CORPORATE REPORT 2019







KAKEN PHARMACEUTICAL CO., LTD.

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

Bringing Smiles to Everyone

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



Corporate Philosophy

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

Business Philosophy

KAKEN
"Three Joys"

"Creating joy for patients"
We strive to create and offer effective drugs that satisfy the needs of patients and medical professionals.

"Creating joy as a company"
We recognize our social responsibility as a pharmaceutical company with a high ethical standard and society's trust.

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

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Editorial Policy
This Report has been edited under the basic policy of helping our various stakeholders (including shareholders and investors) to understand the management foundation and strengths that KAKEN has built so far and the sustainable growth to be achieved by KAKEN through the creation of corporate value in the future, in reference to the disclosure framework provided by the International Integrated Reporting Council (IIRC).
Reporting Period: From April 1, 2018 to March 31, 2019

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

Greetings

By keep enhancing organizational strength of the company, we will cope with the changing business environment and commit ourselves to achieve a leap forward into the future.



Since the foundation of KAKEN in 1948, we have been creating and delivering numbers of prescription drugs through use of our advanced technologies. We are proud to say that, through the supply of our superior pharmaceuticals, we have been supporting improvement of treatments for various diseases in clinical settings especially in the fields of orthopedics and dermatology as our specialties, and we have been thereby contributing to improvement of patients' quality of life.

In recent years, the business environment surrounding the pharmaceutical industry has been undergoing drastic changes, and we are now entering an era that is far more challenging than ever before. We have to recognize that pharmaceutical companies will see their corporate strengths tested for survival, and will need to create new value while simultaneously improving efficiency.

Upon facing this major challenge, we are focusing on human resource development in an effort to maximize strength of our organization through the growth of each and every employee. At the same time, we are making active investments in R&D as well as toward the establishment of a system, with which we can ensure creation and delivery of novel pharmaceuticals with superior efficacy which can meet important medical needs by physicians and patients. It is also of our priority to further accelerate the global expansion of our products through out-licensing to overseas companies, with the aim of acquiring new growth opportunities.

The Medium-Term Business Plan 2021, which was started in FY2019, is a three-year plan that aims to establish a foundation for sustainable growth based on the awareness of these issues. We will make company-wide efforts to steadily carry out this plan and overcome the challenging business environment, and then to achieve a leap forward into the future.

This "Corporate Report" has been compiled to provide detailed introductions focusing on these efforts, through the sharing of our financial and non-financial information. We hope that you find this Report useful for deepening your understanding of the Company.

Tetsuo Onuma
President and Representative Director

History of KAKEN

The origin of Kaken Pharmaceutical Co., Ltd., can be traced back to the Institute of Physical and Chemical Research (Riken), which was established in 1917. In 1948, the Company started its business by manufacturing and selling penicillin utilizing Riken's proprietary technologies.

Since then, KAKEN has been delivering a wide variety of drugs as an R&D-oriented pharmaceutical company.

1948 »»»

Business-related events



1948 The Institute of Physical and Chemical Research reorganized into a stock company Kagaku-Kenkyusho (first president, Yoshio Nishina)
1952 Kagaku-Kenkyusho was renamed Kaken Chemicals
1961 Kaken Chemicals was listed on the Second Section of the Tokyo Stock Exchange
1962 Kaken Chemicals was listed on the First Section of the Tokyo Stock Exchange
1963 Construction of Shizuoka Factory (Fujieda City) was completed
1965 Received the 11th Okochi Memorial Prize
1966 Business offices (present branches) were established in major cities in Japan
1971 Received the 17th Okochi Memorial Prize

Launch of new products

1948 Began production of **Penicillin KAKEN**



1950 Streptomycin KAKEN was launched
1953 **Athletan (anti-trichophyton product)** was launched



1980 »»»

1982 Kaken Chemicals merged with Kakenyaku-Kako to form Kaken Pharmaceutical Co., Ltd.
1988 Kaken Pharma Co., Ltd. was established
1991 Temporarily moved the head office to Urayasu City, Chiba due to the Honkomagome Redevelopment Project
1998 Bunkyo Green Court was completed
Moved the head office to the center office
2000 Shiga Factory was closed and its operation was integrated with the Shizuoka Factory
Recognized as the winner of the FY 2000 3Rs (Reduce, Reuse, and Recycle) Promotion Merit Award, and awarded the Minister of Health and Welfare Prize

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



1988 Adofeed (pain- and inflammation-relieving plaster) was launched
1989 Ebrantil (α1 blocker to treat dysuria and hypertension) was launched
1992 Procylin (oral-use prostaglandin I_2 analog) was launched
Mentax (anti-trichophyton product) was launched
1998 **Seprafilm (absorbable adhesion barrier)** was launched





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

2001 »»

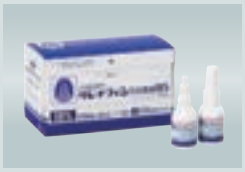
2001 ISO14001 certification obtained at the Shizuoka site
2005 Concluded a license agreement regarding worldwide rights for bFGF
2006 Antifungal compound KP-103 was out-licensed for Europe and the United States
2012 Exclusive distribution rights were acquired for SI-6603 (lumbar disc herniation treatment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

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



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

2014 **Clenafin (topical onychomycosis treatment product)** was launched



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



2018 **Hernicore for Intradiscal Injection (lumbar disc herniation treatment product)** was launched



KAKEN's Value-creating Process

Corporate Philosophy KAKEN helps improve the quality of life for patients by serving as many

Social Issues



Aging population



Unmet medical needs



Growing medical expenses

Pharmaceutical Business Flow

Research → Development → Production → Marketing & Sales

Drug Discovery Focus

- Immune system (Inflammatory skin diseases, allergic diseases, rheumatism, etc.)
- Nervous system (Neuropathic pain, etc.)
- Infectious diseases (Deep mycosis, etc.).

Therapeutic Franchises*

- Orthopedics
- Dermatology
- Other fields (collagen disease, etc.).

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

KAKEN's Business Pharmaceuticals segment (pharmaceuticals, medical devices),

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



agrochemicals segment, and real estate segment

KAKEN's Business

Pharmaceuticals Segment

Pharmaceuticals and Medical Devices

See p.9 for more details

KAKEN specializes in the fields of orthopedics, dermatology. In the orthopedics field, we supply Artz, an anti-osteoarthritis drug, as well as Hernicore, a product to treat lumbar disc herniation treatment product and others. In dermatology, we offer such as Clenafin, a topical treatment for onychomycosis, and Fiblast Spray, a wound-healing drug. All these products are widely used in clinical settings.

In research and development, KAKEN focuses on areas such as the immune system, the nervous system, and infectious diseases in which we can effectively utilize our expertise, technologies, and scientific knowledge.

Efinaconazole (product name: Clenafin/Jublia), a compound discovered by the Company, was launched in Japan in 2014 as Japan's first topical treatment for onychomycosis. In Overseas, it has been out-licensed in North America and Asia, and it has been gradually launched by local partner companies.

Agrochemicals Segment

See p.19 for more details

KAKEN contributes to the safety and reliability of food production, and its operations range from research and development to the manufacture and distribution of agrochemicals, feed additives, and drugs for animals that are considered safe and place less burden on people, animals and the environment.

As for agrochemicals, the Company developed Polyoxins, a group of agricultural fungicides, and Pentoxazone, a rice herbicide, and sells them mainly in Japan, as well as in overseas markets.

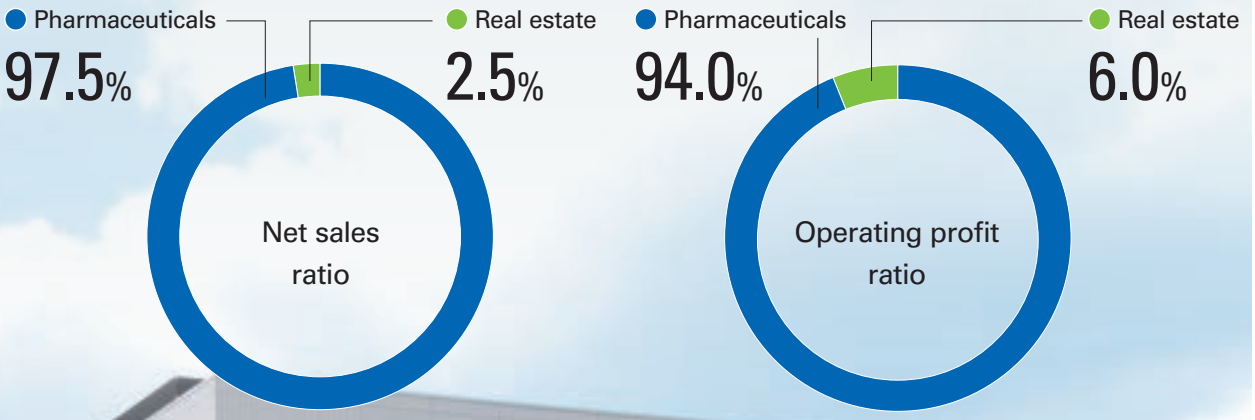
As for feed additives and drugs for animals, the Company sells Salinomycin, an anticoccidial antibiotic for chickens, and Uroston, a drug for cattle, among other drugs.



Real Estate Segment

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





Pharmaceuticals Segment

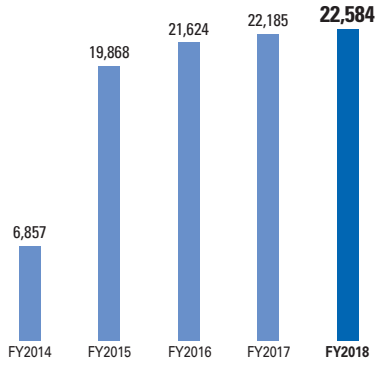
Overview of Major Products

KAKEN provides highly competitive drugs in the global market, focusing on the areas of orthopedics and dermatology.

Clenafin [topical onychomycosis treatment product]



Sales (Millions of yen) *Launched in September 2014.



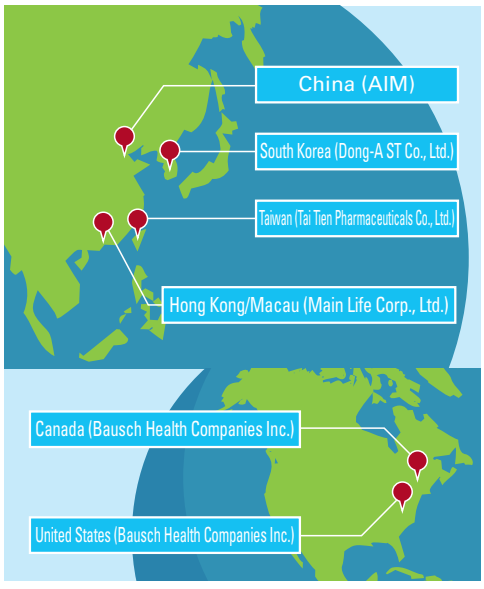
Launched in Japan in September 2014, Clenafin is the country's first topical treatment for onychomycosis. This drug contains efinaconazole, which was discovered by KAKEN, as its active ingredient.

Possessing high antifungal activity against the causative fungus for the infection of onychomycosis, and excellent nail permeability as it has low affinity for keratin, which is the major component of nails, Clenafin has proven effective in treating onychomycosis through a once-daily application to the infected nails.

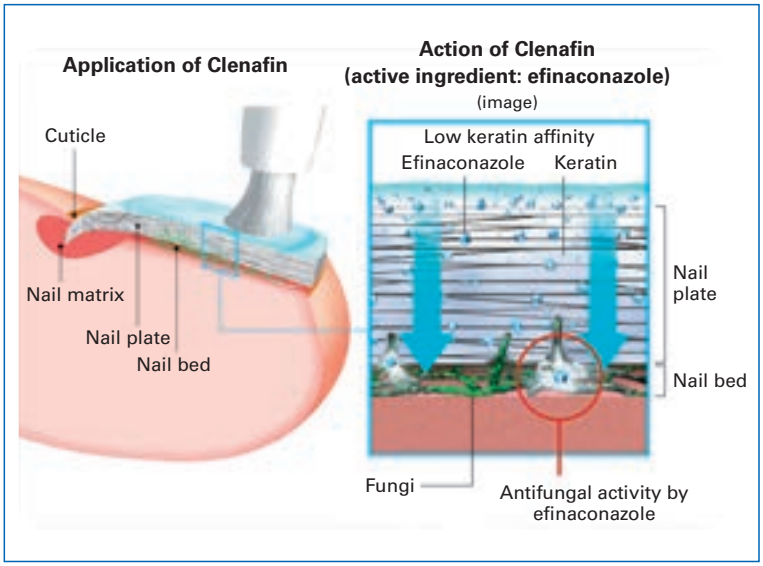
Clenafin comes packaged in a bottle with a connected brush, making it easy to apply the drug across the surface of nails. As a new therapeutic option for onychomycosis, Clenafin is used at many medical institutions, primarily by dermatologists.

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

Global launches of Clenafin (Jublia)



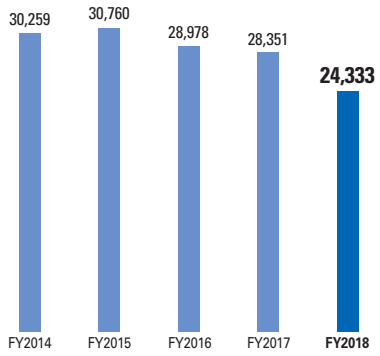
Action Mechanism of Clenafin



Artz [anti-osteoarthritis product]



Sales (Millions of yen)



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

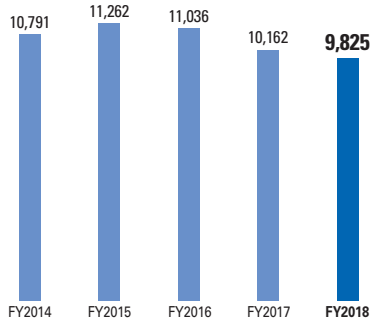
Artz exhibits pharmacological effects, including suppression of cartilage degeneration, pain suppression, improvement in range of joint motion, prevention of tendon adhesion, improvement of lubrication, suppression of synovial membrane inflammation, and improvement in properties of pathological synovial fluid. Possessing such efficacy, Artz was launched in 1987 as the world's first hyaluronic drug indicated to treat osteoarthritis in the knee by intra-articular injection. Later in 1989, an indication for shoulder periarthritis was added. In 2005, an indication for knee joint pain in rheumatoid arthritis was added.

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

Seprafilm [absorbable adhesion barrier]

Sales (Millions of yen)





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

Seprafilm transforms into a hydrated gel within 24 to 48 hours after being applied to tissue that has been damaged by surgery. It then remains in place for approximately seven days, preventing adhesion by forming a physical barrier between the damaged tissue and the healthy tissue surrounding it. Owing to its firm contact with wet tissues, there is no need for sutural attachment. In addition, surgical removal is unnecessary because Seprafilm is a bioabsorbable material composed mainly of sodium hyaluronate and carboxymethyl cellulose, both of which have long been used as pharmaceutical and food additives. Furthermore, it has been proved not to hinder the normal process of wound healing.

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

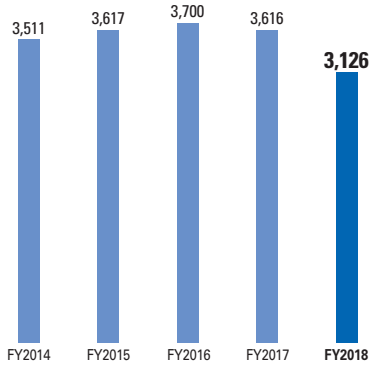
Pharmaceuticals Segment

Overview of Major Products

Fiblast [wound-healing product]



Sales (Millions of yen)



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

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

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

Regroth [medicinal product for periodontal regeneration]

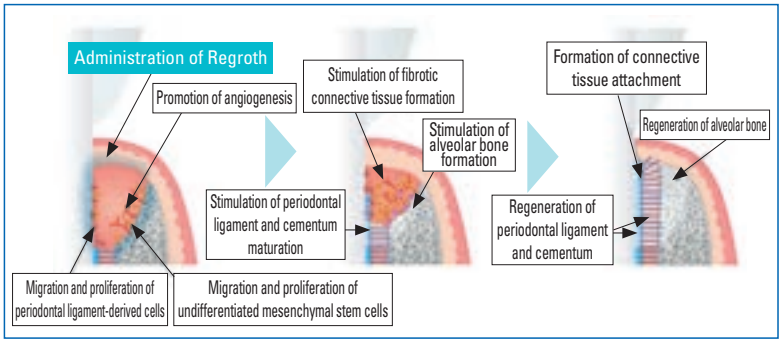


Regroth is the world's first medicinal product for periodontal regeneration. Its active ingredient is trafermin, a recombinant human bFGF (basic fibroblast growth factor).

In addition to the wound-healing effects on various cells demonstrated by Fiblast, which was launched in 2001, bFGF was shown to promote the proliferation of undifferentiated mesenchymal stem cells and periodontal ligament-derived cells as well as facilitate angiogenesis when administered to periodontal tissue defects, demonstrating promotion of periodontal tissue regeneration.

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

Action Mechanism of Regroth



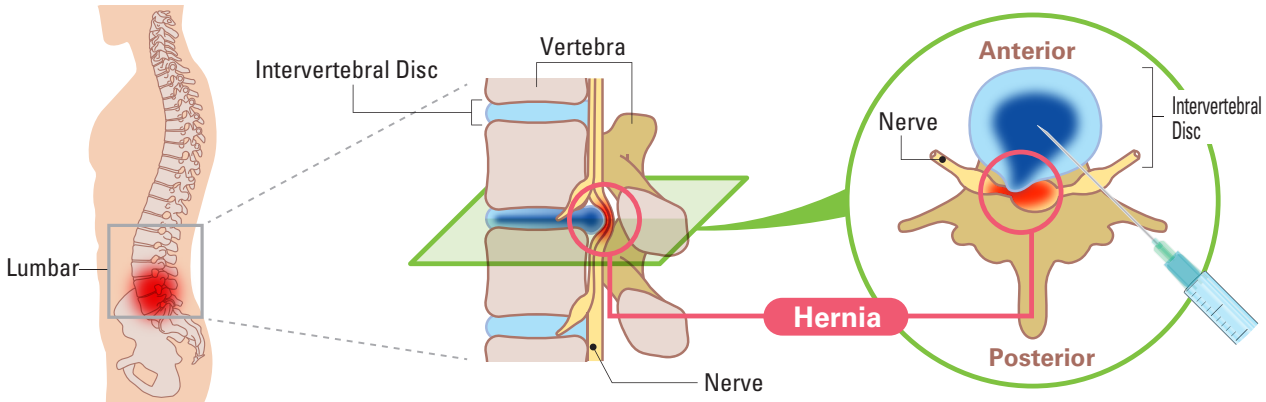
Hernicore [lumbar disc herniation treatment product]

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

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



Image of Hernicore Administration



Other products

Adofeed	Pain- and inflammation-relieving plaster
Ebrantil	α1 blocker to treat dysuria and hypertension
Procylin	Oral-use prostaglandin I_2 analog
Mentax	Anti-trichophyton product
Lipidil	Anti-hyperlipidemia product
Loxoprofen Na Tape	Pain-relieving and anti-inflammatory plaster

Pharmaceuticals Segment

Value Chain and Four Divisions

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

1 R&D

R&D Division



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

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

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

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

2 Pharmaceutical approval

Regulatory Affairs Division



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

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

3 Production

Production Division



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

In order to respond to recent significant changes in the environment surrounding the pharmaceutical industry, we also aim to strengthen our efficient production and quality assurance systems. We built a new factory for external application drugs in 2016 to start the efficient production of Clenafin, which is a topical onychomycosis treatment product. On the other hand, we are outsourcing the manufacture of agrochemical ingredients and are downsizing a fermentation production line which has been operating since our plant was established. Furthermore, our new quality control building was completed in 2018 with a view to improving the test environment and enhancing our quality control system.

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

4 Marketing & sales

Marketing & Sales Division



In order to ensure that the prescription drugs and medical devices sold by the Company are properly used, we provide medical information mainly through three of our units, namely, Sales & Marketing, Science, and Sales Promotion. At Sales & Marketing unit, medical representatives (MRs) provide medical professionals with proper usage information. While providing information, they also concurrently collect information related to product safety and suggestions for product improvement and share the information internally. Such efforts lead to information provision and product improvement that meet the needs of medical practices. In order to respond to changing medical needs, MRs need to have not only knowledge of the products themselves, but also highly-technical knowledge such as related medical information. For this reason, each and every one of the MRs devotes themselves to acquiring new knowledge on a daily basis, undergoing employee education and training with support from Science unit. Sales Promotion unit is in charge of product distribution, delivering to medical institutions via pharmaceutical and medical-device wholesalers.

Some recent initiatives we have implemented to improve the quality and speed of our information provision include such as increased utilization of our website and webinars, introduction of a system to support sales activities, and reorganization of the sales teams. The Company is committed to undertaking higher-quality information provision activities so as to gain an even stronger presence in the fields of orthopedics and dermatology, where its mainstay products are promoted, and become a company essential for community medicine.

Pharmaceuticals Segment

R&D



In order to deliver innovative pharmaceuticals that satisfy unmet medical needs to patients, we are rapidly developing new pharmaceuticals.

Mitsuru Watanuki
General Manager of R&D Planning & Project Management Department
R&D Division

We are striving to develop new pharmaceuticals continuously based on our accumulated technologies and excellent research teams.

KAKEN's Corporate Philosophy is to help improve the quality of life for patients by serving as many people as possible to return smiles of happiness to their faces, through supplying superior pharmaceuticals. The key element to that end is KAKEN's research and development. From the standpoint of striving for in-house drug discovery that is competitive worldwide, and with the objective of bringing smiles of happiness to the faces of as many patients as possible, the Company engages in research and development activities as a prescription drug manufacturer aiming to continually develop new pharmaceuticals that meet unmet medical needs, utilizing its technologies accumulated over many years and excellent research teams.

The Company focuses its investments and human resources in research and development themes within fields where its experience, technologies and foundations can best be utilized: namely, the immune system field, the nervous system field, and infectious diseases field. At present, we have approximately 250 research and development staff members. Research and development expenses in FY2018 amounted to ¥10.2 billion, and ¥10.6 billion is planned for FY2019. Aiming to expand the R&D pipeline, the Company engages in efficient research and development by leveraging on its collaborations with other pharmaceutical companies and research institutions in Japan and overseas through joint research and development, in- and out-licensing of products under development, and outsourcing. Furthermore, the Company has been taking on the challenge of entering new research fields through the enhancement and fusion of its R&D foundations in recent years.

KAKEN's drug discovery research is carried out at the Drug Research Centers in Kyoto and Shizuoka as well as the CMC Center in Shizuoka. The two centers were formed through reorganization in 2014 in order to further optimize efficiency in research and development. The Company has introduced state-of-the-art equipment and technologies to effectively advance its drug discovery research, which requires original and specialized knowledge as well as a long and harsh research process. In addition, drug discovery research is promoted by sharing roles internally, having sufficient communication, and cooperating with each other.

Status of development themes (as of the end of June 2019)

Development code	Indication	Development stage				
		Phase I	Phase II	Phase III	Application	Approval
BB I-4000	Primary axillary hyperhidrosis	Phase III				
KMW-1	Removal of eschar with thermal burns	Phase III				
KP-607	Onychomycosis	Phase I				
KAR (Ivermectin)	Head lice	preparing for clinical trial				

The Company also strives to further enhance researchers' expertise and introduce state-of-the-art technologies and knowledge by dispatching the researchers to research institutions in Japan and overseas.

In FY2018, BBI-4000 (indication: primary axillary hyperhidrosis; in-licensed from Brickell Biotech, Inc. in the United States) and KMW-1 (indication: removal of eschar with thermal burns; in-licensed from MediWound Ltd. in Israel) in developmental stage began Phase III trials (comfirmatory trials). Additionally, the Company began trials of KP-607, which is a successor to Clenafin launched in 2014, a topical treatment for onychomycosis. In terms of in-licensing of products in development, Ivermectin lotion, 0.5% (indication: head lice infestation) was in-licensed by Arbor Pharmaceuticals, LLC. in the United States (preparing for clinical trial), and Lenabasum (indication: systemic sclerosis and dermatomyositis) was in-licensed by Corbus Pharmaceuticals Holdings, Inc. in the United States. In addition to the above, there are a number of themes that progressed into the preclinical stage or the new drug discovery stage, and the Company is strenuously working on their research and development.

Going forward, KAKEN will continue to focus its efforts on the fields of expertise in order to advance research and development efficiently and speedily. In addition, KAKEN endeavors to always engage in research and development to meet the needs of the times by periodically discussing and receiving advice on the Company's research and development themes with and from experts in Japan.

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

In addition to in-house research and development, the Company strenuously works to enhance the R&D pipeline by seeking out candidate products for in-licensing, conducting out-licensing activities for candidate in-house products, and seeking out "seeds" of new drug discovery through joint research, among other means.

In FY2017, the Company concluded a collaborative research agreement for the identification of a multispecific antibody candidate for development in inflammatory diseases with Numab Therapeutics AG in Switzerland, which has a multispecific antibody technology platform. In the same fiscal year, the Company also granted an exclusive license to Bausch Health Companies Inc. in Canada to develop and commercialize topical products containing KP-470, a new chemical entity developed by the Company, in the United States, Canada, and Western and Eastern Europe. An exploratory trial was launched in Canada in 2019.

In addition to the above, the Company is propelling joint research with research institutions and companies in Japan and overseas.

Going forward, KAKEN is committed to continue promoting collaboration with companies and research institutions in Japan and overseas as well as in- and out-licensing of products under development so as to seek out innovative technologies and "seeds" of new pharmaceuticals on global scale, with an aim to accelerate research and development and provide patients with innovative new pharmaceuticals as early as possible.

Member's voice

Leveraging our combined strengths to conduct swift and efficient research and development

Shingo Todo
R&D Planning & Project Management Department
R&D Division



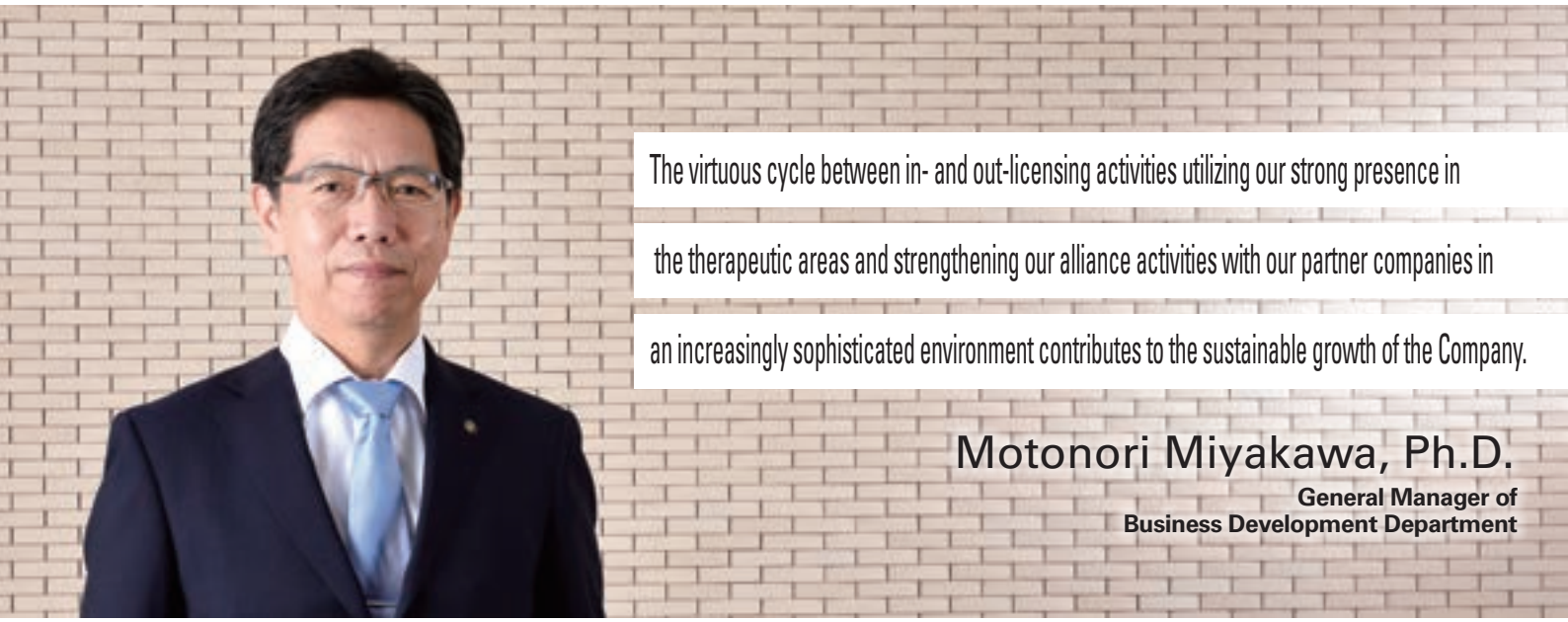
After working on medicinal chemistry at the Drug Research Center in Kyoto and process chemistry at the CMC Center in Shizuoka, I was transferred to the Head Office in Tokyo, where I am in charge of managing a project to develop drugs to treat hyperhidrosis. This is a joint research project with an American company, and the project was launched with being the first in class in Japan as its goal.

The timing of decision-making is vital in order to keep the project on schedule. Nowadays, drug development requires a wide variety of specialized technologies, and this project also has multiple partners such as outsourcing and joint-development companies. Having close communication and sharing the information with the partners are necessary to make decisions with the partners in a timely manner. Within the Company, we have fostered a culture that requires employees to report to, inform, and consult with each other, which does not permit factors that may delay the project schedule to be hidden. Thanks to this, we successfully completed trials from Phase I to confirmatory trial in Phase III after the in-licensing of the project. We are now planning to apply for approvals.

KAKEN is planning to increase the number of its development projects in the future, and the role of the project managers in advancing development efficiently will grow. For this reason, I am also focusing on building a foundation for supporting projects. Also, one of the strengths of being in a medium-sized pharmaceutical company is that I can learn the names and faces of all of the roughly 250-strong staff members in the R&D Division, so there is almost no one that I do not know. We will take maximum advantage of this benefit for close communication to conduct swift research and development at KAKEN through a company-wide unified effort.

Pharmaceuticals Segment

Business Development



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

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

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

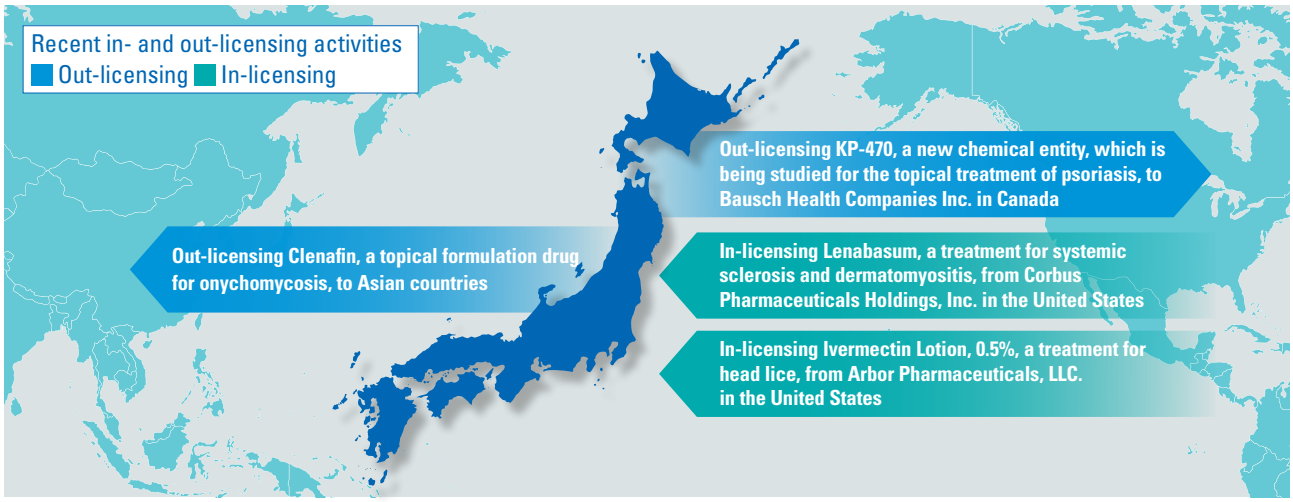
The Business Development Department has consistently worked on the in- and out-licensing activities and the subsequent alliance management with our partner companies. The absorbable adhesion barrier Seprafilm is the in-licensed product from overseas company. And also, the in-licensing activity of basic fibroblast growth factor (bFGF) led to the development and launch of such unique products as Fiblast Spray, a wound-healing product, and Regroth Dental Kit, a medicinal product for periodontal regeneration. In terms of out-licensing activities, our Chinese partner company, Beijing Tide Pharmaceutical Co. Ltd., has greatly increased the sales of Ropion, a nonsteroidal pain-relief injection, in China. Additionally, we out-licensed Clenafin, a topical formulation drug for onychomycosis, which was in the preclinical stage with the development code KP-103, to Dow Pharmaceutical Sciences, Inc. (DPSI; currently Bausch Health Companies Inc.), a U.S. startup company specialized in development of topical formulations. As the result of synergy between our strengths in antifungal research and DPSI's drug formulation technologies and development capabilities in dermatological therapeutic area, Clenafin was simultaneously obtained approval through the global study and launched in Japan and the United States. To deliver Clenafin to the patients with onychomycosis around the world, we have currently out-licensed Clenafin to partner companies in Asian countries. And then, we are making further efforts to expand and develop such partnership all over the world.

Because of the success of Clenafin, the Company has been greatly increased its global recognition and presence in the dermatology area. And also, in recent years, the Company has made the in-licensing agreements with such U.S.-based specialty firms as Brickell Biotech, Inc. (treatment for hyperhidrosis; Phase II in the United States at time of in-licensing), Corbus Pharmaceuticals Holdings, Inc. (treatment for scleroderma; global Phase III study is ongoing), and Arbor Pharmaceuticals, LLC. (treatment for head lice; launched in the U.S. market). We expect these achievements to have positive effects on sales and co-promotion partnerships in the future. We are continuing our efforts to strengthen the capabilities of our team to make further develop this virtuous cycle of partnerships.

To cope with the latest trends and environmental changes in the pharmaceutical industry, we are continuing our efforts to further improve our business capabilities, including the in- and out-licensing activities and alliance management.

The Business Development Department has two groups: the Alliance Management Group and the Licensing Group. The Alliance Management Group is working to maintain business alliance with existing partner companies. The members of Alliance Management Group are making effort to improve their alliance capabilities that can respond appropriately to a variety of business environment changes due to the changes of the markets and regulations in each countries. Such efforts managed to build firm relationships with our partner companies and often lead to new collaborations. The members strive to improve and keep expert skills in the alliance management through workshops and events held by industry organizations.

The Licensing Group leads the processes of scouting and evaluating licensing opportunities and negotiating contracts, aiming to expand R&D pipeline. In addition to the skills negotiating with the licensor, the members of Licensing Group are required strong communication abilities to facilitate internal and external relationship,



as well as the diligence to keep up with progress in the life sciences and pay attention to business and regulatory trends in the pharmaceutical industry, constantly. Simply signing a contract is not our end goal. The group members also support smooth advancement of projects, and for research and development collaborations in particular, provide side-by-side support for communication between project leaders from each company.

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

Member's voice

Flexibly supporting increasingly vital licensing by studying a wide range of fields

Yo Sonoda, Ph.D.
Licensing Group
Business Development Department



For the first 10 years after I joined KAKEN, I was involved in promoting new drug discovery projects as a researcher. At the time, I was involved in the initial stages of drug discovery, with roles including building evaluation systems and primary assessment of small-molecule compounds. In 2014, I was transferred to the department responsible for external research partnerships in drug discovery, and since then I led several research partnerships through the contract negotiation. I am currently in the Licensing Group of the Pharmaceutical Business Development Department.

The Licensing Group is responsible for scouting and evaluating licensing opportunities, and negotiating for domestic and international licensing contracts. An important key to continuously bringing new drugs to market is to in-license pharmaceuticals developed and marketed by other companies in Japan and overseas as well as discovering new drugs in-house. Evaluating a potential in-licensing opportunity requires a multi-faceted assessment including scientific, pharmaceutical regulatory, and economic perspectives, and it is vital to collaborate with many different relevant departments, including research, clinical development, regulatory affairs, marketing & sales, and corporate planning & coordination. Additionally, when negotiating contracts, the Company needs to respond swiftly to requests from negotiating partners. The in-licensing project coordinators must have a wide range of knowledge ranging from R&D to finance and marketing, and must learn on daily basis. On the other hand, it is impossible to have deep expertise in all fields, so they must also maintain constant communication with representatives from each specialized department. I was recently in charge of the in-licensing of Lenabasum, a scleroderma treatment product, and was able to execute the contract in a short period of time through close, company-wide collaboration with relevant departments.

In light of recent changes in the business environment surrounding the pharmaceutical industry, I think that it will become even more vital to enhance our development pipeline and market our products worldwide through collaboration with other companies. The expertise required of the Licensing Group representative differs greatly depending on each project (whether it is in-licensing or out-licensing, the development stage, the type of disease, etc.). I will work continually to take in new information and polish my skills so that I can respond flexibly.

Pharmaceuticals Segment

Agrochemicals Segment

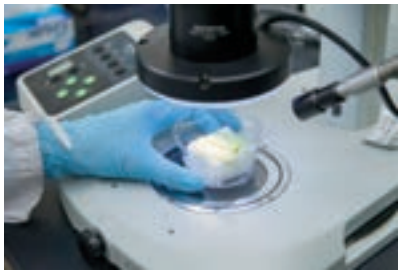
By offering eco-friendly products, KAKEN supports agriculture in an effort to contribute to food safety and security.

Business features

We conduct an integrated operation for agrochemicals, feed additives, and drugs for animals, covering from research and development to marketing. As for agrochemicals, we develop and market focusing on our original products including fungicide, Polyoxin and rice herbicide, Pentoxazone for paddy fields both in and outside Japan. Polyoxin, a substance produced using a fermentation process, exhibits the characteristic mechanism of action known as chitin synthesis inhibition. As fungicides with a high level of safety for humans and animals and a low risk to the environment, they have long been well accepted by farmers both in and outside Japan since its registration as an agrochemical in Japan in 1967. Pentoxazone has excellent herbicidal effects on some annual weeds in paddy fields, and is even effective on weeds resistant to some herbicides, making it an indispensable active ingredient for paddy rice production. Furthermore, we are working to expand our product lineup by introducing and developing Metamifop, a rice herbicide for paddy fields.

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







Herbicides

Pentoxazone

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

Pentoxazone is very safe for paddy rice plants, and it offers a broad application timing, including before, after and simultaneously during rice transplanting. It is marketed in Japan and South Korea.



Metamifop

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

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





Fungicides

Polyoxins

Discovered by the Institute of Physical and Chemical Research in 1961, Polyoxins are substances derived from fermentation culture of *Streptomyces cacaoi* var. *asoensis*, an actinomycete isolated from soil collected from the Aso district of Kumamoto, Japan. Polyoxins are commercially available in two product types: Polyoxin AL based on a Polyoxin complex as the active ingredient, and Polyoxin Z based on Polyoxin D zinc salt as the active ingredient. Both types are environmentally friendly agrochemicals which are also highly safe for both humans and animals. Polyoxin AL exhibits a broad antifungal activity against diseases caused by filamentous fungi on vegetables, fruit trees, flower plants, and the like, and it has been approved for a label expansion as a molting inhibitor for spider mites and thrips. Polyoxin Z is effective not only against turf and vegetable diseases, but also against diseases of nut trees and fruit trees.

Polyoxins have been registered and marketed as an agrochemical in 16 countries, mainly South Korea, China, and in North America. In particular, Polyoxin D zinc salt is exempted from setting maximum residue level (MRL) in countries such as United States, Canada, and New Zealand for its high level of safety.



Feed additives

Salinomycin

Salinomycin, a feed additive discovered and developed by KAKEN in 1968, is a polyether antibiotic obtained from a culture solution of *Streptomyces albus*, a strain of actinomycete. Salinomycin is contributory to poultry production throughout the world, mainly for the prevention of chicken coccidiosis.

Drugs for animals

Uroston

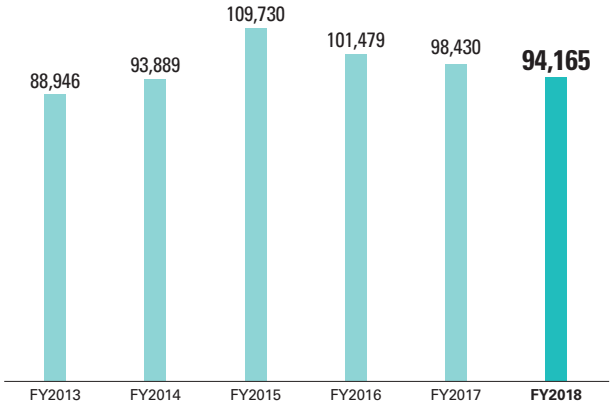
Uroston, an herbal medicine mainly consisting of extracts from naturally occurring *Quercus Salicina Blume*, serves to prevent and treat bovine urolithiasis. It promotes the dissolution of phosphate urinary calculus as well as prevents bovine urinary calculus and facilitates excretion through effects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



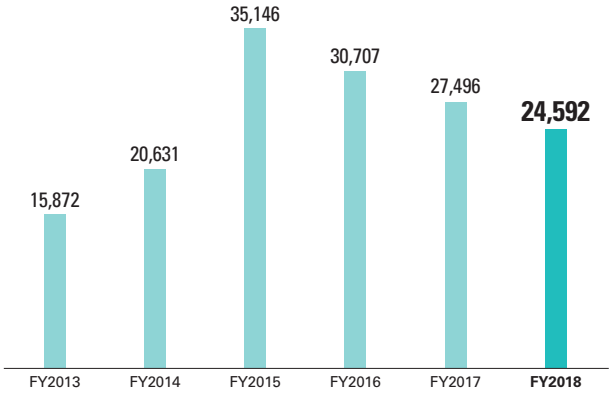
Financial and Non-Financial Highlights

Financial Highlights

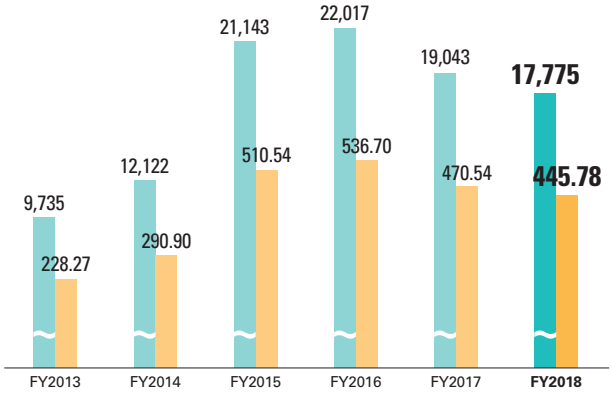
Net sales (Millions of yen)



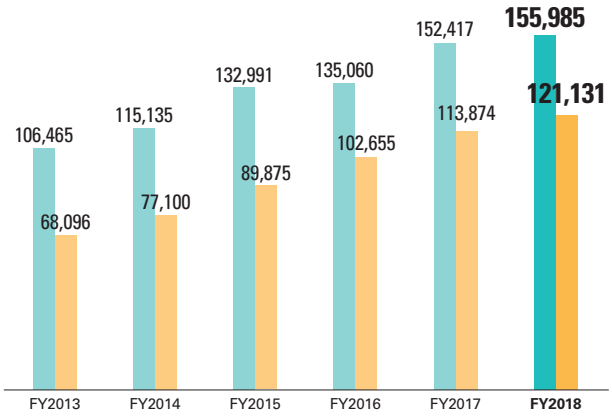
Operating profit (Millions of yen)



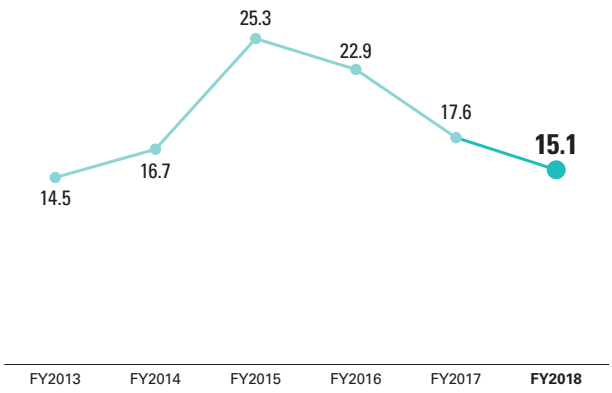
Profit attributable to owners of parent (Millions of yen)
Profit per share (Basic) (Yen)



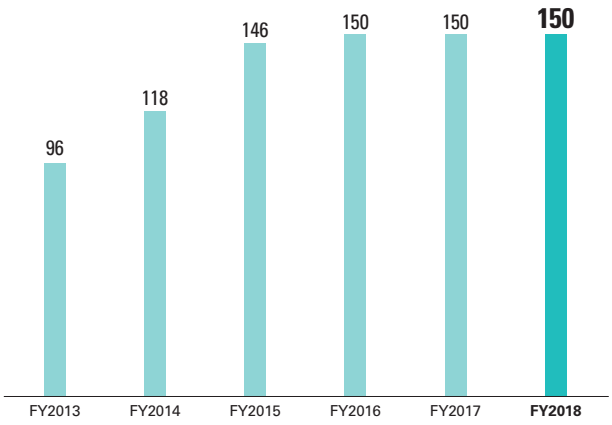
Total assets (Millions of yen)
Net assets (Millions of yen)



ROE (%)



Dividends per share (Yen)

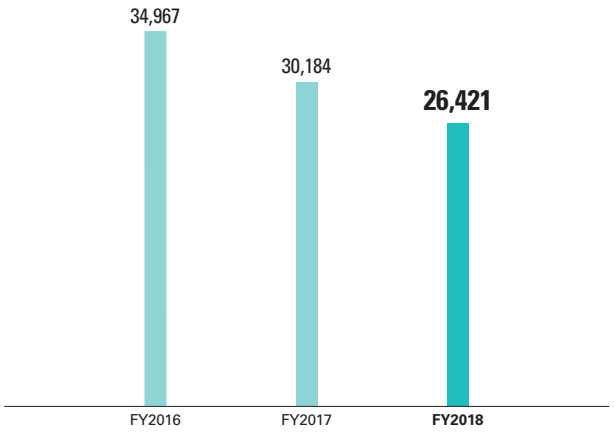


* The Company implemented a one-for-two reverse stock split on October 1, 2015. Dividends paid for the interim period of FY2015 or earlier are calculated on a post-reverse-stock-split basis.

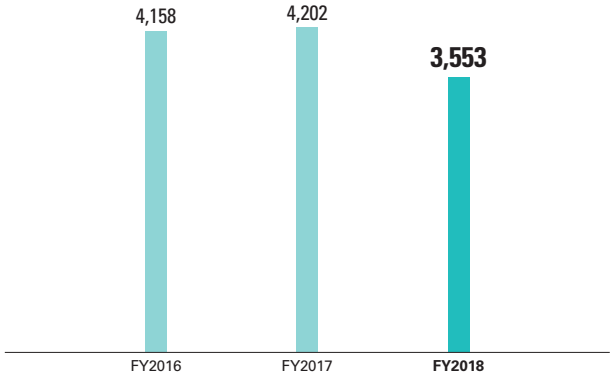
Non-Financial Highlights

Environment-related　Society-related

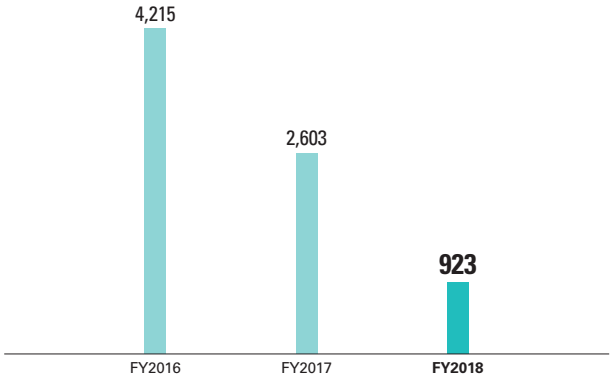
Electricity consumption (1,000 kWh)



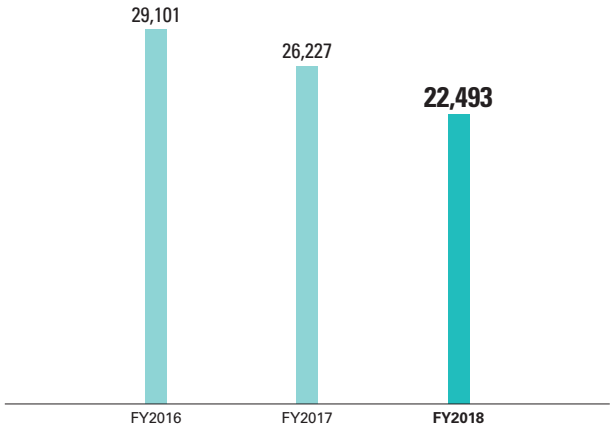
Water consumption at the Shizuoka site and the Drug Research Center in Kyoto (1,000 tons)



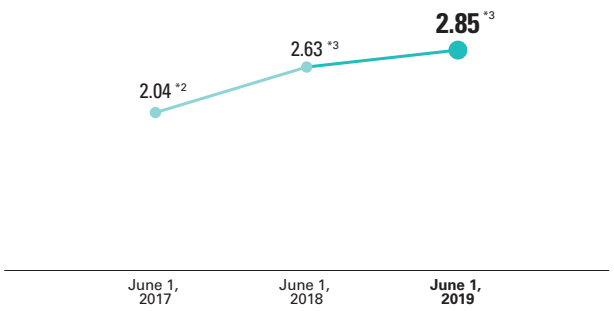
Waste produced at the Shizuoka site and the Drug Research Center in Kyoto (tons)



CO_2 emissions (t-CO_2)



Ratio of employees with disabilities*1 (%)

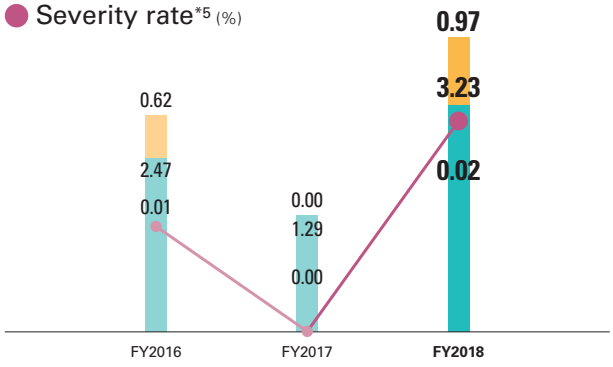


*1 Figures are as of June 1.
*2 Legal employment quota in 2017 was 2.0%.
*3 Legal employment quota in 2018 and 2019 is 2.2%.

Frequency rate of occupational accidents*4 (%)

Lost-time accidents　Accidents not requiring leave from service

Severity rate*5 (%)



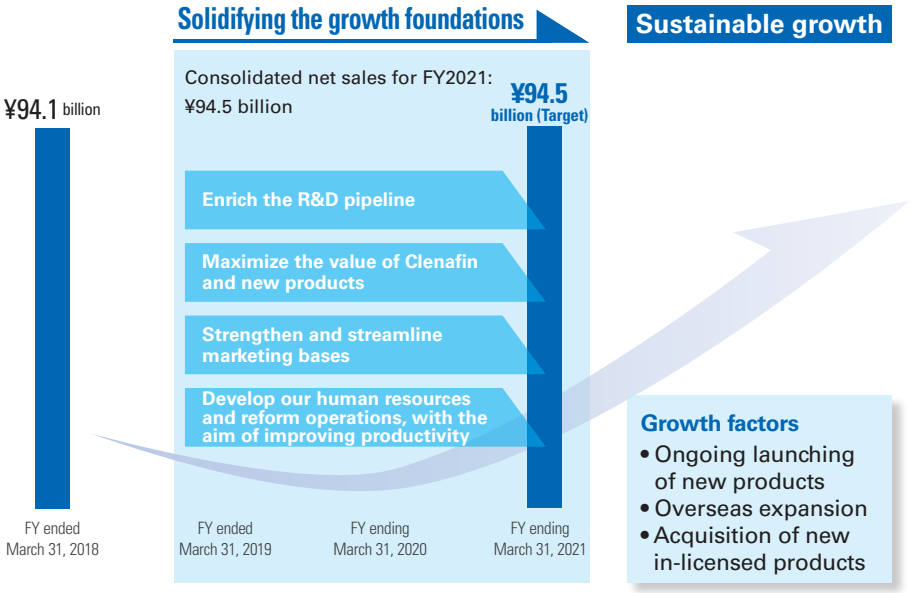
*4 Frequency rate = Number of deaths and injuries from occupational accidents/total number of working hours * 1,000,000
*5 Severity rate = Number of workdays lost/total number of working hours * 1,000

Medium-Term Business Plan 2021

Under the three-year Medium-Term Business Plan that started in 2019, we have set the basic policy of the Plan as "establishment of growth foundations" that will allow us to survive through the difficult times, rather than being constrained only to achieving numerical management targets during the period of the business plan. KAKEN will focus on the following four measures under this business plan.

1. **Set enrichment of the R&D pipeline as our foremost priority, and allocate as many management resources to this task as possible.**
2. **Work to maximize the value of Clenafin and new products through the overseas expansion of Clenafin and the overseas expansion and expanded indications of new products.**
3. **Aim to improve productivity by strengthening and streamlining marketing bases, in order to achieve consolidated net sales of ¥94.5 billion.**
4. **Improve the productivity of all employees through human resource development and human resource training, in order to develop employees with a presence, while endeavoring to streamline our organization and achieve appropriate staffing.**

Performance Forecast (Consolidated)



Numerical management targets for FY2021

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

Achievements of the previous Medium-Term Business Plan

The following steady results were achieved through the three priority measures under the previous three-year Medium-Term Business Plan started in 2016.

❶ Enrich the R&D Pipeline

Started clinical trials for a topical onychomycosis treatment product (KP-607), and in-licensed Ivermectin lotion, 0.5% for head lice from Arbor Pharmaceuticals, LLC. and Lenabasum for systemic sclerosis and dermatomyositis from Corbus Pharmaceuticals Holdings, Inc.

❷ Maximize the value of Clenafin and new products, and strengthen and streamline marketing bases for existing products

Domestic sales of Clenafin grew steadily while out-licensing activities were pursued overseas (South Korea, Taiwan, Hong Kong and Macao, and China). In particular, the product was launched by the licensee companies in South Korea and Taiwan.

❸ Foster personnel with strong creativity suited to an age of transformation

The entire Group worked to strengthen the capabilities of human resources through means such as focusing on the nurturing of leaders who will lead our next generation.

1 Enrich the R&D pipeline

Expansion and fusion of the in-house drug discovery foundations

Enhance technological foundations pillared by the three priority fields



Three year vision for the R&D pipeline

	Current	By FY2021 (planned)
Launch or NDA application		● BBI-4000 ● KMW-1 ● Lenabasum
Clinical trial stage	**Phase III**: BBI-4000/KMW-1/Lenabasum (Corbus Pharmaceuticals Holdings, Inc.) **Phase I**: KP-607 **Preparing for Phase I**: Ivermectin **Exploratory clinical trials (Canada)**: KP-470 (Bausch Health Companies Inc.)	● Ivermectin ● KP-607 ● KP-470 (Domestic in-house development) ● Accelerate the R&D of in-house developed products ● In-licensing of developed products

2 Maximize the value of Clenafin and new products



Maximize the value of Clenafin through overseas expansion

Clenafin

East Asia: Strengthen and promote partnerships with partners in each country
The United States and Canada: Distributed by the licensee company, Bausch Health Companies Inc.
Outside of North America: Return of rights from Bausch Health Companies Inc. ▶ Considering new partners

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

Regroth

Pursue data collection and market analysis in Japan with an aim for overseas expansion

Products in development in Phase III

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

3 Strengthen and streamline marketing bases

Grow sales by utilizing the marketing bases

Foster new products

- Foster Regroth and Hernicore
- Strengthen our presence in dermatology and plastic surgery in preparation for the sales launch of BBI-4000 and KMW-1
- Actively in-license the distribution rights for products that can utilize the marketing bases

Grow core products

- Strengthen the promotion of products including Clenafin, Artz, and Seprafilm

Strengthen marketing bases

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

4 Develop our human resources and reform operations, with the aim of improving productivity

Human resource development and education

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

Reforms in operation and organization

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

President's Message

Starting the Medium-Term Business Plan 2021 to pave the way for sustainable growth

Tetsuo Onuma
President and Representative Director

Q1 Please provide an overview of the business condition while reflecting on FY2018.

A1 Revenue and profit decreased despite a growth in sales of Clenafin.
Research and development expenses were increased, in order to expand investment for growth.

In the domestic pharmaceutical industry, the impact of factors including NHI drug price revisions and promotion of the use of generic drugs, with the aim of curtailing public healthcare expenditure has continued to expand, and the business environment surrounding the Company has continued to become increasingly harsh, in recent years.

Against this backdrop, during FY2018, which was the final year of the three-year Medium-Term Business Plan 2018, although we endeavored to increase sales of pharmaceuticals, net sales were down year on year due to the impact of NHI drug price revisions, as well as a push by competing products and generic drugs. With regard to income, profit decreased as a result of a record-high investment of ¥10.2 billion in research and development expenses toward expanded investment for growth, with the aim of leaping forward into the future, while also being affected by a decline in revenue.

As a result of the above, with regard to the consolidated business results during FY2018, net sales amounted to ¥94,165 million (down 4.3% year on year), operating profit amounted to ¥24,592 million (down 10.6% year on year), ordinary profit amounted to ¥24,972 million (down 10.3% year on year), and profit attributable to owners of parent amounted to ¥17,775 million (down 6.7% year on year).

Looking back on the status of pharmaceuticals, etc., sales grew for Clenafin, the topical onychomycosis treatment product (overseas trade name: Jublia), both domestically and abroad. Overseas, sales were particularly strong in South Korea, where the drug was launched during the previous fiscal year. To promote the further overseas expansion of Clenafin, the Taiwanese licensee, Tai Tien Pharmaceuticals Co., Ltd., started sales, while development and distribution rights in China and distribution rights in Hong Kong and Macao were newly out-licensed to AIM and Main Life Corp., Ltd., respectively. These developments are expected to make a significant contribution to business results in the future.

In FY2018, Hernicore, a treatment for lumbar disc herniation, was launched in August 2018 as a new product. We have focused on providing information to medical institutions to ensure that it is properly used, and the number of institutions that have adopted this treatment has grown steadily.

On the other hand, as a result of the impact of NHI drug price revisions, as well as competing products and generic drugs, as described above, there has been an unavoidable decline in sales of our flagship pharmaceuticals including Artz, an anti-osteoarthritis drug, Seprafilm, an absorbable adhesion barrier, Fiblast Spray, a wound-healing product, and Lipidil, an anti-hyperlipidemia product.

Q2 Please describe the status of the R&D pipeline.

A2 We will accelerate in-house drug discovery efforts while continuing new in-licensing for expansion of the R&D pipeline.

In order to overcome the challenging business environment and improve our corporate value through the provision of superior pharmaceuticals, the Company does not pursue pharmaceutical manufacturing on the scale of ¥100 billion in net sales. Rather, our policy is to steadily launch into the market the pharmaceuticals that meet the needs of medical practices and are also expected to bring out high therapeutic effect, even if



they only generate sales in the range of ¥10 billion. Based on this stance, we have increased research and development expenses in order to expand the R&D pipeline, and are conducting ongoing in-licensing from other companies, while also accelerating in-house drug discovery efforts.

As for the current status of the R&D pipeline, the following two products have moved to Phase III: BBI-4000, a primary axillary hyperhidrosis treatment product, and KMW-1, a burn wound eschar-specific removal product. Furthermore, BBI-4000 is expected to advance to the application phase soon. KP-607, which is developed through in-house discovery as a topical treatment for onychomycosis following Clenafin, has advanced to the Phase I clinical trial stage. In addition, with regard to KP-470, a plaque psoriasis treatment product developed in-house, the licensee, Bausch Health Companies Inc., has started clinical trials in Canada.

In FY2018, we also newly in-licensed Lenabasum with systemic sclerosis and dermatomyositis as the planned indications from Corbus Pharmaceuticals Holdings, Inc., which is currently conducting its international joint Phase III clinical trials. We also in-licensed KAR (Ivermectin lotion, 0.5%), a head lice treatment product, from Arbor Pharmaceuticals, LLC., for which preparations for clinical trials are underway.

In addition to these developments, we are making steady efforts to expand the R&D pipeline to achieve future growth, including research collaboration on antibody drugs with a biotech venture company.

Q3 Please describe the new Medium-Term Business Plan.

A3 This Plan is a three-year period for the development of a structure that is capable of achieving a leap forward into the future and establishing a foundation for sustainable growth.

Under the Medium-Term Business Plan 2018 (FY2016 to FY2018), which has come to an end, we aimed to achieve net sales of ¥110.0 billion in the final year of the Plan, under the basic policy of "the establishment of growth foundations from a forward-looking perspective." However, we struggled due to the impact of the NHI drug price revisions and generic drugs that exceeded the expectations at the time the Plan was formulated, and the numerical targets were not achieved, as a result.

On the other hand, we achieved results for the priority measure to "maximize the value of Clenafin and new products," as we achieved the out-licensing or launch of Clenafin in South Korea, Taiwan, Hong Kong and Macao, and China, as well as the launch of new products including Regroth, a medicinal product for periodontal regeneration, and Hernicore, a treatment for lumbar disc herniation. In addition, regarding another priority measure, which is to "strengthen marketing bases," we improved the quality and efficiency of information provision, through introduction of a sales support system and reorganization of our marketing and sales organization. Moreover, an organizational reform led to the emergence of many younger talents in each division who will lead the next generation, and achievements that are not reflected in the numbers, including the revitalization of our internal culture, were attained as a result.

In light of these achievements and the remaining challenges, we have formulated the Medium-Term Business Plan 2021 as our new three-year plan starting from FY2019. The basic policy of the Plan is "establishment of growth foundations to overcome

President's Message

challenging times," and under this Plan we aim to achieve net sales of ¥94.5 billion, operating profit of ¥25.0 billion, and an ROE of at least 12% as the numerical management targets for FY2021, which is three years from now. These numbers are conservative for being the growth targets of the next three years, since these three years are positioned as a period for continuing to maintain growth investments focused on a high level of research and development expenses, and developing a structure that is capable of achieving a leap forward into the future, while assuming the impact of NHI drug price revisions planned in the future.

The Plan will focus on four priority measures, namely to "enrich the R&D pipeline," to "maximize the value of Clenafin and new products," to "strengthen and streamline marketing bases," and to "develop our human resources and reform operations, with the aim of improving productivity."

Regarding the R&D pipeline, we will aim for market launch or application for BBI-4000, KMW-1, and Lenabasum over the next three years, while securing new growth drivers through the acceleration of R&D for in-house developed products and in-licensing from other companies. Regarding Clenafin, in order to maximize its value through overseas expansion, we will work to strengthen collaboration with partners in each country of East Asia, and will also consider building effective partnerships in other regions. In order to strengthen and streamline marketing bases, we will endeavor to achieve optimal staffing, and create an organization that is capable of responding to changes in the market and regulations. As part of these efforts, we plan to convert our existing formats, and reorganize staffing and organization in accordance with product characteristics and fields. In addition, we will promote management that develops and leverages the strength of each individual, in order to improve the productivity of all employees and develop employees with a stronger presence. In particular, we will focus on the development of human resources who are capable of producing results on a global level, in preparation for future overseas expansion.

Through initiatives based on the priority measures presented above, the Company will establish a foothold for overcoming the current challenging business environment and achieving sustainable growth.

Medium-Term Business Plan 2021

Establishment of growth foundations to overcome challenging times

1. Enrich the R&D pipeline
2. Maximize the value of Clenafin and new products
3. Strengthen and streamline marketing bases
4. Develop our human resources and reform operations, with the aim of improving productivity



Q4 What is your approach to ESG in management?

A4 ESG is a requirement for building strong relationships of trust with stakeholders and achieving sustainable growth.

In order to achieve sustainable growth, it is essential for companies to coexist with the environment and society in mutual prosperity, and to improve their own value by strengthening corporate governance. At the Company, we are committed to regional environmental conservation activities and social contribution activities as a corporate citizen, as we strive to reduce the environmental burden of our business activities. Furthermore, we take pride in the significant social value created through our business of supporting medical practices by supplying superior pharmaceuticals and contributing to improvements in patients' quality of life.

In addition, we are also committed to becoming a company that recognizes its social responsibility as a pharmaceutical company and conducts its business activities with a high ethical standard and society's trust. In the implementation of this commitment, we have positioned the strengthening of corporate governance as one of our top management priorities. In FY2019, we created management frameworks that contribute to improvements in corporate value with higher transparency, by increasing the number of Outside Directors by one (total of three Outside Directors) and introducing a Performance-Linked Stock Compensation Plan for Directors based on the recommendation of the Nomination and Compensation Committee.

Through such ESG activities, we will further strengthen relationships of trust with all of our stakeholders, who include not only patients and medical institutions, but also the business partners, shareholders, local community members, and employees who support our business activities. Realizing a company in which each employee can work with peace of mind and demonstrate their individual capabilities will support the health of patients through the provision of outstanding pharmaceuticals, which in turn will improve business performance and increase our corporate value, leading to the return of profits to our shareholders. In this manner, we would like to be a company that grows and develops together with all of our stakeholders.

I hope that all stakeholders accept my sincerest thanks for their kind attention regarding KAKEN's efforts toward the challenge of achieving sustainable growth, and for their continued long-term support and patronage.

Corporate Governance

Basic approach to corporate governance

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

Corporate governance system

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

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

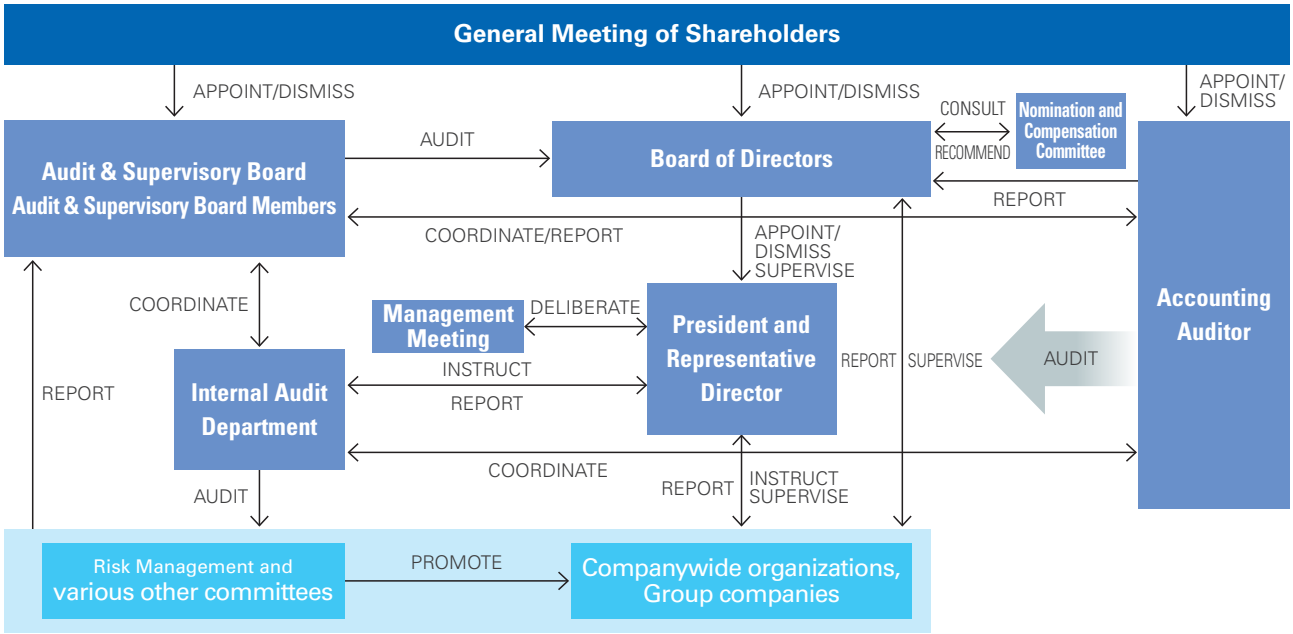
Board of Directors meetings are normally held on a monthly basis, and extraordinary meetings are held when necessary. Three of the Directors are Outside Directors. Furthermore, Audit & Supervisory Board Members, including Outside Audit & Supervisory Board Members, and Corporate Officers attend Board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

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

Board of Directors

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

Corporate governance system



Audit & Supervisory Board Members also attend Board of Directors meetings to express their opinions. In addition, Corporate Officers also attend the meetings for thorough implementation of the management policy.

Audit & Supervisory Board Members and the Audit & Supervisory Board

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

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

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

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

Outside Directors and Outside Audit & Supervisory Board Members

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

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

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

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

Evaluation of effectiveness of the Board of Directors

In FY2018, Board of Directors meetings were held 17 times (12 scheduled meetings and five extraordinary meetings). Directors and Audit & Supervisory Board Members attended the extraordinary Board of Directors meetings, and Corporate Officers also attended the scheduled Board of Directors meetings. They had multifaceted deliberations based on their expertise and experience, and made management decisions in a timely and appropriate manner. Specifically, Outside Directors and Outside Audit & Supervisory Board Members provided a wide range of opinions and questions without being constrained by internal norms. Taking into account this situation and also in reference to the self-evaluation based on questionnaire surveys conducted for each Director as well as interviews with the Chairperson of the Board, the Board of Directors evaluates its effectiveness as being ensured.

Reasons for appointment as Outside Director or Outside Audit & Supervisory Board Member

Name	Major activities	Reason for appointment
Director **Eiki Enomoto**	Mr. Eiki Enomoto attended all 17 Board of Directors meetings held during the fiscal year under review and provided comments as necessary based on his experience gained through engaging in corporate legal work and expert perspective as an attorney at law.	As Mr. Eiki Enomoto has experience and professional expertise gained through engaging in corporate legal work as an attorney at law, the Company has determined that he can utilize these in the management of the Company.
Director **Yoshio Tanabe**	Mr. Yoshio Tanabe attended all 17 Board of Directors meetings held during the fiscal year under review and provided comments as necessary based on his experience, achievements and insights gained from being involved in management at the Ministry of Foreign Affairs and numerous companies.	As Mr. Yoshio Tanabe has experience, achievements and insights gained from being involved in management at the Ministry of Foreign Affairs and numerous companies, the Company has determined that he can utilize these in the management of the Company.
Director **Kiyoko Kamibeppu**	(New appointment)	As Ms. Kiyoko Kamibeppu has extensive professional expertise, experience, and an insight as a Doctor of Health Science and a Professor of Graduate School, the Company has determined that she can utilize these in the management of the Company.
Audit & Supervisory Board Member **Kazuo Hara**	Mr. Kazuo Hara attended all 17 Board of Directors meetings and all 13 Audit & Supervisory Board meetings held during the fiscal year under review and asked questions and provided opinions as necessary as he has in-depth knowledge of and extensive experience in tax affairs and accounting as a certified public tax accountant.	As Mr. Kazuo Hara has in-depth knowledge of and extensive experience in tax affairs and accounting as a certified public tax accountant, the Company has determined that he can utilize these in the audit of the Company.
Audit & Supervisory Board Member **Hirotoshi Endo**	(New appointment)	As Mr. Hirotoshi Endo has extensive experience in the financial industry as well as his achievements as a corporate manager and an insight cultivated through his experience, the Company has determined that he can utilize these in the audit of the Company.

Corporate Governance

Officer Compensation

In an effort to provide an incentive to contribute toward the sustainable growth of KAKEN, the compensation for the Company's officers comprises basic compensation and a performance-linked bonus, which are determined by comprehensively taking into consideration the Company's medium- to long-term performance as well as past payment amounts, in addition to the responsibilities of the officers. The amount of basic compensation is set within the amount approved by the General Meeting of Shareholders, while the bonus is calculated based on comparisons of the consolidated operating profit and the consolidated profit of each fiscal year with those of the previous fiscal year, thereby ensuring a linkage with the Company's performance. However, bonuses are not paid to Outside Directors or Audit & Supervisory Board Members, as they are responsible for the functions of supervision and oversight over management, from an independent standpoint.

Compensation for Directors is determined by the Board of Directors upon deliberation of the basic compensation and bonuses, in accordance with the above standards, by the Nomination and Compensation Committee, the majority of the members of which are Outside Directors. The compensation for Audit & Supervisory Board Members is determined by discussion among the Audit & Supervisory Board Members.

At the General Meeting of Shareholders held on June 27, 2019, the introduction of a Performance-Linked Stock Compensation Plan for the Directors of the Company was resolved. The Plan aims to further clarify the linkage between compensation of the Directors and the corporate performance and stock value of the Company, thereby motivating the Directors to contribute further toward the mid- to long-term improvement of corporate performance and an expansion of corporate value, by sharing with the shareholders not only the benefit of a rise in stock price but also the risk of a decline in stock price.

Total amounts of compensation, etc., total amounts of compensation, etc. by type, and the number of officers paid, by officer category in FY2018

Officer category	Total amounts of compensation, etc. (millions of yen)	Total amounts of compensation, etc. by type (millions of yen)		Number of officers paid
		Fixed compensation	Performance-linked compensation	
Directors (excluding Outside Directors)	282	196	86	6
Audit & Supervisory Board Members (Excluding Outside Audit & Supervisory Board Members)	48	48	—	3
Outside Officers	28	28	—	4

Outside Directors Messages



Eiki Enomoto
Director (Outside)

Steady progress has been made in the development of human resources who will lead the next generation, which can also be evaluated positively from the perspective of strengthening governance.

I believe that the development of candidates for the executives who will lead the next generation is important for KAKEN's future growth. Over the past year, there have been increasing signs of a generational transition, which are evident from younger Corporate Officers in each division. I also recognize that efforts such as enriching our human resources through training and education for mid-career employees brought about changes that are highly appreciated from the perspective of strengthening governance.

In addition, a Performance-Linked Stock Compensation Plan for Inside Directors was introduced from the current fiscal year, as a result of deliberation by the Nomination and Compensation Committee, of which I am also a member. The sharing of the risk of stock price fluctuations by management with shareholders will act to strengthen their commitment toward medium- to long-term growth, more than ever before.

I will check the decisions and execution of business by management from a highly independent external perspective, and live up to the trust of the shareholders, as management aims to continue providing outstanding pharmaceuticals in accordance with the Company's mission as a pharmaceuticals company, and to improve its corporate value, supported by its long tradition of new drug creation, even in the face of significant changes in the management environment.



Yoshio Tanabe
Director (Outside)

I will support efforts aimed at achieving sustainable growth, by taking advantage of the capabilities of human resources during an age of transformation.

During FY2018, KAKEN achieved results in enhancing the R&D pipeline through in-house drug discovery, as well as in-licensing of products in development from other companies and cross-border out-licensing of in-house products. Although business results declined year on year, I feel that steady progress was made in establishing a foundation for sustainable growth.

The Medium-Term Business Plan 2021, which started from FY2019, has been formulated in a way that clarifies the direction as to how the capabilities of our human resources can be exerted in order to withstand adversity in the domestic pharmaceutical industry, and each department has started efforts under this Plan with a sufficient understanding of this direction. Although challenging goals have been set in the growth strategy, I intend to utilize my experience and knowledge to provide advice and recommendations, in order to support the achievement of these goals.

There are now three Outside Directors, and the areas of expertise of each Outside Director encompass a broader scope. We will hold lively discussions from a variety of perspectives, and strengthen the effectiveness of corporate governance.



Kiyoko Kamibeppu
Director (Outside)

I will watch over management from the perspective of a female researcher, while utilizing my knowledge and experience in QOL research.

Although I have not had any direct experience in the pharmaceutical industry thus far, I have served as a professor of health sciences and nursing, established the QOL Research Center within my research lab, and been involved in QOL research education, advice, planning, management, and implementation, including from the perspective of family nursing. I hope that this knowledge and experience will help in the realization of KAKEN's Corporate Philosophy, which is to improve the QOL of patients through the provision of outstanding pharmaceuticals.

When I had the opportunity to speak with the officers of the Company in advance as an Outside Director candidate, I was impressed with how KAKEN has continued to provide unique drugs in line with the needs of medical practices, thus far. Later, when I attended a meeting of the Board of Directors, the free and open exchange of opinions made a strong impression on me. Going forward, I also aim to live up to the mandate from the shareholders by supporting the development of our business as a member of KAKEN and watching over management from perspectives different from those of prior Directors of the Company.

Corporate Governance

Members of the Management Team

Directors



President and Representative Director
Tetsuo Onuma

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



Managing Director
Hiroyuki Horiuchi

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



Managing Director
Atsushi Takaoka

April 1978 Joined The Norinchukin Bank
June 2003 General Manager, Securities Operation Division of The Norinchukin Bank
July 2004 Deputy General Manager, Osaka Branch of The Norinchukin Bank
June 2005 General Manager, JA Bank System Management Division of The Norinchukin Bank
June 2007 Managing Director of The Norinchukin Bank
June 2010 Full-Time Audit & Supervisory Board Member of Nihon Unisys, Ltd.
June 2014 Advisor of Okasan Securities Co., Ltd.
June 2016 Managing Director of the Company (to present)



Director
Fumihiro Watanabe

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



Director
Chikara Ieda

April 1984 Joined the Company
April 2009 General Manager of Clinical Development Department of the Company
April 2014 General Manager of R&D Strategic Planning Department of the Company
January 2015 General Manager of Project Management and Licensing Department of the Company
July 2016 Corporate Officer of the Company
October 2016 Chief Officer of R&D Division of the Company
June 2017 Director of the Company (to present)



Outside Director
Eiki Enomoto

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



Outside Director
Yoshio Tanabe

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



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

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

Audit & Supervisory Board Members



Audit & Supervisory Board Member (Standing)

Atsutada Iwamoto

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



Audit & Supervisory Board Member (Standing)

Naomi Doi, Ph.D.

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



Outside Audit & Supervisory Board Member

Kazuo Hara

April 1968 Joined Fukuoka Regional Taxation Bureau
July 1986 Commissioner's Secretariat of the National Tax Agency
July 2007 Vice President of the National Tax College
July 2008 Regional Commissioner of Kumamoto Regional Taxation Bureau
September 2009 Registered as certified public tax accountant
June 2015 Audit & Supervisory Board Member of the Company (to present)



Outside Audit & Supervisory Board Member

Hirotoshi Endo

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

Corporate Officers

Satoshi Murakami

Chief Officer of Regulatory Affairs Division

Norihide Oizumi

Chief Officer of Production Division, General Manager of Shizuoka Factory

Masahiro Matsuura

General Manager of Corporate Planning & Coordination Department

Naoyuki Ishida

General Manager of Human Resources Department

Masashi Suzudo

General Manager of General Affairs Department

Hirofumi Fujii

General Manager of Eastern Japan Regional Marketing & Sales Department

Corporate Governance

Compliance

Basic approach and system to promote compliance

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

KAKEN has appointed a Compliance Officer who is in charge of promoting compliance-related initiatives on a company-wide basis and designated the Legal Affairs & Intellectual Property Department as the department to promote compliance.

Activities to promote compliance

In April 2002, the Company formulated KAKEN's Activity Principles and Guidelines as a basis for making decisions and taking actions in the performance of duties by executives and employees, and KAKEN's Code of Conduct as a guideline to be followed by executives and employees, both toward the achievement of the Corporate Philosophy and Business Philosophy.

We hung panels displaying "KAKEN's Activity Principles and Guidelines" on the wall at the most easy-to-see location of each office, branch, sales office, and subsidiary to help officers and employees of the Company and its subsidiaries practice compliance, whereby the Company endeavors to promote compliance-based corporate activities.

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

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

Compliance Hotline and whistleblowing contact desk

The Company has put in place the Compliance Hotline for employees to directly report to or consult with the Compliance Officer should such employee become aware of any actual or potential compliance violation inside or outside the Company.

In addition to the internal contact desk, the Company has also established in April 2006 a system for employees to report to, notify or consult with a law firm as a whistleblowing contact desk.

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

Ethical considerations in animal testing

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

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

In conducting animal tests, the Company complies with relevant laws and regulations and internal regulations, gives due consideration to animal welfare, and carries out examinations by the Animal Testing Committee to ensure that the tests are appropriately carried out from a scientific point of view.

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

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

Risk Management

Basic approach and system to promote risk management

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

Overview of the risk management system

- Regulations and other systems concerning the loss risk management
- Regulations and other systems concerning the loss risk management of subsidiaries

1. The Company establishes a system to identify and manage risks that the KAKEN Group is exposed to under which a Risk Management Officer is appointed and the Corporate Planning & Coordination Department is designated as the responsible department.
2. The Company classifies risks and manages them by designating the responsible departments, respectively.
3. The Board of Directors makes management decisions on the handling of material risks from the perspective of the KAKEN Group's management, and such risks are managed by the responsible departments.
4. The Internal Audit Department audits the status of risk management at the KAKEN Group and reports the results to the President, the Board of Directors and the Audit & Supervisory Board.

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

Major risks

Among the matters concerning the status of business, the status of accounting, etc. described in the securities reports, those that may materially affect the decision making of investors shall including those in the table below.

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

Major risks	Status of major risks
Risks related to new drug development	Considerable financial investment and development periods of more than 10 years are required before a new drug can be launched. The Company carefully develops new drugs while taking the efficacy and safety of a particular drug into full consideration. However, it is possible that the development process could be halted before its completion.
Risks related to the side effects	Clinical trials undertaken in the development stage involve the trial administration of the drug to a limited number of patients. Accordingly, after a drug is launched onto the market, we conduct post-marketing surveillance to supplement these clinical trials. In the event that new side effects are identified at this stage, sales of the drug could be halted.
Risks related to policies to curtail public healthcare expenditure	As government initiatives to curtail healthcare expenditure continue, various medical system reforms are also being implemented. These reforms may cause changes in the market environment, which could subsequently affect the Company's performance.
Risks due to competition	Sales competition with other pharmaceutical companies and sales of generic products by other companies may cause declines in sales of KAKEN products. Such factors could subsequently affect the Company's performance.
Risks related to delay or cessation of product supply	The supply of products may be delayed or halted as a result of various factors, such as problems with the manufacturing facilities of the Company or its suppliers, and delays in the procurement of raw materials. These factors could affect the Company's performance.
Risks related to litigation	The Company is exposed to the possibility of litigation arising in relation to its business activities. Such litigation could affect the Company's performance.

Initiatives targeting information security

KAKEN is committed to strengthening information security and preventing information leakage and other incidents from happening in recognition of the critical importance of appropriately protecting information related to management, customers, individuals, trade, technologies, etc., in an information society, while placing information security among the top management priorities.

Environment

Environmental Management System

KAKEN basic environmental philosophy

As a pharmaceutical company which endeavors to improve the quality of life of patients through supplying superior pharmaceuticals, KAKEN shall recognize its social responsibility and work on conservation, maintenance and enhancement of the global environment in all aspects of its business activities.

KAKEN basic environmental policy

1 Establish and maintain an environmental management system
We shall establish an environmental management system and take initiatives to protect the environment. Led by our Environmental Committee and Environmental Measures Task Force, these initiatives shall be systematic and continuous.

2 Comply with environmental laws and regulations
We shall comply with environmental laws and regulations at the national and local level. 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, Recycle). We shall periodically revise our targets in respect to climate change, waste, and chemical emissions, seeking to improve continually.

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 lifecycle, from research and development, production, sales, and distribution to product fate after usage.

5 Cooperate with the community
As a corporate citizen, we shall work with the community to protect the environment. We shall also disclose environmental information and work for mutual understanding with the community.

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

Environmental action plan

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

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

Activity report for FY2018 and activity targets for FY2019 of the Shizuoka site

Environmental policy	FY2018		FY2019 target
	Target	Result	
Energy saving	Reduce CO_2 emissions by 1,500 t-CO_2 by the end of FY2018 compared with the benchmark CO_2 emissions of 20,895 t-CO_2.	Reduced CO_2 emissions by 4,063 t-CO_2 by the end of FY2018 compared with the benchmark CO_2 emissions of 20,895 t-CO_2.	Reduce CO_2 emissions by 1% by the end of FY2019 compared with the benchmark CO_2 emissions of 17,600 t-CO_2.
Management of chemical substances	Ensure proper usage and ascertain the used amount of chemical substances.	Identified the amount of reagents purchased and purchased the reagents in the minimum necessary amount. Carried out daily inspections and drills for accidental leak.	Ensure proper usage and ascertain the used amount of chemical substances.
Reduction of waste	Increase the valuables ratio by 3% compared with FY2014 by the end of FY2018.	Failed to achieve the target, with the valuables ratio of 24.2% compared to 30.4% in FY2014.	Reduce the amount of incinerated waste by 1% (0.4 t) from FY2013-FY2017 average (43.4 t) by the end of FY2019.
Eco-friendly product development	Develop eco-friendly products and improve manufacturing and analysis technologies.	Reduced the amount of organic solvents used in manufacturing and analysis processes, improved the manufacturing method, and provided support to manufacturing contractors.	Develop eco-friendly products and improve manufacturing and analysis technologies.
Proactive participation in environmental protection activities in local communities	Proactively participate in environment-related external organizations. Promote interchange with local residents.	Participated in environment-related organizations and exchanged information. [26 times in total] Participated in cleaning and river beautification activities carried out around the site. [in Apr. 2018 and Sep. 2018] Held an environmental report meeting for local residents. [in Jul. 2018]	Proactively participate in environment-related external organizations. Promote interchange with local residents.

Materials balance of the business activities

At the Shizuoka site and the Drug Research Center in Kyoto, each and every one of the employees recognizes input and output that place burden on the environment during the course of their business activities ranging from research and development to production and office activities, and is working to reduce environmental pollution.

(*The materials balance data shown is the total amounts for FY2018.)

Chemical substances (tons)

(Substances subject to reporting under the PRTR system)	
Acetonitrile	2.3
Normal hexane	1.7
Chloroform	1.0
Zinc compound	0.0
Toluene	5.0
Dichloromethane	11.2

Energy

Electric power	23,955,960kWh
LPG	5 tons
City gas	4,433,373Nm^3

Water

Water	3,553,000 tons

Office paper

1.978 million sheets

Other packaging materials

Plastics
Paper

Raw materials

Corn starch
Soy flour, etc.

IN PUT

Business activities



Research and development activities



Production activities



Office activities

OUT PUT

Discharging into the water system

Volume of wastewater
...2,450,000 tons/year

Emissions into the atmosphere

CO_2
.....21,125t-CO_2

Waste

Waste discharged
.....923t
Amount of final landfill
.....21t

Activity report for FY2018 and activity targets for FY2019 of the Drug Research Center in Kyoto

FY2018			FY2019	
Environmental policy	Target	Result	Environmental policy	Target
Management of electricity consumption	Maintain and manage electricity consumption relative to the data in FY2017.	Compared to approximately 2,370 Mwh in FY2017, it increased by 2.5% to 2,430 Mwh in FY2018. This increase is presumably due to the high annual average temperature. An "A" rating with an achievement degree of 97.3%.	Management of crude oil-equivalent energy usage	Maintain and manage crude oil-equivalent energy usage results of FY2018.
Proper management of chemical substances	Implement concrete measures planned at each department. (38 times during the year)	Although the site planned to carry out measures 37 times a year, measures were not implemented twice, resulting in a "B" rating with an achievement degree of 94.6%.	Proper management of chemical substances	Implement concrete measures planned at each department. (26 times during the year)
Reduction of general waste	Maintain and manage the total volume discharged relative to the data in FY2017.	Compared to 1,147 kg in FY2017, it was 1,027 kg in FY2018, resulting in an "A" rating with an achievement degree of 111.6%.	Reduction of general waste	Maintain and manage the total volume discharged relative to the data in FY2018.
Harmony with the environment	• Cleaning activities around the site: 12 times during the year • Cleaning activities of the Shinomiya River: twice during the year	Performed cleaning activities around the site 12 times with a monthly rotating schedule, as well as river cleaning activities once each in spring and fall, a total of 14 times, resulting in an "A" rating with an achievement degree of 100%.	Harmony with the environment	• Cleaning activities around the site: 12 times during the year • Cleaning activities of the Shinomiya River: twice during the year
Community activities	Participate in regional environmental activities 4 times during the year.	• Flower replanting (Sanjo Dori street flowerbeds): 3 times (Jun./Sep./Dec. 2018) • Firefighting training: once (Jun. 2018) • Yamashina volunteer fire brigade training event: once (Sep. 2018) • Kyoto volunteer fire brigade general training: once (Dec. 2018) At six times/year, resulted in an "A" rating with an achievement degree of 150%.	Preferential selection of environmentally conscious goods	More than 120 goods during the year

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

Environment-related qualifications

The Shizuoka site and the Drug Research Center in Kyoto encourage the acquisition of various public qualifications necessary for environmental management. The number of employees with qualifications is as indicated below (as of April 1, 2019).

Qualification	Number of employees
Poisonous and deleterious substance handler	38
Operations chief of specified chemical substances, etc.	63
Operations chief of organic solvents	80
Air pollution control manager	5
Water pollution control manager	9
Intermediate industrial waste treatment facility engineering manager	2

Qualification	Number of employees
Specially controlled industrial waste manager	9
Hazardous material engineer	166
Qualified person for energy management	5
High pressure gas production safety technical manager	22
Boiler expert	20

Environment

Initiatives for Environmental Protection

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

Conservation of water quality

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

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

Shizuoka site (agreement on pollution control with Fujieda City)

	Agreed values for pollution control	Results (average)
pH	6.0～8.5	7.6
BOD (mg/L)	Average: 35; maximum: 45	2.3
SS (mg/L)	Average: 45; maximum: 65	1.3
Emissions (m³)	20,000 or less	6,760

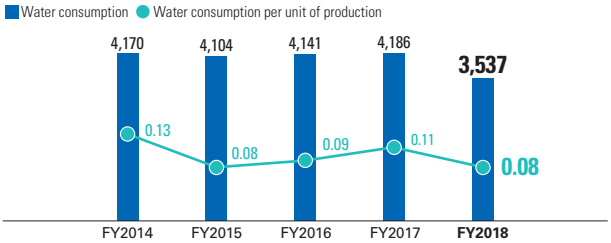
Drug Research Center in Kyoto (internal standards for the Drug Research Center in Kyoto)

	Internal standard values	Results (average)
pH	5.8～8.6	7.0
BOD (mg/L)	1,500 or less	50.6
SS (mg/L)	1,500 or less	83.9

Efficient use of water resources

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

Water consumption and consumption per unit of production at Shizuoka site



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

Conservation of air quality

In order to reduce emissions of carbon dioxide (CO_2), sulfur oxide (SOx), etc., city gas fired boilers were installed to replace the previous boilers at the Shizuoka site and the Drug Research Center in Kyoto in FY2006 and FY2007, respectively. As a result, both of the factories have continued to boast zero emissions of SOx since then.

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

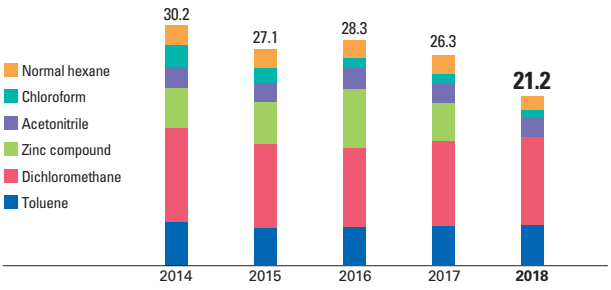
Chemical substance management

Both the Shizuoka site and the Drug Research Center in Kyoto are managing chemical substances on a voluntary basis. In order to reduce exposure to potential risks from using harmful chemical substances, the Company considers possible revisions to its processes for manufacturing and analyzing pharmaceuticals, and it is working to reduce the amount of solvents used and switch to less harmful substances. In addition, the Company has established internal regulations for handling harmful chemical substances, placing them under reliable management, to prevent accidents and environmental pollution at all stages of handling these chemicals, from purchasing to use and then disposal.

The Company also manages chemical substances in an integrated manner together with reagents. Safety data sheets (SDSs) regarding the usage of such substances are kept up to date to ensure readiness for emergencies.

The Shizuoka site and the Drug Research Center in Kyoto monitor the status of use of chemical substances subject to the Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (the "PRTR Act") by, for example, using the network within the sites. They also strive to reduce the amount of such substances used, consider alternative substances, and ensure that they are handled appropriately.

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

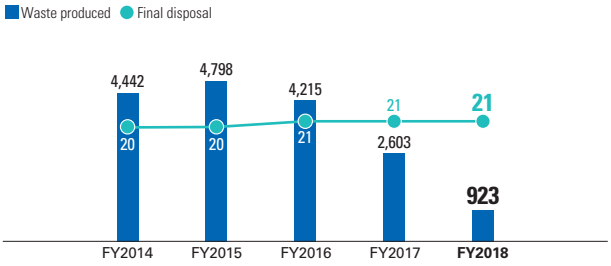


Waste reduction and recycling

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

In FY2018, the total amount of waste produced by the Shizuoka site was 874 tons. Of this, 49% was sludge produced during the treatment of wastewater and residual materials from fermentation processes (animal and plant residues). The entire volume of this sludge and residual materials produced in the year under review was used for composting, etc. The amount of other waste for final landfill was 16 tons owing to our recycling activities. Going forward, the Company will continue to advance activities promoting the reduction and recycling of waste.

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



Reduction of CO_2 emissions and energy saving

As the reduction of CO_2 emissions is necessary for the mitigation of global warming, the Shizuoka site is systematically pushing forward with its measures to this end and carrying out ongoing energy-saving activities such as the introduction of highly-efficient equipment.

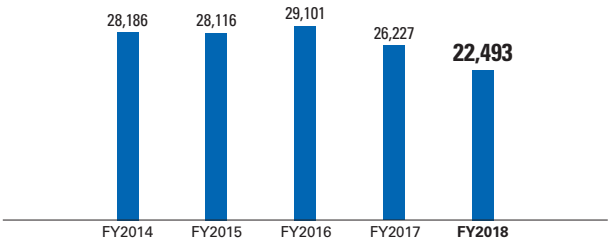
The Drug Research Center in Kyoto has worked on various measures to reduce electricity consumption such as the promotion of air-conditioning temperature control, the reduction of unnecessary lighting, the implementation of measures to prevent people from forgetting to turn off lights, and the transition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

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

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

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

CO_2 emissions (t-CO_2)



CO_2 reduction target of the Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ) and the Company

CO_2 reduction target of FPMAJ and the Company

Reduce CO_2 emissions in FY2020 by 23% compared to CO_2 emissions in FY2005

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

Engagement with Society

Engagement with Customers

Quality assurance policy

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

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

Product quality assurance



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

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

Safety assurance for pharmaceuticals after launch



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

The Company has established the Pharmacovigilance Department, which collects and evaluates data regarding the safety of the pharmaceuticals throughout phases ranging from development to post marketing. It then provides information regarding proper usage methods to medical practitioners.

Pharmaceuticals Information Service Office



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

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

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

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

Engagement with Employees

As a public entity working for the benefit of society, KAKEN complies with laws and regulations in carrying out business activities, engages in environmental activities, etc., that place strong emphasis on the sustainability of the global environment and works to create an environment where each and every one of its employees can reach their potential, such as by creating an employee-friendly workplace and promoting initiatives focused on human rights.

Various aspects of the employment environment

The Company has introduced the "Senior Staff Program" for the post-retirement employment of employees who reach the mandatory retirement age of 60. This program allows various knowledge, technologies and expertise accumulated by employees over many years to be further leveraged even after their retiring age.

The Company also works proactively to hire employees with disabilities as part of its corporate responsibility. The Company strives to expand employment opportunities for people with disabilities by enhancing its support system and ensuring such workers receive appropriate support in the workplace.

Systems to support a balance between work and childcare and/or nursing care are promoted by establishing various types of systems for taking leave of absence and days off, or working shorter hours, etc., with the Regulations for Childcare Leave and the Regulations for Nursing Care Leave at the core. In addition, the Refreshment Leave System under which leave is granted (for five days) to employees based on their length of service and age has been put in place with the objective of energizing our employees and raising their awareness.

Employee health management

As for employee health management, the Company provides regularly scheduled health checkups in the spring and lifestyle disease medical examinations in the fall. Based on the results and through collaboration with industrial physicians, nurses, medical examination centers, etc., the Company cooperates proactively with the follow-up procedures for employees whose checkups and examinations revealed health problems, and with the specified health checkups and health guidance of the health insurance association. The Company thus works to prevent disease and maintain and improve the health of its employees. In terms of measures for mental health, the Company is promoting mental healthcare for employees by, for example, implementing stress checks to ascertain the level of mental health and providing information on the external consultation desk at the health insurance association, counseling services and specialized medical institutions based on the Guidelines for Mental Health Promotion for Workers at Offices (Ministry of Health, Labour and Welfare).

Occupational safety and health

Based on the Regulations for Safety and Health Management, which aims to prevent occupational accidents and diseases from occurring and to create a comfortable working environment, the Company works to eliminate occupational accidents by means such as the holding of Safety and Health Committee meetings on a monthly basis at each office as well as the implementation of safety inspections and remedial measures at each facility and operational environment.

Training programs and self-development

The Company provides various types of training programs including "training for newly hired employees," "training for marketing MRs (medical representatives)," "training to foster next-generation leaders" and "training for new managers" to develop the abilities of employees, and supports employees' self-development efforts such as the taking of correspondence courses to improve individual work skills or to acquire necessary language skills, among other objectives.

Prevention of discrimination and harassment

The Company is obligated to provide all employees with equal employment opportunities based on employment agreements and a comfortable working environment that is free from unfair discrimination, abuse of authority, sexual harassment, pregnancy discrimination, etc. The Company works to ensure that the prevention of discrimination and harassment is thoroughly understood and enforced among all employees through means such as the Rules of Employment, Regulations for Rewards and Punishments, Compliance Guidebook, information meetings for employees in managerial positions and postings on the in-house intranet, etc., in addition to raising awareness of internal consultation channels.



Engagement with Society

Engagement with Society and Local Communities

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

Regional activities of the Shizuoka site

River beautification activities

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



Environmental report meetings

The Shizuoka site holds environmental report meetings every year. Reports are made on various measurement results, the status of employee education and other activities undertaken for the purpose of adherence with laws and regulations, so as to promote better understanding of the Company's environmental initiatives. In FY2018, an event to observe beetles naturally found on the premises was held, inviting children from the neighborhood.

Regional activities of the Drug Research Center in Kyoto



Regional environment beautification activities

The Drug Research Center in Kyoto participates in the beautification campaign for the Lake Biwa-Yodo River water system as a member of the Yamashina Beautification Promotion Corporate Council. A cleaning activity of Shinomiya River, which runs beside the site, is held every May and October, and this is one of the leading activities for the Lake Biwa-Yodo River water system.

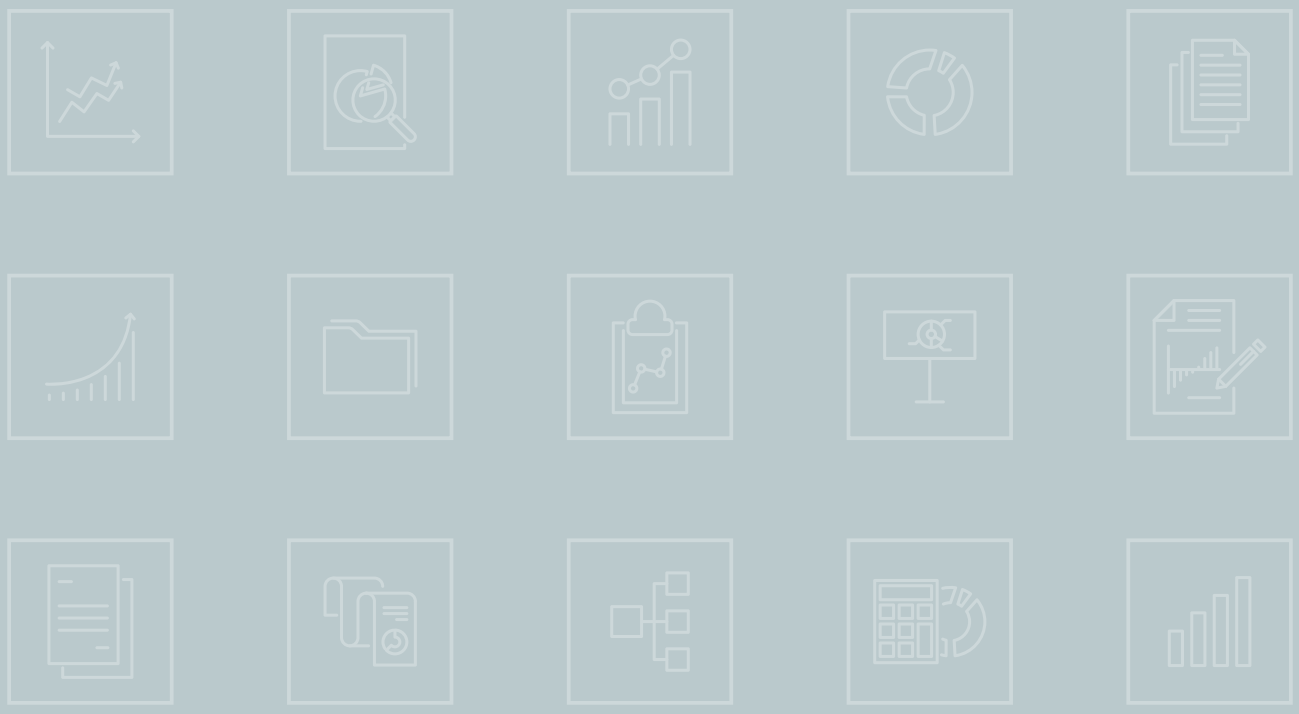
Firefighting and disaster prevention drills and regional agreements for disaster prevention and cooperation

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

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



Financial and Corporate Data



Consolidated Five-Year Summary

	MILLIONS OF YEN					THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	2017	2016	2015	**2019**
FOR THE YEARS ENDED MARCH 31						
Net sales	**¥94,165**	¥98,430	¥101,479	¥109,730	¥93,889	**$848,333**
Operating profit	**24,592**	27,496	30,707	35,146	20,631	**221,550**
Profit attributable to owners of parent	**17,775**	19,043	22,017	21,143	12,122	**160,135**
AT MARCH 31						
Total net assets	**121,131**	113,874	102,655	89,875	77,100	**1,091,270**
Total assets	**155,985**	152,417	135,060	132,991	115,135	**1,405,270**
PER SHARE DATA			YEN			U.S. DOLLARS (NOTE 1)
Profit (Basic)	**¥445.78**	¥470.54	¥536.70	¥510.54	¥290.90	**$4.016**
Cash dividends (Non-Consolidated)	**150.00**	150.00	150.00	—	59.00	**1.351**
RATIOS			%			
ROE	**15.1**	17.6	22.9	25.3	16.7	
Capital adequacy ratio	**77.7**	74.7	76.0	67.6	67.0	

Notes: 1. U.S. dollar amounts are translated, for convenience only, at the rate of ¥111 = U.S.$1.00, effective on March 31, 2019.
2. The Company conducted a 1-for-2 share consolidation on October 1, 2015. Profit per share has been calculated assuming that the share consolidation was conducted at the beginning of the year ended March 31, 2015.
3. The Company conducted a 1-for-2 share consolidation on October 1, 2015. Dividends per share figures up to the year ended March 31, 2015, are presented at the values prior to the share consolidation and dividends per share for the year ended March 31, 2016, is presented as "–." When calculated assuming that the share consolidation was conducted at the beginning of the year ended March 31, 2015, the interim dividend was ¥68.00 per share and the total dividend payment per share was ¥146.00 (including a commemorative dividend of ¥10.00 per share) in the year ended March 31, 2016.

Management Discussion and Analysis

Operating Performance

Consolidated net sales were down 4.3% year on year, to ¥94,165 million, mainly due to the impact from the NHI drug price revisions.

With regard to income, although the cost of sales ratio remained at the same level as the previous year, operating profit decreased 10.6% year on year, to ¥24,592 million, as a result of a decrease in net sales and an increase in selling, general and administrative expenses. Selling, general and administrative expenses increased primarily because research and development costs increased 25.9% year on year, to ¥10,261 million. Ordinary profit declined 10.3% year on year, to ¥24,972 million, and profit attributable to owners of parent was down 6.7% year on year, to ¥17,775 million.

Segment Information

Pharmaceuticals

In pharmaceuticals and medical devices, overall sales were down, mainly due to a decline in sales of Artz, an anti-osteoarthritis drug, and Lipidil, an anti-hyperlipemia product, in spite of an increase in sales of Clenafin, a topical treatment for onychomycosis.

This decline was largely attributable to NHI drug price revisions, in addition to the continued impact of the government policy on promoting the use of generic drugs.

In agrochemicals, sales remained at the same level as the previous year.

As a result of the above, net sales in the pharmaceuticals segment decreased 4.4% year on year, to ¥91,804 million, and segment income* was down 10.5%, to ¥23,116 million.

Net sales from overseas were ¥9,016 million.

Real Estate

In the real estate segment, the majority of revenues are generated through rent fees related to the Bunkyo Green Court commercial facility. Net sales for the real estate segment were down 1.9% year on year, to ¥2,360 million, and segment income* decreased 10.8% year on year, to ¥1,476 million.

* Segment income is based on operating profit.

Financial Position

Total assets were ¥155,985 million as of March 31, 2019, up ¥3,567 million from the previous fiscal year-end, primarily due to an increase in marketable securities.

Total liabilities were ¥34,854 million, down ¥3,688 million, largely as a result of a decrease in notes and accounts payable - trade.

Net assets totaled ¥121,131 million, a rise of ¥7,256 million, mainly following higher retained earnings.

Cash Flows

Cash and cash equivalents as of March 31, 2019, totaled ¥58,555 million, an increase of ¥5,860 million compared with the previous fiscal year-end.

Net cash provided by operating activities was ¥21,129 million, a decrease of ¥573 million year on year, due to factors including a decrease in profit before income taxes.

Net cash used in investing activities stood at ¥5,744 million, an increase of ¥2,498 million year on year, primarily as a result of a rise in purchase of long-term prepaid expenses.

Net cash used in financing activities totaled ¥9,524 million, a decrease of ¥5 million year on year, largely due to a decline in cash dividends paid.

Business Risks

Among the matters concerning the status of business, the status of accounting, etc., described in the securities reports, those that may materially affect the decision making of investors shall include the following.

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

(1) Risks related to new drug development

Considerable financial investment and development periods of more than 10 years are required before a new drug can be launched. The Company carefully develops new drugs while taking the efficacy and safety of a particular drug into full consideration. However, it is possible that the development process could be halted before its completion.

(2) Risks related to the side effects

Clinical trials undertaken in the development stage involve the trial administration of the drug to a limited number of patients. Accordingly, after a drug is launched onto the market, we conduct post-marketing surveillance to supplement these clinical trials. In the event that new side effects are identified at this stage, sales of the drug could be halted.

(3) Risks related to policies to curtail public healthcare expenditure

As government initiatives to curtail healthcare expenditure continue, various medical system reforms are also being implemented. These reforms may cause changes in the market environment, which could subsequently affect the Company's performance.

(4) Risks due to competition

Sales competition with other pharmaceutical companies and sales of generic products by other companies may cause declines in sales of KAKEN products. Such factors could subsequently affect the Company's performance.

(5) Risks related to delay or cessation of product supply

The supply of products may be delayed or halted as a result of various factors, such as problems with the manufacturing facilities of the Company or its suppliers, and delays in the procurement of raw materials. These factors could affect the Company's performance.

(6) Risks related to litigation

The Company is exposed to the possibility of litigation arising in relation to its business activities. Such litigation could affect the Company's performance.

Shareholder Returns

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

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

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

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

Consolidated Balance Sheets

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiary
As of March 31, 2019 and 2018

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	**2019**
ASSETS			
CURRENT ASSETS:			
Cash and deposits (Notes 3 and 9)	**¥ 46,956**	¥ 45,095	**$ 423,027**
Marketable securities (Notes 3, 4 and 9)	**11,599**	7,599	**104,495**
Receivables:			
Notes and accounts receivable–trade (Note 9)	**30,340**	33,315	**273,333**
Accounts receivable–other	**828**	927	**7,459**
	31,168	34,243	**280,793**
Inventories (Note 5)	**13,721**	16,651	**123,613**
Other	**285**	269	**2,568**
Allowance for doubtful accounts	**(0)**	—	**(0)**
Total current assets	**103,731**	103,859	**934,514**
PROPERTY, PLANT AND EQUIPMENT (Notes 6, 7 and 8):			
Buildings and structures	**41,668**	40,658	**375,387**
Machinery, equipment and vehicles	**15,345**	15,677	**138,243**
Tools, furniture and fixtures	**7,380**	6,974	**66,486**
	64,394	63,310	**580,126**
Accumulated depreciation	**(42,483)**	(41,906)	**(382,730)**
	21,911	21,404	**197,396**
Land	**4,324**	4,324	**38,955**
Construction in progress	**166**	412	**1,495**
Total property, plant and equipment	**26,402**	26,141	**237,856**
INVESTMENTS AND OTHER ASSETS:			
Investment securities (Notes 4 and 9)	**17,068**	18,488	**153,766**
Intangible assets	**551**	552	**4,964**
Deferred tax assets (Note 14)	**2,934**	1,621	**26,432**
Long-term prepaid expenses	**4,610**	1,072	**41,532**
Other assets	**685**	681	**6,171**
Total investments and other assets	**25,851**	22,416	**232,892**
TOTAL ASSETS	**¥155,985**	¥152,417	**$1,405,270**

See accompanying Notes to the Consolidated Financial Statements.

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	2019
LIABILITIES AND NET ASSETS			
CURRENT LIABILITIES:			
Short-term bank loans (Notes 6 and 9)	¥ 3,875	¥ 3,875	$ 34,910
Payables:			
Notes and accounts payable–trade (Note 9)	10,729	12,204	96,658
Accounts payable–other	3,639	4,565	32,784
Electronically recorded obligations–operating (Note 9)	1,529	1,248	13,775
	15,899	18,017	143,234
Accrued expenses	427	667	3,847
Provision for bonuses	1,236	1,351	11,135
Provision for sales returns	7	10	63
Provision for sales rebates	314	325	2,829
Income taxes payable (Note 14)	4,042	5,097	36,414
Other	1,777	2,057	16,009
Total current liabilities	27,580	31,401	248,468
NON-CURRENT LIABILITIES:			
Net defined benefit liability (Note 10)	6,642	6,787	59,838
Other	631	354	5,685
Total non-current liabilities	7,274	7,141	65,532
NET ASSETS:			
Shareholders' equity (Notes 2 (p) and 11):			
Common stock			
Authorized: 193,000,000 shares as of March 31, 2019 and 2018			
Issued: 48,439,730 shares as of March 31, 2019 and 2018	23,853	23,853	214,892
Capital surplus	11,408	11,408	102,775
Retained earnings	109,057	97,284	982,495
Treasury stock, at cost: 8,721,768 shares as of March 31, 2019 and 8,120,458 shares as of March 31, 2018	(26,782)	(23,259)	(241,279)
Total shareholders' equity	117,536	109,287	1,058,883
Accumulated other comprehensive income:			
Net unrealized holding gain on securities (Note 2 (c))	4,524	5,510	40,757
Remeasurements of defined benefit plans	(930)	(923)	(8,378)
Total accumulated other comprehensive income	3,594	4,587	32,378
Total net assets	121,131	113,874	1,091,270
TOTAL LIABILITIES AND NET ASSETS	¥155,985	¥152,417	$1,405,270

See accompanying Notes to the Consolidated Financial Statements.

Consolidated Statements of Income

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiary
For the years ended March 31, 2019 and 2018

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	**2019**
NET SALES	**¥94,165**	¥98,430	**$848,333**
COST OF SALES	**40,363**	42,403	**363,631**
Gross profit	**53,802**	56,026	**484,703**
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (Note 12)	**29,209**	28,530	**263,144**
OPERATING PROFIT	**24,592**	27,496	**221,550**
OTHER INCOME (EXPENSES):			
Interest and dividends income	**351**	309	**3,162**
Interest expenses	**(17)**	(16)	**(153)**
Foreign exchange losses	**(39)**	(25)	**(351)**
Loss on cancellation of leases	**(10)**	(4)	**(90)**
Loss on retirement of non-current assets (Note 13)	**(44)**	(165)	**(396)**
Loss on sales of investment securities	**—**	(3)	**—**
Loss on sale of golf club membership	**(4)**	—	**(36)**
Other, net	**95**	96	**856**
	330	189	**2,973**
PROFIT BEFORE INCOME TAXES	**24,922**	27,686	**224,523**
INCOME TAXES (Note 14):			
Current	**8,022**	9,206	**72,270**
Deferred	**(874)**	(563)	**(7,874)**
	7,147	8,643	**64,387**
PROFIT	**17,775**	19,043	**160,135**
PROFIT ATTRIBUTABLE TO OWNERS OF PARENT	**¥17,775**	¥19,043	**$160,135**

	YEN		U.S. DOLLARS (NOTE 1)
	2019	2018	**2019**
PER SHARE DATA:			
Profit (Note 16):			
Basic	**¥445.78**	¥470.54	**$4.016**
Diluted	**—**	—	**—**
Cash dividends applicable to the year (Note 11)	**¥150.00**	¥150.00	**$1.351**

See accompanying Notes to the Consolidated Financial Statements.

Consolidated Statements of Comprehensive Income

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiary
For the years ended March 31, 2019 and 2018

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	**2019**
PROFIT	**¥17,775**	¥19,043	**$160,135**
OTHER COMPREHENSIVE INCOME (LOSS) (Note 17):			
Net unrealized holding gain (loss) on securities	**(985)**	898	**(8,874)**
Remeasurements of defined benefit plans	**(6)**	811	**(54)**
Total other comprehensive income (loss)	**(992)**	1,710	**(8,937)**
COMPREHENSIVE INCOME	**16,782**	20,753	**151,189**
Total comprehensive income attributable to:			
Owners of parent	**¥16,782**	¥20,753	**$151,189**

See accompanying Notes to the Consolidated Financial Statements.

Consolidated Statements of Changes in Net Assets

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiary
For the years ended March 31, 2019 and 2018

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	TOTAL NET ASSETS
BALANCE—March 31, 2017	¥23,853	¥11,407	¥84,331	¥(19,813)	¥ 99,778	¥4,611	¥(1,734)	¥2,876	¥102,655
Changes during the year:									
Cash dividends			(6,089)		(6,089)				(6,089)
Profit attributable to owners of parent			19,043		19,043				19,043
Purchase of treasury stock				(3,445)	(3,445)				(3,445)
Disposal of treasury stock		0		0	0				0
Other, net						898	811	1,710	1,710
Total changes during the year	—	0	12,953	(3,445)	9,508	898	811	1,710	11,219
BALANCE—March 31, 2018	¥23,853	¥11,408	¥97,284	¥(23,259)	¥109,287	¥5,510	¥(923)	¥4,587	¥113,874
Changes during the year:									
Cash dividends			**(6,002)**		**(6,002)**				**(6,002)**
Profit attributable to owners of parent			**17,775**		**17,775**				**17,775**
Purchase of treasury stock				**(3,523)**	**(3,523)**				**(3,523)**
Other, net						**(985)**	**(6)**	**(992)**	**(992)**
Total changes during the year	**—**	**—**	**11,772**	**(3,523)**	**8,249**	**(985)**	**(6)**	**(992)**	**7,256**
BALANCE—March 31, 2019	**¥23,853**	**¥11,408**	**¥109,057**	**¥(26,782)**	**¥117,536**	**¥4,524**	**¥(930)**	**¥3,594**	**¥121,131**

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	TOTAL NET ASSETS
BALANCE—March 31, 2018	$214,892	$102,775	$876,432	$(209,541)	$ 984,568	$49,640	$(8,315)	$41,324	$1,025,892
Changes during the year:									
Cash dividends			**(54,072)**		**(54,072)**				**(54,072)**
Profit attributable to owners of parent			**160,135**		**160,135**				**160,135**
Purchase of treasury stock				**(31,739)**	**(31,739)**				**(31,739)**
Other, net						**(8,874)**	**(54)**	**(8,937)**	**(8,937)**
Total changes during the year	**—**	**—**	**106,054**	**(31,739)**	**74,315**	**(8,874)**	**(54)**	**(8,937)**	**65,369**
BALANCE—March 31, 2019	**$214,892**	**$102,775**	**$982,495**	**$(241,279)**	**$1,058,883**	**$40,757**	**$(8,378)**	**$32,378**	**$1,091,270**

See accompanying Notes to the Consolidated Financial Statements.

Consolidated Statements of Cash Flows

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiary
For the years ended March 31, 2019 and 2018

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Profit before income taxes	**¥24,922**	¥27,686	**$224,523**
Adjustments for:			
Depreciation	**2,153**	2,124	**19,396**
Amortization of long-term prepaid expenses	**446**	76	**4,018**
Increase (decrease) in net defined benefit liability	**(154)**	(69)	**(1,387)**
Interest and dividends income	**(351)**	(309)	**(3,162)**
Interest expenses	**17**	16	**153**
Loss on retirement of non-current assets	**43**	160	**387**
Decrease (increase) in notes and accounts receivable–trade	**2,975**	(5,084)	**26,802**
Decrease (increase) in inventories	**2,930**	(155)	**26,396**
Increase (decrease) in trade payables	**(1,193)**	2,290	**(10,748)**
Other, net	**(1,928)**	1,754	**(17,369)**
Subtotal	**29,861**	28,489	**269,018**
Interest and dividends income received	**351**	309	**3,162**
Interest expenses paid	**(17)**	(16)	**(153)**
Income taxes paid, net	**(9,065)**	(7,078)	**(81,667)**
Net cash provided by (used in) operating activities	**21,129**	21,703	**190,351**
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property, plant and equipment	**(1,908)**	(1,689)	**(17,189)**
Purchase of intangible assets	**(220)**	(199)	**(1,982)**
Purchase of investment securities	**(1)**	(1,253)	**(9)**
Purchase of long-term prepaid expenses	**(3,661)**	(110)	**(32,982)**
Other, net	**47**	6	**423**
Net cash provided by (used in) investing activities	**(5,744)**	(3,245)	**(51,748)**
CASH FLOWS FROM FINANCING ACTIVITIES:			
Net decrease (increase) in treasury stock	**(3,523)**	(3,445)	**(31,739)**
Cash dividends paid	**(6,001)**	(6,085)	**(54,063)**
Net cash provided by (used in) financing activities	**(9,524)**	(9,530)	**(85,802)**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**5,860**	8,927	**52,793**
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	**52,694**	43,767	**474,721**
CASH AND CASH EQUIVALENTS AT END OF YEAR (Note 3)	**¥58,555**	¥52,694	**$527,523**

See accompanying Notes to the Consolidated Financial Statements.

Notes to the Consolidated Financial Statements

1. Basis of Presenting Consolidated Financial Statements

The accompanying consolidated financial statements of KAKEN PHARMACEUTICAL CO., LTD. (the "Company") and its consolidated subsidiary (collectively the "Group") are prepared on the basis of the accounting principles generally accepted in Japan, which are different in certain respects as to the application and disclosure requirements of International Financial Reporting Standards, and are compiled from the consolidated financial statements prepared by the Company as required by the Financial Instruments and Exchange Act of Japan.

In preparing these consolidated financial statements, certain reclassifications and rearrangements have been made to the consolidated financial statements issued domestically in order to present them in a form which is more familiar to readers outside Japan. In addition, certain reclassifications have been made to the 2018 financial statements to conform to the classifications used in 2019.

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 ¥111= U.S.$1.00, the approximate rate of exchange prevailing on March 31, 2019. This translation should not be construed as a representation that Japanese yen amounts have been, could have been, or could in the future be, converted into U.S. dollars at the above or any other rate.

2. Summary of Significant Accounting Policies

(a) Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its subsidiary. For the years ended March 31, 2019 and 2018, the Company had one consolidated subsidiary as follows:

KAKEN PHARMA CO., LTD.

For the years ended March 31, 2019 and 2018, there was no affiliate accounted for using the equity method.

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

(b) Cash and Cash Equivalents

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

(c) Marketable and Investment Securities

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

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

(e) Property, Plant and Equipment
Depreciation is computed using the straight-line method.
The range of useful lives is 3 to 60 years for buildings and structures, and 2 to 8 years for machinery, equipment and vehicles.

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

(g) Long-Term Prepaid Expenses
Depreciation is computed using the straight-line method.

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

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

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

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

(l) Retirement and Pension Plan
The Company applies the benefit formula basis as the attribution method for estimated retirement benefits.
Unrecognized prior service cost is amortized on a straight-line basis over a period within the average remaining years of service of the employees (10 years) from the year in which it arises. Unrecognized actuarial gain or loss is amortized on a straight-line basis over a period within the average remaining years of service of the employees (10 years) from the year following the year in which it arises.

(m) 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.

(n) Consumption Taxes

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

(o) Derivative Financial Instruments and Hedge Accounting

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

Forward foreign exchange contract:

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

Hedge accounting:

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

(1) Hedging instruments and hedged items

Hedging instrument:	Forward foreign exchange contract
Hedged items:	Foreign currency denominated receivables and payables, and forecasted foreign currency denominated transactions

(2) Hedging policy

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

(3) Method for assessment of hedge effectiveness

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

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

(p) 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.

(q) 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.

(r) 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.

(s) New Accounting Standards Not Yet Applied

"Accounting Standard for Revenue Recognition" (Accounting Standards Board of Japan ("ASBJ") Statement No. 29, issued on March 30, 2018)

"Implementation Guidance on Accounting Standard for Revenue Recognition" (ASBJ Guidance No. 30, issued on March 30, 2018)

(1) Overview

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

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

(2) Scheduled date of application

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

(3) Effect of applying the accounting standard and guidance

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

(t) Changes in Presentation

Changes due to application of "Partial Amendments to Accounting Standard for Tax Effect Accounting"

The Company applied "Partial Amendments to Accounting Standard for Tax Effect Accounting" (ASBJ Statement No. 28, issued on February 16, 2018) from the beginning of the year ended March 31, 2019, and accordingly, "Deferred tax assets" and "Deferred tax liabilities" are presented under "Investments and other assets" and "Non-current liabilities," respectively.

As a result, "Deferred tax assets" of ¥1,195 million previously presented under "Current assets" in the consolidated balance sheet as of March 31, 2018 is included in "Deferred tax assets" under "Investments and other assets" of ¥1,621 million.

Changes in presentation of the consolidated balance sheets:

"Long-term prepaid expenses," which was previously included in "Other assets" under "Investments and other assets" as of March 31, 2018, has been presented independently as of March 31, 2019 due to increased materiality. To reflect the changes in presentation, the consolidated balance sheet as of March 31, 2018 has been restated.

As a result, "Other assets" of ¥1,753 million under "Investments and other assets" in the consolidated balance sheet as of March 31, 2018 has been reclassified into "Long-term prepaid expenses" of ¥1,072 million and "Other assets" of ¥681 million.

Changes in presentation of the consolidated statements of income:
"Loss on cancellation of leases," which was previously included in "Other, net" under "Other income (expenses)" for the year ended March 31, 2018, has been presented independently for the year ended March 31, 2019 due to increased materiality. To reflect the changes in presentation, the consolidated statement of income for the year ended March 31, 2018 has been restated.

As a result, "Other, net" of ¥11 million under "Other income (expenses)" in the consolidated statement of income for the year ended March 31, 2018 has been reclassified into "Loss on cancellation of leases" of ¥4 million and "Other, net" of ¥6 million.

Changes in presentation of the consolidated statements of cash flows:
"Amortization of long-term prepaid expenses," which was previously included in "Other, net" under "Cash flows from operating activities" for the year ended March 31, 2018, has been presented independently for the year ended March 31, 2019 due to increased materiality. In addition, "Loss (gain) on sales of investment securities," which was previously presented independently under "Cash flows from operating activities" for the year ended March 31, 2018, has been included in "Other, net" for the year ended March 31, 2019 due to decreased materiality. To reflect these changes in presentation, the consolidated statement of cash flows for the year ended March 31, 2018 has been restated.

As a result, "Loss (gain) on sales of investment securities" of ¥3 million and "Other, net" of ¥1,827 million under "Cash flows from operating activities" in the consolidated statement of cash flows for the year ended March 31, 2018 have been reclassified into "Amortization of long-term prepaid expenses" of ¥76 million and "Other, net" of ¥1,754 million.

"Payments for long-term prepaid expenses," which was previously included in "Other, net" under "Cash flows from investing activities" for the year ended March 31, 2018, has been presented independently for the fiscal year ended March 31, 2019 due to increased materiality. In addition, "Proceeds from sales of investment securities," which was previously presented independently for the year ended March 31, 2018, has been included in "Other, net" for the year ended March 31, 2019 due to decreased materiality. To reflect these changes in presentation, the consolidated statement of cash flows for the year ended March 31, 2018 has been restated.

As a result, "Proceeds from sales of investment securities" of ¥1 million and "Other, net" of ¥(104) million under "Cash flows from investing activities" in the consolidated statement of cash flows for the year ended March 31, 2018 have been reclassified into "Payments for long-term prepaid expenses" of ¥(110) million and "Other, net" of ¥6 million.

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)
	2019	2018	**2019**
Cash and deposits	**¥46,956**	¥45,095	**$423,027**
Marketable securities	**11,599**	7,599	**104,495**
Subtotal	**¥58,555**	¥52,694	**$527,523**
Time deposits due after three months	**—**	—	**—**
Marketable securities due after three months	**—**	—	**—**
Cash and cash equivalents	**¥58,555**	¥52,694	**$527,523**

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)
	2019			2018		
Fair values exceeding carrying amounts	¥ —	¥ —	¥—	¥ —	¥ —	¥—
Fair values not exceeding carrying amounts	9,999	9,999	—	5,999	5,999	—
Total	¥9,999	¥9,999	¥—	¥5,999	¥5,999	¥—

THOUSANDS OF U.S. DOLLARS (NOTE 1)

	Carrying amount	Fair value	Unrealized gain (loss)
	2019		
Fair values exceeding carrying amounts	$ —	$ —	$—
Fair values not exceeding carrying amounts	90,081	90,081	—
Total	$90,081	$90,081	$—

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)
	2019			2018		
Carrying amounts exceeding acquisition costs						
Equity securities	¥16,547	¥ 9,990	¥6,557	¥17,535	¥ 9,487	¥8,047
Other	—	—	—	—	—	—
Subtotal	16,547	9,990	6,557	17,535	9,487	8,047
Carrying amounts not exceeding acquisition costs						
Equity securities	463	498	(35)	894	999	(104)
Other	1,600	1,600	—	1,600	1,600	—
Subtotal	2,063	2,098	(35)	2,494	2,599	(104)
Total	¥18,610	¥12,089	¥6,521	¥20,030	¥12,087	¥7,942

THOUSANDS OF U.S. DOLLARS (NOTE 1)

	Fair value	Acquisition cost	Unrealized gain (loss)
	2019		
Carrying amounts exceeding acquisition costs			
Equity securities	$149,072	$ 90,000	$59,072
Other	—	—	—
Subtotal	149,072	90,000	59,072
Carrying amounts not exceeding acquisition costs			
Equity securities	4,171	4,486	(315)
Other	14,414	14,414	—
Subtotal	18,586	18,901	(315)
Total	$167,658	$108,910	$58,748

Available-for-sale securities sold for the years ended March 31, 2019 and 2018 are summarized as follows:

	MILLIONS OF YEN					
	Proceeds	Gain	Loss	Proceeds	Gain	Loss
	2019			2018		
Equity securities	¥0	¥0	¥—	¥1	¥—	¥3
Total	¥0	¥0	¥—	¥1	¥—	¥3

	THOUSANDS OF U.S. DOLLARS (NOTE 1)		
	Proceeds	Gain	Loss
	2019		
Equity securities	$0	$0	$—
Total	$0	$0	$—

5. Inventories

Inventories as of March 31, 2019 and 2018, comprised the following:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	2019
Merchandise and finished products	¥ 6,113	¥ 7,178	$ 55,072
Work in process	2,647	3,986	23,847
Raw materials and supplies	4,959	5,487	44,676
Total	¥13,721	¥16,651	$123,613

6. Short-term Bank Loans and Pledged Assets

(a) Short-term bank loans

Short-term bank loans outstanding as of March 31, 2019 and 2018, amounting to ¥3,875 million ($34,910 thousand) and ¥3,875 million, respectively, consisted mainly of bank overdrafts. The weighted-average interest rates applicable to short-term bank loans as of March 31, 2019 and 2018 were 0.45%.

(b) Pledged assets

As of March 31, 2019 and 2018, assets pledged as collateral for certain short-term bank loans are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	2019
Assets pledged:			
Buildings and structures	¥ 6,311	¥5,805	$56,856
Machinery, equipment and vehicles	3,084	3,115	27,784
Tools, furniture and fixtures	785	505	7,072
Land	117	117	1,054
Total	¥10,298	¥9,544	$92,775
Liabilities secured:			
Short-term bank loans	¥ 1,400	¥1,400	$12,613
Total	¥ 1,400	¥1,400	$12,613

7. Accounting for Leases

Operating leases

(As a lessor)

Future minimum lease payments receivable under non-cancellable operating leases subsequent to March 31, 2019 and 2018, are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	2019
Due within 1 year	¥ 966	¥ 940	$ 8,703
Due after 1 year	6,952	7,919	62,631
Total	¥7,919	¥8,859	$71,342

8. Investment Properties

The Company owns rental office buildings (including land) mainly in Tokyo and other areas. Operating profit from these rental properties for the years ended March 31, 2019 and 2018 was ¥1,476 million ($13,297 thousand) and ¥1,655 million (Revenue from rental properties and related expenses are reported as net sales and cost of sales), respectively.

Carrying amount, changes during the years ended March 31, 2019 and 2018, and fair value of these properties as of those dates are stated as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	2019
Carrying amount:			
Balance at the beginning of the year	¥10,752	¥11,018	$ 96,865
Changes during the year	(261)	(265)	(2,351)
Balance at the end of the year	10,490	10,752	94,505
Fair value at the end of the year	¥46,234	¥43,722	$416,523

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 based primarily on the "Real estate appraisal standards of Japan."

9. Financial Instruments

(a) Outline of financial instruments

(1) Policy for using financial instruments

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

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

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

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

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

(3) Risk management for financial instruments

a. Credit risk management (customers' default risk)

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

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

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

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

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

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

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

c. Liquidity risk management on fund-raising

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

(4) Supplementary explanation concerning fair values of financial instruments

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

(5) Concentration of credit risks

As of March 31, 2019, 61% of all trade receivables was with specific major accounts.

(b) Fair values of financial instruments

Carrying amount, fair value, and difference of the financial instruments as of March 31, 2019 and 2018 are as follows. Financial instruments whose fair values are extremely difficult to determine are excluded from the following table:

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

	MILLIONS OF YEN		
	Carrying amount	Fair value	Difference
	2018		
(1) Cash and deposits	¥ 45,095	¥ 45,095	¥—
(2) Notes and accounts receivable–trade	33,315	33,315	—
(3) Marketable and investment securities			
a. Held-to-maturity debt securities	5,999	5,999	—
b. Available-for-sale securities	20,030	20,030	—
Total assets	¥104,440	¥104,440	¥—
(1) Notes and accounts payable–trade	¥ 12,204	¥ 12,204	¥—
(2) Electronically recorded obligations–operating	1,248	1,248	—
(3) Short-term bank loans	3,875	3,875	—
Total liabilities	¥ 17,327	¥ 17,327	¥—

	THOUSANDS OF U.S. DOLLARS (NOTE 1)		
	Carrying amount	Fair value	Difference
	2019		
(1) Cash and deposits	$423,027	$423,027	$—
(2) Notes and accounts receivable–trade	273,333		—
Allowance for doubtful accounts*	(0)		
	273,333	273,333	
(3) Marketable and investment securities			
a. Held-to-maturity debt securities	90,081	90,081	—
b. Available-for-sale securities	167,658	167,658	—
Total assets	$954,108	$954,108	$—
(1) Notes and accounts payable–trade	$96,658	$96,658	$—
(2) Electronically recorded obligations–operating	13,775	13,775	—
(3) Short-term bank loans	34,910	34,910	—
Total liabilities	$145,351	$145,351	$—

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

Note:
1. Calculation method of fair values of financial instruments and securities
Assets:
(1) Cash and deposits and (2) Notes and accounts receivable–trade
The carrying amounts of these financial instruments approximate fair values due to their short-term maturities.

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

Liabilities:
(1) Notes and accounts payable–trade, (2) Electronically recorded obligations–operating and (3) Short-term bank loans
The carrying amounts of these financial instruments approximate fair values due to their short-term maturities.

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

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	Carrying amount		
	2019	2018	**2019**
Unlisted equity securities	**¥57**	¥57	**$514**

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

3. Redemption schedules of monetary assets and securities with contractual maturities subsequent to March 31, 2019 and 2018, are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	Within one year		
	2019	2018	**2019**
Cash and deposits	**¥46,956**	¥45,095	**$423,027**
Notes and accounts receivable–trade	**30,340**	33,315	**273,333**
Marketable and investment securities:			
Held-to-maturity debt securities	**9,999**	5,999	**90,081**
Available-for-sale securities with contractual maturities	**1,600**	1,600	**14,414**
Total	**¥88,895**	¥86,010	**$800,856**

4. Redemption schedules for long-term debt and other interest-bearing obligations subsequent to March 31, 2019 and 2018 are omitted since the Company only had short-term bank loans maturing within one year as of March 31, 2019 and 2018.

10. Retirement Benefits

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

Defined benefit plans

(a) Changes in the retirement benefit obligation for the years ended March 31, 2019 and 2018 are as follows (excluding plans applying the simplified method):

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	2019
Retirement benefit obligation–Beginning balance	¥20,549	¥21,173	$185,126
Service cost	750	758	6,757
Interest cost	61	63	550
Actuarial gain or loss	10	26	90
Retirement benefit paid	(1,424)	(1,472)	(12,829)
Retirement benefit obligation–Ending balance	¥19,946	¥20,549	$179,694

(b) Changes in the plan assets for the years ended March 31, 2019 and 2018 are as follows (excluding plans applying the simplified method):

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	2019
Plan assets–Beginning balance	¥13,769	¥13,151	$124,045
Expected return on plan assets	322	307	2,901
Actuarial gain or loss	(378)	555	(3,405)
Employer's contributions	474	581	4,270
Retirement benefit paid	(875)	(827)	(7,883)
Plan assets–Ending balance	¥13,312	¥13,769	$119,928

(c) Changes in the net defined benefit liability applying the simplified method for the years ended March 31, 2019 and 2018 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	2019
Net defined benefit liability–Beginning balance	¥7	¥7	$63
Retirement benefit cost	0	0	0
Net defined benefit liability–Ending balance	¥7	¥7	$63

(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)
	2019	2018	2019
Retirement benefit obligation under funded plan	¥ 19,946	¥ 20,549	$ 179,694
Plan assets	(13,312)	(13,769)	(119,928)
	6,634	6,779	59,766
Retirement benefit obligation under unfunded plan	7	7	63
Net liability recorded on the consolidated balance sheets	6,642	6,787	59,838
Net defined benefit liability	6,642	6,787	59,838
Net liability recorded on the consolidated balance sheets	¥ 6,642	¥ 6,787	$ 59,838

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

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

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	2019
Service cost	¥ 750	¥ 758	$ 6,757
Interest cost	61	63	550
Expected return on plan assets	(322)	(307)	(2,901)
Amortization of actuarial gain or loss	411	675	3,703
Amortization of prior service cost	(33)	(33)	(297)
Net periodic pension cost under simplified method	0	0	0
Net periodic pension cost for defined benefit plans	¥ 868	¥1,156	$ 7,820

(f) The components of remeasurements of defined benefit plans in other comprehensive income (before tax effect) for the years ended March 31, 2019 and 2018 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	2019
Prior service cost	¥(33)	¥ (33)	$(297)
Actuarial gain or loss	23	1,205	207
Total	¥ (9)	¥1,171	$ (81)

(g) The components of remeasurements of defined benefit plans in accumulated other comprehensive income (before tax effect) for the years ended March 31, 2019 and 2018 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	2019
Unrecognized prior service cost	¥ (72)	¥ (105)	$ (649)
Unrecognized actuarial gain or loss	1,412	1,436	12,721
Total	¥1,340	¥1,330	$12,072

(h) Plan assets

(1)Plan assets consist of the following:

	2019	2018
Debt securities	45%	31%
Equity securities	36	50
General account	15	15
Other	4	4
Total	100%	100%

Note: The plan assets include retirement benefit trust which accounted for 5% and 6% of the total plan assets as of March 31, 2019 and 2018, 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):

	2019	2018
Discount rate	0.3%	0.3%
Long-term expected rate of return	2.5%	2.5%

11. Shareholders' Equity

(a) Class and number of shares outstanding and treasury stock

	Class of shares outstanding	Class of treasury stock
	Common stock	Common stock
Number of shares as of April 1, 2018	48,439,730	8,120,458
Increase	—	601,310
Decrease	—	—
Number of shares as of March 31, 2019	48,439,730	8,721,768

Note: Increase in treasury stock (601,310 shares) is due to purchase of shares through the market (600,000 shares) based on the resolution of the Board of Directors' meeting and purchase of shares of less than one unit (1,310 shares).

(b) Matters related to dividends

(1) Dividend payment

Approval by the ordinary general meeting of shareholders held on June 28, 2018, was as follows:

Dividends on common stock

Total amount of dividends	¥3,023 million ($27,234 thousand)
Dividends per share	¥75.00 ($0.68)
Record date	March 31, 2018
Effective date	June 29, 2018

Approval by the Board of Directors' meeting held on November 6, 2018, was as follows:

Dividends on common stock

Total amount of dividends	¥2,978 million ($26,829 thousand)
Dividends per share	¥75.00 ($0.68)
Record date	September 30, 2018
Effective date	November 30, 2018

(2) Dividends whose record date is attributed to the year ended March 31, 2019, but become effective after March 31, 2019

The Company obtained the following approval at the ordinary general meeting of shareholders held on June 27, 2019:

Dividends on common stock

Total amount of dividends	¥2,978 million ($26,829 thousand)
Dividends per share	¥75.00 ($0.68)
Record date	March 31, 2019
Effective date	June 28, 2019

12. Research and Development Costs

Research and development costs included in cost of sales and selling, general and administrative expenses for the years ended March 31, 2019 and 2018 amounted to ¥10,261 million ($92,441 thousand) and ¥8,152 million, respectively.

13. Loss on Retirement of Non-Current Assets

Loss on retirement of non-current assets for the years ended March 31, 2019 and 2018 consists of the followings:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	**2019**
Buildings and structures	**¥ 4**	¥ 15	**$ 36**
Machinery, equipment and vehicles	**18**	5	**162**
Other	**21**	144	**189**
Total	**¥44**	¥165	**$396**

14. Income Taxes

Significant components of deferred tax assets and liabilities as of March 31, 2019 and 2018 are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	**2019**
Deferred tax assets:			
Accounts receivable–trade	**¥ 54**	¥ 44	**$ 486**
Disallowed expensed supplies	**275**	238	**2,477**
Adjustment of gain on sales of land	**2,638**	2,638	**23,766**
Amortization of research & development expenses	**531**	202	**4,784**
Amortization of long-term prepaid expenses	**1,298**	645	**11,694**
Provision for bonuses	**354**	382	**3,189**
Provision for sales rebates	**96**	99	**865**
Net defined benefit liability	**1,783**	2,234	**16,063**
Other	**842**	517	**7,586**
Total	**7,875**	7,004	**70,946**
Valuation allowance	**(2,819)**	(2,819)	**(25,396)**
Deferred tax assets	**5,056**	4,185	**45,550**
Deferred tax liabilities:			
Reserve for tax purpose reduction entry of non-current assets	**(125)**	(131)	**(1,126)**
Net unrealized holding gain on securities	**(1,996)**	(2,432)	**(17,982)**
Deferred tax liabilities	**(2,121)**	(2,563)	**(19,108)**
Deferred tax assets, net	**¥ 2,934**	¥ 1,621	**$ 26,432**

The Group is subject to several taxes based on income, which in the aggregate resulted in statutory tax rates of approximately 30.62% and 30.86% for the years ended March 31, 2019 and 2018, respectively. Reconciliation of the differences between the statutory tax rate and the effective tax rate for the years ended March 31, 2019 and 2018, is as follows:

	2019	2018
Statutory tax rate	**30.62%**	30.86%
Increase (decrease) in taxes resulting from:		
Expenses not deductible for income tax purpose (e.g. entertainment expenses)	**0.34**	0.43
Income not included for income tax purpose (e.g. dividend income)	**(0.09)**	(0.07)
Inhabitant per capita taxes	**0.34**	0.31
Tax credit for research expenses	**(1.92)**	(1.41)
Increase (decrease) in valuation allowance	**—**	0.57
Other	**(0.61)**	0.53
Effective tax rate	**28.68%**	31.22%

15. Related Party Transactions

There are no related party transactions to be disclosed for the years ended March 31, 2019 and 2018.

16. Per Share Information

Per share information as of March 31, 2019 and 2018 and for the years then ended, is as follows:

	YEN		U.S. DOLLARS (NOTE 1)
	2019	2018	**2019**
Net assets per share	**¥3,049.78**	¥2,824.32	**$27.48**
Profit per share	**445.78**	470.54	**4.02**

Note: Diluted Profit per share is not presented due to the absence of dilutive shares.

The basis of calculation for Profit per share for the years ended March 31, 2019 and 2018 is as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	**2019**
Profit	**¥17,775**	¥19,043	**$160,135**
Profit attributable to common stock owners of parent	**17,775**	19,043	**160,135**
Profit not attributable to common stock	**—**	—	**—**
(Number of shares)			
Weighted average number of shares (thousands of shares)	**39,874**	40,470	

17. Comprehensive Income

Reclassification adjustments and income tax effects for each component of other comprehensive income for the years ended March 31, 2019 and 2018, are as follows:

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)
	2019	2018	**2019**
Net unrealized holding gain (loss) on securities:			
Increase (decrease) during the year	**¥(1,421)**	¥1,295	**$(12,802)**
Reclassification adjustments	**(0)**	—	**(0)**
Before income tax effect	**(1,421)**	1,295	**(12,802)**
Income tax effect	**435**	(396)	**3,919**
Net unrealized holding gain (loss) on securities	**¥ (985)**	¥ 898	**$ (8,874)**
Remeasurements of defined benefit plans:			
Increase (decrease) during the year	**¥ (388)**	¥ 529	**$ (3,495)**
Reclassification adjustments	**378**	642	**3,405**
Before income tax effect	**(9)**	1,171	**(81)**
Income tax effect	**3**	(360)	**27**
Remeasurements of defined benefit plans	**¥ (6)**	¥ 811	**$ (54)**
Total other comprehensive income	**¥ (992)**	¥1,710	**$ (8,937)**

18. Segment Information

(a) Overview of reportable segments

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

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

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

"Real estate" mainly rents out Bunkyo Green Court.

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

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

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

(c) Information about reportable segments

MILLIONS OF YEN

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

MILLIONS OF YEN

	Reportable Segment				
	Pharmaceuticals	Real estate	Total	Adjustments	Consolidated
			2018		
Net sales:					
Sales to external customers	¥96,022	¥ 2,407	¥98,430	¥ —	¥ 98,430
Intersegment sales or transfers	—	—	—	—	—
Total	¥96,022	¥ 2,407	¥98,430	¥ —	¥ 98,430
Segment profit	¥25,840	¥ 1,655	¥27,496	¥ —	¥ 27,496
Segment assets	¥85,397	¥10,554	¥95,952	¥56,464	¥152,417
Other items:					
Depreciation and amortization	¥ 1,896	¥ 303	¥ 2,200	¥ —	¥ 2,200
Increase in property, plant and equipment and intangible assets	2,931	41	2,972	—	2,972

THOUSANDS OF U.S. DOLLARS

	Reportable Segment				
	Pharmaceuticals	Real estate	Total	Adjustments	Consolidated
	2019				
Net sales:					
Sales to external customers	$827,063	$21,261	$848,333	$ —	$ 848,333
Intersegment sales or transfers	—	—	—	—	—
Total	$827,063	$21,261	$848,333	$ —	$ 848,333
Segment profit	$208,252	$13,297	$221,550	$ —	$ 221,550
Segment assets	$737,910	$92,586	$830,505	$574,766	$1,405,270
Other items:					
Depreciation and amortization	$ 20,739	$ 2,676	$ 23,423	$ —	$23,423
Increase in property, plant and equipment and intangible assets	57,703	171	57,874	—	57,874

The adjustments to segment assets of ¥63,799 million ($574,766 thousand) and ¥56,464 million as of March 31, 2019 and 2018, respectively, represent corporate assets which are not allocated to each reportable segment. The amounts mainly consist of surplus funds which do not belong to reportable segments.

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

(d) Information on products and services

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

(e) Information by geographical area

(1) Sales

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

(2) Property, plant and equipment

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

(f) Information about major customers

	MILLIONS OF YEN		THOUSANDS OF U.S. DOLLARS (NOTE 1)	
	Net sales			Name of the related segment
	2019	2018	2019	
Alfresa Corporation	¥17,007	¥17,069	$153,216	Pharmaceuticals
SUZUKEN CO., LTD.	14,397	15,779	129,703	Pharmaceuticals
MEDICEO CORPORATION	13,018	14,573	117,279	Pharmaceuticals

19. Subsequent Event

1. Acquisition of treasury stock

Based on the provisions of Article 156 of the Companies Act of Japan (the "Act") applied by replacing the terms and phrases pursuant to the provisions of Article 165 (3) of the Act, the Company resolved to acquire treasury stock at the Board of Directors' meeting held on May 9, 2019.

(a) Reason for acquisition:
To execute flexible capital policy corresponding to changes in management environment.

(b) Class of stock to be acquired:
Common stock

(c) Number of stock to be acquired:
Up to 800,000 shares

(d) Total amount of stock to be acquired:
Up to ¥4,500 million ($40,541 thousand)

(e) Schedule for acquisition:
From May 10, 2019 to December 27, 2019

(f) Method of acquisition:
Purchase on the Tokyo Stock Exchange
Based on the aforementioned resolution, the Company acquired 125,700 shares of its common stock in a total amount of ¥645 million ($5,811 thousand) through May 31, 2019.

2. Retirement of treasury stock

Pursuant to the provision of Article 178 of the Act, the Company resolved to retire a portion of treasury stock at the Board of Directors' meeting held on May 9, 2019 and the retirement was implemented on May 31, 2019 as resolved.

(a) Reason for retirement:
To execute flexible capital policy corresponding to changes in management environment.

(b) Class of stock to be retired:
Common stock

(c) Number of stock to be retired:
2,500,000 shares

(d) Number of outstanding shares after retirement:
45,939,730 shares

(e) Date of retirement:
May 31, 2019

Report of Independent Auditors

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

We have audited the accompanying consolidated financial statements of KAKEN PHARMACEUTICAL CO., LTD. (the "Company") and subsidiary, which comprise the consolidated balance sheet as of March 31, 2019, and the related consolidated statements of income, comprehensive income, changes in net assets, and cash flows for the year then ended, and a summary of significant accounting policies and other explanatory information, all expressed in Japanese yen.

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

Auditor's Responsibility
Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in Japan. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. The purpose of an audit of the consolidated financial statements is not to express an opinion on the effectiveness of the entity's internal control, but in making these risk assessments the auditor considers internal controls relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion
In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company and subsidiary at March 31, 2019, and the consolidated results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in Japan.

Emphasis of Matter
As described in Note 19, at a meeting of the Board of Directors of the Company held on May 9, 2019, the Company approved the acquisition of treasury stock and the retirement of treasury stock.
Our opinion is not qualified in respect of this matter.

Convenience Translation
The amounts expressed in U.S. dollars, which are provided solely for the convenience of the reader have been translated on the basis set forth in Note 1 to the accompanying consolidated financial statements.

Ark Meiji Audit & Co.

ARK MEIJI AUDIT & Co.
Tokyo, Japan
June 27, 2019

Corporate Data and Stock Information

As of March 31, 2019

Company Information

Company Name	KAKEN PHARMACEUTICAL CO., LTD.
Paid-in Capital	¥23,853 million
Incorporated	March 1, 1948
Main Businesses	Production and marketing of pharmaceuticals, quasi-pharmaceutical products, medical devices, drugs for animals, agrochemicals and feed additives, and rental of real estate holdings
Number of Employees	1,341 (consolidated)

Main Offices (as of April 1, 2019)

Head Office	28-8, Honkomagome 2-chome, Bunkyo-ku, Tokyo
Branches	Kitanihon Branch (Sendai City, Miyagi) Kanto Branch I (Toshima-ku, Tokyo) Kanto Branch II (Toshima-ku, Tokyo) Kanto-Koshinetsu Branch (Toshima-ku, Tokyo) Chubu Branch (Nagoya City, Aichi) Kansai Branch (Osaka City, Osaka) Chugoku and Shikoku Branch (Hiroshima City, Hiroshima) Kyushu Branch (Fukuoka City, Fukuoka)
Sales Offices	45 locations across Japan
Drug Research Centers	Kyoto City, Kyoto; Fujieda City, Shizuoka
CMC Center	Fujieda City, Shizuoka
Factory	Fujieda City, Shizuoka




Head Office (Tokyo)

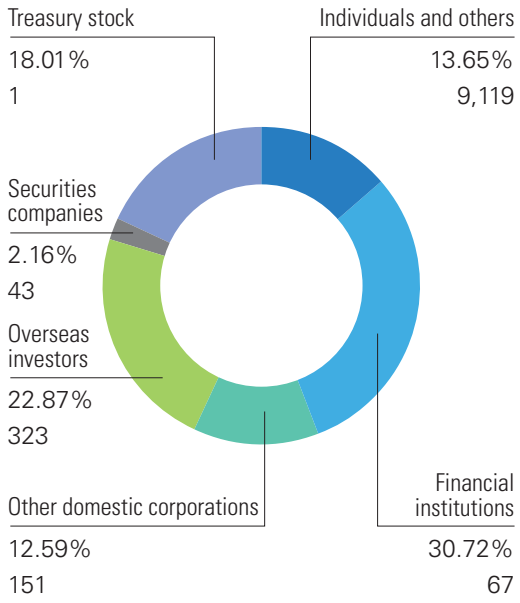

Drug Research Center (Kyoto)


Shizuoka Factory

Stock Information

Authorized:	193,000,000 shares
Issued:	48,439,730 shares
Number of Shareholders:	9,704
Stock Exchange Listing:	Tokyo Stock Exchange
Securities Code:	4521
Shareholder Register Administrator:	Sumitomo Mitsui Trust Bank, Limited

Breakdown by Shareholder Type



Major Shareholders (top 10)

Shareholders	Number of shares (thousands)	Shareholding ratio (%)
The Master Trust Bank of Japan, Ltd. (Trust Account)	2,594	6.53
Toray Industries, Inc.	2,294	5.78
The Norinchukin Bank	1,843	4.64
Japan Trustee Services Bank, Ltd. (Trust Account)	1,692	4.26
Mizuho Bank, Ltd.	1,474	3.71
BNP PARIBAS SECURITIES SERVICES LUXEMBOURG/JASDEC SECURITIES/ UCITS ASSETS	953	2.40
KYORIN Pharmaceutical Co., Ltd.	852	2.15
Japan Trustee Services Bank, Ltd. (Trust Account 5)	707	1.78
Nippon Life Insurance Company	680	1.71
KAKEN Employees' Shareholding Association	587	1.48

(Note) The shareholding ratios are calculated by subtracting the number of treasury stock (8,721,768 shares) from the total number of shares issued.

Information on the "Investor Relations" available on the Company's website

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

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





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