

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 be “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”



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

Reporting Period
FY2020 (April 1, 2020 to March 31, 2021)
Note: Some information from before and after the period above is included.

Scope of This Report
Kaken Pharmaceutical Co., Ltd. and its consolidated subsidiary

Cautionary Statement
This report contains forward-looking statements on the Group’s business. They are projections based on information available at the time this report was written, and may differ from actual results due to a variety of factors. 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.

A History of Value Creation

Maintaining a deep understanding of patient needs and continuously providing new treatment options

Since its establishment, KAKEN has refined its research technologies to quickly develop and provide products that patients genuinely need. With a desire to fully meet the needs of patients, we have synthesized compounds and commercialized products through our own development that are the first of their kind in Japan, or in some cases, the world. Moreover, we collaborate with overseas companies in joint research and clinical development.

Our Track Record of Creating New Value

Founding Ideas

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 as Kagaku Kenkyusho. The Company's first president, Yoshio Nishina, who was called the father of modern physics in Japan, said that his mission was to apply basic scientific research and its findings to industry, and began the manufacture and sale of pharmaceuticals as a way of implementing theoretical research in business.



Athletan (antifungal agent) launched

Developed following initial formulation in Japan involving an animal testing method for topical antifungal agents, this product became the foundation for current antifungal agent development.



Brufen (anti-inflammatory, analgesic and antipyretic agent) launched

With ibuprofen as the active ingredient, Brufen has analgesic and anti-inflammatory effects, making it applicable for a wide range of conditions, including arthralgia and arthritis, in addition to acute upper respiratory tract infection and the common cold.



Mentax (anti-trichophyton agent) launched

The world's first topical anti-trichophyton agent in the benzylamine class. Won the Okochi Memorial Grand Production Prize for the development of butenafine hydrochloride, the active ingredient.



Clenafin (onychomycosis treatment) launched

The first topical agent in Japan for onychomycosis. Its active ingredient, efinaconazole, was discovered by KAKEN. Global sales are expanding through out-licensing to local companies in North America, Asia and Europe.



Hernicore (lumbar disc herniation treatment) launched

A lumbar disc herniation treatment. Provided a new option for hernia treatment that improves symptoms using an intradiscal injection.



Artz (anti-osteoarthritis agent) launched (1987) Artz Dispo launched (1993)

The world's first intra-articular injection solution using hyaluronic acid as the main active ingredient. Improves symptoms including those of knee osteoarthritis and shoulder periarthritis, which are common conditions in the elderly.



Fiblast Spray (wound-healing agent) launched

A spray-on product for periodontal regeneration that promotes wound healing. Became a milestone in regenerative medicine.



Regroth (periodontal regenerative agent) launched

Began development with the idea that bFGF, the active ingredient in Fiblast, could potentially be a drug that regenerates periodontal tissue. Used in periodontal flap surgery, it is a safe periodontal regenerative agent.



Ecclock (primary axillary hyperhidrosis treatment) launched

Provided Japan's first external treatment option for hyperhidrosis, for which few options had been available.



1948

1953

1971

1987

1992

1993

2001

2014

2016

2018

2020

Launched Penicillin KAKEN

Using the technology of Riken, from which it originated, the Company began the manufacturing and sale of penicillin, which was needed by many patients at the time.



1960s

Growth driven by establishment of new research facilities and an upgraded sales structure

1990s

Provided medicines of excellent quality in a drive to be "the best"

2000s

Advancing priority research themes through organizational improvements and concentration of resources

Based on ideas from academia, KAKEN developed products from new viewpoints, including Japan's first digestive enzyme preparation in capsule form and the world's first oral anti-inflammatory enzyme preparation. The Company also applied its technologies to address social problems. In the case of Minamata disease for example, it successfully synthesized an antifungal agent to replace organic mercury compounds that were the primary medicines for athlete's foot at the time. In the 1970s, the Company opened new research facilities, and built a system capable of adapting to increasingly stringent laws and regulations, and enhanced its sales capabilities. The Drug Research Center in Kyoto in particular was equipped with state-of-the-art equipment and tools, enabling highly reliable safety testing (preclinical studies).

In the 1990s, KAKEN expanded its research and development investment and further improved its technologies. The Company became the first in the world to successfully synthesize and develop benzylamine-derived butenafine hydrochloride, which had a chemical structure completely different from that of existing athlete's foot medicines. It grew into strategic global product Mentax. For Artz, which had been sold in an ampoule, the Company launched Artz Dispo, a kit product with a disposable pre-filled syringe, to reduce the risk of infection. Underpinning the Company at this time was its belief, set forth in the late 1980s, in striving to be "the best company, even if not the biggest."

The Drug Research Center and the CMC Center have introduced state-of-the-art equipment and technologies and cooperate in the advancement of drug discovery research. KAKEN focuses its investments and human resources on R&D themes in fields where its experience, technologies and foundations can best be utilized—the immune system, the nervous system and infectious diseases. In FY2017, the Company entered into a collaborative research agreement with Switzerland-based Numab Therapeutics AG—which has a multispecific antibody technology platform—for the identification of a multispecific antibody candidate for the treatment of inflammatory diseases.

Based on KAKEN's belief that the foundation of research and development is people, the Company is promoting human resource development both in-house and externally. As part of that effort, the Company dispatches researchers to research institutions in Japan and abroad to sharpen their expertise, and strives to introduce the latest technologies and knowledge.

KAKEN's Technological Foundation

1940s

Technologies developed by Riken form the roots of Kaken Pharmaceutical

With its roots in Riken, which has made many contributions to modern science in Japan, KAKEN has provided medicines to meet the needs of the times based on its technological development capabilities. The Company applied Riken's culturing techniques to commercialize penicillin, which had been attracting interest as a treatment specifically for pneumonia, an intractable disease at the time. KAKEN took the lead in penicillin production in Japan. Streptomycin, a specific treatment for tuberculosis, led to the development of a variety of fermented products.

Value Creation Process

The KAKEN Group provides medicines and information that contribute to the quality of life of patients from a distinctive viewpoint, with the aim of fulfilling its corporate philosophy of “help 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.” We will continue striving to create value based on our unique strengths.

INPUT

Financial capital

- Safe and sound financial structure
- Equity **¥136,257 million**
(As of March 31, 2021)

Manufactured capital

- Capital investment in new business and capacity expansion
- **¥2,136 million**
(Year ended March 31, 2021)

Intellectual capital

- R&D expenditures **¥6,736 million**
(Year ended March 31, 2021)
- Drug Research Center **2 locations**
(Kyoto and Shizuoka)

Natural capital

- CO₂ emissions **20,605 t-co₂**
- Electricity consumption **25,038 thousand kWh**
- Water consumption (Shizuoka site) **2,888 thousand m³**

Social and relationship capital

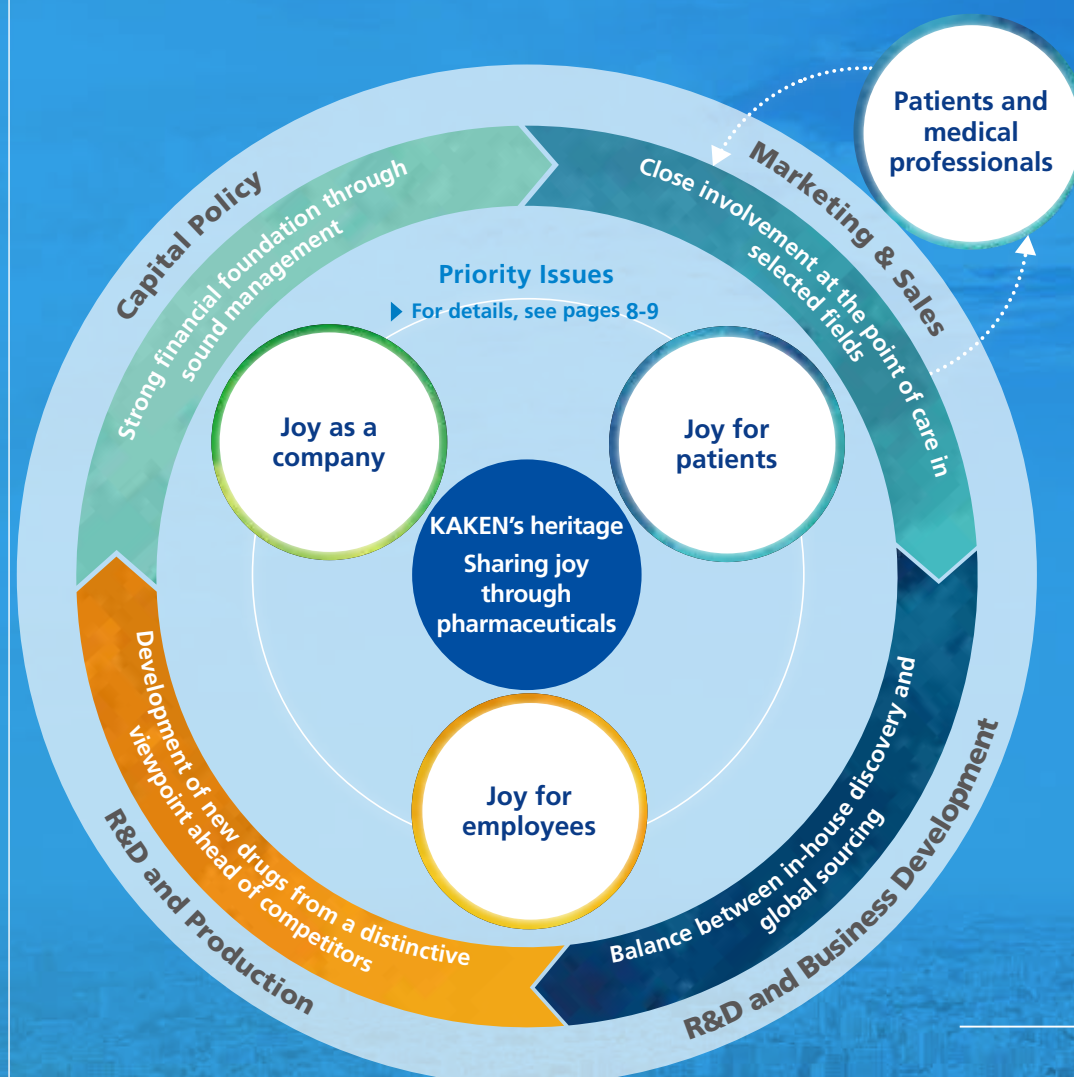
- Main offices **10**
- Sales offices **34**

Human capital

- Number of Group employees **1,215**
(As of March 31, 2021)

BUSINESS MODEL ▶ For details, see pages 6-7

We leverage our strengths to provide new treatment options to patients.



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.

OUTPUT

OUTCOMES

Supplying innovative drugs, including products that are the first in Japan or the world

Medium-Term Business Plan 2021

Priority Task

“Establishment of growth foundations”

▶ For details, see pages 10-11

KAKEN's Growth Strategy

▶ For details, see pages 16-19

Dermatology



Fiblast

Clenafin

Orthopedics



Ecclock

Artz

Other Fields



Hernicore

Regroth

Seprafilm

◻ : First in the world

◼ : First in Japan

Creation of innovative new drugs that satisfy unmet medical needs

Stable supply of quality pharmaceuticals with proven health economics

Provision of proper drug and medical related information

Improving quality of life of patients and their family members

Longer healthy life expectancy

Rewarding workplaces for employees

Stable and continuous returns to shareholders

The Foundation for Creating Value

Corporate Governance
▶ For details, see pages 24-27

Human Resource Strategy
▶ For details, see pages 30-31

Environmental Management
▶ For details, see pages 34-35

Our Business Model: The Source of Value Creation

1 **Marketing & Sales** Involvement on the Frontlines of Healthcare in the Fields We Have Selected

KAKEN has focused on dermatology and orthopedics, backed by efforts to refine technologies and reinforce business operations. By concentrating our efforts in these fields, we have been able to increase the quantity and quality of information we provide to medical professionals, which has helped us build strong relationships of trust with them. It also allows us to reflect the patient feedback that we obtain from medical professionals in new product development and formulation improvements. Our presence is also valued in surgery. For example, our medical representatives (MRs), whose job is to provide information on our pharmaceuticals and other products to medical professionals, go into operating rooms to explain how to use medical devices such as our anti-adhesion materials, and we contribute to perioperative care with adjuvant analgesics, treatments for skin ulcers after surgery, and other products. These initiatives are rare for a pharmaceutical company, and are one of KAKEN's defining characteristics.



As a market leader, KAKEN conducts disease awareness programs that broadly enlighten the public about diseases and treatment options. These activities can lead those suffering from a disease without knowing it to visit a medical facility and get treatment. In this way, our awareness program helps to contribute to patients' quality of life.

4 **Capital Policy** A Solid Financial Foundation through Sound Management and Governance Improvements

To sustainably create value, KAKEN maintains the transparency and soundness of its governance system through proactive measures to bring in outside perspectives. These include increasing the number of outside directors and establishing the Nomination and Compensation Committee. Moreover, the Company's efficient organizational framework, with clear roles based on a simple business structure consisting of the pharmaceuticals and real estate segments, enables quick decision making. In this way, KAKEN is assuredly maintaining its business structure as an R&D-driven pharmaceutical company, and is building a solid financial foundation.

2 **R&D and Business Development** In-house Drug Discovery and Global Sourcing

KAKEN has R&D infrastructure for delivering easy-to-use, distinctive new drugs to patients as quickly as possible. Our R&D staff conduct research and development based on evaluation and judgment capabilities that are backed by flexible inventiveness and scientific knowledge. In addition, we in-license products from domestic and overseas companies for development and marketing, and are active in joint research and joint development with other companies, including multinational clinical studies, as well as outsourcing. Another one of KAKEN's strengths is its ability to develop business by in-licensing innovations not only from established pharmaceutical companies, but also from biotech startups.

We consider it our mission to pursue pharmaceuticals that solve medical issues,

3 **R&D and Production** Leveraging Our Unique Insight to Create New Drugs ahead of Competitors

We deliver new value to medical professionals and patients by continuously identifying unmet medical needs, creating advanced new drugs, drawing up medical plans, generating evidence, and disseminating appropriate information. Clenafin, the first topical onychomycosis treatment launched in Japan, holds the top market share among topical onychomycosis treatments. We co-developed the brush with Pentel Co., Ltd. Having it built into the bottle enhances convenience for patients and reduces side effects. Ecclock, a treatment for primary axillary hyperhidrosis, which causes abnormally excessive sweating, comes with an applicator that allows the gel to be applied without any hand contact, thereby lessening side effects.

Fiblast is a pioneering wound-healing agent in regenerative medicine that we developed based on an active ingredient in-licensed from overseas.



regardless of the product's sales volume. In addition to our stance and business structure for accomplishing that, our ability to identify and assess promising lead compounds and new technologies in Japan and overseas is another source of our value creation in drug discovery.



Taking further advantage of the properties of this active ingredient, we later created Regroth, a medicinal product for dental regeneration that we also out-license for the treatment of perforation of tympanic membrane, in the field of otorhinology. This ability to apply compound properties to the development of products in other areas is another one of our strengths.

We also use information that our MRs obtain from medical professionals in ideas for product formulations and packaging design. Since the launch of Artz, an anti-osteoarthritis agent, we have continued to make improvements that consider safety and ease of use to meet the needs of medical professionals. As a result, they continue to strongly support this product despite its more than 30 years on the market and the existence of generic versions.

Priority Issues

The KAKEN Group delivers value to society and contributes to achieving a sustainable society by practicing its 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.” We believe that this will lead to the sustainable growth of the Group. In order to set out the challenges and initiatives in achieving this objective, we have identified priority issues related to the KAKEN Group’s future value creation.

Process of Identifying Priority Issues



Priority Issues

Business Philosophy Three Joys	Priority Issues	Associated Risks and Opportunities (Risks: ▲, Opportunities: ●)	Main Initiatives	Related SDGs
<p>“Joy for patients”</p> <p>We strive to create and offer efficacious drugs that satisfy the needs of patients and medical professionals.</p>	<p>1 Contributing to medical solutions For details, see pages 16-19</p> <ul style="list-style-type: none">• Creation of innovative new drugs that satisfy unmet medical needs• Provision of pharmaceuticals with proven health economics• Partnerships, including with domestic and overseas companies	<ul style="list-style-type: none">▲ Insufficient development pipeline▲ Changes in healthcare policies and market trends● Fulfillment of unmet medical needs● Contribution to society and heightened Company presence through development of innovative drugs	<ul style="list-style-type: none">• Focus management resources on research and development• Promote alliances with overseas companies (for in-licensing of products under development, out-licensing of in-house products, joint research and other purposes)	
	<p>2 Fulfilling responsibilities as a pharmaceutical company For details, see page 32</p> <ul style="list-style-type: none">• Stable supply of high-quality pharmaceuticals with proven safety• Activities to provide accurate information• Intellectual property strategies	<ul style="list-style-type: none">▲ Decline in corporate value due to disruption in supply of pharmaceuticals▲ Impact of intellectual property risks on business▲ 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 domestic and international standards for good manufacturing practice (GMP)• Contribute to better medical treatment by improving product value in ways such as generating evidence• Utilize digital tools and other means to establish efficient systems for delivering product information• Global intellectual property strategies	
<p>“Joy as a company”</p> <p>We recognize our social responsibility as a pharmaceutical company, engage in all activities with high ethical standards, and aspire to earn society’s trust.</p>	<p>3 Strengthening corporate governance For details, see pages 24-27</p> <ul style="list-style-type: none">• Strengthening relationships with stakeholders• Promotion of compliance• Risk management to ensure business continuity	<ul style="list-style-type: none">▲ Decline in stakeholder trust▲ Disruption of supply chain▲ Increased risk of violations of laws and regulations, misconduct and other inappropriate actions● Earning stakeholder trust	<ul style="list-style-type: none">• Strengthen governance framework• Appropriate and timely information disclosure and dialogue• Training and education in compliance, risk management, and relevant laws and regulations• Contribute to local communities (participation in activities such as local beautification and disaster relief support)• Develop/update disaster and pandemic response plans	
	<p>4 Consideration for the environment For details, see pages 34-35</p> <ul style="list-style-type: none">• Proper management of waste and wastewater• Efficient use of water and other resources• Reduction of CO₂ emissions• Supply of eco-friendly agrochemicals	<ul style="list-style-type: none">▲ Disruption in production due to factors including depletion of water and other resources▲ Decline in public trust due to insufficient efforts● Cost reductions from energy conservation initiatives● Contribution to global food safety	<ul style="list-style-type: none">• Roll out environmental management system• Maintain ISO 14001 certification (Shizuoka Factory)• Continue CO₂ emission reduction initiatives• Research and development of eco-friendly agrochemicals	
<p>“Joy for employees”</p> <p>Our objective is to become a company with vitality and presence whose employees enjoy and take pride in their work.</p>	<p>5 Creating fulfilling workplaces For details, see pages 30-31</p> <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 of human resources• Respect for human rights	<ul style="list-style-type: none">▲ Outflow of personnel▲ Labor issues▲ 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 (including digitalization of work processes)• Appointment of female directors• Enhance systems for employing people with disabilities and seniors• Help protect employees against disease and promote mental healthcare initiatives• Training programs, self-development support, and discrimination/harassment prevention	

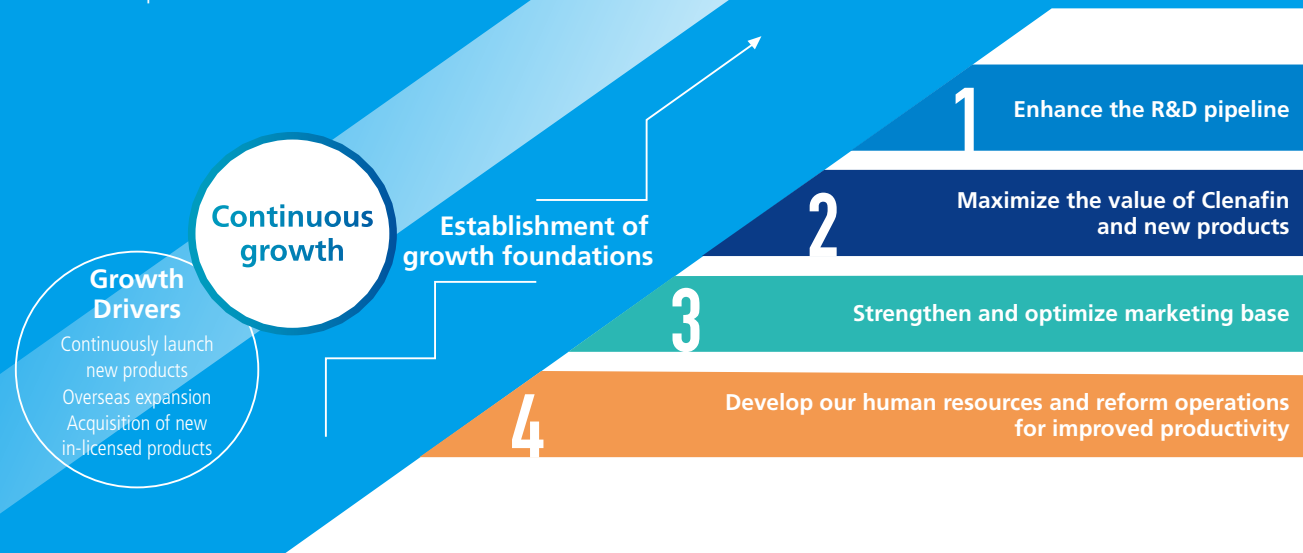
Medium-Term Business Plan 2021

Under the three-year Medium-Term Business Plan that started in 2019, rather than being merely concerned about numerical management targets, we have set our priority task as “establishment of growth foundations,” which will help us to survive through difficult times. We are focusing on four themes under the business plan.

Medium-Term Business Plan 2021 Targets

Net sales:
¥94.5 billion
Operating profit:
¥25.0 billion
ROE: 12% or more

Revised Targets
Net sales:
¥79.2 billion
Operating profit:
¥18.8 billion



The targets we had set for FY2021, the final year of the plan, were net sales of ¥94.5 billion, operating profit of ¥25.0 billion and return on equity (ROE) of 12% or more. However, the decline in visits to medical facilities due to the COVID-19 pandemic and larger-than-expected drug price reductions made achievement of these targets difficult. Therefore, we revised these targets to net sales of ¥79.2 billion and operating profit of ¥18.8 billion.

FY2020 in Review

In FY2020, we obtained approval for Ecclock Gel 5%, the first topical treatment in Japan for primary axillary hyperhidrosis, and launched it in November 2020. In the R&D pipeline, we are now preparing to advance Ivermectin Lotion, 0.5%, (KAR), a topical treatment for head lice, to Phase III, and to move BBI-4000, a treatment of primary palmoplantar hyperhidrosis, into Phase I as an additional indication for Ecclock Gel. We also formed a co-development and regional licensing agreement with Numab Therapeutics AG for development and commercialization in Japan and elsewhere in Asia of a novel multispecific antibody drug candidate for treatment of atopic dermatitis.

Sales of core product Clenafin declined in Japan largely due to the decrease in visits to medical facilities because of the COVID-19 pandemic. Outside Japan, sales of Clenafin by licensee Main Life Corporation Limited began in Macao, while in China a new drug application was submitted to Chinese regulatory authorities through licensee TPR-HUYABIO Advancing Innovative Medicines, and the application was accepted.

To increase productivity, KAKEN is strengthening its marketing base, promoting human resource development and training, streamlining its organization and optimizing staff allocation.

1 Enhance the R&D Pipeline

Expansion and integration of in-house drug discovery foundations

Expand technological foundations in the three priority fields

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		<ul style="list-style-type: none"> BBI-4000 (Primary axillary hyperhidrosis) 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.)	<ul style="list-style-type: none"> 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 partners in each country
United States and Canada: Distributed by licensee Bausch Health Companies Inc.
Outside of North America: Have Bausch Health Companies Inc. return licensed rights ▶ 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 sales development

- Grow sales of Regroth and Herculore
- 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 will have synergy with our marketing base

Grow core products

- Strengthen promotion of Clenafin, Artz, Seprafilm and other products

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 evidence for products 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 the potential of individual employees, taking full advantage of their strengths
- Develop human resources capable of delivering results on a global level

Operational and Organizational Reforms

- Assign the right people to each position, optimize organizations and improve operational efficiency including the IT environment
- Improve the working environment through work-style reforms, etc. that enable optimal performance by all employees
- Reduce manufacturing costs through well-planned and efficient capital investments

President's Message



Hiroyuki Horiuchi

President and Representative Director

We will continuously increase corporate value by applying KAKEN's unique expertise to help patients live healthy lives, both in body and mind.

First, I would like to express my sympathies to everyone who has been affected by COVID-19, and my appreciation for the healthcare professionals and other essential workers who support society. While continuing to take all necessary measures to prevent the spread of infection, we will strive to create social value and increase our corporate value by putting our business philosophy of the “three joys” into practice.

Refine Our Strengths by Combining the Real and Digital Worlds

In Medium-Term Business Plan 2021, which ends in March 2022, we are focusing on “establishment of foundations for sustainable growth,” and are continuing to carry out reforms to that end. In FY2020, however, results were impacted by various factors, including fewer visits by patients to medical facilities due to the COVID-19 pandemic, and the reduction of NHI drug prices. While these certainly pose difficulties, we will continue working to improve the quality of life of patients through supplying superior pharmaceuticals. One of the highlights of FY2020 was the launch in November of Ecclock, Japan's first topical treatment for primary axillary hyperhidrosis. We remain committed to addressing unmet medical needs.

Meanwhile, we are currently living in the age of VUCA, which stands for volatility, uncertainty, complexity and ambiguity. Under such conditions, we will strive for sustainable growth going forward by further enhancing KAKEN's strengths. Reflecting our roots in Riken, our employees are sincere and serious, and thoroughly pursue tasks in their areas of expertise. For example, we are known for our strong sales team. Our medical representatives

(MRs) go so far as to enter the operating room to explain the proper use of Seprafilm, a medical device, and work with doctors in considering the best way to apply the device for each operative method. Our MRs are committed to adapting to changes in the front lines of medicine, so they do more than simply provide drug information to medical professionals. No matter how frequently they may exchange emails and data with doctors online, they cannot see the state of the patient when communicating remotely. When onsite, however, they are able to listen to the views of medical staff and get a clearer picture of the patient's condition. They cannot achieve this without actually being there. For KAKEN and other companies involved in medicine, whether in research and development or sales, people are ultimately at the center. As the environment surrounding patients becomes increasingly digital, a key question is how we should combine the digital and real worlds. I believe that making the best use of digital technology, while applying the real-world strengths we have cultivated in all of our business activities, will help us accelerate our growth.

Concentrating on Priority Areas to Achieve Well-Being

KAKEN conducts its business to create joy for patients, joy as a company, and joy for employees. We do not market many products that affect human life directly, but have narrowed down our drug discovery themes and the fields we focus on in order to concentrate on well-being that helps people lead better lives. Well-being means optimization of daily life, and optimization of human life—in short, enabling people to feel happy. We seek to help people age healthily and live spiritually rich lives. We want them to lead healthy lives in both body and mind, so we develop medicines in fields where there are clear patient needs, even though the market potential may be limited.

The focus of Kaken's early years was the commercialization of the antibiotic streptomycin and related products and discovery research for antifungal agents, followed by the development of products that are on the market now—Mentax (an anti-trichophyton

agent), Fiblast (a wound-healing agent), Clenafin (an onychomycosis treatment agent), and Ecclock (a primary axillary hyperhidrosis treatment). In addition, we have launched products such as Artz (an anti-osteoarthritis agent) and Seprafilm (an absorbable adhesion barrier) through in-licensing from and partnerships with other companies. While these products are not necessarily blockbusters in terms of sales volume, they are all bestsellers, and have continued to sell steadily for a very long time. This is proof that they fit the concept of well-being and are highly valued by society.

At the root of our efforts is a deep commitment to our chosen priority fields, supported by the pursuit of expertise by our sincere and serious employees, as well as the trust we have cultivated with patients and doctors. This commitment sustains the creation of new drugs.

Working as One Team, Always Ready to Respond to Change

To prepare for the post-COVID-19 world, we must drastically change the way we do things. Many game-changers will appear, and society is sure to change further. Simply launching new products in response will not be enough; we must change continuously, including by making various internal reforms. We must always use foresight in preparing for the future so that no matter what happens, we will be ready.

The first key point is to maintain a well-stocked development pipeline. To do that, in-licensing will be important in addition to in-house discovery research. We plan to not only in-license assets whose development concepts have been proven valid, but also to increase the number of cases where we in-license and develop candidate compounds in the early phase of clinical development or at the research stage. Second is reform of the Marketing & Sales

Division. Rather than simply delivering information to doctors in practice, it is important to properly provide patients with knowledge about diseases and information on treatment options. Therefore, we are strengthening our disease awareness activities for the general public, including patients. Third, we must increase our ability to maintain steady supplies of drugs that meet patient expectations and needs.

In addition, we need to step up our efforts to expand our presence globally. Unfortunately, the size and background of our company would not allow us to rapidly expand. Nonetheless, overseas commercialization of Clenafin is underway, primarily in Asia, and we are also supplying this product in North America and Europe through partner companies. Our immediate goal is to pave the way with Clenafin, and then use that experience to pursue global expansion. We will consider a variety

of possibilities from a global viewpoint to develop and market Ecclock (a primary axillary hyperhidrosis treatment) and bFGF (basic fibroblast growth factor; unique to KAKEN worldwide), including cross-licensing with other companies.

Going forward, our corporate image must evolve to fit the times. We have maintained a strong reputation as a traditional and dependable company. We will revamp our image using digital tools and other media.

The key to these changes is the mindset of our employees. As I said at the beginning, we are a company with many sincere and serious employees, but the flipside is that they tend to be quiet and conservative. In today's society, the ability to step out

of one's comfort zone is also necessary. If employees are to be individual pieces of our organization, I want each of them to be a professional piece. I always tell our employees that they should not just do the job they have been given, but to optimize the process by exploring different approaches. Given the current circumstances, I cannot speak with employees about this face-to-face, but I am meeting remotely with as many of them as I can. If all employees have this mindset, the whole company will change. I want to make sure that everyone, from the president to the newest employees, shares the idea that "KAKEN Pharmaceutical employees are working for the Company's corporate value and philosophy as one team."

Bringing Smiles to the Faces of All Stakeholders through Innovative Drug Discovery

Change is well on its way at KAKEN. We will continue to create innovative new medicines as a pharmaceutical company that constantly evolves to stay a step ahead of dramatic changes in society. Our people are our most important asset, and the foundation for accomplishing that, so we will work to reform our human resource strategy. We will also respond to environmental issues and work to build strong corporate governance as we lay the groundwork for our evolution.

For our shareholders, we have maintained annual dividends at ¥150 per share in FY2020 and purchased 600,000 shares of Company stock.

Putting our corporate philosophy into practice, we will continue to bring smiles to the faces of patients and all our stakeholders, and grow together with them. Look forward to greater things from KAKEN!



Growth Strategy

Business Overview

KAKEN's business is divided into the pharmaceuticals and real estate segments. The pharmaceuticals segment consists of pharmaceutical products and medical devices, primarily in the fields of dermatology and orthopedics, as well as agrochemicals, in which we provide highly safe agrochemicals, feed additives and other products. The real estate segment supports the pharmaceuticals segment as a source of stable revenue.

In FY2020, we launched Ecclock Gel 5%, the first topical treatment in Japan for primary axillary hyperhidrosis, and expanded sales of Clenafin, an onychomycosis treatment, in overseas markets. Sales and profit declined from the previous year because of various factors, including market contraction and fewer patient visits to medical facilities due to the COVID-19 pandemic, NHI drug price revisions, and a decrease in overseas sales.

Business Strategies

Research and Development

As part of its efforts to put its corporate philosophy into practice, KAKEN conducts research and development to continuously discover and develop innovative new drugs that offer true value for patients. We focus on R&D fields where we can best utilize our

experience, technologies and foundations—namely, the immune system, the nervous system and infectious diseases—while exploring new fields and new modalities with an eye to the future.



Growth Strategy

We will promote innovation to steadily create distinctive and innovative new drugs that are easier for patients to use.

Mitsuru Watanuki
General Manager of R&D Division

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 aimed at continually developing distinctive new drugs. In recent years, we have been working to sharpen our expertise and introduce the latest technologies and knowledge in various ways. For example, we are utilizing outsourcing to conduct R&D more efficiently, and have expanded and integrated our R&D infrastructure to tackle new research fields. In addition, we are dispatching our researchers to research institutions in Japan and abroad.

Topical onychomycosis treatment KP-607 is currently in Phase II clinical trials. We are also energetically conducting in-house drug discovery with multiple projects in the preclinical and discovery stages.

To enhance our development pipeline, in parallel with our in-house drug discovery, we actively engage in collaborative research and development with other pharmaceutical companies and research institutions in Japan and overseas, as well as in-licensing of products under development. In FY2020, we obtained approval for primary axillary hyperhidrosis treatment

BBI-4000 (in-licensed from Brickell Biotech, Inc. of the United States), and launched it as Ecclock Gel 5%. A Phase I clinical trial for an additional indication is now under way. KMW-1 (in-licensed from MediWound Ltd. of Israel), an eschar-specific removal agent that was designated an orphan drug in Japan, is currently awaiting approval. In addition, we are preparing Phase III clinical trials for Ivermectin Lotion, 0.5% (in-licensed from Arbor Pharmaceuticals, LLC. of the United States) for the treatment of head lice. In the discovery research stage, we are advancing new modalities in drug discovery with Numab Therapeutics AG of Switzerland, which has a multispecific antibody technology platform.

Going forward, we will make use of AI and big data in drug discovery and other areas, step up external collaboration, and actively utilize clinical trial simulations and real-world data to increase our speed and success rate, the greatest challenge in new drug development. Moreover, collaboration among our drug discovery, clinical development and medical affairs operations will allow us to identify medical needs at an early stage and create a steady stream of distinctive new drugs that are easier for patients to use.

Products under Development (As of June 2021)

Development Code	Planned Indication	Development Stage				
		Phase I	Phase II	Phase III	Application	Approval
KMW-1	Removal of eschar	Awaiting Approval				
KAR (Ivermectin)	Head lice	Phase III Preparation				
KP-607	Onychomycosis	Phase II				
BBI-4000	Primary palmo/plantar hyperhidrosis	Phase I				

Business Development

The Business Development Department seeks new in-licensing and out-licensing opportunities that will contribute to KAKEN's sustainable growth, and is working to strengthen relationships with existing partner companies. In recent years, we have set dermatology and orthopedics as our focus fields, and signed an in-licensing agreement with Numab

Therapeutics AG for a novel multispecific antibody for treatment of atopic dermatitis; a co-promotion agreement with Mochida Pharmaceutical Co., Ltd. for osteoporosis treatment Teriparatide BS; and a license and distribution agreement with Almirall, S.A. of Spain for topical onychomycosis treatment Clenafin in Europe.



Growth Strategy

In- and out-licensing activities where we can apply our strengths lead to new alliances, creating a virtuous cycle that contributes to the sustainable growth of the Company.

Motonori Miyakawa, Ph.D.
General Manager of Business Development Department

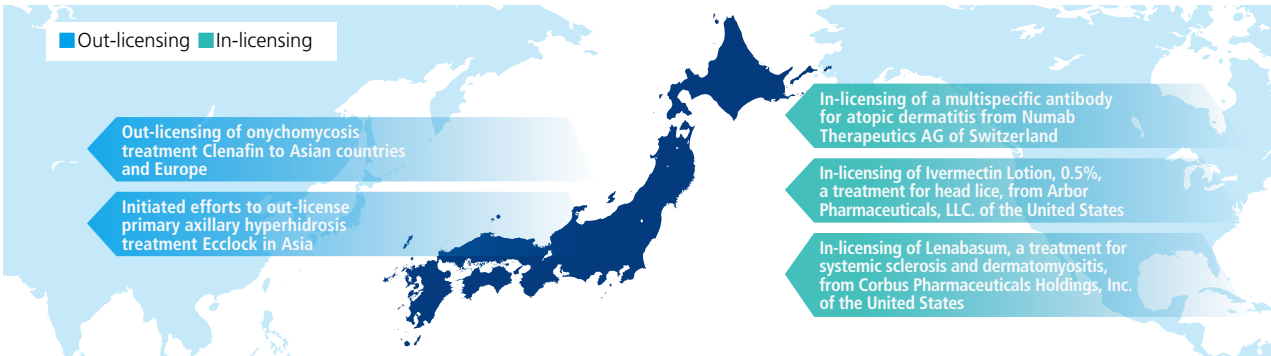
To deliver onychomycosis treatment Clenafin to patients around the world, we have out-licensed it to partner companies in North America and in Asia. Recently, we also selected a partner company (Almirall, S.A.) in Europe, and are steadily expanding our collaborative network. We will continue to seek alliances with new partners and strengthen relationships with existing partners to maximize the value of Clenafin.

Clenafin's success has significantly boosted KAKEN's name recognition and presence in dermatology. An increasing number of domestic and overseas companies have approached us about potential partnerships, which may be a ripple effect of Clenafin's performance. We will take advantage of this opportunity to pursue in-licensing and out-licensing agreements that contribute to KAKEN's sustainable growth.

We are expanding the scope of our search for in-licensing opportunities, which had been centered on small molecule drugs, to other modalities, and are seeking alliance opportunities. As we broaden our view from dermatology and orthopedics to disease areas associated with those fields, we are looking for products that we can in-license for delivery to patients around the world as well as in Japan.

Regarding out-licensing, we have initiated efforts to out-license primary axillary hyperhidrosis treatment Ecclock in the main countries of Asia, and have been approached by numerous interested pharmaceutical companies in the region. We are now working to develop Ecclock into a product that will contribute to our overseas growth as the next strategic product after Clenafin. In addition, we are focusing on overseas expansion of in-house products Fiblast, a wound-healing agent, and Regroth Dental Kit, a medicinal product for periodontal regeneration.

Recent In- and Out-Licensing Results



Marketing & Sales Division

To ensure that the prescription pharmaceuticals and medical devices sold by KAKEN are used properly, medical representatives (MRs) provide medical professionals with proper usage information. While providing information, MRs also collect information related to product safety and suggestions for product improvement, and share this information within the Company. These efforts lead to information provision

and product improvements that meet the needs of medical professionals. In recent years, pharmaceutical companies have been required to provide high value-added information under greater time constraints due to the introduction of guidelines for ethical drug detailing activities, reform of medical professional work-styles, and the COVID-19 pandemic.

Growth Strategy



“All for the Patients!”

Each of us works for patients with a single purpose—to make patients smile!

Tomoyuki Koseki
Chief Officer of Marketing & Sales Division

To ensure that the prescription pharmaceuticals and medical devices we sell are used properly, we provide medical information mainly through three groups: Marketing & Sales, Marketing & Scientific Information and Distribution. In the Marketing & Sales Group, MRs provide medical professionals with proper usage information. While doing so, MRs also collect information related to product safety and suggestions for product improvement and share this information within the Company. These efforts lead to information provision and product improvements that meet the needs of medical professionals. Due to the spread of COVID-19 since last year, pharmaceutical companies have been required to provide high value-added information under greater time constraints. In response to the rapidly changing business environment, we are taking various measures to improve the quality and speed of our information provision, including utilizing digital tools and restructuring our division.

The healthcare industry in Japan is undergoing major changes. In step with the move toward functional differentiation and cooperation among medical institutions, new roles are required to support the integrated care system in community healthcare. Going forward, our MRs will serve as liaisons with community healthcare players that support patients, providing information about medicines from viewpoints such as health economics, safety and adherence in order to achieve continuing care that improves patients' quality of life.

We want to create an organization in which each MR not only has product knowledge, but also in-depth knowledge of related medical information, and always considers options from a patient-first perspective. To further build our presence in dermatology and orthopedics, the fields of our mainstay become an essential company in community healthcare, we will continue to provide even higher-quality information with a focus on the needs of patients.

We help improve patients' quality of life by providing relevant information on medicines and healthcare.



Rie Nozaki
Marketing & Scientific Information Group Manager, Marketing & Sales Department,
Marketing & Sales Division

In the Marketing & Scientific Information Group, we work every day to promote and maximize the value of products by ensuring that the information we provide is optimal, efficient and takes into account the product's unique characteristics.

As a result of the COVID-19 pandemic, the ways in which medical professionals obtain information have diversified. We are responding to their needs by swiftly ramping up our use of multiple channels of communication. In addition to conveying information through our website, we are making changes such as

using the industry's most advanced virtual reality technology to provide information, and developing a patient adherence app.

While we are carrying out digital transformation, we believe that when all is said and done, providing detailed information face-to-face is essential. That's why we are also focusing on helping MRs acquire not only in-depth product knowledge, but also in-depth knowledge of related healthcare information and other matters, so that medical professionals will recognize them as partners in healthcare.

Agrochemicals

We conduct integrated operations for agrochemicals, feed additives and veterinary drugs, from research and development to sales and marketing. For agrochemicals, our development and marketing operations both in Japan and overseas focus on original products such as polyoxins, which are fungicides, and Pentoxazone, a

rice herbicide. To enable sustainable agriculture in harmony with nature, we supply eco-friendly, low-residue products that have a low impact on humans, animals and the environment. In this way, our products help contribute to food safety and security.

Growth Strategy

Demand for food continues to increase in tandem with global population growth, increasing the importance of agriculture as the foundation of food supply. The role of agrochemicals, which are indispensable to agricultural production, is likely to grow. At the same time, strategic initiatives to realize sustainable societies and reduce environmental impact are under way in Japan and around the world. Among them are the Sustainable Development Goals (SDGs), the Strategy for Sustainable Food Systems (MeaDRI) in Japan, and the Farm to Fork Strategy in the EU. These initiatives call for environmentally friendly farming. Given such trends, we foresee a

further increase in needs and expectations for agriculture that is friendly to humans, animals and the environment. To support sustainable agriculture in harmony with nature, we have established a growth strategy based on two pillars: development of agrochemicals that have low impact on humans, animals and the environment, and fermentative production, which can reduce chemical substance waste and energy consumption. By actively researching, developing and commercializing these products and technologies, we will contribute to food safety and security.

Product Line-Up

We have developed and market polyoxin fungicides and the paddy rice herbicides Pentoxazone and Metamifop. Polyoxins exhibit a unique mechanism of action called chitin synthesis inhibition, and have been well accepted by farmers both in and outside Japan for more than 50 years as fungicides with little impact on humans, animals or the environment. Pentoxazone has excellent herbicidal effects on annual weeds in rice paddies, making it an indispensable ingredient for this

form of rice cultivation. Metamifop is highly effective against many weeds of the *Gramineae* family, including barnyard grass of high leaf age, and is therefore expected to enable more efficient weed control in paddy fields.

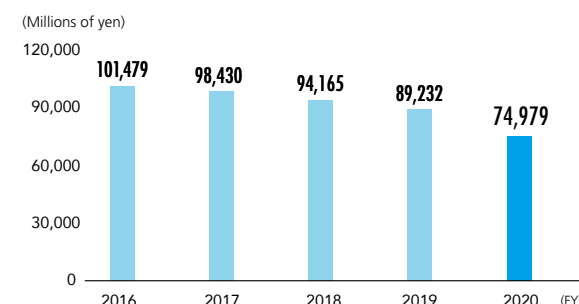
In feed additives and veterinary drugs, we support livestock farmers by marketing Salinomycin, an anticoccidial feed additive for chickens, and Uroston, a drug for cattle.



Financial and Non-Financial Highlights

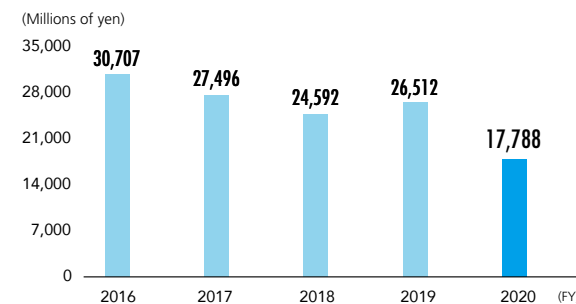
Net Sales

¥74,979 million



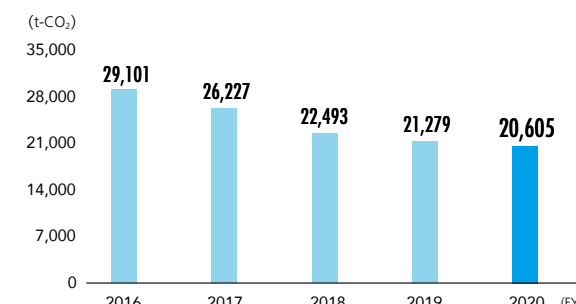
Operating Profit

¥17,788 million



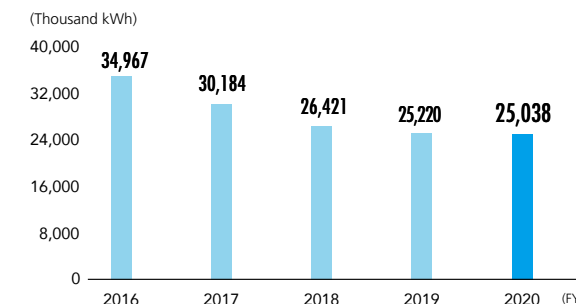
CO₂ Emissions

20,605 t-CO₂



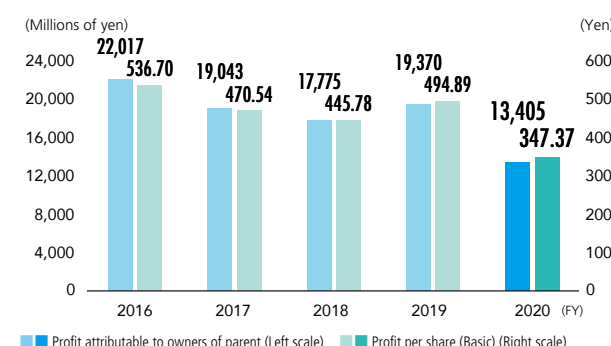
Electricity Consumption

25,038 thousand kWh



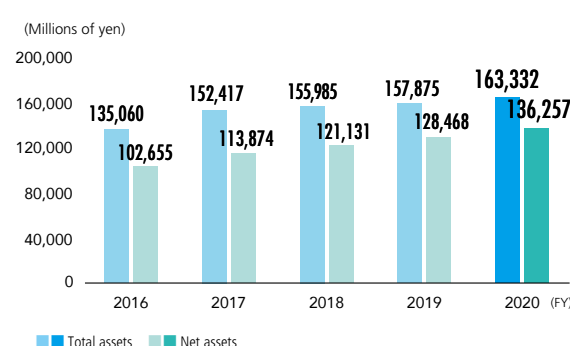
Profit Attributable to Owners of Parent and Profit per Share (Basic)

¥13,405 million / ¥347.37



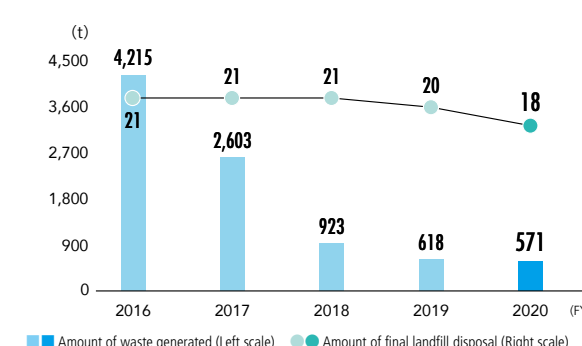
Total Assets and Net assets

¥163,332 million / ¥136,257 million



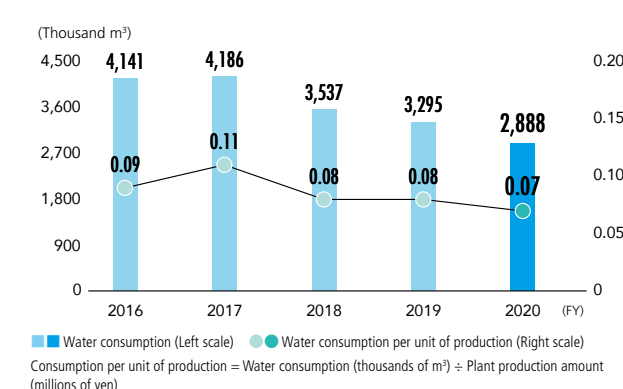
Amounts of Waste Generated and Final Landfill Disposal at Shizuoka Site and Drug Research Center in Kyoto

571 t / 18 t



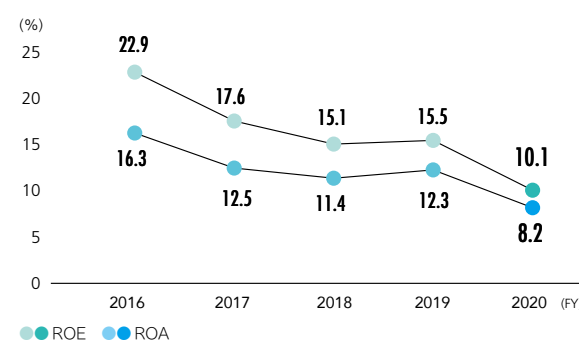
Water Consumption and Consumption per Unit of Production at Shizuoka Site

2,888 thousand m³ / 0.07



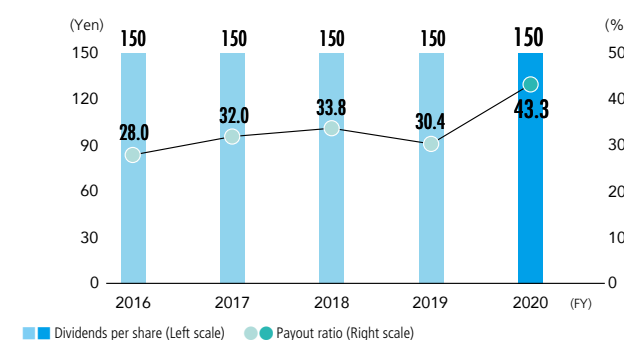
ROE and ROA

10.1% / 8.2%



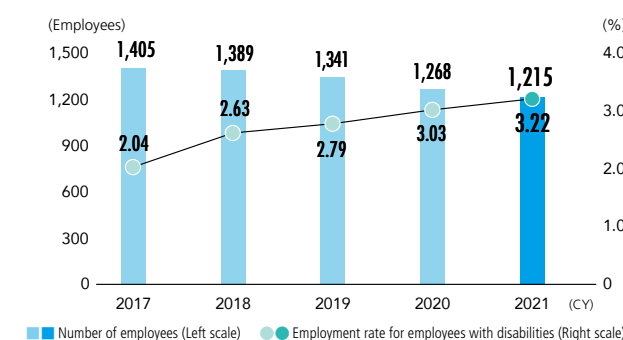
Dividends per Share and Payout Ratio

¥150 / 43.3%



Number of Employees and Employment Rate for Employees with Disabilities*

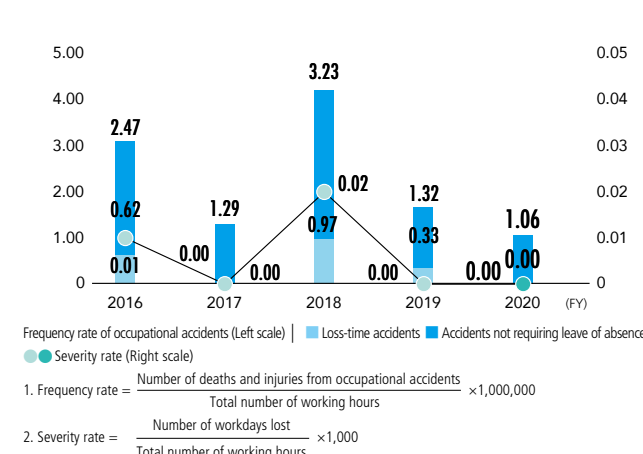
1,215 / 3.22%



* The number of employees is as of March 31. The employment rate for employees with disabilities is of June 1. The legally mandated figures for 2016-2017, 2018-2020 and 2021 were 2.0%, 2.2% and 2.3%, respectively.

Frequency Rate (No Leave of Absence), Frequency Rate (Lost Time) and Severity Rate of Occupational Accidents

1.06 / 0.00 / 0.00



Management Team

Directors



Tetsuo Onuma
Chairman and Representative Director

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



Hiroyuki Horiuchi
President and Representative Director

Apr. 1984 Joined the Company
Oct. 2010 General Manager of Hiroshima Branch
Apr. 2014 General Manager of Osaka Branch
Jul. 2015 Corporate Officer
Apr. 2016 General Manager of Marketing & Sales Department
Jun. 2016 Director
Apr. 2017 Chief Officer of Marketing & Sales Division
Jun. 2018 Managing Director
Jun. 2020 President and Representative Director (to present)



Yoshio Tanabe
Director

Apr. 1978 Joined the Ministry of Foreign Affairs of Japan
Oct. 1989 Joined McKinsey & Company, Inc., Japan
Oct. 1993 Joined Otsuka Pharmaceutical Co., Ltd. (Board Director status)
Jun. 2001 Operating Officer of Otsuka Pharmaceutical Co., Ltd.
Mar. 2008 Senior Managing Executive Officer of TOKUHON Corporation
Jun. 2008 Senior Managing Director of TOKUHON Corporation
Apr. 2009 President and Representative Director of TOKUHON Corporation
Jun. 2013 Advisor of KIZASHI Corporation
Sep. 2014 Partner of KIZASHI Corporation
Jun. 2016 Director of the Company (to present)
Sep. 2017 Representative Director of Medical Opinion Co., Ltd.



Masahiro Matsuura
Director

Apr. 1994 Joined the Company
Apr. 2016 General Manager of Corporate Planning & Coordination Department
Jul. 2018 Corporate Officer
Jun. 2020 Director (to present)



Minoru Ohta
Director

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



Masashi Suzudo
Director

Apr. 1985 Joined The Fuji Bank, Limited (currently Mizuho Bank, Ltd.)
Sep. 2009 President of ZAO Mizuho Corporate Bank (Moscow)
Apr. 2014 General Manager, Global Career Management Division, Mizuho Financial Group, Inc.
Apr. 2016 Joined the Company
Apr. 2018 General Manager of General Affairs Department
Jul. 2019 Corporate Officer
Apr. 2020 General Manager of Corporate Planning & Coordination Department (to present)
Jun. 2021 Director (to present)



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

Apr. 2001 Associate Professor of Nihonbashi Gakkan University (currently Kaichi International University)
Apr. 2002 Associate Professor of Division of Health Sciences and Nursing, Graduate School of Medicine, the University of Tokyo
Dec. 2012 Professor of Division of Health Sciences and Nursing, Graduate School of Medicine, the University of Tokyo
Jun. 2019 Outside Director of the Company (to present)
May 2020 President of QOL Research Center for Children and Family (to present)



Shoichiro Takagi
Outside Director

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



Yasutomo Inoue
Outside Director

Apr. 1999 Registered as attorney at law
Apr. 1999 Joined Takahashi Sogo Law Office
Oct. 2011 Established Nagahama, Mizuno & Inoue Partner of Nagahama, Mizuno & Inoue (to present)
Jun. 2012 Dispute Resolution Center Committee Member, the General Insurance Association of Japan (to present)
Sep. 2015 Outside Auditor of Synchro Food Co., Ltd. (to present)
Jun. 2021 Outside Director of the Company (to present)

Audit & Supervisory Board Members



Atsutada Iwamoto
Audit & Supervisory Board Member (Standing)

Apr. 1979 Joined the Company
Apr. 2008 General Manager of Osaka Branch II
Jul. 2011 General Manager of Purchasing Department
Jun. 2015 Audit & Supervisory Board Member (to present)



Naomi Doi, Ph.D.
Audit & Supervisory Board Member (Standing)

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



Hirotooshi Endo
Outside Audit & Supervisory Board Member

Apr. 1978 Joined The Yasuda Mutual Life Insurance Company (currently Meiji Yasuda Life Insurance Company)
Apr. 2001 General Manager of Net Increase Promotion Department of The Yasuda Mutual Life Insurance Company
Jan. 2004 Branch Manager of Fukuoka Branch of Meiji Yasuda Life Insurance Company
Apr. 2005 General Manager of Sales Planning Department of Meiji Yasuda Life Insurance Company
Dec. 2005 Executive Officer and General Manager of Operations Department of Meiji Yasuda Life Insurance Company
Apr. 2009 Managing Executive Officer of Meiji Yasuda Life Insurance Company
Apr. 2012 Senior Managing Executive Officer of Meiji Yasuda Life Insurance Company
Apr. 2014 President and Representative Director of Meiji Yasuda General Insurance Co., Ltd.
Apr. 2018 Corporate Auditor of Meiji Yasuda Trading Co., Ltd.
Jun. 2019 Outside Audit & Supervisory Board Member of the Company (to present)



Hiroaki Matsumoto
Outside Audit & Supervisory Board Member

Apr. 1981 Joined Tokyo Regional Taxation Bureau
Jul. 2006 District Director of Chichibu Tax Office
Jul. 2016 Chief Internal Inspector, Commissioner's Secretariat of National Tax Agency
Jul. 2018 Regional Commissioner of Kumamoto Regional Taxation Bureau
Sep. 2019 Registered as certified tax accountant
Established Hiroaki Matsumoto Certified Tax Accountant Office (to present)
Sep. 2020 Outside Audit & Supervisory Board Member of Yazaki Corporation (to present)
Jun. 2021 Outside 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

Hirofumi Fujii
In charge of Client Relations

Masanao Shimano, Ph.D.
In charge of R&D Division

Corporate Governance



Tetsuo Onuma

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

Message from the Chairperson of the Board

In recent years, corporations have been called on to further strengthen their governance to facilitate transparent, fair, speedy and resolute decision-making that considers the position of shareholders and other stakeholders.

In 2018, we established the Nomination and Compensation Committee, a majority of which is comprised of outside directors. In 2019, we newly appointed a female outside director, raising the proportion of outside directors on the Board of Directors to over one-third, and took other steps to enhance our corporate governance, such as introducing a Board Benefit Trust stock compensation plan linked to medium- and long-term results.

The revision of Japan's Corporate Governance Code in June 2021 requires that we take more proactive

measures for sustainability. My role as Chairperson of the Board is to further improve the quality of discussions at Board of Directors meetings by bringing out the multifaceted knowledge of board members backed by their diversity of gender, career history and other attributes, to enable the Company to achieve long-term sustainability through speedy and resolute decision-making.

I will continue to draw on the opinions of stakeholders, further strengthen corporate governance, and build a management system that contributes to sustainable growth and increased corporate value, thus making KAKEN worthy of trust.

Basic Approach to Corporate Governance

KAKEN's business philosophy is centered on what we call the "three joys"—"joy for patients," "joy as a company," and "joy for employees." "Joy as a company" is based on the principle that KAKEN 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.

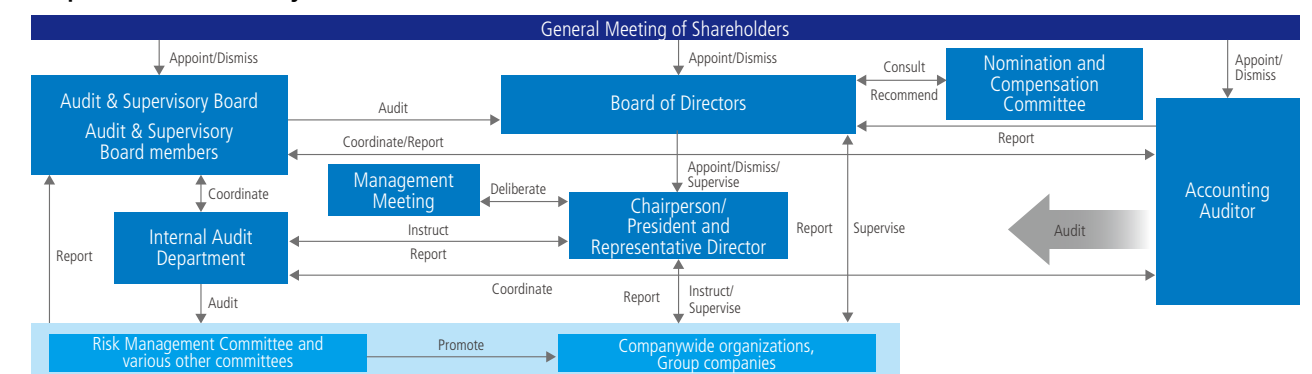
Corporate Governance System

KAKEN has adopted an Audit & Supervisory Board system, taking into consideration the scale of its business, management monitoring functions and other circumstances. Four Audit & Supervisory Board members, including two outside members, attend all important meetings, including Board of Directors meetings, and actively express their opinions. Outside Audit & Supervisory Board members provide their opinions from a neutral standpoint. KAKEN therefore 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 responsibility for the functions of supervision and execution of 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 members, and corporate officers attend Board of Directors meetings. In this way, the Board of Directors ensures the thorough implementation of management policies and the fairness and transparency of its decision-making.

Corporate Governance System



Board of Directors

The Board of Directors consists of nine directors, three of whom are outside directors. The chairman and representative director serves as 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 Board of Directors meetings as stipulated by laws and regulations and the Articles of Incorporation, discusses other important management issues and receives reports on the status of business execution as necessary.

Audit & Supervisory Board Members and the Audit & Supervisory Board

KAKEN has adopted an Audit & Supervisory Board system and has four Audit & Supervisory Board Members, including two standing and two outside members. In addition, KAKEN has appointed one alternate outside Audit & Supervisory Board member. Although no staff has been currently assigned as support staff for Audit & Supervisory Board members, the General Affairs Department assists the Audit & Supervisory Board members and Audit & Supervisory Board meetings.

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 regularly once a month.

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

Nomination and Compensation Committee

Comprised of a majority of outside directors, the Nomination and Compensation Committee serves as an advisory body to the Board of Directors, deliberating on the nomination of directors, Audit & Supervisory Board members and other members, and on the compensation of directors and other members, as well as providing

advice and recommendations to the Board of Directors. Nomination and Compensation Committee meetings are held two to four times a year and further meetings are held on an as-needed basis. All committee members attended all five meetings in FY2020.

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. They contribute to the Company's sustainable growth by directly engaging in decision making of the Board of Directors, as well as to appropriately reflecting the opinions of stakeholders, including minority shareholders, at 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 making appointments, 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.

Reasons for Selection of Outside Directors and Outside Audit & Supervisory Board Members

Name	Attendance at Board of Directors Meetings and Audit & Supervisory Board Meetings		Reason for Selection
	Board of Directors Meetings (16)	Audit & Supervisory Board Meetings (13)	
Kiyoko Kamibeppu	16	—	Ms. Kamibeppu has extensive professional expertise and insight based on experience as a Doctor of Health Science and a professor of a graduate school. The Company believes that Ms. Kamibeppu will provide advice based on her expertise as a professor of a graduate school that contributes to the medium- to long-term growth of Company, and will supervise business execution from an independent standpoint.
Shoichiro Takagi	13	—	Mr. Takagi has experience, insight and a record of achievements from corporate management at several companies including one in the pharmaceutical industry. The Company believes that Mr. Takagi will provide advice based on his knowledge cultivated as a corporate manager that contributes to the medium- to long-term growth of Company, and will supervise business execution from an independent position.
Yasutomo Inoue	(New appointment)	—	As an attorney at law, Mr. Inoue has acquired experience and professional expertise in corporate legal work. The Company believes that Mr. Inoue will provide advice based on his knowledge as an attorney that contributes to the medium- to long-term growth of the Company, and will supervise business execution from an independent position.
Hirotoshi Endo	16	13	Mr. Endo has extensive experience in the financial industry and a record of achievements and insight cultivated as a corporate manager. The Company believes that Mr. Endo will apply this expertise to the Company's audit system.
Hiroaki Matsumoto	(New appointment)	(New appointment)	In addition to being a certified tax accountant, Mr. Matsumoto has extensive experience and a record of achievements at the National Tax Agency, as well as abundant knowledge and insight in the field of finance and accounting. The Company believes that Mr. Matsumoto will apply this expertise to the Company's audit system.

Note: Mr.Takagi attended 13 Board of Directors meetings following his appointment as a director of the Company on June 26, 2020.

Evaluation of Effectiveness of the Board of Directors

In FY2020, Board of Directors meetings were held 16 times (12 regular meetings and four extraordinary meetings). Directors and Audit & Supervisory Board members attended the extraordinary Board of Directors meetings, and corporate officers also attended the regular Board of Directors meetings. All participants contributed to 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 Company norms. Taking into account this situation and referring 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 has evaluated that its effectiveness is secured.

Officer Compensation

In an effort to provide an incentive to contribute to the sustainable growth of KAKEN, the compensation for the Company's directors comprises basic compensation, bonuses 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 directors. Basic compensation is a fixed amount, while bonuses and stock compensation are linked to the Company's business performance. However, bonuses and stock compensation are not paid to outside directors, as they are responsible for supervision and monitoring of management from an independent standpoint.

Basic compensation is fixed monthly compensation, and is determined by taking into consideration the director's position and responsibilities, compensation levels at other companies, the Company's performance, and the director's salary as an employee. The total amount of basic compensation is set within the amount approved at the General Meeting of Shareholders.

Performance-linked compensation is cash compensation that reflects key performance indicators (KPIs). It is intended to increase the commitment of directors to improving performance for each fiscal year. An amount calculated based on year-on-year comparisons of consolidated operating profit and consolidated net profit is paid as a bonus for each fiscal year upon approval at the General Meeting of Shareholders.

Non-cash compensation is paid in the form of stock compensation by a Board Benefit Trust, which is a stock compensation plan linked to business performance that provides stock and other benefits upon retirement. Stock compensation is calculated using coefficients obtained by

prorating the degree of achievement of the KPIs in the medium-term business plan in accordance with the Rules for Share-based Remuneration for Officers. Linked to medium- and long-term performance, it is intended to contribute to increased corporate value and sustainable growth. The total amount of stock compensation is set within the amount approved at the General Meeting of Shareholders.

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.

The ratio of directors' compensation by type is examined by the Nomination and Compensation Committee, which uses similarly sized companies in related industries and lines of business as benchmarks and considers factors such as compensation levels and the Company's performance to date. The Board of Directors (or the delegated representative director and president, as specified below) respects the Nomination and Compensation Committee's recommendations and uses the committee's recommended ratio of compensation by type as a reference point when determining the structure of compensation for individual directors. As a rule of thumb for the ratio of compensation types, KAKEN uses a ratio of 6:3:1 for basic compensation, performance-linked compensation and non-cash compensation (assuming 100% achievement of KPIs). In FY2020, the Nomination and Compensation Committee meeting regarding directors' compensation was held in March 2021. The committee deliberated the draft of basic compensation and performance-linked compensation for individual directors in accordance with the above criteria.

Based on a resolution of the Board of Directors, President and Representative Director Hiroyuki Horiuchi has been delegated to decide the specific details of compensation for individual directors. He has authority over the amount of basic compensation of each director, as well as the evaluation and allocation of bonuses and stock compensation based on the performance of the divisions that each director is responsible for. The representative director and president was delegated with this authority as he is the most appropriate person for evaluating the divisions that each director is responsible for while maintaining a broader view of the Company's overall performance. To ensure that the representative director and president properly exercises this authority, the Board of Directors consults with and receives recommendations from the Nomination and Compensation Committee, of which outside directors comprise a majority. The delegated representative director and president takes these recommendations into consideration when making decisions.

Total Amount of Compensation, Total Amount of Compensation by Type, and Number of Eligible Officers by Category in FY2020					
Officer Category	Total Amount of Compensation (Millions of yen)	Total Amount of Compensation by Type (Millions of yen)			Number of Eligible Officers
		Basic Compensation	Bonuses	Stock Compensation	
Directors (Excluding outside directors)	357	249	80	27	8
Audit & Supervisory Board members (Excluding outside Audit & Supervisory Board members)	48	48	—	—	2
Outside officers	37	37	—	—	6

Note: Stock compensation represents a provision for share-based remuneration for directors in FY2020.

Outside Director's Message

I strictly supervise KAKEN's management while supporting the president's "KAKEN One Team" concept.

In FY2020, KAKEN, like many other companies, was severely impacted by the global spread of COVID-19. I would like to express my sympathy to all stakeholders. In these circumstances, KAKEN quickly reconsidered its meeting committee structure, and held hybrid Board of Directors meetings when necessary. As a result, governance was not hindered. Under Chairperson and Representative Director Tetsuo Onuma, important management-related matters are discussed and decided by President and Representative Director Hiroyuki Horiuchi and (compared with before) a slightly younger group of directors, Audit & Supervisory Board members and corporate officers. Occasionally, questions that we outside directors posed have sparked heated discussions during online meetings. In addition, interviews for evaluating the effectiveness of the Board of Directors were conducted properly as in past years.

Regarding the promotion of the active participation and advancement of women in the workplace, my view is that it is not about making workplaces more supportive just for women. Arranging a pleasant work environment for women and men alike, as well as for people with diverse attributes, helps to attract and retain talented people, which ultimately leads to the sustainable growth of the Company. I offer advice at Board of Directors meetings and elsewhere to encourage management to take the Company beyond the requirements of the Act on Promotion of Women's Participation and Advancement in the Workplace by setting up workplace systems that accommodate employees at various life stages—not just when they are rearing children, but also when they are providing nursing care for a family member or when they themselves are ill. I believe that doing so will enable the Company to achieve its target for the percentage of women in management positions, which is a current issue.

Highlights of FY2020 included the appointment of President and Representative Director Hiroyuki Horiuchi and the launch of Ecclock Gel 5%. How will the Company develop over the next year? We three outside directors, including newly appointed Outside Director Yasutomo Inoue, are committed to strictly supervising management while supporting the president's "KAKEN One Team" concept to increase the Company's corporate value.



Kiyoko Kamibeppu
Outside Director

Compliance and Risk Management

Basic Approach and System for Promoting Compliance

KAKEN believes that compliance-based management is fundamental to 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 to promote compliance-related initiatives on a Companywide basis and has designated the Legal Affairs & Intellectual Property Department Compliance Group as the unit responsible for promoting compliance.

Activities to Promote Compliance

To address changes in the operating environment of the pharmaceutical industry and the Company, in January 2021 we established the KAKEN Charter of Corporate Behavior and Code of Conduct, which are revisions of KAKEN's Activity Principles and Guidelines and KAKEN's Code of Conduct, which were established in April 2002. The KAKEN Charter of Corporate Behavior and Code of Conduct are the basis for making decisions and taking actions in the performance of duties by executives and employees toward the achievement of the corporate philosophy and business philosophy. The charter and code comprise guidelines to be followed by both executives and employees, and expresses KAKEN's basic position on compliance. The KAKEN Charter of Corporate Behavior is disclosed on the Company's English website

Ethical Considerations in Animal Testing

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

The Company has formulated internal regulations that fully reflect the intent 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 gives full consideration to the utilization of alternatives to animal testing, the reduction of the number of animals used, and the mitigation of pain.

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

and both the charter and the code are disclosed on the Company's Japanese website.

We have created panels displaying the corporate philosophy, business philosophy and the KAKEN Charter of Corporate Behavior, as well as a Compliance Check Card and Compliance Guidebook to help executives and employees of the Company and subsidiaries practice compliance. In addition, KAKEN provides compliance education based on position and workplace, and through the Company intranet distributes messages from the compliance officer and provides related information from the Legal Affairs & Intellectual Property Department Compliance Group as appropriate to improve compliance awareness.

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 inspections and self assessments 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. In January 2019, KAKEN received the Accreditation of Animal Experimentation Facilities from the Japan Health Sciences Foundation for the third time.

Basic Approach and System for Promoting 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 for managing the risk of losses
- Regulations and other systems for managing the risk of losses at subsidiaries

- The Company has established a system to identify and manage risks that the KAKEN Group is exposed to under a system in which a risk management officer is appointed and the Corporate Planning & Coordination Department is designated as the responsible department.
- The Company classifies risks and manages them by designating the responsible departments, respectively.
- 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.
- 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 and providing education for each division and department. At the same time, the Risk Management Committee has been set up, chaired by the Risk Management Officer appointed by the Board of Directors. In such ways, the Company has established a system to manage risks on a Companywide basis. Important matters deliberated at Risk Management Committee meetings are submitted for approval or reported to the Board of Directors.

Principal Risks

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

The forward-looking statements contained herein reflect the judgment of the KAKEN Group (KAKEN and its consolidated subsidiary) as of March 31, 2021.

Major Risks	Status of Major Risks
Risks related to legal regulations and administrative developments such as policies to curtail public healthcare expenditures	The pharmaceutical business in Japan is subject to various regulations under the pharmaceutical regulatory system. In addition, various medical system reforms are underway as part of policies to curtail public healthcare expenditures, such as revisions of the drug price standards and measures to promote the use of generic drugs. Revisions of these related laws and regulations and developments in the administrative policies related to the medical system and health insurance could materially affect the KAKEN Group's business performance and financial condition.
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 each drug into full consideration, but development could be halted before completion if the expected efficacy cannot be proven or a safety issue is identified. Such cases could materially affect the KAKEN Group's business performance and financial condition.
Risks related to side effects	Pharmaceutical products are approved and marketed only after sufficient safety tests and thorough review; however, only a limited number of patients are administered experimental drugs during clinical trials undertaken in the development stage. In order to supplement these clinical trials, post-marketing surveillance is conducted after products are launched. If unexpected side effects are identified in post-marketing surveillance, the Company may be compelled to recall the product or discontinue its sales. Such cases could materially affect the KAKEN Group's business performance and financial condition.
Risks due to competition	The pharmaceutical industry is very competitive. Competition with competing products that have similar efficacy and effect and with generic products launched after patents expire may result in declines in sales of our products, which could materially affect the KAKEN Group's business performance and financial condition.
Risks related to intellectual property rights	The KAKEN Group manages its intellectual property properly and takes precautions against infringement by third parties. If a third party infringes the Group's intellectual property rights, the Group may file a lawsuit against the third party to protect such rights. The outcome of such litigation could materially affect the KAKEN Group's business performance and financial condition. The Group also pays close attention to ensure that its projects do not infringe the intellectual property rights of any third party. However, if such an infringement occurs, it may result in a dispute and subsequent compensation for damages and cancellation of the project, which could materially affect the KAKEN Group's business performance and financial condition.
Risks related to litigation	As a company conducting business in both Japan and abroad, KAKEN is at a risk of litigation instituted for side effects of its pharmaceutical products and issues concerning product liability, labor, the environment and fair trade. Such litigation could materially affect the Group's business performance and financial condition.
Risks related to delay or interruption of product supply	Delay or interruption of product supply due to problems with the Company's manufacturing facilities or its suppliers, or delays in the procurement of raw materials, or product recalls due to quality problems could materially affect the Group's business performance and financial condition.
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 action, and loss of public trust. These events could materially affect the Group's business performance and financial condition.
Risks related to large-scale disasters	The occurrence of natural disasters such as earthquakes and typhoons, accidents such as fires, or pandemics could cause extensive damage to the KAKEN Group's offices and business partners. The resulting disruption to business activities or considerable expense required to repair damaged facilities could materially affect the Group's business performance and financial condition.
Risks associated with the spread of COVID-19	Despite the efforts of the KAKEN Group, impacts of the COVID-19 pandemic that are more serious or persistent than the Company expects could materially affect the Group's business performance and financial condition. In addition, even after the COVID-19 pandemic is curbed or contained, the pandemic may continue to have an impact for an extended period of time.

Human Resource Strategy

Engagement with Employees

As a company that emphasizes “joy for employees,” KAKEN places great importance on employees’ human rights, health, safety and hygiene, and promotes the creation of a work environment in which every employee can work with peace of mind and a sense of fulfillment. We also place importance on human resource development and education to create an environment where our employees can grow and fully demonstrate their capabilities.

Job Creation, Worker Retention and Diversity

In order to create a work environment in which all employees are highly motivated, we believe it is important to respond flexibly to and constantly evolve new working styles in light of legal reforms. In addition,

we are implementing diversity management and work-style reforms, including promotion of women’s participation and advancement.

■ Enabling Work-Life Balance

As part of efforts to create worker-friendly environments where employees can work efficiently, in December 2020 we adopted a flextime system Companywide, except for the Production Division and MRs.

■ Support for Childcare and Nursing Care

We have established various systems such as leave of absence, days off and shorter working hours, based on the Regulations for Childcare Leave and the Regulations for Caregiver Leave, so that employees who have difficulty working under normal conditions due to childcare or nursing care issues can continue to work without worry. In FY2021, we established a system in which employees can take special paid leave for the purpose of caring for a family member or for a child’s gradual entry into a new nursery school.

■ Employment of Elderly Workers

The Company has introduced the Senior Staff Program for the reemployment of employees who retired upon reaching the mandatory retirement age of 60. This system has enabled them to continue playing an active role in their respective workplaces even after reaching retirement age, effectively utilizing the experience, expertise and skills they have accumulated over many years.

■ Employment of Persons with Disabilities

As one of our corporate responsibilities, we proactively engage in efforts to hire persons with disabilities. We maintain employment levels that exceed the statutory rate by enhancing our support system to ensure such workers receive appropriate assistance in the workplace.

Employee Health Management

As for employee health management, we provide access to health checkups every spring and lifestyle disease-related examinations (complete medical checkup/brain checkup) every fall. In cooperation with industrial physicians, nurses and medical examination centers, we conduct follow ups for employees whose checkups reveal health problems. In addition, to help prevent illness and maintain and improve the health of our employees, we cooperate proactively in the specified health checkups and health guidance provided by the health insurance association.

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 conducting annual stress checks required by law, to support measures for employees’ mental health we offer simple stress checks that employees can perform voluntarily and provide a wide range of learning materials including a variety of e-learning programs.

The Shizuoka site is taking various steps to improve the work environment. It has appointed a person in charge of promoting mental health measures at each workplace and holds roundtable meetings attended by health supervisors. The site also endeavors to maintain and improve the health of its employees. For example, it has designated a month in spring to promote the health benefits of walking, and in the fall it conducts a physical fitness test as a health campaign. The Company remains committed to the management of employees’ physical and mental health 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 are aimed at preventing occupational accidents and illnesses and creating a comfortable work environment, we hold Safety and Health Committee meetings on a monthly basis at all offices and other workplaces. We work to eliminate occupational accidents by implementing safety inspections and remedial measures at each facility and workplace. We also actively work to improve the work environment by conducting regular questionnaire surveys of our employees.

At the Shizuoka site, health supervisors strive to ensure occupational health and safety through efforts such as holding regular meetings, formulating annual health plans, and conducting tours and onsite inspections of workplaces and work environments. Furthermore, in conjunction with the safety and health week, the site holds various lectures jointly with the employee health insurance association, and conducts activities to promote awareness of safety and physical and mental health issues.

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 work environment that is free from issues including discrimination, abuse of authority, sexual harassment and pregnancy discrimination. We work 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, the Compliance Guidebook, information meetings for employees in managerial positions, and regular postings and education via the in-house intranet. We also keep employees informed of internal consultation channels.

Developing the Next Generation of Human Resources

Human resource development is a fundamental part of corporate management, and the growth of each employee leads to the sustainable growth of the Company. Our basic policy is to foster employees with distinctive capabilities who will be responsible for the future of the Company. We provide comprehensive education and training by employment year and position to foster employees who can make the most of their capabilities to achieve results

at each stage of their careers while gaining experience as members of society. Another purpose of this education and training is to foster 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 to Education and Training

① The purpose of education and training is to foster employees who can accurately grasp the current state of the Company and changes in the industry environment, discern what is best for the Company, and think and act on their own volition based on their new ideas and creativity.

② We have positioned the development of mid-career and young employees as one of our priority issues, and as such work to develop human resources through on-the-job training as well as external training by outside expert instructors.

③ We utilize internal and external training programs to foster the next generation of leaders, as well as training for managers.

■ Training by Position

In addition to developing employees’ capabilities 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.

Training by Position		Self-development support
Basic training for working adults	Training for newly hired employees	
Training by employment year	3rd year training	
	4th year training	
	8th year training	
Training for the next generation of leaders	Training to foster next-term leaders	Support for taking correspondence courses for self-development (For all employees)
Career training	Training for new team leaders	
	Training for new managers	

Engagement with Customers

Quality Assurance Policy

KAKEN is committed to realizing its corporate philosophy and management policy and supplying superior pharmaceuticals. To achieve that, KAKEN will carry out the following activities in serious recognition of the fact that it is engaged in the pharmaceutical business, it pursues higher ethical standards and it places primary and constant 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, and other matters.

- 1 Recognizing that product quality assurance is one of the most important issues related to management responsibility, KAKEN will establish a pharmaceutical quality system that covers all the products it sells.
- 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 comply with laws for ensuring the quality, effectiveness and safety of pharmaceuticals, medical devices and other products, as well as other relevant laws and regulations. In addition, KAKEN follows good practices, including good laboratory practice (GLP), good clinical practice (GCP), good manufacturing practice (GMP), good quality practice (GQP) and good vigilance practice (GVP), and assumes responsibility for its own actions.
- 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 works to return smiles of happiness to the faces of as many patients as possible by supplying superior pharmaceuticals that help improve their quality of life. To that end, we believe that it is absolutely essential that we have a quality assurance system in which both our Head Office (a manufacturer and distributor of pharmaceuticals) and our factory (a manufacturer of pharmaceuticals) fulfill their respective responsibilities and maintain close coordination. At our factory, competencies and appropriateness of each manufacturing process and facility are evaluated to ensure

that suitable manufacturing and quality management practices are followed.

The Quality Assurance Department of the Head Office evaluates and confirms these activities, which we believe results in the creation of a more stringent quality assurance system. Coordinated 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 highest quality throughout all stages of a product's lifecycle.

Safety Assurance for Pharmaceuticals after Launch

Pharmaceuticals receive regulatory 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 concurrent medications. After launch, pharmaceuticals are used by a wider range of patients, which can reveal unexpected side effects. For this reason, we are required

to collect comprehensive safety information, accurately evaluate it and take necessary response measures.

With the establishment of the Pharmacovigilance Department, we strive to minimize the safety risks of patients by collecting and evaluating data regarding the safety of pharmaceuticals from the development phase to post-marketing, and by providing medical professionals with information regarding proper usage.

Pharmaceuticals Information Service Office

Accurate information is essential for the proper usage of prescription drugs. We provide and collect information pertaining to the proper usage of our pharmaceuticals mainly through medical representative (MR) activities; however, we also proactively provide and collect such information through the Pharmaceuticals Information Service Office, a consultation desk related to pharmaceuticals, and via our website. The office promptly and accurately informs customers about proper usage of pharmaceuticals

and reports their valuable opinions and suggestions on pharmaceutical formulations and other matters to relevant departments in the Company, thereby helping to improve pharmaceutical formulations and enhance product information for the benefit of customers.

We receive most inquiries by phone; however, we provide a form on our website for receipt of inquiries, even outside office hours, with the aim of enhancing convenience for customers.

Engagement with Society and Local Communities

Activity Policy

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

Local Community-related Activities of the Shizuoka Site

River Beautification Activities

The Shizuoka site has benefited from the waters of the Oi River, a Class A river in Japan. The site works to protect the environment of the Oi River through river beautification activities conducted every April. While these activities are carried out as part of the site's efforts to contribute to society, they are also an opportunity to foster friendly relationships with newly hired employees. In addition, the site is registered with Fujieda City's "Adopt Program," and in FY2020 the site's support team conducted 19 cleanups of sports fields along the river.



Environmental Report Meetings

The Shizuoka site holds environmental report meetings every year for local residents. Due to the COVID-19 pandemic, in FY2020, information was shared by circulating the report documents from resident to resident. Reports present various statistics on relevant matters, the status of employee education, and other activities for compliance with laws and regulations. Through this report, the site promotes better understanding of the Company's environmental initiatives.

Hosting Elementary School Field Trip

With an eye to contributing to the growth of children who will shape the future, for the first time, in FY2020, the Shizuoka site hosted an elementary school field trip. The tour was a friendly and lively event from start to finish, introducing the children to KAKEN, talking about medicine in a quiz format, and showing them the manufacturing process of Clenafin. Some of the questions they asked were hard even for adults to answer!



Local Community-related Activities of the Drug Research Center in Kyoto

Environmental Beautification Activities

As a member of the Yamashina Beautification Promotion Corporate Council, the Drug Research Center in Kyoto participates in the beautification campaign for the Lake Biwa-Yodo River water system. A cleanup of Shinomiya River, which runs near the site, is held every spring and fall, and is one of the leading beautification activities for the Lake Biwa-Yodo River water system. In addition, the site conducts flower-planting along Sanjo Street, and has made cleaning up around the site an environmental improvement target. Since October 2014, from 9:00 a.m. one day each month, two teams of employees have cleaned the roads around the site.

Firefighting and Disaster Prevention Drills and Local 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 of our sites 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 local agreements for disaster prevention, focused on supplying personnel in the event of a disaster, with two neighboring school districts based on the lessons learned from the Great Hanshin-Awaji Earthquake.

Environmental Management

KAKEN Basic Environmental Philosophy

As a pharmaceutical company that endeavors to improve the quality of life for patients through supplying superior pharmaceuticals, and based on the idea of “joy as a company,” KAKEN shall recognize its social responsibility and work to protect, maintain and enhance the global environment in all aspects of its business activities.

KAKEN Basic Environmental Policy

- 1 Establish and maintain an environmental management system

We shall establish an environmental management system and take initiatives to protect the environment. Led by our Environmental Committee and Environmental Measures Task Force, these initiatives shall be systematic and continuous.
- 2 Comply with environmental laws and regulations

We shall comply with environmental laws and regulations at the national and local levels. We shall further establish independent standards as we strive to protect the environment.
- 3 Reduce environmental burden

We shall set concrete targets for all aspects of our business activities and practice the 3Rs (reduce, reuse and recycle). Aiming for continuous improvement, we shall periodically revise our targets with respect to climate change, waste and chemical emissions.
- 4 Develop eco-friendly products and technologies

As we develop products, we shall work actively to protect the environment. We shall consider the environmental impact of our products over their lifecycles, from research and development, production, sales and distribution to end-of-use/end-of-life (EOU/EOL).
- 5 Cooperate with local communities

As a corporate citizen, we shall work with local communities to protect the environment. We shall also disclose environmental information and work for mutual understanding with those communities.
- 6 Raise environmental awareness

We shall provide environmental training and information to all executives and employees to raise their awareness about environmental protection.

Materials Balance of Business Activities

At the Shizuoka site and the Drug Research Center in Kyoto, each and every employee recognizes input and output that place burden on the environment during the

course of business activities ranging from research and development to production and office activities, and is working to reduce environmental pollution.



Note: Materials balance data shown is the total amounts for FY2020.

Proper Management of Waste and Wastewater

The generation of waste is unavoidable in the manufacturing of products from raw materials. However, the development of a circular economy requires that the generation of waste that ends up as final landfill 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 and recycle).
In FY2020, the total amount of waste generated by the Shizuoka site was 544 tons. Of this, 42% was sludge

produced during the treatment of wastewater and residues from fermentation processes (animal and plant residues). The entire amount of sludge and residues generated was used as composting and related materials. We are also working to recycle other wastes and collected 34 tons of valuable materials (accounting for 11% of total other wastes). The amount of final landfill disposal was 18 tons. Going forward, we will continue to conduct activities promoting the reduction and recycling of waste.

Efficient Use of Water Resources

The Shizuoka site benefits from abundant water resources from the nearby Oi River, but the possibility of a shortage of water resources in the future due to climate change and other factors is also a concern. The Shizuoka site, which includes a factory, switched its water pump to an inverter type to enable fine adjustments in the amount of groundwater drawn. Through this and other steps,

such as stopping unnecessary drawing of well water, the site is working to use water resources more efficiently. We will continue to promote efficient use of water resources from the standpoint of business sustainability.

▶ See page 21 for the Shizuoka site's water consumption and consumption per unit of production.

Reduction of CO₂ Emissions and Energy Saving

We participate in the Commitment to a Low-Carbon Society, a plan that the Federation of Pharmaceutical Manufacturers' Associations of Japan helped to create, and have worked toward achievement of the federation's target of reducing Japan's pharmaceutical industry CO₂ emissions in FY2020 by 23% compared with emissions in FY2005. At the Shizuoka site, which consumes the most energy of any of our sites, we are taking proactive

measures such as installing high-efficiency equipment, and are carrying out ongoing energy-saving activities. At the Kyoto site, Head Office and branch offices, we are taking various measures to reduce electricity consumption, including replacing fluorescent lights with LED lights and installing heat pumps in air conditioning systems. As a result of the success of these measures, we exceeded the aforementioned CO₂ reduction target.

Supply of Eco-Friendly Agrochemicals

Polyoxins, which are agricultural fungicides, are safe for humans and animals, and are a natural substances confirmed to be broken down easily by water, light and microorganisms, and present no risk of being long-term residues. As such, they are eco-friendly agrochemicals. Because they use natural materials as their principal raw materials, fermentatively produced polyoxins help to reduce environmental burden in manufacturing as well. Compared with conventional chemically synthesized agrochemicals, producing polyoxins uses a smaller amount of petrochemical raw materials and generates a smaller amount of waste chemical substances. Currently, our polyoxins are sold in 17 countries, and we are conducting development so that these environmentally friendly products can be supplied to more countries.



Consolidated Balance Sheets

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiary
As of March 31, 2021 and 2020

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
ASSETS			
CURRENT ASSETS:			
Cash and deposits (Notes 3 and 9)	¥ 63,706	¥ 59,722	\$ 579,145
Marketable securities (Notes 3, 4 and 9)	13,599	13,599	123,627
Receivables:			
Notes and accounts receivable—trade (Note 9)	20,549	21,800	186,809
Accounts receivable—other	337	641	3,064
	20,886	22,441	189,873
Inventories (Note 5)	15,198	12,275	138,164
Other	270	297	2,455
Allowance for doubtful accounts	(0)	(0)	(0)
Total current assets	113,662	108,336	1,033,291
PROPERTY, PLANT AND EQUIPMENT (Notes 6, 7 and 8):			
Buildings and structures	41,078	41,821	373,436
Machinery, equipment and vehicles	15,804	15,542	143,673
Tools, furniture and fixtures	7,613	7,393	69,209
	64,496	64,757	586,327
Accumulated depreciation	(44,331)	(43,882)	(403,009)
	20,165	20,875	183,318
Land	4,140	4,324	37,636
Construction in progress	713	317	6,482
Total property, plant and equipment	25,020	25,518	227,455
INVESTMENTS AND OTHER ASSETS:			
Investment securities (Notes 4 and 9)	17,368	15,036	157,891
Intangible assets	625	414	5,682
Deferred tax assets (Note 16)	1,577	3,229	14,336
Long-term prepaid expenses	4,196	4,450	38,145
Other assets	882	888	8,018
Total investments and other assets	24,649	24,020	224,082
TOTAL ASSETS	¥ 163,332	¥ 157,875	\$ 1,484,836

See accompanying Notes to the Consolidated Financial Statements.

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
LIABILITIES AND NET ASSETS			
CURRENT LIABILITIES:			
Short-term bank loans (Notes 6 and 9)	¥ 3,850	¥ 3,850	\$ 35,000
Payables:			
Notes and accounts payable—trade (Note 9)	8,425	7,720	76,591
Accounts payable—other	3,002	2,803	27,291
Electronically recorded obligations—operating (Note 9)	144	962	1,309
	11,572	11,485	105,200
Accrued expenses	324	535	2,945
Provision for bonuses	1,127	1,175	10,245
Provision for sales returns	3	4	27
Provision for sales rebates	302	312	2,745
Income taxes payable (Note 16)	2,292	2,904	20,836
Other	1,803	1,386	16,391
Total current liabilities	21,276	21,655	193,418
NON-CURRENT LIABILITIES:			
Provision for share awards	73	47	664
Net defined benefit liability (Note 10)	5,376	7,303	48,873
Other	348	400	3,164
Total non-current liabilities	5,798	7,750	52,709
NET ASSETS:			
Shareholders' equity (Note 11):			
Common stock			
Authorized: 193,000,000 shares as of March 31, 2021 and 2020			
Issued: 45,939,730 shares as of March 31, 2021 and 45,939,730 shares as of March 31 2020	23,853	23,853	216,845
Capital surplus	11,406	11,406	103,691
Retained earnings	122,462	114,869	1,113,291
Treasury stock, at cost: 7,621,338 shares as of March 31, 2021 and 7,022,576 shares as of March 31, 2020	(26,304)	(23,373)	(239,127)
Total shareholders' equity	131,418	126,756	1,194,709
Accumulated other comprehensive income:			
Net unrealized holding gain on securities	4,739	3,116	43,082
Remeasurements of defined benefit plans	99	(1,404)	900
Total accumulated other comprehensive income	4,839	1,712	43,991
Total net assets	136,257	128,468	1,238,700
TOTAL LIABILITIES AND NET ASSETS	¥ 163,332	¥ 157,875	\$ 1,484,836

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, 2021 and 2020

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
NET SALES	¥ 74,979	¥ 89,232	\$ 681,627
COST OF SALES	34,072	38,750	309,745
Gross profit	40,907	50,481	371,882
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (Note 12)	23,118	23,969	210,164
OPERATING PROFIT	17,788	26,512	161,709
OTHER INCOME (EXPENSES):			
Interest and dividends income	393	393	3,573
Interest expenses	(17)	(17)	(155)
Foreign exchange losses	(12)	(50)	(109)
Gain on sales of non-current assets (Note 13)	379	4	3,445
Loss on retirement of non-current assets (Note 14)	(54)	(68)	(491)
Gain on sales of investment securities	115	3	1,045
Impairment loss (Note 15)	—	(287)	—
Other, net	64	102	582
PROFIT BEFORE INCOME TAXES	868	80	7,891
	18,657	26,592	169,609
INCOME TAXES (Note 16):			
Current	4,979	6,686	45,264
Deferred	272	535	2,473
	5,252	7,222	47,745
PROFIT	13,405	19,370	121,864
PROFIT ATTRIBUTABLE TO OWNERS OF PARENT	¥ 13,405	¥ 19,370	\$ 121,864

	YEN		U.S. DOLLARS (NOTE 1)
	2021	2020	2021
PER SHARE DATA:			
Profit (Note 18):			
Basic	¥347.37	¥494.89	\$3.16
Diluted	—	—	—
Cash dividends applicable to the year (Note 11)	¥150.00	¥150.00	\$1.36

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, 2021 and 2020

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
PROFIT	¥ 13,405	¥ 19,370	\$ 121,864
OTHER COMPREHENSIVE INCOME (LOSS) (Note 19):			
Net unrealized holding gain (loss) on securities	1,623	(1,408)	14,755
Remeasurements of defined benefit plans	1,503	(473)	13,664
Total other comprehensive income (loss)	3,126	(1,882)	28,418
COMPREHENSIVE INCOME	16,532	17,487	150,291
Total comprehensive income attributable to:			
Owners of parent	¥ 16,532	¥ 17,487	\$ 150,291

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, 2021 and 2020

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, 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
Changes during the year:									
Cash dividends			(5,812)		(5,812)				(5,812)
Profit attributable to owners of parentof parent			13,405		13,405				13,405
Purchase of treasury stock				(2,941)	(2,941)				(2,941)
Disposal of treasury stock		0		9	9				9
Other, net						1,623	1,503	3,126	3,126
Total changes during the year	—	0	7,592	(2,931)	4,661	1,623	1,503	3,126	7,788
BALANCE—March 31, 2021	¥23,853	¥11,406	¥122,462	¥ (26,304)	¥131,418	¥4,739	¥ 99	¥4,839	¥136,257

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, 2020	\$216,845	\$103,691	\$1,044,264	\$(212,482)	\$1,152,327	\$28,327	\$(12,764)	\$15,564	\$1,167,891
Changes during the year:									
Cash dividends			(52,836)		(52,836)				(52,836)
Profit attributable to owners of parent			121,864		121,864				121,864
Purchase of treasury stock				(26,736)	(26,736)				(26,736)
Disposal of treasury stock		0		82	82				82
Other, net						14,755	13,664	28,418	28,418
Total changes during the year	—	0	69,018	(26,645)	42,373	14,755	13,664	28,418	70,800
BALANCE—March 31, 2021	\$216,845	\$103,691	\$1,113,291	\$(239,127)	\$1,194,709	\$43,082	\$ 900	\$43,991	\$1,238,700

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, 2021 and 2020

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
CASH FLOWS FROM OPERATING ACTIVITIES:			
Profit before income taxes	¥ 18,657	¥ 26,592	\$ 169,609
Adjustments for:			
Depreciation	2,318	2,312	21,073
Impairment loss	—	287	—
Increase (decrease) in net defined benefit liability	239	(22)	2,173
Interest and dividends income	(393)	(393)	(3,573)
Interest expenses	17	17	155
Loss (gain) on sale of investment securities	(115)	(3)	(1,045)
Loss on retirement of non-current assets	46	61	418
Loss (gain) on sale of property, plant and equipment	(379)	(4)	(3,445)
Decrease (increase) in notes and accounts receivable—trade	1,251	8,539	11,373
Decrease (increase) in inventories	(2,923)	1,446	(26,573)
Increase (decrease) in trade payables	(112)	(3,576)	(1,018)
Other, net	915	(356)	8,318
Subtotal	19,521	34,900	177,464
Interest and dividends income received	393	393	3,573
Interest expenses paid	(17)	(17)	(155)
Income taxes (paid) refund, net	(5,516)	(7,807)	(50,145)
Net cash provided by (used in) operating activities	14,380	27,468	130,727
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property, plant and equipment	(1,973)	(2,159)	(17,936)
Proceeds from sale of property, plant and equipment	874	7	7,945
Purchase of intangible assets	(313)	(43)	(2,845)
Purchase of investment securities	(20)	—	(182)
Proceeds from sale of investment securities	144	5	1,309
Other, net	(357)	(338)	(3,245)
Net cash provided by (used in) investing activities	(1,644)	(2,528)	(14,945)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Net decrease (increase) in short-term bank loans	—	(25)	—
Net decrease (increase) in treasury stock	(2,940)	(4,252)	(26,727)
Cash dividends paid	(5,811)	(5,896)	(52,827)
Net cash provided by (used in) financing activities	(8,752)	(10,173)	(79,564)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	3,983	14,766	36,209
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	73,322	58,555	666,564
CASH AND CASH EQUIVALENTS AT END OF YEAR (Note 3)	¥ 77,305	¥ 73,322	\$ 702,773

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 2020 financial statements to conform to the classifications used in 2021.

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 ¥110= U.S.\$1.00, the approximate rate of exchange prevailing on March 31, 2021. 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, 2021 and 2020, the Company had one consolidated subsidiary as follows:

KAKEN PHARMA CO., LTD.

For the years ended March 31, 2021 and 2020, 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 Awards

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 awards is recorded at an estimated amount of share awards 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 contracts:

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 contracts

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 26, 2021)

(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 guidance

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

(u) Changes in Presentation

Application of Accounting Standard for Disclosure of Accounting Estimates

The Company has applied “Accounting Standard for Disclosure of Accounting Estimates” (ASBJ Statement No. 31, issued on March 31, 2020) for financial statements from the end of the year ending March 31, 2021, and presents notes about key accounting estimates used in preparing the consolidated financial statements. However, in accordance with the transitional treatment stipulated in the proviso of paragraph 11 of the accounting standard, the notes do not cover the year ended March 31, 2020.

Consolidated Statements of Income

“Loss on cancellation of insurance policies,” which was presented as a discrete line item in “Other income (expenses)” for the year ended March 31, 2020 is included in “Other, net” for the year ended March 31, 2021 because it decreased to less than 10% of “Other income (expenses).” The consolidated financial statements for the year ended March 31, 2020 have been restated as follows to reflect this change in presentation.

In the consolidated statements of income, “Loss on cancellation of insurance policies” of ¥25 million has been included in “Other income (expenses).”

“Loss on sale of golf club membership,” which was presented as a discrete line item in “Other income (expenses)” for the year ended March 31, 2020, is included in “Other, net” for the year ended March 31, 2021 because it decreased to less than 10% of “Other income (expenses).” The consolidated financial statements for the year ended March 31, 2020 have been restated as follows to reflect this change in presentation.

In the consolidated statements of income, “Loss on sale of golf club membership” of ¥6 million has been included in “Other, net” in “Other income (expenses).”

Consolidated Statements of Cash Flows

In “Cash flows from operating activities,” “Loss (gain) on sale of investment securities” and “Loss (gain) on sale of property, plant and equipment,” which were included in “Other, net” for the year ended March 31, 2020 are presented as discrete line items for the year ended March 31, 2021 due to increased materiality. In addition, “Amortization of long-term prepaid expenses,” which was presented as a discrete line item for the year ended March 31, 2020, is included in “Other, net” for the year ended March 31, 2021 due to decreased materiality. The consolidated financial statements for the year ended March 31, 2020 have been restated as follows to reflect these changes in presentation.

In “Cash flows from operating activities,” “Other, net” has been restated as negative ¥356 million compared with the previous presentation as negative ¥813 million because of the inclusion of “Amortization of long-term prepaid expenses” of ¥449 million and the presentation of “Loss (gain) on sale of investment securities” and “Loss (gain) on sale of property, plant and equipment” as discrete line items of negative ¥3 million and negative ¥4 million, respectively.

In “Cash flows from investing activities,” “Proceeds from sale of property, plant and equipment” and “Proceeds from sale of investment securities,” which were included in “Other, net” for the year ended March 31, 2020 are presented as discrete line items for the year ended March 31, 2021 due to increased materiality. In addition, “Purchase of long-term prepaid expenses,” which was presented as a discrete line item for the year ended March 31, 2020, is included in “Other, net” for the year ended March 31, 2021 due to decreased materiality. The consolidated financial statements for the year ended March 31, 2020 have been restated as follows to reflect these changes in presentation.

In “Cash flows from investing activities,” “Other, net” has been restated as negative ¥338 million because of the inclusion of “Purchase of long-term prepaid expenses” of negative ¥400 million and the presentation of “Proceeds from sale of property, plant and equipment” and “Proceeds from sale of investment securities” as discrete line items of ¥7 million and ¥5 million, respectively.

(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 Awards 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 awards 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.

Financial and Corporate Data

(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, 2021, the carrying amount and the number of shares of treasury stock were ¥215 million (\$1,955 thousand) and 39,400 shares, respectively. As of March 31, 2020, the carrying amount and the number of shares of the treasury stock were ¥224 million and 41,100 shares, respectively.

Accounting Estimates Associated with the COVID-19 Pandemic

Group initiatives notwithstanding, the impact of the COVID-19 pandemic could affect drug supply systems and R&D activities, even repeatedly, if it becomes more serious or prolonged than the Group expects. Moreover, even if the rate of infection slows and conditions normalize, COVID-19 could continue to affect the Group's business activities, financial position and operating results for some time. Although the COVID-19 pandemic has affected the Group's business activities, the Group has determined that accounting estimates for the year ended March 31, 2021 have not been significantly affected.

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)
	2021	2020	2021
Cash and deposits	¥63,706	¥59,722	\$579,145
Marketable securities	13,599	13,599	123,627
Subtotal	¥77,305	¥73,322	\$702,773
Time deposits due after three months	—	—	—
Marketable securities due after three months	—	—	—
Cash and cash equivalents	¥77,305	¥73,322	\$702,773

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)
	2021			2020		
Fair values exceeding carrying amounts	¥ —	¥ —	¥ —	¥ —	¥ —	¥ —
Fair values not exceeding carrying amounts	10,999	10,999	—	10,999	10,999	—
Total	¥10,999	¥10,999	¥ —	¥10,999	¥10,999	¥ —

	THOUSANDS OF U.S. DOLLARS (NOTE 1)		
	Carrying amount	Fair value	Unrealized gain (loss)
	2021		
Fair values exceeding carrying amounts	\$ —	\$ —	\$ —
Fair values not exceeding carrying amounts	99,991	99,991	—
Total	\$99,991	\$99,991	\$ —

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)
	2021			2020		
Carrying amounts exceeding acquisition costs						
Equity securities	¥16,271	¥ 9,320	¥6,950	¥12,939	¥ 8,073	¥4,866
Other	—	—	—	—	—	—
Subtotal	16,271	9,320	6,950	12,939	8,073	4,866
Carrying amounts not exceeding acquisition costs						
Equity securities	1,019	1,137	(118)	2,039	2,414	(374)
Other	2,600	2,600	—	2,600	2,600	—
Subtotal	3,619	3,737	(118)	4,639	5,014	(374)
Total	¥19,890	¥13,058	¥6,831	¥17,579	¥13,087	¥4,491

	THOUSANDS OF U.S. DOLLARS (NOTE 1)		
	Fair value	Acquisition cost	Unrealized gain (loss)
	2021		
Carrying amounts exceeding acquisition costs			
Equity securities	\$147,918	\$ 84,727	\$63,182
Other	—	—	—
Subtotal	147,918	84,727	63,182
Carrying amounts not exceeding acquisition costs			
Equity securities	9,264	10,336	(1,073)
Other	23,636	23,636	—
Subtotal	32,900	33,973	(1,073)
Total	\$180,818	\$118,709	\$62,100

Available-for-sale securities sold for the years ended March 31, 2021 and 2020 are summarized as follows:

	MILLIONS OF YEN					
	Proceeds	Gain	Loss	Proceeds	Gain	Loss
	2021			2020		
Equity securities	¥144	¥115	¥—	¥5	¥3	¥—
Total	¥144	¥115	¥—	¥5	¥3	¥—

	THOUSANDS OF U.S. DOLLARS (NOTE 1)		
	Proceeds	Gain	Loss
	2021		
Equity securities	\$1,309	\$1,045	\$—
Total	\$1,309	\$1,045	\$—

5. Inventories

Inventories as of March 31, 2021 and 2020 comprised the following:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
Merchandise and finished products	¥ 5,700	¥ 4,762	\$ 51,818
Work in process	3,126	2,829	28,418
Raw materials and supplies	6,371	4,683	57,918
Total	¥15,198	¥12,275	\$138,164

6. Short-term Bank Loans and Pledged Assets

(a) Short-term bank loans

Short-term bank loans outstanding as of March 31, 2021 and 2020, amounting to ¥3,850 million (\$35,000 thousand) and ¥3,850 million, respectively, consisted mainly of bank overdrafts. The weighted-average interest rate applicable to short-term bank loans as of March 31, 2021 and 2020 was 0.45%.

(b) Pledged assets

As of March 31, 2021 and 2020, assets pledged as collateral for certain short-term bank loans are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
Assets pledged:			
Buildings and structures	¥6,126	¥6,114	\$55,691
Machinery, equipment and vehicles	2,527	2,730	22,973
Tools, furniture and fixtures	942	806	8,564
Land	117	117	1,064
Total	¥9,713	¥9,769	\$88,300
Liabilities secured:			
Short-term bank loans	¥1,400	¥1,400	\$12,727
Total	¥1,400	¥1,400	\$12,727

7. Accounting for Leases

Operating leases

(As a lessor)

Future minimum lease payments receivable under non-cancellable operating leases subsequent to March 31, 2021 and 2020 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
Due within 1 year	¥ 966	¥ 966	\$ 8,782
Due after 1 year	5,018	5,985	45,618
Total	¥5,985	¥6,952	\$54,409

8. Investment Properties

The Company owns rental office buildings (including land) mainly in Tokyo. Operating profit from these rental properties for the years ended March 31, 2021 and 2020 was ¥1,418 million (\$12,891 thousand) and ¥1,463 million, respectively. 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, 2021 and 2020, and fair value of these properties as of those dates are stated as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
Carrying amount:			
Balance at the beginning of the year	¥10,186	¥10,490	\$ 92,600
Changes during the year	(23)	(304)	(209)
Balance at the end of the year	10,162	10,186	92,382
Fair value at the end of the year	¥51,100	¥47,709	\$464,545

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, 2021, 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, 2021 and 2020 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
	2021		
(1) Cash and deposits	¥ 63,706	¥ 63,706	¥ —
(2) Notes and accounts receivable—trade	20,549		
Allowance for doubtful accounts*	(0)		
	20,549	20,549	—
(3) Marketable and investment securities			
a. Held-to-maturity debt securities	10,999	10,999	—
b. Available-for-sale securities	19,890	19,890	—
Total assets	¥115,145	¥115,145	¥ —
(1) Notes and accounts payable—trade	¥8,425	¥8,425	¥ —
(2) Electronically recorded obligations—operating	144	144	—
(3) Short-term bank loans	3,850	3,850	—
Total liabilities	¥ 12,420	¥ 12,420	¥ —

	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	¥ —

	THOUSANDS OF U.S. DOLLARS (NOTE 1)		
	Carrying amount	Fair value	Difference
	2021		
(1) Cash and deposits	\$ 579,145	\$ 579,145	\$ —
(2) Notes and accounts receivable—trade	186,809		
Allowance for doubtful accounts*	(0)		
	186,809	186,809	—
(3) Marketable and investment securities			
a. Held-to-maturity debt securities	99,991	99,991	—
b. Available-for-sale securities	180,818	180,818	—
Total assets	\$1,046,773	\$1,046,773	\$ —
(1) Notes and accounts payable—trade	\$76,591	\$76,591	\$ —
(2) Electronically recorded obligations—operating	1,309	1,309	—
(3) Short-term bank loans	35,000	35,000	—
Total liabilities	\$ 112,909	\$ 112,909	\$ —

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

Notes:

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		
	2021	2020	2021
Unlisted equity securities	¥77	¥57	\$700

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, 2021 and 2020 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	Within one year		
	2021	2020	2021
Cash and deposits	¥63,706	¥59,722	\$579,145
Notes and accounts receivable—trade	20,549	21,800	186,809
Marketable and investment securities:			
Held-to-maturity debt securities	10,999	10,999	99,991
Available-for-sale securities with contractual maturities	2,600	2,600	23,636
Total	¥97,855	¥95,123	\$889,591

4. Redemption schedules for long-term debt and other interest-bearing obligations subsequent to March 31, 2021 and 2020 are omitted since the Company only had short-term bank loans maturing within one year as of March 31, 2021 and 2020.

10. Retirement Benefits

The Company has defined benefit plans, i.e., a lump-sum retirement plan and defined benefit corporate pension plan. A retirement benefit trust has been 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, 2021 and 2020 are as follows (excluding plans applying the simplified method):

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
Retirement benefit obligation—Beginning balance	¥19,289	¥19,946	\$175,355
Service cost	701	727	6,373
Interest cost	57	59	518
Actuarial gain or loss	223	(75)	2,027
Retirement benefit paid	(1,251)	(1,368)	(11,373)
Retirement benefit obligation—Ending balance	¥19,021	¥19,289	\$172,918

(b) Changes in the plan assets for the years ended March 31, 2021 and 2020 are as follows (excluding plans applying the simplified method):

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
Plan assets—Beginning balance	¥11,994	¥13,312	\$109,036
Expected return on plan assets	230	316	2,091
Actuarial gain or loss	2,078	(948)	18,891
Employer’s contributions	166	168	1,509
Retirement benefit paid	(824)	(853)	(7,491)
Plan assets—Ending balance	¥13,644	¥11,994	\$124,036

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(c) Changes in the net defined benefit liability applying the simplified method for the years ended March 31, 2021 and 2020 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
Net defined benefit liability—Beginning balance	¥ 7	¥ 7	\$ 64
Retirement benefit cost	0	0	0
Payment of retirement benefit	(8)	—	(73)
Net defined benefit liability—Ending balance	¥ —	¥ 7	\$ —

(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)
	2021	2020	2021
Retirement benefit obligation under funded plan	¥19,021	¥19,289	\$172,918
Plan assets	(13,644)	(11,994)	(124,036)
	5,376	7,295	48,873
Retirement benefit obligation under unfunded plan	—	7	—
Net liability recorded on the consolidated balance sheets	5,376	7,303	48,873
Net defined benefit liability	5,376	7,303	48,873
Net liability recorded on the consolidated balance sheets	¥ 5,376	¥ 7,303	\$ 48,873

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)
	2021	2020	2021
Service cost	¥ 701	¥ 727	\$ 6,373
Interest cost	57	59	518
Expected return on plan assets	(230)	(316)	(2,091)
Amortization of actuarial gain or loss	345	224	3,136
Amortization of prior service cost	(33)	(33)	(300)
Net periodic pension cost under simplified method	0	0	0
Net periodic pension cost for defined benefit plans	¥ 841	¥ 661	\$ 7,645

(f) The components of remeasurements of defined benefit plans in other comprehensive income (before tax effect) for the years ended March 31, 2021 and 2020 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
Prior service cost	¥ (33)	¥ (33)	\$ (300)
Actuarial gain or loss	2,199	(649)	19,991
Total	¥ 2,166	¥ (682)	\$ 19,691

(g) The components of remeasurements of defined benefit plans in accumulated other comprehensive income (before tax effect) as of March 31, 2021 and 2020 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
Unrecognized prior service cost	¥ (5)	¥ (38)	\$ (45)
Unrecognized actuarial gain or loss	(137)	2,062	(1,245)
Total	¥ (142)	¥ 2,023	\$ (1,291)

(h) Plan assets

(1) Plan assets consist of the following:

	2021	2020
Debt securities	31%	50%
Equity securities	48	29
General account	13	16
Other	8	5
Total	100%	100%

Note: The plan assets include retirement benefit trust which accounted for 5% and 4% of the total plan assets as of March 31, 2021 and 2020, 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):

	2021	2020
Discount rate	0.3%	0.3%
Long-term expected rate of return	2.5%	2.0%

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, 2020	45,939,730	7,022,576
Increase	—	600,581
Decrease	—	(1,819)
Number of shares as of March 31, 2021	45,939,730	7,621,338

Notes:

- Increase in treasury stock (600,581 shares) is due to purchase of shares through the market (600,000 shares) based on the resolution of the Board of Directors' meeting and purchase of shares of less than one unit (581 shares).
- Decrease in treasury stock (1,819 shares) is due to placement of Company stock (1,700 shares) in the Board Benefit Trust (BBT) and requests for additional purchase of shares of less than one unit (119 shares).
- The number of treasury shares includes Company shares held by Custody Bank of Japan, Ltd. (Trust Account E) as trust assets of the BBT (39,400 shares as of March 31, 2021 and 41,000 shares as of April 1, 2020).

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

Approval by the ordinary general meeting of shareholders held on June 26, 2020 was as follows:

Dividends on common stock

Total amount of dividends ¥2,921 million (\$26,555 thousand)

Dividends per share ¥75.00 (\$0.68)

Record date March 31, 2020

Effective date June 29, 2020

Approval by the Board of Directors' meeting held on November 5, 2020 was as follows:

Dividends on common stock

Total amount of dividends ¥2,890 million (\$26,273 thousand)

Dividends per share ¥75.00 (\$0.68)

Record date September 30, 2020

Effective date November 30, 2020

(2) Dividends whose record date is attributed to the year ended March 31, 2021 but become effective after March 31, 2021

The Company obtained the following approval at the ordinary general meeting of shareholders held on June 29, 2021:

Dividends on common stock

Total amount of dividends ¥2,876 million (\$26,145 thousand)

Dividends per share ¥75.00 (\$0.68)

Record date March 31, 2021

Effective date June 30, 2021

Note: Total amount of dividends includes ¥2 million (\$18 thousand) of dividends payable for the Company's shares held by Custody Bank of Japan, Ltd. (Trust Account E) as trust assets of the 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, 2021 and 2020 amounted to ¥6,736 million (\$61,236 thousand) and ¥6,418 million, respectively.

13. Gain on Sales of Non-Current Assets

Gain on sales of non-current assets for the years ended March 31, 2021 and 2020 consists of the following:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
Buildings and structures	¥ 189	¥ —	\$ 1,718
Land	188	—	1,709
Other	1	4	9
Total	¥ 379	¥ 4	\$ 3,445

14. Loss on Retirement of Non-Current Assets

Loss on retirement of non-current assets for the years ended March 31, 2021 and 2020 consists of the following:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
Buildings and structures	¥15	¥11	\$ 136
Machinery, equipment and vehicles	5	1	45
Other	32	55	291
Total	¥54	¥68	\$ 491

15. Impairment Loss

No impairment loss was recognized for the year ended March 31, 2021.

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

			MILLIONS OF YEN
Location	Use	Type	Impairment loss
Chuo-ku, Osaka	Business assets	Buildings and structures, etc.	¥287

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 being dismantled based on the resolution to rebuild by the Board of Directors' meeting held on August 28, 2019 and the carrying value was written-down to the recoverable value. The decreased value of buildings and structures, etc. in an amount of ¥117 million and the dismantling costs of ¥169 million were recognized as impairment loss in other income (expenses).

The recoverable value is based on the memorandum value.

16. Income Taxes

Significant components of deferred tax assets and liabilities as of March 31, 2021 and 2020 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
Deferred tax assets:			
Accounts receivable-trade	¥ 46	¥ 58	\$ 418
Disallowed expensed supplies	180	232	1,636
Adjustment of gain on sales of land	2,638	2,638	23,982
Amortization of research & development expenses	276	196	2,509
Amortization of long-term prepaid expenses	952	1,132	8,655
Provision for bonuses	323	333	2,936
Provision for sales rebates	92	95	836
Net defined benefit liability	1,855	1,779	16,864
Other	316	1,075	2,873
Total	6,682	7,542	60,745
Valuation allowance	(2,820)	(2,819)	(25,636)
Deferred tax assets	3,861	4,723	35,100
Deferred tax liabilities:			
Reserve for advanced depreciation of non-current assets	(112)	(118)	(1,018)
Reserve for special account for advanced depreciation of non-current assets	(79)	—	(718)
Net unrealized holding gain on securities	(2,091)	(1,375)	(19,009)
Deferred tax liabilities	(2,284)	(1,493)	(20,764)
Deferred tax assets, net	¥1,577	¥3,229	\$ 14,336

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The Group is subject to several taxes based on income, which in the aggregate resulted in a statutory tax rate of approximately 30.62% for the years ended March 31, 2021 and 2020. Reconciliation of the differences between the statutory tax rate and the effective tax rate for the years ended March 31, 2021 and 2020 is as follows:

	2021	2020
Statutory tax rate	30.62%	30.62%
Increase (decrease) in taxes resulting from:		
Expenses not deductible for income tax purpose (e.g. entertainment expenses)	0.05	0.22
Income not included for income tax purpose (e.g. dividend income)	(0.13)	(0.09)
Inhabitant per capita taxes	0.39	0.28
Tax credit for research expenses	(2.79)	(3.59)
Other	0.01	(0.28)
Effective tax rate	28.15%	27.16%

17. Related Party Transactions

There are no related party transactions to be disclosed for the years ended March 31, 2021 and 2020.

18. Per Share Information

Per share information as of March 31, 2021 and 2020 and for the years then ended is as follows:

	YEN		U.S. DOLLARS (NOTE 1)
	2021	2020	2021
Net assets per share	¥3,555.93	¥3,301.09	\$32.33
Profit per share	347.37	494.89	3.16

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). 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 shares of treasury stock deducted for computation of net assets per share is 39,400 as of March 31, 2021 and 41,100 as of March 31, 2020. The weighted average number of shares of treasury stock deducted for computation of profit per share is 39,926 for the year ended March 31, 2021 and 14,598 for the year ended March 31, 2020.

The basis of calculation for profit per share for the years ended March 31, 2021 and 2020 is as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
Profit	¥13,405	¥19,370	\$121,864
Profit attributable to common stock owners of parent	13,405	19,370	121,864
Profit not attributable to common stock	—	—	—
(Number of shares)			
Weighted average number of shares (thousands of shares)	38,590	39,140	

19. Comprehensive Income

Reclassification adjustments and income tax effects for each component of other comprehensive income for the years ended March 31, 2021 and 2020 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2021	2020	2021
Net unrealized holding gain (loss) on securities:			
Increase (decrease) during the year	¥2,455	¥(2,026)	\$22,318
Reclassification adjustments	(115)	(3)	(1,045)
Before income tax effect	2,340	(2,029)	21,273
Income tax effect	(716)	621	(6,509)
Net unrealized holding gain (loss) on securities	¥1,623	¥(1,408)	\$14,755
Remeasurements of defined benefit plans:			
Increase (decrease) during the year	¥1,854	¥(873)	\$16,855
Reclassification adjustments	311	190	2,827
Before income tax effect	2,166	(682)	19,691
Income tax effect	(663)	209	(6,027)
Remeasurements of defined benefit plans	¥1,503	¥ (473)	\$13,664
Total other comprehensive income	¥3,126	¥(1,882)	\$28,418

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.

Financial and Corporate Data

(c) Information about reportable segments

	MILLIONS OF YEN				
	Reportable Segment			Adjustments	Consolidated
	Pharmaceuticals	Real estate	Total		
	2021				
Net sales:					
Sales to external customers	¥ 72,614	¥ 2,365	¥ 74,979	¥ —	¥ 74,979
Intersegment sales or transfers	—	—	—	—	—
Total	¥ 72,614	¥ 2,365	¥ 74,979	¥ —	¥ 74,979
Segment profit	¥ 16,370	¥ 1,418	¥ 17,788	¥ —	¥ 17,788
Segment assets	¥ 71,658	¥ 10,207	¥ 81,866	¥ 81,466	¥163,332
Other items:					
Depreciation and amortization	¥ 2,455	¥ 292	¥ 2,747	¥ —	¥ 2,747
Increase in property, plant and equipment and intangible assets	2,442	287	2,729	—	2,729

	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

THOUSANDS OF U.S. DOLLARS (NOTE 1)					
	Reportable Segment			Adjustments	Consolidated
	Pharmaceuticals	Real estate	Total		
	2021				
Net sales:					
Sales to external customers	\$ 660,127	\$ 21,500	\$ 681,627	\$ —	\$ 681,627
Intersegment sales or transfers	—	—	—	—	—
Total	\$ 660,127	\$ 21,500	\$ 681,627	\$ —	\$ 681,627
Segment profit	\$ 148,818	\$ 12,891	\$ 161,709	\$ —	\$ 161,709
Segment assets	\$ 651,436	\$ 92,791	\$ 744,236	\$ 740,600	\$ 1,484,836
Other items:					
Depreciation and amortization	\$ 22,318	\$ 2,655	\$ 24,973	\$ —	\$ 24,973
Increase in property, plant and equipment and intangible assets	22,200	2,609	24,809	—	24,809

The adjustments to segment assets of ¥81,466 million (\$740,600 thousand) and ¥78,253 million as of March 31, 2021 and 2020, 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)	
		Net sales		Name of the related segment
	2021	2020	2021	
Alfresa Corporation	¥13,349	¥15,890	\$121,355	Pharmaceuticals
SUZUKEN CO., LTD.	11,375	13,776	103,409	Pharmaceuticals
MEDICEO CORPORATION	11,236	12,611	102,145	Pharmaceuticals

(g) Information about impairment loss by reportable segment

No impairment loss was recognized for the year ended March 31, 2021.

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

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

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 7, 2021.

(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 shares of common stock to be acquired:

Up to 500,000 shares

(d) Total amount of shares of common stock to be acquired:

Up to ¥2,500 million (\$22,727 thousand)

(e) Schedule for acquisition:

From May 10, 2021 to December 24, 2021

(f) Method of acquisition:

Purchase on the Tokyo Stock Exchange

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, 2021 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, 2021, 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.

Key Audit Matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the consolidated financial statements of the current period. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Emphasis of Matter

As described in Note 21, at a meeting of the Board of Directors of the Company held on May 7, 2021, the Company approved the acquisition of treasury stock. Our opinion is not qualified in respect of this matter.

Accounting for Research and Development Costs	
Key audit matter and the basis of our determination	How the matter was addressed in the audit
The Company recorded research and development costs of 6,736 million yen in the consolidated balance sheet for the current fiscal year, and disclosures related to the costs are made in Note 12 (Research and Development Costs). The Company belongs to the pharmaceutical industry and positions the enhancement of the development pipeline as an important issue in its management plan. For this reason, the Company is engaged in research and development and	The primary procedures we performed to assess accounting for research and development costs included the following: <ul style="list-style-type: none">We evaluated the effectiveness of the Company’s internal control development and operation status related to the recording of research and development costs.We confirmed that the accounting treatment of the Company is properly carried out in accordance with the relevant accounting

introduction activities of new drug candidates, and in the process, contracts that require complicated judgments regarding accounting treatment may be concluded. The contract conditions for R&D and introduction transactions differ from contract to contract, and if the contract content is unusual, it is necessary to carefully consider the accounting treatment. Since it is necessary to determine the timing and scope of the recording of research and development costs according to the contract conditions, such as when the content of R&D and introduction transactions is joint research or contract research, there is a need to carefully consider the accounting method. Therefore, we determined that accounting for research and development costs was one of the most significant matters in our audit of the consolidated financial statements for the current fiscal year, and accordingly, a key audit matter.	standards, etc. by examining the contract contents by viewing the contracts, collating materials with the related vouchers, conducting hearing with the department in charge, etc. <ul style="list-style-type: none">In particular, when viewing contracts for introduction transactions, the contents of contracts were examined while paying attention to whether the content corresponds to joint research or contract research. Regarding research and development costs, it was confirmed that the timing and scope of recording as expenses are appropriate in light of the contract conditions, etc.We inspected the minutes of various meetings such as those of the Board of Directors and examined whether the events grasped related to research and development activities were comprehensively reflected.We have confirmed that there has been no change in the method of aggregating research and development costs from the previous year and that the research and development costs have been aggregated appropriately and comprehensively before being displayed.
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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.

Interest required to be disclosed by the Certified Public Accountants Act of Japan

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


Hirofumi Nikaido
Designated Engagement Partner
Certified Public Accountant


Daiki Matsuura
Designated Engagement Partner
Certified Public Accountant

ARK LLC
Tokyo, Japan
September 29, 2021

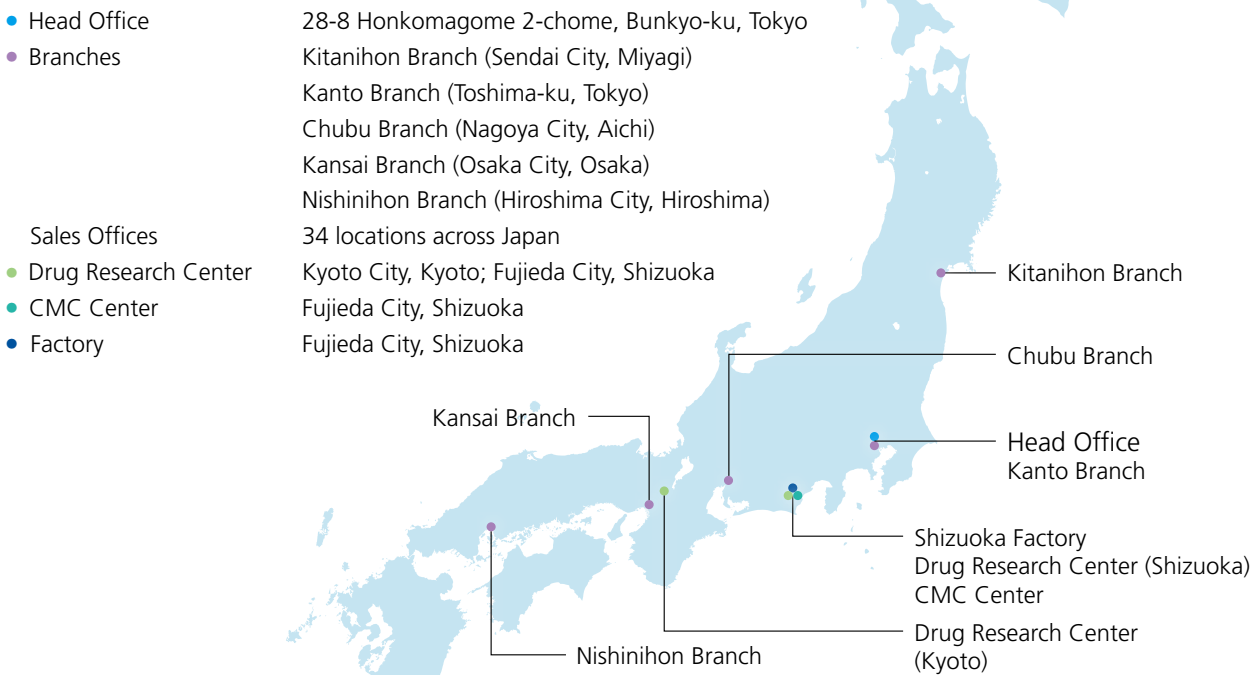
Corporate and Stock Information

(As of March 31, 2021)

Company Overview

Company Name	KAKEN PHARMACEUTICAL CO., LTD.
Incorporated	March 1, 1948
Paid-in Capital	¥23,853 million
Number of Employees	1,215 (consolidated)
Representative	Hiroyuki Horiuchi, President and Representative Director
Head Office	28-8 Honkomagome 2-chome, Bunkyo-ku, Tokyo
Business Description	Production and marketing of pharmaceuticals, medical devices, agrochemicals, feed additives, drugs for animals and rental of real estate holdings

Main Offices (As of April 1, 2021)



Head Office (Tokyo)



Drug Research Center (Kyoto)



Kansai Branch (Osaka; construction completed in April 2021)

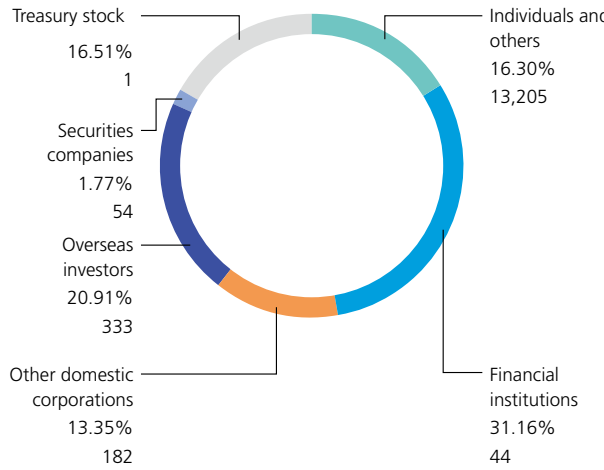


Shizuoka Factory (Shizuoka)

Stock Information

Authorized	193,000,000 shares
Issued	45,939,730 shares
Number of Shareholders	13,819
Stock Exchange Listing	Tokyo Stock Exchange, First Section
Securities Code	4521
Shareholder Register Administrator	Sumitomo Mitsui Trust Bank, Limited

Shareholdings by Shareholder Type



Major Shareholders (Top 10)

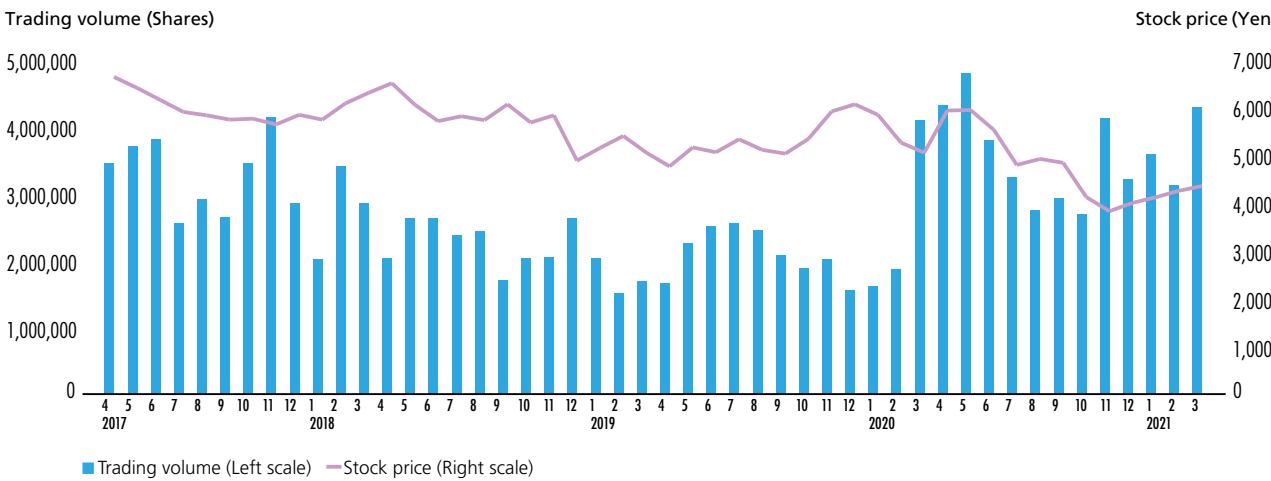
Shareholder	Number of shares held (Thousands)	Shareholding ratio (%)
The Master Trust Bank of Japan, Ltd. (Trust Account)	2,927	7.63
Toray Industries, Inc.	2,294	5.98
The Norinchukin Bank	1,843	4.81
Custody Bank of Japan, Ltd. (Trust Account)	1,552	4.05
Mizuho Bank, Ltd.	1,474	3.85
NORTHERN TRUST CO. (AVFC) RE SILCHESTER INTERNATIONAL INVESTORS INTERNATIONAL VALUE EQUITY TRUST	876	2.28
KYORIN Pharmaceutical Co., Ltd.	852	2.22
Nippon Life Insurance Company	680	1.77
Custody Bank of Japan, Ltd. (Trust Account 7)	630	1.64
KAKEN Employees Shareholding Association	607	1.58

Note: The shareholding ratios are calculated by subtracting the number of treasury shares (7,581,938) from the total number of shares issued.

Total Shareholder Return

FY	2016	2017	2018	2019	2020
(%)	94.6	96.6	80.5	82.7	74.7
(Comparison index: TOPIX Total Return Index)	114.7	132.9	126.2	114.2	162.3

Stock Price and Trading Volume





KAKEN PHARMACEUTICAL CO., LTD.

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<https://www.kaken.co.jp/english>



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