



CORPORATE REPORT 2022



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”



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Editorial Policy

This report has been edited with the objective of helping KAKEN’s various stakeholders (including shareholders and investors) to understand the Company’s management foundation and strengths that it has built to date, as well as the sustainable growth it aspires to achieve through creation of corporate value in the future, using the *International Integrated Reporting Framework* of the Value Reporting Foundation (now integrated in the IFRS Foundation) and *Guidance for Collaborative Value Creation* by the Ministry of Economy, Trade and Industry as reference.

Reporting Period

FY2021 (April 1, 2021 to March 31, 2022)

Note: Some information from before and after the period above is included.

Scope of This Report

Kaken Pharmaceutical Co., Ltd. (“the Company”) 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.

A History of Value Creation

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

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.

Our Track Record of Creating New Value

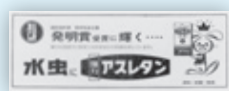
Founding Ideas

The origin of Kaken Pharmaceutical Co., Ltd. can be traced back to the Institute of Physical and Chemical Research (Riken), which was established in 1917. In 1948, the Company started its business as Kagaku Kenkyusho. The Company's first president, Yoshio Nishina, who was called the father of modern physics in Japan, said that his mission was to apply basic scientific research and its findings to industry, and began manufacturing and selling pharmaceuticals as a way of implementing theoretical research in business.



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.



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

Hyaluronic acid has been shown to improve symptoms of knee osteoarthritis, shoulder periarthritis and other joint diseases. This led to the launch of Artz, the world's first intra-articular injection solution using hyaluronic acid as the main active ingredient (manufactured and distributed by Seikagaku Corporation).

Background of Development
The conventional treatments for painful joint diseases such as knee osteoarthritis and shoulder periarthritis were orally administered nonsteroidal anti-inflammatory drugs (NSAIDs) and locally administered anesthetics and steroids. However, because of problems such as gastrointestinal damage caused by NSAIDs and joint disorders caused by steroids, there was a need for a safer, more effective drug.



Launched Clenafin (onychomycosis treatment)

As the first topical treatment for onychomycosis in Japan, Clenafin provided a new treatment option without the drug interactions and adverse drug reactions, such as liver damage, seen with oral antifungal drugs. Global sales are expanding, partly through out-licensing to local companies in North America, Asia and Europe.

Background of Development
Oral antifungal drugs were the only onychomycosis treatment available in Japan, but these drugs were associated with drug interactions and adverse drug reactions, including liver damage. There was a need for a new external medicine that would be effective against onychomycosis while having fewer safety concerns.



Launched Hernicore (lumbar disc herniation treatment)

Hernicore provided a new lumbar hernia treatment option that improves leg pain and other symptoms. Condoliase, the active ingredient, is injected into the intervertebral disc to reduce internal pressure. We are aiming to establish Hernicore as a treatment positioned between conservative therapy and surgery (manufactured and distributed by Seikagaku Corporation).

Background of Development
Previously, lumbar disc herniation treatments were limited to two options—conservative therapy or surgery.



Launched Fiblast (wound-healing agent)

Fiblast, the world's first human bFGF (basic fibroblast growth factor) formulation, promotes healing by acting on various cells related to wound healing. It is also the world's first spray-on wound-healing agent, and is easy to use because it can be easily applied without directly touching the affected area. This product was a milestone in regenerative medicine, and is increasingly being used in the treatment of other conditions.

Background of Development
There was a need for a new treatment to address the increasing incidence of bedsores and intractable skin ulcers due to the aging population in Japan. Moreover, external treatment options for wound healing were limited to ointments.



Launched Regroth (periodontal regenerative agent)

Safe, convenient and covered by national health insurance (NHI-listed) in Japan, Regroth is the world's first periodontal regenerative agent. With its debut, Regroth is expected to increase the value of periodontal regeneration therapy, and has contributed as a new therapeutic option for periodontal disease.

Background of Development
There were no periodontal regeneration drugs sold elsewhere in the world, and the only material approved in Japan for regenerating periodontal tissue was not NHI-listed, so its use was limited.



Launched Ecclock (primary axillary hyperhidrosis treatment)

Ecclock was the first NHI-listed external treatment option for primary axillary hyperhidrosis in Japan. Among other factors, we focused on developing a dosage form that would ensure safe use, including an applicator that allows the gel to be applied without directly touching it.

Background of Development
The first-line treatment for primary axillary hyperhidrosis was an aluminum chloride topical; however, it was not NHI-listed in Japan, and there was a need for a new external medicine for this disorder.



1948

1953

1971

1987

1992

1993

2001

2014

2016

2018

2020

Launched Penicillin KAKEN

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



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

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



Launched Mentax (anti-trichophyton agent)

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



KAKEN's Technological Foundation

1940s Technologies developed by Riken form the roots of Kaken Pharmaceutical

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

1960s 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 address social problems. In the case of Minamata disease for example, it successfully synthesized an antifungal agent to replace organic mercury compounds that were the primary medicines for athlete's foot at the time. In the 1970s, the Company opened new research facilities, and built a system capable of adapting to increasingly stringent laws and regulations, and enhanced its sales capabilities. The Drug Research Center in Kyoto in particular was equipped with state-of-the-art equipment and tools, demonstrating highly reliable safety testing (preclinical studies).

1990s Provided medicines of excellent quality in a drive to be "the best"

In the 1990s, KAKEN expanded 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, which had a chemical structure completely different from that of existing athlete's foot medicines. It grew into strategic global product Mentax. For Artz, which had been sold in an ampoule, the Company launched Artz Dispo, a kit product with a disposable pre-filled syringe, to reduce the risk of infection. Underpinning the Company at this time was its belief, set forth in the late 1980s, in striving to be "the best company, even if not the biggest."

2000s and onward Advance priority research themes through organizational improvements and concentration of resources

The Drug Research Center and the CMC Center have introduced state-of-the-art equipment and technologies, and cooperate in the advancement of drug discovery research. KAKEN focuses its investments and human resources on R&D themes in fields where its experience, technologies and foundations can best be utilized—the immune system, the nervous system and infectious diseases. In FY2017, the Company entered into a collaborative research agreement with Switzerland-based Numab Therapeutics AG—which has a multi-specific antibody technology platform—for the identification of a multi-specific antibody candidate for the treatment of inflammatory diseases. Based on KAKEN's belief that the foundation of research and development is people, the Company is promoting human resource development both in-house and externally. As part of that effort, the Company sends researchers to research institutions in Japan and overseas to sharpen their expertise, and strives to introduce the latest technologies and knowledge.

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.

INPUT

Financial capital

- Safe and sound financial position
- Equity **¥137,747 million**
(As of March 31, 2022)

Manufacturing capital

- Capital expenditures in capacity expansion/renovation **¥3,510 million**
(Year ended March 31, 2022)

Intellectual capital

- R&D investment **¥8,420 million**
(Year ended March 31, 2022)
- Drug Research Center **2 locations** (Kyoto and Shizuoka)

Natural capital

- CO₂ emissions **20,282 t-CO₂**
- Electricity consumption **25,608 thousand kWh**
- Water consumption **2,674 thousand m³**
(Shizuoka Site)

Social capital

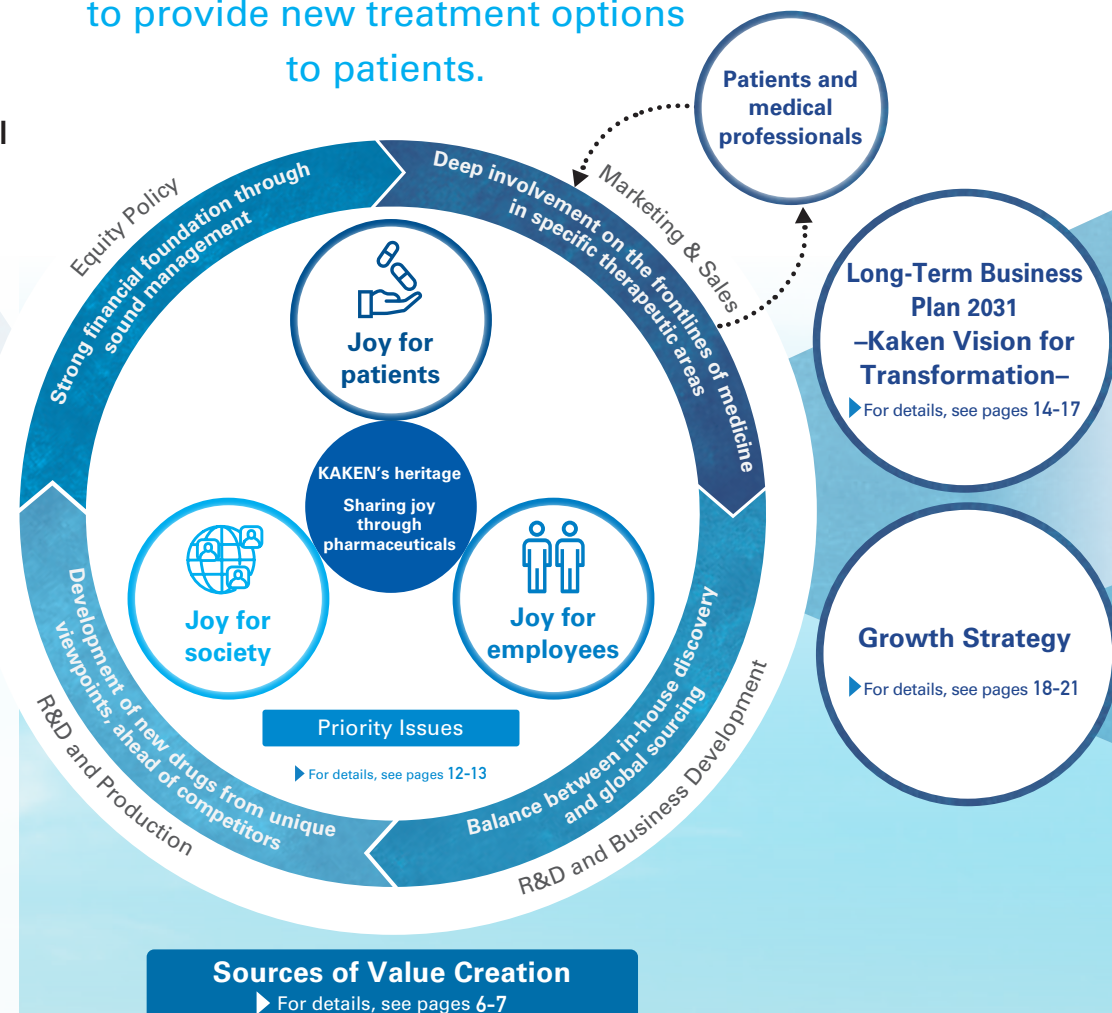
- Main offices **8**
- Sales offices **34**

Human capital

- Number of Group employees **1,164**
(As of March 31, 2022)

BUSINESS MODEL

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



Corporate Philosophy

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

OUTPUT

Innovative drugs, including products that are the first of their kind in Japan or the world

Dermatology

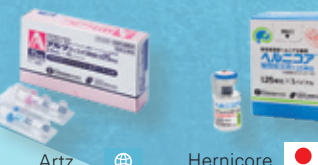


Clenafin Fiblast



Ecclock

Orthopedics



Artz Herculore

Other Areas



Seprafilm

Regroth

First in the world First in Japan

OUTCOMES



Joy for patients

- Longer healthy life expectancy
- Treatments that improve quality of life of patients and their family members
- Meeting medical needs for adequate treatments
- Addressing global needs
- Provision of proper pharmaceutical and related medical information



Joy for society

- Development of sustainable supply chains
- Consideration for local communities and the environment based on high ethical standards
- Stable and continuous returns to shareholders



Joy for employees

- Job satisfaction as professionals who meet patient needs

Contributing to people's well-being through better quality of life

Sources of Value Creation

KAKEN focuses on selected therapeutic areas and delivers new treatment options to patients. Here we describe our unique sources of value creation for accomplishing those tasks.

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 each 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 by assigning them 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 through the frontlines of medicine in new product development and formulation improvements.

Example

We continue to provide products such as the onychomycosis treatment Clenafin and the anti-osteoarthritis agent Artz that have long been appreciated by many patients facing dermatology- and orthopedics-related issues. In earning the trust of doctors, our MRs have improved their expertise and built relationships with a wide range of medical professionals, including pharmacists, nurses and rehabilitation staff. We value the information we get at the frontlines of medicine. For example, having the opportunity to attend surgeries in operating rooms to explain the use of our medical devices such as adhesion barrier materials is an important and rewarding experience as it allows MRs to see our products properly used for the benefit of patients.

Our MRs emphasize face-to-face communication supplemented by digital technology as a tool for efficiently sharing information.



Ability to Meet Needs (Ability to Find Solutions)

Flexible Approach to Finding Solutions

We identify the best solution with a flexible approach by 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 of medicine to devise product formulation and packaging solutions.

Example

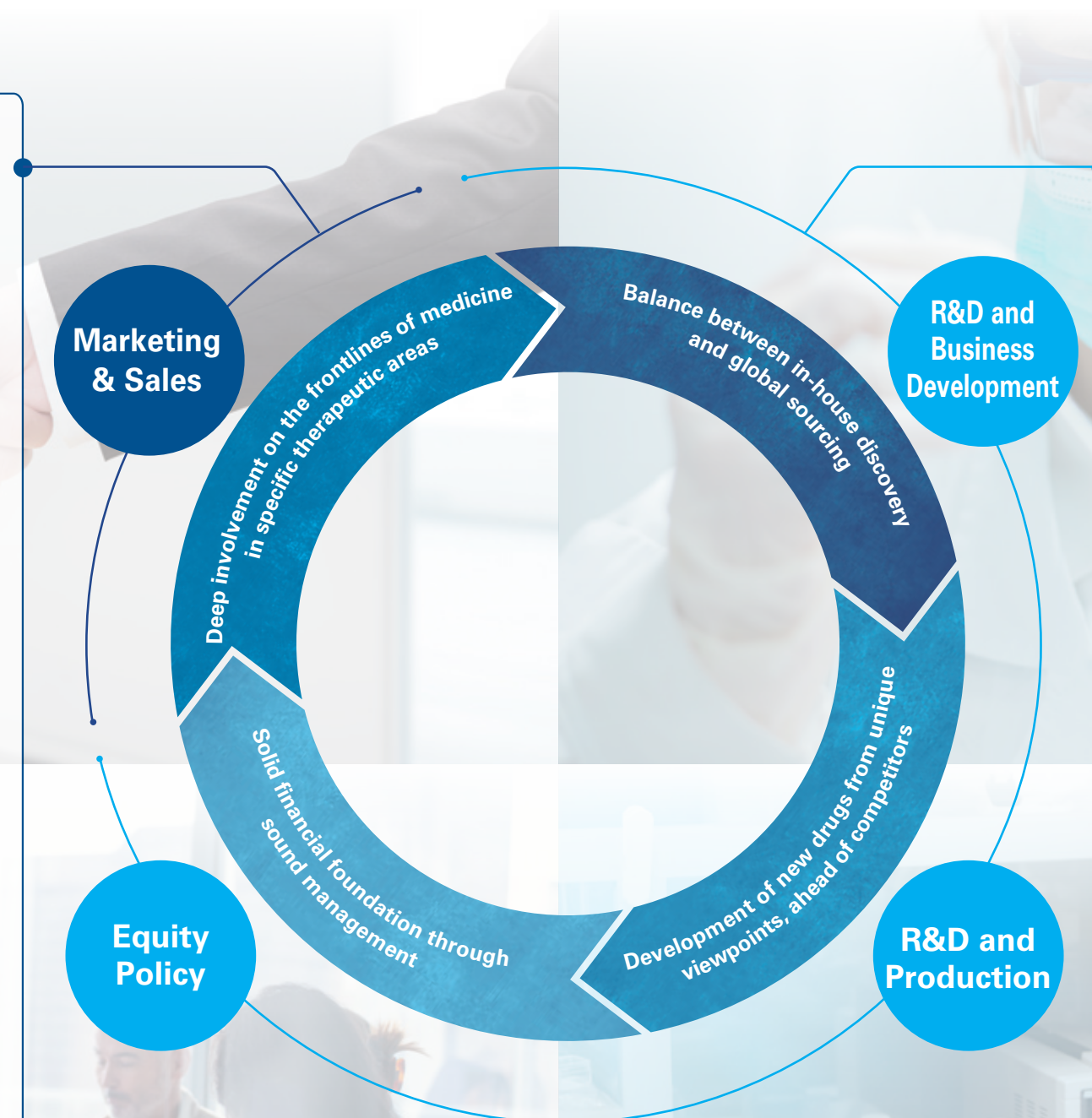
We provide new therapeutic options to help improve the quality of life of patients suffering daily from the symptoms of disease. In addition, we work with doctors to promote patients' disease awareness based on the information we gather and take steps to increase the convenience of drugs by improving formulations and through additional specifications and packaging. We have also introduced a drug discovery platform that uses AI to speed up the research and development of innovative drugs by increasing the probability of success in drug discovery. By combining this platform with our drug discovery experience and knowledge, we will shift to a data-driven discovery research process.

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 through 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.

Example

KAKEN employees multiply their strengths by working toward a common goal as one team through cross-departmental collaboration. Also, our flexible corporate culture has become a strength by maximizing our presence, which has led to collaboration with other companies in the areas of dermatology and orthopedics. The acquisition of ARTham, which has expertise in drug repositioning (for details, see page 8), has augmented our R&D capabilities and is expected to broaden the range of solutions we can provide patients and medical professionals at the frontlines of medicine. Furthermore, through our exploration of new modalities, such as the development of therapeutic antibodies in collaboration with Numab Therapeutics AG, we expect more additive and synergistic effects.



President's Message



KAKEN aims to be a global company that contributes to longer healthy life expectancy by implementing Long-Term Business Plan 2031, composed of “Three Transformations.”

Hiroyuki Horiuchi

President and Representative Director

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

While Results of Medium-Term Business Plan 2021 Fell Short of Certain Objectives, We Implemented Measures for Future Growth

FY2021 was the final year of Medium-Term Business Plan 2021, but due to several factors—patients’ hesitance to visit medical facilities because of the COVID-19 pandemic, larger-than-expected reductions of NHI drug prices, and changes in the competitive landscape, among them—net sales, operating profit and ROE fell short of the numerical targets of the medium-term business plan. On the other hand, during this medium-term period we moved forward toward future global growth. We launched Ecclock in Japan, the first NHI-listed topical treatment for primary axillary hyperhidrosis, and started sales of Clenafin, an onychomycosis treatment, in Hong Kong in addition to North America and South Korea, where the product

is already marketed, and executed a licensing agreement for Europe.

In December 2021, we acquired ARTham Therapeutics Inc. (“ARTham”), a clinical stage biopharmaceutical company in Japan. ARTham is focusing on research and development through drug repositioning, and has products under development in plastic surgery, pediatrics and dermatology. This acquisition will expand our development pipeline, and allow us to further increase our R&D capabilities. We will generate synergy by applying ARTham’s knowledge, technology and experience in drug repositioning to our existing compounds.

Long-Term Business Plan 2031: Aiming to Achieve “Three Transformations”

Our top priority issues are: improving the probability of success of product launches in research and development, expanding the development pipeline, global research and development, and overseas expansion. In FY2022, we formulated and started Long-Term Business Plan 2031 to solve these issues and achieve sustainable growth. Rather than setting a three-year medium-term business plan as we have typically done, we will promote strategies aimed at restoring growth and enhancing corporate value under a long-term business plan with a view to what we believe the Company should be in 10 years.

Our vision for KAKEN in 10 years is to be a company that contributes to longer healthy life expectancy by

developing and providing innovative new drugs in a speedy manner, and to be a research-based pharmaceutical company with a global presence, primarily in the areas of dermatology and orthopedics. We set target KPIs for FY2031 of net sales of ¥100 billion, operating profit of ¥28.5 billion, ROE of 10% or higher, and an overseas sales ratio of 30% or higher.

We will not be able to achieve this 10-year vision by merely continuing to do what we have always done. It requires us to undergo further transformations and new developments. We need to make bold transformations in the areas of research and development, overseas expansion and our management base. In Long-Term

Business Plan 2031, we have set forth these “Three Transformations” as a strategy for achieving our vision. For each transformation, we have further set a vision and priority measures. Our “Three Transformations” are as follows:

- ① R&D strategy: Continuously launch innovative, world-class drugs in our three priority fields of drug discovery.
- ② Overseas expansion strategy: Increase the overseas sales ratio and consolidate our position as an R&D-driven company with mainstay products in the areas of dermatology and orthopedics.
- ③ Management base strategy: Increase corporate value by establishing a strong organizational base that can flexibly respond to changes and by improving operational efficiency.

We also formulated a Sustainability Policy in May 2022 to proactively incorporate sustainability into management. This policy is shared and put into practice by all employees and corporate officers.

As we take on these transformations, we have also renewed our brand logo. Using the letter “K” in KAKEN as the motif, the new logo expresses the “Three Joys” —“Joy for patients,” “Joy for society” and “Joy for employees”— that comprise our business philosophy, and

reflects our dedication to always taking on new challenges. Employees have reacted positively to the new logo, and I feel an emerging sense of unity toward transformation.

Our employees are sincere and serious. That in itself is something to be very proud of, but to achieve transformation, they need to be more dynamic and free-thinking, and to discuss matters thoroughly, in order to provide innovative products that create new value and help resolve social issues. This change must begin with the mindset of employees. I will increase my own communications about transformation and pursue initiatives including review of the human resource evaluation system, strengthening of the education and training system and improvement of the working environment.

I believe there is nothing more important than becoming a team that values good communication. Since becoming president, I have continued to place importance on communicating with employees and have worked to create more opportunities for that. Employees work toward the goals of their departments, but ultimately the reason they do so is to enable the KAKEN team to compete successfully in the intensely competitive global market. To move forward, I want to remove boundaries between divisions to develop KAKEN into a company that works hard as a unified team, eagerly and boldly taking on new challenges.



These long-established products originate from our corporate culture of adapting to the frontlines of medicine. A key part of our sales activities is how much patient feedback we can gather. Remote work improves efficiency, but it does not allow us to see the patient

beyond the doctor. We can only understand true patient needs and unmet medical needs by going to the point of care, listening to the medical staff, picking up nuances and getting a sense of whether patients who come to the clinic feel the effects of the medicine.

Adapting to the Frontlines of Medicine to Grasp Real Needs and Contribute to Well-being

While we do not market many products that affect human life, we have narrowed down our drug discovery projects and development areas to concentrate on supplying products that contribute to well-being through better quality of life. KAKEN has the flexibility to develop drugs even for niche markets to help patients in need live healthy lives. We focus on dermatology and orthopedics in particular, and based on the level of expertise we have attained in these fields, we will continue to explore them deeply to help promote longer healthy life expectancy.

We have many products that have been sold steadily for a long time. Launched in 2014, Clenafin was Japan’s

first topical treatment for onychomycosis, providing a new option to patients who had been unable to get therapeutic intervention. There are still many untreated patients, so this product has room to grow with further market penetration. Regroth, a periodontal regenerative agent launched in 2016, has led the establishment of NHI-approved drug therapies for regenerating periodontal tissue. The continuing growth of this product since its launch is proof that it is bringing smiles to the faces of patients. I am always telling our employees to be aware that bringing smiles to more faces leads to the growth of the Company.

Striving for Transformation as One Team

We have made our tradition of responding to needs on the frontlines of medicine a Companywide strength by assigning employees from sales to various other departments via job rotation. We will build on this strength to accurately assess changes in society and achieve transformation. While we have had our share of failures in the past, we have created long-established products and evolved into what KAKEN is today. We will continue to take on many new challenges as one team.

Continuously providing returns to shareholders is an

important management goal. We maintained total annual dividends at ¥150 per share. We also bought back 500,000 shares of Company stock through the market.

Based on the “Three Joys” comprising our business philosophy—“Joy for patients,” “Joy for society” and “Joy for employees”—we will push on toward achievement of Long-Term Business Plan 2031 to bring smiles to the faces of all of our stakeholders.

We appreciate your continuing support.

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



Long-Term Business Plan 2031

–Kaken Vision for Transformation–

Review of Medium-Term Business Plan 2021 Main Achievements and Unresolved Issues

Under Medium-Term Business Plan 2021, we worked toward the “establishment of growth foundations,” which we had set as our priority task to help us weather the difficult times rather than focusing on the financial performance for that period.

Main Achievements

Maximized Product Value	<ul style="list-style-type: none"> Overseas expansion of Clenafin ✓ Hong Kong/Macao: Main Life Corp. Ltd. (licensee) started distribution. ✓ China: AIM (licensee) is to start local clinical development. ✓ Europe: Concluded exclusive out-licensing and supply agreements in Europe with Almirall S.A.
	<ul style="list-style-type: none"> Overseas expansion of new products and additional indications ✓ Conducting Phase I study in Japan for additional indication of Ecclork for primary palmo-plantar hyperhidrosis.
Stronger and More Efficient Marketing Base	<ul style="list-style-type: none"> ✓ Reorganization of the Marketing & Sales Division into five branch offices and 34 sales offices and the introduction of digital promotion tools improved quality and efficiency of MR activities.
Higher Productivity through HR Development and Operational Transformation	<ul style="list-style-type: none"> ✓ Work-style transformation, such as telecommuting and flextime; developed DX talent at individual divisions. ✓ Improved efficiency of operations in ways such as introducing remote meetings and paperless operations, as well as IT investment.

Unresolved Issues

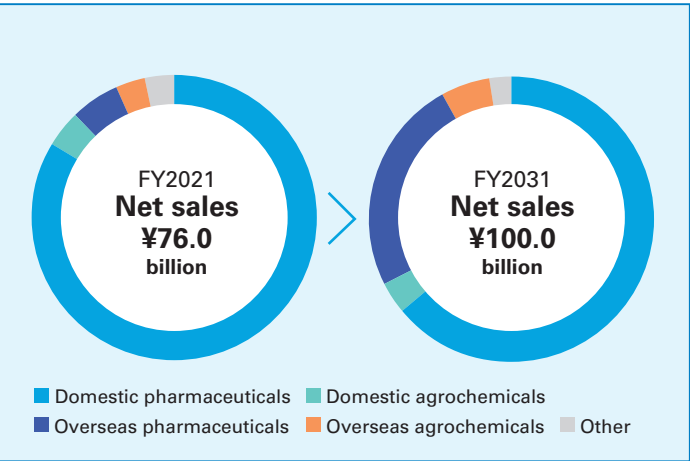
Taking on the Challenge of Broader Drug Discovery Research	<ul style="list-style-type: none"> Expansion of the pipeline through in-house drug discovery, mainly in therapeutic areas where we have advantages. Taking on the challenge of drug discovery research in new therapeutic areas. Taking on the challenge of peptides and other new modalities, beyond small molecules. Taking on the challenge of new areas, such as regenerative medicine.
Accelerate Overseas Expansion	<ul style="list-style-type: none"> Expansion of Fiblast overseas in countries other than South Korea where Regroth is not yet available. Need to accelerate overseas expansion by formulating strategy for each product and region.
Continuous Reinforcement of the Management Base	<ul style="list-style-type: none"> Human Resources: Continuously updating work-style transformation and human resource development by staying current with the times. Digital Transformation: Decision to be made for the intended use and tools to accelerate R&D transformation. Manufacturing: Investment and transformation of employee mindset for a higher-quality and more reliable manufacturing system.

Target KPIs

	FY2021 Result	FY2026	FY2031
Net Sales	¥76.0 billion	¥80.0 billion	¥100.0 billion
Operating Profit	¥17.0 billion	¥18.0 billion	¥28.5 billion
ROE	7.0%	8.0% or higher	10.0% or higher
Overseas Sales Ratio*	9.1%	10.0% or higher	30.0% or higher

* Total for pharmaceuticals and agrochemicals

Targeted Change in Sales Breakdown

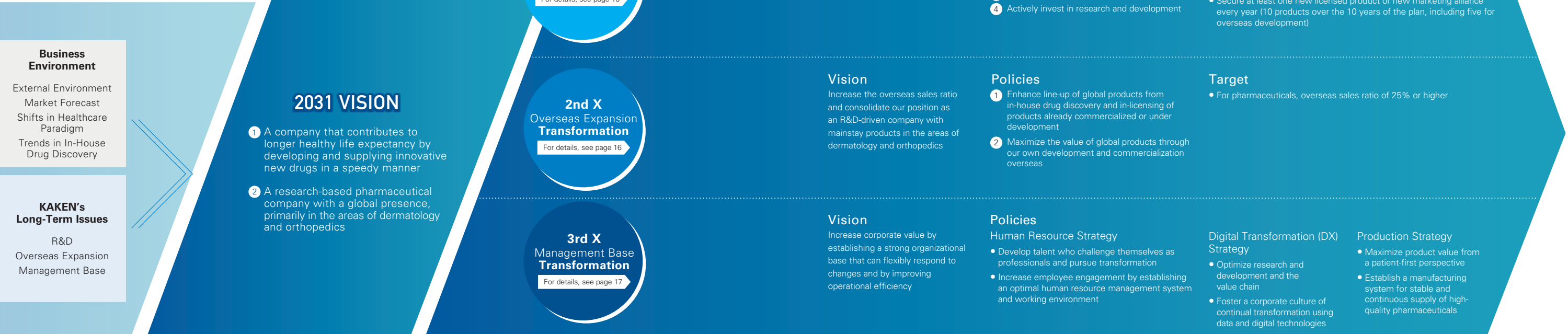


Investment and Shareholder Return Policies

Strategic Investment	¥200 billion or more over the 10 years of the plan
Shareholder Returns	Continuous/Stable dividends Flexible share buybacks

Overview of Long-Term Business Plan 2031

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



Long-Term Business Plan 2031

1st X R&D Transformation

Basic Policies

Utilize KAKEN's Own Research Base

Strengthen in-house research base mainly in the three priority fields of drug discovery (immune system, nervous system, infectious diseases)

Immune system

Inflammatory skin diseases, allergic diseases, rheumatism/osteoarthritis

Nervous system

Neuropathic pain, osteoarthritis pain, sleep disorder, pruritus

Infectious diseases

Deep mycosis

Expand into New Therapeutic Areas

Expand into new therapeutic areas where we have advantages, based on unmet medical needs

Therapeutic areas where we have advantages

Orthopedics

Artz

Hernicore

Dermatology

Clenafin

Ecclock

Fiblast

Other

Seprafilm

Regroth

New therapeutic areas

Diseases with unmet medical needs 10 years in the future

Rare diseases

Take on the Challenge of New Modalities

Enable approaches to drug discovery targets that could not be achieved with small molecule drugs

Areas to take on challenges in research and development

Small molecule drugs

Next-generation antibodies

Peptides

Nucleic acid medicines, etc.

Actively Invest in Research and Development

Allocate ¥200 billion for R&D investment (including ¥80 billion for M&A and in-licensing to expand the pipeline) over the 10 years of the plan

Cooperate with external organizations from the early stage of research and development

Drug discovery seeds exploration: Utilize academia, venture consortiums, and others

Joint research/development, in-licensing: Collaboration with domestic and overseas pharmaceutical related companies, M&A and other entities

Priority Measures

1 Improve Launch Probability

We will take various approaches to shorten development time and improve probability of success, including using AI and cooperating with external organizations in basic research, virtual clinical trials, selection of optimal modalities that fit our drug discovery targets, and promotion of translational research.

2 Expand Pipeline

To ensure that we maintain a pipeline that is sufficient for continuously launching new drugs, we will widen the range of drug candidates in-licensed from modalities, mainly in our priority areas, to include those in the area of rare diseases. To increase in-licensing opportunities, we will consider M&A, establishment of a corporate venture capital (CVC) fund, and investment in funds. In addition, we will promote joint research and development with biopharmaceutical companies and other entities, and in-license projects in early-stage development. Moreover, we will actively pursue additional indications and drug repositioning.

3 Address New Needs and Overseas Expansion

Using big data and other tools, we will identify latent medical needs for future research, propose new drug discovery projects and carry out drug discovery with original targets. We will also build a non-clinical database and establish a system for supplying investigational drugs for overseas expansion.

4 Take on Challenges in New Fields

Through collaboration with specialty companies or the use of in-licensing and M&A, we aim to develop and launch products for regenerative medicine. In addition, we will consider digital therapeutics in dermatology and orthopedics to develop and commercialize digital health products, including medical devices.

2nd X Overseas Expansion Transformation

Priority Measures

1 Expand Global Products

We will focus on expanding the regions where existing global products such as Clenafin and Ecclock are sold, and conducting overseas out-licensing of new global products, including products currently under development. To secure new global products, we aim to in-license at least five products or development projects with global rights over the next 10 years.

Progress of Overseas Expansion by Product



2 Establish Our Own Overseas Development Capabilities

We will establish an in-house overseas clinical development system by utilizing global contract research organizations (CROs), and internal systems that enable us to comply with the regulations of each country. In addition, we will explore the possibility of opening overseas offices for product development.

3 Establish Global Manufacturing and Commercialization Structure

For each product, we will consider in-house manufacturing that complies with the regulations of each country. We will also explore the possibility of conducting our own marketing overseas.

3rd X Management Base Transformation

Priority Measures

1 Human Resource Strategy

We will foster a corporate culture that promotes a spirit of challenge among employees, encouraging them to pursue change as professionals dealing with various issues, adopting a flexible approach to address the issue at hand, rather than maintaining the status quo. We see the increasing importance of human capital as an opportunity to evolve our human resource and work-style system to enable every employee to find satisfaction in their job. We will develop MRs who can flexibly respond to the changing times through convergence of the real and digital worlds.

2 DX Strategy

To create new corporate value, we will recruit and develop talent capable of planning and implementing DX. We will advance DX to innovate R&D processes by using data and digital technologies, such as AI in drug discovery and virtual clinical trials, optimize the value chain and foster a corporate culture of continual transformation.

3 Production Strategy

We will maximize the value of products by developing more patient-friendly dosage forms, as well as by improving formulations of existing products to better meet patient needs. To build a stable and sustainable production system, we will further upgrade our quality assurance system through linkage of systems and utilize digital technology in manufacturing management and quality control. We will also consider introducing new manufacturing methods such as continuous manufacturing.

Other Agrochemicals Business

Increased adoption of initiatives toward achievement of the SDGs in recent years has led to demand in the agricultural sector for more eco-friendly agrochemicals. Polyoxins, natural substances derived from fermentation using microorganisms that are manufactured and sold by KAKEN, have been positively evaluated as non-chemical herbicides with excellent safety profiles. We regard them as a pillar of the long-term growth of our agrochemicals business. Going forward, we will maximize the value of polyoxins in the following three ways.

1 Growth in North America and New Markets

We will promote polyoxins in the organic crops market by leveraging the organic certification obtained in the United States in 2020. At the same time, we will promote polyoxins in the Oceania region where registration was obtained recently.

2 Growth by Entering the EU Market

We anticipate that the import tolerances we plan to submit to the EU will be approved by 2025, which will boost polyoxins use in crops exported for EU consumers. In addition, we plan to obtain registration for plant protection products by 2027 to enter the market.

3 Growth in Japan by Promoting Polyoxin Use

We will promote polyoxins in the eco-friendly and sustainable agriculture market and contribute to improvement in crop productivity as well as food safety for consumers.

Growth Strategy

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

Pharmaceuticals

Pharmaceuticals and Medical Devices

Business Overview and Summary of Results

KAKEN’s pharmaceuticals segment supplies innovative products, mainly in the areas of dermatology and orthopedics, that contribute to improvement of patients’ quality of life. These products include drugs for diseases without adequate treatments and drugs with new dosage forms. In dermatology, we have launched Clenafin (an onychomycosis treatment), Ecclock (a primary axillary hyperhidrosis treatment), and Fiblast (a wound-healing agent). In orthopedics, we have launched Artz (an anti-osteoarthritis agent) and Hernicore (a lumbar disc herniation treatment). These products are widely used to treat their target diseases. In medical devices, we supply Seprafilm, an adhesion barrier used primarily in surgery and in gynecology to reduce complications from post-operative adhesions.

In FY2021, although sales of Clenafin decreased, sales of the pharmaceuticals segment grew overall, driven by increased sales of Ecclock, which was launched in

November 2020, as well as generic drugs in Japan, and Jublia (the product name for Clenafin outside Japan) in overseas markets.

We are expanding the overseas availability of Clenafin, a product from in-house drug discovery. In May 2022, our European licensee Almirall, S.A. of Spain filed for marketing approval with the Federal Institute for Drugs and Medical Devices in Germany and the Italian Medicines Agency in Italy.



Products under Development

To expand 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 finished products, as well as on M&A of companies that have promising development projects. In FY2021, we obtained development projects in the areas of plastic surgery and dermatology by acquiring ARTham, a clinical stage biopharmaceutical company in Japan. ARTham’s projects, ART-001 and ART-648, are currently in Phase II clinical trials for the potential treatment of refractory vascular malformations and bullous pemphigoid, respectively. In other

development projects, in the first half of FY2021 KAKEN filed an application for approval of KMW-1, a burn eschar remover designated as an orphan drug in Japan. KAR, a topical treatment for head lice, is currently in Phase III clinical trials. BBI-4000 is in Phase I clinical studies for the potential treatment of primary palmoplantar hyperhidrosis as an additional indication of Ecclock. Phase I clinical studies are under way for KP-483, an immune-oncology agent developed from in-house drug discovery for the treatment of solid tumors, and for NM26-2198, a multi-specific antibody that KAKEN is co-developing with Numab Therapeutics AG for the potential treatment of atopic dermatitis.

Products under Development (As of June 2022)

Development Code	Planned Indication	Development Stage				Remarks
		Phase I	Phase II	Phase III	Application	
KMW-1	Removal of burn eschar	Filed				In-licensed from MediWound Ltd. Overseas product name: NexoBrid
KAR	Head lice	Phase III				In-licensed from Arbor Pharmaceuticals, LLC Overseas product name: Sklice
ART-001	Refractory vascular malformations	Phase II				Development project of ARTham
ART-648	Bullous pemphigoid	Phase II				Development project of ARTham
BBI-4000	Primary palmoplantar hyperhidrosis	Phase I				Additional indication for Ecclock, which has been approved for primary axillary hyperhidrosis treatment
KP-483	Solid tumors (immune-oncology)	Phase I				Product from in-house drug discovery
NM26-2198	Atopic dermatitis	Phase I				Preparing for Phase I clinical studies Co-development with Numab Therapeutics AG

Agrochemicals

Business Overview and Summary of Results

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 them in 19 countries. Pentoxazone has excellent herbicidal effects on annual weeds, and has a stable high performance, long-lasting residual 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.



Real Estate

Business Overview and Summary of Results

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. FY2021 segment revenue totaled ¥2,410 million, a year-on-year increase of 1.9%.



R&D Growth Strategy

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



Mitsuru Watanuki
Corporate Officer
Chief Officer of R&D Division

We will accelerate transformation of the drug discovery and clinical development processes and continuously create innovative, world-class drugs to realize our R&D growth strategy toward the achievement of Long-Term Business Plan 2031.

To transform the drug discovery process, we will fully utilize our research platform, develop our own drug discovery targets based on unmet medical needs, and further strengthen our discovery research platform. We will drastically reduce development time and increase the probability of success by actively utilizing digital technology, including AI in drug discovery, and by collaborating with external partners. Moreover, in addition to conventional small molecule drugs, we will select other modalities that fit our drug discovery targets as we work to create drugs that are more effective, such as the next-generation antibody we are currently developing.

To transform clinical development processes, we will strengthen cooperation with external organizations and actively incorporate new techniques that make use of digital

technologies, such as remote monitoring and virtual clinical trials, to greatly improve operating efficiency. Additionally, the use of real-world data and translational research¹ will enable us to shorten the clinical trial period and make judgments on PoC² at an early stage. We will also promote KAKEN-led overseas development to accelerate overseas expansion.

Accelerating creation of new drugs through innovation of the drug discovery and clinical development processes will require improvement of manufacturing technologies to handle diverse modalities and target diseases. With close cooperation among drug discovery research, CMC,³ clinical development and medical affairs, we will continuously create distinctive and innovative new drugs that are easy for patients to use.

1. Translational research: A research process that translates the findings of basic medical research to application in clinical practice in the form of diagnosis and treatment
2. Proof of Concept: Proof of the usefulness and efficacy of a new drug candidate in clinical development by administering it to animals or humans
3. Chemistry, Manufacturing and Control: Refers to work involving the chemistry, manufacturing, quality control and analysis of those functions for APIs and drugs



Business Development Growth Strategy

By increasing the overseas sales ratio, we will contribute to KAKEN's sustainable growth as an R&D-driven pharmaceutical company with a global presence, primarily in the areas of dermatology and orthopedics.



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

To deliver onychomycosis treatment Clenafin to patients around the world, we have out-licensed it to partner companies in North America, Europe and Asia. Our collaborative network is steadily expanding. We will continue to seek alliances with new partners in regions where Clenafin has not been launched yet and strengthen relationships with existing partners to maximize the value of this drug.

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

We are expanding the scope of our search for in-licensing opportunities, which had been centered on small molecule

drugs, to other modalities, and are seeking alliance opportunities. While we will continue to focus on dermatology and orthopedics, we will also devote more attention to intractable and rare diseases, and will in-license products that we can deliver to patients around the world as well as in Japan, thereby enhancing our development pipeline.

Meanwhile, we have initiated efforts to out-license primary axillary hyperhidrosis treatment Ecclock in major countries in Asia, and have been approached by interested companies in the region. We are now working to develop Ecclock into a product that will contribute to our overseas growth as our next global product after Clenafin. Starting in Asia, we are also focusing on out-licensing existing global products Fiblast, a wound-healing agent, and Regroth, a periodontal regenerative agent.



Marketing & Sales Growth Strategy

"One for Patients! All for the Smiles of Patients!"
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, Marketing & Scientific Information and Distribution. In the Marketing & Sales Group, MRs provide medical professionals with proper usage information. While doing so, MRs also collect information related to product safety and suggestions for product improvement and share this information within the Company. These efforts lead to information provision and product improvements that meet the needs of medical professionals. Due to the COVID-19 pandemic in the last few years, pharmaceutical companies have been required to provide high-value-added information under greater time constraints. In response to the rapidly changing business environment, we are taking various measures to improve the quality and speed of our information provision, including utilizing digital tools and restructuring our division.

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

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



Agrochemicals Growth Strategy

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



Tsukasa Fujimaki
General Manager of Agrochemicals and
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 2027 to help ensure KAKEN's sustainable growth.

Sustainability Strategy

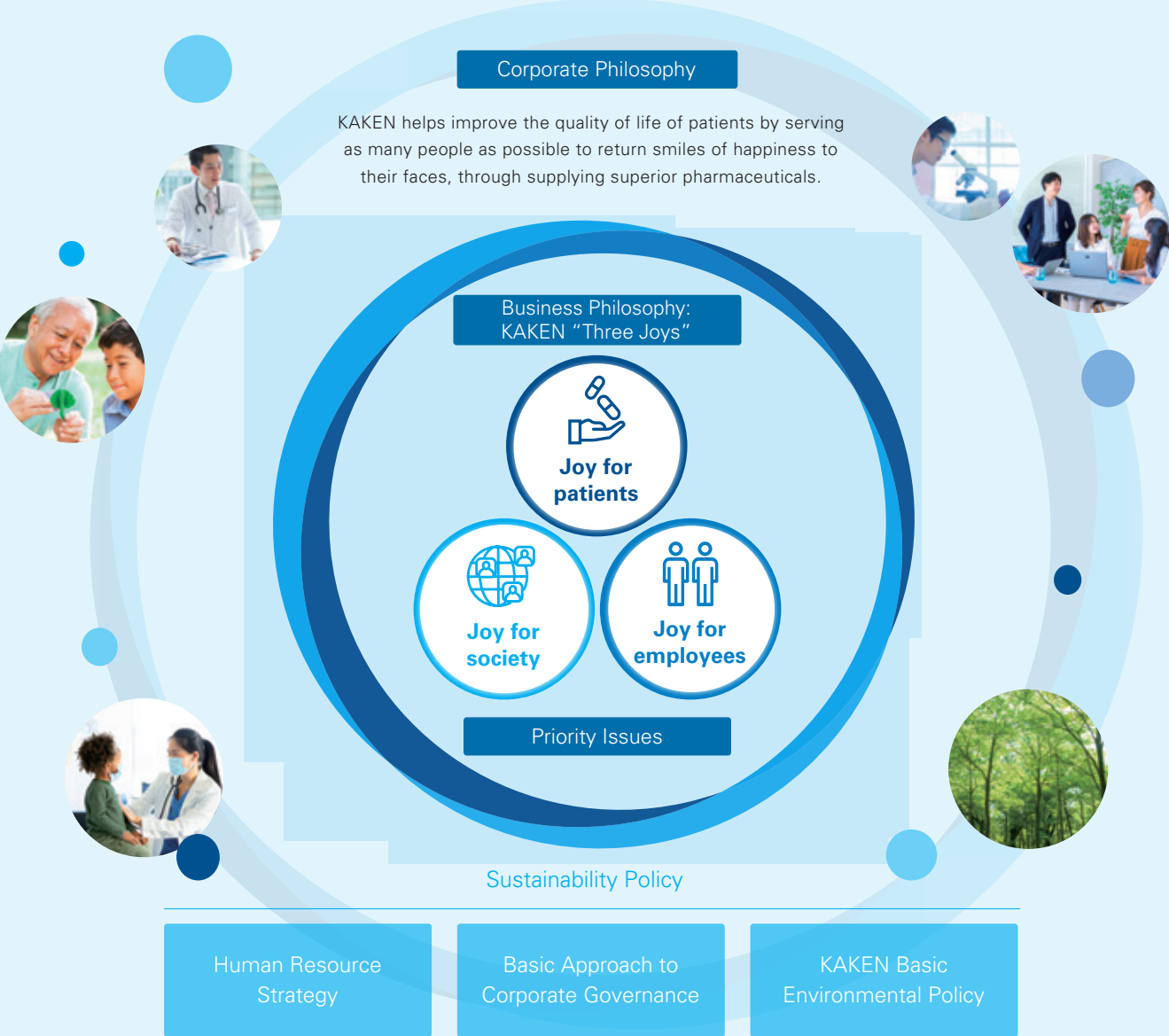
In a rapidly changing business environment, KAKEN has formulated a sustainability policy to speed up initiatives for realizing a sustainable society together with its stakeholders. Based on this policy, we aim to enhance KAKEN’s corporate value as well as create a sustainable society.

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.



Engagement with Customers



Business Philosophy / Priority (Material) Issues / Main Initiatives

Business Philosophy	Priority (Material) Issues	Main Initiatives
Joy for patients	Fulfilling responsibilities as a pharmaceutical company <ul style="list-style-type: none">• Stable supply of high-quality pharmaceuticals with proven safety	<ul style="list-style-type: none">• Maintain domestic and international standards for good manufacturing practice (GMP)

Quality Assurance Policy

KAKEN is committed to realizing its corporate philosophy and management policies and supplying superior pharmaceuticals. To achieve that, KAKEN will carry out the following activities in clear recognition of the fact that it is engaged in the pharmaceutical business, that it pursues higher ethical standards and that it places primary and constant emphasis on quality during the course of such activities. These activities include drug discovery, exploratory research, development, clinical trials, manufacture, post-marketing surveillance, the provision of pharmaceutical information, and other matters.

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

Product Quality Assurance

KAKEN works to return smiles of happiness to the faces of as many patients as possible by supplying superior pharmaceuticals that help improve their quality of life. To that end, we believe that it is absolutely essential that we have a quality assurance system in which both our Head Office (a manufacturer and distributor of pharmaceuticals) and our factory (a manufacturer of pharmaceuticals) fulfill their respective responsibilities and cooperate closely. At our factory, competencies and appropriateness of each manufacturing process and facility are evaluated to ensure that suitable manufacturing and quality management practices are followed.

The Quality Assurance Department of the Head Office evaluates and confirms these activities, which we believe results in the creation of a more 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 throughout all stages of a product’s lifecycle.

Safety Assurance for Pharmaceuticals after Launch

Pharmaceuticals receive regulatory approval after undergoing evaluations based on the results of clinical trials, which have a limited scope in regard to such considerations as patient age, gender, complications and concurrent medications. After launch, pharmaceuticals are used by a wider range of patients, which can reveal unexpected 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.

Pharmaceuticals Information Service Office

Accurate information is essential for the proper usage of prescription pharmaceuticals. We provide and collect information pertaining to the proper usage of our pharmaceuticals mainly through MR activities; however, 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 informs customers about proper usage of pharmaceuticals and reports their valuable opinions and suggestions on pharmaceutical formulations and other matters to relevant departments in the Company, thereby helping to improve pharmaceutical formulations and enhance product information for the benefit of customers.

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

Corporate Governance



Business Philosophy / Priority (Material) Issues / Main Initiatives

Business Philosophy	Priority (Material) Issues	Main Initiatives
Joy for society	Strengthening corporate governance <ul style="list-style-type: none">Strengthening relationships with stakeholdersPromotion of complianceRisk management to ensure business continuity	<ul style="list-style-type: none">Strengthen governance frameworkAppropriate and timely information disclosure and dialogueTraining and education in compliance, risk management, and relevant laws and regulationsContribute to local communities (participation in activities such as local beautification and disaster relief support)Develop/Update disaster and pandemic response plans

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.

Corporate Governance Structure

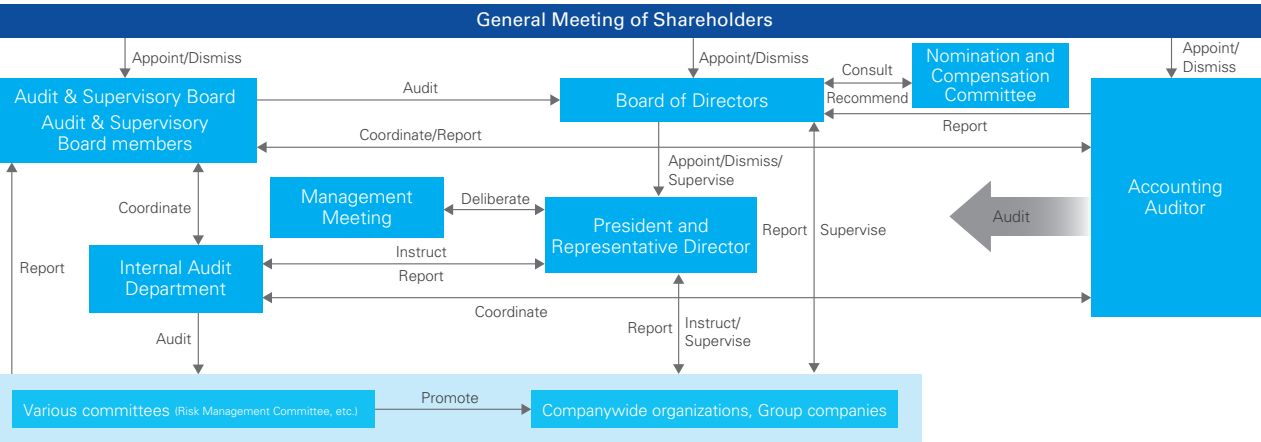
KAKEN has adopted an Audit & Supervisory Board system, taking into consideration the scale of its business, management monitoring functions and other circumstances. Four Audit & Supervisory Board members, including two outside members, attend all important meetings, including Board of Directors meetings, and actively express their opinions. Outside Audit & Supervisory Board members provide their opinions from a neutral standpoint. KAKEN therefore considers its management monitoring functions to be fully functional under its current auditing system.

In addition, KAKEN has adopted the 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.

Corporate Governance Structure



	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 holds scheduled meetings with the Accounting Auditor for proactive discussions and information exchange, in order to create 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 FY2021	16	14	3

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 of the outside directors and outside Audit & Supervisory Board members.

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

Name	Attendance at Board of Directors Meetings and Audit & Supervisory Board Meetings		Reason for Selection
	Board of Directors Meetings (16)	Audit & Supervisory Board Meetings (14)	
Kiyoko Kamibeppu	16	–	Ms. Kamibeppu has extensive professional expertise and insight based on experience as a Doctor of Health Science and a professor of a graduate school. The Company believes that based on her expertise as a professor of 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	13	–	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.
Hirotoishi Endo	16	14	Mr. Endo has extensive experience in the financial industry and a record of achievements and insight cultivated as a corporate manager. The Company believes that Mr. Endo will apply this expertise to the Company’s audit system.
Hiroaki Matsumoto	13	11	In addition to being a certified tax accountant, Mr. Matsumoto has extensive experience and a record of achievements at the National Tax Agency, as well as abundant knowledge and insight in the field of finance and accounting. The Company believes that Mr. Matsumoto will apply this expertise to the Company’s audit system.

Note: 13 Board of Directors meetings were held following Mr. Inoue’s appointment as a director of the Company on June 29, 2021. 13 Board of Directors meetings and 11 Audit & Supervisory Board meetings were held following Mr. Matsumoto’s appointment as an Audit & Supervisory Board member of the Company on June 29, 2021.

Evaluation of Effectiveness of the Board of Directors

In FY2021, 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.

Officer Compensation

In an effort to provide an incentive to contribute to the sustainable growth of KAKEN, the compensation for the Company's directors comprises basic compensation, bonuses and stock compensation, which are determined by comprehensively taking into consideration the Company's medium- to long-term performance as well as past payment amounts, in addition to the responsibilities of the directors. Basic compensation is a fixed amount, while bonuses and stock compensation are linked to the Company's business performance. However, bonuses and stock compensation are not paid to outside directors, as they are responsible for supervision and monitoring of management from an independent standpoint.

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

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

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 the KPIs in business plans 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

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 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 60:30:10 for basic compensation, performance-linked compensation and nonmonetary compensation (assuming 100% achievement of KPIs). KAKEN will change the ratio to 60:25:15 for FY2022 and thereafter.

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 FY2021, the Nomination and Compensation Committee meeting regarding directors' compensation was held in March 2022. The committee deliberated the draft proposal for basic compensation and performance-linked compensation for individual directors in accordance with the above criteria.

Messages from Outside Directors

I will contribute to the creation of a corporate structure that functions as more than the sum of individual employees, as well as to foresighted management judgments.

The Company improved its governance structure by adding an outside director in FY2019, ahead of the June 2021 Corporate Governance Code revisions. Each outside director has a distinct education and career background, and we speak at Board of Directors meetings and other meetings from those perspectives in an effort to raise the effectiveness of corporate governance. I feel my experience as a university professor primarily in research into the quality of life of patients and their families, and in managerial positions encompassing 25 fields, serves me well in my role as a director of KAKEN. When I was first appointed, there were times when I was perplexed by the differences in our ways of thinking, but recently I have come to see that we are all working toward a common goal. I feel that my specialty of family nursing is highly compatible with the pharmaceutical industry in that the ultimate goal is to achieve a higher quality of life of patients and their families. Achieving that goal requires the creation of a corporate structure that enables employees as a whole to be more productive than the sum of each individual's abilities, and foresighted decision-making (i.e., management judgments).

In May 2022, KAKEN took a new step with the formulation of Long-Term Business Plan 2031. Outside directors received repeated advance explanations in the course of crafting the plan, and I witnessed the process as the plan took shape. I am personally interested in the Company's move into new areas and enhancement of the development pipeline with a view toward overseas expansion of research and development. In Board of Directors meetings and explanations, the management team seems to be more energized than before. I remain committed to earning the trust of shareholders and further increasing corporate value by monitoring management decision-making and execution from an independent standpoint.



Kiyoko Kamibeppu
Outside Director

I will support efforts to increase corporate value by identifying issues from diverse perspectives to help achieve the target KPIs.

Long-Term Business Plan 2031 is important as it defines the Company's direction and strategies, and vast amounts of time were spent on its review. Outside directors were given advance explanations of the Company's current condition, a summary of the previous medium-term business plan, future issues and strategies, so we were able to discuss the long-term business plan with a more in-depth understanding.

According to the plan, the Company will make strategic investments of ¥200 billion or more over 10 years, but to achieve the target KPIs it is essential to first improve the quality of strategic investments and research and development capabilities as much as possible, and expand the development pipeline to steadily accumulate results. The number of decisions to be made regarding investment risk will increase, and following those investments, course corrections will be necessary to address changes in the internal and external environment and circumstances. This will require more sophisticated and flexible management decision-making and monitoring capabilities.

Also, no matter how good the plan is, things will not necessarily be successful. One key to executing the plan and guiding it to success will be management's capabilities for transforming (i.e., to reconstruct, reorganize and transform the existing organizational structure and resources), and the other is growth of all employees, without which transformations set forth in Long-Term Business Plan 2031 cannot happen. The management team needs to shape human resource management systems and the working environment in a way that creates energy for growth.

These are some of the issues that need to be addressed in order to achieve the target KPIs, and I believe outside directors will have more opportunities to put their experience and knowledge to use. I will increase my communications with the other board members and do my best to contribute to the enhancement of the Company's corporate value.



Shoichiro Takagi
Outside Director

I provide advice to enhance corporate value, and watch over KAKEN's sound, sustainable growth.

Pharmaceutical companies are an indispensable presence in society because they contribute directly to improving patients' quality of life through the products they provide. To provide stable supplies of effective medicines, pharmaceutical companies must grow soundly.

KAKEN's outside directors, just like its internal directors, make suggestions that contribute to the Company's sustainable growth and increase its corporate value. At the same time, we watch over the Company's management from an outside perspective to make sure there are no conflicts of interest among the Company, its management and its shareholders. We are also expected to maintain the Company's soundness in ways such as working to reflect the views of minority stakeholders.

I have worked as an attorney until now, so I am not an expert on the pharmaceutical industry, but I intend to scrupulously fulfill the role I have outlined here based on the knowledge I have gained as an attorney.

KAKEN formulated Long-Term Business Plan 2031 in May 2022 to achieve sustainable growth together with society. I believe the Company's vision for the future was made clearer by involving employees from a wide range of business operations, primarily the Corporate Planning & Coordination Department and the General Affairs Department, in the review process. They identified the issues inherent or latent in the Company, then narrowed these issues down to those with the highest priority, examined the risks associated with each, and organized the main initiatives. Specific targets and measures for strengthening and enhancing research and development, overseas expansion and the management base have also been incorporated into the plan, and I think they will be valuable guidelines going forward. I hope that with management steering KAKEN in the right direction in response to changes in society, the whole Company will be able to make rapid strides toward ideal objectives.



Yasutomo Inoue
Outside Director

Total Amount of Compensation, Total Amount of Compensation by Type, and Number of Eligible Officers by Category in FY2021

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)	348	253	65	29	7
Audit & Supervisory Board members (Excluding outside Audit & Supervisory Board members)	48	48	—	—	2
Outside officers	37	37	—	—	7

Note: Stock compensation represents a provision for share-based remuneration in FY2021.

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)



Yoshio Tanabe
Director

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



Masahiro Matsuura
Director

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



Minoru Ohta
Director

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



Masashi Suzudo
Director

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



Kiyoko 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, TORII PHARMACEUTICAL CO., LTD.
Jun. 2013 Representative Director, President and Chief Executive Officer of TORII PHARMACEUTICAL CO., LTD.
Mar. 2019 Part-time Advisor of Pharmaceutical Business, Japan Tobacco Inc.
Jun. 2020 Outside Director of the Company (to present)



Yasutomo Inoue
Outside Director

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

Audit & Supervisory Board Members



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

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



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)



Hirotoshi Endo
Outside Audit & Supervisory Board Member

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



Hiroaki Matsumoto
Outside Audit & Supervisory Board Member

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

Corporate Officers

Naoyuki Ishida
General Manager of Human Resources Department

Hirofumi Fujii
In charge of Client Relations

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

Mitsuru Watanuki
Chief Officer of R&D Division

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

Name	Position	Corporate management	Accounting/ Finance	Legal affairs/ Compliance	Knowledge of the industry/ Sales/Marketing	International experience	Risk management/ Corporate governance
Hiroyuki Horiuchi	President and Representative Director	●			●		●
Yoshio Tanabe	Director	●		●		●	
Masahiro Matsuura	Director				●		●
Minoru Ohta	Director	●	●				
Masashi Suzudo	Director		●			●	●
Kiyoko Kamibepu	Outside Director				●		
Shoichiro Takagi	Outside Director	●		●			●
Yasutomo Inoue	Outside Director			●			
Naomi Doi	Audit & Supervisory Board Member (Standing)				●		●
Kazumori Ishiguro	Audit & Supervisory Board Member (Standing)				●		●
Hirotoshi Endo	Outside Audit & Supervisory Board Member	●					●
Hiroaki Matsumoto	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.

Compliance and Risk Management



Basic Approach
to and System
for Promoting
Compliance

KAKEN believes 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, KAKEN 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 making decisions and taking actions in the performance of duties by executives and employees toward the achievement of our corporate philosophy and business philosophy. Our corporate philosophy and business philosophy, and the KAKEN Charter of Corporate Behavior are disclosed on our website in Japanese and English, and the Code of Conduct is disclosed on our website in Japanese.

To help executives and employees of the KAKEN Group engage in compliance-based business activities, we have prepared panels displaying the corporate philosophy, business philosophy and the KAKEN Charter of Corporate Behavior, as well as a Compliance Check Card and Compliance Guidebook. In addition, KAKEN provides level-based compliance education and, through the Company intranet, distributes messages from the compliance officer and related information from the Compliance Group of the Legal Affairs & Intellectual Property Department as appropriate to raise compliance awareness.

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

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

In addition, the Company's initiatives for animal testing have been assessed by an external party as being appropriately carried out in accordance with the policies of the Ministry of Health, Labour and Welfare. In January 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 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 risk management officer is appointed and the Corporate Planning & Coordination Department is designated as the responsible department.
 2. The Company classifies risks and manages them by designating the responsible departments, respectively.
 3. The Board of Directors makes management decisions on the handling of material risks from the perspective of the KAKEN Group's management, and such risks are managed by the responsible departments.
 4. The Internal Audit Department audits the status of risk management at the KAKEN Group and reports the results to the president, the Board of Directors and the Audit & Supervisory Board.
- The Company has formulated Regulations for Risk Management and carries out risk management activities such as identifying risks, taking countermeasures and providing education for each division and department. At the same time, the Risk Management Committee has been set up, chaired by the risk management officer appointed by the Board of Directors. In such ways, the Company has established a system to manage risks on a Companywide basis. Important matters deliberated at Risk Management Committee meetings are submitted for approval or reported to the Board of Directors.

Principal Risks

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

The forward-looking statements contained herein reflect the judgment of the KAKEN Group as of March 31, 2022.

Major Risks	Status of Major Risks
Risks related to legal regulations and administrative developments such as policies to curtail public healthcare expenditures	The pharmaceutical business in Japan is subject to various regulations under the pharmaceutical regulatory system. In addition, various medical system reforms are underway as part of policies to curtail public healthcare expenditures, such as revisions of the drug price standards and measures to promote the use of generic drugs. Revisions of related laws and regulations and developments in the administrative policies related to the medical system and health insurance could materially affect the KAKEN Group's business performance and financial condition.
Risks related to new drug development	Considerable financial investment and development periods of more than 10 years are required for the research and development of drugs; however, the probability of these efforts coming to fruition as a new product or technology is not high. The Company carefully develops new drugs while taking the efficacy and safety of each drug into full consideration, but development could be halted before completion if the expected efficacy cannot be proven or a safety issue is identified. Such cases could materially affect the KAKEN Group's business performance and financial condition.
Risks related to adverse drug reactions	Pharmaceutical products are approved and marketed only after sufficient safety tests and thorough review; however, only a limited number of patients are administered experimental drugs during clinical trials undertaken in the development stage. In order to supplement these clinical trials, post-marketing surveillance is conducted after products are launched. If unexpected adverse drug reactions are identified in post-marketing surveillance, the Company may be compelled to recall the product or discontinue its sales. Such cases could materially affect the KAKEN Group's business performance and financial condition.
Risks due to competition	The pharmaceutical industry is very competitive. Competition with competing products that have similar efficacy and effect and with generic products launched after patents expire may result in declines in sales of our products, which could materially affect the KAKEN Group's business performance and financial condition.
Risks related to intellectual property rights	The KAKEN Group manages its intellectual property properly and takes precautions against infringement by third parties. If a third party infringes the Group's intellectual property rights, the Group may file a lawsuit against the third party to protect such rights. The outcome of such litigation could materially affect the KAKEN Group's business performance and financial condition. The Group also pays close attention to ensure that its projects do not infringe the intellectual property rights of any third party. However, if such an infringement occurs, it may result in a dispute and subsequent compensation for damages and cancellation of the project, which could materially affect the KAKEN Group's business performance and financial condition.
Risks related to litigation	As a company conducting business both in Japan and overseas, KAKEN is at risk of litigation instituted for adverse drug reactions of its pharmaceutical products and issues concerning product liability, labor, the environment and fair trade. Such litigation could materially affect the Group's business performance and financial condition.
Risks related to delay or interruption of product supply	Delay or interruption of product supply due to problems with the Company's manufacturing facilities or its suppliers, or delays in the procurement of raw materials, or product recalls due to quality problems could materially affect the Group's business performance and financial condition.
Risks related to IT security and information management	The Group uses various information systems; therefore, our business operations may be hampered by system failures, computer viruses and cyber-attacks, and other factors. If confidential information including personal information in our possession is leaked to any third party, the Group would face compensation for damages, administrative action, and loss of public trust. These events could materially affect the Group's business performance and financial condition.
Risks related to large-scale disasters	The occurrence of natural disasters such as earthquakes and typhoons, accidents such as fires, or pandemics could cause extensive damage to the KAKEN Group's offices and business partners. The resulting disruption to business activities or considerable expense required to repair damaged facilities could materially affect the Group's business performance and financial condition.
Risks associated with the spread of COVID-19	Despite the efforts of the KAKEN Group, impacts of the COVID-19 pandemic that are more serious or persistent than the Group expects could materially affect the Group's business performance and financial condition. In addition, even after the COVID-19 pandemic is contained, it may continue to have an impact for an extended period of time.

Engagement with Society and Local Communities



Activity Policy

With the aim of deepening engagement with local communities as a corporate citizen, our employees give consideration to how they can contribute to society as individuals, and are proactively engaged in environmental issues familiar to them. In addition, to improve awareness of disaster prevention and strengthen safety measures, each of our sites, including the Head Office, undertakes initiatives such as the provision of a standard first aid course and various 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 FY2021 the site's support team conducted 15 cleanups of sports fields along the river.



Environmental Report Meetings

The Shizuoka Site had been holding environmental report meetings every year for local residents. In FY2020 and FY2021, instead of in-person meetings, information was shared by circulating the report documents from resident to resident to help prevent the spread of COVID-19. Reports present various statistics on relevant matters, the status of employee education, and other activities for compliance with laws and regulations. Through this report, the site promotes better understanding of the Company's environmental initiatives.

Talking about Careers with Students at a Local Junior High School

To help young people who are unable to get first-hand experience regarding careers through company visits due to the impact of the COVID-19 pandemic, in FY2021 employees from the Shizuoka Site visited a nearby junior high school to talk to students about their work. In this first-time initiative, employees introduced KAKEN to the students, talked about medicine in a quiz format and showed a DVD about the manufacturing process of Clenafin. Not only students but also teachers asked many questions regarding topics they do not usually hear about. The event was friendly and lively 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 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.

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



Environmental Management



Business Philosophy / Priority (Material) Issues / Main Initiatives

Business Philosophy	Priority (Material) Issues	Main Initiatives
Joy for society	Consideration for the environment <ul style="list-style-type: none">Proper management of waste and wastewaterEfficient use of water and other resourcesReduction of CO₂ emissionsSupply of eco-friendly agrochemicals	<ul style="list-style-type: none">Roll out environmental management systemMaintain ISO 14001 certification (Shizuoka Site)Continue CO₂ emission reduction initiativesResearch and development of eco-friendly agrochemicals

Environment Basic 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

- 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 Environmental Committee and Environmental Measures Task Force, these initiatives shall be systematic and continuous.
- 2 **Comply with environmental laws and regulations**

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

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

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

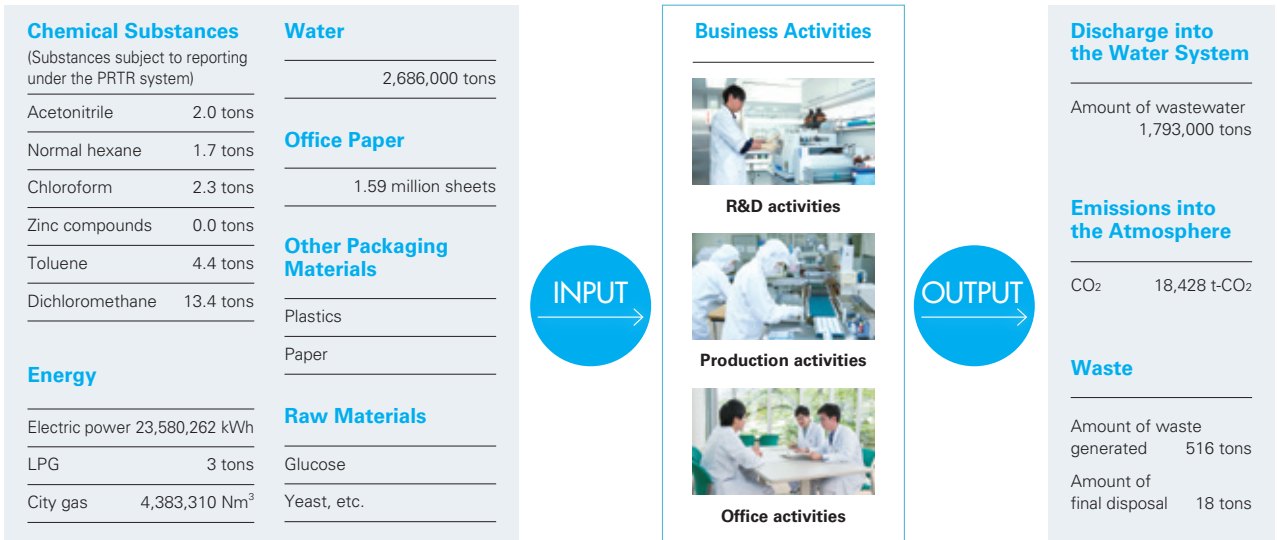
As a corporate citizen, we shall work with local communities to protect the environment. We shall also disclose environmental information and work for mutual understanding with those communities.
- 6 **Raise environmental awareness**

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

Materials Balance of Business Activities

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

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



Note: Materials balance data shown is the total amounts for FY2021.

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 FY2021, the total amount of waste generated by the Shizuoka Site was 487 tons. Of this, 45% 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 79 tons of valuable materials (accounting for 16% of total other wastes). The amount of final disposal was 18 tons. Going forward, we will redouble our efforts to conduct activities promoting the reduction and recycling of waste.

Efficient Use of Water Resources

The Shizuoka Site benefits from a plentiful supply of water resources 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 Shizuoka Site, which includes a factory, switched its water pump to an inverter type to enable fine adjustments in the amount of groundwater drawn. Through this and other steps, such as stopping

unnecessary drawing of well water, the site is working to use water resources more efficiently.

We will continue to promote efficient use of water resources from the standpoint of business sustainability.

▶ For the Shizuoka Site's water consumption and consumption per unit of production, see page 39.

Reduction of CO₂ Emissions

We participate in the Commitment to a Low-Carbon Society, a plan that the Federation of Pharmaceutical Manufacturers' Associations of Japan helped to create, and are curbing CO₂ emissions in support of the federation's goal of reducing CO₂ emissions in FY2030 by 46% compared with FY2013 levels, and its long-term vision of net-zero CO₂ emissions in 2050. 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 carrying out ongoing energy-saving activities. We are also considering the use of carbon-free electricity to further reduce our emissions.

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

Supply of Eco-Friendly Agrochemicals

Polyoxins, which are agricultural fungicides, 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.



Human Resource Strategy

Joy for employees

Business Philosophy / Priority (Material) Issues / Main Initiatives

Business Philosophy	Priority (Material) Issues	Main Initiatives
Joy for employees	Creating fulfilling workplaces <ul style="list-style-type: none">Generating and maintaining employment opportunitiesWork-style reform and improved productivityEmployees' health, occupational safety and welfareDiversityDevelopment of the next generation of human resourcesRespect for human rights	<ul style="list-style-type: none">Work-style reform (including digitalization of work processes)Appoint female directorsEnhance systems for employing people with disabilities and seniorsHelp protect employees against disease and promote mental healthcare initiativesTraining programs, self-development support and discrimination/harassment prevention

Engagement with Employees

As a company that emphasizes "Joy for employees," KAKEN places great importance on employees' human rights, health, safety and hygiene, and promotes the creation of a working environment in which every employee can work with peace of mind and a sense of fulfillment. In addition, we also prioritize fostering a corporate culture that nurtures professionals. We will further refine this policy in Long-Term Business Plan 2031.

Basic Policy of Human Resource Strategy 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, we will review and upgrade the content of education and training at every level. In addition, we will work to develop and recruit talent who will promote digital transformation (DX), as well as global-minded talent.
- 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. In addition to empowering female employees, we will set up workplace systems from various viewpoints in order to make KAKEN a fulfilling place to work for employees at different life stages, such as those raising children or caring for family members, and older employees including those reemployed after retirement.

Human Resource Strategy Priority Measures

Priority Measures	
	① Foster a corporate culture and develop talent that generates innovative challenges <ul style="list-style-type: none">Foster a corporate culture that encourages employees to take on challengesDevelop 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 DXDevelop and recruit global-minded talent to reinforce overseas expansionReinforce the education and training system
	② Pursue a better work-style system and working environment that support the growth of employees <ul style="list-style-type: none">Transform the human resource management and work-style systems and improve the working environmentPromote diversity management
	③ Develop MRs who can flexibly respond to the changing times through convergence of the real and digital worlds <ul style="list-style-type: none">Develop MRs with expertise equivalent to an MSL* in diseases we are focusing on as well as in productsOptimize medical information provision based on data analysis, and use multiple communication channelsDevelop ability to plan and execute as a community healthcare partner based on a patient-first perspective

* 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

Development of the Next Generation of Human Resources

We consider human resource development a fundamental part of corporate management, and seek to improve employees’ abilities. We believe that employees who accurately grasp changes in our business environment and can generate new ideas and act on their own volition will have the traits necessary for shaping the Company in the future. Our basic policy for human resource development is to foster employees who can think and

act on their own, global-minded talent, and core talent—in other words, professionals with distinctive capabilities. We provide comprehensive education and training by employment year and position to foster employees who can make the most of their capabilities, enabling them to achieve results at each stage of their careers while gaining experience as businesspeople.

Approach to Education and Training

- ① The purpose of education and training is to foster employees who can accurately grasp the current state of the Company and changes in the industry environment, discern what is best for the Company, and think and act on their own volition based on their new ideas and creativity.
- ② We have positioned the development of mid-career and junior employees as one of our priority issues, and as such work to develop human resources through on-the-job training as well as external training by outside expert instructors.
- ③ We utilize internal and external training programs to foster the next generation of leaders, as well as training for managers.



A training session in June 2019. Since 2021, we have been conducting training remotely due to the COVID-19 pandemic.

Training by Position

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

Training Programs

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

Self-development support

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

Job Creation, Worker Retention and Diversity

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

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

Enabling Work-Life Balance

As part of efforts to create worker-friendly environments where employees can work efficiently, we adopted a flextime system Companywide, except for the Production Division and MRs. In July 2022, the work-from-home arrangement that we had implemented as a temporary measure in response to the COVID-19 pandemic, was modified and established as the Work-from-Home System, a new work-style option.

Support for Childcare and Nursing Care

We have been establishing various systems such as leave of absence, days off and shorter working hours, based on the Regulations for Childcare Leave and the Regulations for Caregiver Leave, so that employees who have difficulty working under normal conditions due to childcare or nursing care commitments can continue to work without worry. In FY2021, we established a system in which employees can take special paid leave for the purpose of caring for a family member or for a child’s gradual entry into a new nursery school. In FY2022, we changed the childcare leave system so that employees could receive up to five days of paid leave during the childcare leave period, and made amendments to the system for shorter working hours to enable employees using that system to also make use of flextime. We are also taking steps to make it easier for male employees to take childcare leave.

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. This system has enabled 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 proactively engage in efforts to hire persons with disabilities. We maintain employment levels that exceed the statutory rate by enhancing our support system to ensure such workers receive appropriate assistance in the workplace.

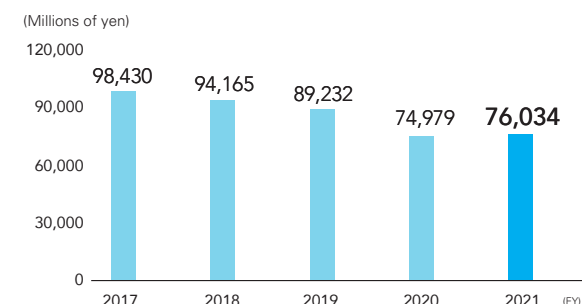
Improvement of the Working Environment

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.
Occupational Safety and Health	Based on the Regulations for Safety and Health Management, which are aimed at preventing occupational accidents and illnesses and creating a comfortable working environment, we hold Safety and Health Committee meetings on a monthly basis at all offices and other workplaces. We work to eliminate occupational accidents by implementing safety inspections and remedial measures at each facility and workplace. We also actively work to improve the working environment by conducting regular questionnaire surveys of our employees.
Creation of a Workplace Free from Discrimination and Harassment	We work to enhance awareness of the prevention of discrimination and harassment among all employees through means such as the Rules of Employment, Regulations for Rewards and Punishments, the Compliance Guidebook, information meetings for employees in managerial positions, and regular postings and education via the Company intranet. We also keep employees informed of internal consultation channels.

Financial and Non-Financial Highlights

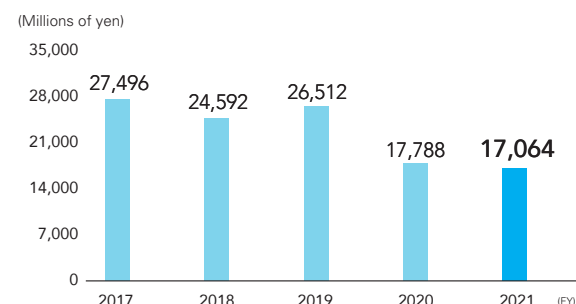
Net Sales

¥76,034 million



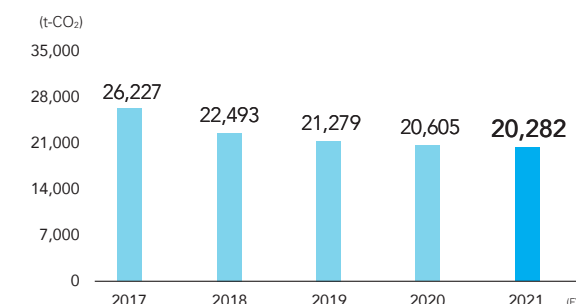
Operating Profit

¥17,064 million



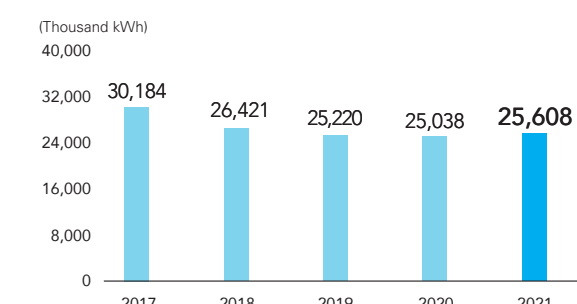
CO₂ Emissions

20,282 t-CO₂



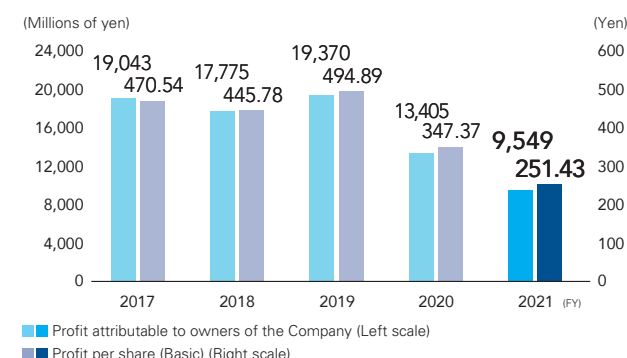
Electricity Consumption

25,608 thousand kWh



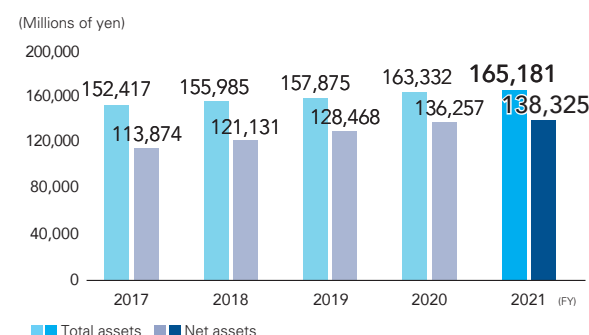
Profit Attributable to Owners of the Company and Profit per Share (Basic)

¥9,549 million / ¥251.43



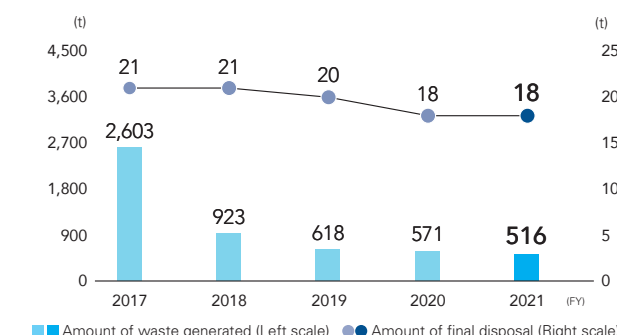
Total Assets and Net Assets

¥165,181 million / ¥138,325 million



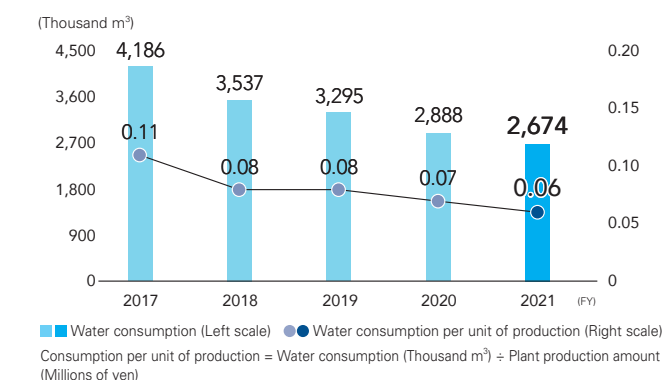
Amounts of Waste Generated and Final Disposal at the Shizuoka Site and the Drug Research Center in Kyoto

516 t / 18 t



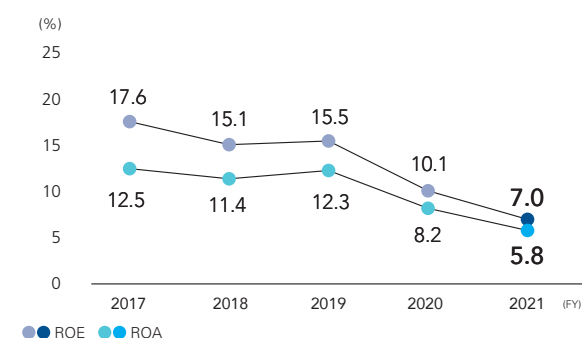
Water Consumption and Consumption per Unit of Production at the Shizuoka Site

2,674 thousand m³ / 0.06



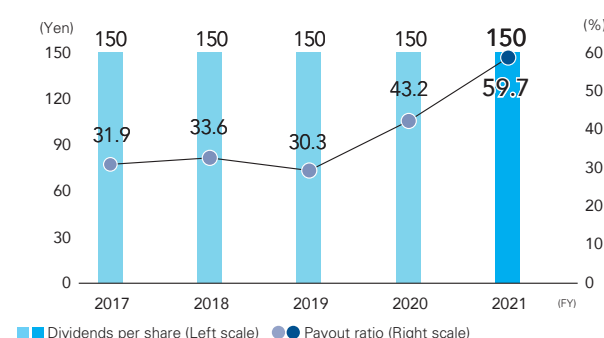
ROE and ROA

7.0% / 5.8%



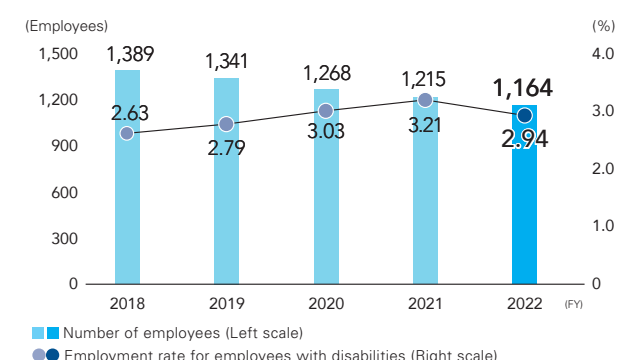
Dividends per Share and Payout Ratio

¥150 / 59.7%



Number of Employees and Employment Rate for Employees with Disabilities*

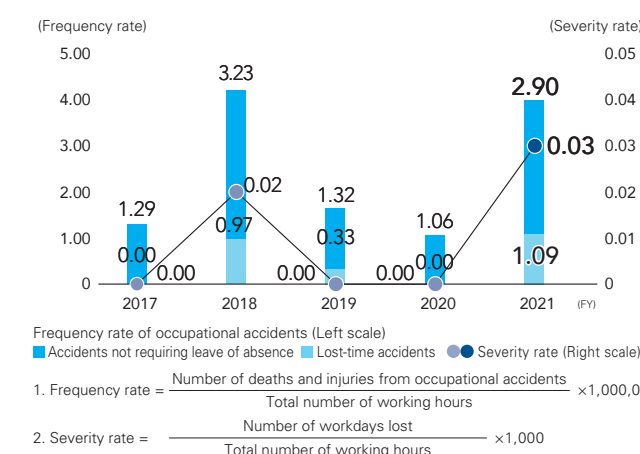
1,164 / 2.94%



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

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

2.90 / 1.09 / 0.03



Frequency rate of occupational accidents (Left scale)
 1. Frequency rate = $\frac{\text{Number of deaths and injuries from occupational accidents}}{\text{Total number of working hours}} \times 1,000,000$
 2. Severity rate = $\frac{\text{Number of workdays lost}}{\text{Total number of working hours}} \times 1,000$

FY2021 Operating Results and Financial Condition

Analysis of Operating Results

In FY2021, the year ended March 31, 2022, net sales increased 1.4% year on year to ¥76,034 million, operating profit decreased 4.1% to ¥17,064 million, and profit attributable to owners of the Company decreased 28.8% to ¥9,549 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 comparisons use figures calculated using a different accounting standard.

FY	2017	2018	2019	2020	2021
Net sales (Millions of yen)	98,430	94,165	89,232	74,979	76,034
Operating profit (Millions of yen)	27,496	24,592	26,512	17,788	17,064
Profit attributable to owners of the Company (Millions of yen)	19,043	17,775	19,370	13,405	9,549
Net assets (Millions of yen)	113,874	121,131	128,468	136,257	138,325
Total assets (Millions of yen)	152,417	155,985	157,875	163,332	165,181
Cash flows from operating activities (Millions of yen)	21,703	21,129	27,468	14,380	13,336
Cash flows from investing activities (Millions of yen)	(3,245)	(5,744)	(2,528)	(1,644)	(7,888)
Cash flows from financing activities (Millions of yen)	(9,530)	(9,524)	(10,173)	(8,752)	(8,129)
Cash and cash equivalents at end of year (Millions of yen)	52,694	58,555	73,322	77,305	74,625
Profit per share (Yen)	470.54	445.78	494.89	347.37	251.43
Dividends per share (Yen)	150.00	150.00	150.00	150.00	150.00
Equity-to-asset ratio (%)	74.7	77.7	81.4	83.4	83.4
Return on equity (%)	17.6	15.1	15.5	10.1	7.0

Segment Sales and Profit

Pharmaceuticals

Sales of pharmaceuticals and medical devices increased. While sales of onychomycosis treatment Clenafin decreased, sales of primary axillary hyperhidrosis treatment Ecclock, generic drugs, and other products increased, and overseas sales increased with the expansion of sales of Jublia (the product name for Clenafin outside Japan).

Sales of agrochemicals increased.

As a result, segment sales totaled ¥73,623 million, a year-on-year increase of 1.4%. Segment profit (operating profit) decreased 4.0% to ¥15,710 million.

Overseas sales were ¥6,956 million, an increase of 41.7%.

Real Estate

The main source of revenue in the Real Estate segment is rental income related to Bunkyo Green Court. Segment revenue increased 1.9% year on year to ¥2,410 million. However, segment profit (operating profit) decreased 4.5% to ¥1,353 million due to expenses incurred for rebuilding the Kansai Branch office.

Cost of Sales

Cost of sales mainly consists of manufacturing costs, cost of goods purchased, and cost of sales of services in the Real Estate segment. Cost of sales in FY2021 was ¥34,458 million, and the ratio of cost of sales to net sales was 45.3%.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses, which mainly consist of labor costs, research and development costs, and sales expenses including advertising and promotional costs, increased 6.0% year on year to ¥24,511 million. The main factor was a 25.0% increase in research and development costs to ¥8,420 million.

Financial Condition

Total assets as of March 31, 2022 were ¥165,181 million, an increase of ¥1,849 million from a year earlier. This was mainly attributable to an increase in in-process research and development.

Total liabilities as of March 31, 2022 were ¥26,855 million, a decrease of ¥219 million from a year earlier. This was mainly due to a decrease in notes and accounts payable-trade.

Net working capital (current assets minus current liabilities) was ¥91,564 million, and financial soundness was maintained with a current ratio of 580.7%.

Net assets as of March 31, 2022 were ¥138,325 million, an increase of ¥2,068 million from a year earlier. This was mainly due to an increase in retained earnings.

The equity-to-asset ratio was 83.4%.

Cash Flows

Cash and cash equivalents as of March 31, 2022 were ¥74,625 million, a decrease of ¥2,680 million from a year earlier.

Cash Flows from Operating Activities

Net cash provided by operating activities was ¥13,336 million, a decrease in cash inflow of ¥1,043 million compared with the previous fiscal year. The main factor was a decrease in profit before income taxes.

Cash Flows from Investing Activities

Net cash used in investing activities was ¥7,888 million, an increase in cash outflow of ¥6,243 million compared with the previous fiscal year. The main factor was purchase of shares of subsidiaries.

Cash Flows from Financing Activities

Net cash used in financing activities was ¥8,129 million, a decrease in cash outflow of ¥623 million compared with the previous fiscal year. The main factor was a decrease in purchase of treasury stock.

The Company believes that its cash and cash equivalents as of March 31, 2022 are at an appropriate level for its business operations, and that it has sufficient liquidity to withstand rapid changes in the business environment. In addition, the impact of the ongoing COVID-19 pandemic has not reached a degree that requires changing this view.

The KAKEN Group requires funding mainly to cover R&D investment and in-licensing expenses for expanding its development pipeline, raw material purchasing costs,

manufacturing costs, cost of goods purchased and capital expenditures to improve the efficiency of research, production and operations. The Company's policy is to actively meet funding requirements to achieve sustainable growth while considering financial soundness. The Company meets these funding requirements primarily with cash on hand accumulated through operating cash flows, but is also able to raise funds by borrowing from financial institutions or other means if additional funds are necessary.

Dividend Policy

KAKEN views stable and continuous return of profits to shareholders as an important management goal. Operating in the pharmaceutical industry entails large risks, requiring us to have a higher level of equity capital than companies in other industries. We employ a flexible dividend policy that sets cash dividends based on performance while maintaining a balance between returns to shareholders and strengthening equity capital.

Our basic policy is to pay dividends from surplus

twice a year, as an interim dividend and a year-end dividend, approved by the Board of Directors and the General Meeting of Shareholders, respectively.

Based on this policy, for FY2021, the interim dividend was ¥75 per share and the year-end dividend was ¥75 per share, for total annual dividends of ¥150 per share.

Internal reserves are invested in research and development and upgrading operating infrastructure to maximize corporate value.

Consolidated Balance Sheets

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiaries
As of March 31, 2022 and 2021

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
ASSETS			
CURRENT ASSETS:			
Cash and deposits (Notes 3 and 10)	¥ 61,025	¥ 63,706	\$ 500,205
Marketable securities (Notes 3, 4 and 10)	13,599	13,599	111,467
Receivables:			
Notes and accounts receivable trade (Note 10)	—	20,549	—
Notes and accounts receivable—trade, and contract assets (Notes 8 and 10)	20,260	—	166,066
Accounts receivable—other	242	337	1,984
	20,502	20,886	168,049
Inventories (Note 5)	14,981	15,198	122,795
Other	504	270	4,131
Allowance for doubtful accounts	—	(0)	—
Total current assets	110,613	113,662	906,664
PROPERTY, PLANT AND EQUIPMENT (Notes 6, 7 and 9):			
Buildings and structures	42,829	41,078	351,057
Machinery, equipment and vehicles	15,708	15,804	128,754
Tools, furniture and fixtures	7,819	7,613	64,090
	66,357	64,496	543,910
Accumulated depreciation	(45,565)	(44,331)	(373,484)
	20,791	20,165	170,418
Land	3,867	4,140	31,697
Construction in progress	1,074	713	8,803
Total property, plant and equipment	25,734	25,020	210,934
INVESTMENTS AND OTHER ASSETS:			
Investment securities (Notes 4 and 10)	17,093	17,368	140,107
Intangible assets			
In-process research and development (Note 2)	7,300	—	59,836
Other intangible assets	936	625	7,672
	8,236	625	67,508
Deferred tax assets (Note 19)	1,725	1,577	14,139
Long-term prepaid expenses	1,190	4,196	9,754
Other assets	587	882	4,811
Total investments and other assets	28,833	24,649	236,336
TOTAL ASSETS	¥ 165,181	¥ 163,332	\$1,353,943

See accompanying Notes to the Consolidated Financial Statements.

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
LIABILITIES AND NET ASSETS			
CURRENT LIABILITIES:			
Short-term bank loans (Notes 6 and 10)	¥ 3,850	¥ 3,850	\$ 31,557
Payables:			
Notes and accounts payable—trade (Note 10)	5,861	8,425	48,041
Accounts payable—other	3,543	3,002	29,041
Electronically recorded obligations—operating (Note 10)	78	144	639
	9,483	11,572	77,730
Accrued expenses	345	324	2,828
Provision for bonuses	1,049	1,127	8,598
Provision for sales returns	—	3	—
Provision for sales rebates	—	302	—
Income taxes payable (Note 19)	2,436	2,292	19,967
Other (Note 8)	1,884	1,803	15,443
Total current liabilities	19,049	21,276	156,139
NON-CURRENT LIABILITIES:			
Provision for share awards	106	73	869
Net defined benefit liability (Note 11)	5,039	5,376	41,303
Deferred tax liabilities	2,229	—	18,270
Other	431	348	3,533
Total non-current liabilities	7,806	5,798	63,984
NET ASSETS:			
Shareholders' equity (Note 12):			
Common stock			
Authorized: 193,000,000 shares as of March 31, 2022 and 2021			
Issued: 45,939,730 shares as of March 31, 2022 and 45,939,730 shares as of March 31 2021	23,853	23,853	195,516
Capital surplus	11,406	11,406	93,492
Retained earnings	126,347	122,462	1,035,631
Treasury stock, at cost: 8,121,361 shares as of March 31, 2022 and 7,621,338 shares as of March 31, 2021	(28,714)	(26,304)	(235,361)
Total shareholders' equity	132,893	131,418	1,089,287
Accumulated other comprehensive income:			
Net unrealized holding gain on securities	4,551	4,739	37,303
Remeasurements of defined benefit plans	301	99	2,467
Total accumulated other comprehensive income	4,853	4,839	39,779
Non-controlling interests	578	—	4,738
Total net assets	138,325	136,257	1,133,811
TOTAL LIABILITIES AND NET ASSETS	¥ 165,181	¥ 163,332	\$1,353,943

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, 2022 and 2021

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
NET SALES	¥ 76,034	¥ 74,979	\$ 623,230
COST OF SALES	34,458	34,072	282,443
Gross profit	41,575	40,907	340,779
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (Note 13)	24,511	23,118	200,910
OPERATING PROFIT	17,064	17,788	139,869
OTHER INCOME (EXPENSES):			
Interest and dividends income	397	393	3,254
Interest expenses	(17)	(17)	(139)
Foreign exchange losses	(31)	(12)	(254)
Loss on cancellation of leases	(7)	(2)	(57)
Gain on sales of non-current assets (Note 15)	195	379	1,598
Loss on retirement of non-current assets (Note 16)	(97)	(54)	(795)
Gain on sales of investment securities	1	115	8
Impairment losses (Note 17)	(2,994)	—	(24,541)
Contract loss (Note 18)	(762)	—	(6,246)
Other, net	136	66	1,115
	(3,179)	868	(26,057)
PROFIT BEFORE INCOME TAXES	13,885	18,657	113,811
INCOME TAXES (Note 19):			
Current	4,513	4,979	36,992
Deferred	(177)	272	(1,451)
	4,336	5,252	35,541
PROFIT	9,549	13,405	78,270
PROFIT ATTRIBUTABLE TO OWNERS OF THE COMPANY	¥ 9,549	¥ 13,405	\$ 78,270

	YEN		U.S. DOLLARS (NOTE 1)
	2022	2021	2022
PER SHARE DATA:			
Profit (Note 23):			
Basic	¥251.43	¥347.37	\$2.06
Diluted	—	—	—
Cash dividends applicable to the year (Note 12)	¥150.00	¥150.00	\$1.22

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, 2022 and 2021

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
PROFIT	¥ 9,549	¥ 13,405	\$ 78,270
OTHER COMPREHENSIVE INCOME (LOSS) (Note 24):			
Net unrealized holding gain (loss) on securities	(187)	1,623	(1,533)
Remeasurements of defined benefit plans	202	1,503	1,656
Total other comprehensive income (loss)	14	3,126	115
COMPREHENSIVE INCOME	¥ 9,563	¥ 16,532	\$ 78,385
Total comprehensive income attributable to:			
Owners of the Company	¥ 9,563	¥ 16,532	\$ 78,385

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, 2022 and 2021

MILLIONS OF YEN										
	SHAREHOLDERS' EQUITY					ACCUMULATED OTHER COMPREHENSIVE INCOME				
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total	Net unrealized holding gain on securities	Remeasurements of defined benefit plans	Total	Non-controlling Interests	TOTAL NET ASSETS
BALANCE—March 31, 2020	¥ 23,853	¥11,406	¥114,869	¥ (23,373)	¥126,756	¥ 3,116	¥ (1,404)	¥ 1,712	¥ —	¥128,468
Changes during the year:										
Cash dividends			(5,812)		(5,812)					(5,812)
Profit attributable to owners of the Company			13,405		13,405					13,405
Purchase of treasury stock				(2,941)	(2,941)					(2,941)
Disposal of treasury stock		0		9	9					9
Other, net						1,623	1,503	3,126		3,126
Total changes during the year	—	0	7,592	(2,931)	4,661	1,623	1,503	3,126	¥ —	7,788
BALANCE—March 31, 2021	¥ 23,853	¥11,406	¥122,462	¥ (26,304)	¥131,418	¥ 4,739	¥ 99	¥ 4,839	¥ —	¥136,257
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

THOUSANDS OF U.S. DOLLARS (NOTE 1)										
	SHAREHOLDERS' EQUITY					ACCUMULATED OTHER COMPREHENSIVE INCOME				
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total	Net unrealized holding gain on securities	Remeasurements of defined benefit plans	Total	Non-controlling Interests	TOTAL NET ASSETS
BALANCE—March 31, 2021	\$195,516	\$93,492	\$1,003,787	\$(215,607)	\$1,077,196	\$38,844	\$811	\$39,664	\$ —	\$1,116,861
Cumulative effect of changes in accounting policies			418		418					418
Restated balance	195,516	93,492	1,004,213	(215,607)	1,077,623	38,844	811	39,664	—	1,117,287
Changes during the year:										
Cash dividends			(46,852)		(46,852)					(46,852)
Profit attributable to owners of the Company			78,270		78,270					78,270
Purchase of treasury stock				(19,787)	(19,787)					(19,787)
Disposal of treasury stock		0		41	41					41
Other, net						(1,533)	1,656	115	4,738	4,861
Total changes during the year	—	0	31,418	(19,746)	11,664	(1,533)	1,656	115	4,738	16,525
BALANCE—March 31, 2022	\$195,516	\$93,492	\$1,035,631	\$(235,361)	\$1,089,287	\$37,303	\$2,467	\$39,779	\$4,738	\$1,133,811

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, 2022 and 2021

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
CASH FLOWS FROM OPERATING ACTIVITIES:			
Profit before income taxes	¥ 13,885	¥ 18,657	\$ 113,811
Adjustments for:			
Depreciation	2,481	2,318	20,336
Impairment losses	2,994	—	24,541
Amortization of goodwill	5	—	41
Increase (decrease) in net defined benefit liability	(44)	239	(361)
Interest and dividends income	(397)	(393)	(3,254)
Interest expenses	17	17	139
Loss (gain) on sale of investment securities	(1)	(115)	(8)
Loss on retirement of non-current assets	97	46	795
Loss (gain) on sale of property, plant and equipment	(195)	(379)	(1,598)
Decrease (increase) in notes and accounts receivable—trade	392	1,251	3,213
Decrease (increase) in inventories	241	(2,923)	1,975
Increase (decrease) in trade payables	(2,630)	(112)	(21,557)
Other, net	542	915	4,443
Subtotal	17,387	19,521	142,516
Interest and dividends income received	397	393	3,254
Interest expenses paid	(17)	(17)	(139)
Income taxes (paid) refund, net	(4,431)	(5,516)	(36,320)
Net cash provided by (used in) operating activities	13,336	14,380	109,311
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property, plant and equipment	(2,986)	(1,973)	(24,475)
Proceeds from sale of property, plant and equipment	704	874	5,770
Purchase of intangible assets	(271)	(313)	(2,221)
Purchase of investment securities	—	(20)	—
Proceeds from sale of investment securities	5	144	41
Purchase of shares of subsidiaries resulting in change in the scope of consolidation	(4,975)	—	(40,779)
Other, net	(365)	(357)	(2,992)
Net cash provided by (used in) investing activities	(7,888)	(1,644)	(64,656)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Net decrease (increase) in treasury stock	(2,414)	(2,940)	(19,787)
Cash dividends paid	(5,714)	(5,811)	(46,836)
Net cash provided by (used in) financing activities	(8,129)	(8,752)	(66,631)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(2,680)	3,983	(21,967)
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	77,305	73,322	633,648
CASH AND CASH EQUIVALENTS AT END OF YEAR (Note 3)	¥ 74,625	¥ 77,305	\$ 611,680

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 ¥122= U.S.\$1.00, the approximate rate of exchange prevailing on March 31, 2022. 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, 2022, the Company had two consolidated subsidiaries as follows:

KAKEN PHARMA CO., LTD.
ARTham Therapeutics Inc.

ARTham Therapeutics Inc. is included in consolidation because it became a consolidated subsidiary in the year ended March 31, 2022 as a result of the Company’s acquisition of 53.3% of its common stock on December 13, 2021.

For the years ended March 31, 2022 and 2021, there was no affiliate accounted for using the equity method.

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

(b) Cash and Cash Equivalents

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

(c) Marketable and Investment Securities

Securities are classified into one of the following three categories: (1) Trading, (2) Held-to-maturity debt securities, and (3) Available-for-sale securities. Trading securities are recorded at market value with unrealized gains or losses recognized in the current year’s earnings. Held-to-maturity debt securities are carried at amortized cost. Available-for-sale securities are expected to be sold in future and those whose fair values are readily determinable are carried at fair value and the related unrealized gains or losses, net of

taxes, are included as a component of “Accumulated other comprehensive income” under net assets. Available-for-sale securities without market quotations are stated at cost determined by the moving average method.

(d) Inventories

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

(e) Property, Plant and Equipment

Depreciation is computed 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 at the amount determined based on the historical write-off rate for ordinary receivables and the estimated uncollectible amount determined based on the analysis of individual recoverability for specific doubtful receivables such as debt with a possibility of default.

(i) Provision for Bonuses

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

(j) Provision for Share Awards

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

(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

In Pharmaceuticals, the Group conducts sales primarily by manufacturing or wholesale. For sales of such merchandise and finished products, the Group has an obligation to deliver them based on a 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 that 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

In 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 risk management of foreign currency risk exposure of its financial assets and liabilities.

Forward foreign exchange contracts:

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

Hedge accounting:

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

(1) Hedging instruments and hedged items

Hedging instrument: Forward foreign exchange contracts

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

(2) Hedging policy

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

(3) Method for assessment of hedge effectiveness

Since material terms related to hedged items and hedging instruments are substantially identical, and the market fluctuations 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 the 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

Calculation of Net Defined Benefit Liability

(1) Amounts recorded in the consolidated financial statements for the years ended March 31, 2021 and 2022 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
Net defined benefit liability	¥5,039	¥5,376	\$41,303

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

Net defined benefit liability is calculated using actuarial assumptions. These assumptions include a discount rate, the long-term expected rate of return on pension plan assets, the retirement rate, mortality and other factors. Management believes that the assumptions used are reasonable; however, changes in these assumptions could have a material impact on the amounts of net defined benefit liability and retirement benefit expenses in the consolidated financial statements for the following fiscal year.

In-Process Research and Development and Valuation of Goodwill

(1) Amounts recorded in the consolidated financial statements for the years ended March 31, 2021 and 2022 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
In-process research and development	¥7,300	¥ —	\$59,836
Goodwill	312	—	2,557

(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, 2022

Measurement of in-process research and development and goodwill is done mainly using the excess earnings method. Decisions on evidence of impairment of in-process research and development and goodwill are based, in principle, on whether the fair value has fallen significantly lower than the carrying amount. In the year ended March 31, 2022, no impairment loss on in-process research and development and goodwill was recognized, as the total amount of undiscounted future cash flows did not fall below the carrying amount of non-current assets.

b. Key assumptions used in calculating amounts recorded in the consolidated financial

statements for the year ended March 31, 2022

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 Revenue Recognition

The Company has applied the "Accounting Standard for Revenue Recognition" (Accounting Standards Board of Japan ("ASBJ") Statement No. 29, revised on March 31, 2020) and relevant ASBJ regulations from the beginning of the year ended March 31, 2022, and recognizes revenue at the estimated amount it will receive in exchange for promised goods or services upon the transfer of control of the promised goods or services to the customer. Under this standard, in Pharmaceuticals, revenue from transfer of intellectual property rights and revenue from upfront and milestone payments based on technology out-licensing agreements are recognized upon the satisfaction of performance obligations. In addition, for transactions in which the Group is an agent in sales to customers, the Company has changed to a method of recognizing revenue on a net basis after subtracting the amount paid to suppliers from the total amount of consideration for sales.

The Company has applied the alternative accounting treatment stipulated in Paragraph 98 of the "Implementation Guidance on Accounting Standard for Revenue Recognition" under which revenue for domestic sales of merchandise or finished products is recognized at the time of shipment if the period from shipment until transfer of control of the merchandise or finished products to the customer is a normal period of time.

In adopting the Accounting Standard for Revenue Recognition and relevant ASBJ regulations, the Company followed the transitional treatment stipulated in the proviso of Paragraph 84 of the Accounting Standard for Revenue Recognition. The cumulative effect of retrospective application (assuming the new accounting policy had been applied to periods prior to the year ended March 31, 2022) was added to or subtracted from retained earnings at the beginning of the year ended March 31, 2022, and the new accounting standard has been applied from this beginning balance. However, the Company has applied the method prescribed in Paragraph 86 of the Accounting Standard for Revenue

Recognition, and the new accounting standard has not been retrospectively applied to contracts in which virtually all revenue amounts were recognized in accordance with the former accounting treatment before the beginning of the year ended March 31, 2022.

In addition, in applying the method prescribed in (1) of Paragraph 86 of the Accounting Standard for Revenue Recognition, the Company accounts for contract changes made prior to the beginning of the year ended March 31, 2022 based on contract terms after all contract changes have been reflected. The cumulative effect was added to or subtracted from retained earnings at the beginning of the year ended March 31, 2022.

In addition, "Notes and accounts receivable—trade" presented in "CURRENT ASSETS" in the consolidated balance sheets for the year ended March 31, 2021 is included in "Notes and accounts receivable—trade, and contract assets" from the year ended March 31, 2022, and "Provision for sales rebates" and "Provision for sales returns," which had been presented in "CURRENT LIABILITIES," are included in "Other" in "CURRENT LIABILITIES" as refund liability from the year ended March 31, 2022. However, in accordance with the transitional treatment stipulated in Paragraph 89-2 of the Accounting Standard for Revenue Recognition, reclassification according to the new presentation method has not been done for the year ended March 31, 2021.

As a result, the effects of the application of the Accounting Standard for Revenue Recognition and relevant ASBJ regulations on results for the year ended March 31, 2022 compared with results prior to its application are as follows.

The effect on the consolidated balance sheets is immaterial. In the consolidated statements of income, net sales and cost of sales decreased by ¥1,154 million and ¥1,142 million, respectively, but the effect on operating profit and profit before income taxes is immaterial.

The effect on the consolidated statements of cash flows is immaterial.

The effect of reflecting the cumulative effect on net assets at the beginning of the year ended March 31, 2022 on the beginning balance of retained earnings in the consolidated statements of changes in net assets is described in the consolidated statements of changes in net assets.

The effect on reportable segments is described in a note ("Segment Information") to the consolidated financial statements.

The effect on per-share information is described in a note ("Per Share Information") to the consolidated financial statements.

In accordance with the transitional treatment stipulated in Paragraph 89-3 of the Accounting Standard for Revenue Recognition, a note concerning revenue recognition has not been included for the year ended March 31, 2021.

Accounting Standard for Fair Value Measurement

The Company has applied the Accounting Standard for Fair Value Measurement (ASBJ Statement No. 30, issued on July 4, 2019) and relevant ASBJ regulations from the beginning of the year ended March 31, 2022. The Company has decided to apply the new accounting policy set forth by the Accounting Standard for Fair Value Measurement and relevant ASBJ regulations prospectively in accordance with the transitional treatment stipulated in Paragraph 19 of the Accounting Standard for Fair Value Measurement and Paragraph 44-2 of the Accounting Standard for Financial Instruments (ASBJ Statement No. 10, revised on July 4, 2019). This change has no effect on the consolidated financial statements.

The Company has also decided to include explanatory notes regarding each level of the fair value of financial instruments in Note 9. "Financial Instruments." However, notes for the year ended March 31, 2021 are not included in accordance with the transitional treatment stipulated in Paragraph 7-4 of the "Implementation Guidance on Disclosures about Fair Value of Financial Instruments" (ASBJ Guidance No. 19, revised on July 4, 2019).

(u) Changes in Presentation

Consolidated Statements of Income

“Loss on cancellation of leases,” which was included in “Other, net” in “Other income (expenses)” for the year ended March 31, 2021, is presented as a discrete line item for the year ended March 31, 2022 because it exceeded 10% of the total of “Other income (expenses).” The consolidated financial statements for the year ended March 31, 2021 have been restated to reflect this change in presentation.

As a result, ¥21 million that was presented in “Other, net” in “Other income (expenses)” in the consolidated statements of income for the year ended March 31, 2021 is restated as “Loss on cancellation of leases” of ¥2 million and “Other, net” of ¥18 million.

(v) Additional Information

Introduction of 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 to enhance their awareness of improving medium- to long-term performances and contributing to an increase of corporate value.

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

(1) Overview of the transaction

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

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

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

The Company’s shares remaining in the Trust are recorded as “Treasury stock” under net assets at the carrying amount in the Trust (except for incidental costs). As of March 31, 2022, the carrying amount and the number of shares of treasury stock were ¥210 million (\$1,721 thousand) and 38,500 shares, respectively. As of March 31, 2021, the carrying amount and the number of shares of treasury stock were ¥215 million and 39,400 shares, respectively.

Accounting Estimates Associated with the COVID-19 Pandemic

Group initiatives notwithstanding, the impact of the COVID-19 pandemic could affect drug supply systems and R&D activities, even repeatedly, if it becomes more serious or prolonged than the Group expects. Moreover, even if COVID-19 subsides, it could continue to affect the Group’s business activities, financial position and operating results for some time.

Although the COVID-19 pandemic has affected the Group’s business activities, the Group has determined that accounting estimates for the year ended March 31, 2022 have not been significantly affected.

3. Cash and Cash Equivalents

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

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
Cash and deposits	¥61,025	¥63,706	\$500,205
Marketable securities	13,599	13,599	111,467
Subtotal	¥74,625	¥77,305	\$611,680
Time deposits due after three months	—	—	—
Marketable securities due after three months	—	—	—
Cash and cash equivalents	¥74,625	¥77,305	\$611,680

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)
	2022			2021		
Fair values exceeding carrying amounts	¥ —	¥ —	¥ —	¥ —	¥ —	¥ —
Fair values not exceeding carrying amounts	10,999	10,999	—	10,999	10,999	—
Total	¥10,999	¥10,999	¥ —	¥10,999	¥10,999	¥ —

	THOUSANDS OF U.S. DOLLARS (NOTE 1)		
	Carrying amount	Fair value	Unrealized gain (loss)
	2022		
Fair values exceeding carrying amounts	\$ —	\$ —	\$ —
Fair values not exceeding carrying amounts	90,156	90,156	—
Total	\$90,156	\$90,156	\$ —

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)
	2022			2021		
Carrying amounts exceeding acquisition costs						
Equity securities	¥13,522	¥ 6,719	¥6,802	¥16,271	¥ 9,320	¥6,950
Other	—	—	—	—	—	—
Subtotal	13,522	6,719	6,802	16,271	9,320	6,950
Carrying amounts not exceeding acquisition costs						
Equity securities	3,493	3,735	(241)	1,019	1,137	(118)
Other	2,600	2,600	—	2,600	2,600	—
Subtotal	6,093	6,335	(241)	3,619	3,737	(118)
Total	¥19,616	¥13,055	¥6,560	¥19,890	¥13,058	¥6,831

	THOUSANDS OF U.S. DOLLARS (NOTE 1)		
	Fair value	Acquisition cost	Unrealized gain (loss)
	2022		
Carrying amounts exceeding acquisition costs			
Equity securities	\$110,836	\$ 55,074	\$55,754
Other	—	—	—
Subtotal	110,836	55,074	55,754
Carrying amounts not exceeding acquisition costs			
Equity securities	28,631	30,615	(1,975)
Other	21,311	21,311	—
Subtotal	49,943	51,926	(1,975)
Total	\$160,787	\$107,008	\$53,770

Available-for-sale securities sold for the years ended March 31, 2022 and 2021 are summarized as follows:

	MILLIONS OF YEN					
	Proceeds	Gain	Loss	Proceeds	Gain	Loss
	2022			2021		
Equity securities	¥5	¥1	¥—	¥144	¥115	¥—
Total	¥5	¥1	¥—	¥144	¥115	¥—

	THOUSANDS OF U.S. DOLLARS (NOTE 1)		
	Proceeds	Gain	Loss
	2022		
Equity securities	\$41	\$8	\$—
Total	\$41	\$8	\$—

5. Inventories

Inventories as of March 31, 2022 and 2021 comprised the following:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
Merchandise and finished products	¥ 5,807	¥ 5,700	\$ 47,598
Work in process	2,964	3,126	24,295
Raw materials and supplies	6,209	6,371	50,893
Total	¥14,981	¥15,198	\$122,795

6. Short-term Bank Loans and Pledged Assets

(a) Short-term bank loans

Short-term bank loans outstanding as of March 31, 2022 and 2021, amounting to ¥3,850 million (\$31,557 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, 2022 and 2021 was 0.45%.

(b) Pledged assets

As of March 31, 2022 and 2021, assets pledged as collateral for certain short-term bank loans are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
Assets pledged:			
Buildings and structures	¥6,433	¥6,126	\$52,730
Machinery, equipment and vehicles	2,207	2,527	18,090
Tools, furniture and fixtures	807	942	6,615
Land	117	117	959
Total	¥9,565	¥9,713	\$78,402
Liabilities secured:			
Short-term bank loans	¥1,400	¥1,400	\$11,475
Total	¥1,400	¥1,400	\$11,475

7. Accounting for Leases

Operating leases

(As a lessor)

Future minimum lease payments receivable under non-cancellable operating leases subsequent to March 31, 2022 and 2021 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
Due within 1 year	¥ 949	¥ 966	\$ 7,779
Due after 1 year	4,094	5,018	33,557
Total	¥5,043	¥5,985	\$41,336

8. Contract assets and liabilities

(a) Among notes receivable—trade, accounts receivable—trade and contract assets, credits and contract assets arising from contracts with customers are as follows:

	MILLIONS OF YEN	THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2022
Notes receivable—trade	¥ 331	\$ 2,713
Accounts receivable—trade	19,651	161,074
Contract assets	277	2,270

(b) Among other, the amounts of contract liabilities are as follows.

	MILLIONS OF YEN	THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2022
Contract liabilities	¥56	\$459

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, 2022 and 2021 was ¥1,353 million (\$11,090 thousand) and ¥1,418 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, 2022 and 2021, and fair value of these properties as of those dates are stated as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
Carrying amount:			
Balance at the beginning of the year	¥10,162	¥10,186	\$ 83,295
Changes during the year	184	(23)	1,508
Balance at the end of the year	10,347	10,162	84,811
Fair value at the end of the year	¥50,408	¥51,100	\$413,180

Notes: 1. The carrying amount represents the acquisition costs less accumulated depreciation.
2. Fair value at the end of the year is calculated, with adjustments using applicable indices, by the Company primarily based on the "Real estate appraisal standards of Japan."

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

Payment terms of trade payables, such as notes and accounts payable—trade and electronically recorded obligations—operating, are mostly 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.

Derivative transactions used by the Company are only forward foreign exchange contracts for the purpose of hedging foreign exchange fluctuation risk of trade receivables and trade payables denominated in foreign currencies. Please see Note 2. "Summary of Significant Accounting Policies" for details regarding hedging instruments, hedged items, hedging policy and method for assessment of 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 concerned department, according to the credit management rules, is managing payment terms and balances of each major customer by regularly monitoring their status, in an effort to achieve early identification and mitigation of default risk of customers arising from their deteriorating financial condition and other factors.

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

credit risk.

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

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

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

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

Derivative transactions are conducted under the authority of the general manager at each concerned department, in accordance with the forward foreign exchange contracts management rules, and the execution result of derivative transactions is reported to the Accounting Department and other concerned departments, as each transaction takes place. At the end of each month, the outstanding balance of forward foreign exchange contracts is reported to the directors in charge, as well as to other concerned departments. The consolidated 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 concerned department.

(4) Supplementary explanation concerning fair values of financial instruments

Since variable factors are incorporated in computing fair values of financial instruments, such fair values may vary depending on different assumptions.

(5) Concentration of credit risks

As of March 31, 2022, 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, 2022		2022	
Marketable and investment securities and other available-for-sale securities	¥19,616	¥19,616	¥ —
Total liabilities	¥19,616	¥19,616	¥ —

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 they 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
	2022
Unlisted equity securities	¥77

	THOUSANDS OF U.S. DOLLARS (NOTE 1)		
	Carrying amount	Fair value	Unrealized gain (loss)
March 31, 2022	2022		
Marketable and investment securities and other available-for-sale securities	\$160,787	\$160,787	\$ —
Total liabilities	\$160,787	\$160,787	\$ —

	THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022
Unlisted equity securities	\$631

	MILLIONS OF YEN		
	Carrying amount	Fair value	Unrealized gain (loss)
March 31, 2021	2021		
Marketable and investment securities	¥19,890	¥19,890	¥ —
Total liabilities	¥19,890	¥19,890	¥ —

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 they have short maturities.
2. Carrying amounts of financial instruments whose fair values are extremely difficult to determine

	MILLIONS OF YEN
	2021
Unlisted equity securities	¥77

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, 2022 and 2021 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	Due within one year		
	2022	2021	2022
Cash and deposits	¥61,025	¥63,706	\$500,205
Notes receivable—trade	331		2,713
Notes and accounts receivable—trade		20,549	
Accounts receivable—trade	19,651		161,074
Marketable and investment securities			
Held-to-maturity debt securities	10,999	10,999	90,156
Available-for-sale securities with contractual maturities	2,600	2,600	21,311
Total	¥94,608	¥97,855	\$775,475

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		
	2022	2021	2022
Short-term bank loans	¥3,850	¥3,850	\$31,557
Total	¥3,850	¥3,850	\$31,557

(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 is measured using observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets

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

Level 3: Fair value is 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			
	2022			
	Fair value			
	Level 1	Level 2	Level 3	Total
Marketable and investment securities and other available-for-sale securities				
Equity securities	¥17,016	¥ —	¥—	¥17,016
Other securities	—	2,600	—	2,600
Asset total	¥17,016	¥2,600	¥—	¥19,616

	THOUSANDS OF U.S. DOLLARS (NOTE 1)			
	2022			
	Fair value			
	Level 1	Level 2	Level 3	Total
Marketable and investment securities and other available-for-sale securities				
Equity securities	\$139,475	\$ —	\$—	\$139,475
Other securities	—	21,311	—	21,311
Asset total	\$139,475	\$21,311	\$—	\$160,787

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, i.e., a lump-sum retirement plan and defined benefit corporate pension plan. A retirement benefit trust has been established for the lump-sum retirement plan. The Company may make additional payments at the time of employees’ retirement in addition to the lump-sum retirement benefits. The simplified method is used for the calculation of retirement benefit obligation of KAKEN PHARMA CO., LTD. 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, 2022 and 2021 are as follows (excluding plans in which the simplified method is applied):

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
Retirement benefit obligation—Beginning balance	¥19,021	¥19,289	\$155,910
Service cost	694	701	5,689
Interest cost	57	57	467
Actuarial gain or loss	(102)	223	(836)
Retirement benefit paid	(1,219)	(1,251)	(9,992)
Retirement benefit obligation—Ending balance	¥18,451	¥19,021	\$151,238

(b) Changes in the plan assets for the years ended March 31, 2022 and 2021 are as follows (excluding plans in which the simplified is applied):

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
Plan assets—Beginning balance	¥13,644	¥11,994	\$111,836
Expected return on plan assets	323	230	2,648
Actuarial gain or loss	75	2,078	615
Employer's contributions	162	166	1,328
Retirement benefit paid	(794)	(824)	(6,508)
Plan assets—Ending balance	¥13,411	¥13,644	\$109,926

(c) Changes in the net defined benefit liability for the years ended March 31, 2022 and 2021 in which the simplified method is applied as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
Net defined benefit liability—Beginning balance	¥—	¥ 7	\$—
Retirement benefit cost	—	0	—
Payment of retirement benefit	—	(8)	—
Net defined benefit liability—Ending balance	¥—	¥—	\$—

(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)
	2022	2021	2022
Retirement benefit obligation under funded plan	¥18,451	¥19,021	\$151,238
Plan assets	(13,411)	(13,644)	(109,926)
	5,039	5,376	41,303
Retirement benefit obligation under unfunded plan	—	—	—
Net liability recorded on the consolidated balance sheets	5,039	5,376	41,303
Net defined benefit liability	5,039	5,376	41,303
Net liability recorded on the consolidated balance sheets	¥ 5,039	¥ 5,376	\$ 41,303

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.

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

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
Service cost	¥ 694	¥ 701	\$5,689
Interest cost	57	57	467
Expected return on plan assets	(323)	(230)	(2,648)
Amortization of actuarial gain or loss	120	345	984
Amortization of prior service cost	(5)	(33)	(41)
Net periodic pension cost under simplified method	—	0	—
Net periodic pension cost for defined benefit plans	¥ 542	¥ 841	\$4,443

(f) The components of remeasurements of defined benefit plans in other comprehensive income (before tax effect) for the years ended March 31, 2022 and 2021 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
Prior service cost	¥ (5)	¥ (33)	\$ (41)
Actuarial gain or loss	297	2,199	2,434
Total	¥ 292	¥2,166	\$ 2,393

(g) The components of remeasurements of defined benefit plans in accumulated other comprehensive income (before tax effect) as of March 31, 2022 and 2021 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
Unrecognized prior service cost	¥ —	¥ (5)	\$ —
Unrecognized actuarial gain or loss	(435)	(137)	(3,566)
Total	¥ (435)	¥ (142)	\$ (3,566)

(h) Plan assets

(1) Plan assets consist of the following:

	2022	2021
Debt securities	44%	31%
Equity securities	37	48
General account	12	13
Other	7	8
Total	100%	100%

Note: The plan assets include retirement benefit trust which accounted for 5% and 5% of the total plan assets as of March 31, 2022 and 2021, 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):

	2022	2021
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, 2021	45,939,730	7,621,338
Increase	—	500,948
Decrease	—	(925)
Number of shares as of March 31, 2022	45,939,730	8,121,361

Notes:

1. Increase in treasury stock (500,948 shares) is due to purchase of shares through the market (500,000 shares) based on the resolution of the Board of Directors' meeting and purchase of shares of less than one unit (948 shares).
2. Decrease in treasury stock (925 shares) is due to placement of Company stock (900 shares) in the Board Benefit Trust (BBT) and requests for additional purchase of shares of less than one unit (25 shares).
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 (38,500 shares as of March 31, 2022 and 39,400 shares as of April 1, 2021).

(b) Matters related to dividends

(1) Dividend payment

Approval at the ordinary general meeting of shareholders held on June 29, 2021 was as follows:

Dividends on common stock	
Total amount of dividends	¥2,876 million (\$23,574 thousand)
Dividends per share	¥75.00 (\$0.61)
Record date	March 31, 2021
Effective date	June 30, 2021

Approval at the Board of Directors' meeting held on November 4, 2021 was as follows:

Dividends on common stock	
Total amount of dividends	¥2,839 million (\$23,270 thousand)
Dividends per share	¥75.00 (\$0.61)
Record date	September 30, 2021
Effective date	November 30, 2021

(2) Dividends whose record date is attributed to the year ended March 31, 2022 but which become effective after March 31, 2022

Approval at the ordinary general meeting of shareholders held on June 29, 2022 was as follows:

Dividends on common stock	
Total amount of dividends	¥2,839 million (\$23,270 thousand)
Source of dividends	Retained earnings
Dividends per share	¥75.00 (\$0.61)
Record date	March 31, 2022
Effective date	June 30, 2022

Note: Total amount of dividends includes ¥2 million (\$16 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, 2022 and 2021 amounted to ¥8,420 million (\$69,016 thousand) and ¥6,736 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, 2021 and 2022 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
	¥ 320	¥88	\$ 2,623

15. Gain on Sales of Non-Current Assets

Gain on sales of non-current assets for the years ended March 31, 2022 and 2021 consists of the following:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
Buildings and structures	¥ 117	¥ 189	\$ 959
Land	77	188	631
Other	0	1	0
Total	¥ 195	¥ 379	\$ 1,598

16. Loss on Retirement of Non-Current Assets

Loss on retirement of non-current assets for the years ended March 31, 2022 and 2021 consists of the following:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
Buildings and structures	¥ 8	¥15	\$ 66
Other	88	38	721
Total	¥97	¥54	\$ 795

17. Impairment Losses

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

			THOUSANDS OF U.S. DOLLARS
Location	Use	Type	Impairment loss
Bunkyo-ku, Tokyo	Exclusive rights to pharmaceutical distribution	Long-term prepaid expenses (distribution rights, etc.)	\$24,541

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.

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.

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

18. Contract Losses

Year ended March 31, 2021

Not applicable

Year ended March 31, 2022

To avoid risks associated with changes in the business environment, the Company recognized a ¥762 million (\$6,246 thousand) 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.

19. Income Taxes

Significant components of deferred tax assets and liabilities as of March 31, 2022 and 2021 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
Deferred tax assets:			
Tax loss carryforwards	¥ 226	¥ —	\$ 1,852
Loss on valuation of inventories	98	27	803
Disallowed expensed supplies	305	180	2,500
Contract loss	176	—	1,443
Adjustment of gain on sales of land	2,638	2,638	21,623
Amortization of research & development expenses	307	276	2,516
Amortization of long-term prepaid expenses	774	952	6,344
Provision for bonuses	303	323	2,484
Net defined benefit liability	1,843	1,855	15,107
Impairment losses	916	—	7,508
Other	358	428	2,934
Total	7,950	6,682	65,164
Valuation allowance for tax loss carryforwards	(226)	—	(1,852)
Valuation allowance	(3,798)	(2,820)	(31,131)
Total	(4,024)	(2,820)	(32,984)
Deferred tax assets	3,925	3,861	32,172
Deferred tax liabilities:			
Reserve for advanced depreciation of non-current assets	(191)	(112)	(1,566)
Reserve for special account for advanced depreciation of non-current assets	—	(79)	—
Net unrealized holding gain on securities	(2,008)	(2,091)	(16,459)
In-process research and development	(2,229)	—	(18,270)
Deferred tax liabilities	(4,429)	(2,284)	(36,303)
Deferred tax assets, net	¥ (503)	¥1,577	\$ (4,123)

Notes:

1. "Accounts receivable—trade" and "Provision for sales rebates," which were presented as discrete line items in the year ended March 31, 2021, were included in "Other" in the year ended March 31, 2022 because their amounts were no longer significant. In addition, "Loss on valuation of inventories," which was included in "Other" in the year ended March 31, 2021, was presented as a discrete line item in the year ended March 31, 2022 in order to enhance clarity. Certain reclassifications have been made for the year ended March 31, 2021 to reflect this change in presentation.

As a result, in deferred tax assets for the year ended March 31, 2021, "Accounts receivable—trade" of ¥46 million and "Provision for sales rebates" of ¥92 million, totaling ¥139 million, were reclassified as "Other" and ¥27 million formerly included in "Other" was reclassified as "Loss on valuation of inventories."

2. Valuation allowance increased ¥1,204 million. This increase was mainly attributable to a valuation allowance for impairment loss of ¥916 million and the recognition of an additional valuation allowance for tax loss carryforwards of ¥226 million at consolidated subsidiary ARTham Therapeutics Inc.

3. Amounts of tax loss carryforwards, valuation allowance and deferred tax assets by expiration of carryforwards as of March 31, 2021 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
	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.

March 31, 2021: None

	THOUSANDS OF U.S. DOLLARS (NOTE 1)						
	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
	2022						
Tax loss carryforwards	\$ —	\$ —	\$ —	\$ —	\$ —	\$1,852	\$1,852
Valuation allowance	—	—	—	—	—	(1,852)	(1,852)
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, 2022 and 2021. Reconciliation of the differences between the statutory tax rate and the effective tax rate for the years ended March 31, 2022 and 2021 is as follows:

	2022	2021
Statutory tax rate	30.62%	30.62%
Increase (decrease) in taxes resulting from:		
Expenses not deductible for income tax purpose (e.g. entertainment expenses)	0.07	0.05
Income not included for income tax purpose (e.g. dividend income)	(0.18)	(0.13)
Inhabitant per capita taxes	0.51	0.39
Tax credit for research expenses	(5.94)	(2.79)
Change in valuation allowance	7.21	—
Other	(1.06)	0.01
Effective tax rate	31.23%	28.15%

20. Business Combination

Business combination through acquisition

(a) Overview of the business combination

(1) Name of the acquired company and description of its business

Name of acquired company: ARTham Therapeutics Inc.

Description of business: Pharmaceutical research and development

(2) Main objectives of the business combination

ARTham Therapeutics Inc. is a clinical stage biopharmaceutical startup whose mission is to deliver truly effective "medicines that matter" to patients with unmet medical needs. The company has ART-001 (for refractory vascular malformations), a development project in the area of orthopedics, and ART-648 (for bullous pemphigoid), a development project in the area of dermatology. Upon completion of this acquisition, the Company and ARTham Therapeutics will collaborate in the development of ART-001 and ART-648 to ensure the success of Phase II clinical trials, which are currently in progress. Upon obtaining successful results from these clinical trials, the Company will take over and pursue further research and development including Phase III clinical trials aimed at obtaining approval in Japan, the United States and Europe.

As a result of this acquisition, in addition to enhancing its development pipeline, the

Company will further improve its R&D capabilities by realizing synergies in ways such as applying ARTham Therapeutics' technology and experience in drug repositioning to the Company's existing compounds.

(3) Date of business combination

December 13, 2021 (deemed acquisition date: December 31, 2021)

(4) Legal form of business combination

Acquisition of shares for cash consideration

(5) Company name after business combination

No change

(6) Percentage of voting rights acquired

100%

(7) Primary basis for determining the acquiring company

The Company acquired an equity stake for cash consideration.

(b) Period of the acquired company's financial results included in the Company's consolidated financial statements

January 1, 2022 to March 31, 2022

(c) Acquisition cost of the acquired company and consideration by type

		MILLIONS OF YEN	THOUSANDS OF U.S. DOLLARS (NOTE 1)
		2022	
Consideration	Cash	¥5,499	\$45,074
Acquisition cost		5,499	45,074

(d) Details and amount of significant acquisition expenses

		MILLIONS OF YEN	THOUSANDS OF U.S. DOLLARS (NOTE 1)
		2022	
Advisor fees, etc.		¥193	\$1,582

(e) Amount, reason for recognition, amortization method and amortization period of goodwill generated

(1) Amount of goodwill generated

¥317million (\$2,598 thousand)

(2) Reason for recognition of goodwill

As the fair value of net assets on the share acquisition date was less than the acquisition cost, the Company recognized the difference as goodwill.

(3) Method and period of amortization of goodwill

Straight-line method over 14 years

(f) Main components and amounts of assets and liabilities acquired on the business combination date

		MILLIONS OF YEN	THOUSANDS OF U.S. DOLLARS (NOTE 1)
		2022	
Current assets		¥815	\$6,680
Non-current assets		2	16
Total assets		¥818	\$6,705
Current liabilities		¥128	\$1,049
Non-current liabilities		—	—
Total liabilities		¥128	\$1,049

(g) Details of contingent consideration provided for in the business combination contract and accounting treatment for the year ended March 31, 2022 and thereafter

(1) Contingent consideration

Additional consideration shall be paid, contingent upon the future progress of development of the acquired company.

(2) Future accounting treatment

If additional consideration is paid for the acquisition, it shall be regarded as having been paid on the acquisition date, the acquisition cost shall be revised, and the amounts of goodwill and amortization of goodwill shall be revised.

(h) Amounts allocated to intangible assets other than goodwill, description of major categories in which those amounts were allocated, and weighted average amortization period of intangible assets overall and by major category

Category	Amount	Weighted average amortization period
2022		
In-process research and development	¥7,300 million	12 years
In-process research and development	\$59,836 thousand	12 years

(i) Approximate amount of and method for calculating the effect of the business combination on the consolidated statements of income for the year ended March 31, 2022, assuming that the business combination had been completed on the first day of the year ended March 31, 2022.

The amount of the effect on the consolidated statements of income for the year ended March 31, 2022 was immaterial, so it has been omitted.

No audit certification was received with respect to calculation of the amount of the effect.

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: 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 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 and revenue recognized when control of the goods is transferred to the customer. For the sale of goods 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 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, 2022 and 2021.

23. Per Share Information

Per share information as of March 31, 2022 and 2021 and for the years then ended is as follows:

	YEN		U.S. DOLLARS (NOTE 1)
	2022	2021	2022
Net assets per share	¥3,642.34	¥3,555.93	\$29.86
Profit per share	251.43	347.37	2.06

Notes:

1. Diluted profit per share is not presented due to the absence of dilutive shares.

2. The Company has introduced the Board Benefit Trust (BBT). The Company's shares held by the BBT, which are recorded as treasury stock in shareholders' equity, are included in the treasury stock to be deducted from the total number of shares outstanding at the end of the year for computation of net assets per share, and are also included in the treasury stock to be deducted when calculating the weighted average number of shares for computation of profit per share.

The number of shares of treasury stock deducted for computation of net assets per share is 38,500 as of March 31, 2022 and 39,400 as of March 31, 2021. The weighted average number of shares of treasury stock deducted for computation of profit per share is 38,776 for the year ended March 31, 2022 and 39,926 for the year ended March 31, 2021.

3. As stated in Note 2. (t) "Changes in Accounting Policies," the Company has adopted the Accounting Standard for Revenue Recognition and relevant ASBJ regulations. The effect of this change on per share information is immaterial.

The basis of calculation for profit per share for the years ended March 31, 2022 and 2021 is as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
Profit	¥ 9,549	¥13,405	\$ 78,270
Profit attributable to common stock owners of the Company	9,549	13,405	78,270
Profit not attributable to common stock owners	—	—	—
(Number of shares)			
Weighted average number of shares of common stock (thousands of shares)	37,978	38,590	

24. Comprehensive Income

Reclassification adjustments and income tax effects for each component of other comprehensive income for the years ended March 31, 2022 and 2021 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2022	2021	2022
Net unrealized holding gain (loss) on securities:			
Increase (decrease) during the year	¥ (269)	¥2,455	\$ (2,205)
Reclassification adjustments	(1)	(115)	(8)
Before income tax effect	(270)	2,340	(2,213)
Income tax effect	82	(716)	672
Net unrealized holding gain (loss) on securities	¥ (187)	¥1,623	\$ (1,533)
Remeasurements of defined benefit plans:			
Increase (decrease) during the year	¥ 177	¥1,854	\$ 1,451
Reclassification adjustments	114	311	934
Before income tax effect	292	2,166	2,393
Income tax effect	(89)	(663)	(730)
Remeasurements of defined benefit plans	¥ 202	¥1,503	\$ 1,656
Total other comprehensive income	¥ 14	¥3,126	\$ 115

25. Segment Information

(a) Overview of reportable segments

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

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

"Pharmaceuticals" mainly comprises production and sale of medical products, medical devices, and agrochemicals.

"Real estate" mainly comprises 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.
As stated in Note 2. (t) "Changes in Accounting Policies," the Company applied the Accounting Standard for Revenue Recognition and relevant ASBJ regulations from the beginning of the year ended March 31, 2022 and changed its method of accounting for revenue recognition. Consequently, the method for measuring profit or loss in each reportable segment has also changed.

As a result, compared with results using the previous method, net sales of the Pharmaceuticals segment under the revised accounting method decreased by ¥1,154 million (\$9,459 thousand) in the year ended March 31, 2022, but the effect of the revised method on segment profit (operating profit) is immaterial.

(c) Information about reportable segments

MILLIONS OF YEN					
	Reportable Segment				
	Pharmaceuticals	Real estate	Total	Adjustments	Consolidated
	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

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

THOUSANDS OF U.S. DOLLARS (NOTE 1)					
	Reportable Segment				
	Pharmaceuticals	Real estate	Total	Adjustments	Consolidated
	2022				
Net sales:					
Sales of merchandise and finished goods	\$587,221	\$ —	\$587,221	\$ —	\$ 587,221
License agreements for sale, etc. of finished products	16,246	—	16,246	—	16,246
Revenue from contracts with customers	603,467	—	603,467	—	603,467
Other revenue	—	19,754	19,754	—	19,754
Net sales to external customers	603,467	19,754	623,230	—	623,320
Intersegment sales or transfers	—	—	—	—	—
Total	\$603,467	\$ 19,754	\$623,230	\$ —	\$ 623,230
Segment profit	\$128,770	\$ 11,090	\$139,869	\$ —	\$ 139,869
Segment assets	\$619,516	\$ 85,189	\$704,705	\$649,230	\$1,353,943
Other items:					
Depreciation and amortization	\$ 22,123	\$ 2,639	\$ 24,770	\$ —	\$ 24,770
Amortization of goodwill	41	—	41	—	41
Increase in property, plant and equipment and intangible assets	93,008	4,164	97,180	—	97,180

The adjustments to segment assets of ¥79,206 million (\$649,230 thousand) and ¥81,466 million as of March 31, 2022 and 2021, respectively, represent corporate assets which are not allocated to each reportable segment. The amounts mainly consist of surplus funds which do not belong to reportable segments.

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

(d) Information on products and services

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

(e) Information by geographical area

(1) Sales

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

(2) Property, plant and equipment

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

(f) Information about major customers

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)		Name of the related segment
	Net sales				
	2022	2021	2022		
Alfresa Corporation	¥13,486	¥13,349	\$110,541		Pharmaceuticals
MEDICEO CORPORATION	11,237	11,236	92,107		Pharmaceuticals
SUZUKEN CO., LTD.	11,192	11,375	91,738		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 year ended March 31, 2022:

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

THOUSANDS OF U.S. DOLLARS						
	Reportable Segment			Other	Adjustments	Consolidated
	Pharmaceuticals	Real estate	Total			
	2022					
Impairment loss	\$24,541	—	\$24,541	—	—	\$24,541

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

(h) Amortization of goodwill and unamortized balance by reportable segment for the years ended March 31, 2021 and 2022 are as follows:
Year ended March 31, 2022

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			
	2022					
Amount amortized during the year	\$ 41	\$ —	\$ 41	\$ —	\$ —	\$ 41
Unamortized balance at end of the year	\$2,557	\$ —	\$2,557	\$ —	\$ —	\$2,557

Year ended March 31, 2021
Not applicable

26. Subsequent Event

Acquisition of treasury stock

Based on the provisions of Article 156 of the Companies Act of Japan (the “Act”) applied by replacing the terms and phrases pursuant to the provisions of Article 165 (3) of the Act, the Company resolved at the Board of Directors’ meeting held on May11, 2022 to acquire treasury stock.

(a) Reason for acquisition:

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

(b) Class of stock to be acquired:

Common stock

(c) Number of shares of common stock to be acquired:

Up to 350,000 shares

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

Up to ¥1,500 million (\$12,295 thousand)

(e) Schedule for acquisition:

From May 12, 2022 to December 28, 2022

(f) Method of acquisition:

Purchase on the Tokyo Stock Exchange

INDEPENDENT AUDITOR'S REPORT

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

Report on the Audit of the Consolidated Financial Statements

Opinion

We have audited the consolidated financial statements of KAKEN PHARMACEUTICAL CO., LTD. and its consolidated subsidiaries (the Group), which comprise the consolidated balance sheets as at March 31, 2022 and the consolidated statements of income, consolidated statements of comprehensive income 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, 2022, 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.

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.

Allocation of Acquisition Cost for Acquisition of ARTham Therapeutics Inc.	
Key audit matter and the basis of our determination	How the matter was addressed in the audit
As described in Note 2 (Summary of Significant Accounting Policies), the Company acquired ARTham Therapeutics Inc. ("ARTham"), with December 31, 2021 as the deemed acquisition date, and included it in the scope of consolidation. Upon such acquisition, the Company utilized an external valuation expert to recognize and calculate identifiable assets and liabilities and allocated the acquisition cost. As a result, as of the date of the business combination, the Company recorded 7,300 million yen in intangible assets for in-process research and development and goodwill of 317 million yen. The market value, as of the business combination date for intangible assets to which the acquisition cost was allocated, was	In order to verify the acquisition cost allocation as of the date of the business combination, we performed mainly the following audit procedures. We <ul style="list-style-type: none"> • Examined due diligence and valuation materials related to the acquisition of ARTham, as well as related minutes of meetings of the Board of Directors, etc. and confirmed consistency with the business plan. • Considered the reasonableness of the business plan by viewing data regarding material assumptions, such as future sales forecast in the business plan (number of patients, drug prices), probability of R&D success, and discount rates, and asking questions to the person in charge of creating the business plan. • Considered the suitability, competence, and

calculated by the income approach (excess earnings method). The business plan used for the calculation contains material assumptions, such as future sales forecasts (number of patients, drug prices), probability of R&D success, and discount rates. If the material assumptions used for the calculations or the calculations performed are not appropriate, there is a risk that intangible assets will not be calculated appropriately. Material assumptions used in calculating intangible assets include estimation uncertainties and involve subjective judgment by management. Based on the above, the allocation of the acquisition cost associated with the acquisition of ARTham was particularly important in the audit of the consolidated financial statements for the fiscal year ended March 31, 2022. Therefore, the matter was judged as a key audit matter.	objectivity of the external valuation expert used by the Company. <ul style="list-style-type: none"> • Asked questions to the external valuation expert to gauge the valuation method adopted and the assumptions used in the valuation, and evaluated whether they were reasonable in light of the purpose of the calculations. • Compared material assumptions used in the calculation of intangible assets, such as discount rates, with available external data to confirm their reasonableness. • Verified the calculation process and confirmed whether intangible assets were calculated accurately.
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Other Information

The other information comprises the information included in the securities report, but does not include the consolidated financial statements, the 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 directors' execution of duties relating to the design and operating effectiveness of the controls over the Group's reporting process for 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, as well as pay attention to whether there are any indications of other material misstatements of the other information.

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 when performing risk assessment procedures, 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 matters communicated with Audit & Supervisory Board Members and the Audit & Supervisory Board, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters 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 1 (Basis of Presenting Consolidated Financial Statements) 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 Kikuchi

Designated Engagement Partner
Certified Public Accountant

Daiki Matsumura

Designated Engagement Partner
Certified Public Accountant

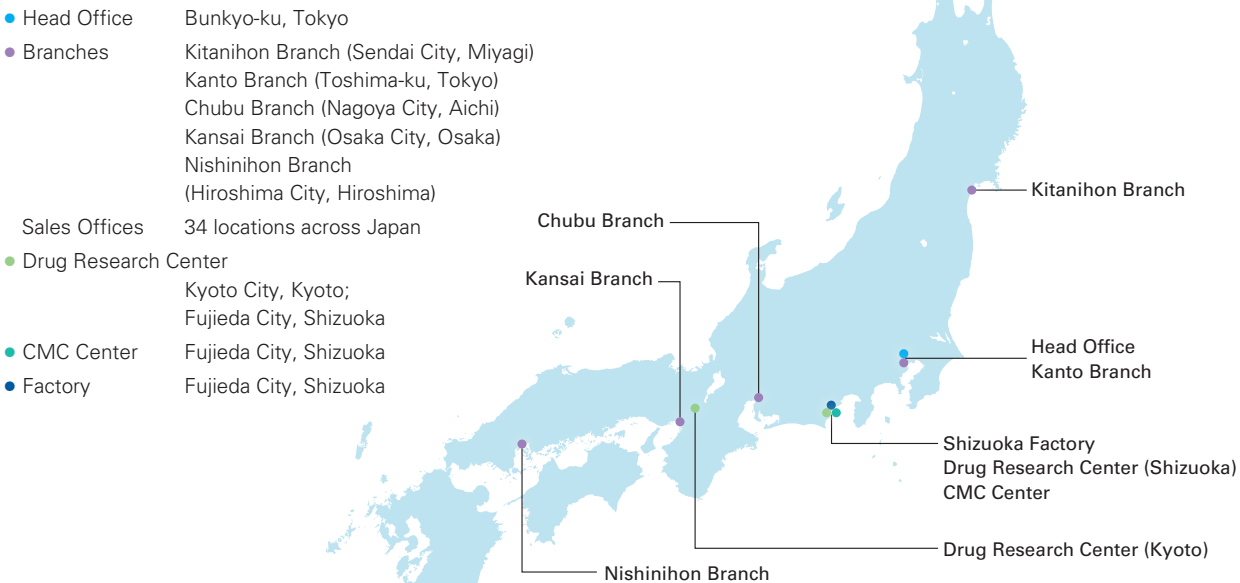
ARK LLC
Tokyo, Japan
October 25, 2022

Corporate and Share Information (As of March 31, 2022)

Company Overview

Company Name	KAKEN PHARMACEUTICAL CO., LTD.
Incorporated	March 1, 1948
Paid-in Capital	¥23,853 million
Number of Employees	1,164 (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, 2022)



Head Office (Tokyo)



Drug Research Center (Kyoto)



Kansai Branch (Osaka; construction completed in April 2021)

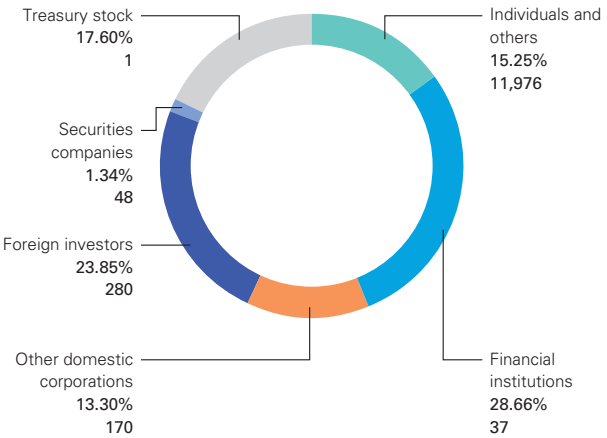


Shizuoka Factory (Shizuoka)

Share Information

Authorized	193,000,000 shares
Issued	45,939,730 shares
Number of Shareholders	12,512
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)

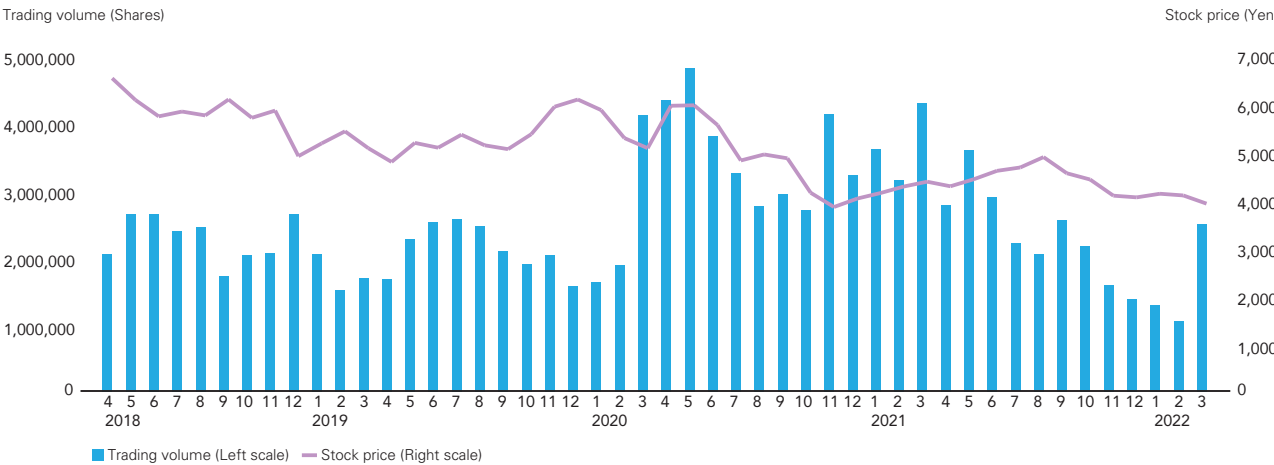
Shareholder	Number of shares held (Thousands)	Shareholding ratio (%)
The Master Trust Bank of Japan, Ltd. (Trust Account)	4,622	12.21
Toray Industries, Inc.	2,294	6.06
The Norinchukin Bank	1,843	4.87
NORTHERN TRUST CO. (AVFC) RE SILCHESTER INTERNATIONAL INVESTORS INTERNATIONAL VALUE EQUITY TRUST	1,627	4.30
Custody Bank of Japan, Ltd. (Trust Account)	1,485	3.92
Mizuho Bank, Ltd.	1,474	3.90
NORTHERN TRUST CO. (AVFC) RE U.S. TAX EXEMPTED PENSION FUNDS	869	2.30
KYORIN Pharmaceutical Co., Ltd.	852	2.25
Nippon Life Insurance Company	612	1.62
KAKEN Employees Shareholding Association	606	1.60

Note: The shareholding ratios are calculated after subtracting the number of shares of treasury stock (8,082,861) from the total number of shares issued.

Total Shareholder Return

FY	2017	2018	2019	2020	2021
(%)	102.2	84.7	87.1	78.5	73.8
(Comparison index: TOPIX Total Return Index)	115.9	110.0	99.6	141.5	144.3

Stock Price and Trading Volume





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