥1,400	¥ 1,400	\$12,963

7. Accounting for Leases**Operating leases**

(As a lessor)

Future minimum lease payments receivable under non-cancellable operating leases subsequent to March 31, 2020 and 2019, are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
Due within 1 year	¥ 966	¥ 966	\$ 8,944
Due after 1 year	5,985	6,952	55,417
Total	¥6,952	¥7,919	\$64,370

8. Investment Properties

The Company owns rental office buildings (including land) mainly in Tokyo and other areas.

Operating profit from these rental properties for the years ended March 31, 2020 and 2019 was ¥1,463 million (\$13,546 thousand) and ¥1,476 million (Revenue from rental properties and related expenses are reported as net sales and cost of sales), respectively.

Carrying amount, changes during the years ended March 31, 2020 and 2019, and fair value of these properties as of those dates are stated as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
Carrying amount:			
Balance at the beginning of the year	¥10,490	¥10,752	\$ 97,130
Changes during the year	(304)	(261)	(2,815)
Balance at the end of the year	10,186	10,490	94,315
Fair value at the end of the year	¥47,709	¥46,234	\$441,750

Notes: 1. The carrying amount represents the acquisition costs less accumulated depreciation.

2. Fair value at the end of the year is calculated, with adjustments using applicable indices, by the Company primarily based on the "Real estate appraisal standards of Japan."

9. Financial Instruments

(a) Outline of financial instruments

(1) Policy for using financial instruments

The Group is managing its cash surplus in the form of low-risk financial instruments with high liquidity, while raising short-term working capital through loans from financial institutions including banks. Derivatives are used, not for speculative purposes, but to manage exposure to financial risks as described below.

(2) Nature and extent of risks arising from financial instruments

Trade receivables such as notes and accounts receivable—trade are exposed to customers' credit risk. Trade receivables denominated in foreign currencies are exposed to foreign exchange fluctuation risk. Marketable and investment securities are mainly held-to-maturity debt securities and equity securities, which are exposed to the risk of market price fluctuations.

Payment terms of trade payables, such as notes and accounts payable—trade and electronically recorded obligations—operating, are mostly less than one year. Trade payables in foreign currencies in connection with the import transactions of raw materials are exposed to foreign exchange fluctuation risk. Bank loans are used for short-term working capital.

Derivative transactions used by the Company are only forward foreign exchange contracts for the purpose of hedging foreign exchange fluctuation risk of trade receivables and trade payables denominated in foreign currencies. Please see Note 2. Summary of Significant Accounting Policies, (p) Derivative Financial Instruments and Hedge Accounting for details.

(3) Risk management for financial instruments

a. Credit risk management (customers' default risk)

For the purpose of managing credit risk of trade receivables within the Group, each concerned department, according to the credit management rules, is managing payment terms and balances of each major customer by regularly monitoring their status, in an effort to achieve early identification and mitigation of default risk of customers arising from their deteriorating financial condition and other factors.

Held-to-maturity debt securities held by the Company are, under the short-term investment rules, restricted to those with superior ratings only, involving minimal credit risk.

The Company enters into derivative transactions only with high credit rating financial institutions to mitigate the counterparty risk.

b. Market risk management (foreign exchange and interest rate fluctuation risks)

The Company uses forward foreign exchange contracts as appropriate to hedge foreign exchange fluctuation risk associated with trade receivables and trade payables denominated in foreign currencies.

With respect to marketable and investment securities, the Company is periodically monitoring fair values and financial positions of the related issuers (business counterparties), etc.

Derivative transactions are conducted under the authority of the general manager at each concerned department, in accordance with the forward foreign exchange contracts management rules, and the execution result of derivative transactions is reported to the Accounting Department and other concerned departments, as each transaction takes place. At the end of each month, the outstanding balance of forward foreign exchange contracts is reported to the directors in charge, as well as to other concerned departments. The consolidated subsidiary is not engaged in derivative transactions.

c. Liquidity risk management on fund-raising

The Company manages its liquidity risk by the Accounting Department preparing and updating the cash management plan as appropriate based on the report from each concerned department.

(4) Supplementary explanation concerning fair values of financial instruments

Fair values of financial instruments comprise values determined based on market prices, if available, and reasonably determined values if quoted market prices are not available. Since variable factors are incorporated in computing the relevant fair values of financial instruments whose quoted market prices are not available, such fair values may vary depending on different assumptions.

(5) Concentration of credit risks

As of March 31, 2020, 61% of all trade receivables was with specific major accounts.

(b) Fair values of financial instruments

Carrying amount, fair value, and difference of the financial instruments as of March 31, 2020 and 2019 are as follows. Financial instruments whose fair values are extremely difficult to determine are excluded from the following table:

	MILLIONS OF YEN		
	Carrying amount	Fair value	Difference
	2020		
(1) Cash and deposits	¥ 59,722	¥ 59,722	¥—
(2) Notes and accounts receivable—trade	21,800		
Allowance for doubtful accounts*	(0)		
	21,800	21,800	—
(3) Marketable and investment securities			
a. Held-to-maturity debt securities	10,999	10,999	—
b. Available-for-sale securities	17,579	17,579	—
Total assets	¥110,102	¥110,102	¥—
(1) Notes and accounts payable—trade	¥ 7,720	¥ 7,720	¥—
(2) Electronically recorded obligations—operating	962	962	—
(3) Short-term bank loans	3,850	3,850	—
Total liabilities	¥ 12,532	¥ 12,532	¥—

	MILLIONS OF YEN		
	Carrying amount	Fair value	Difference
	2019		
(1) Cash and deposits	¥ 46,956	¥ 46,956	¥—
(2) Notes and accounts receivable—trade	30,340		
Allowance for doubtful accounts*	(0)		
	30,340	30,340	—
(3) Marketable and investment securities			
a. Held-to-maturity debt securities	9,999	9,999	—
b. Available-for-sale securities	18,610	18,610	—
Total assets	¥105,906	¥105,906	¥—
(1) Notes and accounts payable—trade	¥ 10,729	¥ 10,729	¥—
(2) Electronically recorded obligations—operating	1,529	1,529	—
(3) Short-term bank loans	3,875	3,875	—
Total liabilities	¥ 16,134	¥ 16,134	¥—

THOUSANDS OF U.S. DOLLARS (NOTE 1)			
	Carrying amount	Fair value	Difference
	2020		
(1) Cash and deposits	\$ 552,981	\$ 552,981	\$—
(2) Notes and accounts receivable—trade	201,852		
Allowance for doubtful accounts*	(0)		
	201,852	201,852	—
(3) Marketable and investment securities			
a. Held-to-maturity debt securities	101,843	101,843	—
b. Available-for-sale securities	162,769	162,769	—
Total assets	\$1,019,463	\$1,019,463	\$—
(1) Notes and accounts payable—trade	\$ 71,481	\$ 71,481	\$—
(2) Electronically recorded obligations—operating	8,907	8,907	—
(3) Short-term bank loans	35,648	35,648	—
Total liabilities	\$ 116,037	\$ 116,037	\$—

*Allowance for doubtful accounts is related to notes and accounts receivable—trade.

Note:

1. Calculation method of fair values of financial instruments and securities

Assets:

(1) Cash and deposits and (2) Notes and accounts receivable—trade

The carrying amounts of these financial instruments approximate fair values due to their short-term maturities.

(3) Marketable and investment securities

Fair values of equity securities are based on the quoted market prices on stock exchanges while those of debt securities are based on the quoted market prices on relevant exchanges, or those quoted by counterparty financial institutions. For the information on securities by holding purpose, please see Note 4. "Marketable and Investment Securities."

Liabilities:

(1) Notes and accounts payable—trade, (2) Electronically recorded obligations—operating and (3) Short-term bank loans

The carrying amounts of these financial instruments approximate fair values due to their short-term maturities.

2. Financial instruments whose fair values are extremely difficult to determine

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	Carrying amount		
	2020	2019	2020
Unlisted equity securities	¥57	¥57	\$528

The above securities are not included in "(3) Marketable and investment securities" because no quoted market price is available and it is extremely difficult to determine its fair value.

3. Redemption schedules of monetary assets and securities with contractual maturities subsequent to March 31, 2020 and 2019, are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	Within one year		
	2020	2019	2020
Cash and deposits	¥59,722	¥46,956	\$552,981
Notes and accounts receivable—trade	21,800	30,340	201,852
Marketable and investment securities:			
Held-to-maturity debt securities	10,999	9,999	101,843
Available-for-sale securities with contractual maturities	2,600	1,600	24,074
Total	¥95,123	¥88,895	\$880,769

4. Redemption schedules for long-term debt and other interest-bearing obligations subsequent to March 31, 2020 and 2019 are omitted since the Company only had short-term bank loans maturing within one year as of March 31, 2020 and 2019.

10. Retirement Benefits

The Company has defined benefit plans, i.e., a lump-sum retirement plan and defined benefit corporate pension plan. Retirement benefit trust is established for the lump-sum retirement plan. The Company may make additional payments at the time of employees' retirement in addition to the lump-sum retirement benefits. The simplified method is used for the calculation of retirement benefit obligation of the consolidated subsidiary.

Defined benefit plans

(a) Changes in the retirement benefit obligation for the years ended March 31, 2020 and 2019 are as follows (excluding plans applying the simplified method):

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
Retirement benefit obligation—Beginning balance	¥19,946	¥20,549	\$184,685
Service cost	727	750	6,731
Interest cost	59	61	546
Actuarial gain or loss	(75)	10	(694)
Retirement benefit paid	(1,368)	(1,424)	(12,667)
Retirement benefit obligation—Ending balance	¥19,289	¥19,946	\$178,602

(b) Changes in the plan assets for the years ended March 31, 2020 and 2019 are as follows (excluding plans applying the simplified method):

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
Plan assets—Beginning balance	¥13,312	¥13,769	\$123,259
Expected return on plan assets	316	322	2,926
Actuarial gain or loss	(948)	(378)	(8,778)
Employer's contributions	168	474	1,556
Retirement benefit paid	(853)	(875)	(7,898)
Plan assets—Ending balance	¥11,994	¥13,312	\$111,056

(c) Changes in the net defined benefit liability applying the simplified method for the years ended March 31, 2020 and 2019 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
Net defined benefit liability—Beginning balance	¥7	¥7	\$65
Retirement benefit cost	0	0	0
Net defined benefit liability—Ending balance	¥7	¥7	\$65

(d) Reconciliation between the net liability recorded in the consolidated balance sheets and the balances of defined benefit obligation and plan assets are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
Retirement benefit obligation under funded plan	¥ 19,289	¥ 19,946	\$ 178,602
Plan assets	(11,994)	(13,312)	(111,056)
	7,295	6,634	67,546
Retirement benefit obligation under unfunded plan	7	7	65
Net liability recorded on the consolidated balance sheets	7,303	6,642	67,620
Net defined benefit liability	7,303	6,642	67,620
Net liability recorded on the consolidated balance sheets	¥ 7,303	¥ 6,642	\$ 67,620

Notes: 1. Retirement benefit obligation and plan assets under the Company's funded plan include those for the lump-sum retirement plan.
2. A plan applying simplified method is included.

(e) The components of the net periodic pension cost are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
Service cost	¥ 727	¥ 750	\$ 6,731
Interest cost	59	61	546
Expected return on plan assets	(316)	(322)	(2,926)
Amortization of actuarial gain or loss	224	411	2,074
Amortization of prior service cost	(33)	(33)	(306)
Net periodic pension cost under simplified method	0	0	0
Net periodic pension cost for defined benefit plans	¥ 661	¥ 868	\$ 6,120

(f) The components of remeasurements of defined benefit plans in other comprehensive income (before tax effect) for the years ended March 31, 2020 and 2019 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
Prior service cost	¥ (33)	¥(33)	\$ (306)
Actuarial gain or loss	(649)	23	(6,009)
Total	¥(682)	¥ (9)	\$(6,315)

(g) The components of remeasurements of defined benefit plans in accumulated other comprehensive income (before tax effect) as of March 31, 2020 and 2019 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
Unrecognized prior service cost	¥ (38)	¥ (72)	\$ (352)
Unrecognized actuarial gain or loss	2,062	1,412	19,093
Total	¥2,023	¥1,340	\$18,731

(h) Plan assets

(1) Plan assets consist of the following:

	2020	2019
Debt securities	50%	45%
Equity securities	29	36
General account	16	15
Other	5	4
Total	100%	100%

Note: The plan assets include retirement benefit trust which accounted for 4% and 5% of the total plan assets as of March 31, 2020 and 2019, respectively.

(2) Long-term expected rate of return on plan assets is determined based on current and expected allocation of plan assets and long-term rate of returns expected currently and in the future from the various components of the plan assets.

(i) Major assumptions used for actuarial calculation are as follows (weighted average):

	2020	2019
Discount rate	0.3%	0.3%
Long-term expected rate of return	2.0%	2.5%

11. Shareholders' Equity**(a) Class and number of shares outstanding and treasury stock**

	Class of shares outstanding	Class of treasury stock
	Common stock	Common stock
Number of shares as of April 1, 2019	48,439,730	8,721,768
Increase	—	800,808
Decrease	(2,500,000)	(2,500,000)
Number of shares as of March 31, 2020	45,939,730	7,022,576

Notes:

1. Decrease in number of shares outstanding (2,500,000 shares) is due to cancellation of treasury stock based on the resolution of the Board of Directors' meeting.
2. Increase in treasury stock (800,808 shares) is due to purchase of shares through the market (800,000 shares) based on the resolution of the Board of Directors' meeting and purchase of shares of less than one unit (808 shares).
3. Decrease in treasury stock (2,500,000 shares) is due to cancellation of treasury stock based on the resolution of the Board of Directors' meeting.
4. The number of treasury stock includes the Company's shares held by Trust & Custody Services Bank, Ltd. (Trust Account E) as trust assets of the Board Benefit Trust (BBT) (41,100 shares as of March 31, 2020 and 0 share as of April 1, 2019).

(b) Matters related to dividends**(1) Dividend payment**

Approval by the ordinary general meeting of shareholders held on June 27, 2019, was as follows:

Dividends on common stock

Total amount of dividends	¥2,978 million (\$27,574 thousand)
Dividends per share	¥75.00 (\$0.69)
Record date	March 31, 2019
Effective date	June 28, 2019

Approval by the Board of Directors' meeting held on November 6, 2019, was as follows:

Dividends on common stock

Total amount of dividends	¥2,918 million (\$27,019 thousand)
Dividends per share	¥75.00 (\$0.69)
Record date	September 30, 2019
Effective date	November 29, 2019

(2) Dividends whose record date is attributed to the year ended March 31, 2020, but become effective after March 31, 2020

The Company obtained the following approval at the ordinary general meeting of shareholders held on June 26, 2020:

Dividends on common stock

Total amount of dividends ¥2,921 million (\$27,046 thousand)

Dividends per share ¥75.00 (\$0.69)

Record date March 31, 2020

Effective date June 29, 2020

(Note) Total amount of dividends include ¥3 million (\$28 thousand) of dividends payable for the Company's shares held by Trust & Custody Services Bank, Ltd. (Trust Account E) as trust assets of the Board Benefit Trust (BBT).

12. Research and Development Costs

Research and development costs included in cost of sales and selling, general and administrative expenses for the years ended March 31, 2020 and 2019 amounted to ¥6,418 million (\$59,426 thousand) and ¥10,261 million, respectively.

13. Gain on Sales of Non-Current Assets

Gain on sales of non-current assets for the years ended March 31, 2020 and 2019 consists of the followings:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
Machinery, equipment and vehicles	¥3	¥—	\$28
Other	0	—	0
Total	¥4	¥—	\$37

14. Loss on Retirement of Non-Current Assets

Loss on retirement of non-current assets for the years ended March 31, 2020 and 2019 consists of the followings:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
Buildings and structures	¥11	¥ 4	\$102
Other	57	39	528
Total	¥68	¥44	\$630

15. Impairment Loss

The Group recognizes impairment loss for the following asset group for the year ended March 31, 2020:

Location	Use	Type	MILLIONS OF YEN	THOUSANDS OF U.S. DOLLARS (NOTE 1)
			Impairment loss	
Chuo-ku, Osaka	Business assets	Buildings and structures, etc.	¥287	\$2,657

The Group categorizes its business assets based principally on the segment by types of business, and rental properties, idle assets, etc. are grouped on an individual basis.

The above assets are now under dismantling based on the resolution to rebuild by the Board of Directors' meeting held on August 28, 2019 and the carrying value is written-down to the recoverable value. The decreased value of buildings and structures, etc. in an amount of ¥117 million (\$1,083 thousand) and the dismantling costs of ¥169 million (\$1,565 thousand) are recognized as impairment loss under other income (expenses).

The recoverable value is based on the memorandum value.

No impairment loss was recognized for the year ended March 31, 2019.

16. Income Taxes

Significant components of deferred tax assets and liabilities as of March 31, 2020 and 2019 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
Deferred tax assets:			
Accounts receivable-trade	¥ 58	¥ 54	\$ 537
Disallowed expensed supplies	232	275	2,148
Adjustment of gain on sales of land	2,638	2,638	24,426
Amortization of research & development expenses	196	531	1,815
Amortization of long-term prepaid expenses	1,132	1,298	10,481
Provision for bonuses	333	354	3,083
Provision for sales rebates	95	96	880
Net defined benefit liability	1,779	1,783	16,472
Other	1,075	842	9,954
Total	7,542	7,875	69,833
Valuation allowance	(2,819)	(2,819)	(26,102)
Deferred tax assets	4,723	5,056	43,731
Deferred tax liabilities:			
Reserve for tax purpose reduction entry of non-current assets	(118)	(125)	(1,093)
Net unrealized holding gain on securities	(1,375)	(1,996)	(12,731)
Deferred tax liabilities	(1,493)	(2,121)	(13,824)
Deferred tax assets, net	¥ 3,229	¥ 2,934	\$ 29,898

The Group is subject to several taxes based on income, which in the aggregate resulted in statutory tax rates of approximately 30.62% for the years ended March 31, 2020 and 2019. Reconciliation of the differences between the statutory tax rate and the effective tax rate for the years ended March 31, 2020 and 2019, is as follows:

	2020	2019
Statutory tax rate	30.62%	30.62%
Increase (decrease) in taxes resulting from:		
Expenses not deductible for income tax purpose (e.g. entertainment expenses)	0.22	0.34
Income not included for income tax purpose (e.g. dividend income)	(0.09)	(0.09)
Inhabitant per capita taxes	0.28	0.34
Tax credit for research expenses	(3.59)	(1.92)
Other	(0.28)	(0.61)
Effective tax rate	27.16%	28.68%

17. Related Party Transactions

There are no related party transactions to be disclosed for the years ended March 31, 2020 and 2019.

18. Per Share Information

Per share information as of March 31, 2020 and 2019 and for the years then ended, is as follows:

	YEN		U.S. DOLLARS (NOTE 1)
	2020	2019	2020
Net assets per share	¥3,301.09	¥3,049.78	\$30.57
Profit per share	494.89	445.78	4.58

Notes:

1. Diluted profit per share is not presented due to the absence of dilutive shares.
2. The Company has introduced the Board Benefit Trust (BBT) from the year ended March 31, 2020. The Company's shares held by the BBT, which are recorded as treasury stock in shareholders' equity, are included in the treasury stock to be deducted from the total number of shares outstanding at the end of the year for computation of net assets per share, and are also included in the treasury stock to be deducted when calculating the weighted average number of shares for computation of profit per share.
The number of treasury stock deducted for computation of net assets per share is 41,100 shares as of March 31, 2020 and the weighted average number of shares of treasury stock deducted for computation of profit per share is 14,598 shares for the year ended March 31, 2020.

The basis of calculation for profit per share for the years ended March 31, 2020 and 2019 is as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
Profit	¥19,370	¥17,775	\$179,352
Profit attributable to common stock owners of parent	19,370	17,775	179,352
Profit not attributable to common stock	—	—	—
(Number of shares)			
Weighted average number of shares (thousands of shares)	39,140	39,874	

19. Comprehensive Income

Reclassification adjustments and income tax effects for each component of other comprehensive income for the years ended March 31, 2020 and 2019, are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2020	2019	2020
Net unrealized holding gain (loss) on securities:			
Increase (decrease) during the year	¥(2,026)	¥(1,421)	\$ (18,759)
Reclassification adjustments	(3)	(0)	(28)
Before income tax effect	(2,029)	(1,421)	(18,787)
Income tax effect	621	435	5,750
Net unrealized holding gain (loss) on securities	¥(1,408)	¥ (985)	\$ (13,037)
Remeasurements of defined benefit plans:			
Increase (decrease) during the year	¥ (873)	¥ (388)	\$ (8,083)
Reclassification adjustments	190	378	1,759
Before income tax effect	(682)	(9)	(6,315)
Income tax effect	209	3	1,935
Remeasurements of defined benefit plans	¥ (473)	¥ (6)	\$ (4,380)
Total other comprehensive income	¥(1,882)	¥ (992)	\$ (17,426)

20. Segment Information

(a) Overview of reportable segments

The Group's reportable segments are those for which separate financial information is available and regular evaluation by the Board of Directors is being performed in order to decide how resources are allocated within the Group.

The Group produces and sells medical products, medical devices and agrochemicals and rents real estate, operating each business by category of industry. Each business operates on its own initiative, and creates comprehensive business strategies in conducting its business activities. The Group consists of segments by category of industry based on the operation of business; therefore, it consists of two reportable segments: "Pharmaceuticals" and "Real estate."

"Pharmaceuticals" mainly produces and sells medical products, medical devices, and agrochemicals.

"Real estate" mainly rents out Bunkyo Green Court.

(b) Method of calculating net sales, profit, assets, and other items by reportable segment

Accounting policies for the reportable segments are consistent with those described in Note 2.

"Summary of Significant Accounting Policies." Profit by reportable segment is based on operating profit.

Corporate assets are not allocated to each reportable segment. However, related expenses are allocated to each reportable segment using reasonable criteria.

(c) Information about reportable segments

MILLIONS OF YEN

	Reportable Segment			Adjustments	Consolidated
	Pharmaceuticals	Real estate	Total		
	2020				
Net sales:					
Sales to external customers	¥86,853	¥ 2,378	¥89,232	¥ —	¥ 89,232
Intersegment sales or transfers	—	—	—	—	—
Total	¥86,853	¥ 2,378	¥89,232	¥ —	¥ 89,232
Segment profit	¥25,048	¥ 1,463	¥26,512	¥ —	¥ 26,512
Segment assets	¥69,597	¥10,024	¥79,621	¥78,253	¥157,875
Other items:					
Depreciation and amortization	¥ 2,464	¥ 297	¥ 2,761	¥ —	¥ 2,761
Increase in property, plant and equipment and intangible assets	1,680	44	1,724	—	1,724

MILLIONS OF YEN

	Reportable Segment			Adjustments	Consolidated
	Pharmaceuticals	Real estate	Total		
2019					
Net sales:					
Sales to external customers	¥91,804	¥ 2,360	¥94,165	¥ —	¥ 94,165
Intersegment sales or transfers	—	—	—	—	—
Total	¥91,804	¥ 2,360	¥94,165	¥ —	¥ 94,165
Segment profit	¥23,116	¥ 1,476	¥24,592	¥ —	¥ 24,592
Segment assets	¥81,908	¥10,277	¥92,186	¥63,799	¥155,985
Other items:					
Depreciation and amortization	¥ 2,302	¥ 297	¥ 2,600	¥ —	¥ 2,600
Increase in property, plant and equipment and intangible assets	6,405	19	6,424	—	6,424

THOUSANDS OF U.S. DOLLARS (NOTE 1)

	Reportable Segment			Adjustments	Consolidated
	Pharmaceuticals	Real estate	Total		
	2020				
Net sales:					
Sales to external customers	\$804,194	\$22,019	\$826,222	\$ —	\$ 826,222
Intersegment sales or transfers	—	—	—	—	—
Total	\$804,194	\$22,019	\$826,222	\$ —	\$ 826,222
Segment profit	\$231,926	\$13,546	\$245,481	\$ —	\$ 245,481
Segment assets	\$644,417	\$92,815	\$737,231	\$724,565	\$1,461,806
Other items:					
Depreciation and amortization	\$ 22,815	\$ 2,750	\$ 25,565	\$ —	\$ 25,565
Increase in property, plant and equipment and intangible assets	15,556	407	15,963	—	15,963

The adjustments to segment assets of ¥78,253 million (\$724,565 thousand) and ¥63,799 million as of March 31, 2020 and 2019, respectively, represent corporate assets which are not allocated to each reportable segment. The amounts mainly consist of surplus funds which do not belong to reportable segments.

Depreciation and amortization, and increase in property, plant and equipment and intangible assets include long-term prepaid expenses.

(d) Information on products and services

Information on products and services has not been disclosed since the classification by products and services is the same as the reportable segments.

(e) Information by geographical area**(1) Sales**

Information on sales by geographical areas has not been disclosed since sales in Japan accounted for more than 90% of sales on the consolidated statements of income.

(2) Property, plant and equipment

Information on property, plant and equipment by geographical areas has not been disclosed since all property, plant and equipment are located in Japan.

(f) Information about major customers

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)		Name of the related segment
	2020	2019	2020		
Alfresa Corporation	¥15,890	¥17,007	\$147,130		Pharmaceuticals
SUZUKEN CO., LTD.	13,776	14,397	127,556		Pharmaceuticals
MEDICEO CORPORATION	12,611	13,018	116,769		Pharmaceuticals

(g) Information about impairment loss by reportable segment

	MILLIONS OF YEN					
	Reportable Segment					
	Pharmaceuticals	Real estate	Total	Other	Adjustments	Consolidated
	2020					
Impairment loss	¥287	—	¥287	—	—	¥287

	THOUSANDS OF U.S. DOLLARS (NOTE 1)					
	Reportable Segment					
	Pharmaceuticals	Real estate	Total	Other	Adjustments	Consolidated
	2020					
Impairment loss	\$2,657	—	\$2,657	—	—	\$2,657

No impairment loss was recognized for the year ended March 31, 2019.

21. Subsequent Event:**Acquisition of treasury stock**

Based on the provisions of Article 156 of the Companies Act of Japan (the "Act") applied by replacing the terms and phrases pursuant to the provisions of Article 165 (3) of the Act, the Company resolved to acquire treasury stock at the Board of Directors' meeting held on May 22, 2020.

(a) Reason for acquisition:

To execute flexible capital policy corresponding to changes in management environment.

(b) Class of stock to be acquired:

Common stock

(c) Number of stock to be acquired:

Up to 600,000 shares

(d) Total amount of stock to be acquired:

Up to ¥3,500 million (\$32,407 thousand)

(e) Schedule for acquisition:

From May 25, 2020 to December 25, 2020

(f) Method of acquisition:

Purchase on the Tokyo Stock Exchange

NOTE TO READERS:

The following is an English translation of the Independent Auditor's Report filed under the Financial Instruments and Exchange Act of Japan.

INDEPENDENT AUDITOR'S REPORT

To the Board of Directors of KAKEN PHARMACEUTICAL CO., LTD.:

Report on the Audit of the Consolidated Financial Statements

Opinion

We have audited the consolidated financial statements of KAKEN PHARMACEUTICAL CO., LTD. and its subsidiaries (the Group), which comprise the consolidated balance sheet as at March 31, 2020 and the consolidated statement of income, consolidated statement of comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the year then ended, and notes to the consolidated financial statements, including a summary of significant accounting policies.

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 JICPA Code of Ethics (JICPA Code), and we have fulfilled our other ethical responsibilities in accordance with the JICPA Code. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Emphasis of Matter

As described in Note 21, at a meeting of the Board of Directors of the Company held on May 22, 2020, the Company approved the acquisition of treasury stock. Our opinion is not qualified in respect of this matter.

Responsibilities of Management, Audit & Supervisory Board Members and the Audit & Supervisory Board for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of the 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 appropriateness of using the going concern basis of accounting and disclosing, as applicable, matters related to going concern in accordance with accounting principles generally accepted in Japan as applicable.

Audit & Supervisory Board Members and the Audit & Supervisory Board are responsible for overseeing director's execution of duties with regard to design and operation of 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 misstatements, 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 judgement 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, select and perform the audit procedures based on the auditor's judgement and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion.
- Consider internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, while the objective of the financial statement audit is not for the purpose of expressing an opinion on the effectiveness of the entity's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and the appropriateness of 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 as well as whether presentation and disclosures of the consolidated financial statements comply 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 Audit & Supervisory Board Members and the Audit & Supervisory Board 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 Audit & Supervisory Board Members and the Audit & Supervisory Board with a statement that we have complied with relevant ethical requirements regarding independence, 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.

Convenience Translation

Our audit also comprehended the translation of Japanese yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made in accordance with the basis stated in Note 1 to the consolidated financial statements. Such U.S. dollar amounts are presented solely for the convenience of readers outside Japan.

A handwritten signature in black ink that reads "Ark Llc". The letters are cursive and fluid.

ARK LLC
Tokyo, Japan
June 26, 2020

Corporate Data and Stock Information

As of March 31, 2020

Company Information

Company Name	KAKEN PHARMACEUTICAL CO., LTD.
Paid-in Capital	¥23,853 million
Incorporated	March 1, 1948
Main Businesses	Production and marketing of pharmaceuticals, quasi-pharmaceutical products, medical devices, drugs for animals, agrochemicals and feed additives, and rental of real estate holdings
Number of Employees	1,268 (consolidated)

Main Offices	● Head Office	28-8 Honkomagome 2-chome, Bunkyo-ku, Tokyo
(as of April 1, 2020)	● Branches	Kitanihon Branch (Sendai City, Miyagi)

	Kanto Branch (Toshima-ku, Tokyo)
	Kanto Branch II (Toshima-ku, Tokyo)
	Chubu Branch (Nagoya City, Aichi)
	Kansai Branch (Osaka City, Osaka)
	Chugoku and Shikoku Branch (Hiroshima City, Hiroshima)
	Kyushu Branch (Fukuoka City, Fukuoka)
● Sales Offices	34 locations across Japan
● Drug Research Centers	Kyoto City, Kyoto; Fujieda City, Shizuoka
● CMC Center	Fujieda City, Shizuoka
● Factory	Fujieda City, Shizuoka



Head Office (Tokyo)



Drug Research Center (Kyoto)

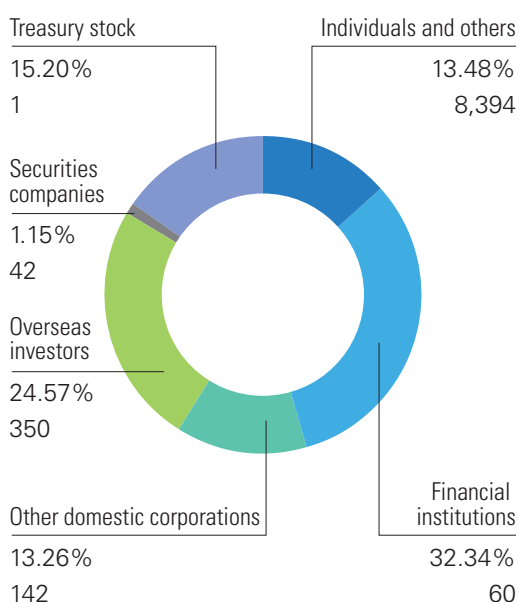


Shizuoka Factory

Stock Information

Authorized:	193,000,000 shares
Issued:	45,939,730 shares
Number of Shareholders:	8,989
Stock Exchange Listing:	Tokyo Stock Exchange
Securities Code:	4521
Shareholder Register Administrator:	Sumitomo Mitsui Trust Bank, Limited

Breakdown by Shareholder Type



Major Shareholders (top 10)

Shareholders	Number of shares (thousands)	Shareholding ratio (%)
The Master Trust Bank of Japan, Ltd. (Trust Account)	2,586	6.64
Toray Industries, Inc.	2,294	5.89
The Norinchukin Bank	1,843	4.73
Japan Trustee Services Bank, Ltd. (Trust Account)	1,615	4.15
Mizuho Bank, Ltd.	1,474	3.79
KYORIN Pharmaceutical Co., Ltd.	852	2.19
Japan Trustee Services Bank, Ltd. (Trust Account 5)	696	1.79
Nippon Life Insurance Company	680	1.75
GOVERNMENT OF NORWAY	678	1.74
Japan Trustee Services Bank, Ltd. (Trust Account 7)	672	1.73

(Note) The shareholding ratios are calculated by subtracting the number of treasury stock (6,981,476 shares) from the total number of shares issued.



Information on the “Investor Relations” available on the Company’s website

You will have access to financial statements, Corporate Reports, investor relations (IR) meeting materials and other latest information related to IR by clicking “Investor Relations” on the top page of the website.

http://www.kaken.co.jp/english/investor_relations/index.html





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