

## CORPORATE REPORT 2018

## **E** KAKEN PHARMACEUTICAL CO., LTD.

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







## Bringing Smiles to Everyone

MAKEN 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**

## "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"

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). The contents of the Annual Reports (English version) and the Environmental and Social Reports that have been published separately until 2017 are integrated in this Report. Reporting Period: From April 1, 2017 to March 31, 2018



In 1948, KAKEN was founded through the reorganization of the Institute of Physical and Chemical Research (Riken) into a stock company. Since then, the Company has delivered a large number of prescription drugs including in-house developed and in-licensed products for over 70 years. We are proud to say that our efforts have supported clinical fields through supplying superior pharmaceuticals such as Artz, an anti-osteoarthritis drug, Mentax, an anti-trichophyton product, Fiblast Spray, a wound-healing product, and more recently, Clenafin, a topical treatment for onychomycosis and Regroth, a medicinal product for periodontal regeneration. In turn, we have contributed to improving patients' quality of life.

With the aim of achieving in-house drug discovery that is competitive worldwide, and from the standpoint of broadly providing pharmaceuticals sought after by more patients, the Company has been focusing not only on making active investment in research and development and human resource development, but also joint research through collaboration with external parties and global sales of products by out-licensing to overseas companies. Amid the increasingly harsh environment for the domestic pharmaceuticals industry, the management issue ahead for the Company will be to further improve efficiency and speed up operations, building a system that ensures the creation and sales of pharmaceuticals, for which high efficacy and demand are expected.

On top of this, the Company intends to maintain a robust corporate governance system, secure sound and sustainable business growth and expand its corporate value, so as to meet the expectations of our stakeholders and continue to thrive as a pharmaceutical company essential to society.

This "Corporate Report" is published to provide detailed introduction of such challenges we are taking on 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.

## 1948-2000









1948 Started manufacturing Penicillin KAKEN

**1953** Athletan, an anti-trichophyton product, was launched

**1987**Artz, an anti-osteoarthritis drug, was launched

1998
Seprafilm, an absorbable adhesion barrier, was launched

| 1948 | The Institute of Physical and Chemical Research |
|------|---|
|      | reorganized into a stock company Kagaku-        |
|      | Kenkyusho (first president, Yoshio Nishina)     |
|      | Penicillin KAKEN was launched                   |

1950 Streptomycin KAKEN was launched

**1952** Kagaku-Kenkyusho was renamed Kaken Chemicals

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

**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

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

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

**1988** Kaken Pharma Co., Ltd. was established Adofeed (pain- and inflammation-relieving plaster) was launched

**1989** Ebrantil (α1 blocker to treat dysuria and hypertension) was launched

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

**1992** Procylin (oral-use prostaglandin  $I_2$  analog) was launched

Mentax (anti-trichophyton product) was launched

1998 Bunkyo Green Court was completed
Moved the head office to the center office
Seprafilm (absorbable adhesion barrier) was
launched

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

## 2001-2018









2001 Fiblast Spray, a wound-

healing product, was

2011 Lipidil Tablet, an antihyperlipidemia product, was 2014 Clenafin, a topical onychomycosis treatment product, was launched

2016 Regroth, a medicinal product for periodontal regeneration, was launched

2001 ISO14001 certification obtained at the Shizuoka

Fiblast Spray (wound-healing product) was launched

- 2002 Mentax (anti-trichophyton product) was launched as an over-the-counter (OTC) drug in the United States
- 2005 GHRP KAKEN 100 Injection (diagnostic agent for growth hormone deficiency) was launched Concluded a license agreement regarding worldwide rights for bFGF
- 2006 Antifungal compound KP-103 was out-licensed for Europe and the United States
- 2007 Berasus LA Tablet 60µg (pulmonary arterial hypertension treatment product) was launched
- 2010 Clexane Subcutaneous Injection Kit 2000 IU (anticoagulant product) was launched
- 2011 Lipidil Tablet (anti-hyperlipidemia product) was launched
- 2012 Exclusive distribution rights were acquired for SI-6603 (lumbar disc herniation treatment product) in the Japanese market

- 2014 Clenafin (topical onychomycosis treatment product) was launched
- 2015 Exclusive rights were acquired for development, manufacture, and distribution of BBI-4000 (primary focal 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

Regroth (medicinal product for periodontal regeneration) was launched

- 2017 Launched collaborative research with Numab Therapeutics AG to develop a new antibody
- Clenafin (topical onychomycosis treatment product) was out-licensed for Taiwan 2018 KP-470, a new compound for psoriasis, was
  - out-licensed Hernicore (lumbar disc herniation treatment product) was launched

### **KAKEN's Business**



## Pharmaceuticals Segment



KAKEN specializes in the fields of orthopedics, dermatology, and surgery. In the orthopedics field, we supply Artz, an anti-osteoarthritis drug, as well as various transdermal absorption-type anti-inflammatory analgesic patches. In dermatology, we offer Clenafin, a topical treatment for onychomycosis, and Fiblast Spray, a wound-healing drug, which are widely used for the treatment of targeted diseases.

In research and development, KAKEN focuses on themes in which it can effectively utilize its experience, technologies, and foundations, namely inflammation and allergies, fungal infection, pain relief, and the perioperative period. Efinaconazole, a compound discovered by the Company, was launched in 2014 as Clenafin, Japan's first topical treatment for onychomycosis.



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.

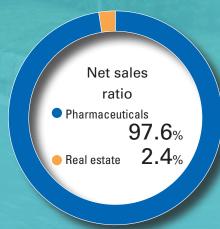
As for feed additives and drugs for animals, the Company sells Salinomycin, an anticoccidial antibiotic for chickens, and Uroston, a drug for cattle, among other drugs.



## 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.







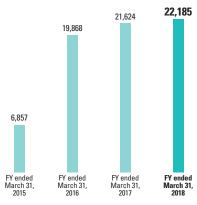
## Pharmaceuticals Segment | Overview of Major Products

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

#### Clenafin [topical onychomycosis treatment product]

Sales (Millions of yen)



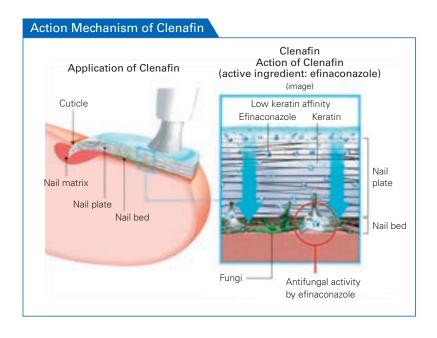


\*Launched in September 2014.

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.



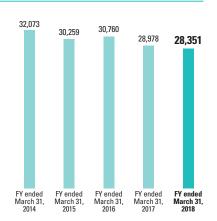
Outside Japan, Clenafin is marketed by licensee companies in respective regions. It has been marketed under the trade name Jublia by Bausch Health Companies Inc. in Canada since 2014, and by Dong-A ST Co., Ltd. in South Korea since 2017. In Taiwan, it was licensed out to Tai Tien Pharmaceuticals Co., Ltd., a subsidiary of Mitsubishi Tanabe Pharma Corporation, in 2017; Tai Tien Pharmaceuticals gained marketing approval from Taiwan FDA in 2018 and is preparing to launch the drug under the trade name Jublia.

#### Artz [anti-osteoarthritis product]

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





Sales (Millions of yen)

adhesion, improvement of lubrication, suppression of synovial membrane inflammation, and improvement in properties of pathological synovial fluid. Possessing such efficacy, Artz was introduced into the market in 1987 as the world's first hyaluronic drug indicated to treat osteoarthritis in the knee by intra-articular injection. Later in 1989, an indication for shoulder periarthritis was added. In 2005, an indication for knee joint pain in rheumatoid arthritis was added.

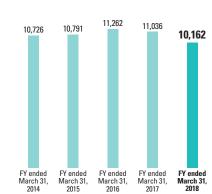
In 1992, Artz Dispo, a kit product with disposable pre-filled syringe, was launched mainly to make injection procedures simpler and faster as well as to reduce the infection risk. Since then, its formulation has been improved to meet various needs.

### Seprafilm [absorbable adhesion barrier]

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

Seprafilm transforms into a hydrated gel within 24 to 48 hours after being applied to tissue that has been damaged by surgery. It





Sales (Millions of yen)

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. With its high adhesion to 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.

There are four types of Seprafilm available, thus allowing practitioners to select one depending on usage.

#### Pharmaceuticals Segment | Overview of Major Products

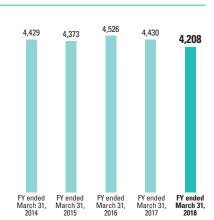
#### Lipidil [anti-hyperlipemia product]

Containing fenofibrate as the active ingredient, Lipidil is a fibrate-type antihyperlipidemic drug developed by Groupe Fournier SA of France (presently Mylan N.V. Group).

The drug improves overall lipid metabolism by activating peroxisome proliferator activated receptor  $\alpha$  (PPAR $\alpha$ ), a nuclear receptor in the liver cells, to adjust the expression of various lipid metabolism-related proteins.

Lipidil is marketed in over 90 countries. In

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Sales (Millions of yen)

Japan, Grelan Pharmaceutical Co., Ltd. (presently ASKA Pharmaceutical Co., Ltd.) began developing a capsular formulation in 1989, and it was successfully launched by KAKEN and Grelan Pharmaceutical Co., Ltd. (presently ASKA Pharmaceutical Co., Ltd.) in 1999. Leveraging its proprietary pharmaceutical formulation technology, ASKA Pharmaceutical Co., Ltd. developed a Japanese original tablet formulation, which had increased absorbability and was smaller in size compared to Lipidils marketed overseas. This formulation has been marketed by KAKEN and ASKA Pharmaceutical Co., Ltd. since 2011.

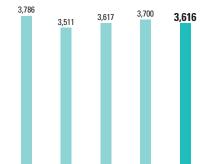
#### Fiblast [wound-healing product]

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

the migration and proliferation of various cells mediating wound repair.





Sales (Millions of yen)

in 1986. As recombinant bFGF became available, dramatic advances in basic and clinical application research demonstrated that bFGF promotes

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.

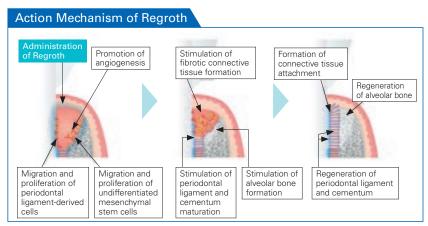
#### Regroth [medicinal product for periodontal regeneration]

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.



#### 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 water-retaining 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.

## 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.



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 as well as evaluates their pharmacological effects,

pharmacokinetics, and toxicity in animals. The CMC Center studies 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.

#### **R&D** Division



R&D



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) or 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.





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 is currently under construction 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.

#### **Production Division**



### Marketing & Sales Division

Medical representatives (MRs) provide medical professionals such as doctors and pharmacists with proper usage information, the latest scientific information, etc., related to the products in order to ensure that the prescription drugs and medical devices sold by the Company are properly used. 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. To effectively communicate with medical professionals, MRs need to have not only knowledge of the products themselves, but also highly-technical knowledge of relevant scientific information, information on the medical system, etc. For this reason, each and every one of the MRs devotes themselves to acquiring new knowledge on a daily basis with the support of the Science Department.

In FY2017, the Company introduced a system to support sales activities and reorganized the sales organization. Through these

initiatives and more, the Company works to improve the quality and speed of its information provision. The Company is committed to undertaking higher-quality information provision activities so as to gain an even stronger presence in the fields of orthopedics, dermatology, surgery, etc., where its mainstay products are promoted, and become a company essential for community medicine.





## 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 develop new pharmaceuticals on a continuous basis, based on its technologies accumulated over many years and an 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 be best utilized: namely, inflammation and allergies, fungal infection, pain relief, and perioperative period fields. At present, we have approximately 250 research and development staff. Research and development expenses in FY2017 amounted to ¥8.2 billion, and ¥11.7 billion is planned to be invested in FY2018. Aiming to expand the R&D pipeline, the Company engages in efficient research and development by leveraging on its collaborations with other 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 is taking on the challenge of entering new research fields 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.

As a result of the drug discovery research efforts it had mounted, the Company received numerous awards, as shown below, in recognition of its high level of fundamental technologies.

#### 2009

## Asahi Kasei Encouraging Award from the Academy of Pharmaceutical Science and Technology, Japan

Received for the development of Itraconazole products by utilizing novel technology

#### 2011

## Prize for the Outstanding Pharmaceutical Science Thesis from the Academy of Pharmaceutical Science and Technology, Japan

Received for formulation design of Latanoprost eye drops

#### Status of development themes (as of the end of July 2018)

| Development | Indication                           | Development stage |          |           |             |          |
|-------------|--------------------------------------|-------------------|----------|-----------|-------------|----------|
| code        | Indication                           | Phase I           | Phase II | Phase III | Application | Approval |
| BBI-4000    | Primary focal<br>hyperhidrosis       | Phase III         |          |           |             |          |
| KMW-1       | Removal of eschar with thermal burns | Phase III         |          |           |             |          |
| KAG-308     | Ulcerative colitis                   | Phase II          |          |           |             |          |
| KP-607      | Onychomycosis                        | Phase I           |          |           |             |          |



#### 2012

#### Best Presentation Award at Annual Meeting of Academy of Pharmaceutical Science and Technology, Japan

Received for research of in vitro-in vivo correlation of percutaneous drug absorption

The Company is promoting its drug discovery research efforts by leveraging such superior research technologies. The Company also strives to introduce state-of-the-art technologies and knowledge by dispatching researchers to research institutions in Japan and overseas.

In FY2017, BBI-4000 (indication: primary focal hyperhidrosis; in-licensed from Brickell Biotech, Inc. in the United States) and KMW-1 (indication: removal of eschar with thermal burns; inlicensed from MediWound Ltd. in Israel) in developmental stage progressed into Phase III. KP-607, which is a successor to Clenafin launched in 2014, a topical treatment for onychomycosis, also progressed into Phase I. 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 leading researchers 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 pipeline by seeking out candidate products for in-licensing, conducting out-licensing activities for candidate in-house products, and seeking out new technologies and "seeds" of new drugs 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 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.

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 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.

#### Major products under development

#### **BBI-4000**

An topical primary focal hyperhidrosis agent that is anticholinergic in the skin, where sweat glands are distributed, and will be promptly metabolized in blood. Therefore, it is expected to become an agent with fewer concerns for systemic side effects. On March 31, 2015, KAKEN obtained a license from Brickell Biotech, Inc. in the United States to exclusively develop, sell and manufacture the product in Japan and major Asian countries.

#### KMW-1

An topical enzymatic product that easily and promptly removes eschar with thermal burns in the early postburn period without damaging the normal tissue. On April 26, 2016, KAKEN obtained a license from MediWound Ltd. in Israel to exclusively develop and sell the product in Japan.

## Pharmaceuticals Segment | Agrochemical & Animal Health Products Division

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





#### **Business features**

At the Agrochemicals & Animal Health Products Division, 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. Since March 2018, two formulations have been marketed: TODOME MF granules and TODOME MF emulsion

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.



### 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

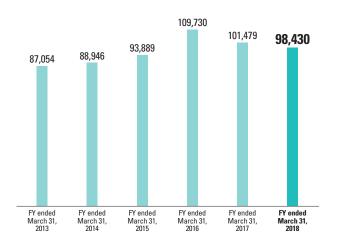
Uroston, an herbal medicine mainly consisting of extracts from naturally occurring *Quercus Salicina Blume*, serves to prevent and treat bovine urolithiasis. It promotes the dissolution of phosphate urinary calculus as well as prevents bovine urinary calculus and facilitates excretion through effects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



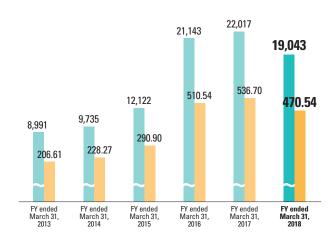
## Financial and Non-Financial Highlights

### Financial Highlights

Net sales (Millions of yen)



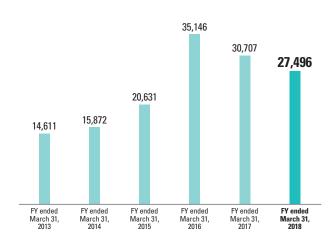
Profit attributable to Owners of Parent (Millions of yen)
Profit per share (Basic)(Yen)



ROE (%)

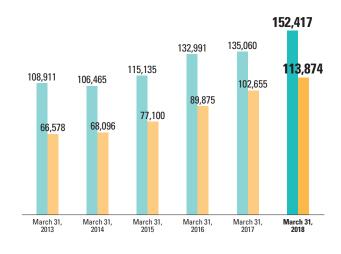


Operating profit (Millions of yen)

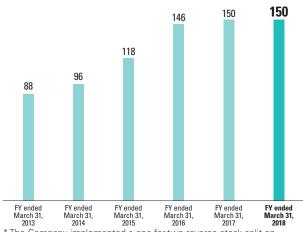


Total assets (Millions of yen)

Net assets (Millions of yen)



#### Dividends per share (Yen)

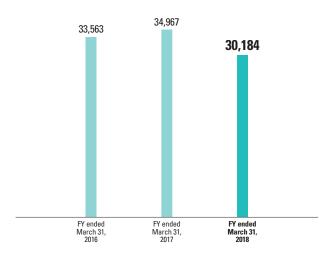


\*The Company implemented a one-for-two reverse stock split on October 1, 2015. Dividends paid for the interim period of the fiscal year ended March 31, 2016 or earlier are calculated on a post-reversestock-split basis.

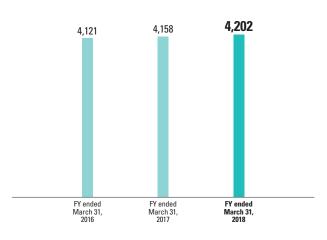
### Non-Financial Highlights — Environment-related — Society-related



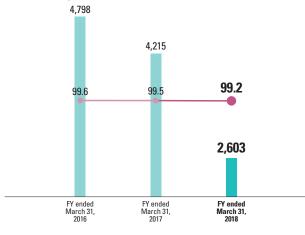
Electricity consumption (1,000 kWh)



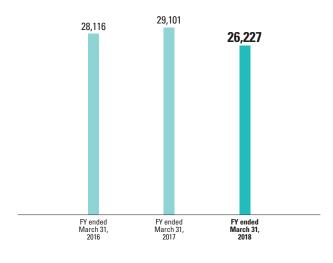
Water consumption at the Shizuoka site and the Drug Research Center in Kyoto (1,000 tons)



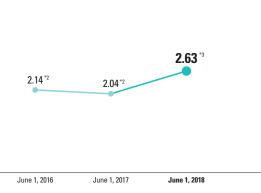
- Waste discharged at the Shizuoka site and the Drug Research Center in Kyoto (tons)
- Waste recycling rate at the Shizuoka site and the Drug Research Center in Kyoto (%)



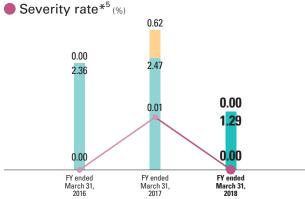
CO2 emissions (t-CO2)



Ratio of employees with disabilities\*1(%)



Frequency rate of occupational accidents\*4(%) Lost-time accidents Accidents not requiring leave from service



- \*1 Figures are as of June 1.
- \*2 Legal employment quota in 2016 and 2017 was 2.0%.

- \*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

<sup>\*3</sup> Legal employment quota in 2018 is 2.2%.



## Developing pharmaceuticals with a view to overcoming the increasingly harsh business environment and prevailing over the competition

The business environment surrounding the domestic pharmaceuticals industry has significantly changed in the past one or two years, growing increasingly harsh. As social security-related expenditures rise due to the aging population, with medical expenditure borne by the national treasury topping ¥11 trillion, the Japanese Government strives to suppress the expansion of expenses such as by lowering drug prices.

On the other hand, the commercialization of pharmaceuticals requires a significant amount of development expense and, with the low success rate, is by no means an easy mission. Going forward, we will be required to work even harder to increase the success rate in our research and development activities. In order

to succeed in the severe environment, rather than pursuing products with sales of ¥100 billion, we need to be sure to introduce highly-effective products into the market in line with demands, even if they only generate around ¥10 billion in sales.

At KAKEN, the major success of Clenafin, launched as Japan's first topical treatment for onychomycosis in 2014, has led the Company's recent business performance through the expansion of sales within Japan and out-licensing to overseas markets, primarily in the United States. KAKEN recognizes its key issues for the future; namely, to establish an in-house system that enables the Company to continuously develop new pharmaceuticals that follow Clenafin and promote them

worldwide while continuing to maximize revenue generated from Clenafin; and to respond to changes in the environment while maintaining an appropriate number of employees for its business scale. KAKEN will continue to make advancement by boldly taking on challenges, aiming to become a company that contributes to society through "supplying superior pharmaceuticals," as set out in our Corporate Philosophy.

## Income from overseas Clenafin licensing decreased, but the development pipeline is steadily growing

In the consolidated results for FY2017, KAKEN reported a decrease in both income and profit.

Sales of Clenafin in Japan remained solid, while income from overseas licensing decreased (marketed overseas under the trade name of "Jublia"). In addition, net sales as a whole amounted only to ¥98,430 million (down 3.0% year on year) as sales of the absorbable adhesion barrier Seprafilm remained weak due to the entry of new competing products, among other reasons. Of the amount, net sales from overseas amounted to ¥7,110 million (down 2.1% year on year).

With regard to income, operating profit amounted to \$27,496 million (down 10.5% year on year), ordinary profit amounted to \$27,854 million (down 10.1% year on year) and profit attributable to owners of parent amounted to \$19,043 million (down 13.5% year on year), mainly due to the expenditure of \$8,152 million (up 26.4% year on year) as research and development expenses aimed at enhancing and advancing the pipeline.

In FY2017, the Company pushed forward with initiatives aimed at strengthening the marketing bases in relation to out-licensing of Clenafin (Jublia), such as concluding a local licensing agreement with Tai Tien Pharmaceuticals Co., Ltd. in Taiwan in November 2017, following the commencement of sales of the product by South Korean licensee, Dong-A ST Co., Ltd., in June 2017. In addition, the Company has also entered contract negotiations with out-licensing candidates in China, Hong Kong and Macau. The promotional activities in

China in particular advanced significantly as the application for the clinical trial was approved by the competent authority.

With regard to research and development alliances, the Company concluded a collaborative research agreement for new antibody preparations targeted at inflammatory diseases with Numab Therapeutics AG in Switzerland in June 2017, which marked the beginning of new initiatives for drug discovery.

In addition, in February 2018, the Company granted a license for new KP-470 compounds developed by the Company to a subsidiary of Bausch Health Companies Inc. in Canada. KP-470 is a compound that has a new mechanism of action and is expected to be effective when externally applied to skin diseases such as psoriasis.

The current status of the development pipeline (as of July 2018) is that the following two products have moved to Phase III: BBI-4000 (licensed from Brickell Biotech, Inc. in the United States), an external anticholinergic with indication for primary focal hyperhidrosis; and KMW-1 (licensed from MediWound Ltd. in Israel), an external enzymatic product that is under development for use in the removal of eschar with thermal burns. Meanwhile, KP-607, an in-house product and a treatment for onychomycosis, positioned as the successor to Clenafin, also advanced to Phase I and is showing steady progress. (See p. 15 for the development pipeline.)

## Steady results under the Medium-Term Business Plan, which set growth strategies based on priority measures

Since FY2016, KAKEN has been carrying out the three-year Medium-Term Business Plan 2018, formulated under the theme of "the establishment of growth foundations from a forward-looking perspective." FY2018 is the final year of the Plan. Under the Plan, we have set the numeric target of achieving consolidated net sales of ¥110.0 billion in FY2018. However, we revised the target downward to ¥94.8 billion, because environmental changes have materialized mainly in relation to NHI drug price revisions and the government policy on promotion of generic drugs, exceeding what

we had expected at the time the Plan was formulated, in addition to the delay in our sales plan for Clenafin (Jublia).

On the other hand, the Company has carried out growth strategies based on the priority measures of the Plan, namely to "enhance R&D pipeline," to "maximize value of Clenafin and new products/strengthen marketing bases and efficiency for existing products" and to "foster personnel with strong creativity," steadily achieving progress for each issue during the past two years.

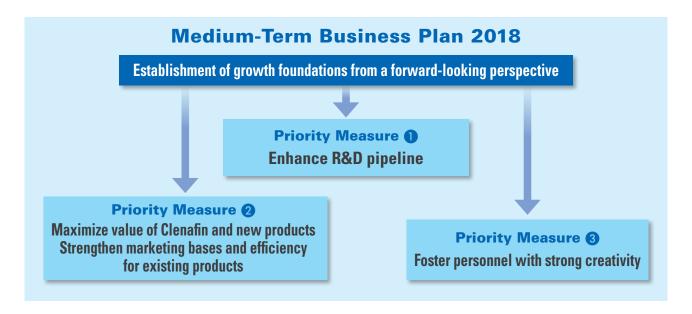
#### President's Message

During FY2018, the final year of the Plan, the Company forecasts a decrease in both income and profit as the growth in sales of Clenafin could not completely offset the impact from the NHI drug price revisions, and research and development expenses are expected to continue to grow. To be more specific, the Company projects net sales of ¥94.8 billion (down 3.7% year on year), operating profit of ¥22.5 billion (down 18.2% year on year), ordinary profit of ¥22.8 billion (down 18.1% year on year) and profit attributable to owners of parent of ¥16.4 billion (down 13.9% year on year). As for research and development expenses, the Company plans to invest ¥11.7 billion, about ¥3.5 billion more than the current fiscal year.

In FY2018, in addition to promoting Clenafin, the Company intends to push forward with efforts to expand the market for Regroth, a medicinal product for periodontal regeneration, sell Hernicore, a treatment for lumbar disc herniation for which Seikagaku Corporation

has obtained approval for manufacture and distribution, and promote Clenafin (Jublia) through out-licensing to countries abroad. We believe that we can pave the way for the sales expansion of Clenafin (Jublia) in the Chinese market in FY2018, as prospects for out-licensing in the market are in sight following the aforementioned approval of the clinical trial application.

As for the issues to be addressed in the future, the Company needs to improve productivity by restructuring the Marketing & Sales Division system and appropriately allocating personnel. In the R&D Division, the Company aims to enhance productivity by particularly focusing on fostering younger employees and providing them with plenty of opportunities for active participation. It is the policy of the Company to promote foundation improvement on a company-wide basis from a medium-to long-term perspective concurrently with the aforementioned initiatives, with the aim of continuing to make proactive research and development investment.



## Improved corporate governance effectiveness through the utilization of monitoring by and advice from outside officers

We are committed to becoming a company realizing its social responsibility as a pharmaceutical company conducting its business with both a high ethical standard and society's trust. In the practice of the commitment, we position the strengthening of corporate governance as one of our top management priorities.

Specifically, the Company has consistently maintained its stance to always seek and respect the opinions and recommendations from two Outside Directors and two Outside Audit & Supervisory Board Members in its effort to ensure the transparency and soundness of management and achieve higher corporate value

through monitoring by and advice from independent outside officers. So far, the opinions and advice from independent outside officers have brought various benefits to the business development of the Company in many aspects.

The Company is also working to promote better understanding among Directors and Audit & Supervisory Board Members of the roles and responsibilities demanded of them and support them in learning required knowledge by providing them with opportunities to participate in external seminars and exchange meetings. For independent outside officers in particular, the Company endeavors to provide them with



opportunities for interchange with management executives, for on-site inspections of the Company' offices, and other engagements upon request. In addition, as a system to support Outside Directors, the Company distributes materials for the Board of Directors meetings and provides explanations in advance, allowing Outside Directors to conduct interviews with Directors and Corporate Officers and inspect the minutes of important meetings, among other information. Outside Audit & Supervisory Board Members are notified of the matters submitted to important meetings such as the Management Meeting, results of audits by standing Audit & Supervisory Board Members, internal information, etc., at monthly Audit & Supervisory Board meetings.

Objectivity from an external point of view and insight based on abundant experience are necessary for the Company to make precise management decisions and take necessary risks under the circumstances where uncertainty in the business environment is increasing and it becomes more and more difficult to foresee medium- and long-term developments in the future. The Company's policy is to continue to seek proactive feedback from independent outside officers and to work to invigorate the Board of Directors meetings and the Management Meeting, thereby enhancing the effectiveness of corporate governance.

The Company will continue to focus on strengthening corporate governance so as to quickly respond to the ever-changing business environment and achieve sustainable growth.

## Unwavering dedication to the "three joys," as a commitment to all stakeholders

As a commitment to all stakeholders associated with its corporate activities, KAKEN is always pursuing the three joys of "creating joy for patients," "creating joy for our employees" and "creating joy as a company" as stipulated in its business philosophy. This is a clear statement of our aspirations, based on the Company's Corporate Philosophy, to help to improve the quality of life for patients to fulfill our social mission as a manufacturer that supplies effective pharmaceuticals needed by patients to medical practices; by so doing, to heighten its own corporate value and improve shareholder returns; and, furthermore, to facilitate the growth of employees and provide them with a high level of satisfaction through work and returns. The three joys will endow the Company with the presence and trust necessary for creating social value through its business.

The Company is aiming to become "the best" company that is recognized by society, and a company where each and every one of the employees can work for many years with peace of mind while fulfilling their respective mission, rather than a company that is only interested in expanding the scope of its business.

As a company having its roots in the Institute of Physical and Chemical Research, it is meaningful for KAKEN to take pride in its origin; however, above all, I hope that KAKEN makes strong progress and a further leap forward as a company with vitality and a sense of presence, and which employees can be proud of.

I hope that all stakeholders accept my sincerest thanks for looking forward to KAKEN's further challenges and for their long-term support and patronage.

(July 31, 2018, at the Head Office)

### **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 realizing its social responsibility as a pharmaceutical company conducting 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.

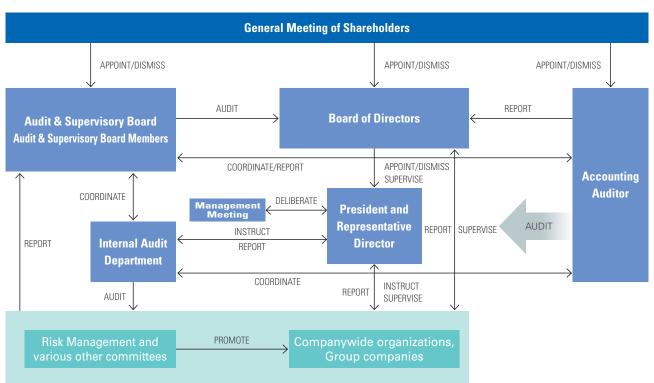
Board of Directors meetings are normally held on a monthly basis, and extraordinary meetings are held when necessary. Two of the Directors are Outside Directors. Furthermore, Audit & Supervisory Board Members, including Outside Audit & Supervisory Board Members, and Corporate Officers attend Board of 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   | 2   |  |
| Number of Independent Directors                                     | 2   |  |

#### **Board of Directors**

The Board of Directors consists of seven Directors, including two Outside Directors (as of June 28, 2018). 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

#### Corporate governance system



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.

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 (as of June 28, 2018), including two standing Audit & Supervisory Board Members and two Outside Audit & Supervisory Board Members (part-time). In addition, KAKEN has appointed one Substitute Outside Audit & Supervisory Board Member. 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 two 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.

Outside Directors and Outside Audit & Supervisory Board Members exchange opinions and information through attendance at Board of Directors meetings.

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 FY2017, Board of Directors meetings were held 16 times (12 scheduled meetings and four extraordinary meetings). Directors and Audit & Supervisory Board Members attended the extraordinary Board of Directors meetings, and Corporate Officers also attended the scheduled Board of Directors meetings. They had multifaceted deliberations based on their expertise and experience, and made management decisions in a timely and appropriate manner. Specifically, Outside Directors and Outside Audit & Supervisory Board Members provided a wide range of opinions and questions without being constrained by internal norms. Taking into account this situation and also in reference to the self-evaluation based on questionnaire surveys conducted for each Director and 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<br><b>Eiki Enomoto</b>                                 | Mr. Eiki Enomoto attended all 16 Board of Directors meetings held during the fiscal year under review and provided comments as necessary based on his experience gained through engaging in corporate legal work and expert perspective as an attorney at law.  | The Company has determined that Mr. Eiki Enomoto can utilize his experience and professional expertise gained through engaging in corporate legal work as an attorney at law in the management of the Company.  |  |
| Director Yoshio Tanabe  | Mr. Yoshio Tanabe attended all 16 Board of Directors meetings<br>held during the fiscal year under review and provided comments<br>as necessary based on his experience, achievements and<br>insights gained from being involved in management at the<br>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. |  |
| Audit &<br>Supervisory<br>Board Member<br><b>Toshio Sakurai</b> | Mr. Toshio Sakurai attended all 16 Board of Directors meetings and all 13 Audit & Supervisory Board meetings held during the fiscal year under review and asked questions and provided opinions as necessary based on his abundant experience in the financial industry and in-depth knowledge of governance, accounting and overall business management. | As Mr. Toshio Sakurai has abundant experience in the financial industry and in-depth knowledge of governance, accounting and overall business management, the Company has determined that he can utilize these in the audit of the Company.               |  |
| Audit &<br>Supervisory<br>Board Member<br><b>Kazuo Hara</b>     | Mr. Kazuo Hara attended all 16 Board of Directors meetings and all 13 Audit & Supervisory Board meetings held during the fiscal year under review and asked questions and provided opinions as necessary as he has in-depth knowledge of and extensive experience in tax affairs and accounting as a certified public tax accountant.                     | 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.                                |  |

## Corporate Governance | Members of the Management Team



(Seated) Tetsuo Onuma (Standing, from left) Yoshio Tanabe, Chikara leda, Atsushi Takaoka, Hiroyuki Horiuchi, Fumihiro Watanabe and Eiki Enomoto

#### 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

June 2007 Managing Director of the Company

June 2011 President and Representative Director of the Company (to present)

#### **Outside Director** Eiki Enomoto

Anril 1999

April 2018

Professor of The Legal Training and Research

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 (to present) April 2014 Auditor of Dai-ichi Tokyo Bar Association June 2014 Director of the Company (to present)

#### **Managing Director** Hiroyuki Horiuchi

April 1984 Joined the Company October 2010 General Manager of Hiroshima Branch (currently General Manager of Chugoku and Shikoku 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)

#### **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.

#### **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)

#### Audit & Supervisory Board Member (Standing) Atsutada Iwamoto

Anril 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)

#### 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)

#### Audit & Supervisory Board Member (Standing) Naomi Doi

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)

#### Director Chikara leda

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 (to present) June 2017 Director of the Company (to present)

#### Outside Audit & Supervisory Board Member Toshio Sakurai

April 1972 Joined The Fuji Bank Limited (currently Mizuho Bank, Ltd.) March 2003 Joined Seishin Sogyo K.K. June 2006 Full-time Audit & Supervisory Board Member of Mizuho Business Financial Center Co., Ltd. June 2011 Audit & Supervisory Board Member of the Company (to present)

#### Outside Audit & Supervisory Board Member Kazuo Hara

Anril 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 Audit & Supervisory Board Member of the Company (to present)

Institute, The Supreme Court of Japan (to present)

## Corporate Governance | Outside Directors Messages

# I will support the shaping of the future of KAKEN, passing down the philosophy of "supplying superior pharmaceuticals."

Eiki Enomoto, Director (Outside)

This is my fifth year serving as an Outside Director of KAKEN. I myself believe that the mission entrusted to me by shareholders is to monitor and supervise operations so as to realize fair and transparent management, and to identify and encourage the making of decisions that will drive improvement in corporate value, drawing on my experience in corporate legal work as an attorney at law.

One of the corporate governance issues to be addressed in KAKEN's management system going forward is to secure human resources to lead the next generation. I am committed to further strengthening the mechanism for fostering management executive candidates and enriching the pool of human resources aiming for future business continuity.

The domestic pharmaceuticals industry is facing a major turning point associated with drug price system reform, and companies in the industry are required to make difficult management decisions for their survival. However, I believe that KAKEN has ample potential to ride through the harsh environmental changes and enhance its corporate value while passing down the corporate DNA of "supplying superior pharmaceuticals." As a member of the Board of Directors, I will do my very best to support the shaping of the future of KAKEN.





### I will help KAKEN accelerate its next leap forward drawing on my many years of experience in the pharmaceuticals industry.

Yoshio Tanabe, Director (Outside)

Since the launch of Clenafin in 2014, KAKEN has further expanded its business contents and built a foundation for growth centered on in-house drug discovery, development and sales. In the meantime, the domestic pharmaceuticals industry is facing difficulty in continuing the business based on conventional business models, and companies in the industry are being forced to change their business strategies. Under such circumstances, I believe my role as an Outside Director of KAKEN since assuming office in 2016 is to help KAKEN accelerate its next leap forward drawing on my 20 years of experience in development and sales of pharmaceuticals in this industry.

Looking at the Company from an external point of view over the past two years, I have the impression that opinions are exchanged in management-related discussions at Board of Directors meetings, etc., in a manner that reflects a faithful and diligent corporate culture, and that KAKEN retains corporate governance functions under a proper Plan-Do-Check-Action (PDCA) cycle.

Going forward, KAKEN aims to achieve further advancement by establishing a foundation for sustainable growth, securing drivers for in-house products that follow Clenafin, and building a sense of ownership in the overseas markets. As an Outside Director, I will work diligently to help the Company achieve this goal.

## 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.

#### KAKEN's Activity Principles and Guidelines

Each executive and employee of KAKEN and its subsidiaries is strongly committed to compliance with all relevant Japanese and foreign laws and regulations, respecting different cultures and customs, and adopting high ethical standards in business operations.

- We recognize the preciousness of life and shall contribute to the welfare of society by channeling all our efforts into the enhancement of people's health and patients' quality of life.
- 2. We recognize the importance of maintaining appropriate relations with all medical practitioners as well as our shareholders, investors, employees, business partners, and local communities.
- 3. We shall compete in a fair and free manner, conducting our business activities in an appropriate way.
- 4. We shall handle all KAKEN's assets, including information, in a legitimate and proper manner to facilitate the smooth running of our business operations.
- 5. We shall respect the human rights and individuality of employees, pay attention to health and safety issues, and endeavor to foster a fair and honest workplace culture.
- 6. We shall manage KAKEN's information appropriately and disclose information in a timely and appropriate manner.
- 7. We shall take seriously the impact of our activities on the global environment and contribute to society as a good corporate citizen, including through environmental protection efforts.
- 8. We shall not tolerate terrorism and other anti-social behavior.

#### 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.



Compliance Check Card

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 training

#### 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 2016 for the second time following January 2013.

## Corporate Governance | Risk Management

#### Basic approach to 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.
- 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 include the following. The forward-looking statements reflect judgment and

forecasts made by the KAKEN Group (KAKEN and its consolidated subsidiaries) based on information available as of the end of the fiscal year under review. Furthermore, the risks faced by the KAKEN Group are not limited to those listed below.

| 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 may result in a drop in the sales price of products. In addition, 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.

#### 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 FY2017.)

#### **Chemical substances (tons)**

(Substances subject to reporting under the PRTR system)

Acetonitrile: 2.3 Chloroform: 1.2 Toluene: 4.9

Normal hexane: 2.4 Zinc compound: 4.9 Dichloromethane: 10.6

#### Energy

Electric power: 29,461,032 kWh LPG: 5 tons City gas: 5,010,156 Nm<sup>3</sup>

#### Water

Water: 4,202,000 tons

#### Office paper

2.152 million sheets

#### Other packaging materials

- Plastics
- Paper

#### Raw materials

- Corn starch
- Soy flour, etc



Research and development activities



Production activities



Office activities

#### **Discharging** into the water system

Volume of wastewater: 3,034,000 tons/year

#### **Emissions** into the atmosphere

CO2: 25,613 t-CO2

#### Waste

Waste discharged: 2,603 tons Amount of final landfill: 21 tons

#### **Environment | Environmental Management System**

#### 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.

Activity report for FY2017 and activity targets for FY2018 of the Shizuoka site and the Drug Research Center in Kyoto

| Environmental  | FY2017  |   | EV2019 toward  |  |
|--|---|---|--|--|
| policy   | Target  | Result  | FY2018 target  |  |
| Energy saving  | Reduce steam consumption by 3,000 tons compared with FY2013 (69,609 tons) by the end of FY2017.   | Reduced steam consumption by 5,951 tons from 69,609 tons in FY2013.   | Reduce CO <sub>2</sub> emissions by 1,500 t-CO <sub>2</sub> by the end of FY2018 compared with the benchmark CO <sub>2</sub> emissions of 20,895 t-CO <sub>2</sub> . |  |
| 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 2% compared with FY2014 by the end of FY2017.   | Valuables ratio of 32.7%, up from 30.4% in FY2014.  | Increase the valuables ratio by 3% compared with FY2014 by the end of FY2018.  |  |
| Eco-friendly<br>product<br>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<br>participation in<br>environmental<br>protection<br>activities in local<br>communities           | Proactively participate in environment-related external organizations. Promote interchange with local residents.  | Participated in environment-related organizations and exchanged information. [27 times in total] Participated in cleaning and river beautification activities carried out around the site. [on Apr. 20 and Oct. 5] Held an environmental report meeting for local residents. [on Nov. 15] | Proactively participate in environment-related external organizations. Promote interchange with local residents.   |  |
| Management of electricity consumption  | Maintain and manage electricity consumption relative to the data in FY2016.   | Failed to achieve the target, as electricity consumption increased by 10.8% compared with FY2016.   | Maintain and manage electricity consumption relative to the data in FY2017.  |  |
| Proper<br>management of<br>chemical<br>substances  | Implement concrete measures planned at each department. (23 times during the year)  | Achieved the target by implementing measures of each department to manage chemical substances 23 times during the year.   | Implement concrete measures planned at each department. (38 times during the year)   |  |
| Reduction of general waste   | Maintain and manage the total volume discharged relative to the data in FY2016.   | Achieved the target, as the total volume discharged decreased by 11.8% compared with FY2016.  | Maintain and manage the total volume discharged relative to the data in FY2017.  |  |
| Harmony with the environment   | <ul> <li>Cleaning activities around the site:</li> <li>12 times during the year</li> <li>Cleaning activities of the Shinomiya<br/>River: twice during the year</li> </ul> | Achieved the targets, as cleaning activities were carried out 12 times around the site and twice at the river.  | <ul> <li>Cleaning activities around the site:<br/>12 times during the year</li> <li>Cleaning activities of the Shinomiya<br/>River: twice during the year</li> </ul> |  |
| Community activities   | Participate in regional environmental activities 4 times during the year.   | Achieved the target, participating in regional environmental activities 4 times during the year.  | Participate in regional environmental activities 4 times during the year.  |  |

#### 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, 2018).

| Qualification  | Number of employees |
|--|---------------------|
| Poisonous and deleterious substance handler                          | 40                  |
| Operations chief of specified chemical substances, etc.              | 54                  |
| Operations chief of organic solvents                                 | 64                  |
| Air pollution control manager  | 6                   |
| Water pollution control manager                                      | 9                   |
| Intermediate industrial waste treatment facility engineering manager | 2                   |
|  |                     |

| Qualification   | Number of employees |
|---|---------------------|
| Specially controlled industrial waste manager         | 6                   |
| Environmental management internal auditor             | _                   |
| Hazardous material engineer                           | 164                 |
| Qualified person for energy management                | 4                   |
| High pressure gas production safety technical manager | 22                  |
| Boiler expert   | 19                  |

### **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) |
|----------------|-------------------------------------|-------------------|
| рН             | 6.0 - 8.5                           | 7.5               |
| BOD (mg/L)     | Average: 35;<br>maximum: 45         | 2.5               |
| SS (mg/L)      | Average: 45;<br>maximum: 65         | 2.3               |
| Emissions (m³) | 20,000 or less                      | 8,304             |
|                |                                     |                   |

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

|            | Internal standard values | Results (average) |
|------------|--------------------------|-------------------|
| рН         | 5.8 – 8.6                | 7.1               |
| BOD (mg/L) | 1,500 or less            | 28.7              |
| SS (mg/L)  | 1,500 or less            | 43.5              |
|            |                          |                   |

#### Conservation of air quality

In order to reduce emissions of carbon dioxide (CO<sub>2</sub>), sulfur oxide (SO<sub>x</sub>), etc., city gas fired boilers were installed to replace the previous boilers at the Shizuoka site and the Drug Research Center in Kyoto in FY2006 and FY2007, respectively. As a result, both of the factories have continued to boast zero emissions of SO<sub>x</sub> 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

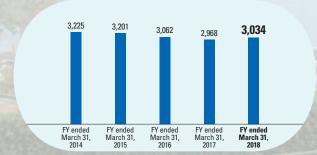
Both the Shizuoka site and the Drug Research Center in Kyoto are managing chemical substances on a voluntary basis. In order to reduce exposure to potential risks from using harmful chemical substances, the Company considers possible revisions to its processes for manufacturing and analyzing pharmaceuticals, 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.

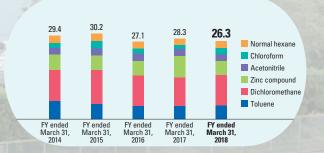
The Shizuoka site and the Drug Research Center in Kyoto monitor the status of use of chemical substances subject to the Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (the "PRTR Act") by, for example, 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.

Volume of wastewater at the Shizuoka site and the Drug Research Center in Kyoto

Volume of wastewater (1,000 tons)



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



#### **Environment | Initiatives for Environmental Protection**

#### 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 FY2017, the total amount of waste produced by the Shizuoka site was 2,542 tons. Of this, 91% 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.

#### Reduction of CO<sub>2</sub> emissions and energy saving

As the reduction of CO<sub>2</sub> 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.



Installation of highly-efficient boilers in the Injection Building (Shizuoka site)

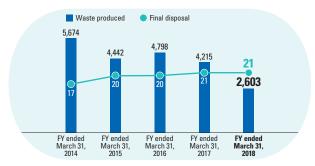


Installation of molded transformers in the Oral Solid Formulation Building (Shizuoka site)

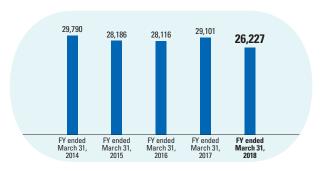


LED lighting and motion sensors installed at fire escapes in the Takadanobaba site. Lights are dimmed when nobody is present.

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



#### CO2 emissions (t-CO2)



# 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.

- 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.
- 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, evaluates and analyzes data regarding the safety of the pharmaceuticals in phases ranging from development to post marketing. It then addresses any issues and 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 Society | 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.

## 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.

## 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 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.



# 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

#### Installation of green walls

"Green walls" have been installed at the Shizuoka site as part of activities to reduce energy consumption in the summer. The Fujieda City Government is also promoting green walls as one of the familiar measures to conserve energy and combat global warming, and holds contests on this theme. In FY2016, KAKEN won the Excellence Award in the "Group" category.

#### **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.

## 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.





## **Consolidated Five-Year Summary**

|   | MILLIONS OF YEN |          |          |          |          | THOUSANDS OF<br>U.S. DOLLARS<br>(NOTE 1) |
|---|-----------------|----------|----------|----------|----------|--|
|   | 2018            | 2017     | 2016     | 2015     | 2014     | 2018                                     |
| FOR THE YEARS ENDED MARCH 31            |                 |          |          |          |          |  |
| Net sales                               | ¥ 98,430        | ¥101,479 | ¥109,730 | ¥ 93,889 | ¥ 88,946 | \$ 928,585                               |
| Operating profit                        | 27,496          | 30,707   | 35,146   | 20,631   | 15,872   | 259,396                                  |
| Profit attributable to owners of parent | 19,043          | 22,017   | 21,143   | 12,122   | 9,735    | 179,651                                  |
| AT MARCH 31 Total net assets            | 113,874         | 102,655  | 89,875   | 77,100   | 68,096   | 1,074,283                                |
| Total net assets                        | 113,874         | 102,655  | 89,875   | 77,100   | 68,096   | 1,074,283                                |
| Total assets                            | 152,417         | 135,060  | 132,991  | 115,135  | 106,465  | 1,437,896                                |
| PER SHARE DATA                          |                 |          | YEN      |          |          | U.S. DOLLARS<br>(NOTE 1)                 |
| Profit (Basic)                          | ¥470.54         | ¥536.70  | ¥510.54  | ¥290.90  | ¥228.27  | \$4.439                                  |
| Cash dividends (Non-Consolidated)       | 150.00          | 150.00   | _        | 59.00    | 48.00    | 1.415                                    |
| RATIOS                                  |                 |          | %        |          |          |  |
| ROE                                     | 17.6            | 22.9     | 25.3     | 16.7     | 14.5     | _  |
| Capital adequacy ratio                  | 74.7            | 76.0     | 67.6     | 67.0     | 64.0     | -  |

Notes: 1. U.S. dollar amounts are translated, for convenience only, at the rate of ¥106 = \$1.00, effective on March 31, 2018.

- 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 fiscal year ended March 31, 2014.
- 3. The Company conducted a 1-for-2 share consolidation on October 1, 2015. Dividends per share figures up to and including the fiscal year ended March 31, 2015, are displayed at the values prior to the share consolidation and dividends per share for the fiscal year ended March 31, 2016, are displayed as "-." When calculated on a post-share consolidation basis, the interim dividend was ¥68 per share and the total dividend payment per share was ¥146 (including a commemorative dividend of ¥10.00 per share) in the fiscal year ended March 31, 2016.

## Management Discussion and Analysis

#### **Operating Performance**

Consolidated net sales were down 3.0% year on year, to ¥98,430 million, and operating profit decreased 10.5%, to ¥27,496 million, while ordinary profit declined 10.1%, to ¥27,854 million. Profit attributable to owners of parent was down 13.5%, to ¥19,043 million.

#### **Segment Information**

## **Pharmaceuticals**

In pharmaceuticals and medical devices, overall sales were down due to the decreased sales of Seprafilm, an absorbable adhesion barrier, and the reduced revenues from overseas licensees of Clenafin, topical treatment for onychomycosis, although sales of Clenafin and Artz, anti-osteoarthritis drug, were about the same level year on year.

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 3.1% year on year, to ¥96,022 million, and segment income\* was down 11.1%, to ¥25,840 million.

Net sales from overseas were ¥7,110 million.

#### **Real Estate**

In the real estate segment, the majority of revenues are generated through rent fees related to the Bunkyo Green Court commercial facility. Net sales for the real estate segment were up 0.9% year on year, to ¥2,407 million, and segment income\* increased 1.6% year on year, to ¥1,655 million.

\* Segment income is based on operating profit.

## **Financial Position**

Total assets were  $\pm 152,417$  million as of March 31, 2018, up  $\pm 17,357$  million from the previous fiscal year-end, primarily due to an increase in cash and deposits.

Total liabilities were ¥38,543 million, up ¥6,137 million, largely as a result of an increase in notes and accounts payable - trade.

Net assets totaled ¥113,874 million, a rise of ¥11,219 million, mainly following higher retained earnings.

#### **Cash Flows**

Cash and cash equivalents as of March 31, 2018, totaled ¥52,694 million, an increase of ¥8,927 million compared with the previous fiscal year-end.

Net cash provided by operating activities was ¥21,703 million, an increase of ¥6,375 million year on year, due to factors including a decrease in income taxes paid.

Net cash used in investing activities stood at ¥3,245 million, a decrease of ¥258 million year on year, primarily as a result of a decline in purchase of property, plant and equipment

Net cash used in financing activities totaled ¥9,530 million, a decrease of ¥270 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 may result in a drop in the sales price of products. In addition, 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, 2018 and 2017

|   | MILLION  | THOUSANDS OF<br>U.S. DOLLARS (NOTE 1) |             |
|---|----------|---------------------------------------|-------------|
| ASSETS  | 2018     | 2017                                  | 2018        |
| CURRENT ASSETS:                                   |          |                                       |             |
| Cash and deposits (Notes 3 and 9)                 | ¥ 45,095 | ¥ 33,867                              | \$ 425,425  |
| Marketable securities (Notes 3, 4 and 9)          | 7,599    | 9,899                                 | 71,689      |
| Receivables:                                      |          |                                       |             |
| Notes and accounts receivable-trade (Note 9)      | 33,315   | 28,231                                | 314,292     |
| Accounts receivable-other                         | 927      | 832                                   | 8,745       |
|   | 34,243   | 29,063                                | 323,047     |
| Inventories (Note 5)                              | 16,651   | 16,495                                | 157,085     |
| Deferred tax assets (Note 14)                     | 1,195    | 928                                   | 11,274      |
| Other   | 269      | 239                                   | 2,538       |
| Total current assets                              | 105,055  | 90,494                                | 991,085     |
|   |          |                                       |             |
|   |          |                                       |             |
| PROPERTY, PLANT AND EQUIPMENT (Notes 6, 7 and 8): |          |                                       |             |
| Buildings and structures                          | 40,658   | 40,058                                | 383,566     |
| Machinery, equipment and vehicles                 | 15,677   | 16,035                                | 147,896     |
| Tools, furniture and fixtures                     | 6,974    | 6,799                                 | 65,792      |
|   | 63,310   | 62,894                                | 597,264     |
| Accumulated depreciation                          | (41,906) | (41,116)                              | (395,340)   |
| ·   | 21,404   | 21,777                                | 201,925     |
| Land  | 4,324    | 4,324                                 | 40,792      |
| Construction in progress                          | 412      | 168                                   | 3,887       |
| Total property, plant and equipment               | 26,141   | 26,271                                | 246,613     |
|   |          |                                       |             |
| INVESTMENTS AND OTHER ASSETS:                     |          |                                       |             |
| Investment securities (Notes 4 and 9)             | 18,488   | 15,943                                | 174,415     |
| Intangible assets                                 | 552      | 372                                   | 5,208       |
| Deferred tax assets (Note 14)                     | 426      | 887                                   | 4,019       |
| Other assets                                      | 1,753    | 1,091                                 | 16,538      |
| Total investments and other assets                | 21,220   | 18,293                                | 200,189     |
| TOTAL ASSETS                                      | ¥152,417 | ¥135,060                              | \$1,437,896 |

|  | MILLION  | THOUSANDS OF<br>U.S. DOLLARS (NOTE 1) |             |
|--|----------|---------------------------------------|-------------|
| LIABILITIES AND NET ASSETS   | 2018     | 2017                                  | 2018        |
| CURRENT LIABILITIES:   |          |                                       |             |
| Short-term bank loans (Notes 6 and 9)  | ¥ 3,875  | ¥ 3,875                               | \$ 36,557   |
| Payables:  |          |                                       |             |
| Notes and accounts payable–trade (Note 9)                                      | 12,204   | 9,854                                 | 115,132     |
| Accounts payable-other   | 4,565    | 3,086                                 | 43,066      |
| Electronically recorded obligations-operating (Note 9)                         | 1,248    | 1,307                                 | 11,774      |
|  | 18,017   | 14,248                                | 169,972     |
| Accrued expenses   | 667      | 394                                   | 6,292       |
| Provision for bonuses  | 1,351    | 1,399                                 | 12,745      |
| Provision for sales returns  | 10       | 12                                    | 94          |
| Provision for sales rebates  | 325      | 408                                   | 3,066       |
| Income taxes payable (Note 14)   | 5,097    | 3,049                                 | 48,085      |
| Other  | 2,057    | 631                                   | 19,406      |
| Total current liabilities  | 31,401   | 24,020                                | 296,236     |
|  |          |                                       |             |
| NON-CURRENT LIABILITIES:   |          |                                       |             |
| Net defined benefit liability (Note 10)  | 6,787    | 8,029                                 | 64,028      |
| Other  | 354      | 355                                   | 3,340       |
| Total non-current liabilities  | 7,141    | 8,384                                 | 67,368      |
|  |          |                                       |             |
| NET ASSETS:  |          |                                       |             |
| Shareholders' equity (Notes 2 (o) and 11):                                     |          |                                       |             |
| Common stock   |          |                                       |             |
| Authorized: 193,000,000 shares as of March 31, 2018 and 2017                   |          |                                       |             |
| Issued: 48,439,730 shares as of March 31, 2018 and 2017                        | 23,853   | 23,853                                | 225,028     |
| Capital surplus  | 11,408   | 11,407                                | 107,623     |
| Retained earnings  | 97,284   | 84,331                                | 917,774     |
| Treasury stock, at cost: 8,120,458 shares in 2018 and 7,568,472 shares in 2017 | (23,259) | (19,813)                              | (219,425)   |
| Total shareholders' equity   | 109,287  | 99,778                                | 1,031,009   |
| Accumulated other comprehensive income:  |          |                                       |             |
| Net unrealized holding gain on securities (Note 2 (c))                         | 5,510    | 4,611                                 | 51,981      |
| Remeasurements of defined benefit plans  | (923)    | (1,734)                               | (8,708)     |
| Total accumulated other comprehensive income                                   | 4,587    | 2,876                                 | 43,274      |
| Total net assets   | 113,874  | 102,655                               | 1,074,283   |
| TOTAL LIABILITIES AND NET ASSETS   | ¥152,417 | ¥135,060                              | \$1,437,896 |

# **Consolidated Statements of Income**

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiary For the years ended March 31, 2018 and 2017

|  | MILLIONS OF YEN |          | THOUSANDS OF U.S. DOLLARS (NOTE 1) |
|--|-----------------|----------|------------------------------------|
|  | 2018            | 2017     | 2018                               |
| NET SALES  | ¥98,430         | ¥101,479 | \$928,585                          |
| COST OF SALES  | 42,403          | 44,027   | 400,028                            |
| Gross profit   | 56,026          | 57,452   | 528,547                            |
| SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (Note 12) | 28,530          | 26,745   | 269,151                            |
| OPERATING PROFIT                                       | 27,496          | 30,707   | 259,396                            |
| OTHER INCOME (EXPENSES):                               |                 |          |                                    |
| Interest and dividends income                          | 309             | 283      | 2,915                              |
| Interest expenses                                      | (16)            | (21)     | (151)                              |
| Foreign exchange losses                                | (25)            | (34)     | (236)                              |
| Loss on retirement of non-current assets (Note 13)     | (165)           | (123)    | (1,557)                            |
| Gain (loss) on sales of investment securities          | (3)             | 252      | (28)                               |
| Loss on sale of golf club membership                   | _               | (18)     | _                                  |
| Other, net   | 91              | 47       | 858                                |
|  | 189             | 384      | 1,783                              |
| PROFIT BEFORE INCOME TAXES                             | 27,686          | 31,092   | 261,189                            |
| INCOME TAXES (Note 14):                                |                 |          |                                    |
| Current  | 9,206           | 8,147    | 86,849                             |
| Deferred   | (563)           | 928      | (5,311)                            |
|  | 8,643           | 9,075    | 81,538                             |
| PROFIT   | 19,043          | 22,017   | 179,651                            |
| PROFIT ATTRIBUTABLE TO OWNERS OF PARENT                | ¥19,043         | ¥ 22,017 | \$179,651                          |

|   | YE      | EN      | U.S. DOLLARS (NOTE 1) |  |  |
|---|---------|---------|-----------------------|--|--|
| PER SHARE DATA:                                 | 2018    | 2017    | 2018                  |  |  |
| Profit (Note 16):                               |         |         |                       |  |  |
| Basic   | ¥470.54 | ¥536.70 | \$4.439               |  |  |
| Diluted   | _       | _       | _                     |  |  |
|   |         |         |                       |  |  |
| Cash dividends applicable to the year (Note 11) | ¥150.00 | ¥150.00 | \$1.415               |  |  |

# **Consolidated Statements of Comprehensive Income**

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiary For the years ended March 31, 2018 and 2017

|   | MILLION | THOUSANDS OF U.S. DOLLARS (NOTE 1) |           |
|---|---------|------------------------------------|-----------|
|   | 2018    | 2017                               | 2018      |
| PROFIT                                      | ¥19,043 | ¥22,017                            | \$179,651 |
|   |         |                                    |           |
| OTHER COMPREHENSIVE INCOME (Note 17):       |         |                                    |           |
| Net unrealized holding gain on securities   | 898     | 187                                | 8,472     |
| Remeasurements of defined benefit plans     | 811     | 382                                | 7,651     |
| Total other comprehensive income            | 1,710   | 570                                | 16,132    |
| COMPREHENSIVE INCOME                        | 20,753  | 22,587                             | 195,783   |
|   |         |                                    |           |
| Total comprehensive income attributable to: |         |                                    |           |
| Owners of parent                            | ¥20,753 | ¥22,587                            | \$195,783 |

# **Consolidated Statements of Changes in Net Assets**

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiary For the years ended March 31, 2018 and 2017

## MILLIONS OF YEN

|  | SHAREHOLDERS' EQUITY |                    |                   |                   | ACCUMULATED OTHER COMPREHENSIVE INCOME |   |   | _      |                     |
|--|----------------------|--------------------|-------------------|-------------------|--|---|---|--------|---------------------|
|  | Common<br>stock      | Capital<br>surplus | Retained earnings | Treasury<br>stock | Total                                  | Net unrealized<br>holding gain<br>on securities | Remeasurements<br>of defined<br>benefit plans | Total  | TOTAL NET<br>ASSETS |
| BALANCE—March 31, 2016                     | ¥23,853              | ¥11,407            | ¥68,609           | ¥(16,301)         | ¥ 87,568                               | ¥4,423  | ¥(2,117)                                      | ¥2,306 | ¥ 89,875            |
| Changes during the year:                   |                      |                    |                   |                   |  |   |   |        |                     |
| Cash dividends                             |                      |                    | (6,295)           |                   | (6,295)                                |   |   |        | (6,295)             |
| Profit attributable to<br>owners of parent |                      |                    | 22,017            |                   | 22,017                                 |   |   |        | 22,017              |
| Purchase of treasury stock                 |                      |                    |                   | (3,512)           | (3,512)                                |   |   |        | (3,512)             |
| Other, net                                 |                      |                    |                   |                   |  | 187   | 382   | 570    | 570                 |
| Total changes during the year              | _                    | _                  | 15,722            | (3,512)           | 12,209                                 | 187   | 382   | 570    | 12,779              |
| 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            |

## THOUSANDS OF U.S. DOLLARS (NOTE 1)

|   |              | SHAREHOLDERS' EQUITY |                   |                   |             | ACCUMULATED OTHER COMPREHENSIVE INCOME          |   |          |                     |
|---|--------------|----------------------|-------------------|-------------------|-------------|---|---|----------|---------------------|
|   | Common stock | Capital<br>surplus   | Retained earnings | Treasury<br>stock | Total       | Net unrealized<br>holding gain<br>on securities | Remeasurements<br>of defined<br>benefit plans | Total    | TOTAL NET<br>ASSETS |
| BALANCE—March 31, 2017                  | \$225,028    | \$107,613            | \$795,575         | \$(186,915)       | \$ 941,302  | \$43,500  | \$(16,358)                                    | \$27,132 | \$ 968,443          |
| Changes during the year:                |              |                      |                   |                   |             |   |   |          |                     |
| Cash dividends                          |              |                      | (57,443)          |                   | (57,443)    |   |   |          | (57,443)            |
| Profit attributable to owners of parent |              |                      | 179,651           |                   | 179,651     |   |   |          | 179,651             |
| Purchase of treasury stock              |              |                      |                   | (32,500)          | (32,500)    |   |   |          | (32,500)            |
| Disposal of treasury stock              |              | 0                    |                   | 0                 | 0           |   |   |          | 0                   |
| Other, net                              |              |                      |                   |                   |             | 8,472   | 7,651   | 16,132   | 16,132              |
| Total changes during the year           | _            | 0                    | 122,198           | (32,500)          | 89,698      | 8,472   | 7,651   | 16,132   | 105,840             |
| BALANCE—March 31, 2018                  | \$225,028    | \$107,623            | \$917,774         | \$(219,425)       | \$1,031,009 | \$51,981  | \$ (8,708)                                    | \$43,274 | \$1,074,283         |

# **Consolidated Statements of Cash Flows**

Kaken Pharmaceutical Co., Ltd. and its Consolidated Subsidiary For the years ended March 31, 2018 and 2017

|  | MILLION | THOUSANDS OF<br>U.S. DOLLARS (NOTE 1) |           |
|--|---------|---------------------------------------|-----------|
|  | 2018    | 2017                                  | 2018      |
| CASH FLOWS FROM OPERATING ACTIVITIES:                      |         |                                       |           |
| Profit before income taxes                                 | ¥27,686 | ¥31,092                               | \$261,189 |
| Adjustments for:   |         |                                       |           |
| Depreciation   | 2,124   | 1,937                                 | 20,038    |
| Increase (decrease) in net defined benefit liability       | (69)    | (275)                                 | (651)     |
| Interest and dividends income                              | (309)   | (283)                                 | (2,915)   |
| Interest expenses  | 16      | 21                                    | 151       |
| Loss (gain) on sales of investment securities              | 3       | (252)                                 | 28        |
| Loss on retirement of non-current assets                   | 160     | 122                                   | 1,509     |
| Decrease (increase) in notes and accounts receivable-trade | (5,084) | 1,637                                 | (47,962)  |
| Decrease (increase) in inventories                         | (155)   | (1,987)                               | (1,462)   |
| Increase (decrease) in notes and accounts payable-trade    | 2,290   | (1,094)                               | 21,604    |
| Other, net   | 1,827   | (2,005)                               | 17,236    |
| Subtotal   | 28,489  | 28,912                                | 268,764   |
| Interest and dividends income received                     | 309     | 283                                   | 2,915     |
| Interest expenses paid                                     | (16)    | (21)                                  | (151)     |
| Income taxes paid, net                                     | (7,078) | (13,846)                              | (66,774)  |
| Net cash provided by (used in) operating activities        | 21,703  | 15,327                                | 204,745   |
| CASH FLOWS FROM INVESTING ACTIVITIES:                      |         |                                       |           |
| Purchase of property, plant and equipment                  | (1,689) | (2,166)                               | (15,934)  |
| Purchase of intangible assets                              | (199)   | (188)                                 | (1,877)   |
| Purchase of investment securities                          | (1,253) | (1,502)                               | (11,821)  |
| Proceeds from sales of investment securities               | 1       | 483                                   | 9         |
| Other, net   | (104)   | (130)                                 | (981)     |
| Net cash provided by (used in) investing activities        | (3,245) | (3,503)                               | (30,613)  |
| CASH FLOWS FROM FINANCING ACTIVITIES:                      |         |                                       |           |
| Net decrease (increase) in treasury stock                  | (3,445) | (3,512)                               | (32,500)  |
| Cash dividends paid  | (6,085) | (6,288)                               | (57,406)  |
| Net cash provided by (used in) financing activities        | (9,530) | (9,800)                               | (89,906)  |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS       | 8,927   | 2,023                                 | 84,217    |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR             | 43,767  | 41,744                                | 412,896   |
| CASH AND CASH EQUIVALENTS AT END OF YEAR (Note 3)          | ¥52,694 | ¥43,767                               | \$497,113 |

## 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 in the 2017 financial statements to conform to the classifications used in 2018.

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 yen amounts solely for convenience and, as a matter of arithmetic computation only, at ¥106 = U.S. \$1.00, the approximate rate of exchange prevailing on March 31, 2018. This translation should not be construed as a representation that 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 consolidated financial statements include the accounts of the Company and its subsidiary. For the years ended March 31, 2018 and 2017, the Company had one consolidated subsidiary as follows:

KAKEN PHARMA CO., LTD.

For the years ended March 31, 2018 and 2017, 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 composed 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 from 3 years to 60 years for buildings and structures, and from 2 years to 8 years for machinery, equipment and vehicles.

## (f) Intangible Assets

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

## (g) Provision for Bonuses

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

#### (h) Provision for Sales Returns

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

#### (i) 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 accounts receivable-trade as of the balance sheet date by the expected ratio for sales rebates.

## (j) Retirement and Pension Plan

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

Unrecognized actuarial difference is amortized on a straight-line basis over 10 years from the year following the year in which it arises. Unrecognized prior service cost is amortized on a straight-line basis over 10 years from the year in which it arises.

## (k) 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.

#### (I) 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.

## (m) 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 accounts receivable and payable and cash flows generated from anticipated 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 anticipated 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, assessment method for 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 forecast

foreign currency denominated transactions

#### (2) Hedging policy

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

#### (3) Assessment method for hedge effectiveness

Since material terms related to hedged items and hedging instruments are substantially identical, and such hedging transactions are deemed to be highly effective so that the market fluctuations may be completely offset continuously 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.

## (n) 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.

## (o) Shareholders' Equity

Japanese companies are subject to the Companies Act of Japan. 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.

## (p) New Accounting Standards Not Yet Applied

"Implementation Guidance for Tax Effect Accounting" (Accounting Standards Board of Japan ("ASBJ") Guidance No. 28, issued on February 16, 2018)

"Implementation Guidance on Recoverability of Deferred Tax Assets" (ASBJ Guidance No. 26, issued on February 16, 2018)

#### (1) Overview

The treatment of future taxable temporary differences pertaining to shares, etc. of subsidiaries in the non-consolidated financial statements has been revised, and the treatment of recoverability of deferred tax assets in companies that fall under (Category 1) has been clarified.

#### (2) Scheduled date of application

The Implementation Guidance is scheduled to be applied from the beginning of the year ending March 31, 2019.

(3) Effect of application of the accounting standards

The financial effect is currently under evaluation.

"Accounting Standard for Revenue Recognition" (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

This standard is a comprehensive accounting standard for recognition of revenue. 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 application of the accounting standards

The financial effect is currently under evaluation.

## 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:

|   | MILLION | MILLIONS OF YEN |           |  |
|---|---------|-----------------|-----------|--|
|   | 2018    | 2017            | 2018      |  |
| Cash and deposits                                   | ¥45,095 | ¥33,867         | \$425,425 |  |
| Marketable securities                               | 7,599   | 9,899           | 71,689    |  |
| Subtotal  | ¥52,694 | ¥43,767         | \$497,113 |  |
| Time deposits due in more than three months         | _       | _               | _         |  |
| Marketable securities due in more than three months | _       | _               | _         |  |
| Cash and cash equivalents                           | ¥52,694 | ¥43,767         | \$497,113 |  |

## 4. Marketable and Investment Securities:

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

| MILLION                | S OF YEN        |            |                        |
|------------------------|-----------------|------------|------------------------|
| Unrealized gain (loss) | Carrying amount | Fair value | Unrealized gain (loss) |
|                        |                 | 2017       |                        |
| ¥—                     | ¥ —             | ¥ —        | ¥—                     |
|                        |                 |            |                        |

|   | Carrying amount | Fair value | Unrealized gain<br>(loss) | Carrying amount | Fair value | Unrealized gain<br>(loss) |
|---|-----------------|------------|---------------------------|-----------------|------------|---------------------------|
|   |                 | 2018       |                           |                 | 2017       |                           |
| Fair values exceeding carrying amount     | ¥ –             | ¥ –        | ¥—                        | ¥ —             | ¥ —        | ¥—                        |
| Fair values not exceeding carrying amount | 5,999           | 5,999      | _                         | 8,999           | 8,999      | _                         |
| Total                                     | ¥5,999          | ¥5,999     | ¥—                        | ¥8,999          | ¥8,999     | ¥—                        |

## THOUSANDS OF U.S. DOLLARS (NOTE 1)

|   | Carrying amount | Fair value | Unrealized gain (loss) |
|---|-----------------|------------|------------------------|
|   |                 | 2018       |                        |
| Fair values exceeding carrying amount     | \$ <b>—</b>     | \$ -       | \$-                    |
| Fair values not exceeding carrying amount | 56,594          | 56,594     | _                      |
| Total                                     | \$56,594        | \$56,594   | \$-                    |

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<br>(loss) | Fair value | Acquisition cost | Unrealized gain (loss) |
|---|------------|------------------|---------------------------|------------|------------------|------------------------|
|   |            | 2018             |                           |            | 2017             |                        |
| Carrying amounts exceeding acquisition cost     |            |                  |                           |            |                  |                        |
| Equity securities                               | ¥17,535    | ¥ 9,487          | ¥8,047                    | ¥15,155    | ¥ 8,484          | ¥6,671                 |
| Other   | _          | _                | _                         | _          |                  | _                      |
| Subtotal  | 17,535     | 9,487            | 8,047                     | 15,155     | 8,484            | 6,671                  |
| Carrying amounts not exceeding acquisition cost |            |                  |                           |            |                  |                        |
| Equity securities                               | 894        | 999              | (104)                     | 725        | 749              | (24)                   |
| Other   | 1,600      | 1,600            | _                         | 900        | 900              | _                      |
| Subtotal  | 2,494      | 2,599            | (104)                     | 1,625      | 1,649            | (24)                   |
| Total   | ¥20,030    | ¥12,087          | ¥7,942                    | ¥16,781    | ¥10,133          | ¥6,647                 |

## THOUSANDS OF U.S. DOLLARS (NOTE 1)

|   | Fair value | Acquisition cost | Unrealized gain<br>(loss) |
|---|------------|------------------|---------------------------|
|   |            | 2018             |                           |
| Carrying amounts exceeding acquisition cost     |            |                  |                           |
| Equity securities                               | \$165,425  | \$ 89,500        | \$75,915                  |
| Other   | _          | _                | _                         |
| Subtotal  | 165,425    | 89,500           | 75,915                    |
| Carrying amounts not exceeding acquisition cost |            |                  |                           |
| Equity securities                               | 8,434      | 9,425            | (981)                     |
| Other   | 15,094     | 15,094           | _                         |
| Subtotal  | 23,528     | 24,519           | (981)                     |
| Total   | \$188,962  | \$114,028        | \$74,925                  |

Available-for-sale securities sold for the years ended March 31, 2018 and 2017 are summarized as follows:

## MILLIONS OF YEN

|                   | Proceeds | Gain | Loss | Proceeds | Gain | Loss |
|-------------------|----------|------|------|----------|------|------|
|                   |          | 2018 |      |          | 2017 |      |
| Equity securities | ¥1       | ¥—   | ¥3   | ¥483     | ¥252 | ¥—   |
| Total             | ¥1       | ¥—   | ¥3   | ¥483     | ¥252 | ¥—   |

## THOUSANDS OF U.S. DOLLARS (NOTE 1)

|                   | Proceeds | Gain | Loss |
|-------------------|----------|------|------|
|                   |          | 2018 |      |
| Equity securities | \$9      | \$-  | \$28 |
| Total             | \$9      | \$-  | \$28 |

## 5. Inventories:

Inventories as of March 31, 2018 and 2017, comprised the following:

|                                   | MILLIONS OF YEN |         | U.S. DOLLARS (NOTE 1) |  |
|-----------------------------------|-----------------|---------|-----------------------|--|
|                                   | 2018            | 2017    | 2018                  |  |
| Merchandise and finished products | ¥ 7,178         | ¥ 8,004 | \$ 67,717             |  |
| Work in process                   | 3,986           | 2,341   | 37,604                |  |
| Raw materials and supplies        | 5,487           | 6,150   | 51,764                |  |
| Total                             | ¥16,651         | ¥16,495 | \$157,085             |  |

## 6. Short-term Bank Loans and Pledged assets:

## (a) Short-term bank loans

Short-term bank loans outstanding as of March 31, 2018 and 2017, amounting to  $\pm$ 3,875 million (\$36,557 thousand) and  $\pm$ 3,875 million, consisted mainly of bank overdrafts. The weighted-average interest rates applicable to short-term bank loans as of March 31, 2018 and 2017 were 0.45% and 0.43%, respectively.

## (b) Pledged assets

As of March 31, 2018 and 2017, assets pledged as collateral for certain short-term bank loans are as follows:

|                                   | MILLIONS OF YEN |        | THOUSANDS OF U.S. DOLLARS (NOTE 1) |
|-----------------------------------|-----------------|--------|------------------------------------|
|                                   | 2018            | 2017   | 2018                               |
| Assets pledged:                   |                 |        |                                    |
| Buildings and structures          | ¥5,805          | ¥5,804 | \$54,764                           |
| Machinery, equipment and vehicles | 3,115           | 3,513  | 29,387                             |
| Tools, furniture and fixtures     | 505             | 462    | 4,764                              |
| Land                              | 117             | 117    | 1,104                              |
| Total                             | ¥9,544          | ¥9,897 | \$90,038                           |
|                                   |                 |        |                                    |
| Liabilities secured:              |                 |        |                                    |
| Short-term bank loans             | ¥1,400          | ¥1,400 | \$13,208                           |
| Total                             | ¥1,400          | ¥1,400 | \$13,208                           |

## 7. Accounting for Leases:

## Operating leases

Future minimum lease payments receivable under non-cancellable operating leases subsequent to March 31, 2018 and 2017, are as follows:

|                   | MILLIONS OF YEN |        | THOUSANDS OF<br>U.S. DOLLARS (NOTE 1) |  |
|-------------------|-----------------|--------|---------------------------------------|--|
|                   | 2018            | 2017   | 2018                                  |  |
| Due within 1 year | ¥ 940           | ¥ 239  | \$ 8,868                              |  |
| Due after 1 year  | 7,919           | 1,610  | 74,708                                |  |
| Total             | ¥8,859          | ¥1,849 | \$83,575                              |  |

## 8. Investment Properties:

The Company mainly owns rental office buildings (including land) in Tokyo and other areas. Rental income from these properties for the years ended March 31, 2018 and 2017 was ¥1,655 million (\$15,613 thousand) and ¥1,629 million (Revenue from rental properties and its related expenses are reported as net sales and cost of sales), respectively.

Carrying amount, changes during the years ended March 31, 2018 and 2017, and fair value of these properties are stated as follows:

MILLIONS OF YEN

THOUSANDS OF U.S. DOLLARS (NOTE 1)

|                                      | 2018    | 2017    | 2018      |
|--------------------------------------|---------|---------|-----------|
| Carrying amount:                     |         |         |           |
| Balance at the beginning of the year | ¥11,018 | ¥11,199 | \$103,943 |
| Changes during the year              | (265)   | (181)   | (2,500)   |
| Balance at the end of the year       | 10,752  | 11,018  | 101,434   |
| Fair value at the end of the year    | ¥43,722 | ¥41,653 | \$412,472 |

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

2. Fair value at March 31, 2018 and 2017 is calculated, with adjustments using indexes, by the Company based primarily on the "Real estate appraisal standards of Japan."

#### 9. Financial Instruments:

#### (a) Outline of financial instruments

#### (1) Policy for 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 later.

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

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 shares held to maintain business collaborations with clients and trade partners, which are exposed to the risk of market price fluctuations.

Payment terms of payables, such as notes and accounts payable–trade and electronically recorded obligations–operating, are within one year. Payables in foreign currencies incurred from the import transactions of raw materials are exposed to foreign exchange fluctuation risk. 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 exposed to trade receivables and payables denominated in foreign currencies. Please see Note 2. Summary of Significant Accounting Policies, (m) 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 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 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 connections), etc.

Derivative transactions are conducted under the authority of the general manager at each concerned department, under the forward foreign exchange contracts management rules, and the actual performance of derivative transactions is reported to the concerned departments including the Accounting Department, as each transaction takes place. Then at the end of each month, the outstanding balance of forward 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

The Company manages its liquidity risk by the Accounting Department preparing and updating the cash flow 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 and values determined reasonably when there is no market price. Since variable factors are incorporated in computing the relevant fair values, such fair values may vary depending on different assumptions.

(5) Concentration of credit risks

As of March 31, 2018, 66% 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, 2018 and 2017 are as below. Financial instruments whose fair values are not readily determinable are excluded from the following table:

|   |                 | 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        | ¥—         |

|   |                 | MILLIONS OF YEN |              |  |  |  |
|---|-----------------|-----------------|--------------|--|--|--|
|   | Carrying amount | Fair value      | Difference   |  |  |  |
|   |                 | 2017            |              |  |  |  |
| (1) Cash and deposits                             | ¥33,867         | ¥33,867         | ¥—           |  |  |  |
| (2) Notes and accounts receivable–trade           | 28,231          | 28,231          | _            |  |  |  |
| (3) Marketable and investment securities          |                 |                 |              |  |  |  |
| a. Held-to-maturity debt securities               | 8,999           | 8,999           | _            |  |  |  |
| b. Available-for-sale securities                  | 16,781          | 16,781          | _            |  |  |  |
| Total assets                                      | ¥87,879         | ¥87,879         | ¥—           |  |  |  |
| (1) Notes and accounts payable–trade              | ¥ 9,854         | ¥ 9,854         | ¥—           |  |  |  |
| (2) Electronically recorded obligations-operating | 1,307           | 1,307           | <del>_</del> |  |  |  |
| (3) Short-term bank loans                         | 3,875           | 3,875           | _            |  |  |  |
| Total liabilities                                 | ¥15,036         | ¥15,036         | ¥—           |  |  |  |
|   |                 |                 |              |  |  |  |

#### THOUSANDS OF U.S. DOLLARS (NOTE 1)

|   | Carrying amount | Fair value | Difference |
|---|-----------------|------------|------------|
|   |                 | 2018       |            |
| (1) Cash and deposits                             | \$425,425       | \$425,425  | \$-        |
| (2) Notes and accounts receivable–trade           | 314,292         | 314,292    | _          |
| (3) Marketable and investment securities          |                 |            |            |
| a. Held-to-maturity debt securities               | 56,594          | 56,594     | _          |
| b. Available-for-sale securities                  | 188,962         | 188,962    | _          |
| Total assets                                      | \$985,283       | \$985,283  | \$-        |
| (1) Notes and accounts payable–trade              | \$115,132       | \$115,132  | \$-        |
| (2) Electronically recorded obligations–operating | 11,774          | 11,774     | _          |
| (3) Short-term bank loans                         | 36,557          | 36,557     | _          |
| Total liabilities                                 | \$163,462       | \$163,462  | \$-        |

#### Notes

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

#### Assets:

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

These assets are recorded using carrying amounts because fair values approximate carrying amounts due to their short-term maturities.

## (3) Marketable and investment securities

Fair values of equity securities are based on the prices quoted on stock exchanges while those of debt securities are based on the prices quoted on stock exchanges, or those quoted by correspondent financial institutions. For the notes 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
These payables are recorded using carrying amounts because fair values approximate carrying amounts due to their short-term maturities.

2. Financial instruments whose fair values are not readily determinable

MILLIONS OF YEN

THOUSANDS OF U.S. DOLLARS (NOTE 1)

|                            | Carrying amount |     |       |
|----------------------------|-----------------|-----|-------|
|                            | 2018 2017 2018  |     |       |
| Unlisted equity securities | ¥57             | ¥61 | \$538 |

The above item is not included in "(3) Marketable and investment securities" because there is no market price and it is very difficult to identify fair values.

3. Redemption schedules of monetary assets and securities with contractual maturities subsequent to March 31, 2018 and 2017, are as follows:

MILLIONS OF YEN

THOUSANDS OF U.S. DOLLARS (NOTE 1)

Within one year

|   | ,       |         |           |
|---|---------|---------|-----------|
|   | 2018    | 2017    | 2018      |
| Cash and deposits   | ¥45,095 | ¥33,867 | \$425,425 |
| Notes and accounts receivable–trade                       | 33,315  | 28,231  | 314,292   |
| Marketable and investment securities:                     |         |         |           |
| Held-to-maturity debt securities                          | 5,999   | 8,999   | 56,594    |
| Available-for-sale securities with contractual maturities | 1,600   | 900     | 15,094    |
| Total   | ¥86,010 | ¥71,998 | \$811,415 |

4. Redemption schedules for long-term debt and other interest-bearing obligations subsequent to March 31, 2018 and 2017 are omitted since the Company only had short-term bank loans maturing within one year as of March 31, 2018 and 2017.

## 10. Retirement Benefits:

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

## Defined benefit plans

(a) Changes in the retirement benefit obligation for the years ended March 31, 2018 and 2017 are as follows (excluding plans under the simplified method):

|   | MILLIONS OF YEN |         | THOUSANDS OF U.S. DOLLARS (NOTE 1) |
|---|-----------------|---------|------------------------------------|
|   | 2018            | 2017    | 2018                               |
| Retirement benefit obligation-Beginning balance | ¥21,173         | ¥21,918 | \$199,745                          |
| Service cost                                    | 758             | 766     | 7,151                              |
| Interest cost                                   | 63              | 65      | 594                                |
| Actuarial differences                           | 26              | 59      | 245                                |
| Retirement benefit paid                         | (1,472)         | (1,637) | (13,887)                           |
| Retirement benefit obligation–Ending balance    | ¥20,549         | ¥21,173 | \$193,858                          |

(b) Changes in the plan assets for the years ended March 31, 2018 and 2017 are as follows (excluding plans under the simplified method):

|                                | MILLIONS OF YEN |         | THOUSANDS OF<br>U.S. DOLLARS (NOTE 1) |
|--------------------------------|-----------------|---------|---------------------------------------|
|                                | 2018            | 2017    | 2018                                  |
| Plan assets-Beginning balance  | ¥13,151         | ¥13,067 | \$124,066                             |
| Expected return on plan assets | 307             | 305     | 2,896                                 |
| Actuarial differences          | 555             | (22)    | 5,236                                 |
| Employer's contributions       | 581             | 590     | 5,481                                 |
| Retirement benefit paid        | (827)           | (790)   | (7,802)                               |
| Plan assets-Ending balance     | ¥13,769         | ¥13,151 | \$129,896                             |

(c) Changes in the net defined benefit liability under the simplified method for the years ended March 31, 2018 and 2017 are as follows:

|   | MILLIONS OF YEN |      | THOUSANDS OF<br>U.S. DOLLARS (NOTE 1) |
|---|-----------------|------|---------------------------------------|
|   | 2018            | 2017 | 2018                                  |
| Net defined benefit liability-Beginning balance | ¥7              | ¥6   | \$66                                  |
| Retirement benefit cost                         | 0               | 0    | 0                                     |
| Net defined benefit liability–Ending balance    | ¥7              | ¥7   | \$66                                  |

(d) Net balance of the retirement benefit obligation and plan assets, and net balances shown on the consolidated balance sheets are as follows:

|   | MILLIONS OF YEN |          | THOUSANDS OF U.S. DOLLARS (NOTE 1) |
|---|-----------------|----------|------------------------------------|
|   | 2018            | 2017     | 2018                               |
| Retirement benefit obligation under funded plan       | ¥ 20,549        | ¥ 21,173 | \$ 193,858                         |
| Plan assets   | (13,769)        | (13,151) | (129,896)                          |
|   | 6,779           | 8,022    | 63,953                             |
| Retirement benefit obligation under non-funded plan   | 7               | 7        | 66                                 |
| Net balances shown on the consolidated balance sheets | 6,787           | 8,029    | 64,028                             |
| Net defined benefit liability                         | 6,787           | 8,029    | 64,028                             |
| Net balances shown on the consolidated balance sheets | ¥ 6,787         | ¥ 8,029  | \$ 64,028                          |

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 under simplified method is included.

(e) The components of retirement benefit cost are as follows:

|   | MILLIONS OF YEN |        | THOUSANDS OF<br>U.S. DOLLARS (NOTE 1) |
|---|-----------------|--------|---------------------------------------|
|   | 2018            | 2017   | 2018                                  |
| Service cost                                      | ¥ 758           | ¥ 766  | \$ 7,151                              |
| Interest cost                                     | 63              | 65     | 594                                   |
| Expected return on plan assets                    | (307)           | (305)  | (2,896)                               |
| Amortization of actuarial differences             | 675             | 668    | 6,368                                 |
| Amortization of prior service cost                | (33)            | (33)   | (311)                                 |
| Retirement benefit cost under simplified method   | 0               | 0      | 0                                     |
| Retirement benefit cost for defined benefit plans | ¥1,156          | ¥1,162 | \$10,906                              |

(f) The components of remeasurements of defined benefit plans in other comprehensive income (before tax effect) for the years ended March 31, 2018 and 2017 are as follows:

|                       | MILLIONS OF YEN |        | THOUSANDS OF<br>U.S. DOLLARS (NOTE 1) |
|-----------------------|-----------------|--------|---------------------------------------|
|                       | 2018            | 2017   | 2018                                  |
| Prior service cost    | ¥ (33)          | ¥ (33) | \$ (311)                              |
| Actuarial differences | 1,205           | 586    | 11,368                                |
| Total                 | ¥1,171          | ¥553   | \$11,047                              |

(g) The components of remeasurements of defined benefit plans in accumulated other comprehensive income (before tax effect) for the years ended March 31, 2018 and 2017 are as follows:

|                                    | MILLIONS OF YEN |         | THOUSANDS OF<br>U.S. DOLLARS (NOTE 1) |
|------------------------------------|-----------------|---------|---------------------------------------|
|                                    | 2018            | 2017    | 2018                                  |
| Unrecognized prior service cost    | ¥ (105)         | ¥ (138) | \$ (991)                              |
| Unrecognized actuarial differences | 1,436           | 2,641   | 13,547                                |
| Total                              | ¥1,330          | ¥2,502  | \$12,547                              |

#### (h) Plan assets

(1)Plan assets consist of the following:

|                   | 2018 | 2017 |
|-------------------|------|------|
| Debt securities   | 31%  | 42%  |
| Equity securities | 50   | 38   |
| General account   | 15   | 16   |
| Other             | 4    | 4    |
| Total             | 100% | 100% |

Note: The plan assets include retirement benefit trust which accounted for 6% and 7% of the total plan assets as of March 31, 2018 and 2017, respectively.

- (2) Long-term expected rate of return on plan assets is determined based on assumptions about allocation of plan assets and long-term expected rate of returns on such assets.
- (i) Major assumptions used for actuarial calculation are as follows (weighted average):

|                                   | 2018 | 2017 |
|-----------------------------------|------|------|
| 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, 2017  | 48,439,730                  | 7,568,472               |
| Increase                              | _                           | 552,130                 |
| Decrease                              | _                           | (144)                   |
| Number of shares as of March 31, 2018 | 48,439,730                  | 8,120,458               |

- Notes: 1. Increase in treasury stock (552,130 shares) is due to purchase of shares in the market (550,000 shares) based on the resolution of the Board of Directors' meeting and purchase of shares of less than one unit (2,130 shares).
  - 2. Decrease in treasury stock (144 shares) is due to purchase demand from shareholders holding share of less than one unit.

## (b) Matters related to dividends

(1) Dividend payment

Approvals by the ordinary general meeting of shareholders held on June 29, 2017, were as

follows:

Dividends on common stock

Total amount of dividends ¥3,065 million (\$28,915 thousand)

Dividends per share \$75.00 (\$0.71)

Record date March 31, 2017

Effective date June 30, 2017

Approvals by the Board of Directors' meeting held on November 6, 2017, were as follows:

Dividends on common stock

Total amount of dividends ¥3,024 million (\$28,528 thousand)

Dividends per share \$\ \text{\fomalian} \text{\fomalian} (\\$0.71)\$

Record date \$\ \text{September 30, 2017}\$

Effective date \$\ \text{November 30, 2017}\$

(2) Dividends whose record date is attributed to the accounting period ended March 31, 2018, but become effective after the said accounting period

The Company obtained the following approval at the ordinary general meeting of shareholders held on June 28, 2018:

Dividends on common stock

Total amount of dividends ¥3,023 million (\$28,519 thousand)

Dividends per share \$75.00 (\$0.71)

Record date March 31, 2018

Effective date June 29, 2018

## 12. Research and Development Costs:

Research and development costs included in selling, general and administrative expenses for the years ended March 31, 2018 and 2017 amounted to ¥8,152 million (\$76,906 thousand) and ¥6,450 million, respectively.

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

Loss on retirement of non-current assets for the years ended March 31, 2018 and 2017 consists of the followings:

|                                   | MILLION | U.S. DOLLARS (NOTE 1) |         |
|-----------------------------------|---------|-----------------------|---------|
|                                   | 2018    | 2017                  | 2018    |
| Buildings and structures          | ¥ 15    | ¥ 19                  | \$ 142  |
| Machinery, equipment and vehicles | 5       | 17                    | 47      |
| Construction in progress          | _       | 23                    | _       |
| Other                             | 144     | 63                    | 1,358   |
| Total                             | ¥165    | ¥123                  | \$1,557 |

## 14. Income Taxes:

Significant components of deferred tax assets and liabilities as of March 31, 2018 and 2017 are as follows:

|  | MILLIONS OF YEN |         | THOUSANDS OF<br>U.S. DOLLARS (NOTE 1) |  |
|--|-----------------|---------|---------------------------------------|--|
|  | 2018            | 2017    | 2018                                  |  |
| Deferred tax assets:   |                 |         |                                       |  |
| Accounts receivable-trade  | ¥ 44            | ¥ 56    | \$ 415                                |  |
| Loss of supplies   | 238             | 206     | 2,245                                 |  |
| Adjustment of gain on sales of land                                | 2,638           | 2,638   | 24,887                                |  |
| Amortization of research and development expenses                  | 202             | 83      | 1,906                                 |  |
| Amortization of long-term prepaid expenses                         | 645             | 334     | 6,085                                 |  |
| Provision for bonuses  | 382             | 394     | 3,604                                 |  |
| Provision for sales rebates  | 99              | 126     | 934                                   |  |
| Net defined benefit liability                                      | 2,234           | 2,614   | 21,075                                |  |
| Other  | 517             | 199     | 4,877                                 |  |
| Total  | 7,004           | 6,653   | 66,075                                |  |
| Valuation allowance  | (2,819)         | (2,664) | (26,594)                              |  |
| Deferred tax assets  | 4,185           | 3,989   | 39,481                                |  |
| Deferred tax liabilities:  |                 |         |                                       |  |
| Reserve for advanced depreciation of property, plant and equipment | (131)           | (138)   | (1,236)                               |  |
| Net unrealized holding gain on securities                          | (2,432)         | (2,035) | (22,943)                              |  |
| Deferred tax liabilities   | (2,563)         | (2,173) | (24,179)                              |  |
| Deferred tax assets, net   | ¥ 1,621         | ¥ 1,815 | \$ 15,292                             |  |

The Group is subject to several taxes based on income, which in the aggregate resulted in statutory tax rates of approximately 30.86% for the years ended March 31, 2018 and 2017. Reconciliation of the differences between the statutory tax rate and the effective tax rate for the years ended March 31, 2018 and 2017, is as follows:

|  | 2018   | 2017   |
|--|--------|--------|
| Statutory tax rate   | 30.86% | 30.86% |
| Increase (decrease) in taxes resulting from:                                 |        |        |
| Expenses not deductible for income tax purpose (e.g. entertainment expenses) | 0.43   | 0.39   |
| Income not included for income tax purpose (e.g. dividend income)            | (0.07) | (0.06) |
| Inhabitant per capita taxes  | 0.31   | 0.27   |
| Tax credit for research expenses   | (1.41) | (1.88) |
| Increase (decrease) in valuation allowance                                   | 0.57   | (0.06) |
| Other  | 0.53   | (0.33) |
| Effective tax rate   | 31.22% | 29.19% |

## **15. Related Party Transactions:**

There is nothing to be noted according to the disclosure requirements in Japan for the years ended March 31, 2018 and 2017.

## 16. Per Share Information:

Per share information for the years ended March 31, 2018 and 2017, is as follows:

|                      | YE        | U.S. DOLLARS (NOTE 1) |         |
|----------------------|-----------|-----------------------|---------|
|                      | 2018      | 2017                  | 2018    |
| Net assets per share | ¥2,824.32 | ¥2,511.68             | \$26.64 |
| Profit per share     | 470.54    | 536.70                | 4.44    |

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, 2018 and 2017 is as follows:

|  | MILLION | THOUSANDS OF<br>U.S. DOLLARS (NOTE 1) |           |
|--|---------|---------------------------------------|-----------|
|  | 2018    | 2017                                  | 2018      |
| Profit   | ¥19,043 | ¥22,017                               | \$179,651 |
| Profit attributable to common stock owners of parent | 19,043  | 22,017                                | 179,651   |
| Profit not attributable to common stock              | _       | _                                     | _         |
| (Share data)   |         |                                       |           |
| Average number of shares (thousand)                  | 40,470  | 41,022                                |           |

## 17. Comprehensive Income:

Recycling and income tax effects for each component of other comprehensive income for the years ended March 31, 2018 and 2017, are as follows:

|  | MILLION | MILLIONS OF YEN |          |
|--|---------|-----------------|----------|
|  | 2018    | 2017            | 2018     |
| Net unrealized holding gain on securities: |         |                 |          |
| Amount increased for the year              | ¥1,295  | ¥ 523           | \$12,217 |
| Recycling                                  | _       | (252)           | _        |
| Before income tax effect                   | 1,295   | 270             | 12,217   |
| Income tax effect                          | (396)   | (82)            | (3,736)  |
| Net unrealized holding gain on securities  | ¥ 898   | ¥ 187           | \$ 8,472 |
| Remeasurements of defined benefit plans:   |         |                 |          |
| Amount increased for the year              | ¥ 529   | ¥ (81)          | \$ 4,991 |
| Recycling                                  | 642     | 635             | 6,057    |
| Before income tax effect                   | 1,171   | 553             | 11,047   |
| Income tax effect                          | (360)   | (170)           | (3,396)  |
| Remeasurements of defined benefit plans    | ¥ 811   | ¥ 382           | \$ 7,651 |
| Total other comprehensive income           | ¥1,710  | ¥ 570           | \$16,132 |

## 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.

(b) Method of calculating net sales, income, 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." Income 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.

<sup>&</sup>quot;Real estate" mainly rents out Bunkyo Green Court.

## (c) Information about reportable segments

#### MILLIONS OF YEN

|   | Reportable segment |             |         |             |              |
|---|--------------------|-------------|---------|-------------|--------------|
|   | Pharmaceuticals    | Real estate | Total   | Adjustments | Consolidated |
|   |                    |             | 2018    |             |              |
| Net sales:  |                    |             |         |             |              |
| Outside sales   | ¥96,022            | ¥ 2,407     | ¥98,430 | ¥ –         | ¥ 98,430     |
| Intersegment sales or transfers                                 | _                  | _           | _       | _           | _            |
| Total   | ¥96,022            | ¥ 2,407     | ¥98,430 | ¥ –         | ¥ 98,430     |
| Segment income  | ¥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        |

#### MILLIONS OF YEN

|   |                 | Reportable segment |          |             |              |
|---|-----------------|--------------------|----------|-------------|--------------|
|   | Pharmaceuticals | Real estate        | Total    | Adjustments | Consolidated |
|   |                 |                    | 2017     |             |              |
| Net sales:  |                 |                    |          |             |              |
| Outside sales   | ¥99,093         | ¥ 2,386            | ¥101,479 | ¥ —         | ¥101,479     |
| Intersegment sales or transfers                                 | _               | _                  | _        | _           | _            |
| Total   | ¥99,093         | ¥ 2,386            | ¥101,479 | ¥ —         | ¥101,479     |
| Segment income  | ¥29,078         | ¥ 1,629            | ¥ 30,707 | ¥ —         | ¥ 30,707     |
| Segment assets  | ¥76,876         | ¥10,815            | ¥ 87,692 | ¥47,367     | ¥135,060     |
| Other items:  |                 |                    |          |             |              |
| Depreciation and amortization                                   | ¥ 1,780         | ¥ 317              | ¥ 2,098  | ¥ —         | ¥ 2,098      |
| Increase in property, plant and equipment and intangible assets | 1,603           | 87                 | 1,690    | _           | 1,690        |
|   |                 |                    |          |             |              |

## THOUSANDS OF U.S. DOLLARS (NOTE 1)

|   | Reportable segment |             |           |             |              |
|---|--------------------|-------------|-----------|-------------|--------------|
|   | Pharmaceuticals    | Real estate | Total     | Adjustments | Consolidated |
|   |                    |             | 2018      |             |              |
| Net sales:  |                    |             |           |             |              |
| Outside sales   | \$905,868          | \$22,708    | \$928,585 | <b>\$</b> — | \$ 928,585   |
| Intersegment sales or transfers                                 | _                  | _           | _         | _           | _            |
| Total   | \$905,868          | \$22,708    | \$928,585 | \$ -        | \$ 928,585   |
| Segment income  | \$243,774          | \$15,613    | \$259,396 | \$ -        | \$ 259,396   |
| Segment assets  | \$805,632          | \$99,566    | \$905,208 | \$532,679   | \$1,437,896  |
| Other items:  |                    |             |           |             |              |
| Depreciation and amortization                                   | \$ 17,887          | \$ 2,858    | \$ 20,755 | \$ -        | \$ 20,755    |
| Increase in property, plant and equipment and intangible assets | 27,651             | 387         | 28,038    | _           | 28,038       |

The adjustments to segment assets of  $\pm 56,464$  million ( $\pm 532,679$  thousand) and  $\pm 47,367$  million for the years ended March 31, 2018 and 2017, respectively, present corporate assets which do not allocate 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 has not been disclosed since sales in Japan constituted more than 90% of sales on the consolidated statements of income.

## (2) Property, plant and equipment

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

## (f) Information about major customers

|                     | MILLIONS OF YEN |         | U.S. DOLLARS (NOTE 1) |                             |
|---------------------|-----------------|---------|-----------------------|-----------------------------|
|                     | Sales           |         |                       | Name of the related segment |
|                     | 2018            | 2017    | 2018                  |                             |
| Alfresa Corporation | ¥17,069         | ¥17,375 | \$161,028             | Pharmaceuticals             |
| SUZUKEN CO., LTD.   | 15,779          | 16,357  | 148,858               | Pharmaceuticals             |
| MEDICEO CORPORATION | 14,573          | 15,016  | 137,481               | Pharmaceuticals             |

## 19. Subsequent Event:

## Acquisition of treasury stock

Based on the provisions of Article 156 of the Companies Act (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, 2018.

## (a) Reason for acquisition:

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

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

Common stock

## (c) Number of stock to be acquired:

Up to 600,000 shares

## (d) Total amount of stock to be acquired:

Up to ¥4,000 million (\$37,736 thousand)

## (e) Schedule for acquisition:

From May 10, 2018 to December 28, 2018

## (f) Method of acquisition:

Purchase on the Tokyo Stock Exchange

Based on the aforementioned resolution, the Company acquired 92,800 shares of its common stock in a total amount of ¥568 million (\$5,358 thousand) by the end of May 2018.

## **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, 2018, 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, 2018, 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, to the consolidated financial statements, the Company resolved to acquire treasury stock at the Board of Directors' meeting held on May 9 2018.

#### 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 meije andit & Co

Tokyo, Japan June 28, 2018

# **Corporate Data and Stock Information**

As of March 31, 2018

## **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 1,389 (consolidated)

Branches Sapporo Branch (Sapporo City, Hokkaido)

Sendai Branch (Sendai City, Miyagi) Tokyo Branch and Tokyo Branch II (Toshima-ku, Tokyo)

Nagoya Branch (Nagoya City, Aichi) Osaka Branch (Osaka City, Osaka) Chugoku and Shikoku Branch

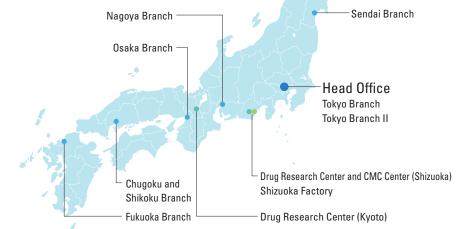
(Hiroshima City, Hiroshima)
Fukuoka Branch

● Sales Offices (Fukuoka City, Fukuoka)
49 locations across Japan

(as of August 1, 2018)

Drug Research Centers Kyoto City, Kyoto; Fujieda City, Shizuoka

●CMC Center Fujieda City, Shizuoka ●Factory Fujieda City, Shizuoka



Sapporo

Branch



Head Office (Tokyo)



Drug Research Center (Kyoto)



Shizuoka Factory

## Stock Information

Authorized: 193,000,000 shares Issued: 48,439,730 shares

Number of Shareholders: 10,268

Stock Exchange

Listing:

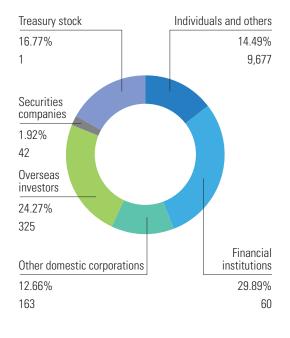
Tokyo Stock Exchange

Securities Code: 4521

Shareholder Register Sumitomo Mitsui Trust Bank,

Administrator: Limited

## Breakdown by Shareholder Type



## Major Shareholders (top 10)

| Shareholders   | Number of shares (thousands) | Shareholding ratio (%) |
|--|------------------------------|------------------------|
| The Master Trust Bank of Japan,<br>Ltd. (Trust Account)                          | 2,433                        | 6.03                   |
| Toray Industries, Inc.   | 2,294                        | 5.69                   |
| The Norinchukin Bank   | 1,843                        | 4.57                   |
| Japan Trustee Services Bank, Ltd. (Trust Account)                                | 1,552                        | 3.85                   |
| Mizuho Bank, Ltd.  | 1,474                        | 3.66                   |
| BNP PARIBAS SECURITIES SERVICES<br>LUXEMBOURG/JASDEC SECURITIES/<br>UCITS ASSETS | 1,003                        | 2.49                   |
| KYORIN Pharmaceutical Co., Ltd.  | 852                          | 2.11                   |
| Japan Trustee Services Bank, Ltd. (Trust Account 5)                              | 689                          | 1.71                   |
| Nippon Life Insurance Company  | 680                          | 1.69                   |
| GOVERNMENT OF NORWAY   | 631                          | 1.57                   |

(Note) The shareholding ratios are calculated by subtracting the number of treasury stock (8,120,458 shares) from the total number of shares issued.

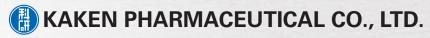


Information on the "Investor Relations" available in the Company's website

You will have access to financial statements, Annual 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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