

# CORPORATE REPORT 2023



KAKEN PHARMACEUTICAL CO., LTD.





# 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, society and our employees.

We also hope to contribute to society by demonstrating KAKEN’s distinctive and vigorous presence.

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

**Business Philosophy** KAKEN “Three Joys”

**Joy for patients**

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

**Joy for society**

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

**Joy for employees**

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

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#### Editorial Policy

Our policy in issuing this report is to help KAKEN’s various stakeholders (including shareholders and investors) to understand the Company’s management foundation and strengths, as well as the sustainable growth it aspires to achieve through creation of corporate value in the future. We have compiled the report using the *International Integrated Reporting Framework* by the IFRS Foundation and *Guidance for Collaborative Value Creation* by the Ministry of Economy, Trade and Industry as reference.

#### Reporting Period

FY2022 (April 1, 2022 to March 31, 2023)  
Note: Some information from before and after the period above is included.

#### Scope of This Report

Kaken Pharmaceutical Co., Ltd. (“the Company” or “KAKEN”) and its consolidated subsidiaries (collectively, “the KAKEN Group” or “the Group”)

#### 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.

#### Position of the Corporate Report in Information Disclosure

To communicate with stakeholders, we use various tools to disseminate a wide range of information in addition to the information in this report. Our purpose in issuing this report is to tell our value creation story by integrating financial and non-financial information.

Financial	Non-Financial
Investor relations section of the Company website	
Corporate Report	
Presentation materials	ESG data (Japanese only)
Annual Securities Report (Japanese only) and Consolidated financial results	Sustainability section of the Company website
	Corporate Governance Report (Japanese only)

Investor relations section of the Company



ESG data (Japanese only)



Sustainability section of the Company website





# A History of Value Creation

With a deep dedication to meeting the needs of patients, KAKEN conducts collaborative research and development and clinical development with companies in Japan and overseas, in addition to in-house drug discovery, to provide products that are the first of their kind in Japan or the world.

## KAKEN's History

1940s

1960s

1990s

2000s and beyond

### Founding Ideas

With its origins in the Institute of Physical and Chemical Research (Riken), which was established in 1917, the Company started its business in 1948 as Kagaku Kenkyusho. Its first president, Yoshio Nishina, who has been 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 manufacturing and selling pharmaceuticals as a way of implementing theoretical research in business.



### 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. It went on to introduce streptomycin, a specific treatment for tuberculosis, as well as related products, forming the business foundation that led to the KAKEN of today.



The Company's first office building

### Growth driven by establishment of new research facilities and a strengthened sales structure

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 addressing social problems. In response to Minamata disease (methylmercury poisoning), 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 Kyoto Research Institute in particular was equipped with state-of-the-art equipment and tools, demonstrating highly reliable safety testing (preclinical studies).



Kyoto Research Institute (established in 1975)

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

In the 1990s, KAKEN increased its R&D investment and further improved its technologies. The Company became the first in the world to successfully synthesize and develop benzylamine-derived butenafine hydrochloride. Used as a treatment for athlete's foot, it had a chemical structure completely different from that of existing athlete's foot medicines, and grew into strategic global product Mentax. For Artz, which had been sold in ampoule form, 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."



Mentax, which was awarded the Okochi Memorial Grand Production Prize

### Advancing priority research themes through organizational improvements and concentration of resources Started Long-Term Business Plan 2031 in FY2022

The Drug Research Center and the CMC Center cooperate and collaborate in discovery research, focusing their financial and human resources on R&D themes in fields where their strengths can best be utilized—the immune system, the nervous system and infectious diseases. In FY2022, KAKEN launched Long-Term Business Plan 2031, and is working to enhance its corporate value based on its vision of being 1) a company that contributes to longer healthy life expectancy by developing and supplying innovative new drugs in a speedy manner, and 2) a research-based pharmaceutical company with a global presence, primarily in the areas of dermatology and orthopedics. In addition, we renewed our brand logo to gain broader recognition from stakeholders as we develop our business globally. The shape of the logo, which spreads out in three directions, uses the "K" in KAKEN as a motif to express the "Three Joys"—Joy for patients, Joy for society, and Joy for employees—that comprise our business philosophy. It reflects our dedication to always taking on new challenges while pursuing more advanced technology and reliable quality.



Brand logo renewal

1953

### Launched Athletan (antifungal agent)

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. It was the first product from in-house drug discovery and played a significant role in building the Company's corporate image.

2014

### Launched Clenafin (onychomycosis treatment)

As the first topical treatment for onychomycosis in Japan, Clenafin gave patients a new treatment option that can be applied with a brush. It was discovered and developed in-house, and global sales are expanding as the product becomes available to patients worldwide, partly through out-licensing to local companies in North America, Asia and Europe.

1987

### Launched Artz (anti-osteoarthritis agent)

The world's first hyaluronic acid drug administered by intra-articular injection, Artz has been marketed for more than 30 years. Widely used to treat osteoarthritis of the knee and periarthritis of the shoulder, it is one of the products that greatly expanded KAKEN's presence in the area of orthopedics.

2021

### Acquired Domestic Biotech Startup ARTham Therapeutics Inc.

KAKEN bolstered its development pipeline by making its first acquisition since the Company was incorporated. By applying ARTham's technology and experience in drug repositioning, KAKEN will also enhance its own R&D capabilities.

## Product History

### Antifungal agent Athletan



### Anti-inflammatory, analgesic and antipyretic agent Brufen



### Anti-osteoarthritis agent Artz Dispo



### Wound-healing agent Fiblast



### Onychomycosis treatment Clenafin



### Primary axillary hyperhidrosis treatment Ecclock



### Bum eschar removal agent NexoBrid



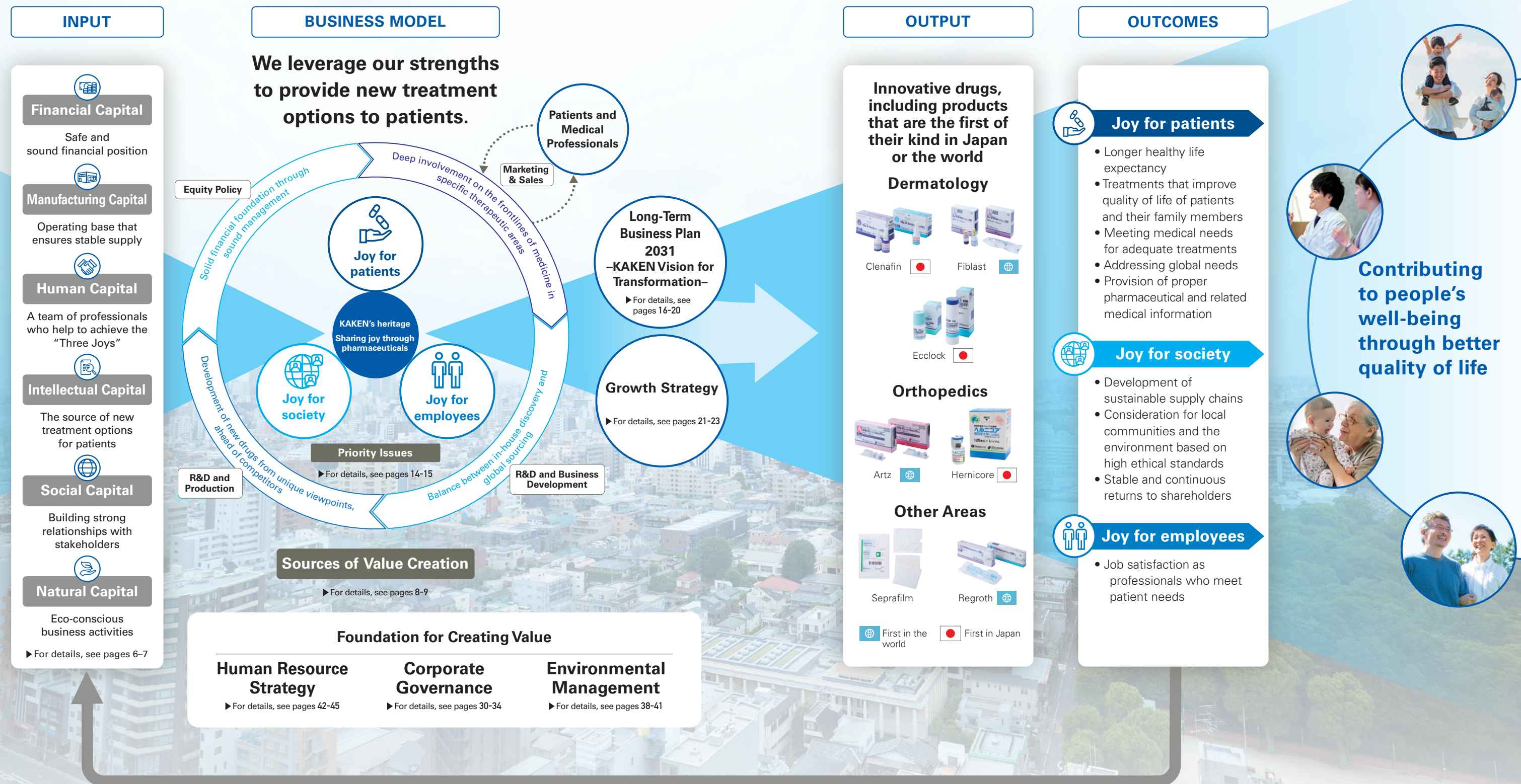


# Value Creation Process

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,” the KAKEN Group provides drugs and information that contribute to the quality of life of patients from a distinctive viewpoint. We will continue striving to create value based on our unique strengths.

## 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.






# KAKEN's Six Types of Capital

We have continued to provide new treatment options to patients using the capital we have accumulated since the Company was founded.

To continue to understand and meet needs on the frontlines of healthcare, we will further build up that capital in pursuit of greater value creation.



Financial Capital

Safe and sound financial position


Operating cash flow

Equity-to-asset ratio

¥9,253million

81.9%

Our continuous launch of new drugs is a stable source of revenue, based on which we are able to maintain a sound financial position, which in turn enables us to make proactive growth investments to enhance our future earnings foundation. In allocating the cash flow generated from our business activities, we give priority to research and development to create innovative new drugs that will provide joy to patients and society. By doing so, we will achieve sustainable growth in corporate value.



Intellectual Capital

The source of new treatment options for patients

R&D investment


Number of projects under development

¥15,789million

8

(As of August 2023)

We deliver new treatment options for patients primarily through products in the areas of dermatology and orthopedics. In FY2022, we in-licensed two development projects for the treatment of rare diseases in new therapeutic areas. In addition to our efforts in therapeutic areas where we are strong, we will expand into rare diseases and other new areas, aggressively investing in research and development to steadily create world-class, innovative drugs.



Manufacturing Capital

Operating base that ensures stable supply

Capital expenditures

Manufacturing base

¥1,968million

Shizuoka Factory

Delivering stable, continuous supplies of high-quality pharmaceuticals to patients is our responsibility as a pharmaceutical company, and the Shizuoka Factory is our manufacturing site for that purpose. At the Shizuoka Factory, we are proactively investing to expand or upgrade pharmaceutical manufacturing facilities. We will improve production efficiency by making use of digital technology in production control and quality control as we work to establish and maintain a system for providing a stable supply of pharmaceuticals.



Social Capital

Building strong relationships with stakeholders

Sales offices

Number of countries/regions where efinaconazole is available

33

6

(As of April 2023)

In supplying drugs to patients in Japan and overseas, it is essential to build strong relationships of trust with a wide range of stakeholders, including medical professionals and licensees. To ensure that KAKEN's pharmaceutical products are used properly, we have sales offices nationwide and have established a system for providing appropriate product information. We are also out-licensing products overseas, primarily Clenafin (INN: efinaconazole), a drug from in-house drug discovery.



Human Capital

A team of professionals who help to achieve the "Three Joys"

Number of employees (Kaken Pharmaceutical)

Average tenure

1,117

Male employees: 17.8 years

Female employees: 19.1 years

To achieve the "Three Joys" of our business philosophy, we endeavor to create an environment in which employees can enjoy and take pride in their work as professionals and can continue working with a sense of fulfillment. To foster a corporate culture that encourages employees to take on challenges, we offer personal development and reskilling opportunities, and develop employees with distinctive capabilities who can adapt to changing times. In doing so, we are transforming our organization into one where diverse people collaborate as one team.



Natural Capital

Eco-conscious business activities

CO<sub>2</sub> emissions

Energy consumption

Water consumption

21,667 t-CO<sub>2</sub>

11,779 kl

2,808 thousand m<sup>3</sup>

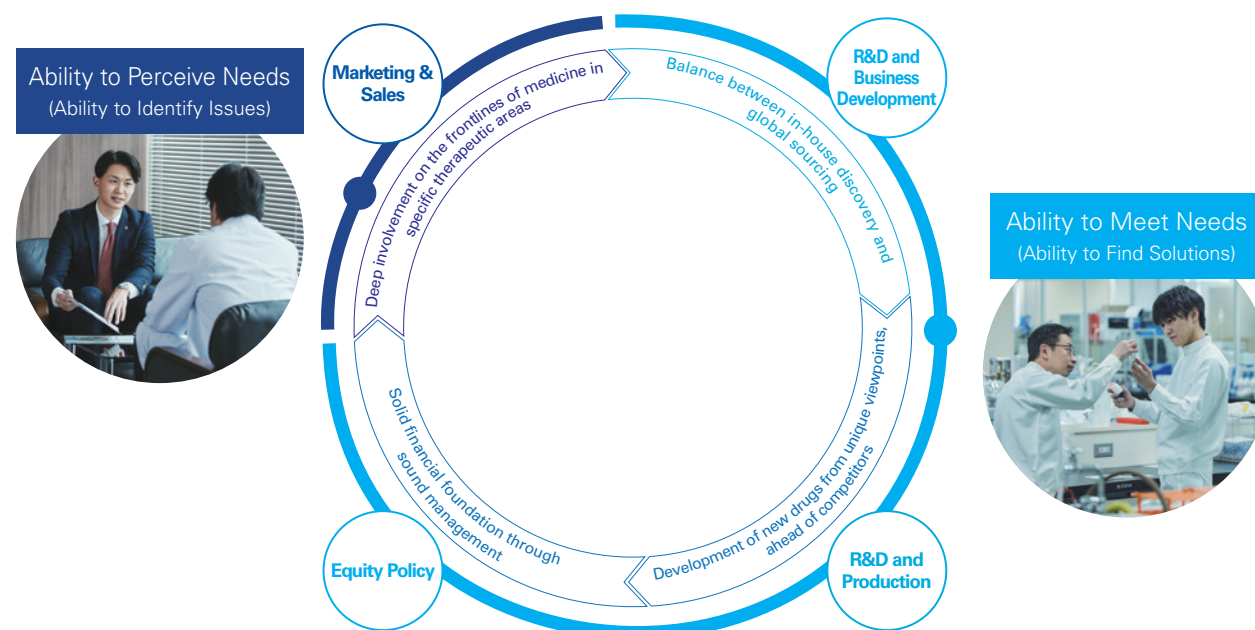
Consideration for the environment is one of our priority issues. We are taking steps to reduce our environmental burden in all aspects of our business activities. We have set a long-term target for reduction of CO<sub>2</sub> emissions and are implementing ongoing energy-saving activities to achieve it. Under the KAKEN Basic Environmental Philosophy, we recognize our social responsibility as a pharmaceutical company and shall take measures to address climate change and other environmental issues, and contribute to the realization of a sustainable, prosperous society.



# Sources of Value Creation

KAKEN focuses on selected therapeutic areas and delivers new treatment options to patients.

Our ability to do so comes from our ability to perceive needs (our ability to identify issues) based on our corporate culture of adapting to the frontlines of medicine, and our ability to meet needs (our ability to find solutions) by applying a flexible approach.



## Ability to Perceive Needs (Ability to Identify Issues)

### Expertise and Networks from Focusing on Specific Therapeutic Areas

We focus on dermatology and orthopedics, and have useful, innovative products in both of these areas. By concentrating our efforts in these areas, we have raised the quantity and quality of the specialized knowledge of our medical representatives (MRs), and when assigned to specific regions they are able to tailor the information they provide to the medical needs of those regions. These actions have helped us build strong relationships of trust with medical professionals. As a result, we are able to reflect the patient feedback that we obtain from medical professionals at the frontlines of medicine in new product development and formulation improvements.



**I frequently go to the frontlines, and I value the information that can only be obtained by being there.**

Shin Ito Tokyo Sales Office 1, Regional Marketing & Sales Department I

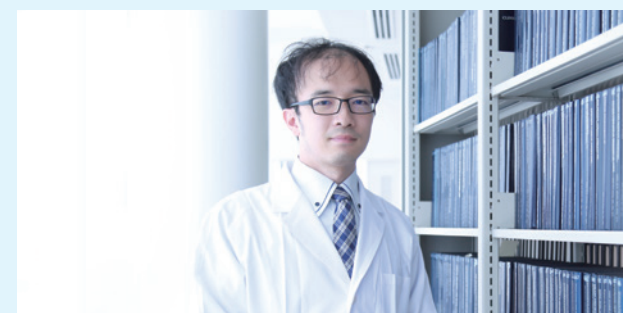
KAKEN has a history of continuously providing products that are appreciated by many patients, mainly in dermatology and orthopedics. Behind that success are the strong relationships of trust we have built with medical professionals, which are the source of the Company's presence and product value. Our MRs do more than just provide information to doctors and pharmacists; by meeting frequently with medical professionals who are in close contact with patients, such as nurses and rehabilitation staff, we can explain diseases and inform them about how to use our products, as well as obtain feedback from more patients, which we then apply in our everyday work.

Although we are a pharmaceutical company, we also provide adhesion barrier materials, which are a medical device. Because of this, our MRs have opportunities to attend surgeries in operating rooms to explain the proper use of these products. By providing support to medical professionals in this setting, MRs can deepen trust. Moreover, being present to see our products properly used for the benefit of patients is a uniquely rewarding experience that other drug manufacturers do not offer. We remain committed to being a trusted medical partner through information-sharing activities.

## Ability to Meet Needs (Ability to Find Solutions)

### Flexible Approach to Finding Solutions

We identify the best solution by applying a flexible approach and analyzing unmet medical needs using the patient feedback we obtain from medical professionals at the frontlines of medicine. We strive to speed up the R&D process to provide the innovative drugs that patients need as quickly as possible, not only by leveraging our own technologies and experience, but also by using advanced technologies and knowledge from outside the Company. We also apply the information that MRs obtain at the frontlines to devise product formulation and packaging solutions.



**We are utilizing AI and other technologies to drive innovation in the drug discovery process.**

Hitoshi Kesamaru

In Silico Analysis Group, Chemistry Department, Drug Research Center

The R&D Division aims to rapidly create innovative new drugs. We apply computerized simulations and analysis in addition to testing hypotheses through conventional experiments as we work to increase the speed of drug discovery research and improve the probability of success. In addition to utilizing an AI drug discovery platform called Elix Discovery™, we are constructing a new AI prediction

model that applies KAKEN's expertise to raise our compound design to a higher level. Through collaboration and joint research with a partnership research organization (PRO), we are also strengthening our bioinformatics platform and innovating the drug discovery process by combining our in-house research infrastructure with the latest technologies.

### Flexible Cooperation

To create advanced drugs that address new needs and make those drugs available to patients as quickly as possible, we assemble cross-departmental project teams for specific objectives. Through free and lively discussion based on their expertise, team members carry out efficient drug discovery. This serious and passionate approach across departmental boundaries is one of KAKEN's strengths.

We are striving to create further value, taking on new challenges by increasing cooperation with domestic and overseas biopharmaceutical startups that have innovative technologies, and with companies that have unique technologies in other areas.



**As a team, we are flexibly pursuing what is best for patients through open communication and smooth cooperation across departments.**

Takuya Nabeshima Medical Affairs Department

The Medical Affairs Department is responsible for drug fostering and evolution (DFE), in other words, for increasing the value of pharmaceuticals with the information it provides to medical professionals and patients. For Nexobrid, a drug for burn eschar removal launched in August 2023, we shared information obtained from outside medical science experts, licensee MediWound and overseas scientific papers in an internal cross-departmental project from the early stages of

development. This information was reflected in easy-to-understand information materials for medical professionals and a video on drug preparation procedures, which have helped to ensure the appropriate use of the product.

We will continue working as a unified team to maximize the value of pharmaceuticals, cooperating with the highly professional employees in each department to solve problems.



# President's Message



## The First Step toward 2031 VISION

**We will promote the “Three Transformations” to contribute to well-being through better quality of life.**

**Hiroyuki Horiuchi**

President and Representative Director

## The First Year of Long-Term Business Plan 2031

For FY2022, as a positive result that will contribute in the long term, we enhanced our development pipeline by in-licensing two drugs in late-stage development for rare diseases—seladelpar, a primary biliary cholangitis treatment, and tildacerfont, a congenital adrenal hyperplasia treatment. Furthermore, in December 2022 we obtained regulatory approval for NexoBrid, a drug for burn eschar removal, and launched it in August 2023. Currently approved in over 40 countries, this topical agent removes necrotic burn tissue, or eschar, through proteolysis, a process that uses proteolytic enzymes extracted from the stem of the pineapple plant as its active ingredient. A major initiative taken on by KAKEN is to in-license products that have been launched overseas and launch them as new treatment options in Japan, where they were previously unavailable. Our hope is that these products will contribute to improved quality of life

for more patients.

On the other hand, financial results for FY2022 fell short of our original plan. Net sales declined due to National Health Insurance (NHI) drug price reductions in Japan and competition from rival products, and profit decreased mainly because of an increase in R&D expenses and an impairment loss associated with the termination of a development project by ARTham Therapeutics, a consolidated subsidiary. We regret that we were unable to achieve good results in the first year of Long-Term Business Plan 2031.

We also made organizational changes in April 2023. In the Marketing & Sales Division, we restructured the five branches into three new regional marketing & sales departments in charge of the Greater Tokyo and Chubu, Western Japan, and Eastern Japan regions and changed to a structure in

which the Marketing & Sales Division directly supervises the 33 sales offices nationwide. This organization will enable faster coordination between the Marketing & Sales Division and frontline operations, ensuring decisions reach frontline operations smoothly and allowing frontline staff to move quickly and gather information and identify needs. In addition to our culture of adapting to the frontlines of medicine—the source of our ability to identify unmet medical

needs and create enduring products—we believe these changes to our organization will reinforce and deepen our unique strength of solving problems as a team and will speed up decision-making to achieve results. I have a real sense that we took positive steps in FY2022 toward achieving Long-Term Business Plan 2031, and were able to gauge the challenges we need to overcome to achieve our vision.

## Promoting R&D Transformation and Overseas Expansion Transformation

Long-Term Business Plan 2031 presents “Three Transformations” as a strategy for achieving our vision.

In the first, “R&D Transformation,” we envision continuously launching innovative, world-class drugs in our three priority fields of drug discovery. In FY2022, we established the In Silico Analysis Group and

began using AI in drug discovery to shorten the R&D period and improve the success rate of in-house drug discovery.

In January 2023, we started collaboration for creation of innovative new drugs with Axcellead Drug Discovery Partners, Inc., which has the wide range



of platform capabilities and extensive experience necessary for drug discovery. We will rapidly transform our discovery research process to be more data-driven so that we can produce positive results during the period of Long-Term Business Plan 2031.

The second of the “Three Transformations” is “Overseas Expansion Transformation.” Here, we envision increasing our overseas sales ratio to 30% or higher by FY2031 and consolidating our position as an R&D-driven company with mainstay products in the areas of dermatology and orthopedics.

In our current product mix, we are expanding the regions where we launch our existing overseas products. For example, in May 2022 our European licensee Almirall S.A. filed an application for approval of Clenafin, an onychomycosis treatment, and in June 2023 we out-licensed Ecclock, a primary axillary hyperhidrosis treatment, to a company in South Korea. We are now preparing for our own clinical trial for KP-001, a treatment for refractory vascular malformations, in the United States. We intend to cooperate with partner companies to expand our presence in the United States, the center of the market for new drugs.

## Becoming an Organization That Nurtures Professionals and Where People with Diverse Abilities Cooperate as One Team

In the third of our “Three Transformations,” “Management Base Transformation,” we envision increasing corporate value by establishing a strong organizational base that can flexibly respond to changes and by improving operational efficiency.

The core of our management base is human capital, and we are focusing efforts on nurturing professionals and the next generation of leaders. In my view, professionals are people who take responsibility for their work, who do not limit themselves to a single competency, but aim for more and reliably achieve goals. To develop such people, it is important to create the right environment. When I was in charge of marketing and sales, rather than giving specific instructions to each medical representatives (MRs), I encouraged them to act on their own volition. Asking them “What do you think?” helps them to think and act independently. I have come to believe that doing this consistently leads to the growth of each individual.

To nurture the next generation of leaders, we have expanded and enhanced comprehensive education and training programs by employment year and position, and through internal and external training programs. I want employees who are not currently leaders to do their jobs with an image of

when they do become leaders. I believe this will lead to their growth.

We will also take steps to boost employee motivation. Considering the current trend of reskilling, we are enhancing online learning services for employees. For example, we have set up an environment for employees who want to work in overseas operations to learn English. In fact, I find it encouraging that more employees are taking online courses on their own volition, without being told to do so by the Company.

During the past fiscal year, we actively recruited experienced professionals in areas such as research and data science. Based on needs that our MRs can only perceive by being on the frontlines of medicine, we want to go a step further and conduct flexible problem-solving that incorporates digital technology. To do that, it is important to approach problems collaboratively as one team, integrating people who have diverse abilities. I myself create opportunities to talk with as many employees as I can, going to their workplaces to hear from them directly. If employees know that their work is being noticed and counted on, I think it motivates them to try even harder.



## Pursuing Sustainability Based on the “Three Joys” and Striving to Achieve 2031 VISION

We established the Sustainability Committee in April 2023. Our main businesses of manufacturing and selling pharmaceuticals and agrochemicals are, in essence, sustainability initiatives, and combining them with other efforts to address sustainability issues has created a structure for sustainability management unique to KAKEN. Placing our business philosophy comprising the “Three Joys”—“Joy for patients,” “Joy for society,” and “Joy for employees”—at the center of our sustainability initiatives, we strive to become a company that can bring even greater joy to society by pursuing the well-being of our stakeholders.

As part of our consideration for the environment, we adopted the recommendations of the Task Force on Climate-related Disclosures (TCFD) in February 2023 and began disclosure in line with the four core elements of these recommendations in the first half of FY2023.

Our policy for shareholder returns is to provide shareholder returns aligned with profit growth by paying stable, continuous dividends and making flexible share buybacks. The annual dividend per share for FY2022 was ¥150, the same as in FY2021.

Creating KAKEN’s distinctive value and providing it to society is the key to achieving 2031 VISION: “A company that contributes to longer healthy life expectancy by developing and supplying innovative new drugs in a speedy manner” and “A research-based pharmaceutical company with a global presence, primarily in the areas of dermatology and orthopedics.” Long-Term Business Plan 2031 describes our vision for 10 years in the future, but it is important to know where we are headed in the first five years. We are fully committed to creating drugs that will ultimately increase our corporate value, and appreciate your continuing support as we strive for further success.



# Priority (Material) Issues

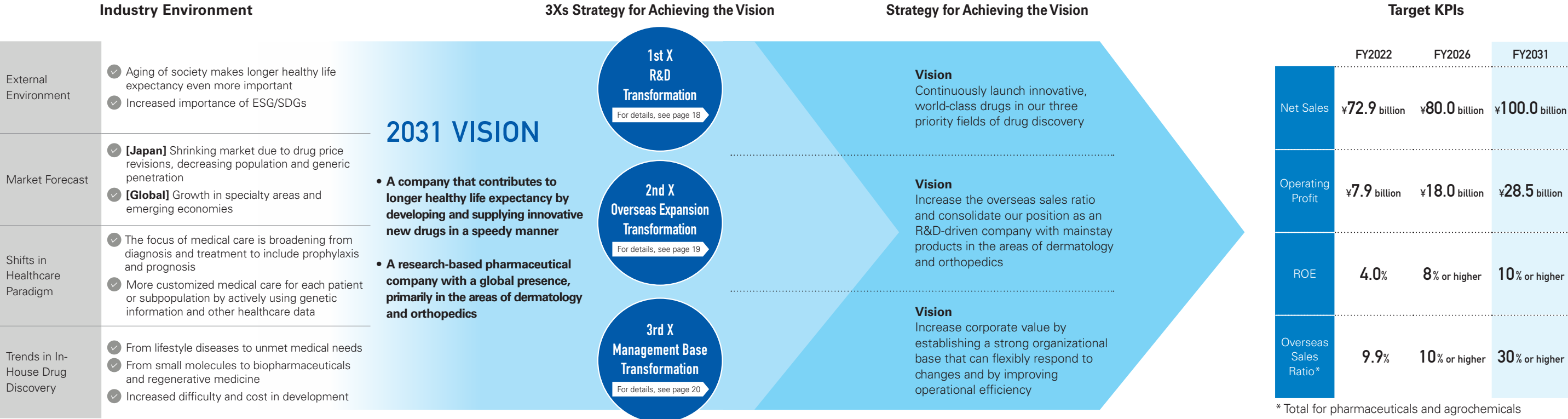
The KAKEN Group delivers value to society and contributes to achieving a sustainable society by practicing its corporate philosophy: “KAKEN helps improve the quality of life of patients by serving as many people as possible to return smiles of happiness to their faces, through supplying superior pharmaceuticals.” 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 (Material) Issues





Due to the aging of Japanese society and tighter public finances for medical care, the prescription pharmaceutical industry's business environment is expected to change dramatically. To respond to projected changes, in 2022 KAKEN created a vision for the 10 years to 2031 based on its long-term issues and set out the "3Xs" ("Three Transformations") as a strategy for achieving the vision.



## Message from the Director in Charge of the R&D Division



Mitsuru Watanuki  
Director  
Chief Officer of R&D Division

**We will further accelerate transformation of R&D processes to generate innovation for quickly creating and supplying breakthrough new drugs.**

FY2022 was the first year of Long-Term Business Plan 2031. To improve the probability of a successful launch, we focused mainly on innovation of drug discovery and other R&D processes, as well as on the progress and expansion of our development pipeline.

In new drug development, the low success rate, long development periods, and increasing development costs year after year are major challenges. Moreover, in order to demonstrate the value of their existences, pharmaceutical companies must continuously launch truly superior drugs, while the list of diseases with unmet medical need is tapering.

We are focusing on in-house drug discovery as an R&D-driven pharmaceutical company. In order to further establish a new drug discovery process that incorporates external research (contracting of drug discovery research), we began

collaboration with Axcelead Drug Discovery Partners Inc. (Axcelead DDP). Additionally, the digital transformation of research and development taking place across the pharmaceutical industry has the potential to dramatically shorten development periods. We have therefore introduced AI drug discovery engines, including Elix Discovery™, an all-in-one drug discovery platform, to start data-driven drug discovery processes quickly.

In expanding our development pipeline, a cornerstone of Long-Term Business Plan 2031, we began a Phase III clinical trial for KP-001 (ART-001) in Japan. KP-001 is under development for the treatment of refractory vascular malformations, and we expect to expand its development and sales overseas in the future. In addition, a Phase I clinical trial for NM26-2198 began in the United States in collaboration with Numab Therapeutics AG for the treatment of atopic dermatitis, and for KP-910 in Japan, a drug discovered in-house for the treatment of peripheral neuropathic pain. Seladelpar and tildacerfont, which we in-licensed this year, have also been

added to our development pipeline, for a total of eight ongoing projects.

Research and development of various new modalities is taking place in addition to traditional small-molecule compounds and antibodies. We continue to explore ways to provide effective treatments by using appropriate modalities for each target molecule.

In FY2023, it is important to demonstrate that the data-driven drug discovery process we implemented in FY2022 and the various collaborations we have engaged in contribute to shortening the development period for each project, the search for original targets, and more. We will start by promoting the transformation of the R&D process. We will appropriately manage the development pipeline portfolio, ensuring the steady progress of development and drug discovery projects, including overseas development of KP-001, and determining early proof of concept (PoC).



Long-Term Business Plan 2031 —KAKEN Vision for Transformation—  
Progress and Achievements

1st X R&D Transformation: Progress of Priority Measures

We are promoting transformation of the drug discovery process through various initiatives, including the introduction of an AI drug discovery platform and the partnership with Axcelead DDP. To expand our development pipeline, we have been widening the range of drug candidates for in-licensing opportunities and speeding up our assessment. These initiatives led to the in-licensing of two drugs under development, seladelpar and tildacerfont. As an in-house initiative for advancing overseas clinical trials, we began preparations for a clinical trial for KP-001 in the United States. At the same time, we are investigating new modalities and digital therapeutics, and are considering cooperation with biopharmaceutical startups and other companies. We will continue to promote transformation of the R&D process to continuously launch innovative, world-class drugs.

	FY2031 Goals	FY2022 Progress
(1) Improve Launch Probability	<ul style="list-style-type: none"><li>Shorten the period from drug discovery to NDA by two-thirds</li><li>Triple the frequency of product launches from in-house drug discovery</li></ul>	<ul style="list-style-type: none"><li>Began operation of drug discovery AI (Elix Discovery™) to shorten development period</li><li>Established a minimal non-clinical package plan</li><li>Started collaboration with drug discovery solution provider Axcelead DDP, including exploration of original targets using bioinformatics for a higher success rate</li></ul>
(2) Expand Pipeline	<ul style="list-style-type: none"><li>More than six projects discovered in-house in Phase I or later stage (including in-licensed pre-PoC projects)</li><li>In-license (or enter sales alliances for) at least one late-stage development project every year</li></ul>	<ul style="list-style-type: none"><li>Projects under development: 7 projects (May 2022) → 8 projects (May 2023)</li><li>In-licensed two late-stage development projects (seladelpar and tildacerfont)</li><li>Searching candidate projects for in-licensing through investment in Axil Life Science &amp; Healthcare Fund II (from January 2023)</li><li>Refined procedures and systems for in-licensing evaluation</li><li>Started collaboration with Axcelead DDP to explore new targets</li></ul>
(3) Address New Needs and Overseas Expansion	<ul style="list-style-type: none"><li>Promote drug discovery on our original targets</li><li>Promote in-house global development</li></ul>	<ul style="list-style-type: none"><li>Started exploration of original targets using bioinformatics</li><li>Started preparation for a clinical trial for KP-001 in the United States</li></ul>
(4) Take on Challenges in New Fields	<ul style="list-style-type: none"><li>Develop and launch regenerative medicine products</li><li>Develop and launch digital health products</li></ul>	<ul style="list-style-type: none"><li>Discussing potential collaboration with several companies that have new modalities, such as cell therapy and mRNA therapeutics</li><li>Discussing potential collaborations with several companies that develop digital therapeutics for chronic pain</li></ul>

Highlights

Starting Phase III Clinical Trial in Japan for KP-001

Refractory vascular malformations, the target of KP-001, are anomalies of the blood and lymphatic vessels. Since they progress with the patient's age and do not spontaneously regress, lifetime treatment and management are required. KP-001 selectively inhibits PI3Kα, which is involved in vasculogenesis, and is therefore expected to have an inhibitory effect on vascular overgrowth with anomalies. As such, it is promising as a drug for improving quality of life of patients with unmet medical needs.

Two Development Projects In-licensed for Treatment of Rare Diseases

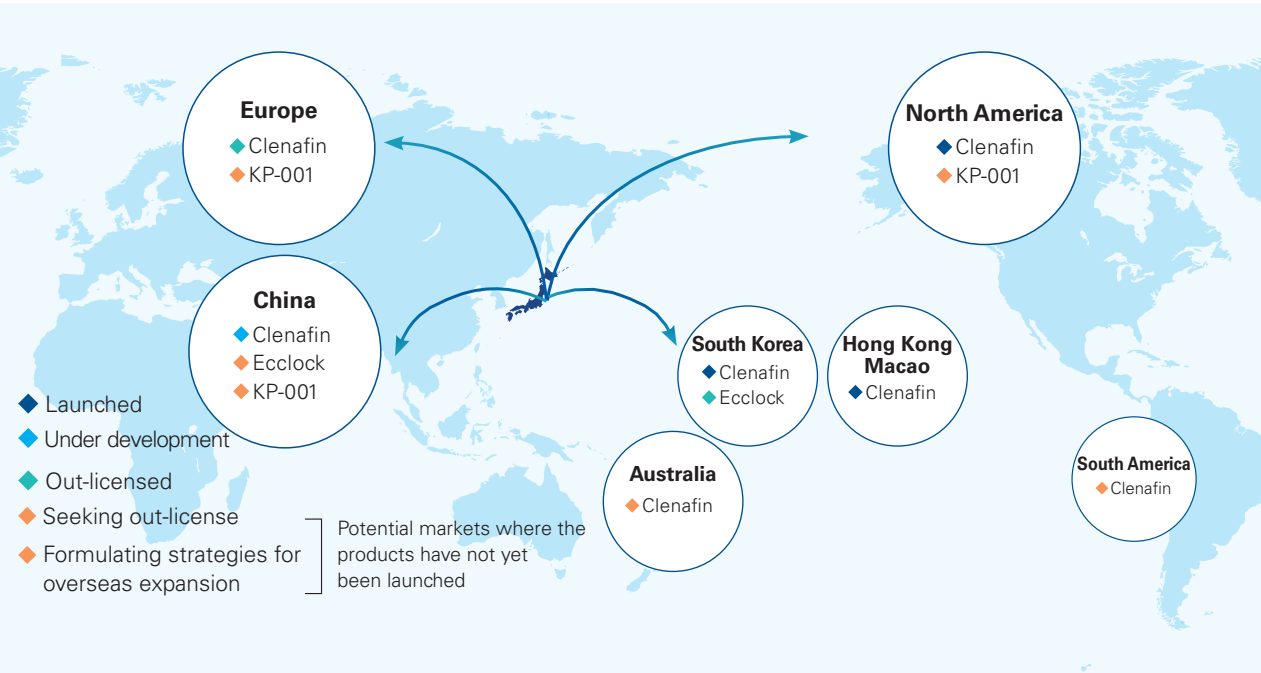
In January 2023, KAKEN in-licensed tildacerfont and seladelpar for treatment of rare diseases. Tildacerfont is under development for the treatment of congenital adrenal hyperplasia. This disease is caused by a congenital deficiency of the enzymes involved in corticosteroid biosynthesis. In particular, adrenal insufficiency due to inadequate production of glucocorticoids is a life-threatening illness. We expect to offer tildacerfont as a new therapy that balances corticosteroid levels when used in combination with low-dose steroids. Seladelpar is under development for the treatment of primary biliary cholangitis. This is a disease that activates immune cells, causing chronic inflammation that damages the bile ducts in the liver. It is important to stop the progression of the disease, as it progresses to cirrhosis and liver cancer. Seladelpar inhibits this progression, and is expected to be a new treatment option for patients.

2nd X Overseas Expansion Transformation: Progress of Priority Measures

To further expand existing global products overseas, our alliance partner in Europe filed for marketing approval of Clenafin, which is now under review by regulatory authorities. In China, we began a Phase III clinical trial for the drug in cooperation with our local partner. In addition, we signed an out-licensing agreement for Ecclock in South Korea and in cooperation with the licensee we are preparing for a regulatory filing for marketing approval. We also continue to explore out-licensing to other major countries in Asia.

To promote new global products and establish our own overseas development capabilities, we have started preparations to conduct an overseas clinical trial for KP-001 on our own, including building an in-house development system.

Progress of Overseas Expansion by Product



Highlights

Filing for Marketing Approval for Onychomycosis Treatment Clenafin in Europe

Almirall S.A. of Spain, to which KAKEN granted exclusive rights for the development and commercialization of Clenafin in Europe, filed an application for marketing authorization of Clenafin with the regulatory authorities of Germany and Italy under the European decentralized procedure in May 2022. The application is currently under review, with Germany acting as the Reference Member State. Clenafin has previously been approved in six countries and regions other than Japan. Using this experience and knowledge, KAKEN partnered with Almirall to deal with regulatory authorities in order to obtain approval as quickly as possible in Germany and Italy.

Out-Licensing of Primary Axillary Hyperhidrosis Treatment Ecclock in South Korea

In June 2023, KAKEN executed an out-licensing agreement with Dong-Wha Pharm Co., Ltd., granting it exclusive rights for the development and commercialization of Ecclock in South Korea. Currently, we are preparing to file for marketing approval in cooperation with Dong-Wha. We will continue our out-licensing efforts to make Ecclock available to patients in China and other countries in Asia.



Long-Term Business Plan 2031 —KAKEN Vision for Transformation—  
Progress and Achievements

3rd X Management Base Transformation: Progress of Priority Measures

We are promoting initiatives that lead to enhancement of corporate value, such as establishing a strong organizational base and building efficient operations that can respond flexibly to changes in the business environment by empowering all employees to maximize their potential as professionals.

Human Resource Strategy

We aim to make KAKEN a great place to work for all employees by shaping a corporate culture that creates opportunities to take on new challenges and establishing an internal environment for professional development. In terms of the working environment, we are offering more flexible work-style systems to enable work-life balance and support childcare and nursing care. In human resource development, we will actively promote individuals who demonstrate advanced professional skills and assign personnel to jobs according to aptitude. Moreover, in education and training, we are introducing online learning tools to enhance training programs and provide opportunities for personal development and reskilling.

DX Strategy

Our basic policy for digital transformation (DX) is to optimize research and development and the value chain, and foster a corporate culture of continual transformation. We have formulated a Companywide DX roadmap centering on research and development, sales and marketing, and production, and have executed measures while ascertaining transformative

effects and overall consistency. In research and development, we have incorporated AI technology into new drug creation; in sales and marketing, we have established a platform for AI analysis and data utilization as a sales support measure; and in production, we have worked on infrastructure environment design at production sites. Going forward, we will provide digital content and other new learning opportunities to foster DX literacy and a transformation mindset among employees.

Production Strategy

Our production strategy is aimed at maximizing product value from a patient-first perspective. Part of that entails changing the formulations of various products. For the container of primary axillary hyperhidrosis treatment Ecclock, we developed a new twist-off top bottle that is more compact and easier to use, and launched it in June 2023. We are also focusing efforts on building a production line to ensure a stable, continuous supply of high-quality pharmaceuticals. We have begun prototyping demonstration machinery for continuous production, aimed at reducing human error and adapting flexibly to fluctuations in demand.

Agrochemicals Business

The agrochemicals business achieved its sales target for FY2022, the first year of the long-term business plan, backed by a rise in global food demand and a move toward more eco-friendly agrochemicals. In particular, polyoxin fungicides are natural substances derived from fermentation, and are gaining acceptance as extremely safe, non-chemical synthetic agrochemicals even in new overseas markets. We are developing polyoxins to further expand new markets, which will lead to a growth pillar of the long-term business plan through higher sales.



Highlights

Toward Agrochemical Registration of Polyoxins in Europe

In Australia, the launch of polyoxins in 2021 was followed by certification as organic materials in October 2022, and the increased use of polyoxins in organic agriculture should further expand sales in Australia, as in the United States and New Zealand, where they are already certified. In addition, various safety tests aimed at setting a maximum imported crop residue level (import tolerance) in Europe for polyoxins are progressing as planned. Setting this import tolerance will spur expanded use for crops in the European market, further moving us toward our goal of plant protection product registration in Europe.

Growth Strategy

Pharmaceuticals and Medical Devices

Business Overview

KAKEN's pharmaceutical business centers on the development of innovative drugs that help to improve patients' quality of life, including drugs targeting diseases that still have no adequate treatments and drugs with novel dosage forms, primarily in the areas of dermatology and orthopedics.

We have launched onychomycosis treatment Clenafin, primary axillary hyperhidrosis treatment Ecclock, and wound-healing agent Fiblast in the area of dermatology, and anti-osteoarthritis agent Artz and lumbar disc herniation treatment Hernicore in the area of orthopedics. These products are widely used to treat their target diseases. In the medical devices category, we supply Seprafilm, an adhesion barrier used primarily

in surgery and in gynecology to reduce complications from post-operative adhesions.



Main Pharmaceuticals and Medical Devices

Product	Therapeutic Area	Efficacy/Indication	Year Launched	Net Sales (FY2022; Billions of yen)
Clenafin	Onychomycosis treatment	• Onychomycosis	2014	17.9
Artz	Anti-osteoarthritis agent	• Knee osteoarthritis • Shoulder periarthritis, etc.	1987	17.0
Seprafilm	Post-operative adhesion barrier	• Reduction of post-operative adhesion	1998	7.7
Fiblast	Wound-healing agent	• Bedsores • Skin ulcers (burns and leg ulcers)	2001	2.7
Ecclock	Primary axillary hyperhidrosis treatment	• Primary axillary hyperhidrosis	2020	1.2
Regroth	Periodontal regenerative agent	• Alveolar bone loss due to periodontitis	2016	0.8
Hernicore	Lumbar disc herniation treatment	• Lumbar disc hernia (subligamentous extrusion)	2018	0.3

Highlights

Launched NexoBrid, a drug for burn eschar removal

NexoBrid obtained approval and launched in August 2023. This product is a topical agent that is applied to the burn wound and then removed, selectively, easily and quickly removing necrotic tissue without harming the surrounding healthy tissue.

We will contribute to improving the quality of life of more patients with severe burns by providing a drug for burn eschar removal as a new, non-invasive treatment option. We will conduct information provision activities to support that goal.

Growth Strategy

Projects under Development

To enhance our development pipeline, in parallel with in-house drug discovery we actively engage in collaborative research and development with other pharmaceutical companies and research institutions in Japan and overseas. We are also focusing on in-licensing of development projects and products, as well as considering M&A of companies that have promising development projects. We have begun Phase III clinical trial for KP-001, a potential treatment for refractory vascular malformations that has made progress, based on the results of a Phase II clinical trial conducted by subsidiary Artham Therapeutics Inc. in Japan. NM26-

2198, being co-developed for atopic dermatitis with Numab Therapeutics AG of Switzerland, has started Phase I clinical trial in the United States. In addition, three new development projects have been added to our pipeline in the Phase I stage. KP-910, a drug discovered in-house, will be developed for peripheral neuropathic pain. Seladelpar and tildacerfont were both in-licensed in FY2022. We discontinued the development of ART-648, which had been under development by subsidiary ARTham Therapeutics Inc. for the treatment of bullous pemphigoid.

Projects under Development (As of May 2023)

Development Code	Planned Indication	Development Stage				Remarks
		Phase I	Phase II	Phase III	Application	
KAR	Head lice	Phase III				In-licensed from Arbor Pharmaceuticals, LLC Product name in the United States: Sklice®
KP-001 (ART-001)	Refractory vascular malformations	Phase III				Development project transferred through succession from ARTham Therapeutics Inc.
BBI-4000	Primary palmoplantar hyperhidrosis	Phase I				Additional indication for Ecclock
KP-483	Solid tumors (immuno-oncology)	Phase I				Product discovered in-house
NM26-2198	Atopic dermatitis	Phase I				Co-development with Numab Therapeutics AG
KP-910	Peripheral neuropathic pain	Phase I				Product discovered in-house
Seladelpar	Primary biliary cholangitis	Phase I				In-licensed from CymaBay Therapeutics, Inc.
Tildacerfont	Congenital adrenal hyperplasia	Phase I				In-licensed from Spruce Biosciences, Inc.

Growth Strategy of Marketing & Sales Division

As a participant in community healthcare, we will provide high-quality information with a focus on the needs of patients.



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, 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 the frontlines of medicine. Enhancement and support of the medical institutions that support community healthcare will play an increasingly important role in protecting the health and well-being of residents. To play a part in that, our MRs will serve as liaisons with local medical professionals, and will utilize digital tools and other means to provide information on continuing care, including drugs that enhance patient quality of life, from viewpoints such as health economics, safety and adherence. The healthcare industry in Japan is changing rapidly, so we must transform our approach to providing marketing information. With that in mind, we have restructured our marketing and sales organization to respond flexibly and quickly to needs on the frontlines of medicine.

We intend to create an organization in which our MRs have not only product knowledge, but also in-depth knowledge of related medical information, are attuned to the needs of the frontlines of medicine, and are able to consider what they can do for patients. We will continue to provide even higher-quality information with a focus on the needs of patients to further build our presence in dermatology and orthopedics, the areas of our core products, and become an essential company in community healthcare.

Agrochemicals

Business Overview

We support agriculture by supplying eco-friendly agrochemicals, feed additives and veterinary drugs to meet the need for safe and plentiful diets. We develop and market polyoxin fungicides and the paddy rice herbicides Pentoxazone and Metamifop. Polyoxins have been well accepted by farmers for more than 50 years as natural fungicides (produced by fermentation) that have little impact on humans, animals or the environment. We have actively expanded sales globally, and are now marketing these products in 19 countries. Pentoxazone has excellent herbicidal effects on annual weeds, and has a stable high performance, long-lasting efficacy against weeds that are resistant to sulfonylurea herbicides. Metamifop is highly effective against weeds

of the Gramineae family, including barnyard grass of high leaf age. These herbicides are widely used for more efficient weed control in paddy fields. In feed additives and veterinary drugs, we support livestock farmers through sales of Salinomycin, an anticoccidial feed additive for chickens, and Uroston, a drug for cattle. In FY2022, this business faced even more challenging conditions due to soaring material prices worldwide, but sales increased due to growth in demand for polyoxins in Australia and demand for use on organic crops in the United States. In addition, polyoxins have received ACO (Australian Certified Organic) certification, which will support further expansion of their use.

Growth Strategy of Agrochemicals & Animal Health Products Division

We will contribute to global food production by providing eco-friendly agrochemicals.



Tsukasa Fujimaki  
General Manager of Agrochemicals & Animal Health Products Division

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 SDGs, the Strategy for Sustainable Food Systems (MeaDRI) in Japan, the Farm to Fork Strategy in the EU, and the Agriculture Innovation Agenda in the United States. These initiatives call for eco-friendly farming. In particular, specific goals have been set in the EU and Japan to reduce agrochemical use by 50% (on a risk basis) and to expand the area of land used for organic farming to 25% of all farmland. Given such trends, we anticipate a further increase in needs and expectations for agrochemicals that are friendly to humans, animals and the environment. To support sustainable agriculture in harmony with the environment, we have established a growth strategy based on two pillars: development of agrochemicals that have little impact on humans, animals and the environment, and fermentation products that can reduce chemical substance waste and energy consumption. By actively researching, developing and commercializing these products, we will contribute to food safety and security. Polyoxins, which are natural substances produced by fermentation, acquired organic certification in the United States in 2020, and we will push to expand their sales in the U.S. organic crop market. In 2021, polyoxins were registered as agriculture chemicals in Australia and India, and we are working to expand their sales in those markets. We also plan to enter the EU market by 2028 to help ensure KAKEN's sustainable growth. To prepare for this, we intend to submit a maximum imported crop residue level (import tolerance) to EU authorities in 2024.

Real Estate

Business Overview

KAKEN assumed ownership of land in Bunkyo ward, Tokyo from RIKEN, the Institute of Physical and Chemical Research, when the Company was established in 1948, and set up its Head Office, factory and research laboratory. In 1989, the Honkomagome Improvement Plan was initiated to redevelop this property as a multi-purpose complex consisting of offices and residential and

commercial facilities. Bunkyo Green Court was completed in 1998, and KAKEN conducts business activities from its Head Office located in the office building. The Real Estate segment's main revenue is rental income from Bunkyo Green Court. This segment complements KAKEN's core pharmaceuticals segment as a stable source of revenue.



# Sustainability Strategy

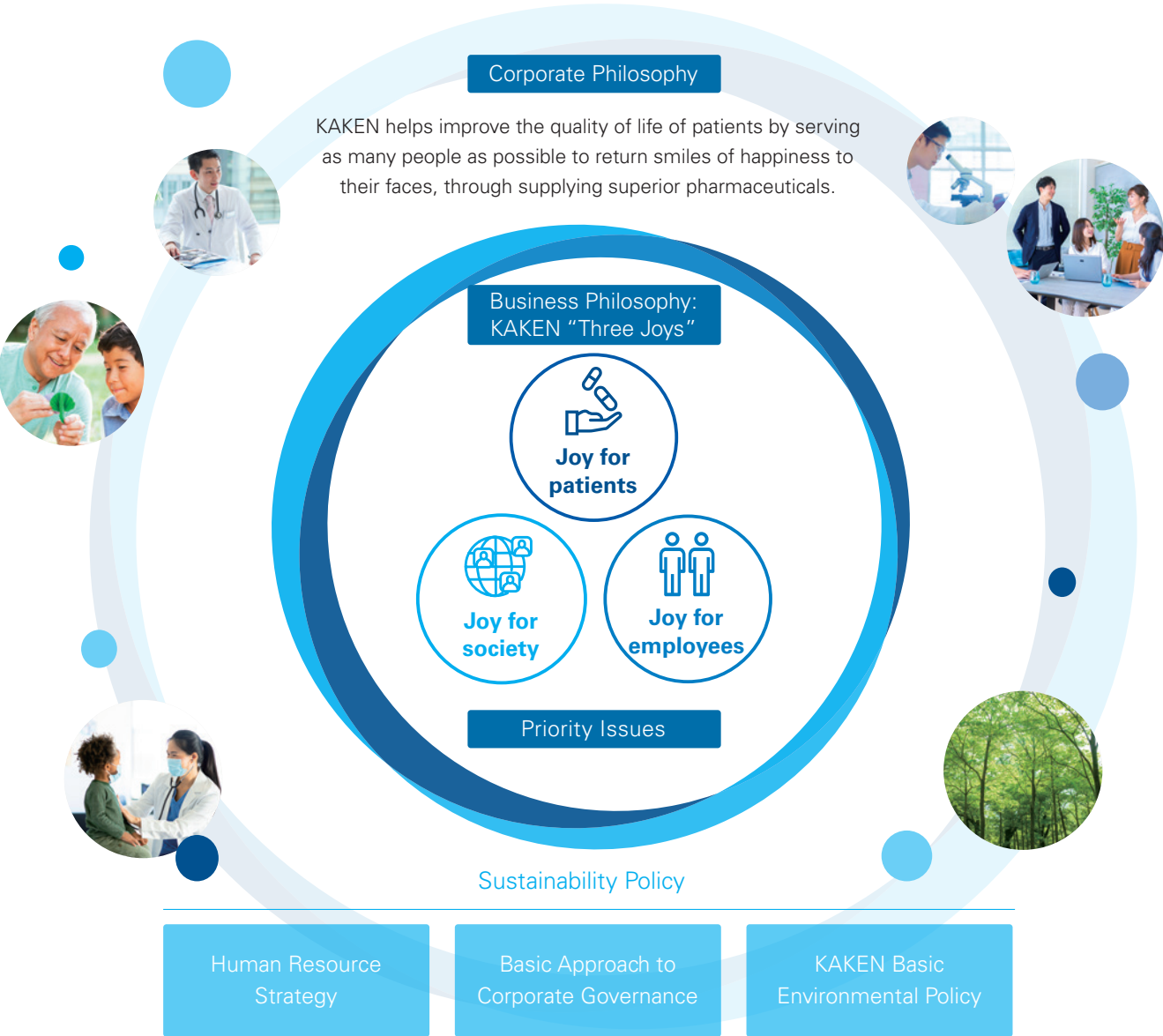
In a rapidly changing business environment, KAKEN has formulated a sustainability policy to speed up initiatives for realizing a sustainable society together with its stakeholders.  
Based on this policy, we aim to enhance KAKEN’s corporate value as well as create a sustainable society.

## Sustainability Policy

KAKEN will work to achieve sustainable growth and contribute to the sustainable development of society by providing pharmaceutical products that address unmet medical needs and eco-friendly agrochemicals.  
To accomplish these goals, KAKEN will pursue the “Three Joys” in its business philosophy to create many smiles together with its stakeholders.

### —Pursuit of the “Three Joys”—

- We will pursue “Joy for patients” by identifying needs on the frontlines of medicine and working to provide new treatment options from unique viewpoints.
- We will pursue “Joy for society” by practicing flexible and sustainable management that is also responsive to the needs of society through the supply of pharmaceutical products.
- We will pursue “Joy for employees” by ensuring our employees take pride in their work of bringing smiles to many people and creating new value.

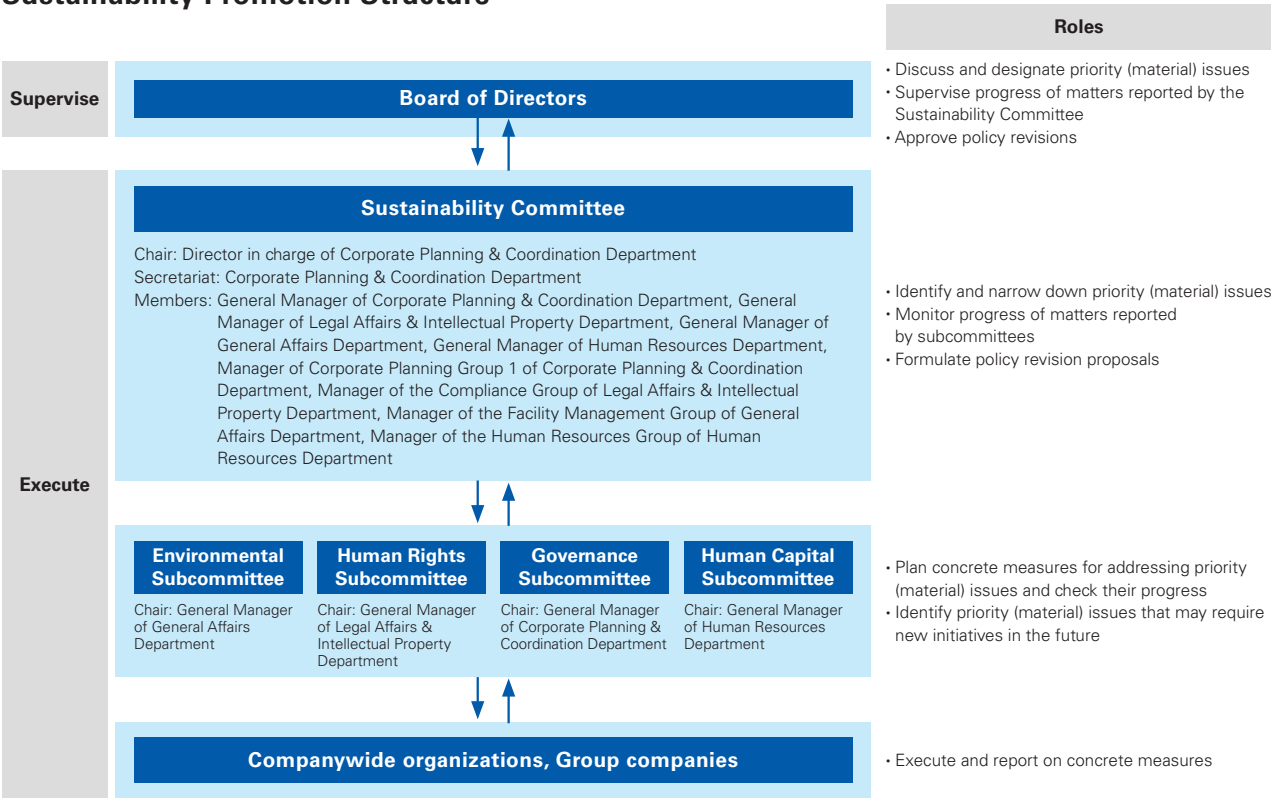


## Sustainability Promotion Structure

KAKEN is promoting sustainability management with the mission of delivering value to society and contributing to achievement of a sustainable society by putting its corporate philosophy into practice. The Sustainability Committee, chaired by the Director in charge of the Corporate Planning & Coordination Department, has been established to advance that effort. The general managers of the Corporate Planning & Coordination Department, Legal Affairs & Intellectual Property Department, General Affairs Department and Human Resources Department serve as members of the committee. They identify and narrow down the list

of priority (material) issues, deliberate and review concrete measures for addressing these issues, and report the results to the Board of Directors. The Board of Directors discusses and designates the priority (material) issues from those selected by the Sustainability Committee and supervises the progress of matters reported by the Sustainability Committee. In addition, Environmental, Human Rights, Governance and Human Capital subcommittees have been set up as subordinate organizations of the Sustainability Committee to conduct specialized reviews of priority (material) issues.

## Sustainability Promotion Structure



## Activities

First, the Sustainability Committee identified social issues, taking into account the Company’s business, business plans, GRI standards and ISO 26000, among other factors. These issues were then narrowed down on two axes—“Relevance to KAKEN’s business” and “Impact on stakeholders.” Based on this, it designated priority (material) issues in the Company’s sustainability management. In addressing these priority (material) issues, the progress of the concrete measures reported

by the subcommittees is being monitored and activity policies are being formulated. Our aim continues to be the sustainable growth of the Company based on the Sustainability Policy. At the same time, we will contribute to the sustainable development of society by carrying out specific initiatives for addressing priority issues related to the environment (including climate change), human rights, governance, human capital and other subjects.

# Engagement with Customers

 Joy for patients

## Business Philosophy / Priority (Material) Issues / Main Initiatives

Business Philosophy	Priority (Material) Issues	Main Initiatives
Joy for patients	<b>Fulfilling responsibilities as a pharmaceutical company</b> <ul style="list-style-type: none"><li>Stable supply of high-quality pharmaceuticals with proven safety</li><li>Activities to provide accurate information</li></ul>	<ul style="list-style-type: none"><li>Maintain domestic and international standards for good manufacturing practice (GMP)</li><li>Utilize digital tools and other means to establish efficient systems for delivering information</li></ul>

## Product Quality Assurance

For product quality assurance, KAKEN believes that it is absolutely essential to create a quality management system in which both its Head Office (a marketing authorization holder of pharmaceuticals) and our factory (a manufacturer of pharmaceuticals) fulfill their respective responsibilities and cooperate closely.

At our factory, we implement suitable manufacturing and quality control, verifying conformance to required standards and adequacy of each manufacturing process and facility and we are fostering a quality culture by educating workers and instilling the corporate philosophy. In addition, we are further reinforcing the quality assurance system through the use of computerized

systems that strengthen checking of manufacturing and quality management systems, among others.

The Quality Assurance Department of the Head Office evaluates and confirms these activities, which we believe results in a more robust quality assurance system. Cooperative 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 at all stages of a product's lifecycle.

We have established a Quality Assurance Policy to achieve a stable supply of high-quality pharmaceuticals. Please refer to our website for details.

Quality Assurance Policy: <https://www.kaken.co.jp/english/sustainability/social/#anc2>

## Stable Supply of Pharmaceuticals

We are taking various measures to ensure the stable supply of pharmaceuticals. In sourcing pharmaceutical raw materials, we are increasing supply stability by diversifying suppliers to spread risk. In manufacturing processes, we have introduced manufacturing management, quality management and document management systems, and strive to maintain and enhance product quality by strictly managing bulk drug manufacturing,

drug manufacturing and quality testing. We also optimize production plans based on demand forecasts and market trends, and secure appropriate stockpiles of raw materials and products to ensure that a stable supply of medicines is maintained even during emergencies. In addition, we are strengthening partnerships with suppliers in Japan and abroad, and establishing a framework for information sharing and cooperation.

## 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 adverse drug reactions. 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 safety risks by collecting and evaluating safety data throughout the product lifecycle from the development phase to post-marketing, and by providing information in a timely manner necessary for ensuring the safety of patients.

## Promoting Proper Usage of Pharmaceuticals

In order to ensure proper usage of prescription pharmaceuticals and medical devices, providing appropriate sales information based on high ethical standards and scientific evidence is essential. To that end, we have established internal regulations and standard operating procedures, and organize systems that enable such activities. We have established the Drug Information & Marketing Supervision Department to handle supervision and guidance, including monitoring of information provision activities and screening of materials used in them. This department educates and provides guidance to MRs and other employees about information provision activities.

We provide and collect information pertaining to the proper usage of our pharmaceuticals and medical devices mainly

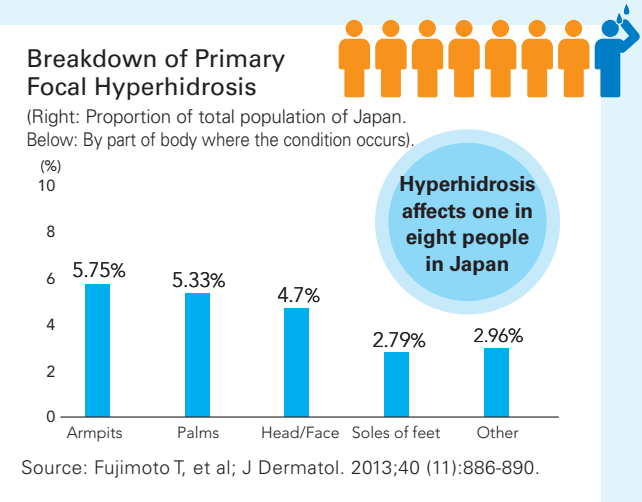
through MR activities. We also proactively provide and collect such information through the Pharmaceuticals Information Service Office, a consultation desk for pharmaceutical-related matters, and via our website. The office promptly and accurately answers questions from medical professionals and patients about proper usage of pharmaceuticals and reports their valuable opinions and suggestions on our products and other matters to relevant departments in the Company, thereby leading to the improvement of pharmaceutical formulations and enhancement of product information.

We receive most inquiries by phone; however, for customers' convenience we provide a contact form on our website for inquiries.

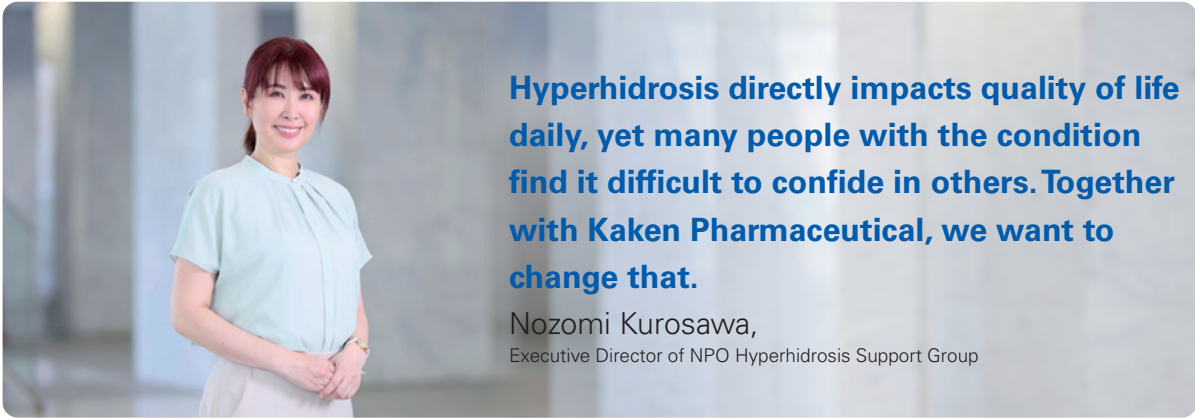


## Outcome Case Study Joy for patients

To realize “Joy for patients,” KAKEN conducts various initiatives, such as disease awareness activities. For example, we launched a website to raise awareness of hyperhidrosis, which is still not well known, and hold lectures for the general public.



Hyperhidrosis is a condition characterized by excessive sweating caused by hyperthermia of the head, face, palms, soles of the feet and armpits, or by emotional distress, or issues independent of those factors. As such, it interferes with daily activities. According to the primary focal hyperhidrosis diagnosis guidelines, symptoms of primary focal hyperhidrosis (excessive sweating of armpits, palms or other parts of the body despite the absence of other illnesses or disabilities that cause increased sweating) are reported in 12.76% of Japanese people (about one in eight). Most primary focal hyperhidrosis patients suffer from sweating of the armpits, affecting 5.75% of Japanese people. On the other hand, only 6.3% of primary focal hyperhidrosis patients have sought medical treatment for the condition, and about 48% deal with it by using over-the-counter ointments and deodorants, indicating that many potential patients have not yet been diagnosed or treated. Hyperhidrosis can interfere with daily activities and reduce quality of life, and is reported to negatively impact student performance and work. The resulting economic loss is estimated to be ¥312.0 billion per month in Japan.



**Hyperhidrosis directly impacts quality of life daily, yet many people with the condition find it difficult to confide in others. Together with Kaken Pharmaceutical, we want to change that.**

Nozomi Kurosawa,  
Executive Director of NPO Hyperhidrosis Support Group

I have hyperhidrosis that causes profuse sweating from my palms and the soles of my feet, and have had to deal with various inconveniences as a result. For example, I can't wear sandals because my feet slip, and I have trouble writing because the sweat on my hand makes the paper wet. It began when I was in elementary school, and as I approached adolescence I had a hard time because I was afraid that my classmates would notice. About 10 years ago, the sweat on my feet caused me to slip and fall on the stairs, fracturing my tailbone. People tend to think of this condition as “just sweat,” but every day I face various risks from sweat.

Hyperhidrosis is a condition that reduces quality of life every day. In particular, some young people suffering from the condition are unable to feel positive about interacting with others or even about life itself. Yet there was not a single support group for these people. I wanted to do something to support other people with hyperhidrosis and raise awareness of the disease, so I established the Hyperhidrosis Support Group in 2022.

I think recognition of the term “hyperhidrosis” has been gradually increasing recently because social media has made it easy to access information. Still, I feel that many people continue to think of it as “just sweating more than others,” not as a serious condition. We will continue working toward a society in which everyone can live life in their own way and realize their true potential without limits even if they have hyperhidrosis.

I am thankful to Kaken Pharmaceutical for providing a primary axillary hyperhidrosis medication that is covered by national health insurance. I had been in touch with KAKEN employees even before I founded the NPO, and found them to be sincere and serious. We will continue to send out accurate information about hyperhidrosis through dialogue and look forward to working together with KAKEN to make it easier for the many people suffering from hyperhidrosis to talk about it and get appropriate treatment.



Management Team

Directors



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)



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  
Jun. 2021 Director (to present)



Mitsuru Watanuki  
Director

Apr. 1989 Joined the Company  
Apr. 2015 General Manager of Clinical Development Department  
Apr. 2017 General Manager of R&D Planning & Project Management Department  
Apr. 2020 Deputy Chief Officer of R&D Division  
Jul. 2021 Chief Officer of R&D Division (to present)  
Jul. 2022 Corporate Officer  
Jun. 2023 Director (to present)



Kiyoko Kamibepu  
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)  
Apr. 2022 Professor of Graduate School of Health and Welfare Sciences, Master's & Doctoral Program in Family Nursing, International University of Health and Welfare (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 of 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 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



Kazumori Ishiguro  
Audit & Supervisory Board Member (Standing)

Apr. 1986 Joined the Company  
Jul. 2011 General Manager of Sendai Branch  
Apr. 2014 General Manager of Tokyo Branch  
Apr. 2016 General Manager of Osaka Branch  
Apr. 2019 Deputy General Manager of General Affairs Department in charge of Secretary Team  
Jun. 2022 Audit & Supervisory Board Member (Standing) (to present)



Naoyuki Ishida  
Audit & Supervisory Board Member (Standing)

Apr. 1993 Joined the Company  
Apr. 2013 Manager of Marketing Planning & Coordination Department  
Apr. 2016 General Manager of Human Resources Department  
Jul. 2018 Corporate Officer  
Jun. 2023 Audit & Supervisory Board Member (Standing) (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)



Masahiro Koyama  
Outside Audit & Supervisory Board Member

Apr. 1984 Joined The Yasuda Mutual Life Insurance Company (currently Meiji Yasuda Life Insurance Company)  
Apr. 2009 General Manager of Morioka Regional Office of Meiji Yasuda Life Insurance Company  
Apr. 2013 General Manager of Utsunomiya Regional Office of Meiji Yasuda Life Insurance Company  
Apr. 2015 Associate Officer and General Manager of Utsunomiya Regional Office of Meiji Yasuda Life Insurance Company  
Apr. 2016 Associate Officer and General Manager of Agency Department of Meiji Yasuda Life Insurance Company  
Apr. 2017 Operating Officer and General Manager of Agency Department of Meiji Yasuda Life Insurance Company  
Apr. 2019 Managing Operating Officer and Deputy Chief Executive of Corporate Marketing Division of Meiji Yasuda Life Insurance Company  
Apr. 2022 Chairman of the Board of Meiji Yasuda Business Plus Co., Ltd. (to present)  
Jun. 2023 Outside Audit & Supervisory Board Member of the Company (to present)

Corporate Officers

Masanao Shimano, Ph.D.  
Chief Officer of Production Division,  
Chief of Shizuoka Factory

Tatsuhiro Harada  
Deputy Chief Officer of R&D Division,  
Chief of Drug Research Center

Masaru Ogawa  
Chief Officer of Regulatory Affairs Division

Tomoyuki Koseki  
Chief Officer of Marketing & Sales Division

Expertise of Directors and Audit & Supervisory Board Members (Skill Matrix)

Name	Position	Corporate management	Life science (Research and development)	Accounting/ Finance	Legal affairs/ Compliance/Risk management	Sales/ Marketing	International experience	Human resources/Talent development
Hiroyuki Horiuchi	President and Representative Director	●			●	●		
Masahiro Matsuura	Director				●	●		
Minoru Ohta	Director	●		●				
Masashi Suzudo	Director			●	●		●	●
Mitsuru Watanuki	Director		●					
Kiyoko Kamibepu	Outside Director		● (Healthcare)					
Shoichiro Takagi	Outside Director	●		●	●	●		
Yasutomo Inoue	Outside Director				● (Attorney at law)			
Kazumori Ishiguro	Audit & Supervisory Board Member (Standing)				●	●		
Naoyuki Ishida	Audit & Supervisory Board Member (Standing)				●	●		●
Hiroaki Matsumoto	Outside Audit & Supervisory Board Member			● (Certified tax accountant)				
Masahiro Koyama	Outside Audit & Supervisory Board Member	●			●			●

Note: The above table shows the areas in which directors and Audit & Supervisory Board members demonstrate their primary expertise or other skills based on their experience and other factors. It does not show all the knowledge they possess.

Corporate Governance



Business Philosophy / Priority (Material) Issues / Main Initiatives

Business Philosophy	Priority (Material) Issues	Main Initiatives
Joy for society	<b>Strengthening corporate governance</b> <ul style="list-style-type: none"><li>Strengthening relationships with stakeholders</li><li>Promotion of compliance</li><li>Risk management to ensure business continuity</li></ul>	<ul style="list-style-type: none"><li>Strengthen governance framework</li><li>Appropriate and timely information disclosure and dialogue</li><li>Training and education in compliance, risk management and relevant laws and regulations</li><li>Contribute to local communities (participation in activities such as local beautification and disaster relief support)</li><li>Develop/Update disaster and pandemic response plans</li></ul>

Basic Approach to Corporate Governance

KAKEN's business philosophy is centered on what we call the "Three Joys"—"Joy for patients," "Joy for society" and "Joy for employees." "Joy for society" 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, ensuring the transparency of management, and providing our stakeholders with proper explanations of the Company's activities are among our top management priorities.

Strengthening Governance

To achieve sustainable growth and increase corporate value over the medium to long term, KAKEN aims to realize efficient, fair and highly transparent management by being accountable and building good relationships with all stakeholders. The Company will continue working to evolve and strengthen corporate governance.

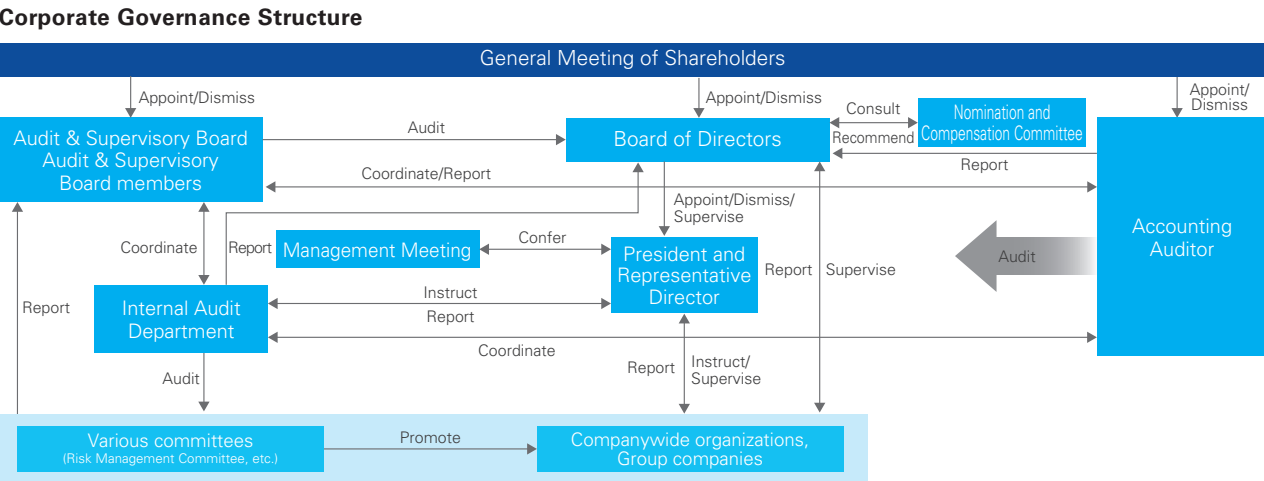
	FY2018	FY2019	FY2020	FY2021	FY2022
Total number of members of the Board of Directors	7	8	9	9	8
Outside directors incl. in above	2	3 (incl. 1 female member)	3 (incl. 1 female member)	3 (incl. 1 female member)	3 (incl. 1 female member)
Total number of Audit & Supervisory Board members	4	4	4	4	4
Outside members incl. in above	2	2	2	2	2
Committee (Advisory body to the Board of Directors)	• Establishment of Nomination and Compensation Committee				
Officer compensation		• Introduction of performance-linked stock compensation plan			• Increase in nonmonetary compensation ratio
Chairperson of the Board of Directors	Tetsuo Onuma				Hiroyuki Horiuchi
Diversity of the Board of Directors		• Appointment of female director			• Disclosure of skill matrix
Corporate Governance Code	Fully complied	Fully complied	Fully complied	Fully complied (Code prior to revision)	Explanation: 2 items (Revised code)

Corporate Governance Structure

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 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 corporate 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.



	Board of Directors	Audit & Supervisory Board Members and the Audit & Supervisory Board	Nomination and Compensation Committee
Composition	5 internal directors 3 outside directors (Chairperson: President)	2 standing Audit & Supervisory Board members 2 outside Audit & Supervisory Board members	1 internal director 2 outside directors (Chairperson: Internal director)
Purpose	Board of Directors meetings are regularly held once a month, 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. It also discusses other important management issues and receives reports on the status of business execution, as necessary. Audit & Supervisory Board members attend meetings of the Board of Directors and express their opinions. Corporate officers also participate to ensure that management policies are implemented thoroughly.	Audit & Supervisory Board members attend important meetings, including Board of Directors meetings, to ensure the fairness and transparency of management decision-making and execution by auditing the execution of duties. Audit & Supervisory Board meetings are regularly held once a month. The Audit & Supervisory Board also holds scheduled meetings with the Accounting Auditor for proactive discussions and information exchange, as part of a system where fair audits are implemented.	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 when necessary.
Number of Meetings in FY2022	16	13	4



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 at meetings of the Board of Directors, and 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 outside director or outside Audit & Supervisory Board member.

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 at a graduate school. The Company believes that based on her expertise as a professor at a graduate school, Ms. Kamibeppu will provide advice that contributes to the medium- to long-term growth of the Company and will supervise business execution from an independent standpoint.
Shoichiro Takagi	16	—	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 based on his knowledge cultivated as a corporate manager, Mr. Takagi will provide advice that contributes to the medium- to long-term growth of the Company and will supervise business execution from an independent standpoint.
Yasutomo Inoue	16	—	As an attorney at law, Mr. Inoue has acquired experience and professional expertise in corporate legal work. The Company believes that based on his knowledge as an attorney, Mr. Inoue will provide advice that contributes to the medium- to long-term growth of the Company and will supervise business execution from an independent standpoint.
Hiroaki Matsumoto	16	13	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.
Masahiro Koyama	(New appointment)	(New appointment)	Mr. Koyama has extensive experience in the financial industry, achievements as an executive, and the insight he has cultivated through his experience. The Company believes that Mr. Koyama will apply this expertise to the Company’s audit system.

Training for Directors and Audit & Supervisory Board Members

KAKEN provides opportunities for directors and Audit & Supervisory Board members to participate in external seminars and informal gatherings to facilitate understanding of their required roles and responsibilities and to assist them in acquiring the knowledge the Company deems necessary. The Company particularly strives to provide opportunities in response to the

requests of outside directors and outside Audit & Supervisory Board members, such as exchanges with senior management and visits to business sites. As appropriate, the Company also holds training sessions and other events led by external lecturers on new issues that must be addressed as a company and other topics that should be shared.

Evaluation of Effectiveness of the Board of Directors

In FY2022, 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. The Board of Directors has judged that its effectiveness is secured, 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 of Directors.

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 employee salary levels. 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.

Nonmonetary 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 business plan KPIs for financial results, development pipeline, in-licensing and other items in accordance with the Officer Stock Benefit Regulations. 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.

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 past compensation levels. The Board of Directors (or the delegated President and Representative Director, as specified below) takes into account 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 ratio of compensation types for individual directors. As a rule of thumb, KAKEN has used a ratio of 60:25:15 for basic compensation, performance-linked compensation and nonmonetary compensation (assuming 100% achievement of KPIs).

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 will have 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. To ensure that the President and Representative Director properly exercises this authority, the Board of Directors consults with and receives recommendations on the draft proposal for compensation from the Nomination and Compensation Committee, of which outside directors comprise a majority. The delegated President and Representative Director takes these recommendations into account when making decisions.

In FY2022, the Nomination and Compensation Committee meeting regarding directors’ compensation was held in March 2023. The committee deliberated the draft proposal for basic compensation and performance-linked compensation for individual directors in accordance with the above criteria.

Total Amount of Compensation, Total Amount of Compensation by Type, and Number of Eligible Officers by Category in FY2022

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)	253	197	23	32	6
Audit & Supervisory Board members (Excluding outside Audit & Supervisory Board members)	48	48	—	—	3
Outside officers	37	37	—	—	5

Note: Stock compensation represents a provision for share awards in FY2022.

Policy on Cross-Shareholdings

KAKEN owns stocks as cross-shareholdings only when it has determined that they will contribute to the improvement of the corporate value of the KAKEN Group from a medium- to long-term perspective, taking into consideration factors such as their necessity for business strategy and maintaining and strengthening business relationships. As appropriate, the Company reduces holdings of stocks for which it judges ownership to have low significance.

Each year, the Board of Directors comprehensively examines the significance, purpose, circumstances of acquisition, and the benefits and risks associated with each of its cross-held stocks in both qualitative and quantitative

terms, including capital costs, trading conditions, and cost performance in terms of changes in share value, dividends and other factors, to determine the benefits and risks of continuing to hold them. This examination was conducted at the Board of Directors meeting held in December 2022. In FY2022, the Company sold a portion of its holdings in one issue of such stock.

KAKEN appropriately exercises voting rights for the shares it holds based on a comprehensive judgment of matters including whether or not such exercise will contribute to the improvement of the corporate value of the Company and the investees from a medium- to long-term perspective.

# Messages from Outside Directors

## Stepping Up the Enhancement of Corporate Value in a Year of Steady Forward-Looking Investments

In May 2022, KAKEN announced Long-Term Business Plan 2031 and took a new step forward with its “Three Transformations.” I have been conducting oversight of the Board of Directors with an interest in entering new areas in anticipation of expanding research and development overseas and enhancing the development pipeline. In KAKEN’s earlier acquisition of a clinical stage biopharmaceutical company in Japan, I felt the Company gained a great deal from having different indications in the development pipeline and a different approach to drug repositioning. As part of KAKEN’s aggressive efforts to treat rare diseases, it entered into two collaboration and license agreements at the beginning of 2023 for the development and commercialization in Japan of an investigational drug—one with Spruce Biosciences Inc. and the other with CymaBay Therapeutics, Inc., both U.S. companies. The Company thus made management decisions on forward-looking upfront investments during the first year of Long-Term Business Plan 2031 that will be key to the plan’s success.

Many Board of Directors meetings were held online during the COVID-19 pandemic, but since 2022 they have been held face-to-face, with outside directors also attending. Face-to-face meetings facilitate information exchange and discussion, and I feel that the change has enlivened the meetings. I intend to continue to earn the trust of shareholders by overseeing management decision-making and execution from an independent standpoint to further enhance corporate value.



Kiyoko Kamibeppu  
Outside Director

## Off to a Flying Start and the Future!

In FY2022, the first year of Long-Term Business Plan 2031, KAKEN made a good start on the priority issue of expanding its pipeline by entering into license agreements for two investigational drugs—Seladelpar and Tildacerfont. Although it entailed considerable preparations, the nearly simultaneous acquisition of two projects was the commendable result of the efforts of all parties involved.

Going forward, KAKEN must concurrently develop these two in-licensed drugs in addition to KP-001, which the Company previously acquired, and NM26-2198, which it is co-developing, as it further expands the pipeline through ongoing in-licensing activities and other measures. The Company must also have the operational capacity to steadily generate the ¥200 billion earmarked for strategic investment during the plan, as well as to comprehensively manage the strategic investments.

I want to stress that continuous reform and evolution of the management base under Long-Term Business Plan 2031 will be crucial for achieving the desired results. This includes developing human resources, acquiring organizational capabilities, and upgrading systems and environments. A good start raises expectations of future success, but it does not guarantee it. To respond appropriately and learn more from the challenges KAKEN will face in the future, I would like to encourage discussion that is unconstrained by Company norms, and contribute to the enhancement of corporate value over the medium to long term.



Shoichiro Takagi  
Outside Director

## A Commitment to Management That Emphasizes Multifaceted and Human Capital Perspectives

A year has passed since the announcement of Long-Term Business Plan 2031. Based on agenda topics at Board of Directors meetings, I believe the Company is making more concrete progress toward its vision of becoming a pharmaceutical company with a global presence that contributes to longer healthy life expectancy through its strategy of “Three Transformations”: “R&D Transformation,” “Overseas Expansion Transformation,” and “Management Base Transformation.” KAKEN is considering the possibility of multiple collaborations to enter new areas, but the increasingly unstable global situation has given rise to downsides unforeseen when drafting Long-Term Business Plan 2031. On the other hand, practical studies of issues such as overseas base establishment are moving forward. Other examples include investing in human capital and conducting digitalization to strengthen the management base, which is indispensable for carrying out the plan.

The Board of Directors also recognizes that human capital management is fundamental to the Company. The board actively discusses and implements measures related to developing human resources and improving the internal environment to increase employee engagement. At the same time, as digitalization progresses in every aspect of society and use of AI grows, I sense the need to respond by developing digital talent in-house.

From an external standpoint, I will continue to provide advice and oversight on the issues I have raised, as well as support on their legal-related issues as an attorney.



Yasutomo Inoue  
Outside Director

# Compliance and Risk Management



## Basic Approach to and System for Promoting Compliance

We believe that compliance-based business activities are fundamental to earning the trust of society and promoting the healthy development of a company. KAKEN promotes compliance-based management in accordance with this belief.

In order to achieve compliance-based management, the Company has appointed a compliance officer and has designated the Compliance Group of the Legal Affairs & Intellectual Property Department as the unit responsible for instilling a compliance-based mindset in executives and employees.

## Activities to Promote Compliance

Based on our corporate philosophy and business philosophy, we have established the KAKEN Charter of Corporate Behavior and Code of Conduct. The charter and code comprise guidelines to be followed by all executives and employees, and express KAKEN’s basic position on compliance. They serve as the basis for the decisions and performance of duties by executives and employees toward the achievement of the Company’s corporate philosophy and business philosophy. The charter and code are available on our website, along with our corporate philosophy and business philosophy (Code of Conduct in Japanese only).

To raise awareness of compliance, we have prepared a Compliance Check Card and Compliance Guidebook, provide level-and workplace-based compliance education and distribute messages through the Company intranet from the compliance officer and related information from the Compliance Group as appropriate. The content of training is chosen from a variety of themes, including the corporate philosophy, prevention of bribery and other corrupt practices, prevention of harassment, and internal reporting (consultation), to facilitate trainees’ understanding and practice.

## 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 3Rs: the utilization of alternatives to animal testing (replacement), the reduction of the number of animals used (reduction), and the mitigation of pain (refinement).

In conducting animal tests, the Company complies

with relevant laws and regulations and internal regulations, gives due consideration to animal welfare, while the Animal Testing Committee established internally carries out examinations 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 animal testing initiatives 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 2022, KAKEN received the Accreditation of Animal Experimentation Facilities from the Japan Pharmaceutical Information Center for the fourth time.

## Basic Approach to and System for Promoting Risk Management

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

## 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

1. For risks the KAKEN Group is exposed to, the Company has established a system for identifying and managing such risks under which a director is designated to be in charge of risk management and the Corporate Planning & Coordination Department is designated as the responsible department.
2. The Company classifies risks and manages them by designating the responsible departments.



3. The Board of Directors makes decisions on the handling of material risks from the perspective of the KAKEN Group's management, and such risks are managed by the responsible departments.

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

The Company has formulated 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 director in charge of risk management designated 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 as having the potential to materially affect KAKEN's financial position, business performance and cash flows, and their countermeasures, are as shown below.		The forward-looking statements contained herein reflect the judgment of the KAKEN Group as of March 31, 2023.
Category	Details	Countermeasures
(1) Legal regulations and administrative developments	<ul style="list-style-type: none"><li>Impact of various medical system reforms to curtail public healthcare expenditures, such as revisions of NHI drug price standards, revisions of related laws and regulations, and developments in administrative policies related to the medical system and health insurance</li></ul>	<ul style="list-style-type: none"><li>Implementation of sales strategies taking administrative policies into account</li><li>Timely and appropriate understanding of and response to related laws and regulations, the medical system, and administrative policies</li></ul>
(2) New drug development	<ul style="list-style-type: none"><li>Substantial R&amp;D expenses and long development periods for new drugs</li><li>Discontinuation of development due to failure to achieve expected efficacy or safety</li></ul>	<ul style="list-style-type: none"><li>Strengthening of the earnings structure by developing new drugs with high added value</li><li>Innovation and streamlining of processes to shorten the R&amp;D period</li><li>Diversification of approaches to improve the probability of success</li><li>Strengthening of cooperation with external parties in early-stage development, and proactive and effective utilization of external resources</li></ul>
(3) Adverse drug reactions	<ul style="list-style-type: none"><li>Occurrence of unexpected adverse drug reactions after product launch, and associated product recalls and discontinuation of sales</li></ul>	<ul style="list-style-type: none"><li>Strengthening and thorough implementation of safety monitoring activities</li><li>Strengthening provision of safety information to promote proper use</li></ul>
(4) Competition	<ul style="list-style-type: none"><li>Competition with rival products of similar efficacy and effects, and with generic products</li></ul>	<ul style="list-style-type: none"><li>Gathering of scientific data to increase product value</li><li>Improvement of containers to increase convenience, such as ease of use</li></ul>
(5) Intellectual property rights	<ul style="list-style-type: none"><li>Impact of legal proceedings in the event of infringement of intellectual property rights by a third party</li><li>Disputes, payment of damages or discontinuation of business in the event of infringement of a third party's intellectual property rights</li></ul>	<ul style="list-style-type: none"><li>Appropriately managing and monitoring intellectual property rights</li><li>Taking preemptive measures to investigate, identify and avoid the risk of infringing the intellectual property rights of third parties</li><li>Establishment of a system for dealing with intellectual property disputes when they arise</li></ul>
(6) Litigation	<ul style="list-style-type: none"><li>Impact of legal proceedings instituted for adverse drug reactions, product liability, labor, environment or fair trade, or other matters</li></ul>	<ul style="list-style-type: none"><li>Strengthening of collaboration with lawyers and other experts</li><li>Improvement of compliance awareness among executives and employees</li><li>Executing contracts minimizing various risks</li></ul>
(7) Delay or interruption of product supply	<ul style="list-style-type: none"><li>Delay or interruption of product supply due to problems with production equipment or delays in raw material procurement</li><li>Product recalls due to quality problems</li></ul>	<ul style="list-style-type: none"><li>Securing of appropriate inventory and diversification of raw material suppliers</li><li>Thorough quality control system in compliance with good quality practice (GQP) and good manufacturing practice (GMP)</li></ul>
(8) IT security and information management	<ul style="list-style-type: none"><li>Business interruptions due to system failures, cyber-attacks or other factors</li><li>Payment of damages, administrative action, or loss of public trust due to leaks of confidential information</li></ul>	<ul style="list-style-type: none"><li>Implementation of robust multi-stage security measures for internal systems</li><li>Regular security education for executives and employees</li><li>Development of a security system with detection and response capabilities against cyber-attack, virus infection, etc.</li></ul>
(9) Large-scale disasters	<ul style="list-style-type: none"><li>Suspension of business activities due to natural disasters, fires and other accidents, pandemics or other events</li><li>Substantial expenses for repair of facilities or other property damaged by disasters or other causes</li></ul>	<ul style="list-style-type: none"><li>Formulation of a business continuity plan (BCP) and implementation of emergency drills</li><li>Development and operation of measures to prevent the spread of infection in the event of a pandemic</li><li>Purchase of insurance to mitigate financial impact</li></ul>

# 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 enhance safety measures, each of our sites, including the Head Office, undertakes initiatives such as the provision of a standard first aid course and various 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 FY2022 the site's support team conducted nine cleanup drives of sports fields along the Oi River.



### Environmental Report Meetings

The Shizuoka Site had been holding environmental report meetings every year for local residents. But for the last few years, the site could not hold any meetings and has only circulated environmental reports to neighboring residents. In FY2022, however, the site was able to hold an in-person meeting for the first time in three years, after implementing COVID-19 control measures. The site's environmental performance data, status of employee education, and other activities for compliance with laws and regulations were reported, giving attendees a better understanding of the Company's environmental initiatives.



### Talking about Careers with Students at a Local High School

In FY2022, employees from the Shizuoka Site visited a high school in Fujieda City to talk with the students about careers. Employees who had graduated from the school introduced KAKEN, gave a quiz about medicine, spoke about their jobs and gave job-hunting advice. The students responded with many questions for their alumni, such as "What kind of qualifications are useful in getting hired?" All in all, the atmosphere of the event was friendly from start to finish.

## 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 drive 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, one morning each month, two teams of employees have cleaned the roads around the site.



## Firefighting and Disaster Prevention Drills and Local Agreements for Disaster Response

As the property owner, KAKEN is responsible for fire and disaster prevention management at Bunkyo Green Court, the site of its Head Office. The Company also actively engages in local fire and disaster prevention activities in cooperation with fire departments and the facilities management company. More than 30% of employees at our Head Office have completed lifesaving training, and the Head Office received a certificate of excellence from the Tokyo Fire Department for actively conducting lifesaving training.

In FY2021, the Head Office was also certified by the Tokyo Metropolitan Government as a "Company That Promotes the Reduction of Simultaneous Commuting" by taking proactive measures to prevent employees from heading home all at once in the event of a disaster.

Based on the lessons learned from the Great Hanshin-Awaji Earthquake, the Drug Research Center in Kyoto has entered into agreements for disaster response with two neighboring school districts, focused on dispatching personnel in the event of a disaster.



Environmental Management



Business Philosophy / Priority (Material) Issues / Main Initiatives

Business Philosophy	Priority (Material) Issues	Main Initiatives
Joy for society	<b>Consideration for the environment</b> <ul style="list-style-type: none"><li>• Proper management of waste and wastewater</li><li>• Efficient use of water and other resources</li><li>• Reduction of CO<sub>2</sub> emissions</li><li>• Supply of eco-friendly agrochemicals</li></ul>	<ul style="list-style-type: none"><li>• Roll out environmental management system</li><li>• Maintain ISO 14001 certification (Shizuoka Site)</li><li>• Continue CO<sub>2</sub> emission reduction initiatives</li><li>• Research and development of eco-friendly agrochemicals</li></ul>

KAKEN Basic Environmental Philosophy

As a pharmaceutical company that endeavors to improve the quality of life of patients through the supply of superior pharmaceuticals, and based on the idea of “Joy for society,” 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

In line with its basic environmental philosophy, KAKEN shall take measures to address climate change and other environmental issues, and contribute to the realization of a sustainable, prosperous society.

- 1 Establish and maintain an environmental management system

We shall establish an environmental management system and undertake initiatives to protect the environment. Led by our Sustainability Committee and the Environmental Subcommittee, 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 addressing 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 pursue mutual understanding with those communities by disclosing environmental information.
- 6 Raise environmental awareness

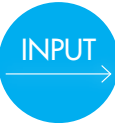
We shall provide environmental training and information to all executives and employees to raise their awareness about environmental protection.

Materials Balance of Business Activities

Each and every employee at the Shizuoka Site and the Drug Research Center in Kyoto recognizes input and output that place burden on the environment during the course

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

Chemical Substances	Water
(Substances subject to reporting under the PRTR system)	2,808 thousand tons
Acetonitrile 2.0 tons	
Normal hexane 0.3 tons	
Chloroform 0.4 tons	
Zinc compounds 0.0 tons	
Toluene 6.0 tons	
Dichloromethane 11.1 tons	
	<b>Office Paper</b>
	1.38 million sheets
	<b>Other Packaging Materials</b>
	Plastics
	Paper
	<b>Raw Materials</b>
	Glucose
	Yeast, etc.
Energy	
Electric power 24,213,092 kWh	
LPG 3.0 tons	
City gas 4,441,033 Nm <sup>3</sup>	



Business Activities



R&D activities



Production activities



Office activities



Discharge into the Water System

Amount of wastewater 1,748 thousand tons

Emissions into the Atmosphere

CO<sub>2</sub> 18,794 t-CO<sub>2</sub> (excludes 382 t-CO<sub>2</sub> from carbon-free electricity)

Waste

Amount of waste generated 661 tons

Amount of final disposal 18 tons

Proper Management of Waste and Wastewater

The generation of waste is unavoidable in business activities. However, the development of a circular economy requires that the generation of waste that ends up as final disposal be reduced to the maximum 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 FY2022, the total amount of waste generated by the Shizuoka Site was 633 tons. Of this, 57% 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 81 tons of valuable materials (accounting for 13% of total wastes). The amount of final disposal (landfill) was 18 tons. Going forward, we will redouble our efforts to promote the reduction and recycling of waste.

As for wastewater, the Shizuoka Site separates wastewater from production activities into organic and other wastewater. Organic wastewater undergoes treatment using activated sludge, after which it is mixed with other wastewater until the mixture is diluted to within domestic wastewater standards. It is subsequently discharged into rivers. In 1976, the site entered into an agreement with Fujieda City, Shizuoka Prefecture, regarding pollution prevention. At the Drug Research Center in Kyoto, organic wastewater undergoes treatment using activated sludge, after which it is mixed with wastewater from other systems before being discharged into public sewers. When discharging such wastewater, the Drug Research Center adheres to its own internal standards, which are stricter than those of the city of Kyoto, and periodically reports the results of its measurements.

For information on waste generated and final disposal, see page 87.

Efficient Use of Water Resources

The Shizuoka Site benefits from a plentiful supply of water from the 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 site has taken various measures to use water resources more efficiently, such as switching its water pump to an inverter type to

enable fine adjustments in the amount of groundwater drawn, and stopping unnecessary drawing of well water. We will continue to promote efficient use of water resources from the standpoint of business sustainability.

For the Shizuoka Site's water consumption and consumption per unit of production, see page 87.

Reduction of CO<sub>2</sub> 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 (FPMAJ) helped to create, and are working toward the FPMAJ's long-term vision of net zero CO<sub>2</sub> emissions in 2050. In addition, we are curbing CO<sub>2</sub> emissions to achieve our own goal of reducing CO<sub>2</sub> emissions in FY2030 by 51% compared with FY2016 levels. At the Shizuoka Site and the Drug Research Center in Kyoto, which account for more than 90% of our energy consumption, we are proactively installing high-efficiency equipment and conducting ongoing energy-saving activities. We have also begun

introducing carbon-free electricity at the Shizuoka Site to further reduce our emissions.

At the Head Office and sales offices, we are replacing fluorescent lights with LED lights and optimizing air conditioner temperature settings to reduce electricity consumption.



For information on CO<sub>2</sub> emissions, see page 87.

Supply of Eco-Friendly Agrochemicals

Polyoxins, which are natural fungicides derived through microbial fermentation, are safe for humans and animals. They are natural substances confirmed to be decomposed 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 19 countries, and we are conducting development so that these eco-friendly products can be supplied to more countries.





Climate-Related Disclosure Based on TCFD Recommendations



KAKEN adopted the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD) in February 2023. We analyzed the risks and opportunities that climate change will bring to our business, and, in accordance with the TCFD recommendations, organized them into four categories—governance, strategy, risk management, and metrics and targets.

Governance

To promote sustainability management, KAKEN has formed the Sustainability Committee chaired by the director in charge of the Corporate Planning & Coordination Department. The Sustainability Committee meets twice a year in principle to identify and organize the Company's priority (material) issues, including climate-related issues, and to discuss and examine concrete measures for solving them. The priority issues selected by the Sustainability Committee are then discussed

and specified by the Board of Directors, and the Board of Directors supervises their progress. In addition, the Environmental Subcommittee has been established as a subordinate body of the Sustainability Committee. It conducts expert reviews of important issues related to the environment, including climate change, and reports the progress and results of those reviews to the Sustainability Committee.

Main Risks and Opportunities, and KAKEN's Strategies

Maximum Rise in Average Annual Temperature by Scenario	Issue	Risks/ Opportunities	Description	Expected Time Frame*	Expected Financial Impact (Millions of yen)*	KAKEN's Strategy
4°C	Intensification of climate change	Risks	• Damage to the Company's operating sites due to intensification of climate change • Raw material delivery delays and price increases due to logistical disruptions	Short to long term	Between -570 and -280 <sup>1</sup>	• Formulate a business continuity plan that includes determining flooding of sites/facilities based on hazard maps. • Consider decentralized procurement.
		Opportunities	• Growing requests for stable pharmaceutical supply capability in the event of a disaster, and an increase in customers and sales if KAKEN is able to respond adequately		Small	
	Changes in climate patterns	Risks	• Increase in pharmaceutical quality control costs during manufacturing, storage and distribution as a result of rising temperatures	Medium to long term	Between -30 and -20 <sup>2</sup>	• Install high-efficiency equipment in factories and research centers. • Adopt third-party logistics to improve logistical efficiency, and conduct joint transportation. • Conduct related research and product development.
		Opportunities	• Increase in demand for pharmaceuticals due to increased specific disease risks or infectious diseases resulting from rising temperatures • Increase in demand for agrochemical products due to switching crops and increasing damage from plant disease caused by climate change		Small	
1.5°C	Decrease in biodiversity	Opportunities	• Expectations for eco-friendly materials will increase, and demand for fermentation-derived agrochemicals will increase.	Medium to long term	Small	• Maximizing value based on growth strategy of polyoxin fungicides derived through microbial fermentation.
	Change in energy costs	Risks/ Opportunities	• Change in operating costs due to fluctuating prices for electricity used at each site	Medium to long term	Between -30 and -20 <sup>3</sup>	• Set greenhouse gas reduction targets, with carbon neutrality in 2050 as a long-term vision. • Switched to carbon-free electricity for 20% of the electricity used at the Shizuoka Site in January 2023. Planning a gradual increase. • Switching from fluorescent lights to LED lighting and optimizing temperature settings of air conditioning to reduce energy consumption at the Head Office and branch offices.
	Introduction of carbon tax	Risks	• Increase in cost of each activity at business sites and transportation due to introduction of carbon tax	Medium to long term	Between -600 and 0 <sup>4</sup>	

\* "Short term" is defined as 0-1 year, "medium term" as 1-5 years, and "long term" as 5-30 years. Under expected financial impact, "Large" means that the financial impact on the Group's businesses is expected to increase significantly, and "Small" means that the financial impact on the Group's businesses is expected to increase slightly.

1. The cost of damage from disasters at each location is estimated based on the *Manual for Economic Evaluation of Flood Control Investment* (Ministry of Land, Infrastructure, Transport and Tourism). Damage information (damage rate, number of days business disrupted/suspended) is specified for each location on the flood hazard map.

2. Estimated from the Company's electricity consumption, future electricity prices and the rate of increase in air conditioning usage (referring to figures in *World Energy Outlook 2019* and *The Future of Cooling*, both publications of the International Energy Agency)

3. Estimated from the Company's electricity consumption and future electricity prices (referring to figures in *World Energy Outlook 2019* of the International Energy Agency)

4. Estimated from the Company's greenhouse gas emissions and future carbon tax prices (referring to figures in *World Energy Outlook 2021* of the International Energy Agency)

Strategy

We participate in the Commitment to a Low-Carbon Society, a plan created by the FPMAJ, and are working toward the FPMAJ's long-term vision of net zero CO<sub>2</sub> emissions in 2050 as well as our own goal of reducing CO<sub>2</sub> emissions by 51 % compared with FY2016 levels by FY2030.

We examined the qualitative and quantitative risks and opportunities for FY2030, our target year for CO<sub>2</sub> reduction, and 2050, the FPMAJ's target year for achieving net zero CO<sub>2</sub> emissions. In that process, we referred to the 1.5°C scenario (and partially to the 2°C scenario), which assumes more ambitious climate change measures are taken for decarbonization, and the 4°C scenario, which assumes climate change

intensifies as no climate change measures beyond current measures are taken.

Scenario analyses revealed that no climate-related risks with a significant financial impact on our business activities are expected in either scenario, and that as an opportunity, demand for our pharmaceutical products and agrochemicals may increase. As a pharmaceutical company that endeavors to improve the quality of life of patients through the supply of superior pharmaceuticals, KAKEN recognizes its social responsibility, and will work to protect, maintain and enhance the global environment in all aspects of its business activities.

Risk Management

KAKEN engages in risk management initiatives with the aim of appropriately managing risks that could hinder the realization of the corporate philosophy and the achievement of the business plan, fulfilling its social responsibility, and contributing to sustainable corporate value improvement. We recognize that climate change is a risk category related to the priority issues we need to address for sustainable growth, and as such we will work to protect, maintain and enhance the global environment in all aspects of our business activities.

Enterprise risk management is carried out by the Risk Management Committee, while climate-related risk management is primarily handled by the Sustainability Committee. This committee identifies social issues, taking into account the status of the

Company's business, business plans, GRI standards, ISO 26000 and other factors, narrowing them down from two perspectives—relevance to KAKEN's business and impact on stakeholders—and evaluating them both qualitatively and quantitatively. The Sustainability Committee narrows down and regularly monitors the risk categories that the Company should give priority to addressing, considering the impact of its business activities on society, the financial impact on the Company, and the likelihood of occurrence. In addition, the Sustainability Committee reports to the Board of Directors regarding the status of response to risk categories that are important in sustainability management, and the Board of Directors supervises appropriate responses.

Metrics and Targets

We participate in the Commitment to a Low-Carbon Society, a plan created by the FPMAJ, and are working toward the FPMAJ's long-term vision of net zero CO<sub>2</sub> emissions in 2050 as well as our own goal of reducing CO<sub>2</sub> emissions by 51 % compared with FY2016 levels by FY2030.

To reach these targets, we are proactively installing high-efficiency equipment and conducting ongoing energy-saving activities at the Shizuoka Site and the Drug Research Center in Kyoto, which account for more than 90% of our energy consumption.

To further reduce emissions, in January 2023 we switched to carbon-free electricity for 20% of the electricity used at the Shizuoka Site. We plan to raise this percentage in stages.

At the Head Office and branch offices, we are replacing fluorescent lights with LED lights and optimizing air conditioner temperature settings to reduce electricity consumption.

# Human Resource Strategy

 Joy for employees

Engagement  
with  
Employees

“Joy for employees” is a key component of our business philosophy. We place great importance on employees’ human rights, health, safety and hygiene, and strive to create a working environment in which every employee can work with peace of mind and a sense of fulfillment. We believe that this will lead to the development of professionals who find their jobs meaningful and satisfying. By implementing the human resource strategy in Long-Term Business Plan 2031, we will foster a corporate culture that increases employee engagement.

Business Philosophy / Priority (Material) Issues / Main Initiatives

Business Philosophy	Priority (Material) Issues	Main Initiatives
Joy for employees	<b>Creating fulfilling workplaces</b> <ul style="list-style-type: none"><li>•Generating and maintaining employment opportunities</li><li>•Work-style reform and improved productivity</li><li>•Employees’ health, occupational safety and welfare</li><li>•Diversity</li><li>•Development of the next generation of human resources</li><li>•Respect for human rights</li></ul>	<ul style="list-style-type: none"><li>•Work-style reform (including digitalization of work processes)</li><li>•Appoint female directors</li><li>•Enhance systems for employing people with disabilities and seniors</li><li>•Help protect employees against disease and promote mental healthcare initiatives</li><li>•Training programs, self-development support and discrimination/harassment prevention</li></ul>

Basic Policy in Long-Term Business Plan 2031

(1) Develop talent who challenge themselves as professionals and pursue transformation

To develop employees with distinctive capabilities who can adapt to changing times, as well as specialists in each field, we will enhance various measures, such as providing education and training as well as personal development and reskilling opportunities for all employees. We will further boost motivation by assigning people according to aptitude and promoting high-performing employees.

(2) Increase employee engagement by establishing an optimal human resource management system and working environment

To nurture professional human resources, foster our corporate culture and support the growth of employees, we need to create more advanced human resource management and work-style systems.

We will also set up workplace systems from various perspectives to make KAKEN a fulfilling place to work for every employee.

Human Resource Strategy Priority Measures

Priority Measures

(1) Foster a corporate culture and develop talent that generates innovative challenges

- Foster a corporate culture that encourages employees to take on challenges
- Develop employees with distinctive capabilities as professionals (Employees who think for themselves, take action, and get results)
- Develop and recruit digital talent who are suitable for the promotion of DX
- Develop and recruit global-minded talent to reinforce overseas expansion
- Reinforce the education and training system

(2) Pursue a better work-style system and working environment that support the growth of employees

- Transform the human resource management and work-style systems and improve the working environment
- Promote diversity management

(3) Develop MRs who can flexibly respond to the changing times through convergence of the real and digital worlds

- Develop MRs with expertise equivalent to an MSL\* in diseases we are focusing on as well as in products
- Optimize medical information provision based on data analysis, and use multiple communication channels
- Develop ability to plan and execute as a community healthcare partner based on a patient-first perspective

A corporate culture that encourages employees to take on challenges

A spirit of challenge and innovation

Enhancement of employee well-being and engagement

\* Medical Science Liaison: A person who is assigned to a unit independent from the Marketing & Sales Division, and whose primary role is to interact with outside experts in medicine and science

Human Resource Development

We believe that human resource development is fundamental to company management, and strive to enhance the abilities of all employees. Based on the policy of the human resource strategy in Long-Term Business Plan 2031, we are developing employees with distinctive capabilities as professionals. In professional skill development, we are using internal and external training programs to enhance the content of training

by position and management training, and provide personal development and reskilling opportunities for every employee. We need employees who can think and act on their own, global-minded talent, and core talent—in other words, professionals with distinctive capabilities. Given the changes in our business environment, we also seek to develop people who can creatively tackle new challenges.

Training by Position

In order for an organization to develop sustainably, all employees must have an awareness of issues, think and act on their own initiative, and grow. Accordingly, we have a full range of training programs to equip employees with the skills they need at each level. We provide general training on basic business skills for newly hired young employees, management candidate

training to develop employees who will lead the next generation, and training for new team leaders and new managers to learn about management and the mindset required of leaders and managers. We also plan to conduct training to further raise the skill levels of managers.

Company Training		Department Training
Management Training	Manager upskilling training (planned)	<ul style="list-style-type: none"><li>• Introductory training for MRs and medical affairs staff</li><li>• Training for 2nd and 3rd year MRs and medical affairs staff</li><li>• Training for 4th year MRs and medical affairs staff</li><li>• Training for 8th year MRs</li><li>• Language training</li></ul>
	Training for new managers	
	Training for new team leaders	
Training for the next generation of leaders	Training for management candidates	
Training by employment year	3rd year training	
Basic training for working adults	General training for newly hired employees	



Scene for general training for newly hired employees in April 2023

Feedback from Training Program Participants

3rd year training participant, 20s

Through communicating with colleagues in other departments who joined the company in the same year, I realized that we have common competencies required for work, but also have competencies that vary widely depending on our environment. As a result, I gained a better understanding of the abilities that are uniquely required in my own job.

Management candidate training participant, Research and Development, 40s

Having the opportunity to interact with the instructor and people from other industries gave me many insights related to the fundamentals of management. I want to take the experience I gained from this training back to my own workplace to show leadership appropriate for the workplace and apply it in my future work.

New managers training participant, Research and Development, 40s

By working on the same tasks as employees of other departments, I was able to absorb various opinions from perspectives different from my own, and broadened my field of view. I will engage in my job, closely observing, deepening understanding and building a high level of trust with my team members even more than before.

New managers training participant, Marketing and Sales, 40s

It was sobering to feel again the similarity between managers and corporate management in terms of their mental attitude and role, and the importance of doing things with a corporate management perspective. Also, I learned a lot about how to communicate with my team members and how to give instructions, which are things I was anxious about when I became a manager. I felt the training was very helpful.

Upskilling/Reskilling

In order for all employees to grow into professionals, personal development that maximizes the strengths of each individual is important. We have introduced an online study service that enables employees to learn on their own initiative for the purpose of upskilling and

reskilling that cannot be accomplished with job position-based training alone. We will provide opportunities for employees to develop various skills, such as promotion of digital transformation by improving IT literacy, and encourage them to use those skills in every situation.



Diversity and Inclusion

We believe that fostering a corporate culture and developing talent that generates innovative challenges means respecting diverse values and having an environment in which every employee can excel, regardless of their race, nationality, creed, gender, age, sexual orientation, or disability. In addition to

empowering women, we are improving the working environment to make KAKEN a fulfilling place to work for employees at different life stages, such as those in childcare or nursing care, and older employees, to create an environment in which employees can do their jobs with a high level of motivation.

Recruitment of New Graduates and Mid-Career Professionals

When recruiting new university graduates, we offer internships and conduct presentations about the Company to give students a better understanding of KAKEN's corporate stance and the rewarding jobs available in each occupation. In determining who to select from those who have attended the presentations and completed their internships, we focus on hiring

fresh talent who are full of potential and interested in working at KAKEN.  
In hiring people with experience, we look for candidates who have advanced skills or career backgrounds that we lack within the Company to support the organizational development of the relevant departments.

Promotion of Women’s Empowerment

We actively promote capable women and are establishing working environments in which employees can work with peace of mind regardless of gender. Such conditions pave the way for the sustained success of female employees. We have set the goal of raising the percentage of women in all management positions to at least 7% in our action plan for FY2022–FY2025 based on the Act on Promotion

of Women’s Participation and Advancement in the Workplace. In maintaining supportive workplace environments for female employees, we have established reduced working hour and flextime systems and a system that allows employees to use special paid time off in order to flexibly accommodate needs such as childcare and nursing care.

Support for Childcare and Nursing Care

We have established various systems such as leave and shorter working hour for childcare leave and nursing care, so that employees with childcare or nursing care commitments can balance those obligations with their jobs and continue to work with peace of mind.  
• A system that allows employees to take special paid time off for the purpose of caring for a family member, for a child’s gradual entry into a nursery school, or to

undergo fertility treatment  
• A system that allows employees with shorter working hours to also use the flextime system  
• To make it easier for male employees to also take childcare leave, we have modified the system to make childcare leave partially paid (up to five days), and are conducting in-house training and education for managers.

Employment of Seniors

We have introduced the Senior Staff Program for the reemployment of employees who retired upon reaching the mandatory retirement age of 60, allowing them to work up until the month of their 65th birthday. This

system enables them to continue playing an active role in their respective workplaces 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 take a proactive approach to hiring persons with disabilities. At the Shizuoka Site, we have a support team that provides employment support for people with disabilities, and have established an environment to

ensure that such workers can work with peace of mind while receiving appropriate assistance in the workplace. For the Company as a whole, we maintain employment levels that exceed the statutory rate.

Work-Style Reforms

We have introduced systems that enable our employees in different life stages to choose from an array of work-style options to balance work with their private lives.

We also strive to be a company that increases employee engagement and is a fulfilling place to work for every employee.

Work-Life Balance

1) To support flexible work styles for employees, we have introduced a flextime system (except for the Production Division and MRs) and a work-from-home system.  
2) To promote healthy, well-balanced work styles, both physically and mentally, for all employees, we are creating a corporate culture that makes it easier to

take annual paid vacation and anniversary time off (paid time off for special occasions).  
3) For employees who are transferred to a different location, we have company housing and a solo transfer system to accommodate their family circumstances as much as possible.

Increasing Employee Engagement

In the intensely competitive environment of the pharmaceutical industry, it is important to boost retention by increasing the motivation of employees. Therefore, in FY2023 we introduced a system to measure the level of employee engagement as a

metric to gauge the job satisfaction of employees. We will periodically assess employee engagement as a company, and implement the human resource strategy in Long-Term Business Plan 2031 with an awareness of current challenges.

Occupational Safety and Health

Employee Health Management

To manage employee health, we provide access to health checkups every spring and lifestyle disease-related examinations every fall. In cooperation with industrial physicians and medical examination centers, we conduct follow-ups for employees whose checkups reveal health problems.  
In addition to conducting annual stress checks required by law, we support measures for employees’ mental health by offering simple stress checks that

employees can perform voluntarily and by providing a wide range of learning materials including a variety of e-learning programs.  
The Company remains committed to the management of employees’ physical and mental health, one aspect of which is the utilization of the external consultation desk at the health insurance association and counseling services.

Safety and Health Measures at Facilities and Workplaces

Based on the Regulations for Safety and Health Management, which are aimed at preventing occupational accidents and illnesses and creating a comfortable working environment, we hold Safety and Health Committee meetings on a monthly basis at all offices and other workplaces. This committee is made up of the General Safety and Health Manager (Shizuoka Site), safety officers, health officers, and an industrial

physician, as well as members selected from the company and the labor union. Safety inspections and remedial measures are implemented at each facility and workplace in an effort to eliminate occupational accidents. We also actively work to improve the working environment by conducting regular questionnaire surveys of employees.

Creation of a Workplace Free from Discrimination and Harassment

We strive to enhance awareness of the prevention of discrimination and harassment among all employees through the Rules of Employment, Regulations for Rewards and Punishments, the Compliance Guidebook, and regular postings and education via the Company

intranet. We also keep employees informed of internal consultation channels. Furthermore, we make efforts to prevent workplace bullying and harassment by conducting annual training for managers that includes training on prevention of bullying and harassment.

# FY2022 Operating Results and Financial Condition

## Analysis of Operating Results

In FY2022, the year ended March 31, 2023, net sales decreased 4.0% year on year to ¥72,984 million, operating profit decreased 53.1% to ¥7,998 million, and profit attributable to owners of the Company decreased 43.0% to ¥5,440 million.

KAKEN has applied the Accounting Standard for Revenue Recognition (ASBJ Statement No. 29, revised on March 31, 2020) from the beginning of FY2021. FY2020 and prior fiscal years use figures calculated using a different accounting standard.

FY	2019	2020	2021	2022	2023
Net sales (Millions of yen)	94,165	89,232	74,979	76,034	72,984
Operating profit (Millions of yen)	24,592	26,512	17,788	17,064	7,998
Profit attributable to owners of the Company (Millions of yen)	17,775	19,370	13,405	9,549	5,440
Net assets (Millions of yen)	121,131	128,468	136,257	138,325	136,836
Total assets (Millions of yen)	155,985	157,875	163,332	165,181	166,328
Cash flows from operating activities (Millions of yen)	21,129	27,468	14,380	13,336	9,253
Cash flows from investing activities (Millions of yen)	(5,744)	(2,528)	(1,644)	(7,888)	(2,627)
Cash flows from financing activities (Millions of yen)	(9,524)	(10,173)	(8,752)	(8,129)	(6,990)
Cash and cash equivalents at end of year (Millions of yen)	58,555	73,322	77,305	74,625	74,260
Profit per share (Yen)	445.78	494.89	347.37	251.43	144.80
Dividends per share (Yen)	150.00	150.00	150.00	150.00	150.00
Equity-to-asset ratio (%)	77.7	81.4	83.4	83.4	81.9
Return on equity (%)	15.1	15.5	10.1	7.0	4.0

### Segment Sales and Profit

#### Pharmaceuticals, Medical Devices & Agrochemicals

Sales of pharmaceuticals and medical devices decreased. While sales of primary axillary hyperhidrosis treatment Ecclock increased, sales of anti-osteoarthritis agent Artz, post-operative adhesion barrier Seprafilm and other products decreased. Factors include the impact of National Health Insurance (NHI) drug price revisions and competing products. Sales of agrochemicals increased.

As a result, segment sales totaled ¥70,562 million, a year-on-year decrease of 4.2%. Segment profit (operating profit) decreased 57.3% to ¥6,707 million.

Overseas sales were ¥7,232 million, an increase of 4.0%.

#### Real Estate

The main source of revenue in the Real Estate segment is rental income from Bunkyo Green Court. Segment revenue increased 0.5% year on year to ¥2,422 million and segment profit (operating profit) decreased 4.6% to ¥1,290 million.

### Cash Flows

Net cash provided by operating activities was ¥9,253 million, a decrease in cash inflow of ¥4,083 million compared with the previous fiscal year. The main factor was a decrease in profit before income taxes. Net cash used in investing activities was ¥2,627 million, a decrease in cash outflow of ¥5,261 million compared with the previous fiscal year. The main factor was the purchase of shares of subsidiaries in FY2021. Net cash used in financing activities was ¥6,990 million, a decrease in cash outflow of ¥1,139 million compared with the previous fiscal year. The main factor was a decrease in purchase of treasury stock. As a result, cash and cash equivalents as of March 31, 2023 totaled ¥74,260 million, a decrease of ¥364 million from a year earlier.

**We will conduct strategic investment with a medium- to long-term perspective and provide shareholder returns aligned with profit growth.**

Masashi Suzudo Director (in charge of Corporate Planning & Coordination Department)



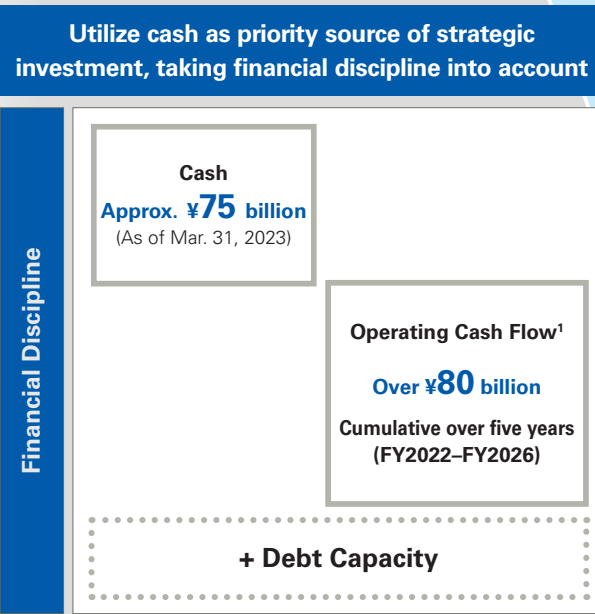
To carry out Long-Term Business Plan 2031, we have set strategic investment at ¥200 billion over 10 years in order to continuously launch innovative world-class drugs, and will allocate cash flow to research and development as a top priority. Taking financial discipline into account, we will utilize cash as the priority source of strategic investment in allocations up to FY2026, investing around ¥70 billion in research and development and around ¥30 billion in M&A, in-licensing and other expenses.

In addition, the Company considers continuous shareholder returns to be an important management goal, and will strive for a dividend payout ratio of 30% or higher and a shareholder return ratio of 50% or higher. We aim to maintain the current level in paying continuous and stable dividends, which are the core of shareholder returns. We will also flexibly conduct share buybacks after comprehensively considering factors such as our business performance, capital situation, and the market environment including our stock price.

### Cash Flow Allocation (FY2022–FY2026)

**Under Long-Term Business Plan 2031, prioritize ¥200 billion in strategic investment in allocating cash flow and provide shareholder returns aligned with profit growth.**

#### Cash at Hand and Operating Cash Flow



#### Cash Flow Allocation

Strategic Investment	<b>R&amp;D Investment</b> (incl. CapEx and DX Investment)	<b>Around ¥70 billion</b> FY2022–FY2026 (¥120 billion FY2022–FY2031)
	<b>M&amp;A, In-licensing, etc.</b>	<b>Around ¥30 billion</b> FY2022–FY2026 (¥80 billion FY2022–FY2031)
Shareholder Returns	<b>Shareholder Returns Policy</b>	Dividend Payout Ratio: <b>30% or higher</b> Shareholder Return Ratio: <b>50% or higher<sup>2</sup></b>
	Dividends	Continuous and stable dividends in consideration of current level
	Share Buybacks	Flexible Share Buybacks

1. Cumulative operating cash flow is calculated excluding R&D investment and one-time fees for in-licensing.

2. Dividend payout ratio and shareholder return ratio are calculated excluding one-time fees for strategic investment from profit attributable to owners of the Company.



# Consolidated Balance Sheets

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiaries  
As of March 31, 2023 and 2022

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
<b>ASSETS</b>			
CURRENT ASSETS:			
Cash and deposits (Notes 3 and 10)	¥ 59,561	¥ 61,025	\$ 447,827
Marketable securities (Notes 3, 4 and 10)	14,699	13,599	110,519
Receivables:			
Notes and accounts receivable—trade, and contract assets (Notes 8 and 10)	19,268	20,260	144,872
Accounts receivable—other	230	242	1,729
	19,498	20,502	146,602
Inventories (Note 5)	15,564	14,981	117,023
Other	579	504	4,353
Allowance for doubtful accounts	(0)	—	(0)
Total current assets	109,903	110,613	826,338
PROPERTY, PLANT AND EQUIPMENT (Notes 6, 7 and 9):			
Buildings and structures	43,066	42,829	323,805
Machinery, equipment and vehicles	16,612	15,708	124,902
Tools, furniture and fixtures	8,463	7,819	63,632
	68,143	66,357	512,353
Accumulated depreciation	(47,190)	(45,565)	(354,812)
	20,952	20,791	157,534
Land	3,867	3,867	29,075
Construction in progress	677	1,074	5,090
Total property, plant and equipment	25,498	25,734	191,714
INVESTMENTS AND OTHER ASSETS:			
Investment securities (Notes 4 and 10)	17,511	17,093	131,662
Intangible assets			
In-process research and development (Note 2)	5,800	7,300	43,609
Other intangible assets	941	936	7,075
	6,741	8,236	50,684
Deferred tax assets (Note 20)	3,873	1,725	29,120
Long-term prepaid expenses	1,012	1,190	7,609
Other assets	1,788	587	13,444
Total investments and other assets	30,927	28,833	232,534
TOTAL ASSETS	¥ 166,328	¥ 165,181	\$1,250,586

See accompanying Notes to the Consolidated Financial Statements.

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
<b>LIABILITIES AND NET ASSETS</b>			
CURRENT LIABILITIES:			
Short-term bank loans (Notes 6 and 10)	¥ 3,850	¥ 3,850	\$ 28,947
Payables:			
Notes and accounts payable—trade (Note 10)	6,130	5,861	46,090
Accounts payable—other	5,824	3,543	43,789
Electronically recorded obligations—operating (Note 10)	89	78	669
	12,044	9,483	90,556
Accrued expenses	596	345	4,481
Provision for bonuses	966	1,049	7,263
Income taxes payable (Note 20)	2,004	2,436	15,068
Other (Note 8)	1,377	1,884	10,353
Total current liabilities	20,838	19,049	156,677
NON-CURRENT LIABILITIES:			
Provision for share awards	117	106	880
Net defined benefit liability (Note 11)	6,349	5,039	47,737
Deferred tax liabilities	1,771	2,229	13,316
Other	414	431	3,113
Total non-current liabilities	8,653	7,806	65,060
NET ASSETS:			
Shareholders' equity (Note 12):			
Common stock			
Authorized: 193,000,000 shares as of March 31, 2023 and 2022			
Issued: 45,939,730 shares as of March 31, 2023 and 45,939,730 shares as of March 31 2022	23,853	23,853	179,346
Capital surplus	11,406	11,406	85,759
Retained earnings	126,135	126,347	948,383
Treasury stock, at cost: 8,466,780 shares as of March 31, 2023 and 8,121,361 shares as of March 31, 2022	(30,026)	(28,714)	(225,759)
Total shareholders' equity	131,368	132,893	987,729
Accumulated other comprehensive income:			
Net unrealized holding gain on securities	4,724	4,551	35,519
Remeasurements of defined benefit plans	165	301	1,241
Total accumulated other comprehensive income	4,889	4,853	36,759
Non-controlling interests	578	578	4,346
Total net assets	136,836	138,325	1,028,842
TOTAL LIABILITIES AND NET ASSETS	¥ 166,328	¥ 165,181	\$1,250,586

See accompanying Notes to the Consolidated Financial Statements.

## Consolidated Statements of Income

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiaries  
For the years ended March 31, 2023 and 2022

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
NET SALES	¥ 72,984	¥ 76,034	\$ 548,752
COST OF SALES	33,428	34,458	251,338
Gross profit	39,555	41,575	297,406
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (Note 13)	31,556	24,511	237,263
OPERATING PROFIT	7,998	17,064	60,135
OTHER INCOME (EXPENSES):			
Interest and dividends income	439	397	3,293
Subsidy income	149	37	1,120
Interest expenses	(17)	(17)	(128)
Foreign exchange losses	—	(31)	—
Loss on investment in investment partnership	(27)	—	(203)
Gain on sales of non-current assets (Note 15)	2	195	15
Loss on sales of non-current assets (Note 16)	(1)	—	(8)
Loss on retirement of non-current assets (Note 17)	(48)	(97)	(361)
Gain on sales of investment securities	1	1	8
Impairment losses (Note 18)	(1,863)	(2,994)	(14,008)
Contract loss (Note 19)	—	(762)	—
Other, net	184	91	1,383
	(1,181)	(3,179)	(8,880)
PROFIT BEFORE INCOME TAXES	6,817	13,885	51,256
INCOME TAXES (Note 20):			
Current	3,998	4,513	30,060
Deferred	(2,621)	(177)	(19,707)
	1,377	4,336	10,353
PROFIT	5,440	9,549	40,902
PROFIT ATTRIBUTABLE TO OWNERS OF THE COMPANY	¥ 5,440	¥ 9,549	\$ 40,902

	YEN		U.S. DOLLARS (NOTE 1)
	2023	2022	2023
PER SHARE DATA:			
Profit (Note 23):			
Basic	¥144.80	¥251.43	\$ 1.09
Diluted	—	—	—
Cash dividends applicable to the year (Note 12)	¥150.00	¥150.00	\$ 1.13

See accompanying Notes to the Consolidated Financial Statements.

## Consolidated Statements of Comprehensive Income

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiaries  
For the years ended March 31, 2023 and 2022

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
PROFIT	¥ 5,440	¥ 9,549	\$ 40,902
OTHER COMPREHENSIVE INCOME (LOSS) (Note 24):			
Net unrealized holding gain (loss) on securities	172	(187)	1,293
Remeasurements of defined benefit plans	(136)	202	(1,023)
Total other comprehensive income (loss)	35	14	263
COMPREHENSIVE INCOME	¥ 5,475	¥ 9,563	\$ 41,165
Total comprehensive income attributable to:			
Owners of the Company	¥ 5,475	¥ 9,563	\$ 41,165

See accompanying Notes to the Consolidated Financial Statements.



# Consolidated Statements of Changes in Net Assets

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiaries  
For the years ended March 31, 2023 and 2022

MILLIONS OF YEN										
	SHAREHOLDERS' EQUITY					ACCUMULATED OTHER COMPREHENSIVE INCOME			Non-controlling Interests	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, 2021	¥ 23,853	¥11,406	¥122,462	¥ (26,304)	¥131,418	¥ 4,739	¥ 99	¥ 4,839	¥ —	¥136,257
Cumulative effect of changes in accounting policies			51		51					51
Restated balance	23,853	11,406	122,514	(26,304)	131,470	4,739	99	4,839	—	136,309
Changes during the year:										
Cash dividends			(5,716)		(5,716)					(5,716)
Profit attributable to owners of the Company			9,549		9,549					9,549
Purchase of treasury stock				(2,414)	(2,414)					(2,414)
Disposal of treasury stock		0		5	5					5
Other, net						(187)	202	14	578	593
Total changes during the year	—	0	3,833	(2,409)	1,423	(187)	202	14	578	2,016
BALANCE—March 31, 2022	¥ 23,853	¥11,406	¥126,347	¥ (28,714)	¥132,893	¥ 4,551	¥ 301	¥ 4,853	¥ 578	¥138,325
Changes during the year:										
Cash dividends			(5,652)		(5,652)					(5,652)
Profit attributable to owners of the Company			5,440		5,440					5,440
Purchase of treasury stock				(1,340)	(1,340)					(1,340)
Disposal of treasury stock				27	27					27
Other, net						172	(136)	35	—	35
Total changes during the year	—	—	(211)	(1,312)	(1,524)	172	(136)	35	—	(1,489)
BALANCE—March 31, 2023	¥ 23,853	¥ 11,406	¥126,135	¥ (30,026)	¥131,368	¥ 4,724	¥ 165	¥ 4,889	¥ 578	¥136,836

THOUSANDS OF U.S. DOLLARS (NOTE 1)										
	SHAREHOLDERS' EQUITY					ACCUMULATED OTHER COMPREHENSIVE INCOME			Non-controlling Interests	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, 2022	\$ 179,346	\$ 85,759	\$ 949,977	\$ (215,895)	\$ 999,195	\$ 34,218	\$ 2,263	\$ 36,489	\$ 4,346	\$1,040,038
Changes during the year:										
Cash dividends			(42,496)		(42,496)					(42,496)
Profit attributable to owners of the Company			40,902		40,902					40,902
Purchase of treasury stock				(10,075)	(10,075)					(10,075)
Disposal of treasury stock				203	203					203
Other, net						1,293	(1,023)	263	—	263
Total changes during the year	—	—	(1,586)	(9,865)	(11,459)	1,293	(1,023)	263	—	(11,195)
BALANCE—March 31, 2023	\$ 179,346	\$ 85,759	\$ 948,383	\$ (225,759)	\$ 987,729	\$ 35,519	\$ 1,241	\$ 36,759	\$ 4,346	\$1,028,842

See accompanying Notes to the Consolidated Financial Statements.

# Consolidated Statements of Cash Flows

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiaries  
For the years ended March 31, 2023 and 2022

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
CASH FLOWS FROM OPERATING ACTIVITIES:			
Profit before income taxes	¥ 6,817	¥ 13,885	\$ 51,256
Adjustments for:			
Depreciation	2,546	2,481	19,143
Impairment losses	1,863	2,994	14,008
Amortization of goodwill	22	5	165
Increase (decrease) in net defined benefit liability	(77)	(44)	(579)
Interest and dividends income	(439)	(397)	(3,301)
Interest expenses	17	17	128
Loss on investment in investment partnership	27	—	203
Loss (gain) on sale of investment securities	(1)	(1)	(8)
Loss on retirement of non-current assets	48	97	361
Loss (gain) on sale of property, plant and equipment	(0)	(195)	(0)
Decrease (increase) in notes and accounts receivable—trade	972	392	7,308
Decrease (increase) in inventories	(583)	241	(4,383)
Increase (decrease) in trade payables	280	(2,630)	2,105
Other, net	1,746	542	13,128
Subtotal	13,240	17,387	99,549
Interest and dividends income received	439	397	3,301
Interest expenses paid	(17)	(17)	(128)
Income taxes (paid) refund, net	(4,409)	(4,431)	(33,150)
Net cash provided by (used in) operating activities	9,253	13,336	69,571
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property, plant and equipment	(1,987)	(2,986)	(14,940)
Proceeds from sale of property, plant and equipment	12	704	90
Purchase of intangible assets	(219)	(271)	(1,647)
Purchase of investment securities	(200)	—	(1,504)
Proceeds from sale of investment securities	5	5	38
Purchase of shares of subsidiaries resulting in change in the scope of consolidation	—	(4,975)	—
Other, net	(237)	(365)	(1,782)
Net cash provided by (used in) investing activities	(2,627)	(7,888)	(19,752)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Net decrease (increase) in treasury stock	(1,340)	(2,414)	(10,075)
Cash dividends paid	(5,649)	(5,714)	(42,474)
Net cash provided by (used in) financing activities	(6,990)	(8,129)	(52,556)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(364)	(2,680)	(2,737)
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	74,625	77,305	561,090
CASH AND CASH EQUIVALENTS AT END OF YEAR (Note 3)	¥ 74,260	¥ 74,625	\$ 558,346

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 subsidiaries (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.

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 ¥133= U.S.\$1.00, the approximate rate of exchange prevailing on March 31, 2023. 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 subsidiaries. For the year ended March 31, 2023, the Company had two consolidated subsidiaries as follows:

KAKEN PHARMA CO., LTD.  
ARTham Therapeutics Inc.

For the years ended March 31, 2023 and 2022, there were no affiliates 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 generally stated at cost determined by

the moving average method.

Investments in investment limited partnerships and other similar partnerships (deemed to be marketable securities under Article 2 (2) of the Financial Instruments and Exchange Act), are recorded at the net amount equivalent to the Company's equity interest based on the most recent financial statements available as of the financial reporting date stipulated in the partnership agreement.

### (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 mainly 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 for internal use (5 years) using the straight-line method.

In-process research and development is amortized using the straight-line method over the estimated useful life of the product being developed, once the product can be used.

### (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 in accounts receivable, etc., allowance for doubtful accounts is provided according to individual analysis of recoverability for specific doubtful receivables such as debt with a possibility of default, based on the historical write-off rate for ordinary receivables

### (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 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 award obligations as of the balance sheet date.

### (k) Retirement and Pension Plan

The Company applies the benefit formula basis in attributing estimated retirement benefits to periods up to the end of the fiscal year under review.

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

### (l) 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.

(m) Accounting Standards for Significant Revenue and Expenses

The main performance obligations in significant businesses related to revenue from contracts with customers of the Group, and the point in time when said performance obligations are normally satisfied (the point when revenue is normally recognized), are as follows.

(1) Sale of merchandise and finished products

For Pharmaceuticals, the Group conducts sales primarily by manufacturing or wholesale distribution. When selling such merchandise and finished products, the Group has an obligation to deliver based on the sales contract with the customer. This performance obligation is deemed to be satisfied when the merchandise or finished product is delivered to the customer and the customer acquires control of the merchandise or finished product, and revenue is recognized at the time of delivery. For domestic sales of merchandise and finished products, revenue is recognized at the time of shipment if the period from shipment until transfer of control of the merchandise or finished product to the customer is a normal period of time.

For transactions in which the Group is involved in the sale of merchandise as an agent, the net amount is recognized as revenue.

(2) License agreements for sale, etc. of finished products

For Pharmaceuticals, the Group enters into contracts for the transfer of intellectual property rights or for technology out-licensing, etc., and for royalties. For contracts for the transfer of intellectual property rights or technology out-licensing, etc., the Group has a performance obligation based on the contract with the customer, and revenue is recognized when the performance obligation is satisfied by granting the rights to the customer. For royalty contracts, a calculation is performed based on customer sales, etc., and revenue is recognized after taking into consideration the timing of the sales.

(n) Derivative Financial Instruments and Hedge Accounting

Derivative instruments, which include forward foreign exchange contracts, are used as a part of the Company's management of the 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) Methods of assessing hedge effectiveness

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

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

(o) Amortization Method and Amortization Period of Goodwill

Goodwill is amortized by the straight line method over 14 years.

(p) Significant Accounting Estimates

In-Process Research and Development and Valuation of Goodwill

(1) Amounts recorded in the consolidated financial statements for the years ended March 31, 2023 and 2022 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
In-process research and development	¥5,800	¥7,300	\$43,609
Goodwill	230	312	1,729

(2) Details of significant accounting estimates related to identified items

a. Method of calculating amounts recorded in the consolidated financial statements for the year ended March 31, 2023

Measurement of in-process research and development and goodwill is done mainly using the excess earnings method. Decisions on recognition of impairment losses on in-process research and development and goodwill are based on whether the total amount of undiscounted future cash flows of each development program has fallen below the carrying amount. In the year ended March 31, 2023, because the total amount of undiscounted future cash flows of the asset group targeting bullous pemphigoid fell below the carrying amount, an impairment loss was recorded to reduce the carrying amount to the recoverable amount.

b. Key assumptions used in calculating amounts recorded in the consolidated financial statements for the year ended March 31, 2023

Key assumptions used in estimating future cash flows and the discount rate are based on business plans, etc. that the Group has formulated.

c. Impact on consolidated financial statements for the following fiscal year

Any changes in these estimates and assumptions necessitated by changes in the business environment could have a significant impact on the valuation of in-process research and development and goodwill.

**(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) Changes in Accounting Policies**

Accounting Standard for Fair Value Measurement

The Company has applied the "Implementation Guidance on Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 31, June 17, 2021) from the beginning of the year ended March 31, 2023. The Company will apply the new accounting policies set forth in the Guidance prospectively, in accordance with the transitional treatment stipulated in paragraph 27-2 of the same Guidance. The effect of this change on the consolidated financial statements is immaterial.

**(u) New Accounting Standards Not Yet Adopted**

Accounting Standards for Income Taxes, etc.

- Accounting Standard for Current Income Taxes (ASBJ Statement No. 27, revised October 28, 2022)
- Accounting Standard for Presentation of Comprehensive Income (ASBJ Statement No. 25, revised October 28, 2022)
- Implementation Guidance on Accounting Standard for Tax Effect Accounting (ASBJ Guidance No. 28, October 28, 2022)

**(1) Overview**

The above standards define the accounting classification of income taxes and other taxes when other comprehensive income is taxable, and the handling of tax effects related to the sale of shares of subsidiaries or affiliates when the group taxation regime is applied.

**(2) Scheduled date of application**

The above standards and guidance are scheduled to be applied from the beginning of the year ending March 31, 2025.

**(3) Effects of application of the standards**

The effects of the application were under assessment when these consolidated financial statements were being prepared.

Practical Solution on the Accounting for and Disclosure of the Issuance and Holding of Electronically Recorded Transferable Rights That Must Be Indicated on Securities, etc. (ASBJ Practical Issue Task Force (PITF) No. 43, August 26, 2022)

**(1) Overview**

The above practical solution prescribes the accounting treatment and handling of disclosure when issuing or holding "electronically recorded transferable rights that must be indicated on securities, etc." as defined in Article 1, paragraph 4, item 17 of the Cabinet Office Ordinance on Financial Instruments Business, etc. (Cabinet Office Ordinance No. 52 of 2007).

**(2) Scheduled date of application**

The above accounting standard is scheduled to be applied from the beginning of the year ending March 31, 2024.

**(3) Effects of application of the accounting standard**

The effects of the application were under assessment when these consolidated financial statements were being prepared.

**(v) Changes in Presentation**

Consolidated Statements of Income

"Subsidy income," which was included in "Other, net" in "Other income (expenses)" for the year ended March 31, 2022, is presented as a discrete line item for the year ended March 31, 2023 because it exceeded 10% of the total of "Other income (expenses)." The consolidated financial statements for the year ended March 31, 2022 have been restated to reflect this change in presentation.

As a result, ¥146 million that was presented in "Other, net" in "Other income (expenses)" in the consolidated statements of income for the year ended March 31, 2022 is restated as "Subsidy income" of ¥37 million and "Other, net" of ¥109 million.

"Loss on cancellation of leases," which was presented as a discrete line item in "Other income (expenses)" in the consolidated statements of income for the year ended March 31, 2022, is included in "Other, net" in "Other income (expenses)" for the year ended March 31, 2023 because it fell below 10% of the total of "Other income (expenses)." The consolidated financial statements for the year ended March 31, 2022 have been restated to reflect this change in presentation.

As a result, "Loss on cancellation of leases" of ¥7 million and "Other, net" of ¥9 million that were presented in "Other income (expenses)" in the year ended March 31, 2022 are restated as "Other, net" of ¥17 million.

**(w) Additional Information**

Introduction of the Board Benefit Trust ("BBT")

Based on the resolution of the 99th ordinary general meeting of shareholders held on June 27, 2019, the Company 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.") with the aim of enhancing their awareness of improving medium- to long-term performance and contributing to an increase in 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 (the trust established pursuant to the Plan hereinafter referred to as the “Trust”), and the Company’s shares and cash equivalents of such shares at their market value (hereinafter “the Company’s shares, etc.”) are granted through the Trust to the directors, etc. pursuant to the rules on share distribution to officers established by the Company.

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

(2) Company 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, 2023, the carrying amount and the number of shares of treasury stock were ¥182 million (\$1,368 thousand) and 33,400 shares, respectively. As of March 31, 2022, the carrying amount and the number of shares of treasury stock were ¥210 million and 38,500 shares, respectively.

### 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)
	2023	2022	2023
Cash and deposits	¥59,561	¥61,025	\$447,827
Marketable securities	14,699	13,599	110,519
Subtotal	¥74,260	¥74,625	\$558,346
Time deposits due after three months	—	—	—
Marketable securities due after three months	—	—	—
Cash and cash equivalents	¥74,260	¥74,625	\$558,346

### 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)
	2023			2022		
Fair values exceeding carrying amounts	¥ —	¥ —	¥—	¥ —	¥ —	¥—
Fair values not exceeding carrying amounts	11,999	11,999	—	10,999	10,999	—
Total	¥11,999	¥11,999	¥—	¥10,999	¥10,999	¥—

	THOUSANDS OF U.S. DOLLARS (NOTE 1)		
	Carrying amount	Fair value	Unrealized gain (loss)
	2023		
Fair values exceeding carrying amounts	\$ —	\$ —	\$—
Fair values not exceeding carrying amounts	90,218	90,218	—
Total	\$90,218	\$90,218	\$—

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)
	2023			2022		
Carrying amounts exceeding acquisition costs						
Equity securities	¥13,713	¥ 6,367	¥7,345	¥13,522	¥ 6,719	¥6,802
Other	—	—	—	—	—	—
Subtotal	13,713	6,367	7,345	13,522	6,719	6,802
Carrying amounts not exceeding acquisition costs						
Equity securities	3,547	4,084	(536)	3,493	3,735	(241)
Other	2,700	2,700	—	2,600	2,600	—
Subtotal	6,247	6,784	(536)	6,093	6,335	(241)
Total	¥19,961	¥13,151	¥6,809	¥19,616	¥13,055	¥6,560

	THOUSANDS OF U.S. DOLLARS (NOTE 1)		
	Fair value	Acquisition cost	Unrealized gain (loss)
	2023		
Carrying amounts exceeding acquisition costs			
Equity securities	\$103,105	\$47,872	\$55,226
Other	—	—	—
Subtotal	103,105	47,872	55,226
Carrying amounts not exceeding acquisition costs			
Equity securities	26,669	30,707	(4,030)
Other	20,301	20,301	—
Subtotal	46,970	51,008	(4,030)
Total	\$150,083	\$98,880	\$51,195

Available-for-sale securities sold for the years ended March 31, 2023 and 2022 are summarized as follows:

	MILLIONS OF YEN					
	Proceeds	Gain	Loss	Proceeds	Gain	Loss
	2023			2022		
Equity securities	¥5	¥1	¥—	¥5	¥1	¥—
Total	¥5	¥1	¥—	¥5	¥1	¥—

	THOUSANDS OF U.S. DOLLARS (NOTE 1)		
	Proceeds	Gain	Loss
	2023		
Equity securities	\$38	\$8	\$—
Total	\$38	\$8	\$—

## 5. Inventories

Inventories as of March 31, 2023 and 2022 comprised the following:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
Merchandise and finished products	¥ 6,734	¥ 5,807	\$ 50,632
Work in process	2,481	2,964	18,654
Raw materials and supplies	6,348	6,209	47,729
Total	¥15,564	¥14,981	\$117,023

## 6. Short-term Bank Loans and Pledged Assets

### (a) Short-term bank loans

Short-term bank loans outstanding as of March 31, 2023 and 2022, amounting to ¥3,850 million (\$28,947 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, 2023 and 2022 was 0.45%.

### (b) Pledged assets

As of March 31, 2023 and 2022, assets pledged as collateral for certain short-term bank loans are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
Assets pledged:			
Buildings and structures	¥6,134	¥6,433	\$46,120
Machinery, equipment and vehicles	2,690	2,207	20,226
Tools, furniture and fixtures	1,041	807	7,827
Land	117	117	880
Total	¥9,984	¥9,565	\$75,068
Liabilities secured:			
Short-term bank loans	¥1,400	¥1,400	\$10,526
Total	¥1,400	¥1,400	\$10,526

## 7. Accounting for Leases

### Operating leases

(As a lessor)

Future minimum lease payments receivable under non-cancellable operating leases subsequent to March 31, 2023 and 2022 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
Due within 1 year	¥ 949	¥ 949	\$ 7,135
Due after 1 year	3,276	4,094	24,632
Total	¥4,226	¥5,043	\$31,774

## 8. Contract Assets and Liabilities

(a) Among “Notes receivable—trade,” “Accounts receivable—trade,” and “Contract assets,” the amounts of credits and contract assets arising from contracts with customers are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023		
Notes receivable—trade	¥ 282		\$ 2,120
Accounts receivable—trade	18,607		139,902
Contract assets	379		2,850

(b) Among “Other,” the amounts of contract liabilities are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023		
Contract liabilities	¥100		\$752

## 9. 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, 2023 and 2022 was ¥1,290 million (\$9,699 thousand) and ¥1,353 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, 2023 and 2022, and fair value of these properties as of those dates are stated as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
Carrying amount:			
Balance at the beginning of the year	¥10,347	¥10,162	\$ 77,797
Changes during the year	(299)	184	(2,248)
Balance at the end of the year	10,047	10,347	75,541
Fair value at the end of the year	¥51,010	¥50,408	\$383,534

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

2. Fair value at the end of the year is calculated based on real estate appraisal reports issued by external real estate appraisers. If there have been no material changes in an appraisal value and applicable indices that are considered to appropriately reflect market values, since the time of acquisition or the most recent valuation, the fair value at the end of the year is adjusted using such an appraisal value and applicable indices.

## 10. 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 customer 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 one year or less. 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.

The only derivative transactions used by the Company are forward foreign exchange contracts for the purpose of hedging the foreign exchange fluctuation risk of trade receivables and trade payables denominated in foreign currencies. Please see Note 2. “Summary of Significant Accounting Policies” for details regarding hedging instruments, hedged items, hedging policy and methods of assessing hedge effectiveness.

### (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 relevant department, according to the credit management rules, manages payment terms and balances of each major customer by regularly monitoring their status, in an effort to achieve early identification and mitigation of customer default risk arising from the deterioration of their 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 banks and other financial institutions to mitigate the counterparty risk.

The maximum credit risk exposure of financial assets as of March 31, 2023 is limited to the carrying amounts of the financial assets on the consolidated balance sheets.

#### 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 periodically monitors fair values and financial positions of the related issuers (business counterparties), etc. For securities other than held-to-maturity debt securities, the Company continuously reviews its holdings status by taking into account the relationships with the business counterparties.

Derivative transactions are conducted under the authority of the general manager at each relevant 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 relevant 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 relevant departments. The consolidated subsidiaries are not engaged in derivative transactions.

#### c. Liquidity risk management on fund-raising (risk of delinquency)

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 relevant department.

### (4) Supplementary explanation concerning fair values of financial instruments

Since variable factors are incorporated in computing the fair values of financial instruments, such fair values may vary depending on the initial premises.

### (5) Concentration of credit risks

As of March 31, 2023, 59% of all trade receivables was with specific major accounts.

### (b) Fair Values of Financial Instruments

The carrying amount, fair value and net unrealized gains/losses of financial instruments are as follows:

	MILLIONS OF YEN		
	Carrying amount	Fair value	Unrealized gain (loss)
March 31, 2023	2023		
Marketable and investment securities and other available-for-sale securities	¥19,961	¥19,961	¥—
Asset total	¥19,961	¥19,961	¥—

Notes: 1. Cash and deposits, marketable securities (held-to-maturity debt securities), notes receivable–trade, accounts receivable–trade, notes and accounts payable–trade, electronically recorded obligations–operating, and short-term bank loans are excluded from the table above as their carrying amounts approximate fair value because they are cash or have short maturities.  
2. Securities with no quoted market price available are not included in “Marketable and investment securities and other available-for-sale securities.” The carrying amounts of such financial instruments are as follows.

MILLIONS OF YEN	
	2023
Unlisted equity securities	¥ 77
Investment in investment limited partnership	172

	THOUSANDS OF U.S. DOLLARS (NOTE 1)		
	Carrying amount	Fair value	Unrealized gain (loss)
March 31, 2023	2023		
Marketable and investment securities and other available-for-sale securities	\$150,083	\$150,083	\$—
Asset total	\$150,083	\$150,083	\$—

THOUSANDS OF U.S. DOLLARS (NOTE 1)	
	2023
Unlisted equity securities	\$ 579
Investment in investment limited partnership	1,293

	MILLIONS OF YEN		
	Carrying amount	Fair value	Unrealized gain (loss)
March 31, 2022	2022		
Marketable and investment securities and other available-for-sale securities	¥ 19,616	¥ 19,616	¥—
Asset total	¥ 19,616	¥ 19,616	¥—

Notes: 1. Cash and deposits, marketable securities (held-to-maturity debt securities), notes and accounts receivable–trade, notes and accounts payable–trade, electronically recorded obligations–operating, and short-term bank loans are excluded from the table above as their carrying amounts approximate fair value because they are cash or have short maturities.  
2. Carrying amounts of financial instruments whose fair values are extremely difficult to determine.

MILLIONS OF YEN

	2022
Unlisted equity securities	¥77

Note: The above securities are not included in "Marketable and investment securities" because no quoted market price is available and it is extremely difficult to determine their fair value.

Redemption schedules of monetary assets and securities with contractual maturities subsequent to March 31, 2023 and 2022 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	Due within one year		
	2023	2022	2023
Cash and deposits	¥59,561	¥61,025	\$447,827
Notes receivable—trade	282	331	2,120
Accounts receivable—trade	18,607	19,651	139,902
Marketable and investment securities			
Held-to-maturity debt securities	11,999	10,999	90,218
Available-for-sale securities with contractual maturities	2,700	2,600	20,301
Total	¥93,150	¥94,608	\$700,376

Redemption schedules for bonds, long-term borrowings, lease obligations and other interest-bearing debt are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	Due within one year		
	2023	2022	2023
Short-term bank loans	¥3,850	¥3,850	\$28,947
Total	¥3,850	¥3,850	\$28,947

### (c) Fair Values of Financial Instruments by Level

The fair values of financial instruments are categorized into the following three levels according to the observability and significance of the inputs used in the fair value measurement.

Level 1: Fair value measured using observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets

Level 2: Fair value measured using observable inputs other than Level 1 inputs

Level 3: Fair value measured using unobservable inputs

If multiple inputs are used that are significant to the fair value measurement, the fair value measurement is categorized in its entirety in the level of the lowest level input that is significant to the entire measurement.

### (1) Financial Instruments Reported on the Consolidated Balance Sheet at Fair Value

MILLIONS OF YEN

	2023			
	Fair value			
	Level 1	Level 2	Level 3	Total
Marketable and investment securities and other available-for-sale securities				
Equity securities	¥17,261	¥ —	¥—	¥17,261
Other securities	—	2,700	—	2,700
Asset total	¥17,261	¥2,700	¥—	¥19,961

THOUSANDS OF U.S. DOLLARS (NOTE 1)

	2023			
	Fair value			
	Level 1	Level 2	Level 3	Total
Marketable and investment securities and other available-for-sale securities				
Equity securities	\$129,782	\$ —	\$—	\$129,782
Other securities	—	20,301	—	20,301
Asset total	\$129,782	\$20,301	\$—	\$150,083

Note: Description of valuation methods and inputs used in the fair value measurement

Marketable and investment securities

Listed equity securities are valued using quoted market prices. As listed equity securities are traded in active markets, their fair value is categorized in Level 1. However, the fair values of other available-for-sale securities held by the Company (negotiable certificates of deposit) are categorized in Level 2 as they are not considered to be quoted market prices in active markets due to the low frequency of trading.

### 11. Retirement Benefits

The Company has defined benefit plans, namely, a lump-sum retirement plan and a 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 to calculate KAKEN PHARMA CO., LTD.'s retirement benefit obligation. ARTham Therapeutics Inc. does not have a retirement benefit plan.

#### Defined benefit plans

(a) Changes in the retirement benefit obligation for the years ended March 31, 2023 and 2022 are as follows (excluding plans in which the simplified method is applied):

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
Retirement benefit obligation—Beginning balance	¥18,451	¥19,021	\$138,729
Service cost	671	694	5,045
Interest cost	55	57	414
Actuarial gain or loss	9	(102)	68
Retirement benefit paid	(1,141)	(1,219)	(8,579)
Retirement benefit obligation—Ending balance	¥18,045	¥18,451	\$135,677



(b) Changes in the plan assets for the years ended March 31, 2023 and 2022 are as follows (excluding plans in which the simplified method is applied):

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
Plan assets—Beginning balance	¥13,411	¥13,644	\$100,835
Expected return on plan assets	319	323	2,398
Actuarial gain or loss	(278)	75	(2,090)
Employer's contributions	157	162	1,180
Retirement benefit paid	(723)	(794)	(5,436)
Plan assets—Ending balance	¥12,886	¥13,411	\$ 96,887

(c) Changes in the net defined benefit liability for the years ended March 31, 2023 and 2022 in which the simplified method is applied as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
Net defined benefit liability—Beginning balance	¥—	¥—	\$—
Retirement benefit cost	0	—	0
Net defined benefit liability—Ending balance	¥ 0	¥—	\$ 0

(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)
	2023	2022	2023
Retirement benefit obligation under funded plan	¥18,045	¥18,451	\$135,677
Plan assets	(12,886)	(13,411)	(96,887)
	5,159	5,039	38,789
Retirement benefit obligation under unfunded plan	0	—	0
Net liability recorded on the consolidated balance sheets	5,159	5,039	38,789
Net defined benefit liability	6,349	5,039	47,737
Net liability recorded on the consolidated balance sheets	¥ 5,159	¥ 5,039	\$ 38,789

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 in which simplified method is applied is included.  
3. Assets related to retirement benefits of ¥1,190 million (\$8,947 thousand) are recorded in "Other assets" in "Investments and other assets" on the consolidated balance sheets for the year ended March 31, 2023.

(e) Net periodic pension cost and its components are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
Service cost	¥ 671	¥ 694	\$ 5,045
Interest cost	55	57	414
Expected return on plan assets	(319)	(323)	(2,398)
Amortization of actuarial gain or loss	90	120	677
Amortization of prior service cost	—	(5)	—
Net periodic pension cost under simplified method	0	—	0
Net periodic pension cost for defined benefit plans	¥ 497	¥ 542	\$ 3,737

(f) The components of remeasurements of defined benefit plans in other comprehensive income (before tax effect) for the years ended March 31, 2023 and 2022 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
Prior service cost	¥ —	¥ (5)	\$ —
Actuarial gain or loss	(197)	297	(1,481)
Total	¥ (197)	¥292	\$(1,481)

(g) The components of remeasurements of defined benefit plans in accumulated other comprehensive income (before tax effect) as of March 31, 2023 and 2022 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
Unrecognized actuarial gain or loss	¥(237)	¥(435)	\$(1,782)
Total	¥(237)	¥(435)	\$(1,782)

(h) Plan assets

(1) Plan assets consist of the following:

	2023	2022
Debt securities	43%	44%
Equity securities	40	37
General account	12	12
Other	5	7
Total	100%	100%

Note: The plan assets include retirement benefit trust which accounted for 6% and 5% of the total plan assets as of March 31, 2023 and 2022, 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):

	2023	2022
Discount rate	0.3%	0.3%
Long-term expected rate of return	2.5%	2.5%

## 12. 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, 2022	45,939,730	8,121,361
Increase	—	350,519
Decrease	—	(5,100)
Number of shares as of March 31, 2023	45,939,730	8,466,780

Notes:

1. Increase in treasury stock (350,519 shares) is due to purchase of shares through the market (350,000 shares) based on the resolution of the Board of Directors' meeting and purchase of shares of less than one unit (519 shares).
2. Decrease in treasury stock (5,100 shares) is due to placement of Company stock in the Board Benefit Trust (BBT).
3. The number of shares of treasury stock includes Company shares held by Custody Bank of Japan, Ltd. (Trust Account E) as trust assets of the BBT (33,400 shares as of March 31, 2023 and 38,500 shares as of April 1, 2022).

### (b) Matters related to dividends

#### (1) Dividend payment

The following payment was approved at the general meeting of shareholders held on June 29, 2022:

Dividends on common stock	
Total amount of dividends	¥2,839 million (\$21,346 thousand)
Dividends per share	¥75.00 (\$0.56)
Record date	March 31, 2022
Effective date	June 30, 2022

The following payment was approved at the Board of Directors' meeting held on November 8, 2022:

Total amount of dividends	¥2,812 million (\$21,143 thousand)
Dividends per share	¥75.00 (\$0.56)
Record date	September 30, 2022
Effective date	November 30, 2022

Notes:

1. Total amount of dividends approved at the ordinary general meeting of shareholders on June 29, 2022 includes ¥2 million (\$15 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.
2. Total amount of dividends approved at the Board of Directors' meeting on November 8, 2022 includes ¥2 million (\$15 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.

(2) Dividends whose record date is attributed to the year ended March 31, 2023 but which become effective after March 31, 2023

Approval at the ordinary general meeting of shareholders held on June 29, 2023 was as follows:

Dividends on common stock	
Total amount of dividends	¥2,812 million (\$21,143 thousand)
Source of dividends	Retained earnings
Dividends per share	¥75.00 (\$0.56)
Record date	March 31, 2023
Effective date	June 30, 2023

Note: Total amount of dividends includes ¥2 million (\$15 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.

## 13. Research and Development Costs

Research and development costs included in manufacturing costs and selling, general and administrative expenses for the years ended March 31, 2023 and 2022 amounted to ¥15,789 million (\$118,714 thousand) and ¥8,420 million, respectively.

## 14. Loss on Revaluation of Inventories

The ending balance of inventories is the amount after writing down book values based on decreased profitability, and the following loss on revaluation of inventories is included in cost of sales. The amounts at March 31, 2023 and 2022 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
	¥42	¥320	\$316

## 15. Gain on Sale of Non-Current Assets

Gain on sale of non-current assets for the years ended March 31, 2023 and 2022 consists of the following:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
Buildings and structures	¥—	¥117	\$—
Tools, furniture and fixtures	2	0	15
Land	—	77	—
Total	¥ 2	¥195	\$15

## 16. Loss on Sale of Non-Current Assets

Loss on sale of non-current assets for the years ended March 31, 2023 and 2022 consists of the following:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
Machinery, equipment and vehicles	¥1	¥—	\$8
Total	¥1	¥—	\$8

## 17. Loss on Retirement of Non-Current Assets

Loss on retirement of non-current assets for the years ended March 31, 2023 and 2022 consists of the following:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
Buildings and structures	¥ 5	¥ 8	\$ 38
Other	43	88	323
Total	¥48	¥97	\$361



18. Impairment Losses

The Group recognized impairment loss for the following asset groups for the year ended March 31, 2023:

MILLIONS OF YEN			
Location	Use	Type	Impairment loss
Fujieda, Shizuoka Pref.	Production facilities	Buildings and structures	¥ 304
Bunkyo-ku, Tokyo	Business assets	In-process research and development	1,559
THOUSANDS OF U.S. DOLLARS			
Location	Use	Type	Impairment loss
Fujieda, Shizuoka Pref.	Production facilities	Buildings and structures	\$ 2,286
Bunkyo-ku, Tokyo	Business assets	In-process research and development	11,722

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.

For buildings and structures, the carrying amount is reduced to the recoverable amount based on the resolution on reconstruction approved by the Board of Directors on April 27, 2022, and the ¥48 million (\$361 thousand) decrease in buildings and structures and ¥255 million (\$1,917 thousand) in dismantlement costs are accounted for as impairment losses in “Other income (expenses).”

The recoverable amount is measured using the utility value and calculated as the depreciation expense equivalent for the period of expected production.

For in-process research and development, the carrying amount is reduced to the recoverable amount based on the resolution for termination of development of a bullous pemphigoid treatment approved by the Board of Directors on April 12, 2023. The resulting decrease of ¥1,500 million (\$11,278 thousand) in in-process research and development and decrease of ¥59 million (\$444 thousand) in goodwill are accounted for as impairment losses in “Other income (expenses).”

The recoverable amount is measured using the utility value. However, the utility value of asset groups that are not expected to be valued based on future cash flows is estimated to be zero.

The Group recognized impairment loss for the following asset group for the year ended March 31, 2022:

MILLIONS OF YEN			
Location	Use	Type	Impairment loss
Bunkyo-ku, Tokyo	Exclusive rights to pharmaceutical distribution	Long-term prepaid expenses (distribution rights, etc.)	¥ 2,994

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

As future cash flow from the distribution rights of the above asset group is no longer expected due to changes in business conditions, the utility value is estimated to be zero, and an impairment loss equal to the carrying amount is recorded.

19. Contract Losses

Year ended March 31, 2023  
Not applicable

Year ended March 31, 2022

To avoid risks associated with changes in the business environment, the Company recognized a ¥762 million contract loss due to accelerated amortization of manufacturing equipment costs at a contract manufacturer as a special loss in the year ended March 31, 2022.

20. Income Taxes

The significant components of deferred tax assets and liabilities as of March 31, 2023 and 2022 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
Deferred tax assets:			
Tax loss carryforwards	¥ 296	¥ 226	\$ 2,226
Loss on valuation of inventories	56	98	421
Disallowed expensed supplies	401	305	3,015
Contract loss	167	176	1,256
Adjustment of gain on sales of land	2,638	2,638	19,835
Amortization of research & development expenses	2,577	307	19,376
Amortization of long-term prepaid expenses	594	774	4,466
Provision for bonuses	290	303	2,180
Net defined benefit liability	1,823	1,843	13,707
Impairment losses	1,010	916	7,594
Other	300	358	2,256
Total	10,158	7,950	76,376
Valuation allowance for tax loss carryforwards	(296)	(226)	(2,226)
Valuation allowance	(3,720)	(3,798)	(27,970)
Total	(4,017)	(4,024)	(30,203)
Deferred tax assets	6,140	3,925	46,165
Deferred tax liabilities:			
Reserve for advanced depreciation of non-current assets	(182)	(191)	(1,368)
Net unrealized holding gain on securities	(2,084)	(2,008)	(15,669)
In-process research and development	(1,771)	(2,229)	(13,316)
Deferred tax liabilities	(4,038)	(4,429)	(30,361)
Deferred tax assets, net	¥ 2,102	¥ (503)	\$ 15,805

Note:  
Tax loss carryforwards, valuation allowance and deferred tax assets by expiration of carryforwards as of March 31, 2023 and 2022 are as follows:

	MILLIONS OF YEN						
	Within 1 year	Between 1 and 2 years	Between 2 and 3 years	Between 3 and 4 years	Between 4 and 5 years	Beyond 5 years	Total
	2023						
Tax loss carryforwards	¥—	¥—	¥—	¥—	¥—	¥ 296	¥ 296
Valuation allowance	—	—	—	—	—	(296)	(296)
Deferred tax assets	—	—	—	—	—	—	—

Note: Tax loss carryforwards are measured using the effective statutory tax rates.

	MILLIONS OF YEN						Total
	Within 1 year	Between 1 and 2 years	Between 2 and 3 years	Between 3 and 4 years	Between 4 and 5 years	Beyond 5 years	
	2022						
Tax loss carryforwards	¥—	¥—	¥—	¥—	¥—	¥ 226	¥ 226
Valuation allowance	—	—	—	—	—	(226)	(226)
Deferred tax assets	—	—	—	—	—	—	—

Note: Tax loss carryforwards are measured using the effective statutory tax rates.

	THOUSANDS OF U.S. DOLLARS (NOTE 1)						Total
	Within 1 year	Between 1 and 2 years	Between 2 and 3 years	Between 3 and 4 years	Between 4 and 5 years	Beyond 5 years	
	2023						
Tax loss carryforwards	\$—	\$—	\$—	\$—	\$—	\$ 2,226	\$ 2,226
Valuation allowance	—	—	—	—	—	(2,226)	(2,226)
Deferred tax assets	—	—	—	—	—	—	—

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, 2023 and 2022. Reconciliation of the differences between the statutory tax rate and the effective tax rate for the years ended March 31, 2023 and 2022 is as follows:

	2023	2022
Statutory tax rate	30.62%	30.62%
Increase (decrease) in taxes resulting from:		
Expenses not deductible for income tax purpose (e.g. entertainment expenses)	0.24	0.07
Income not included for income tax purpose (e.g. dividend income)	(0.40)	(0.18)
Inhabitant per capita taxes	0.97	0.51
Tax credit for research expenses	(9.98)	(5.94)
Change in valuation allowance	(0.27)	721
Other	(0.98)	(1.06)
Effective tax rate	20.20%	31.23%

## 21. Revenue Recognition

### 1. Revenue from Contracts with Customers

The breakdown of revenue from contracts with customers is presented in “25. Segment Information.”

### 2. Basis for Understanding Revenue from Contracts with Customers

The Group recognizes revenue based on the following five-step approach.

Step 1: Step 1: Identify the contract with a customer.

Step 2: Identify the separate performance obligations in the contract.

Step 3: Determine the transaction price.

Step 4: Allocate portions of the transaction price to the separate performance obligations in the contract.

Step 5: Recognize revenue when (or as) each performance obligation is satisfied.

#### (a) Sale of merchandise and finished goods

Revenue from sale of merchandise and finished goods is primarily a result of sales from manufacturing or wholesaling, and where performance obligations to deliver such goods are based on the sales contract with the customer. These performance obligations are deemed to be satisfied when control of the goods is transferred to

the customer, whereupon the revenue is recognized. When goods are sold in Japan, revenue is recognized upon shipment if the time from shipment to the transfer of control of the goods to the customer is a normal period of time.

For transactions in which the Group is involved in the sale of goods as an agent, revenue is recognized on a net basis.

The transaction price is calculated by subtracting any discounts or rebates from the consideration promised in the contract with the customer.

Consideration for the sale of goods is generally received within one year after the performance obligation is satisfied, in accordance with payment terms that have been separately determined, and does not include a significant financing component.

#### (b) Revenue from license agreements related to the sale of goods

Revenue from license agreements related to the sale of goods consists of intellectual property transfers or technology licensing agreements and royalties. Intellectual property transfers or technology licensing agreements have performance obligations based on contracts with customers, and these performance obligations are recognized as revenue when the rights are granted to the customer. Royalties are calculated based on customer sales and other factors, and are recognized as revenue with reference to when the sales occur.

Consideration for licenses related to the sale of goods is generally received within one year after the performance obligation is satisfied, in accordance with the payment terms that have been separately determined, and does not include a significant financing component.

### 3. Relationship between Satisfaction of Performance Obligations Based on the Contract with the Customer and Cash Flows Arising from That Contract, and the Amount and Timing of Revenue Expected to be Recognized in the Following Fiscal Year or Later from Contracts Existing at the End of the Fiscal Year under Review

#### (a) Balance of contract assets and contract liabilities

The Group's contract assets and contract liabilities are not disclosed as their balances are immaterial and there are no significant changes. In addition, the amount of revenue (mainly changes in transaction price) recognized in the fiscal year under review from performance obligations that were satisfied (or partially satisfied) in previous fiscal years is immaterial.

#### (b) Transaction price allocated to remaining performance obligations

In the Group, the transaction price allocated to remaining performance obligations is not disclosed as there are no significant contracts that were initially expected to last more than one year. In addition, there are no significant variable considerations in the amount of consideration received from contracts with customers that are not included in the transaction price.



## 22. Related Party Transactions

There are no related party transactions to be disclosed for the years ended March 31, 2023 and 2022.

## 23. Per Share Information

Per share information as of March 31, 2023 and 2022 and for the years then ended is as follows:

	YEN		U.S. DOLLARS (NOTE 1)
	2023	2022	2023
Net assets per share	¥3,636.17	¥3,642.34	\$27.34
Profit per share	144.80	251.43	1.09

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 of common stock for computation of profit per share.

The number of shares of treasury stock deducted for computation of net assets per share is 33,400 as of March 31, 2023 and 38,500 as of March 31, 2022. The weighted average number of shares of treasury stock deducted for computation of profit per share is 35,021 for the year ended March 31, 2023 and 38,776 for the year ended March 31, 2022.

3. The basis of calculation for profit per share for the years ended March 31, 2023 and 2022 is as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
Profit	¥ 5,440	¥ 9,549	\$ 40,902
Profit attributable to common stock owners of the Company	5,440	9,549	40,902
Profit not attributable to common stock owners (Number of shares)	—	—	—
Weighted average number of shares of common stock (thousands of shares)	37,571	37,978	\$282,489

4. The basis of calculation for net assets per share for the years ended March 31, 2023 and 2022 is as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
Total net assets	¥136,836	¥138,325	\$1,028,842
Amount subtracted from total net assets	578	578	4,346
(Non-controlling interests included in above)	(578)	(578)	(4,346)
Net assets attributable to common stock at end of period	136,258	137,747	1,024,496
Number of shares of common stock used in calculation of net assets per share at end of period (thousands of shares)	37,472	37,818	281,744

## 24. Comprehensive Income

Reclassification adjustments and income tax effects for each component of other comprehensive income for the years ended March 31, 2023 and 2022 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2023	2022	2023
Net unrealized holding gain (loss) on securities:			
Increase (decrease) during the year	¥ 249	¥(269)	\$ 1,872
Reclassification adjustments	(1)	(1)	(8)
Before income tax effect	248	(270)	1,865
Income tax effect	(76)	82	(571)
Net unrealized holding gain (loss) on securities	¥ 172	¥(187)	\$ 1,293
Remeasurements of defined benefit plans:			
Increase (decrease) during the year	¥(287)	¥ 177	\$ (2,158)
Reclassification adjustments	90	114	677
Before income tax effect	(197)	292	(1,481)
Income tax effect	60	(89)	451
Remeasurements of defined benefit plans	¥(136)	¥ 202	\$ (1,023)
Total other comprehensive income	¥ 35	¥ 14	\$ 263

## 25. Segment Information

(a) Overview of reportable segments

The Group's reportable segments are constituent units of the Group for which separate financial information is available, and which the Board of Directors regularly evaluates in order to decide how to allocate resources within the Group and evaluate business performance.

The Group produces and sells medical products, medical devices and agrochemicals and rents real estate, operating each business with a different management style appropriate for the industry category. 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 encompasses the production and sale of medical products, medical devices, and agrochemicals.

"Real estate" mainly encompasses the renting out of Bunkyo Green Court.

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

Accounting policies for the reportable segments are consistent with those described in Note 2. "Summary of Significant Accounting Policies." Profit by reportable segment is based on operating profit.

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

(c) Information about reportable segments

MILLIONS OF YEN					
	Reportable Segment			Adjustments	Consolidated
	Pharmaceuticals	Real estate	Total		
	2023				
Net sales:					
Sales of merchandise and finished goods	¥68,785	¥ —	¥68,785	¥ —	¥ 68,785
License agreements for sale, etc. of finished products	1,776	—	1,776	—	1,776
Revenue from contracts with customers	70,562	—	70,562	—	70,562
Other revenue	—	2,422	2,422	—	2,422
Net sales to external customers	70,562	2,422	72,984	—	72,984
Intersegment sales or transfers	—	—	—	—	—
Total	¥70,562	¥ 2,422	¥72,984	¥ —	¥ 72,984
Segment profit	¥ 6,707	¥ 1,290	¥ 7,998	¥ —	¥ 7,998
Segment assets	¥74,223	¥10,090	¥84,314	¥82,013	¥166,328
Other items:					
Depreciation and amortization	¥ 2,747	¥322	¥ 3,070	¥ —	¥ 3,070
Amortization of goodwill	22	—	22	—	22
Increase in property, plant and equipment and intangible assets	2,770	19	2,789	—	2,789

	MILLIONS OF YEN				
	Reportable Segment			Adjustments	Consolidated
	Pharmaceuticals	Real estate	Total		
2022					
Net sales:					
Sales of merchandise and finished goods	¥71,641	¥ —	¥71,641	¥ —	¥ 71,641
License agreements for sale, etc. of finished products	1,982	—	1,982	—	1,982
Revenue from contracts with customers	73,623	—	73,623	—	73,623
Other revenue	—	2,410	2,410	—	2,410
Net sales to external customers	73,623	2,410	76,034	—	76,034
Intersegment sales or transfers	—	—	—	—	—
Total	¥73,623	¥ 2,410	¥76,034	¥ —	¥ 76,034
Segment profit	¥15,710	¥ 1,353	¥17,064	¥ —	¥ 17,064
Segment assets	¥75,581	¥10,393	¥85,974	¥ 79,206	¥165,181
Other items:					
Depreciation and amortization	¥ 2,699	¥ 322	¥ 3,022	¥ —	¥ 3,022
Amortization of goodwill	5	—	5	—	5
Increase in property, plant and equipment and intangible assets	11,347	508	11,856	—	11,856

THOUSANDS OF U.S. DOLLARS (NOTE 1)					
	Reportable Segment				
	Pharmaceuticals	Real estate	Total	Adjustments	Consolidated
	2023				
Net sales:					
Sales of merchandise and finished goods	\$517,180	\$ —	\$517,180	\$ —	\$ 517,180
License agreements for sale, etc. of finished products	13,353	—	13,353	—	13,353
Revenue from contracts with customers	530,541	—	530,541	—	530,541
Other revenue	—	18,211	18,211	—	18,211
Net sales to external customers	530,541	18,211	548,752	—	548,752
Intersegment sales or transfers	—	—	—	—	—
Total	\$530,541	\$18,211	\$548,752	\$ —	\$ 548,752
Segment profit	\$ 50,429	\$ 9,699	\$ 60,135	\$ —	\$ 60,135
Segment assets	\$558,068	\$75,865	\$633,940	\$616,639	\$1,250,586
Other items:					
Depreciation and amortization	\$ 20,654	\$ 2,421	\$ 23,083	\$ —	\$ 23,083
Amortization of goodwill	165	—	165	—	165
Increase in property, plant and equipment and intangible assets	20,827	143	20,970	—	20,970

Notes:

1. The adjustments to segment assets of ¥82,013 million (\$616,639 thousand) and ¥79,206 million as of March 31, 2023 and 2022, 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.
2. Depreciation and increase in property, plant and equipment and intangible assets include long-term prepaid expenses.

(d) Information by product and service

Information by product and service has not been disclosed since the classification by product and service is the same as the reportable segments.

(e) Information by geographical area

(1) Sales

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

(f) Information about major customers

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)		Name of the related segment
	Net sales				
	2023	2022	2023		
Alfresa Corporation	¥13,132	¥13,486	\$98,737	Pharmaceuticals	
MEDICEO CORPORATION	10,420	11,237	78,346	Pharmaceuticals	
SUZUKEN CO., LTD.	10,349	11,192	77,812	Pharmaceuticals	

(g) Information about impairment loss on non-current assets by reportable segment

The Group recognized impairment loss for the following asset group for the years ended March 31, 2023 and 2022:

MILLIONS OF YEN						
	Reportable Segment			Other	Adjustments	Consolidated
	Pharmaceuticals	Real estate	Total			
	2023					
Impairment loss	¥ 1,863	¥—	¥ 1,863	¥—	¥—	¥ 1,863

	MILLIONS OF YEN					
	Reportable Segment					
	Pharmaceuticals	Real estate	Total	Other	Adjustments	Consolidated
	2022					
Impairment loss	¥ 2,994	¥—	¥ 2,994	¥—	¥—	¥ 2,994

THOUSANDS OF U.S. DOLLARS						
	Reportable Segment			Other	Adjustments	Consolidated
	Pharmaceuticals	Real estate	Total			
	2023					
Impairment loss	\$14,008	\$—	\$ 14,008	\$—	\$—	\$14,008

(h) Amortization of goodwill and unamortized balance by reportable segment for the years ended March 31, 2023 and 2022 are as follows:  
Year ended March 31, 2023

MILLIONS OF YEN						
	Reportable Segment			Other	Corporate and eliminations	Total
	Pharmaceuticals	Real estate	Total			
	2023					
Amount amortized during the year	¥ 22	¥—	¥ 22	¥—	¥—	¥ 22
Unamortized balance at end of the year	¥230	¥—	¥230	¥—	¥—	¥230

Note: Goodwill impairment of ¥59 million (\$444 thousand) is recorded in the Pharmaceuticals segment.

MILLIONS OF YEN						
	Reportable Segment			Other	Corporate and eliminations	Total
	Pharmaceuticals	Real estate	Total			
2022						
Amount amortized during the year	¥ 5	¥—	¥ 5	¥—	¥—	¥ 5
Unamortized balance at end of the year	¥312	¥—	¥312	¥—	¥—	¥312

THOUSANDS OF U.S. DOLLARS (NOTE 1)						
	Reportable Segment			Other	Corporate and eliminations	Total
	Pharmaceuticals	Real estate	Total			
	2023					
Amount amortized during the year	\$ 165	\$—	\$ 165	\$—	\$—	\$ 165
Unamortized balance at end of the year	\$1,729	\$—	\$1,729	\$—	\$—	\$1,729

## 26. Subsequent Event

### Disposal of treasury stock through third-party allotment

Under the Share Purchase Agreement signed upon the acquisition of ARTham Therapeutics Inc., which was announced on November 30, 2021, the Company resolved at the Board of Directors' meeting held on June 21, 2023 to dispose of treasury stock through a third-party allotment as contingent consideration for the acquisition following confirmation of the achievement of milestones relating to the refractory intravascular malformation treatment KP-001 (former development code: ART-001).

(a) Overview of disposal of treasury stock:

- (1) Date of disposal: July 7, 2023
- (2) Class of shares to be disposed of: Common stock
- (3) Number of shares to be disposed of: 392,289 shares
- (4) Value of shares to be disposed of: ¥3,679 (\$27.66) per share
- (5) Total amount of disposal: ¥1,443,231,231 (\$10,851,363)
- (6) Method of disposal: Third-party allotment
- (7) Planned recipients of shares: Shareholders and holders of share subscription rights of ARTham Therapeutics Inc. as defined in the Share Purchase Agreement

(b) Accounting treatment:

For the contingent consideration, the acquisition cost deemed to have been paid on the acquisition date will be revised, and the amounts of goodwill and amortization of goodwill shall be revised.

(c) Other:

The disposal of treasury stock shall be contingent upon notification under the Financial Instruments Act taking effect.

At the above meeting of the Board of Directors, the Company resolved to enter into a share subscription agreement with the planned recipients of shares mentioned above, taking into account the fact that the non-achievement of the milestones associated with the bullous pemphigoid treatment ART-648 had become certain. Consequently, no contingent consideration will arise from the transfer of shares with respect to the ART-648 milestones.



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 consolidated subsidiaries (“the Group”), which comprise the consolidated balance sheets as at March 31, 2023 and the consolidated statements of income, consolidated statements of comprehensive income, consolidated statements of changes in net assets and consolidated statements 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, 2023, and its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with accounting principles generally accepted in Japan.

Basis for Opinion

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

Emphasis of Matter

As described in Note 26, the Company resolved at the Board Directors' meeting held on June 21, 2023 to dispose of treasury stock through third-party allotment.. Our opinion is not qualified in respect of this matter.

Key Audit Matter

Key audit matter is the matter that, in our professional judgement, was of most significance in our audit of the consolidated financial statements of the current period. This matter was 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 this matter.

Evaluation of in-process research and development related to ARTham Therapeutics Inc.	
A key audit matter and the basis of our determination	How the matter was addressed in our audit
As described in Note 2 (Summary of Significant Accounting Policies (p) Significant Accounting Estimates), the Group recorded 5,800 million yen of in-process research and development as intangible fixed assets on the consolidated balance sheet as of March 31, 2023. This in-process research and development was recognized due to the acquisition of ARTham Therapeutics Inc. in the previous fiscal year.	We mainly performed the following audit procedures in examining the evaluation of the in-process research and development of ARTham Therapeutics Inc.  • We evaluated the effectiveness of the Group's internal controls in relation to the evaluation of the relevant intangible fixed assets.

Since the Group decided to discontinue a certain development program, an impairment loss of 1,559 million yen was recognized in the consolidated statements of income.

The company evaluates in-process research and development mainly based on the excess earnings method. Decisions on recognition of impairment losses on in-process research and development are based on whether the total amount of undiscounted future cash flows of each development program has fallen below the carrying amount. Undiscounted future cash flows are calculated based on the business plan formulated for each development program. Each business plan contains key assumptions such as sales projection (number of patients and drug prices) and probability of success. These key assumptions are subject to change, primarily due to changes in pharmaceutical market conditions and the status of research and development.

In addition, when the Group recognized in-process research and development, investment decisions were made after evaluating the associated business value. If a potent new drug is placed on the market, or if the effectiveness of the research is not maintained, the Group decides to terminate the program because there is no economic rationale to continue research and development. Therefore, management's decision to continue development programs has a significant impact on the valuation of intangible assets.

Because the key assumptions included in the business plan are subject to uncertainty and involve subjective judgment by management, we have determined that the evaluation of the in-process research and We determined this matter to be a key audit matter because it is of particular importance in our audit of the consolidated financial statements for this fiscal year.

• Regarding the progress of research and development related to the relevant intangible fixed assets, we confirmed consistency with the content confirmed in the minutes of the Board of Directors’ meetings and interviews with the management.

• Regarding important assumptions such as the number of patients, drug prices, and the probability of success of research and development, which are the basis for future sales projection in the business plans for each development program, we inspected basic information, compared with available external information, made inquiries to the person in charge of preparation of business plans and the person in charge of research and development, and examined the rationality of the business plan. In addition, regarding the discontinued development program, we made inquiries to the person in charge of research and development to understand the background leading to the decision to discontinuance of the program, as well as whether there will be any impact on the probability of success of other development programs and the decision to continue these programs.

• We verified the calculation process of undiscounted future cash flow and ascertained whether the evaluation of in-process research and development was performed appropriately.

Other Information

The other information comprises the information included in the Corporate report 2023, but does not include the consolidated financial statements and our auditor’s report thereon. Management is responsible for the preparation and presentation of the other information. Audit & Supervisory Board Members and the Audit & Supervisory Board are responsible for overseeing the Directors’ execution of duties relating to the design and operating effectiveness of the controls over the other information.

Our opinion on the consolidated financial statements does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the consolidated financial statements, our responsibility is to read the



other information and, in doing so, consider whether the other information is materially inconsistent with the consolidated financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

#### **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 the Directors' execution of duties relating to the design and operating effectiveness of the controls over 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 audit in order to design audit procedures that are appropriate in the circumstances, while the objective of the consolidated financial statement audit is not to express an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation as well as whether overall presentation and disclosures of the consolidated financial statements are in accordance with accounting principles generally accepted in Japan.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with 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.

From the matter communicated with Audit & Supervisory Board Members and the Audit & Supervisory Board, we determine the matter that was of most significance in the audit of the consolidated financial statements of the current period and is therefore the key audit matter. We describe this matter in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

#### **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 XX 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*

Hirofumi Nikaido  
Designated Engagement Partner  
Certified Public Accountant

*Daiki Matsuura*

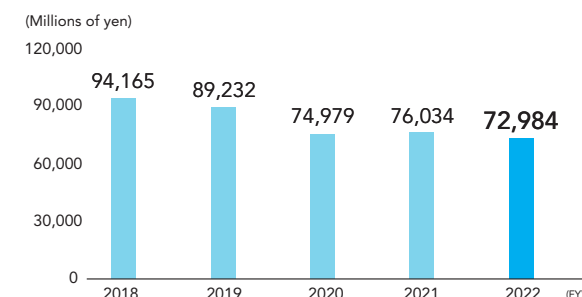
Daiki Matsuura  
Designated Engagement Partner  
Certified Public Accountant

ARK LLC  
Tokyo, Japan  
October 24, 2023

# Financial and Non-Financial Highlights

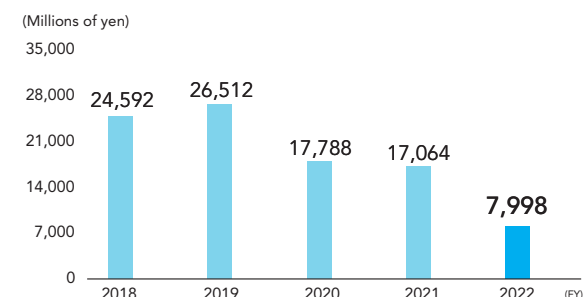
## Net Sales

¥72,984 million



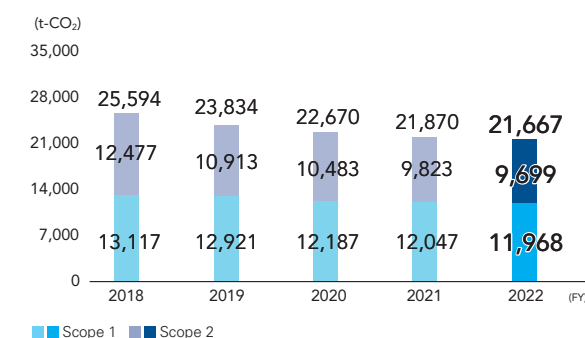
## Operating Profit

¥7,998 million



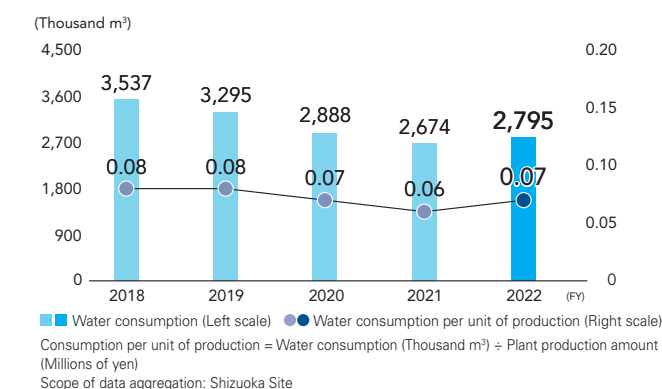
## CO<sub>2</sub> Emissions

Scope 1 11,968 t-CO<sub>2</sub> Scope 2 9,699 t-CO<sub>2</sub>  
Scope 3 126,563 t-CO<sub>2</sub> (FY2021)



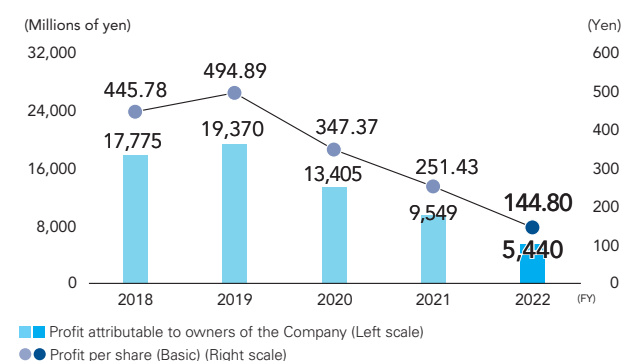
## Water Consumption and Consumption per Unit of Production

2,795 thousand m<sup>3</sup> / 0.07



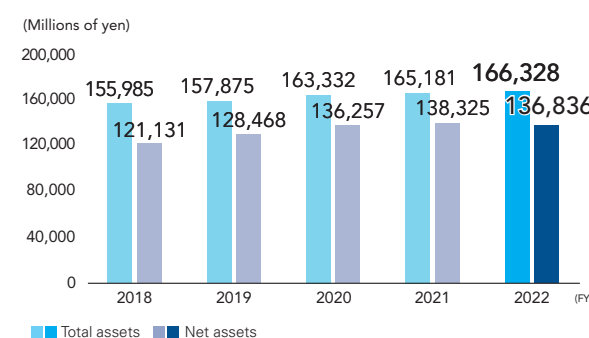
## Profit Attributable to Owners of the Company and Profit per Share (Basic)

¥5,440 million / ¥144.80



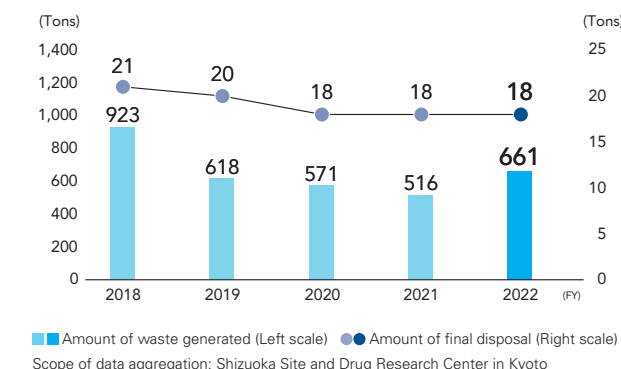
## Total Assets and Net Assets

¥166,328 million / ¥136,836 million



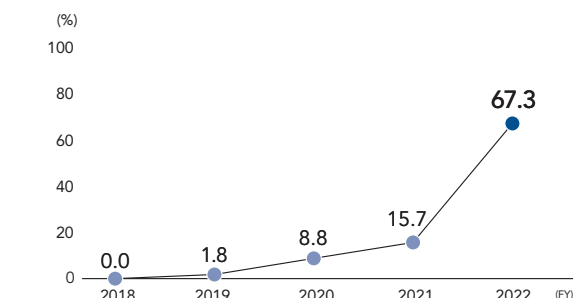
## Amounts of Waste Generated and Final Disposal

661 tons / 18 tons



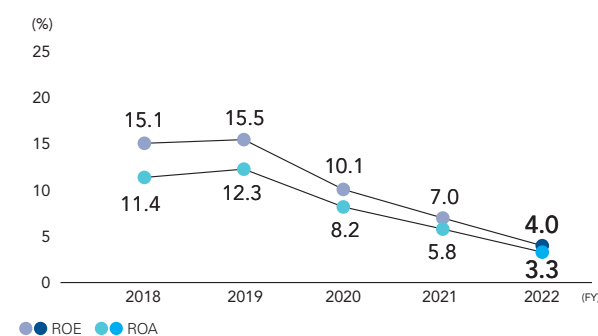
## Percentage of Eligible Male Employees Taking Childcare Leave

67.3%



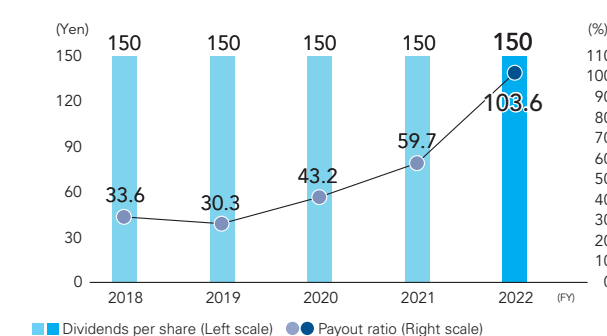
## ROE and ROA

4.0% / 3.3%



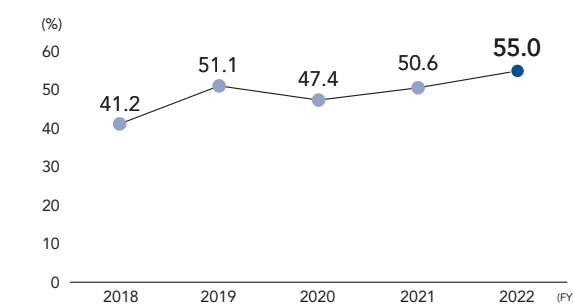
## Dividends per Share and Payout Ratio

¥150 / 103.6%



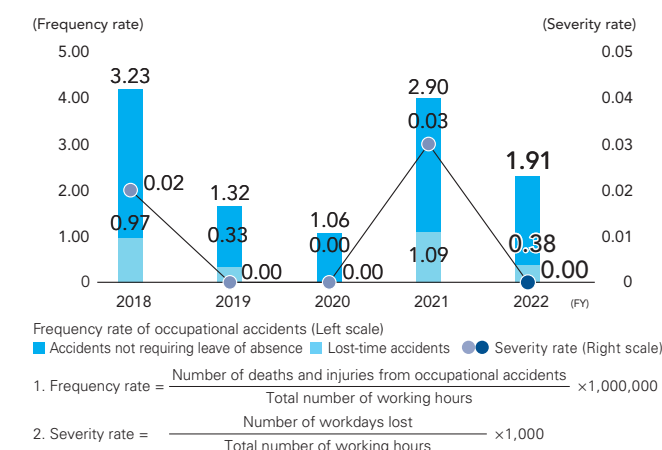
## Percentage of Paid Holidays Taken

55.0%



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

1.91 / 0.38 / 0.00





# Corporate and Share Information (As of March 31, 2023)

## Company Overview

Company Name	KAKEN PHARMACEUTICAL CO., LTD.
Incorporated	March 1, 1948
Paid-in Capital	¥23,853 million
Number of Employees	1,130 (consolidated)
Representative	Hiroyuki Horiuchi, President and Representative Director
Head Office Location	28-8, Honkomagome 2-chome, Bunkyo-ku, Tokyo
Business	Manufacturing and marketing of pharmaceuticals, medical devices, agrochemicals, feed additives and drugs for animals, as well as real estate leasing

### Main Offices (As of April 1, 2023)

● Head Office

● Branch Offices

● Sales Offices

● Drug Research Center

● CMC Center

● Factory

Bunkyo-ku, Tokyo

Sapporo (Sapporo City, Hokkaido)

Sendai (Sendai City, Miyagi)

Tokyo (Toshima-ku, Tokyo)

Nagoya (Nagoya City, Aichi)

Osaka (Osaka City, Osaka)

Hiroshima (Hiroshima City, Hiroshima)

Fukuoka (Fukuoka City, Fukuoka)

33 across Japan

Kyoto City, Kyoto

Fujieda City, Shizuoka

Fujieda City, Shizuoka

Fujieda City, Shizuoka

Nagoya Office

Osaka Office

Fukuoka Office

Hiroshima Office

Shizuoka Factory

Drug Research Center (Shizuoka)

CMC Center

Drug Research Center (Kyoto)

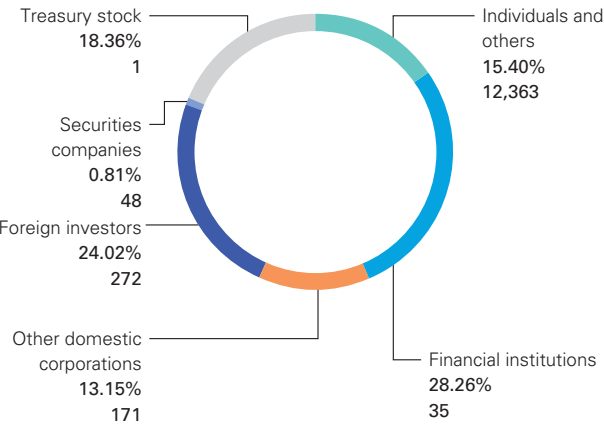
Sendai Office

Head Office Tokyo Office

## Share Information

Authorized	193,000,000 shares
Issued	45,939,730 shares
Number of Shareholders	12,890
Listing	Tokyo Stock Exchange, Prime Market
Securities Code	4521
Shareholder Register Administrator	Sumitomo Mitsui Trust Bank, Limited

## Shareholdings by Shareholder Type



## Major Shareholders (Top 10)

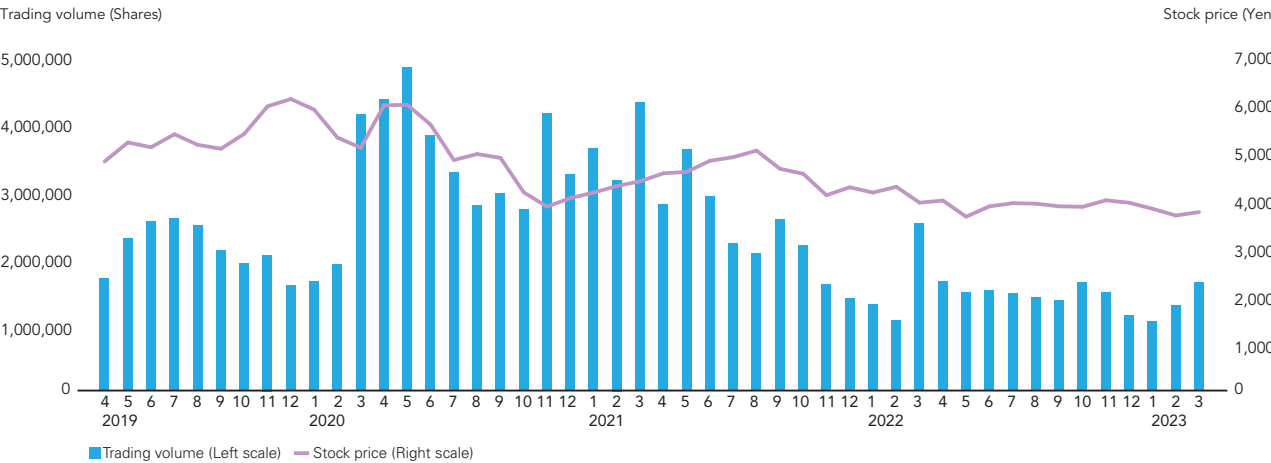
Shareholder	Number of shares held (Thousands)	Shareholding ratio (%)
The Master Trust Bank of Japan, Ltd. (Trust Account)	4,702	12.54
Toray Industries, Inc.	2,294	6.12
NORTHERN TRUST CO. (AVFC) RE SILCHESTER INTERNATIONAL INVESTORS INTERNATIONAL VALUE EQUITY TRUST	1,909	5.09
The Norinchukin Bank	1,843	4.91
Custody Bank of Japan, Ltd. (Trust Account)	1,672	4.46
Mizuho Bank, Ltd.	1,474	3.93
NORTHERN TRUST CO. (AVFC) RE U.S. TAX EXEMPTED PENSION FUNDS	867	2.31
KYORIN Pharmaceutical Co., Ltd.	852	2.27
NORTHERN TRUST CO. (AVFC) RE USL NON-TREATY CLIENTS ACCOUNT	727	1.94
NORTHERN TRUST CO. (AVFC) RE NON TREATY CLIENTS ACCOUNT	658	1.76

1. The number of shares held is rounded down to the nearest thousand.  
2. The shareholding ratios are calculated after subtracting the number of shares of treasury stock (8,433,380) from the total number of shares issued.  
3. The shareholding ratios are rounded to the nearest second decimal place.

## Total Shareholder Return

FY	2018	2019	2020	2021	2022
(%)	82.5	84.9	76.2	71.5	70.8
(Comparison index: TOPIX Total Return Index)	95.0	85.9	122.1	124.6	131.8

## Stock Price and Trading Volume



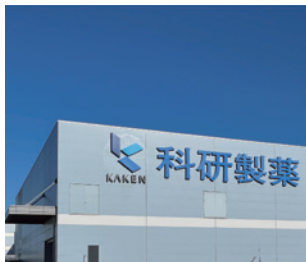
Head Office (Tokyo)



Drug Research Center (Kyoto)



Osaka Office (Osaka)



Shizuoka Factory (Shizuoka)



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