

# ANNUAL REPORT Year ended March 31, 2018

# Kyorin continues to fulfill its mission of cherishing life and benefiting society by contributing to better health.

**Long-Term Vision** 

HOPE100 (Aim for Health Of People and our Enterprises)

#### Statement

The Kyorin Group will promote diversified healthcare business expansion and by 2023 be recognized both within and outside as a company that supports sound and healthy lifestyles.

#### Five HOPEs Corporate Objectives

Be a company that contributes to people's health through the Consumer Healthcare Business Company that Suppor Be a company employees can be proud of, **Healthy Lifestyles** Be a company that promotes business expansion overseas have trust in, and make united efforts for Around the World Be a company that is well-regarded Be a company that maintains for its products and services and practices The Leading A Company that positive business results excellent Monozukuri Company for Career Company that Sustains Growth and excellent financial standing **Customers Trust** Be a company with a positive brand image **Fulfillment** Be a company that works to foster positive relationships A Company that with society Seeks to Co-Exist Be a company that acts with the social good in mind with Society

#### Contents

To Our Stakeholders · · · · · · · · · · · · · · · · · · ·	2	Ethical Drugs Business · · · · · 14	Financial Analysis · · · · · · · · · · · · · · · · · ·	40
History of the Kyorin Group	4	Healthcare Business	Consolidated Financial	42
The Kyorin Group's Vision	4	Reliability Assurance 25	Statements	42
and Value Creation Process		Corporate Governance	Notes to Consolidated Financial Statements	47
Performance Highlights · · · · · · · · · · · · · · · · · · ·	8	· ·		
Overview of Medium-Term Business Plan H0PE100–Stage 2–	9	Directors, Corporate Auditors, and Corporate Officers	Independent Auditor's Report	67
Interview with the President · · · · · · · · · · · · · · · · · · ·	10	Corporate Social Responsibility	Corporate Overview/ Stock Information	68

**Editorial Policy** 

Annual Report 2018 integrates financial reports with information on the Group's environmental, social and governance (ESG) activities. In line with the framework established by the International Integrated Reporting Council, the report combines results and other financial data with nonfinancial information relating to value creation by the Kyorin Group, including business processes and strategies. Through this approach, we aim to help stakeholders gain a deeper understanding of the Group's activities.

Target Readers Shareholders, investors and other stakeholders

Period Covered by Report

Fiscal 2017 (April 1, 2017 to March 31, 2018); some information also relates to fiscal 2018 activities.





#### Corporate Mark

The corporate mark consists of three curved lines that form a heart-shaped apricot. The lines represent the smiles of patients, their families, and workers in medical services, as well as Kyorin's three core businesses, namely prevention, treatment, and prognosis.

Orange: Honesty and warmth

Violet: The technology that brings confidence

Light Green: Free and lively creativity

#### To Our Stakeholders

To realize our corporate philosophy, "Kyorin continues to fulfill its mission of cherishing life and benefiting society by contributing to better health," the Kyorin Group formulated HOPE100 as a long-term vision for 2023, which marks the 100th anniversary of the founding of our core subsidiary, KYORIN Pharmaceutical Co., Ltd.

Going forward, we will strive to enhance corporate value over the medium to long term by comprehensively integrating our ethical drugs and healthcare businesses and working to disperse business risks, with the aim of achieving healthy, continuous growth as "a company that supports sound and healthy lifestyles."



Minoru Hogawa Representative Director, President and Chief Executive Officer

# Consolidating the strength of all employees to implement a speedy "transformation," based on the medium-term business plan HOPE100-Stage 2-

Against a backdrop of efforts to preserve financial resources to cover the cost of Japan's social security system through the pursuit of increased efficiency in medical expenditures and the reining in of drug prices, the ethical drugs industry is experiencing unprecedented, major changes at a speed that had not been anticipated.

Given this situation, the achievement of continuous growth will require that we anticipate changes in the external environment and appropriately address those changes more quickly. We also consider it important to lay out new growth scenarios, and to act independently and autonomously. The Kyorin Group is currently operating under the medium-term business plan HOPE100–Stage 2–, covering the period from fiscal 2016 to 2019, as the second step toward the achievement of the long-term vision HOPE100, as we strive for continuous growth and the creation of corporate value over the medium to long term. Our statement for Stage 2 is "making reforms (changes and innovations) and achieving continuous growth in an effort to realize our long-term vision," as we pursue our business strategies (four priority strategies and two development strategies) and organization strategies. In fiscal 2018, all Group employees will work together as one to implement a speedy transformation, while specifically striving to achieve the plan's numerical targets with a maximum focus on strengthening our foundation for growth and increasing our earnings strength.

We ask for the continued understanding and support of all of our stakeholders.

July 2018

Minoru Hogawa

mho

Representative Director, President and Chief Executive Officer KYORIN Holdings, Inc.

# History of the Kyorin Group

KYORIN Pharmaceutical Co., Ltd., the core company within the Kyorin Group, was established 95 years ago. During that time, we have worked sincerely to embody our corporate philosophy of "Benefiting society by contributing to better health." We will tirelessly continue to pursue this challenge by evolving as a company that supports sound and healthy lifestyles through businesses related to curing and preventing disease and maintaining and promoting health.

1923»1950

1951>>1980

1981»2001











#### •198

Mucodyne, a mucoregulant, was launched

#### •1982

Norfloxacin (NFLX) was licensed to Astra (Sweden, present AstraZeneca) and Boots (U.K., present Abbott).

#### •1983

Norfloxacin (NFLX) was licensed to American Home Products (U.S.A., present Pfizer).

#### 1984

Baccidal (NFLX), a broad-spectrum oral antibacterial agent, was launched

#### **•**1986

Fleroxacin (FLRX), an antibacterial agent, was licensed to F. Hoffmann-La Roche (Switzerland).

#### •1989

Ketas, for bronchial asthma and cerebrovascular disorders, was launched.

Baccidal Eyedrops, a broad-spectrum ophthalmic antibacterial agent, was launched.

#### •1993

Megalocin (FLRX), a long-acting new quinolone agent, was launched.

#### •1996

Gatifloxacin (GFLX) was licensed to Bristol-Myers Squibb (U.S.A.).

#### •2000

Gatifloxacin-eyedrops was licensed to Allergan (U.S.A.).

#### •2001

Kipres, a leukotriene receptor antagonist and bronchial asthma treatment medicine, was launched.

#### •196

Behyd, a diuretic and antihypertensive agent, was launched.

#### •1965

KYORIN AP-2, an analgesic, was launched. Deamelin-S, an oral hypoglycemic agent, was launched.

#### •1971

Cholexamin, a lipid metabolism and peripheral circulation improving agent, was launched.

#### •1974

Hespander, a plasma substitute and extracorporeal circulation flow improver, was launched.

#### •1976

Hydroxyethylstarch (HES) was licensed to Pfrimmer (Germany, present Baxter Deutschland).

#### •1980

Norfloxacin (NFLX), an antibacterial agent, was licensed to Merck & Co. (U.S.A.).

#### 1923

Toyo Shinyaku Sha, the predecessor of KYORIN Pharmaceutical Co., Ltd., was founded.

#### • 1931

Kyorin Chemical Laboratory was established.

#### • 1940

Kyorin Chemical Laboratory was renamed KYORIN Pharmaceutical Co., Ltd., and Kyorin Yakuhin Co., Ltd. was organized as an independent marketing division.

#### •10/17

The Okaya Plant was started

#### 1957

The medical journal bulletin "Doctor Salon" was started.

#### 1962

Kyorin Chemical Laboratory (later Technical Center of Development) was established.

#### 100F

The Head Office was completed in Kanda Surugadai.

#### •1977

Central Research Laboratories were established.

#### **a**1000

KYORIN Pharmaceutical Co., Ltd. and Kyorin Yakuhin Co., Ltd. were merged, and the new KYORIN Pharmaceutical Co., Ltd. was founded.

#### •1995

The Noshiro Plant was started.

#### **•**1996

A joint venture, Nisshin KYORIN Pharmaceutical Co., Ltd., was established with Kyorin's capital participation.

The Research Center (now the WATARASE Research Center)

#### •1998

Milton, an effervescent disinfectant business, was acquired from P&G

#### 1000

Listed on the Tokyo Stock Exchange, Second Section.

#### • 2000

Listed on the Tokyo Stock Exchange, First Section.

#### •200

A subsidiary company, Kyorin USA, Inc. (U.S.A.), was established.

#### Origin of the Name "Kyorin"

The name Kyorin originated from two Chinese characters that represent a truly virtuous way of practicing medicine. It is derived from Chinese folklore, and embodies the Kyorin Group's aspirations to continuously contribute to the betterment of people's health in any day and age.

Long ago, a Chinese physician named Dong Feng treated the sick free of charge, and asked those who recovered from serious illness to plant five apricot tree saplings and those cured of minor illness to plant one. As time went by, a thick forest of apricot trees was formed in the area. (A story that comes from a Chinese legend named Shinsen-den) "Kyorin" is a compound of "kyo," the Chinese word for "apricot," and "rin," the Chinese word for "woods." Praising the virtue of Dong Feng, the characters were transported from China to Japan as those representing medicine and medical treatment in general.



#### **Corporate Vision for 2023**

Long-Term Vision HOPE100 (FY2010-FY2023)

2002>>2013



--»2023







•2002

Gatiflo (GFLX), a broad-spectrum oral antibacterial agent, was launched.

**2007** 

Uritos Tablets 0.1 mg, an overactive bladder drug, was launched.

Kipres Fine Granules 4 mg, a bronchial asthma treatment drug, was launched.

A business transfer agreement was made with the Fresenius Kabi AG Group in Germany concerning Hespander and Salinhes, plasma substitutes and hemodilution agents.

Kipres Tablets 5 mg, a bronchial asthma and allergic rhinitis treatment drug, was launched

•2009

A license agreement for Neramexane, a tinnitus drug, was made with Merz Pharmaceuticals (Germany) for the Japan region.

Mucodyne DS 50%, a mucoregulant, was launched.

Uritos Orally Disintegrating (OD) Tablets 0.1 mg, an overactive bladder drug,

•2012

RUBYSTA, a multi-purpose disinfectant cleaner, was launched. Transfer of business related to a topical antifungal prescription drug Pekiron cream 0.5% to Galderma S.A. (Switzerland).

Pentasa Suppositories 1 g, a treatment for ulcerative colitis, was launched. Flutiform, a combination drug for asthma treatment, was launched.

A subsidiary company, Kyorin Europe GmbH (Germany), was established.

2004

ActivX Biosciences, Inc. (U.S.A.) became a wholly owned subsidiary.

The stock of Toyo Pharma Co., Ltd. (present KYORIN Rimedio Co., Ltd.) was acquired, making it into a subsidiary company.

Dr. Program Co., Ltd. became a wholly owned subsidiary.

The Kyorin Group shifts to a holding company structure through a share exchange with KYORIN Co., Ltd.

The new Noshiro Plant began operating.

·2008

KYORIN Pharmaceutical Co., Ltd. merged with Nisshin Kyorin Pharmaceutical Co., Ltd.

•2010

KYORIN Co., Ltd. changed its name to KYORIN Holdings, Inc.

The Shiga Plant of MSD K.K. was acquired (conversion into subsidiary) and KYORIN Pharmaceutical Facilities Co., Ltd. (head office: Shiga Prefecture) was established

The Head Office was moved to Ochanomizu sola city in Kanda Surugadai.

Medium-Term Business Plan Fiscal 2010–2015

Stage

Business Plan Fiscal 2016–2019

Stage 2

Medium-Term Business Plan Fiscal 2020 – 2023

Stage 3

A company that supports

Signed a license agreement concerning Vibegron, a therapeutic agent for overactive bladder, with Merck & Co. (U.S.A.).

•2015

Eklira Genuair, a treatment for COPD, was launched. FPR2 Agonist Program was licensed to Bristol-Myers Squibb Company (U.S.A.). Kipres OD, a treatment for bronchial asthma and allergic rhinitis, was launched. Pentasa Granules 94%, a treatment for ulcerative colitis and Crohn's disease, was launched.

Montelukast Tablets "KM" was launched. Desalex 5 mg Tablets, an antiallergic agent, was launched.

**2018** 

Signed a license agreement with SANWA KAGAKU KENKYUSHO CO., LTD. for KRP-N118 (SK-1404), a therapeutic agent for the treatment of nocturia, covering Japan and Asia. Acquired the exclusive distribution rights in Japan for NASONEX® Nasal, a therapeutic agent for allergic rhinitis using a metered-dose manual pump spray unit, from MSD K.K.

KYORIN Pharmaceutical Co., Ltd.'s WATARASE Research Center was established.

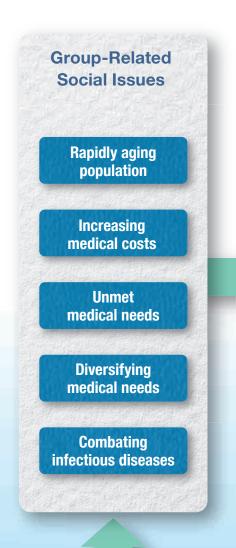
All shares of Dr. Program Co., Ltd. were transferred to Taisho Pharmaceutical Co., Ltd. KYORIN Rimedio Co., Ltd.'s Takaoka Drug Discovery Laboratory was established. KYORIN Pharmaceutical Co., Ltd. acquired all of the outstanding shares of jTAS Inc., and carried out an absorption-type merger of jTAS.

2018

New manufacturing subsidiary, KYORIN Pharmaceutical Group Facilities Co., Ltd. (head office: Tokyo), commences operations

# The Kyorin Group's Vision and Value Creation Process

The Kyorin Group's mission is to create and provide innovative new drugs that contribute to the health of people around the world on an ongoing basis, and we consider this to be the source of our value creation. We aim to continue to grow with the ethical drugs business as our core business. At the same time, we are meeting diverse medical needs by developing an integrated healthcare business as a way to supplement the growth of the ethical drugs business. We are also working to address social issues from an environment, social, and governance (ESG) perspective as we strive to enhance our corporate value.





The long-term vision HOPE100 was formulated in 2010 in anticipation of the 100<sup>th</sup> anniversary of the founding of KYORIN Pharmaceutical, the Group's core subsidiary, in 2023. The period covered by HOPE100 is broken down into three stages (Stage 1: fiscal 2010–15; Stage 2: fiscal 2016–19; Stage 3: fiscal 2020–23), and we are currently operating under the medium-term business plan HOPE100–Stage 2–.

Corporate Vision for 2023 Long-Term Vision

HOPE100

A Company That Supports Healthy Lifestyles

Aiming to integrate our ethical drugs business and healthcare business and to disperse business risks with a focus on enhancing corporate value over the medium to long term, for healthy, continuous growth.



## **Healthcare Business**

#### **Environmental hygiene**

Working to grow into a core business

#### Over-the-counter drugs and others

• Contributing to diversified needs such as self-medication

**Production** 

Sales

**Governance (ESG) Activities** 

Value Provided to Stakeholders

**Creation of new innovative products** 

Providing outstanding products and services

Responding to unmet medical needs

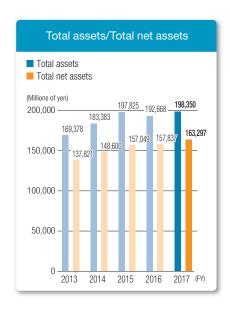
Enhancing the quality of life of patients and their families

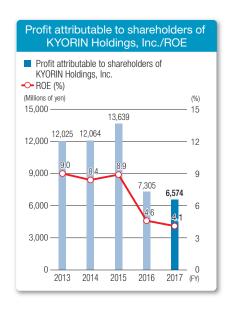
Combating infectious disease through environmental hygiene, diagnosis, and medical treatment

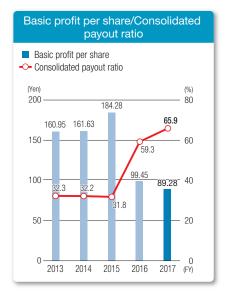
## **Performance Highlights**

#### Consolidated Financial Highlights

KYORIN Holdings, Inc. and Consolidated Subsidiaries					Millions of yen
Fiscal years ended March 31/As of March 31	FY2013	FY2014	FY2015	FY2016	FY2017
Net sales	¥111,400	¥113,121	¥119,483	¥115,373	¥110,640
Operating income	17,607	14,737	19,636	10,413	8,822
Profit attributable to shareholders of KYORIN Holdings, Inc.	. 12,025	12,064	13,639	7,305	6,574
Net cash provided by operating activities	19,293	6,391	11,137	16,386	10,456
Net cash provided by (used in) investing activities	(2,477)	(1,364)	650	(13,142)	(6,038)
Net cash used in financing activities	(3,704)	(5,233)	(2,245)	(5,721)	(3,735)
Free cash flow	16,816	5,027	11,787	3,244	4,418
R&D expenses	11,359	13,514	13,019	13,569	14,243
Capital expenditures	6,500	2,655	7,218	3,051	2,885
Depreciation and amortization	3,153	3,053	3,730	3,619	3,628
Total assets	169,378	183,383	197,825	192,668	198,350
Total net assets	137,821	148,600	157,049	157,837	163,297
	,	,	,	,	Yen
Amounts per Share					
Net assets	¥1,844.61	¥2,009.45	¥2,131.67	¥2,146.83	¥2,214.13
Basic profit	160.95	161.63	184.28	99.45	89.28
Cash dividends	52.00	52.00	58.00	58.00	58.00
Key Performance Indicators					
Operating income margin (%)	15.8	13.0	16.4	9.0	8.0
Profit attributable to shareholders of KYORIN Holdings, Inc. / Net sales ratio (%)	10.8	10.7	11.4	6.3	5.9
R&D expenses / Net sales ratio (%)	10.2	11.9	10.9	11.8	12.9
Total shareholders' equity ratio (%)	81.4	81.0	79.4	81.9	82.3
ROE (%)	9.0	8.4	8.9	4.6	4.1
ROA (%)	7.4	6.8	7.2	3.7	3.4
Consolidated payout ratio (%)	32.3	32.2	31.8	59.3	65.9
Number of employees	2,452	2,445	2,420	2,382	2,348







## Overview of Medium-Term Business Plan HOPE100-Stage 2-

With the business environment for the ethical drugs business becoming ever more challenging and the patent on one of our main products having expired, the Kyorin Group is facing major changes in its operating environment. Given these significant external changes, we need to implement a dynamic transformation of the way we have done business to date and create and implement new measures that go beyond our historical growth track. We have established "making reforms (changes and innovations) and achieving continuous growth" as our statement for our HOPE100–Stage 2– medium-term business plan, and are pursuing the areas of **Strategy** (business strategies: four priority strategies and two development strategies) and **Organization** (organizational strategies) to achieve **Performance** (performance targets).



#### **5**trategy

#### **Priority strategies**

Enhancing drug discovery capabilities: Initiatives for first-in-class new drug discovery

Increasing the ratio of new drugs group:
Significantly increase the ratio of new drugs group by promoting the group to the greatest extent possible

Promoting generic drugs business by making the most of its characteristics

Enhancing cost reductions:
Change of cost structure
by ensuring optimization
within the Group

#### **Priority items**

#### Build a structure that continuously creates innovative new drugs

- Identify novel drug discovery targets in franchise customer areas.
- Create first-in-class new drugs utilizing existing drug discovery platforms based on low molecular weight (kinase and receptors) and new technologies (peptides, gene therapy, etc.).
- Aim for early collaboration with global partners to accelerate the global expansion and development of original new drugs.

#### Increase the ratio of new drugs group to offset sales declines

- Aim to launch four new drugs (Desalex, KRP-AM1977X/KRP-AM1977Y, and KRP-114V) and promote these new products along with Flutiform to the greatest extent possible.
   Realign the marketing structure
- Restructure along the lines of area management based on franchise customer strategy.

#### Proactively address authorized generics (AG)

- Aim to acquire a large share within the generics market for Montelukast Tablets "KM".
- Consider new AG acquisitions to follow Montelukast Tablets "KM".

#### Comprehensively optimize production capabilities through cooperation within the Group

- Manufacture at appropriate locations without regard to distinctions between new drugs group, original drugs group, and generic drugs group.
- Remove imbalances in plant capacity utilization and pursue the efficient use of assets.

#### **Development strategies**

**Overseas expansion** 

**Enhancing healthcare business** 

#### **Priority items**

- Partner to promote the global expansion of innovative new drugs created by Kyorin (with early inroads into the U.S. and Europe) and capture overseas sales.
- Work in collaboration with other companies to lay the foundations for future direct expansion (ethical drugs business, healthcare business), with a focus on Asia.
- Expand the environmental hygiene business and strengthen cooperation with existing businesses to create a core business.



#### Organization

#### Aiming to be the leading company for career fullfillment for employees

#### Establishing and operating a system for managing human resources

 Build and operate a human resources management system that is based on creating mutually beneficial cooperation and symbiotic long-term relationships between the Company and its employees.

#### Strengthening human resources development

•Work to strengthen management capabilities.



#### Performance

#### **Numerical targets**

#### Final targets for Stage 2

- Consolidated net sales: average annual growth rate of 3% or more
- •Consolidated operating income margin: 15% or more

#### Capital policy

- Invest for growth and provide stable returns to shareholders while maintaining a healthy financial base
- Returns to shareholders: stable dividends



The growth of Japan's ethical drug industry slowed during fiscal 2017, on efforts to make medical expenditures more efficient and rein in drug prices, against a backdrop of preserving financial resources needed to fund social security expenses. At the Kyorin Group, the full-year effect on sales from the expiry of the patent of our main product created a situation requiring unprecedented corporate action. During fiscal 2017, we worked to refine our pharmaceutical business model to facilitate continuous growth at the ethical drugs business while searching for new core businesses to drive the healthcare business, under a management policy of "Promoting reform by consolidating diverse knowledge."



## How would you summarize Kyorin's financial results for fiscal 2017?



Sales and profit declined owing to certain factors including lower sales of new drugs in Japan.

Net sales in fiscal 2017 declined ¥10.1 billion from the previous year with large decreases in long listed drugs including Kipres and Mucodyne, though solid growth from Flutiform and Desalex, our main new drug products in Japan, was confirmed. Overseas sales of new drugs grew ¥2.5 billion, on one-time income from progress in the development of the out-licensed FPR2 agonist program, and sales of generic drugs rose ¥2.7 billion, on increased

sales of Montelukast Tablets "KM." Sales at the healthcare business were roughly flat, with sales of hand hygiene products offsetting the effect of a business transfer in skincare products. As a result, consolidated net sales for the year declined 4.1% from the previous year, to ¥110,640 million.

Profit declined mainly from a decrease in gross profit as a result of lower new drug sales in Japan, an increase in disposals of inventory assets, and the effects of foreign exchange rate movements. The cost of sales declined on progress in cost reductions, despite an increase in research and development expenses from one-time outlays for in-licensing contracts. As a result, operating income declined 15.3% from the previous year, to ¥8,822 million.



What progress has been made under the medium-term business plan HOPE100 –Stage 2–?



We moved forward aggressively with our priority strategies and development strategies, with the aim of fully achieving our targets.

We moved forward aggressively with the strategies included in the medium-term business plan HOPE100–Stage 2– (from fiscal 2016 to 2019): the four priority strategies of enhancing drug discovery capabilities, increasing the ratio of the new drugs group, promoting the generic drugs business by making the most of its characteristics, and enhancing cost reductions, and the two development strategies of enhancing the healthcare business and overseas expansion.

Enhancing our drug discovery capabilities is the most important issue we face, and in addition to proprietary drug discovery through cooperation between the WATA-RASE Research Center in Japan and ActivX Biosciences of the United States, we pursued open innovation with domestic and overseas pharmaceutical companies, academic institutions, and venture start-ups to revitalize existing drug discovery platforms and make use of new technologies (peptides, gene therapy, and so forth).

To increase the ratio of the new drugs group, we strove to generate further growth from Flutiform and Desalex and to increase prescriptions of Uritos and Pentasa Granules, to counteract the decline in new drugs with other new drugs. In addition, in May 2018 we acquired the exclusive sales rights for NASONEX Nasal spray, a therapeutic agent for allergic rhinitis using a metered-dose manual pump spray unit, from MSD K.K., and plan to commence sales in August 2018. In addition, KRP-114V and KRP-AM1977X are moving closer to market launches, and we aim to achieve the medium-term business plan's final-year target of having a new drug ratio of at least 50% of the ethical drugs business in fiscal 2019.

With regard to promoting the generic drugs business by making the most of its characteristics, Montelukast Tablets "KM" has achieved a more than 50% share in the generic market. We will pursue the development of next authorized generics going forward.

To enhance cost reductions, we have consolidated our group manufacturing functions by establishing the new manufacturing subsidiary KYORIN Pharmaceutical Facilities Co., Ltd., and in April 2018 we merged KYORIN Pharmaceutical's Noshiro Plant, KYORIN Rimedio's Manufacturing Division, and the former KYORIN Pharmaceutical

Facilities into this new subsidiary. This is intended to enhance cost reductions by removing imbalances in plant capacity utilization and making more efficient use of assets.

With regard to our development strategies, the health-care business is marking sales growth from hand hygiene products that we began selling in the previous fiscal year, and we intend to expand the business further with products related to environmental hygiene. We are also developing a new diagnostic business using the GeneSoC® ultrahigh-speed genetic measurement device, and will work to grow this business into a next core business.

Through these activities, we will work to strengthen our foundation for growth and increase our earnings strength in fiscal 2018.



Please tell us more about your efforts "to strengthen the foundation for growth and increase earnings strength" in fiscal 2018.



We intend to strengthen our foundation for continuous growth and create new markets through new drug discovery.

Today, it has become clearer than ever that new drugs are the source of growth for our core business of ethical drugs, and we intend to strengthen our foundation for growth by putting even more effort into the new drug business. Determined to become a first-in-class drug discovery company, we will work to be able to carry out multilayered program development on a single theme, while strongly pursuing selection and concentration in drug discovery programs, to create innovative new drugs with global potential. We will also proactively explore external drug discovery programs, and quickly build a structure for an assessment system as we strive to bolster our drug discovery programs and proactively pursue open innovation in drug discovery research.



Furthermore, in terms of our medium- to long-term growth trajectory, we need a promising R&D pipeline. Our top priority is the rapid expansion of our pipeline through stepped-up investment in in-licensing, and we will work to build a platform for continuous growth over the medium term by creating a continuous stream of new drugs.

KYORIN Pharmaceutical Co., Ltd. is currently carrying out research and development of seven compounds, and one compound is being out-licensed. In terms of progress in domestic development during fiscal 2017, we began Phase III clinical trials for KRP-108P, a combination drug for asthma treatment, in June 2017. The application for marketing approval of KRP-114V, an overactive bladder treatment, was filed in September 2017, and we aim to bring this product to market during fiscal 2018. Following additional non-clinical trials, the review has recommenced for KRP-AM1977X, a quinolone synthetic antibacterial agent for which the application was filed in April 2017, and we are now aiming for a market launch early in fiscal 2019.

In the priority area of urology, we concluded a licensing agreement with Sanwa Kagaku Kenkyusho Co., Ltd. for KRP-N118 (SK-1404), a therapeutic agent for the treatment of nocturia, in March 2018. With regard to out-licensing, the U.S. company Bristol-Myers Squibb has begun Phase I clinical trials of the FPR2 agonist program, which is a promising sign for Kyorin's future.

The Kyorin Group is also working to increase the speed at which we maximize the market presence of our major products and make an early penetration of our new drugs to the market. During fiscal 2018, as noted previously, we will bring KRP-114V to market, while at the same time further increasing sales of our main products, Flutiform and Desalex, and marketing NASONEX Nasal spray, which is currently in co-promotion, and aim to work to create new markets with new drugs.

Flutiform has recorded solid sales growth since its release in 2013, and we are forecasting fiscal 2018 sales of ¥12.3 billion. Based on its appeal and our efforts to promote this drug based on its superior ability to penetrate and reach the whole lung system from central to peripheral airways, Flutiform is aimed to acquire a position as a first-line drug in asthma treatment.

Desalex was launched in 2016, and since then has been a focus of the Group's marketing strength in otolaryngology (ear, nose, and throat). As a result, Desalex jumped to the No. 2 position among otolaryngological prescriptions as of the end of fiscal 2017, and we aim for it to become the No. 1 drug in its field during fiscal 2018 in recognition

of its high degree of effectiveness, lack of associated drowsiness, and ease of use. Drug manufacturers have released new drugs for numerous antiallergy treatments in recent years, and this itself appears to have stimulated the market. We expect the market to continue to grow, and are forecasting a ¥3.2 billion increase in Desalex sales in fiscal 2018, to ¥8.1 billion.

NASONEX Nasal spray has one of the largest shares of the roughly ¥43 billion market for steroid nasal sprays. KYORIN Pharmaceutical Co., Ltd. began a co-promotion agreement with MSD K.K., the manufacturer and seller of NASONEX Nasal spray, in 2016, and concluded a contract for the exclusive distribution rights in Japan. We are forecasting sales of ¥10.1 billion in fiscal 2018. In the growing market for overactive bladder treatments, we plan to launch KRP-114V during fiscal 2018, and with this product in addition to Uritos, a drug for overactive bladder treatments, we expect our share of the market for overactive bladder treatments to increase.

**A**-2

We are working to accelerate growth at peripheral businesses and increase our earnings strength, as we proactively pursue even lower costs.

At the generic drug business, one of the Kyorin Group's main businesses, we are continuing with the proactive development of authorized generics. KYORIN Rimedio Co., Ltd. has received approval to manufacture and sell an authorized version of NASONEX Nasal spray, so we expect to be able to continue with smooth operations after the patent has expired. We plan to have the diagnostic business operation by 2020, and are considering its global expansion. The healthcare business is placing its top priority on increasing earnings, and we will continue to invest the profits from these peripheral businesses into new drugs which are the driving force of the Group's growth.

In addition, with annual revisions of drug prices potentially occurring, lowering manufacturing costs and reducing manufacturing expenses are pressing issues. We are working toward the early establishment of a new manufacturing structure organized around KYORIN Pharmaceutical Facilities, our new manufacturing subsidiary, and along with setting a firm course for removing imbalances in plant capacity utilization and making effective use of assets, we are carrying out reviews at existing businesses with the aim of reducing all expenses.

Through these activities "to strengthen the foundation for growth and increase earnings strength," we will make every effort to achieve a 3.4% increase in net sales, to ¥114.4 billion, in fiscal 2018, with a 2.5% decrease in operating income, to ¥8.6 billion.



Please tell us about your environmental, social, and governance (ESG) initiatives.



We are proactively addressing ESG issues, with the aim of continuous growth and the enhancement of corporate value over the medium to long term.

We recognize that contributing to all stakeholders – from patients and medical professionals to shareholders and investors, employees, business partners, and local communities - is essential to the Kyorin Group's continuous growth. Based on this recognition, and given the recent heightened increase globally in environmental and social issues, we are stepping up our efforts to address environmental, social, and governance issues.

In addition to working proactively for the continuous creation of innovative new drugs that are the source of the Group's corporate value, and contributing to people's health, the long-term vision HOPE100 also identifies compliance and risk management, human resources management, environmental management, and social contribution activities as key themes, and we are addressing ESG issues as a corporate citizen. Based on the belief that invigorated employees and organizations are the driving force behind corporate growth, we value employees and aim to be their first choice as a satisfying place to work. Along with restructuring our human resources management and strengthening the development of human resources, we are beginning environmental preservation activities with a sense of being part of the local communities in which we operate and new social contribution activities in which all employees participate.

With regard to corporate governance, we are concentrating on expediting decision making, strengthening appropriate management oversight functions, and ensuring transparency in corporate activities firmly rooted in our corporate ethics, to create and bolster a management environment that will be trusted by the general public. We have established a voluntary Committee on Remuneration and Nominations, and actively engage our outside directors. Through these initiatives, we will strive for the enhancement of corporate value and continuous growth.



#### Do you have a message for stakeholders?



By implementing speedy transformation, we are working to meet our fiscal 2018 numerical targets in full, and achieve our medium-term business plan.

Under the medium-term business plan HOPE100-Stage 2-, the Kyorin Group's basic capital policy is to maintain a healthy financial foundation while investing for growth and providing a stable return to shareholders. Although we are facing a period of temporary profit decline with the expiry of the patent for Kipres occurring during the period covered by the medium-term business plan, we expect this to be followed by an earnings recovery, and based on this outlook and our policy of maintaining a stable recovery, we kept the full-year dividend for fiscal 2017 unchanged at ¥58 per share.

We will continue to aim to achieve the numerical targets for fiscal 2018 set in the medium-term business plan HOPE100-Stage 2- as we work toward the achievement of the long-term vision HOPE100. I ask for the continued support of all stakeholders going forward.







## **Medium-Term Business Plan**

HOPE100-Stage 2-

**Priority Strategies** 

Enhancing drug discovery capabilities

Initiatives for first-in-class new drug discovery

The Kyorin Group considers its mission to be the continuous creation of innovative new drugs that address medical needs and contribute to the health of people around the world. At the WATARASE Research Center, our research and development base, we are clarifying our areas of priority research, selecting drug discovery programs and focusing on those programs, and pursuing multilayered drug discovery activities to create original new drugs with global potential. At the same time, we proactively search for and introduce outside drug discovery programs, for even faster first-in-class new drug discovery.

#### **Selection and Concentration**

By strengthening cooperation between the WATARASE Research Center, which possesses technology in low molecular weight drug discovery, and ActivX Biosciences in the US, which has the KiNativ™ platform (exhaustive analysis technology for kinase/protease), we are making maximum use of the two research sites' potential. These activities are concentrating resources and working on themes that have global potential, in the pursuit of effective drug discovery activities to create novel compound drugs.

By focusing our research on the priority project of kinase research and fibrosis research, we are working to bolster our early-exploration-stage themes (feasibility themes) both quantitatively and qualitatively, while at the same time acquiring backup compounds and multiple pharmacophores, to pursue multilayered drug discovery with a stronger backup structure that simultaneously evaluates different compounds from multiple basic structures.

#### Exploratory Research for New Targets Using Kinase Technology

The WATARASE Research Center is working with US affiliated company ActivX Biosciences in drug discovery that uses kinase analysis technology. There are more than 500 types of kinases, which control complex biological functions like cell specialization, multiplication, and apoptosis, and many of these functions have yet to be identified. ActivX has advanced, proprietary technologies that can

perform exhaustive analysis of kinases' activities at the cellular and organ level, and are also used in the U.S. National Institutes of Health (NIH) databases. The incorporation of this cutting-edge technology in our group is a major strength as our research pursues the creation of new, original drugs with global potential.

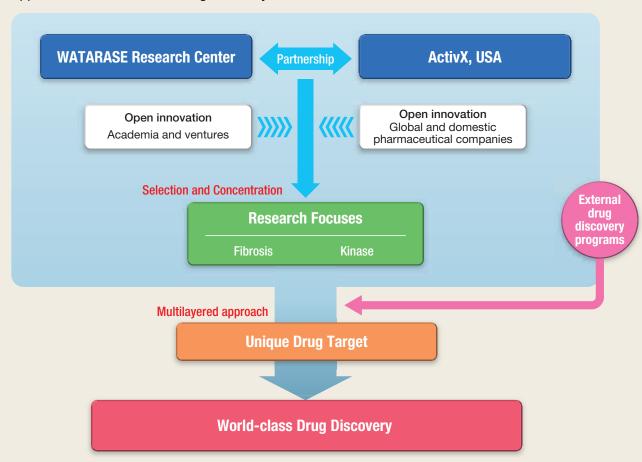


#### **Pursuit of Open Innovation**

KYORIN Pharmaceutical is supplementing and further strengthening its proprietary drug discovery by proactively searching for external drug discovery programs and external early-stage compounds, and using its own evaluation technology platforms in areas including bladder function, auditory function, and infectious diseases to create a structure that can carry out speedy evaluations. Part of this involves pursuit of open innovation with academic institutions, venture start-ups, and domestic and overseas pharmaceutical companies for multiple drug discovery approaches to drug creation targets.

In addition to our existing low molecular weight drug discovery, we are exploring new compounds including medium molecular weight compounds and nucleic acid medicines, and working in gene therapy to pursue possibilities in new modalities and create new, original drugs with global potential, while also promoting best-in-class new drug discovery with a high degree of completion.

#### Approach to "First-in-Class" Drug Discovery











## Medium-Term Business Plan

HOPE100-Stage 2-

**Priority Strategies** 

Increasing the ratio of the new drugs group

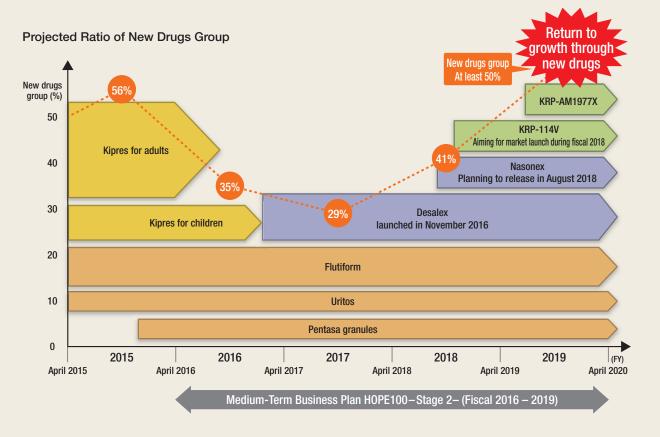
Significantly increase the ratio of new drugs group by promoting the group to the greatest extent possible

The Kyorin Group is strengthening its new drugs business to achieve continuous growth, and in particular we see increasing the ratio of the new drugs group as our top priority. In addition to promoting to the greatest extent possible key products on which we have patents, we are expanding our development pipeline to discover a constant stream of new drugs and create new markets.

#### Accelerating a Return to Growth Through the New Drugs Group and New Products

The expiry of the patent on Kipres, our main product, and an accelerating shift from long listed drugs to generics are creating a challenging business environment for the Kyorin Group, and against this backdrop, under "Stage 2" we are working to bring the ratio of the new drugs group, which at one point had fallen to the 20% level, to at least 50% by fiscal 2019. To achieve continuous growth, we will need to promote to the greatest extent possible new drugs still covered by patents (Flutiform, Desalex, Uritos, and Pentasa granules), and also bring drugs currently under development (KRP-114V, KRP-AM1977X/Y) to market without fail and begin promoting them for rapid market penetration. We aim to achieve our targets by strengthening our efforts related to the new drugs group.

During fiscal 2017, we applied for approval of KRP-AM1977X in April and for KRP-114V in September, and concluded Phase III clinical trials for KRP-AM1977Y. We are responding to inquiries related to the testing of KRP-114V, and aim to receive approval during fiscal 2018. In addition, sales of existing drugs during fiscal 2017 included an 18.1% increase for Flutiform, to ¥11.9 billion, and a 404.8% increase for Desalex, to ¥4.9 billion. We also concluded an in-licensing agreement for KRP-N118 as a new addition to our R&D pipeline, as we worked to expand our product portfolio to achieve continuous growth.



#### Raising Our Presence in the FC Fields

KYORIN Pharmaceutical, which handles new drugs, aims to establish a presence in the field of franchise customers (FC), focusing on the specific fields of respiratory, otolaryngology, and urology. Roughly 750 medical representatives (MRs) regularly visit specialist doctors to provide, collect, and pass on information regarding the appropriate use of pharmaceutical products.

During fiscal 2017, in the FC field of otolaryngology, MRs strove to promote a better understanding of the special features of high effectiveness, lack of drowsiness, and ease of use for the product Desalex, an antiallergic agent in its second year after release, and sales have shown solid growth. In addition, we have obtained the exclusive distribution rights in Japan for NASONEX® Nasal, a therapeutic agent for allergic rhinitis using a metered-dose manual pump spray unit, from MSD K.K., and intend to commence sales in August 2018. Together with the anti-bronchial asthma and allergic rhinitis drug Kipres, we have a product lineup that can meet a wide range of needs for the treatment of allergic rhinitis, and we expect our presence in the field of otolaryngology to grow further.

	Main Products	Development Pipeline
Respiratory	Flutiform Kipres Mucodyne Desalex Nasonex*	KRP-AM1977X/Y Ad-SGE-REIC KRP-108P
Urology	Uritos	KRP-114V KRP-N118 KRP-116D

<sup>\*</sup>Sales transferred from MSD K.K. (sales scheduled to commence in August 2018)

#### **Promoting Area Management**

KYORIN Pharmaceutical's marketing organization has introduced a "team structure" in which several MRs are responsible for a specific geographic area.

To address medical needs as they change with the times, area coverage is based on secondary medical districts, in an effort to understand the particular needs of various medical

professionals in their respective geographic areas. This area information is complicated, and by promoting our proprietary area management, we are able to respond swiftly and systematically, as we work proactively to be a company that is recognized by patients and medical professionals for the value we provide.

#### Addressing Unmet Medical Needs—Nocturia due to Nocturnal Polyuria

Nocturia is a condition in which a person has to wake up to urinate after having gone to sleep, and as the frequency increases with age, this becomes a significant impediment to a person's daily life. It is the most frequently diagnosed condition related to urination, and studies\* have shown that roughly 45 million men and women aged 40 and over wake up once during the night to urinate, and roughly 8.5 million wake up three times or more. Causes include nocturnal polyuria, decreased bladder capacity, and sleep disorders. Currently, there are no medications recommended for the treatment of nocturia due to nocturnal polyuria, and existing overactive bladder medications do not always bring sufficient improvement. KYORIN Pharmaceutical has acquired the exclusive development and sales rights in Asia and Japan for KRP-N118, a treatment for nocturia due to nocturnal

polyuria, from SANWA KAGAKU KENKYUSHO CO., LTD. By offering a new choice to persons who suffer from nocturia, we aim to contribute to an improved quality of life for patients.

#### **Causes of Nocturia** Nocturia **Overactive Nocturnal** Bladder (OAB) **Polyuria** Uritos (Anticholinergic agent)) KRP-N118 (Vasopressin V2 KRP-114V receptor agonist) (β3 receptor agonist)

\*Source: Honma, etc., "Epidemiologic Study Related to Urination" (2003)

#### **Four New Pharmaceutical Products**

## **Respiratory and Otolaryngology**



#### **Flutiform**

General name: Fluticasone/Formoterol Indication: Bronchial asthma

2013 Released:



## **Respiratory and Otolaryngology**



#### Desalex

General name: Desloratadine Indication: Allergic disease

2016 Released:

Co-promotion with Kaken Pharmaceutical Co., Ltd.,

in field of dermatology

#### Net sales (Billions of yen) 8 6 4.9 2 1.0 2016 2017 (FY)

## Urology



#### **Uritos**

General name: Imidafenacin Indication: Overactive bladder

2007 Released:

Co-development and joint sales with Ono Pharmaceutical Co., Ltd. (sold by Ono Pharmaceutical under the

name Staybla®)



## IBD\*



#### **Pentasa**

Released:

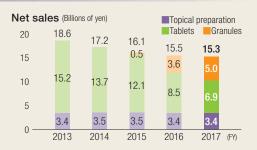
General name: Mesalazine

Indications: Ulcerative colitis, Crohn's

disease

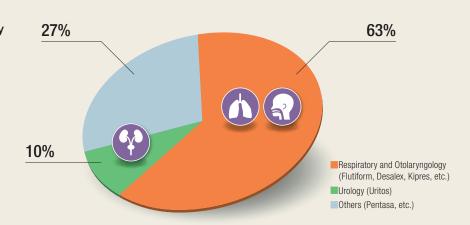
1996 2015 (granules)

\*Inflammatory Bowel Diseases



#### Percentage of sales by diagnostic category

Domestic pharmaceutical products (KYORIN Pharmaceutical)



#### Products under Development (As of May 10, 2018)

#### Ph III - Approval

Compound/Code	Therapy area/Action	Origin	Features				Stage			
				PhI		PhⅡ	<b>&gt;</b>	PhⅢ	<b>&gt;</b>	NDA
KRP-114V	Overactive bladder	Merck & Co. Inc. (U.S.A.)	<ul> <li>Expectation of high compliance in taking medicine with less side effects than conventional drugs for overactive bladder</li> <li>Less drug interaction as β3 receptor agonist</li> <li>β3 agonist including this agonist may constitute a first-line drug for treatment of overactive bladder.</li> </ul>		>		>		>	9/2017
KRP-AM1977X (Oral agent)	New quinolone synthetic antibacterial agent	In-house	Superior clinical efficacy of one 75 mg dose per day has been confirmed (community-acquired infection for respiratory and otolaryngology).  Shows strong antimicrobial activity against pathogenic bacteria for respiratory and otolaryngological infections and against beta-lactam and macrolide antimicrobial resistant strains.  Favorable penetration for lung tissue, more than 10 times that of blood plasma		>		>		>	4/2017
KRP-AM1977Y (Injection)	New quinolone synthetic antibacterial agent	In-house	A ravidable periodular for long issue, more than 10 times that of blood plasma ratio     Expectations for high level of safety     Lower likelihood of concerns associated with the same strain of antibacterial agent, including abnormal blood sugar levels, photosensitivity, arthropathy, and digestive symptoms.		>			3/2016		
KRP-116D	Interstitial cystitis	_	Dimethyl sulfoxide (DMSO), an unapproved and off-label drug with high medical needs		>			3/2017	>	
KRP-108P	Bronchial asthma	Vectura (U.K.)	Additional indication of pediatric use for Flutiform combination drug for asthma treatment		>			6/2017		

#### POC Project (Ph I - Ph II)

Compound/Code	d/Code   Therapy area/Action   Origin   Features					Stage				
				PhI		PhⅡ	<b>&gt;</b>	Ph <b>Ⅲ</b>	<b>&gt;</b>	NDA
KRP-N118 (SK-1404)	Nocturia due to nocturnal polyuria	SANWA KAGAKU KENKYUSHO CO., LTD.	A vasopressin V2 receptor agonist that promotes the reabsorption of water by the collecting duct of the kidney to reduce the amount of urine (antidiuretic action). With its high efficacy and safety, the drug is expected to be a therapeutic agent for nocturia due to nocturnal polyuria.						>	
Ad-SGE-REIC	Malignant pleural mesothelioma	Okayama University	A gene therapy drug that uses the new cancer-inhibiting gene REIC that was discovered at Okayama University. It is expected to induce the active development of cancer cell selective apoptosis and anticancer immunity.	7	7/2015	;			>	

#### Licensing Development (Preclinical)

Compound/Code	Licensee/Collaborative research	Therapy area/Action	Origin	Features	Comments		Stage			
						Preclinical Ph I	Ph∏	<b>Ph Ⅲ</b>	<b>&gt;</b> N	NDA
FPR2 agonist program	Bristol-Myers Squibb Company (U.S.A.)	Non-disclosure	In-house	FPR-2 agonists that mainly inhibit the migration of neutrophils and exhibit anti-inflammatory action	License agreement with Bristol-Myers Squibb (12/2015)	<b>&gt;</b>		<b>&gt;</b>	>	

#### Development Strategies)

#### Overseas expansion

As we move forward with the realignment of policies from a global perspective, overseas expansion is an important issue for the Kyorin Group. We are therefore developing initiatives that anticipate partnering and direct expansion focusing on Asia, to provide original new drugs to people around the world.

#### Alliance Strategy

KYORIN Pharmaceutical is working to reinforce and enhance its product pipeline. This is an important priority for us as a drug maker, and our approach includes both in-house drug discovery and active collaboration with external partners. We intend to continue striving to build an even more attractive product pipeline going forward.







## **Medium-Term Business Plan**

HOPE100-Stage 2-

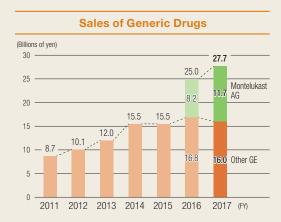
Priority Strategies

Promoting generic drugs business by making the most of its characteristics

KYORIN Rimedio Co., Ltd. is the core company for the Kyorin Group's generic drugs business, and is pursuing the priority strategy of promoting the generic drugs business by making the most of its characteristics. Generic drugs are now expected to account for 80% of the pharmaceutical market by volume in September 2020, and going forward, we will enhance our capability to respond to environmental changes as a manufacturer of generic versions of new types of drugs. Taking advantage of our integrated development, manufacturing, and sales functions, we aim to achieve high productivity and lower costs.

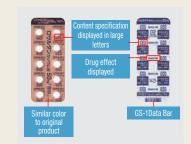
#### **Initiatives in Authorized Generics**

Our first product in this area was Montelukast Tablets "KM," the authorized generic version of Kipres. By handling both the original Kipres and the authorized generic within the Group, we are able to meet the various needs of patients and medical professionals, and this benefit has been recognized as we have steadily gained market share. We have maintained an approximately 60% share of the market for generic versions of Kipres, surpassing our initial target of 50%. The Kyorin Group has also received approval to begin working on an authorized generic version of NASONEX as our next authorized generic product. The timing for the release of this product will be strategically decided, as we work toward that point while following changes in the business environment.



#### Strengthening Drug Development at the Takaoka Drug Discovery Laboratory

To provide generic drugs that can be used with greater peace of mind, KYORIN Rimedio has been working on formulations and packaging that address ease of use by medical institutions and the needs of patients when taking drugs, from the perspectives of both medical professionals and patients. The Takaoka Drug Discovery Laboratory commenced full-scale operations in July 2017, with the aim of further strengthening our drug development. The Laboratory aims to develop higher quality drugs more quickly, and to offer attractive generic drug products with unique characteristics.





#### Licensing Agreement with Vietnamese Company for Drug Manufacturing Technology

In November 2017, KYORIN Rimedio concluded a licensing agreement with BinhDinh Pharmaceutical and Medical Equipment JSC of Vietnam for generic drug manufacturing technologies, under which we will begin offering licensed, locally manufactured products in Vietnam. Using Kyorin's drug manufacturing technologies to create new drug markets will contribute to people's health in Vietnam. We will also consider the possibility of subcontracted drug manufacturing.

# Special Feature

## **New Challenges in Diagnosing Infectious Diseases**

Business related to diagnosis of infectious diseases —

In recent years, while the inappropriate use of antimicrobial drugs has led to a global increase in drug-resistant bacteria, there has also been a decline in the development of new antimicrobial drugs, creating a major issue of an increasing number of deaths from infections by drug-resistant bacteria. Efforts to address antimicrobial resistance (AMR) are gaining urgency; the World Health Organization's 2015 World Health Assembly adopted a Global Action Plan on Antimicrobial Resistance, and in April 2016, the Japanese government formulated a National Action Plan on Antimicrobial Resistance (AMR) 2016–2020.

Going forward, the treatment of infectious diseases will require more robust measures to ensure that "appropriate drugs" are used "only when necessary" and "in appropriate amounts for appropriate periods of time." Early-stage promotion of examinations and diagnosis are also needed so that appropriate drugs can be selected at academic conferences on infectious disease and at medical facilities.

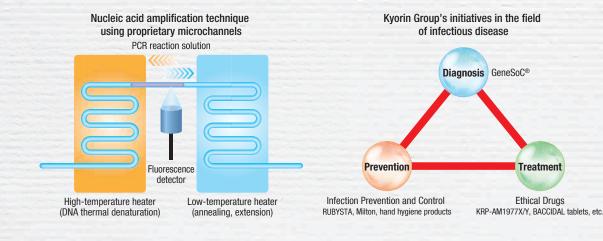
The Kyorin Group is taking up a new challenge by entering businesses related to the diagnosis of infectious diseases, to help address the international problem of AMR.

## Quickly bringing GeneSoC® to market and developing new diagnostics for infectious diseases into next core business

In July 2017, KYORIN Pharmaceutical Co., Ltd. acquired all of the outstanding shares of jTAS Inc., developer of the GeneSoC® ultrahigh-speed genetic measurement device, and subsequently carried out an absorption-type merger of the company. The GeneSoC® employs a nucleic acid amplification technique using proprietary microchannels to genetically test for pathogenic microorganisms in five to six minutes, enabling quick, accurate, and simple identification of pathogenic microorganisms. The device is a compact, table-top size, which makes it possible to select appropriate antimicrobial drugs on-site where the diagnosis is being made, and is therefore expected to be used for the diagnosis of infectious diseases that contribute to the appropriate use of antimicrobial



drugs. The use of the GeneSoC® ultrahigh-speed genetic measurement device in point of care testing (POCT) is diagnostic testing provided at, or near the patient bedside, making it possible to select appropriate drugs during the diagnosis, and we believe this will help to address AMR by promoting the proper use of antimicrobials. We are working to bring this product to market as quickly as possible, and to develop this into a next core business.







## **Medium-Term Business Plan**

HOPE100-Stage 2-

Priority Strategies

Enhancing cost reductions

Change of cost structure by ensuring optimization within the Group

Given the drastic environmental changes in Japan's pharmaceutical market, combined with lower sales of long listed drugs and the effect of annual drug price revisions on the Kyorin Group, we anticipate further declines in profitability. In response, we are consolidating and optimizing overall Group manufacturing functions in the pursuit of low-cost operations with a greater sense of speed, to build a competitive Group manufacturing structure that provides a stable supply of high-quality, low-cost products.

#### **New Manufacturing Subsidiary Commences Operations**

One of the priority strategies outlined in the HOPE100-Stage 2-medium-term business plan is "Enhancing cost reductions: Change of cost structure by ensuring optimization within the Group." To achieve this, we merged KYORIN Pharmaceutical's Noshiro Plant, KYORIN Rimedio's Manufacturing Division, and KYORIN Pharmaceutical Facilities into a new manufacturing subsidiary, KYORIN Pharmaceutical Group Facilities Co., Ltd., which commenced operations in April 2018. By consolidating the Group's manufacturing functions, the new manufacturing subsidiary will combine the respective strengths of its three plants – low-cost, high-volume manufacturing of new drugs, small-lot manufacturing of a large number of generic drug products, and subcontracted pharmaceutical manufacturing at global standards – to remove imbalances in plant capacity utilization and make efficient use of assets, which will lead to

increased productivity. We will further strengthen our efforts to maintain quality, ensure stable supplies, and reduce costs, and also build and operate a human resources management system that includes personnel exchanges and the sharing of information. We will also raise our Good Manufacturing Practices (GMP) level and technological level to enhance quality even further. These activities will contribute to the Group's development, and at the same time we will also concentrate on earnings growth by increasing subcontracted operations from outside the Group.

KYORIN Pharmaceutical Group Facilities will build a competitive manufacturing structure that offers a stable supply of high-quality products at a low cost, with the aim of becoming a pharmaceutical manufacturing subcontractor that is relied upon both inside and outside the Group.

#### **Strategic Promotion of Supply Chain Management**

Aiming to establish solid earnings strength in the face of environmental changes, the Kyorin Group is working to build a structure for more efficient manufacturing that offers a stable supply, with flexibility to address changes in demand, by comprehensively addressing the Group's entire supply chain. We are pursuing supply chain management (SCM) that manages (makes visible) the entire process from domestic and

overseas procurement of raw materials to manufacturing (production management, manufacturing), warehousing, and supply (shipping) on an individual product basis. By reducing lead times from orders to delivery and quickly addressing issues as they arise, we are working to ensure stable supplies and reduce risks, for reliable, stable supplies of products.

#### Supply Chain Management (SCM)



#### **Overview of KYORIN Pharmaceutical Group Facilities' Plants**

Noshiro Plant

Low-cost, high-volume manufacturing. Integrated manufacturing from pharmaceutical ingredients to finished products.

The Noshiro Plant began operating as KYORIN Pharmaceutical's pharmaceutical ingredient manufacturing plant, and a line that met global standards for finished product manufacturing began operating in 2006, resulting in a structure that can efficiently manufacture technologically advanced products in large volumes. High productivity resultant from automation makes it possible to manufacture large volumes at a low cost by the automated transport of pharmaceutical ingredients and intermediate products, and robotic arms. We will use this strength to manufacture generics for which demand is growing, in addition to new drugs, and also to increase subcontracted manufacturing from outside the Group.



(Noshiro City, Akita Prefecture)

Inami Plant

Small-lot manufacturing of numerous types of products, focusing on generic drugs.

The Inami Plant is our primary facility for generic drug manufacturing, and began operating as a Kyorin Group plant in 2005. The plant manufactures more than 200 products, including subcontracted manufacturing from outside the Group. The plant's specialty is its flexibility that enables it to manufacture small volumes of pharmaceutical products in various forms, including solid formulations taken internally, and liquid formulations including sterilized formulations for injections, eyedrops, and nose drops. Visits from drug manufacturers subcontracting to the plant provide information that has enabled the facility to gain expertise in maintaining stable supplies of high-quality products. To meet the growing demand for generic pharmaceutical products seen in recent years, manufacturing capacity is being increased, and efforts are being made to raise productivity and reliability even higher by optimizing the overall manufacturing structure in cooperation with the Noshiro Plant and the Shiga Plant.



(Inami, Nanto City, Toyama Prefecture)

Shiga Plant

#### Focusing on subcontracted manufacturing incorporating global GMP.

For many years the Shiga Plant was a manufacturing base for a non-Japanese pharmaceutical manufacturer, and in 2012 it began operating as part of the Kyorin Group. In addition to manufacturing the Group's main products, the plant is unique for its high portion of manufacturing subcontracted from outside the Group, including the manufacturing of pharmaceutical products to be sold in Japan by overseas manufacturers. Since its establishment, the facility has been compliant with GMP and has used manufacturing equipment with an awareness of waste containment, and today it continues to use the latest equipment to enable manufacturing that keeps pace with the needs of the times. Making use of the extensive experience and expertise gained from subcontracted manufacturing from overseas global companies, the facility is proactively working to increase subcontracted manufacturing from outside the Group and contribute to earnings growth.



(Koka City, Shiga Prefecture)



## **Medium-Term Business Plan**

HOPE100-Stage 2-

Development Strategy

Based on the medium-term business plan's development strategy to "Grow businesses related to environmental hygiene and strengthen their links to existing businesses to create a core business," the Kyorin Group is striving to expand our product lineup and increase sales in the area of environmental hygiene. With further growth at businesses related to environmental hygiene and stronger ties to existing businesses, we will build a core business, and proactively work to pave the way for potential new businesses.



#### Environmental Hygiene

Given the growing importance in recent years of preventing infections in daily operations at medical institutions, the Kyorin Group is developing and promoting hygiene management products to control the risk of various infections.

#### Multi-Purpose Disinfectant Cleaner RUBYSTA

The multi-purpose disinfectant cleaner RUBYSTA is widely used at medical institutions around the world to prevent infections and stop the spread of pathogenic microbes. In addition to expanding the business's product lineup, we are obtaining scientific evaluation data for further product promotion. Overseas, domestic sales have begun in Indonesia through PT. Meiji Indonesian Pharmaceutical Industries, a subsidiary of Meiji Seika Pharma Co., Ltd., and we are also considering new business possibilities in light of heightened awareness of infection management in the ASEAN region.



#### **Expansion of Hand Hygiene Products**

Hand hygiene is the most fundamental way of preventing infection through physical contact, therefore, medical practitioners are required to always maintain hand hygiene. In 2017, the Kyorin Group concluded a sales agreement with Air Liquide Japan, Ltd., expanding our lineup of hand hygiene products. We will continue to promote total hand hygiene as a way of preventing infection.



#### Milton Brand

Since its release in 1963, Milton has assisted mothers in protecting the healthy growth of infants, and today it is the leading brand of baby bottle disinfectant. Through its brand message, "unchanging safety into the future," Milton has achieved steady sales with the support of medical practitioners and general consumers that continues today. The lineup has been expanded further with the launch of Detergent Milton, which can be used to clean baby bottles, milkers, and vegetables, and we are also providing a wide range of information about the importance and appropriate methods for disinfecting in advance, which is necessary for ensuring complete disinfection.





#### Over-the-Counter Drugs

We are addressing diversifying health needs by offering over-the-counter drugs that can be used with peace of mind.

#### Over-the-Counter Drugs Addressing Diversifying Health Needs

With the Japanese government's introduction of a "self-medication tax system" (special tax deductions for medical expenses) in January 2017, people have become more aware of their health and health needs have been diversifying. The Kyorin Group sells the COOL ONE series of over-the-counter drugs that apply ingredients used in ethical drugs. This series is highly regarded because we are able to provide accurate information regarding the product's effectiveness and safety gained at the ethical drugs business. We will continue to work to provide products that are able to address diversifying health needs.



\*COOL ONE Cough Medicine GX tablets and syrup and COOL ONE expectorant capsules, are eligible under the self-medication tax system.

## **Reliability Assurance System**

### Reliability Assurance System

KYORIN Pharmaceutical's corporate vision aims to be "a pharmaceutical manufacturer that is trusted by patients and medical professionals, and is recognized for its presence in society." To achieve this, the company continuously needs to provide products and information that are trusted by broad sectors of society, and we consider this to be our highest priority. We take a unified approach to all operations—from (research

and) development to sales—and place a maximum emphasis on compliance with relevant laws and regulations, and on ensuring reliability. The Quality Assurance & Reliability HQs has primary responsibility in this area, and is independent from research and development, manufacturing, and sales divisions, and proactively works to provide products and information that patients and medical professionals can use with peace of mind.



GMP: Good Manufacturing Practice

GCP: Good Clinical Practice

GQP: Good Quality Practice

GVP: Good Vigilance Practice

GPSP: Good Post-marketing Study Practice



#### **Quality Assurance**

Quality assurance is carried on investigational new drugs based on GMP at the development stage, through compliance with GMP and GQP after sales, and by confirming that products are manufactured using appropriate equipment and according to

designated procedure manuals. After-sales inquiries regarding quality collected from patients and medical professionals are given the highest priority, and are addressed sincerely and quickly.



#### Safety Management

Drugs can be effective for treating patients (benefits) but can have adverse reactions (risks), and side effects that were not foreseen at the development stage can become apparent after sales. This is why it is important to collect and analyze a wide range of information regarding benefits and risks after a product is launched, and to provide appropriate information swiftly to medical facilities while taking into account the balance

between benefits and risks. At Kyorin, we strive to ensure safety and promote proper use by carrying out drug monitoring activities based on GVP. Post-manufacturing surveillance is carried out adhering to GPSP to collect and evaluate information regarding a drug's safety and effectiveness after the product is launched. The analyzed information is provided to medical professionals, and released in professional publications.

To achieve the long-term vision "The Kyorin Group will promote diversified healthcare business expansion and by 2023 be recognized both within and outside as a company that supports sound and healthy lifestyles." we consider it important to build a sophisticated system for ensuring the reliability of drugs handled by the Group and products sold by the healthcare business. By working to ensure the consistent reliability of Kyorin products and providing users with high-quality products that can be used "safely and with peace of mind," we are gaining the trust of broad sectors of society.

## **Corporate Governance**

The Kyorin Group will work to improve sustainable corporate value in order to gain the confidence and live up to the expectations of all stakeholders. As part of these efforts, the Group considers strengthening and enhancing corporate governance to be an important management issue.

#### **Basic Policy on Corporate Governance**

The most important management goal for KYORIN Holdings, Inc. is to continue raising shareholder value. To achieve this goal requires fostering a management environment that enables us to build trust with the general public. Therefore, having given better corporate governance a high priority, we seek to ensure prompt decision making, strong monitoring of the appropriateness of management, and to secure ethical and transparent corporate activities. To ensure transparency and fair disclosure, we release appropriate information without delay for the benefit of shareholders and investors. In the future, we intend to actively increase our disclosure of information, and expand and improve our communications with all stakeholders.

KYORIN Holdings, Inc. has appointed three outside directors to further strengthen the supervision of the business execution of directors, and to further enhance the transparency and fairness of management.

Kyorin is a company with a board of corporate auditors based on the Companies Act of Japan. The Board of Corporate Auditors, including the three outside corporate auditors, endeavors to fully demonstrate its auditing and supervising functions and to ensure the transparency of the decisions being made by the Board of Directors. At the same time, corporate auditors carry out a diverse range of activities in fulfilling their auditing

function. In addition to participating in important meetings, including those of the Board of Directors and the Management Committee, corporate auditors implement comprehensive audits by checking documents and other materials relating to important decisions and inspecting Group companies.

In addition, in recognition of our corporate social responsibility (CSR), for every Kyorin Group company we appoint compliance and risk management promotion officers. We have established a Group-wide compliance and risk management system that is administered by the Compliance Committee and Risk Management Committee. We have established guidelines for each affiliated company based on the Kyorin Compliance Guidelines and set up a system for employees to report and seek advice about possible irregularities. As well as the above measures, we have created management guidelines for affiliated companies and built a system of support that respects their autonomy. Under this system, we receive regular business reports from these companies and hold meetings with their management before deciding important issues. The Internal Audit Office conducts audits of affiliated companies based on internal audit guidelines. Based on the results of these audits, departments that oversee the operations of the affiliated companies issue instructions or warnings and provide appropriate guidance.

#### Corporate Governance System

Key Items	Description
Organizational design	Company with corporate auditors
Number of directors (including outside directors)	11 (3)
Number of corporate auditors (including outside corporate auditors)	5 (3)
Number of the Board of Directors' meetings (held during fiscal 2017)  (Average attendance rate of outside directors)  (Average attendance rate of outside corporate auditors)	12 times (100%) (94.4%)
Number of the Board of Corporate Auditors' meetings (held during fiscal 2017) (Average attendance rate of outside corporate auditors)	13 times (97.4%)
Term of office of directors	1 year
Adoption of the corporate officer system	Yes
Voluntary Committee of the Board of Directors	Committee on Remuneration and Nominations
Accounting auditing firm	Ernst & Young ShinNihon LLC

#### **Corporate Governance System**

#### **■** Board of Directors

The Company's Board of Directors comprises eleven directors (including three outside directors as of June 22, 2018). The Board of Directors usually meets once a month, deciding important operational matters in a timely manner after debating issues as well as supervising each director's duties.

#### **■** Board of Corporate Auditors

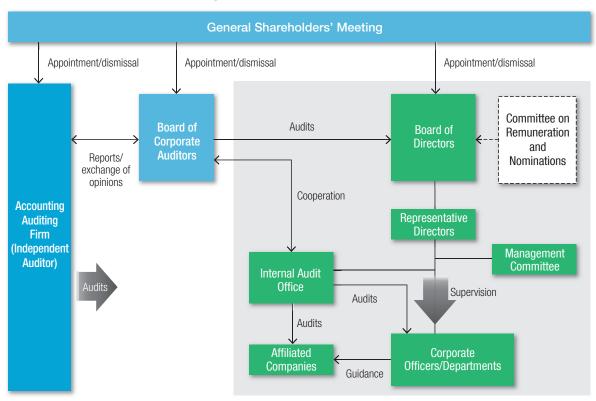
The Board of Corporate Auditors comprises two statutory corporate auditors and three outside corporate auditors, for a total of five corporate auditors (as of June 22, 2018). By capitalizing on such auditing and supervisory functions, we have built a system that facilitates highly transparent decision-making. Decisions on remuneration are made by the Board of Directors after monitoring by the voluntary Committee on Remuneration and Nominations.

Nomination of a candidate to become a director or corporate auditor is based on the selection of candidates regardless of gender or nationality, and who have outstanding characteristics and knowledge and appropriately strong awareness of compliance with laws and corporate ethics.

#### **■ Business Execution System**

To oversee business execution, we established a Management Committee, comprising the president and directors, which discusses key operational matters concerning the Group. In addition, the Company has introduced a corporate officer system in order to clarify the roles of those who are responsible for making business decisions and supervising business execution, and those who are responsible for business execution. As of June 22, 2018, the Company has four corporate officers.

#### Corporate Governance and Management Structure (As of June 22, 2018)



#### **Outside Directors and Outside Corporate Auditors**

Kyorin has three outside directors and three outside corporate auditors.

As an attorney well-versed in corporate law, outside director Noriyuki Shikanai has also served on the board of Keio University and in other important positions, and with his high degree of specialization and rich experience, was deemed well-qualified overall for appointment to outside director. In addition, no risk of conflicts of interest arising with our general shareholders was found that might affect the performance of his duties as outside director, and we recognize that he brings a high degree of independence to the position.

Outside director Ken Shigematsu has experience as an officer of Isetan Mitsukoshi Holdings Ltd. and other companies. With his wide-ranging insight developed from his rich management experience, Mr. Shigematsu was deemed well-qualified overall for appointment to outside director.

Outside director Yoh Goto has experience as an officer of the Teijin Group. With his wide-ranging insight developed from his rich management experience, Mr. Goto was deemed well-qualified overall for appointment to outside director.

Kyorin has three outside corporate auditors who are neutrally positioned and not compromised by relationships with management or specified parties having a special interest. These

outside corporate auditors all have a considerable level of knowledge of corporate legal matters, and matters of finance and accounting. We utilize their specialist understanding and wide-ranging knowledge and experience to strengthen and enhance our auditing functions. Outside corporate auditor Masaji Obata is well-versed in Corporation Law as a lawyer, and has considerable knowledge concerning finance and accounting. Outside corporate auditor Takao Yamaguchi has a considerable level of knowledge in matters of finance and accounting as a certified public accountant and a certified tax accountant.

Kyorin selects outside directors and outside corporate auditors based on a review of the individuals' backgrounds and relationship with Kyorin, and, from a standpoint independent from that of management, on the assumption that sufficient independence can be ensured that said individuals are able to adequately carry out their duties as outside directors and outside corporate auditors. The appointment of outside directors Noriyuki Shikanai and Ken Shigematsu and outside corporate auditors Masaji Obata and Takao Yamaguchi as independent directors/corporate auditors has been reported to the Tokyo Stock Exchange.

#### **Compensation of Directors and Corporate Auditors**

There are two forms of compensation for directors and corporate auditors: basic compensation and stock options. These are provided as incentives and compensation for the roles that directors and corporate auditors should play. Under the Kyorin Group corporate philosophy, the roles of the directors and corporate auditors include executing management based on management policy and taking into consideration the value creation of various stakeholders, and enhancing corporate value through the sustainable and stable growth of the Group. However, as outside

directors and outside corporate auditors perform their role of supervising and overseeing management from an independent position, payment is not linked to performance each year.

The voluntary Committee on Remuneration and Nominations deliberates in advance on the remuneration system for directors and basic policies, using industry standards and the Company's performance as reference, and the Board of Directors makes a decision based on such deliberations.

## Total compensation paid to each director or corporate auditor, total paid by type of compensation, and number of applicable directors and corporate auditors

Director or	Total compensation paid	Total paid by type of compensation (Millions of yen)	Number of applicable directors
corporate auditor	(Millions of yen)	Basic compensation	and corporate auditors (People)
Directors (Excluding outside directors)	253	253	9
Corporate auditors (Excluding outside corporate auditors)	34	34	2
Outside directors or corporate auditors	48	48	8

Note: The number of directors above includes three directors who retired as of April 1, 2017 and upon the conclusion of the 59th Ordinary General Shareholders' Meeting held on June 23, 2017.

#### **Internal Audits and Audits Conducted by Corporate Auditors**

Internal audits are conducted by the Internal Audit Office, which is staffed by six employees who report directly to the president, and is independent from other sections. Based on yearly auditing plans, the Internal Audit Office regularly assesses and evaluates the effectiveness and efficiency of the legal compliance and internal control systems in the parent and Group companies. After an audit, the office communicates any problems or areas that need improvement directly to the president and makes the appropriate recommendations.

Another function of the office is to evaluate the Group's internal controls over financial reporting. The office evaluates the development and operation of these internal controls according to a predetermined scope for evaluation, and makes a report to the president.

Corporate auditors conduct audits in line with an auditing policy and plan set by the Board of Corporate Auditors at the beginning of each fiscal year. In addition to participating in important meetings, including those of the Board of Directors and the Management Committee, corporate auditors implement comprehensive audits by checking documents and other

materials relating to important decisions and inspecting departments, facilities, and Group companies. In order to ensure that audits are conducted effectively by corporate auditors, the accounting auditing firm explains to corporate auditors the contents of accounting audits and exchanges information with them. The firm also cooperates with the Internal Audit Office to conduct appropriate communication and to effectively perform the audits.

Under our adopted system, if someone discovers that an executive officer or employee is acting in contravention of either laws and regulations, or the Company's Articles of Incorporation, they immediately notify the corporate auditors. We are working to establish an environment conducive to more efficient audits by corporate auditors by coordinating closely with executives and regular employees and by fostering deeper understanding of audits. Furthermore, we assign auditing staff to assist the duties of the corporate auditors as necessary, and these human resources are carefully checked by directors and corporate auditors to ensure that they are independent.

#### **Internal Control System and Risk Management System**

Kyorin is building an internal control system in accordance with the following basic policy.

Basic Policy Under the corporate philosophy, "Kyorin continues to fulfill its mission of cherishing life and benefiting society by contributing to better health," the Kyorin Group will conduct its activities in every country based on a high standard of corporate ethics, respecting human rights and observing all laws, as well as standards of conduct and the spirit thereof.

#### **■ Compliance Committee**

We established the Compliance Committee, which is chaired by a director in charge and includes the Director of the Internal Audit Office who serves as a member of the committee. Thoroughgoing guidance is provided to executives and regular employees via training programs, while the Corporate Ethics Hotline has been set up for consultations and reporting matters concerning internal violations. Moreover, we have set Company rules to ensure the accuracy of financial reporting, and developed systems for ensuring the validity and reliability of internal controls over financial reporting of the Group.

#### ■ Risk Management Committee

We have built and are operating a structure for reducing and preventing risks. As part of this structure, we established the Risk Management Committee, chaired by a director in charge, with the General Affairs & Human Resources Department responsible for overseeing the committee. For risks concerning compliance, the environment and accidents, we also formulated the Risk Management Guidelines and the Corporate Ethics and Compliance Guidelines as part of a quick-response structure. Additionally, to handle crisis management when dealing with any contingencies, we have set up the Contingency Measures Headquarters under the leadership of the president.

We have established the Compliance Committee and the Risk Management Committee for every Kyorin Group company, while the Group Compliance Committee and the Group Risk Management Committee supervise and promote a Group-wide compliance and risk management system. We have also set up a system for employees for the entire Group to report and seek advice about possible irregularities.

### Directors, Corporate Auditors, and Corporate Officers (As of June 25, 2018)

#### Representative Director, President and Chief Executive Officer



#### Minoru Hogawa

Representative Director, President and Chief Executive Officer

KYORIN Pharmaceutical Co., Ltd.
Representative Director, President and Chief Executive Officer

Representative Director, President and Chief Executive Officer

December 1975 Joined Kyorin Yakuhin Co., Ltd.

June 2004 Corporate Officer, General Manager of Management Planning Department of KYORIN Pharmaceutical Co., Ltd.

June 2005 Executive Director, Senior Executive Officer, Management Strategy Office of KYORIN Pharmaceutical Co., Ltd.

January 2006 Executive Director, Management Strategy Office, General Manager of KYORIN Pharmaceutical Co., Ltd.

April 2010 Executive Director, Formangement Strategy Office, General Manager of Management Planning Department, in charge of Finance & Accounting Department of KYORIN Holdings, Inc.

June 2010 Senior Executive Director, General Manager of Management Planning Department of KYORIN Holdings, Inc.

June 2012 Senior Managing Director, General Manager of Management Planning Department of KYORIN Holdings, Inc.

June 2015 Representative Director, President and Chief Executive Officer, in Charge of Auditing Office of KYORIN Holdings, Inc.

Representative Director, President and Chief Executive Officer of KYORIN Pharmaceutical Co., Ltd. (current)

#### **Executive Director**



#### Masahiro Yamashita

**Executive Director and Advisor** 

April 1969

Joined Kyorin Yakuhin Co., Ltd.
Representative Director, President and Chief Executive
Officer of Bister Co., Ltd.
April 2004

April 2004

June 2004

Executive Director, Cyprorate Officer, Head of Sales & Marketing
Headquarters of KYDRIN Pharmaceutical Co., Ltd.
Executive Director, Corporate Officer, Head of Sales & Marketing Headquarters of KYORIN Pharmaceutical Co.,

Executive Director Senior Executive Officer Head of

June 2005

Executive Director, Senior Executive Officer, Head of Sales & Marketing Headquarters of KYORIN Pharmaceutical Co., Ltd. Executive Director of KYORIN Holdings, Inc. Executive Director of KYORIN Holdings, Inc. Executive Director, Executive Vice President, President's Assistant, in charge of Sales of KYORIN Holdings, Inc. Representative Director, President and Chief Executive Officer of KYORIN Holdings, Inc. Representative Director, President and Chief Executive Officer, in charge of Auditing Office of KYORIN Holdings, Inc.

June 2015 Representative Director, Chairman of KYORIN Holdings.

Executive Director and Advisor of KYORIN Holdings, Inc. (current)

#### **Executive Directors**



#### Yutaka Ogihara

Senior Executive Director

President's Office

President s Unice
April 1990 Joined KYORIN Pharmaceutical Co., Ltd.
June 2011 Executive Director, President's Office, in charge of Corporate
Communication Department and Information System
Management Department of KYORIN Holdings, Inc.
June 2015 Executive Director, President's Office of KYORIN Holdings, Inc.
June 2016 Senior Executive Director, President's Office of KYORIN
Holdings, Inc. (current)
June 2016 Senior Executive Director of KYORIN Pharmaceutical Co., Ltd.
(current)



#### Shigeru Ogihara

Senior Executive Director

Intellectual Property

Research and Development

April 1979 Joined Kyorin Yakuhin Co., Ltd
June 2009 Corporate Officer of KYORIN Pharmaceutical Co., Ltd.
April 2011 Representative Director, President and Chief Executive
Officer of KYORIN Rimedio Co., Ltd.
June 2011 Corporate Officer of KYORIN Holdings, Inc.
April 2012 Senior Corporate Officer of KYORIN Holdings, Inc.
June 2013 Executive Director of KYORIN Holdings. Inc.

June 2013 Executive Director of KYORIN Holdings, Inc.

June 2015 Executive Director, in charge of Drug Discovery Strategy of

KYORIN Holdings, Inc.

June 2016 Senior Executive Director, Head of Discovery Research
Headquarters and WATARASE Research Center of KYORIN

Pharmaceutical Co., Ltd. (current)
June 2016 Senior Executive Director, in charge of Intellectual Property

Senior Executive Director, in charge of intellectual Property Department of KYORIN Holdings, Inc. Senior Executive Director, in charge of Intellectual Property Department and Research and Development of KYORIN June 2017

Holdings, Inc. (current)

#### **Executive Directors**



#### Kenji Akutsu

Executive Director

General Affairs & Human Resources

Heatincare Business
April 1978 Joined KYORIN Pharmaceutical Co., Ltd.
June 2009 Corporate Officer, Product Strategy Office of KYORIN Pharmaceutical
Co., Ltd.
April 2014 Corporate Officer, General Manager of Discovery Research
Management Department of KYORIN Pharmaceutical Co., Ltd.
April 2015 Representative Director, President and Chief Executive Officer of
KYORIN Medical Supply Co., Ltd.
April 2016 Executive Director of KYORIN Holdings, Inc.
April 2017 Executive Director, General Manager of General Affairs & Human
Resources Department, in charge of Human Resources of KYORIN
Holdings, Inc.

Resources Department, in charge of Human Resources of KYORIN Holdings, Inc.
Executive Director, General Manager of General Affairs & Human Resources Department, in charge of Human Resources and Healthcare Business of KYORIN Holdings, Inc.
Executive Director, General Manager of Human Resources Department of KYORIN Pharmaceutical Co., Ltd. (current)
Executive Director, General Manager of General Affairs & Human Resources Department, in charge of Finance & Accounting Department, and Healthcare Business of KYORIN Holdings, Inc. (current)



#### Tomiya Sasahara

**Executive Director** 

Promotion Compliance & External Relations

Quality Assurance & Reliability

April 1886 Jolined KYORIN Pharmaceutical Co., Ltd.
April 2013 Corporate Officer, Quality Assurance & Reliability Office of
KYORIN Pharmaceutical Co., Ltd.
April 2015 Corporate Officer, Head of Quality Assurance & Reliability
Headquarters of KYORIN Pharmaceutical Co., Ltd.
June 2016 Executive Director, Head of Quality Assurance & Reliability
Headquarters of KYORIN Pharmaceutical Co., Ltd. (current)

Headquarters of KYUHIN Pharmaceutica Lo., Ltd. (current)
June 2017 Executive Director, in charge of Quality Assurance &
Reliability of KYORIN Holdings, Inc.
June 2018 Executive Director, in charge of Quality Assurance &
Reliability and Promotion Compliance & External Relations
Department of KYORIN Holdings, Inc. (current)

#### **Executive Directors**



#### Michiro Oonota

**Executive Director** 

KYORIN Pharmaceutical Group Facilities Co., Ltd. Representative Director, President and Chief Executive Officer
April 1985 Joined KYORIN Pharmaceutical Co., Ltd.

April 1985 Jolinea KYORIN Pharmaceutical Co., Ltd.
April 2015 Representative Director, President and Chief Executive Officer of
KYORIN Rimedio Co., Ltd
April 2015 Corporate Officer of KYORIN Holdings, Inc.
June 2017 Executive Director of KYORIN Holdings, Inc. (current)
Representative Director, President and Chief Executive Officer of
KYORIN Pharmaceutical Group Facilities Co., Ltd. (current)
June 2018 Executive Director of KYORIN Pharmaceutical Co., Ltd. (current)



#### Koichiro Hagihara

**Executive Director** 

Legal Clinical Development

Upment Joined Nisshin Flour Milling Inc.
Dispatched to Nisshin KYORIN Pharmaceutical Co., Ltd.
Joined KYORIN Pharmaceutical Co., Ltd.
Corporate Officer, General Manager of Discovery
Research Department of KYORIN Pharmaceutical Co., April 1983 April 1998

Elu. Senior Corporate Officer, Head of Clinical Development Center, General Manager of Discovery Research Management Department of KYORIN Pharmaceutical Co.

April 2017

Ltd.
Senior Corporate Officer, Deputy General Manager of Discovery Research Headquarters, Head of Clinical Development Center of KYORIN Pharmaceutical Co., Ltd. Executive Director, in charge of Legal Department and Clinical Development of KYORIN Holdings, Inc. (current) Executive Director, Deputy General Manager of Discovery Research Headquarters, Head of Clinical Development Capter of KYORIN Holdings for Contract Capter of KYORIN Holdings for Contract Processing Contracts of Contract Processing Contracts of Contract Processing Contracts of Cont

Center of KYORIN Pharmaceutical Co., Ltd. (current)

#### **Outside Director**



#### Noriyuki Shikanai

Outside Director

October 1971 Passed the National Bar Examination
April 1974 Registered with Daini Tokyo Bar Assot
March 1977 Established Shikanai Law Office(curre Registered with Daini Tokyo Bar Association
Established Shikanai Law Office (currently Kyobashi Law
Office) (current)

October 2010 Councilior of Keio University (current)
October 2010 Trustee of Keio University (current)
April 2012 Auditor of J. F. Oberlin University (current)
June 2013 Outside Director of KYORIN Holdings, Inc. (current)

#### **Outside Director**



#### Ken Shigematsu

Outside Director

rector

Joined Mitsukoshi, Ltd.
Executive Officer, General Manager of Product Planning
Division, Sales Headquarters of Mitsukoshi, Ltd.
Director, Executive Officer, Depuly General Manager of Sales
Headquarters of Mitsukoshi, Ltd.
Director, Managing Executive Officer, General Manager of
Merchandising Headquarters of Mitsukoshi, Ltd.
Director, Managing Executive Officer, Store Manager of
Mitsukoshi Gira of Mitsukoshi, Ltd.
Managing Executive Officer of Isetan Mitsukoshi Holdings Ltd.
Director, Senior Managing Executive Officer, Special
Appointive Officer of Mitsukoshi, Ltd.
Senior Managing Executive Officer of Isetan Mitsukoshi
Holdings Ltd.
Representative Director, President and Chief Executive Officer
Representative Director, President and Chief Executive Officer April 1971 March 1999 May 2002 March 2004 March 2005 April 2008 April 2009

Holdings Ltd. Telepresentative Director, President and Chief Executive Officer of Nagoya Mitsukoshi Ltd.

October 2011 Representative Director, President and Chief Executive Officer frendo Manufacturing Co., Ltd.

October 2015 Representative Director, President and Chief Executive Officer of MESI Co., Ltd.

June 2017 Outside Director of KYORIN Holdings, Inc. (current)

#### **Outside Director**



#### Yoh Goto

Outside Director

Joined Teijin Limited
Executive Officer of the Teijin Group
General Manager of Engineering Division of the Teijin
Group
Executive Officer of Teijin Limited
General Manager of Technology Division of Teijin Limited
Member of the Board of Teijin Limited
Senior Executive Officer, Representative Director of the
Board of Teijin Limited
Member of the Board of Teijin Limited
Outside Director of KYORIN Holdings, Inc. (current) April 1977 June 2009 April 2012 April 2013 April 2014 June 2014 April 2015

#### **Senior Corporate Auditors**

Tomiharu Matsumoto Syuugo Tamaki

#### **Outside Corporate Auditors**

Masaji Obata Takao Yamaquchi Naohiro Kamei

#### **Senior Corporate Officer**

Yoh Ito

#### **Corporate Officers**

Yasuo Nii Kikou Obi

Hiroshi Hashizume

#### Major Activities of Outside Directors and Outside Corporate Auditors (Year ended March 31, 2018)

Position	Name	Major Activities	Attendance at Meetings
Outside Directors	Noriyuki Shikanai	Utilizing his high degree of specialization and rich experience as an attorney, he makes appropriate comments to perform the monitoring function.	Attended 12 out of 12 Board of Directors' meetings
	Ken Shigematsu	Utilizing his rich experience and wide-ranging insight in corporate management, he makes appropriate comments to perform the monitoring function.	Attended 9 out of 9 Board of Directors' meetings*
	Yoh Goto	Utilizing his rich experience and wide-ranging insight in corporate management, he makes appropriate comments.	Attended 9 out of 9 Board of Directors' meetings*
Outside Corporate Auditors	Masaji Obata	He makes comments as necessary based mainly on his specialist understanding as an attorney.	Attended 12 out of 12 Board of Directors' meetings and 13 out of 13 Board of Corporate Auditors' meetings
	Yuji Konishi	He makes comments appropriately to ensure accurate decision-making by the Board of Directors. In addition, he makes appropriate comments based on his experience and insight at meetings of the Board of Corporate Auditors.	Attended 12 out of 12 Board of Directors' meetings and 13 out of 13 Board of Corporate Auditors' meetings
	Takao Yamaguchi	He makes comments as necessary based mainly on his specialist understanding of finance and accounting as a certified public accountant and a certified tax accountant.	Attended 10 out of 12 Board of Directors' meetings and 12 out of 13 Board of Corporate Auditors' meetings

\*Achievements since assumption of office in June 2017

## **Corporate Social Responsibility**

Under the corporate philosophy, "KYORIN continues to fulfill its mission of cherishing life, and benefiting society by contributing to better health," the Kyorin Group works to make a significant contribution to the creation of an energetic society and economic development through activities based on the ESG (environment, society and governance) viewpoint. Through these activities, the Group also aims to achieve sustainable corporate growth and create corporate value in the medium to long term. To achieve this, we consider it important to take our Corporate Charter to heart, and to build and maintain relationships of trust with all stakeholders\*, and provide reliable products and services as a "company that supports healthy lifestyles," while at the same time continuously striving as a corporate citizen to fulfill our corporate social responsibility (CSR), beginning with the fundamentals of compliance and risk management and also emphasizing themes including human resources management, environmental management, and activities that contribute to society.

\*The Kyorin Group's stakeholders: patients and medical professionals, shareholders and investors, employees, business partners and local communities



#### **Identification and Awareness of Priority Issues and Risks**

The Kyorin Group seeks sustainable growth by resolving social issues through our businesses.

We are therefore working to identify risks that could impede our achievement of the HOPE100 long-term vision, and by clarifying the important issues we will consider responses to risk events across the entire organization.

#### **Sustainable Development Goals**

The 2030 Agenda for Sustainable Development was adopted at a United Nations summit in September 2015, and sets international targets to be achieved from 2016 to 2030. The Agenda comprises 17 goals and 169 targets for the realization of a sustainable world. The Kyorin Group is proactively working to identify social issues related to the Group's businesses.



#### Compliance/Risk Management

The Kyorin Group abides by all laws, regulations, and codes of conduct, and the spirit thereof, and acts with high ethical standards, as well as promoting activities to appropriately manage internal and external risk pertaining to the business with a view to the ongoing enhancement of corporate value. Each Group company establishes a Compliance Committee and a Risk Management Committee that adopt a variety of measures to raise awareness and otherwise promote Group compliance and risk management.

#### **Compliance**

#### **Basic Policy**

An enterprise should pursue profits through fair competition as an economic entity, and at the same time should be a force for the greater good of society. Based on its corporate philosophy, the Kyorin Group will conduct its activities in every country based on a high standard of corporate ethics, respecting human rights and observing all laws, as well as standards of conduct and the spirit thereof.

#### **Corporate Charter and Compliance Guidelines**

To ensure that the Kyorin Group's activities are based on a high standard of corporate ethics, we established the KYORIN Holdings Corporate Charter and Compliance Guidelines (August 2006). Furthermore, we have also built and promoted a compliance system by establishing a Compliance Committee that meets on a monthly basis, and other measures.

 The KYORIN Holdings Corporate Charter was developed to specify matters of corporate ethics and compliance in accordance with our corporate philosophy, and serves as the starting point for our corporate activities.



- The Compliance Guidelines complement the KYORIN Holdings Corporate Charter by clarifying the standards to be followed for sound and proper business activities.
- 3. The Compliance Committee was established to provide overall supervision of corporate ethics and compliance systems. Each Kyorin company has a compliance promotion manager who is responsible for the understanding and instilling of corporate ethics and compliance.

#### **Education and Training**

Internal training is held to ensure an understanding and familiarity with Kyorin's corporate philosophy and compliance.

- 1. Focusing on departments responsible for compliance and each division's compliance promotion managers, Companywide level-specific training (newly hired employees, newly appointed managers, etc.) and functional training are held to teach corporate ethics and compliance, and efforts are made to ensure that an understanding and consideration of compliance is reflected in the work performed by directors, corporate auditors and officers, and employees.
- 2. June and November are designated as "compliance enhancement months," with the Corporate Charter and Compliance Guidelines read out at morning meetings and other activities to ensure a thorough understanding and familiarity with compliance Groupwide.

#### Risk Management

Kyorin established a Risk Management Committee in order to prevent risks from materializing and deal with any risks that do materialize. The committee's roles are as follows:

- Direct risk assessments to related divisions to identify and understand latent risks.
- 2. Prepare various guidelines and operation manuals for related divisions, and implement training for employees and other preventive measures as necessary, to ensure that latent risks do not materialize.
- 3. Prepare procedure manuals and carry out simulated drills at related divisions, and take out insurance and implement other measures as necessary, to minimize losses in the event a risk event does occur. Also, a risk management promotion officer has been appointed at each company to raise awareness relating to risk management.

#### Initiatives Related to Transparency in Relationships with Medical Institutions and Other Parties

The mission of an R&D-driven pharmaceutical company is to contribute to the realization of patient-focused medical care, through continuous research and development of new drugs and their stable supply, thereby contributing to global medical care and people's health. To fulfill this mission, partnerships between pharmaceutical companies, research laboratories and medical institutions including universities and others are essential, and we are required to properly manage our relationships where there is a potential conflict of interest with pharmaceutical companies.

Under these circumstances, the Kyorin Group established the Guidelines for Transparency of Relationships between Corporate Activities and Medical Institutions, etc., and the Guidelines on Transparency of Relationships between Corporate Activities and Patient Groups. In accordance with these guidelines, we publish information about capital funding to medical institutions, patient groups, and others on our website.

#### **Human Resources Management**

The Kyorin Group considers it fundamental for its sustained operations and growth to ensure that its employees are passionate about their work. As such, we create, operate, and establish new human resources management systems with the aim of engendering in our employees the sense that this is the very best place to work. The Group is also striving to improve its level of safety and health with the goal of attaining zero workplace injuries, by preventing work accidents, improving the health of everyone who works here and further enhancing the comfort of the working environment.

#### **Human Resources Management System**

The Group positions valuing employees and empowering people/organizations as the most important challenge under the long-term vision for executing business strategy and realizing achievements. We therefore aim to be "the leading company for career fulfillment," where employees take pride in their work, have trust in the Company and its organizations, and

work in solidarity with their coworkers. We are working to restructure the human resources management system (hiring, assigning, training, evaluation, transfers, compensation, social welfare, etc.) and strengthen training at all Group companies under our basic policy for human resources management.

#### Basic Concepts of the Human Resources Management System

#### "Long-Term Reciprocal Partnership"

By continuously fulfilling the responsibilities expected of each other over the long term, the Company and its employees become partners for their mutual benefit (employees contribute to the Company's development, the Company contributes to rich and rewarding lives for employees).

#### Employees

By carrying out their duties, contribute to achievement of the Company's (organization's) goals and targets.

- Carry out duties by performing operations proactively with a sense of initiative.
- Strive to maintain and enhance their own humanity and ability in carrying out their duties.
- Cooperate with coworkers for the success of the organization.

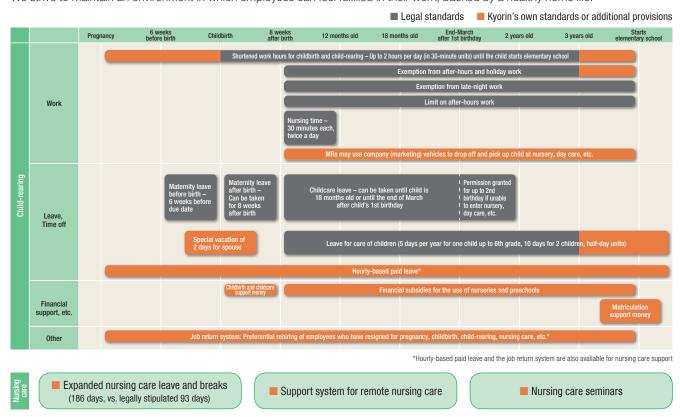
#### Company

People are considered assets (drivers of growth) of the Company, which values its employees and supports their growth.

- Each employee is assigned duties that conform to their abilities and work style.
- Each employee's contribution is comprehensively understood, and employees are evaluated and treated fairly and consistently.
- The Company provides a comfortable and rewarding work environment that fosters a "desire to work" among employees.

#### Support for Employees' Childcare and Nursing Care

KYORIN Pharmaceutical Co., Ltd. supports employees' daily lives throughout their life cycle, including when they require childcare or nursing care, with the aim of providing an environment in which they are easily able to balance their lives between work and family. We strive to maintain an environment in which employees can feel fulfilled in their work, backed by a healthy home life.



#### **Respect for Human Rights**

The Kyorin Group respects the human rights of all people. The Compliance Guidelines state that "There will be no discrimination or harassment inside or outside the Company based on race, ethnicity, nationality, gender, age, religion, beliefs, ideology, academic background, disability, or disease." The Company also respects the individuality of each employee, and has

formulated guidelines to prevent harassment, to create a comfortable workplace environment where employees feel at ease. These guidelines cover sexual and power harassment, as well as harassment related to pregnancy, childbirth, and childcare and nursing care leave.

#### **Regular Surveys on Employee Satisfaction**

The Kyorin Group seeks to create a comfortable and rewarding work environment that further enhances its employees' "desire to work." To this end, the Group conducts surveys on job satisfaction with all of its employees.

This survey has been carried out annually for the past eight years. The results of the survey are used as reference in creating our unique human resources management system, with the aim of becoming "the leading company for career fulfillment," where employees take pride in their work, have trust in the Company, and work in solidarity with their coworkers.

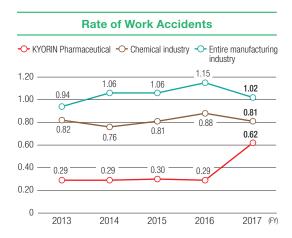
#### **Mental Health**

KYORIN Pharmaceutical Co., Ltd. provides mental-health education to managers and employees. Our manager training focuses on prevention and early detection of mental illness, by encouraging managers to pay attention to their subordinates and promoting understanding of the specific symptoms of mental disorders. We also encourage employees to gain knowledge about maintaining mental health via our intranet and other

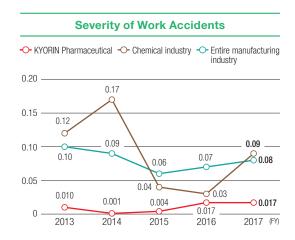
means, and have created a hassle-free system for employees and their families to seek help. When a mental health issue arises, the employee's department, industrial psychiatrists, public health nurses, and Human Resources Department work together to help the employee recover, return to work, and prevent relapse.

#### **Industrial Safety and Hygiene**

KYORIN Pharmaceutical Co., Ltd. has not had a fatality due to a work-related accident since its founding, and the rate and severity of work accidents are substantially below the industry averages.



Rate of work accidents: Number of deaths and injuries due to industrial accidents per total working hours times one million (indicates frequency of accidents) Calculation method: No. of deaths and injuries due to industrial accidents / Total working hours x 1,000,000



Severity of work accidents: Number of lost working days per total working hours times one thousand (indicates magnitude of accidents) Calculation method: No. of lost working days / Total working hours x 1,000

#### **Environmental Management**

The Kyorin Group regards environmental issues as a challenge shared by all humanity, and is actively striving to preserve the environment and prevent pollution by establishing and reviewing objectives and targets as needed; promoting the reduction of substances that place a burden on the environment, for example through energy and resource saving, waste reduction, and enhanced management of chemicals; and promoting the effective use of our limited resources.

#### **Environmental Conservation Initiatives**

We are actively committed to environmental conservation, focusing on the following major themes: preventing global warming, protecting resources, and living in harmony with the natural environment. We are working to reduce the environmental burden and promote effective use of limited resources by conserving energy and resources, reducing waste and strengthening our management of chemical substances. In 2004, all plants of KYORIN Pharmaceutical Co., Ltd. obtained certification in the ISO 14001 international standard for environmental management systems.

In our efforts to reduce CO<sub>2</sub> emissions to combat global warming, we set a target of reducing CO<sub>2</sub> emissions by 2% on average annually until fiscal 2019, based on CO<sub>2</sub> emissions of fiscal 2015 (19,840 tons) and are promoting such efforts. In fiscal 2017, our CO<sub>2</sub> emissions were 16,978 tons.

#### Materials Energy Water Raw materials Total heat: 289,532GJ 450t Total: 488t Total: 106,100t rude oil equivalent: 7,470kl (PRTR substances: 9.9t) Materials: 442t Drinking water: 86 400t Electricity: 17.833 thousand kWh Paper usage: 46t Heavy oil: 453k@ Groundwater: 19,700t Kerosene: 2.687k@ CO<sub>2</sub> emissions Waste Wastewater Amount: 400t Amount recycled: 180t Amount landfilled: 12t 16.978t 79.300t Total: 654t

**KYORIN Pharmaceutical's Material Flow (fiscal 2017)** 

#### Introducing Hybrid Cars to Reduce CO<sub>2</sub> Emissions

KYORIN Pharmaceutical Co., Ltd. is proactively introducing low-emission cars, hybrid cars, and other environmentally friendly vehicles for its sales force as a way of preventing global warming. As of March 2018, all 936 vehicles used by the sales force met the standard for having low emission (a 75% reduction in emissions from the 2005 standard), and of these, 614 (approximately 66%) are hybrid vehicles, which were introduced in 2004. In addition, these vehicles adhere to the Ministry of the Environment's "Eco-Driving" guidelines, as their operation regards the impact on the environment and traffic safety.



#### **Biodiversity**

KYORIN Pharmaceutical Co., Ltd.'s Noshiro Plant participates in a citizen's volunteer activity to protect the Kaze-no-Matsubara pine forest near the plant, to provide local residents with a place to relax. In fiscal 2017, a total of 27 plant employees removed dead brush as part of an activity to preserve local biodiversity.

In addition, KYORIN Pharmaceutical's WATARASE Research Center has installed birdhouses in trees adjacent to the Watarase Yusuichi wetland and confirmed the location of nests as a way to enhance the environment for wild animals in the Center's grounds.



#### **Environmentally Friendly R&D Center**

In May 2017, the ReHP technology newly installed at the WATARASE Research Center, which commenced operations in fiscal 2015, was awarded an honorable mention for the Kanto chapter of the Japanese Association of Building Mechanical and Electrical Engineers' carbon neutral prize for construction equipment contributing to the achievement of a low-carbon society. During fiscal 2017, this system reduced electric power consumption by 104,078 kWh and CO<sub>2</sub> emissions by roughly 53 tons compared with conventional heat pumps for air conditioning and heating, for approximately 36% in energy savings.

A Renewable Energy Heat Pump (ReHP) is a highly efficient heat pump that uses renewable energy, and the ReHP installed at two adjacent buildings (CS and LAB1) at the WATARASE Research Center uses geothermal heat and unused waste heat from a water chiller as a heat source, and circulates heated water in a single loop, which is used by air conditioning and water heating equipment, to increase energy efficiency.

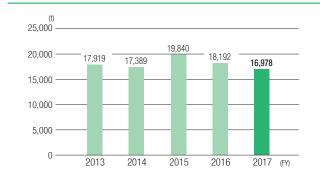


#### KYORIN Pharmaceutical Co., Ltd. Environmental Targets and Progress (Fiscal 2017)

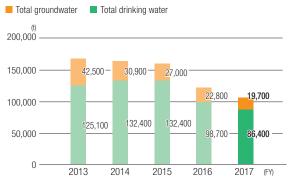
Target initiatives	Method for achieving	Fiscal 2017 plan (incl. numerical targets)	Fiscal 2017 actual	Self- assessment
Preventing global warming	Reduce fuel consumption (crude oil equivalent) through new capital investment	7,854kℓ (92.6%) (fiscal 2016 actual)	7,470kℓ (95.1%)	***
(CO <sub>2</sub> reduction and energy conservation)	Use hybrid cars to improve fuel efficiency and reduce exhaust emissions	466/940 (49.6%, fiscal 2016 actual)	614/936 (65.6%)	***
	Reduce total CO <sub>2</sub> emissions	17,828t	16,978t	***
	Reduce total waste	434t (fiscal 2016 actual)	400t	***
Reducing waste volume	Promote recycling	43.3% (fiscal 2016 actual)	45.0%	***
2. Reducing waste volume	Amount landfilled	12t (fiscal 2016 actual)	12t	***
	Zero-landfill challenge	2.8%	3.0%	**
Managing chemical substances	Manage substances covered by the Pollutant Release and Transfer Register (PRTR) Law and revise management method	9.8t (fiscal 2016 actual)	9.9t	**
Preventing atmospheric pollution	Measure and control amounts of soot and smoke, nitrogen oxide (NOx) and sulfur oxide (SOx) emitted by boilers and generators	Continuous measurement	At or below standards	***
5. Preventing water pollution	Process wastewater, including by primary processing plants, and management of pH, biochemical oxygen demand (BOD), and suspended solids (SS) levels	Continuous measurement	At or below standards	***
6. Preventing deforestation	Recycle paper, use recycled paper, and promote a paperless office environment	51t (fiscal 2016 actual)	46t	***
7. Protecting destruction of ozone layer	Eliminate all devices that use Chlorofluorocarbon (CFC) and Hydrofluorocarbon (HFC)	Elimination completed in fiscal 2010	_	***
Preventing ground subsidence	Reduce groundwater usage and increase drinking water reuse	81.7% (fiscal 2016 actual)	81.4%	**
9. Noise reduction	Periodic measurement	Continuous measurement	At or below standards	***
10. Protecting biodiversity	Communicate with local communities (activities to contribute to local communities)	Plan for each business facility	Achieved targets at all business facilities	***
11. Publishing environmental information	Create and publish environmental report	Publish on website in August	Published on website in August	***

\*Self-assessment scale: ★★★ achieved; ★★ largely achieved; ★ more work required

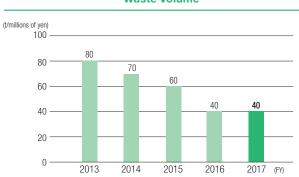
#### **CO<sub>2</sub> Emissions from Factories and Research Laboratories**



### **Volume of Water Used** Total drinking water



#### **Waste Volume**



#### **Social Contribution Activities**

The Kyorin Group endeavors to contribute to society in cooperation with local communities in order to realize a mutually beneficial relationship with society. The Group promotes social contribution activities that are fitting for "a company that supports healthy lifestyles," in order to create vibrant local communities where the foundation of its business activities lies so that people can live healthy, affluent lives, and to ensure that the Group continues to develop in a sustainable manner.

#### **Initiatives to Nurture the Next Generation**

#### **Classroom Visits**

Since fiscal 2017, we have planned and organized visits to schools by employees to teach and demonstrate in an easy-tounderstand manner correct ways of using medicine and how

to wash your hands to elementary and junior high school children, to nurture the next generation. This is one of our social contribution activities that embodies our corporate philosophy of "Contributing to better health."



### **Work Experience Programs**

Each Group facility offers internships, provides workplace tours and hands-on workshops for junior and senior high school students, and sends staff to teach in classrooms.



#### **Health Information Website for Children**

The Kyorin Group has supported the "Kyorin Group Presents the Great Adventure for the Body's Secrets" since 2016. During fiscal 2017, we produced a portal site related to the event, "Teacher, Teach Me about the Body's Secrets" that shows health-related videos that explain diseases and how the body works by showing the "impure things in the body." (The target

audience is children in nursery school through early elementary school.) This is an effort to have children enjoy learning accurate, health-related information.



URL: http://www.karada-kyorin.com

#### **Sponsoring Sporting Events**

The annual Shimotsuke Soccer Workshop in Nogi was held for the 18th time. Many local children attended, and we saw them giving their all playing soccer under the coaching of former Japan national team player Tetsuo Nakanishi. The Kyorin Group supports many other events that contribute to people's health.



#### **Activities with Patients and Medical Professionals**

#### **Meeting Needs from Patients' Perspectives**

We endeavor to meet a variety of needs, listening to feedback from clinical practice. We put ourselves in our patients' shoes, striving to develop pharmaceutical forms that are easy to administer, and imprinting them with their names to keep patients from taking the wrong medicine.

#### "Drug Information Center" Helpline

We opened the "Drug Information Center" as a helpline for inquiries relating to Kyorin products. We respond swiftly and accurately to various inquiries from physicians and pharmacists, from the standpoint of correct usage. We also provide accurate and easy-to-understand responses to inquiries from patients and the general public. In fiscal 2017, we responded to more than 20,000 inquiries.

#### **Providing Information via "Doctor Salon"**

At the Kyorin Group, we provide information by sponsoring "Doctor Salon," a radio program for physicians, on Radio NIKKEI (shortwave), producing and distributing brochures, and offering back issues on the web. "Doctor Salon" is a program that provides answers to issues that are highly relevant to clinical practice. It is extremely popular among physicians, especially primary-care doctors.



#### **Communication with Local Communities**

#### **Health Challenge Program**

The Health Challenge program was launched in 2017 as a new activity to promote employees' health and to contribute to local communities by donating items that are useful for maintaining health. All Group employees form teams at their workplace and count how many steps they take during a two-month period, competing in terms of average points, with health equipment donated to a social welfare center located near the workplaces of the two top teams. In total, 263 teams participated, and health equipment including a "body composition monitor" and "rehabilitation support machine" was donated to facilities in Chiyoda Ward, Tokyo, and Nanto City, Toyama Prefecture, where the two top teams are located.



#### First-Aid and Lifesaving Courses for Employees

As part of KYORIN Pharmaceutical Co., Ltd.'s CSR activities, the Company's approximately 750 medical representatives receive first-aid training, covering the necessity of first aid, CPR, the use of AEDs, and ways to stop bleeding. Some employees from the head offices of KYORIN Holdings Inc., KYORIN Pharmaceutical Co., Ltd., and KYORIN Rimedio Co., Ltd. also attend these classes. In addition to its corporate activities of collecting and providing information regarding the appropriate use of pharmaceutical products, the Kyorin Group strives to coexist in harmony as a corporate citizen of local communities.

#### **Initiative to Raise Awareness of Maternity Mark**

In fiscal 2017, KYORIN Pharmaceutical Co., Ltd. placed "Milton" advertisements near priority seats in various trains mainly in Tokyo regions. The advertisements raise awareness of the Maternity Mark, with the aim of increasing recognition of the symbol and contribute to creating an environment that is friendly to pregnant women.





#### **Support for Great East Japan Earthquake Recovery**

Since fiscal 2011, KYORIN Pharmaceutical Co., Ltd. has supported the Sunflower Project, which brings cheer to regions affected by the Great East Japan Earthquake. We continued our support in fiscal 2018, growing 300 pots of sunflower seedlings at WATARASE Research Center, and donating them to the city of Natori, in Miyagi Prefecture.



### **Publishing Websites for Medical Professionals**

As a way of providing information through websites to medical professionals, we created Kyorin Medical Bridge. We endeavor to meet the needs of medical professionals by enhancing information about our products, latest academic news, and information that will be useful in day-to-day clinical practice.



Kyorin Medical Bridge, a website for medical professionals

### **Providing Ailments Information**

At the Kyorin Group, we provide assistance to help patients correctly understand their ailments and improve their quality of life by creating informed-consent tools and providing patients with information about their ailments through their healthcare providers.

#### **Support for the Department of Drug Discovery Medicine**

To cultivate innovative human resources for Japan's drug discovery in the post-genome era through cooperation with industry and academia, KYORIN Pharmaceutical Co., Ltd. helped establish and provides assistance to the Department of Drug Discovery Medicine at the Kyoto University Graduate School of Medicine.

## **Financial Analysis**

#### **Industry Trends in Japan**

During fiscal 2017, Japan's pharmaceutical industry transitioned to a low-growth market as measures to make medical spending more efficient and to rein in drug prices moved forward in an effort to preserve financial resources required to cover the costs of the social security system. With the expiry of patents on our main products having a full-year effect on net sales, the Kyorin Group entered a critical period requiring unprecedented corporate activities. Revisions to the National Health Insurance (NHI) drug pricing system were deliberated based on the Basic Policy for Fundamental Reform of the Drug Pricing System, and new measures were implemented from April 2018.

Against this backdrop, the Kyorin Group pursued its long-term vision HOPE100, operating under the medium-term business plan HOPE100–Stage 2–, which covers the period from fiscal 2016 through fiscal 2019. Under this plan, during fiscal 2017, we worked to evolve our pharmaceutical business model to facilitate continuous growth at the ethical drugs business while creating new core businesses and searching for next candidates for a new core business to drive the healthcare business, under a management policy of "Promoting reform by consolidating diverse knowledge," as we strove to achieve the plan's performance targets and gain the increased support and approval of stakeholders.

#### **Consolidated Operating Results**

Consolidated net sales for the fiscal year declined ¥4,732 million, or 4.1%, from the previous fiscal year, to ¥110,640 million. Despite increased sales of new drugs overseas and of generic drugs, lower sales of new drugs in Japan resulted in a decline from the previous year in sales in the ethical drugs business, while sales in the healthcare business were roughly the same as the previous fiscal year.

In terms of profit, despite one-time revenue from new drugs overseas, lower sales of new drugs in Japan combined with an increase in loss on retirement of inventories resulted in a ¥2,949 million decrease in gross profit from the previous fiscal year. On the other hand, with cost reductions absorbing an increase in R&D expenses, SG&A expenses declined ¥1,359 million, but nevertheless, operating income fell ¥1,590 million, or 15.3%, from the previous fiscal year, to ¥8,822 million. Profit attributable to shareholders of KYORIN Holdings, Inc. declined 10.0% from the previous year, to ¥6,574 million, which included roughly ¥600 million in extraordinary income from the transfer of shares of Dr. Program Co., Ltd., roughly ¥400 million in costs related to the settlement of a class-action lawsuit for violation of U.S. antitrust laws in connection with an out-licensed product (Gatifloxacin-eyedrops), and a roughly ¥400 million extraordinary loss on a debt guarantee regarding a trust-type employee stock ownership incentive plan.

#### **Assets, Liabilities, and Net Assets**

As of March 31, 2018, current assets had declined ¥4,168 million from the previous fiscal year-end, with decreases in short-term investments, merchandise and finished goods and other current assets more than offsetting increases in cash and cash

in banks and in notes and accounts receivable. Fixed assets grew ¥9,851 million over the same period, mainly on an increase in investment securities. As a result, total assets stood at ¥198,350 million as of March 31, 2018, for a ¥5,682 million increase from the previous fiscal year-end.

Liabilities as of March 31, 2018 were ¥35,053 million, marking a ¥221 million increase from the previous fiscal year-end, with increases in accrued income taxes, deferred tax liabilities, and the liability for retirement benefits, and decreases in notes and accounts payable and in other long-term liabilities.

Net assets grew ¥5,460 million from the previous fiscal yearend, to ¥163,297 million as of March 31, 2018, mainly from increases in retained earnings and in the unrealized holding gain on other securities.

As a result, the equity ratio stood at 82.3% as of March 31, 2018, a 0.4 percentage-point increase from the previous fiscal year-end.

#### **Cash Flows**

Operating activities during fiscal 2017 generated a net cash inflow of ¥10,456 million, with profit before income taxes of ¥9,061 million, depreciation and amortization of ¥3,644 million, a ¥1,842 million increase in notes and accounts receivable, a ¥901 million decrease in inventories, an ¥834 decrease in notes and accounts payable, a ¥912 million decrease in consumption taxes payable, and income taxes paid of ¥1,655 million.

Investing activities resulted in a net cash outflow of \$6,038 million, with the main items being outlays of \$3,387 million for the purchase of property, plant and equipment, and \$7,099 million for the purchase of investment securities, with a \$5,000 million inflow from the proceeds from sales and redemption of investment securities.

Financing activities resulted in a net cash outflow of ¥3,735 million, with proceeds from long-term debt of ¥1,712 million being more than offset by outlays of ¥1,297 million for repayments of long-term debt and ¥4,325 million in cash dividends paid.

As a result, cash and cash equivalents at the end of fiscal 2017 totaled ¥42,971 million, for a ¥471 million increase from the previous fiscal year-end.

#### **Outlook for Fiscal 2018**

With the enactment of drastic reforms to the drug pricing system (including an industrywide 7.5% revision in prices) effective April 2018, we expect the ethical drugs business in Japan to face an increasingly challenging operating environment.

In response, the Kyorin Group will pursue its long-term vision HOPE100, operating under the medium-term business plan HOPE100–Stage 2–, which was formulated in fiscal 2016 and covers the period from fiscal 2016 through fiscal 2019, to evolve our pharmaceutical business model to facilitate continuous growth in the ethical drugs business, while creating new core businesses and searching for next candidates for a new core business to drive the healthcare business, as we strive to achieve the plan's performance targets and gain the increased support and approval of stakeholders.

In terms of net sales for fiscal 2018, in the ethical drugs business we are forecasting lower sales of new drugs overseas and

of generic drugs, but also anticipate higher sales of new drugs in Japan, as well as sales growth in the healthcare business, for an overall increase in net sales. Although sales of new drugs in Japan will be affected by the drug price revisions that took effect in April 2018 (Kyorin's revision is in the 7% range), we are forecasting sales growth from increased sales of main products Flutiform and Desalex, and the commencement of sales of NASONEX following the conclusion of a contract with MSD K.K. The main factor behind the forecast of lower sales of new drugs

overseas is the absence of one-time revenue from out-licensing recorded in the previous fiscal year.

In terms of profit, although we expect gross profit to decline from the effect of drug price revisions and the absence of one-time out-licensing revenue, we are forecasting a significant reduction in SG&A expenses, including R&D expenses, so anticipate profit to be on a similar level with the previous fiscal year.

#### **Business Risks**

We have described below the risk factors that could affect the business performance or financial health of the Group. Although the Group has taken organizational and systematic measures to minimize risk, the outline does not include every risk or variable that could affect its business.

#### 1. Legal Regulations

Legal regulations in Japan, such as the Pharmaceutical and Medical Device Act, the NHI system, NHI drug prices and laws in other countries can affect the Group's business. Every stage of our operations, including pharmaceutical development, production, import, and distribution, is regulated by various approval and licensing systems. Unforeseen substantial shifts in future healthcare administration policy could affect our business performance and financial health.

#### 2. Pharmaceutical R&D

Ethical drug development requires substantial R&D investment over lengthy periods. Furthermore, the success rate is low for companies seeking to discover original compounds and bring pharmaceutical products to market. Currently, several of KYORIN Pharmaceutical Co., Ltd.'s ethical drugs are undergoing clinical trials. The clinical development of such drugs could be terminated as a consequence of various factors, such as unforeseeable side effects or failure to achieve intended results.

#### 3. Increased Competition

The pharmaceutical industry is experiencing rapid technological change. Sales of the Group's principal products could be affected if a competitor developed and brought to market drugs that were more useful or produced the same effects.

#### 4. NHI Drug Price Revisions

Japan's healthcare system, including NHI drug prices, is being revised. When forecasting business results, the Kyorin Group does its best to predict and factor in the effects of such changes. Nevertheless, our performance could suffer as a result of greater than expected NHI drug price revisions or changes to the NHI system.

#### 5. Side Effects

Information concerning the safety of new pharmaceuticals is based only on clinical trials using a limited number of subjects and therefore cannot eliminate the possibility of all side effects. If a drug in general use is found to have unknown and unreported side effects after its launch, its usage may be restricted or, in some cases, its sale could be discontinued.

#### 6. Slowdowns or Delays in Production

Technical or regulatory problems, natural disasters and accidents, including fires, could cause slowdowns or delays in production or the cessation of operations, thereby affecting the Group's performance. Operations at the Noshiro Plant (Noshiro, Akita

Prefecture, Japan) of Kyorin Group company KYORIN Pharmaceutical Co., Ltd. were not affected by the Great East Japan Earthquake that struck on March 11, 2011. No plant personnel were injured, and the plant itself sustained no physical damage from the disaster.

#### 7. Pharmaceutical Recalls

If the Group's pharmaceuticals are shown to be defective due to contamination or other causes, they will be recalled. Such a situation would adversely affect the Group's business results.

#### 8. Intellectual Property Protection

There is a risk that the Group may become unable to protect its intellectual property effectively in Japan or overseas. In this event, third parties could exploit the Group's technology and reduce demand for its principal products and related pharmaceuticals. If the Group's other activities are deemed to infringe on another company's patents or threaten its intellectual property rights relating to its products, the Group may become involved in legal disputes and have to terminate some business operations.

#### 9. Lawsuits

The Group could become the subject of a lawsuit for alleged patent infringements, violations of the Product Liability Act or the Antimonopoly Act or as a result of environmental issues or labor disputes.

#### 10. Exchange Rate Fluctuations

As the Group imports and exports pharmaceutical products, its sales are vulnerable to exchange rate fluctuations.

#### 11. Cancellations of Tie-Up Agreements

The Group promotes strategic alliances to make efficient use of external capital. Through tie-up agreements with other pharmaceutical companies in and outside of Japan, the subsidiary allocates sales rights for some of its products and collaborates in sales, R&D, and other activities. A cancellation of these tie-up agreements for any reason could affect the forecast performance of the Group.

#### 12. IT Security and Information Management

In the course of business operations, the Group utilizes numerous IT systems. This means business operations are vulnerable to disruptions caused by system faults or outside causes such as computer viruses. Furthermore, the leakage of information could cause a loss of trust in the Group and materially affect the business performance of the Group.

# **Consolidated Balance Sheet**

 $\begin{tabular}{ll} KYORIN Holdings, Inc. and Consolidated Subsidiaries \\ As of March 31 \end{tabular} \label{table}$ 

			Thousands of U.S. dollars
Assets	2018	Millions of yen 2017	(Note 3)
Current assets:	2010	2017	2016
Cash and cash in banks (Notes 4 and 10)	¥ 44,117	¥ 43,619	\$ 415,141
Notes and accounts receivable (Note 10)	47,862	46,192	450,381
Short-term investments (Notes 5 and 10)	599	5,007	5,637
Inventories:	333	0,001	0,001
Merchandise and finished goods	11,749	12,901	110,558
Work in process	1,282	1,521	12,064
Raw materials and supplies	10,276	9,956	96,697
Deferred tax assets (Note 12)	2,152	2,136	20,250
Other	4,101	4,976	38,590
Less allowance for doubtful accounts	(43)	(44)	(405)
Total current assets	122,098	126,267	1,148,941
- Committee additional	122,000	120,201	1,140,041
Property, plant and equipment:			
Land	2,082	2,010	19,592
Buildings and structures	31,663	33,187	297,949
Machinery and vehicle	21,387	20,957	201,252
Leased assets	589	591	5,542
Construction in progress	41	1,041	386
Other	8,405	7,871	79,091
Less accumulated depreciation and impairment loss	(42,269)	(43,227)	(397,751)
Property, plant and equipment, net	21,901	22,432	206,088
- Topology plant and oquipment, not			
Investments and other assets:			
Investment and other assets:	E0 71 F	40.647	477.000
Investment securities (Notes 5 and 10)	50,715	40,647	477,228
Long-term loans	4	100	38
Asset for retirement benefits (Note 11)	133	109	1,252
Deferred tax assets (Note 12)	188	381	1,769
Other	3,356	2,893	31,580
Less allowance for doubtful accounts	(47)	(65)	(442)
Total investments and other assets	54,350	43,968	511,433
Total assets	¥198,350	¥192,668	\$1,866,472

		NATU: 6	Thousands of U.S. dollars
Liabilities and net assets	2018	Millions of yen 2017	(Note 3) 2018
Current liabilities:			
Notes and accounts payable (Note 10)	¥ 10,266	¥ 11,157	\$ 96,603
Short-term bank loans (Note 6)	957	1,321	9,005
Lease obligations (Note 6)	99	98	932
Accrued income taxes (Note 12)	2,317	1,194	21,803
Accrued bonuses to employees	2,381	2,690	22,405
Reserve for sales returns	52	32	489
Provision for point card certificates	_	36	_
Provision for loss on guarantees	428	_	4,027
Other	8,631	8,502	81,218
Total current liabilities	25,134	25,033	236,511
Long-term liabilities:			
Long-term debt (Note 6)	3,912	3,630	36,812
Lease obligations (Note 6)	411	478	3,868
Deferred tax liabilities (Note 12)	2,870	2,067	27,007
Accrued retirement benefits for directors and corporate auditors	_	16	_
Provision for stock-based payments	4	_	38
Liability for retirement benefits (Note 11)	2,136	1,676	20,100
Other	582	1,928	5,477
Total long-term liabilities	9,918	9,797	93,328
Contingent liabilities (Note 15)			
Net assets:			
Shareholders' equity (Note 7):			
Common stock, no par value:			
Authorized – 297,000,000 shares in 2018 and 2017			
Issued - 74,947,628 shares in 2018 and 2017	700	700	6,587
Capital surplus	4,752	4,752	44,716
Retained earnings	152,542	150,301	1,435,419
Treasury stock, at cost:			
1,194,974 shares in 2018			
1,426,589 shares in 2017	(2,506)	(3,168)	(23,581)
Total shareholders' equity	155,489	152,585	1,463,150
Accumulated other comprehensive income:			
Unrealized holding gain on other securities	10,101	7,645	95,050
Translation adjustments	83	115	781
Retirement benefits liability adjustments	(2,377)	(2,510)	(22,368)
Total accumulated other comprehensive income	7,808	5,251	73,473
Total net assets	163,297	157,837	1,536,624
Total liabilities and net assets	¥198,350	¥192,668	\$1,866,472

# **Consolidated Statement of Income**

KYORIN Holdings, Inc. and Consolidated Subsidiaries For the year ended March 31, 2018

				nousands of U.S. dollars
		Millions of yen		(Note 3)
	2018	2017		2018
Net sales	¥110,640	¥115,373	\$1	,041,122
Cost of sales	49,064	50,847		461,692
Gross profit	61,576	64,526		579,430
Selling, general and administrative expenses (Note 8)	52,753	54,113		496,405
Operating income	8,822	10,413		83,015
Other income (expenses):				
Interest and dividend income	398	374		3,745
Interest expense	(24)	(29)		(226)
Equity in gains of affiliates	28	23		263
Foreign exchange loss	(53)	(5)		(499)
Losses on sales and retirement of property, plant and equipment, net (Note 9)	(51)	(135)		(480)
Gain on sales of investment securities, net (Note 5)	_	(3)		_
Gain on sales of shares of subsidiaries and affiliates	(576)	_		(5,420)
Settlement-related costs	(379)	(1,025)		(3,566)
Provision for loss on guarantees	(428)	_		(4,027)
Other, net	172	97		1,619
Other income (expenses), net	238	(696)		2,240
Profit before income taxes	9,061	9,716		85,264
Income taxes (Note 12):				
Current	2,759	1,597		25,962
Deferred	(272)	814		(2,560)
Total income taxes	2,486	2,411		23,393
Profit	6,574	7,305		61,861
Profit attributable to shareholders of KYORIN Holdings, Inc.	¥ 6,574	¥ 7,305	\$	61,861

See notes to consolidated financial statements.

# **Consolidated Statement of Comprehensive Income**

KYORIN Holdings, Inc. and Consolidated Subsidiaries For the year ended March 31, 2018

		Millions of yen		
	2018	2017	2018	
Profit	¥6,574	¥7,305	\$61,861	
Other comprehensive income (Note 13):				
Unrealized holding gain (loss) on other securities	2,456	(2,732)	23,111	
Translation adjustments	(31)	(45)	(292)	
Retirement benefits liability adjustments	133	781	1,252	
Share of other comprehensive income of affiliates accounted for using equity method	(0)	5	(0)	
Total other comprehensive income	2,557	(1,990)	24,061	
Comprehensive income	¥9,132	¥5,315	\$85,932	
Total comprehensive income attributable to: Shareholders of KYORIN Holdings, Inc. Non-controlling interests	¥9,132 —	¥5,315 —	\$85,932 —	

Thousands of

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

KYORIN Holdings, Inc. and Consolidated Subsidiaries For the year ended March 31, 2018

										Mi	llions of yen
					Sharel	nolders' equity				nulated other	
	Number of shares issued (Common stock)	Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Unrealized holding gain (loss) on other securities	Translation adjustments	Retirement benefits liability adjustments	Total accumulated other comprehensive income	Total net assets
Balance as of April 1, 2016	74,947,628	¥700	¥4,752	¥147,331	¥(2,975)	¥149,808	¥10,372	¥160	¥(3,292)	¥7,241	¥157,049
Cash dividends	_	_	_	(4,333)	_	(4,333)	_	_	_	_	(4,333)
Profit attributable to shareholders of KYORIN Holdings, Inc.	_	_	_	7,305	_	7,305	_	_	_	_	7,305
Purchase of treasury stock	_	_	_	_	(832)	(832)	_	_	_	_	(832)
Disposals of treasury stock	_	_	_	_	639	639	_	_	_	_	639
Other changes	_	_	_	_	_	_	(2,726)	(45)	781	(1,990)	(1,990)
Net changes during the year	_	_	_	2,971	(193)	2,778	(2,726)	(45)	781	(1,990)	788
Balance as of April 1, 2017	74,947,628	700	4,752	150,301	(3,168)	152,585	7,645	115	(2,510)	5,251	157,837
Cash dividends	-	_	-	(4,333)	-	(4,333)	-	-	-	-	(4,333)
Profit attributable to shareholders of KYORIN Holdings, Inc.	_	_	_	6,574	_	6,574	_	_	_	_	6,574
Purchase of treasury stock	_	_	_	_	(0)	(0)	_	_	_	_	(0)
Disposals of treasury stock	_	_	_	_	662	662	_	_	_	_	662
Other changes	_	_	_	_	_	_	2,455	(31)	133	2,557	2,557
Net changes during the year	_	_	_	2,241	662	2,903	2,455	(31)	133	2,557	5,460
Balance as of March 31, 2018	74,947,628	¥700	¥4,752	¥152,542	¥(2,506)	¥155,489	¥10,101	¥ 83	¥(2,377)	¥7,808	¥163,297

	Thousands of U.S. dollars							dollars (Note 3)			
					Share	holders' equity				nulated other nsive income	
	Number of shares issued (Common stock)	Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Unrealized holding gain (loss) on other securities	Translation adjustments	Retirement benefits liability adjustments	Total accumulated other comprehensive income	Total net assets
Balance as of April 1, 2017	74,947,628	\$6,587	\$44,716	\$1,414,331	\$(29,811)	\$1,435,824	\$71,939	\$1,082	\$(23,619)	\$49,412	\$1,485,245
Cash dividends	_	-	_	(40,774)	_	(40,774)	_	_	_	_	(40,774)
Profit attributable to shareholders of KYORIN Holdings, Inc.	_	_	_	61,861	_	61,861	_	_	_	_	61,861
Purchase of treasury stock	_	_	_	_	(0)	· ·	_	_	_	_	(0)
Disposals of treasury stock		_	_	_	6,229	6,229	_	_	_	_	6,229
Other changes	_	-	_	_	_	-	23,102	(292)	1,252	24,061	24,061
Net changes during the year	_	_		21,088	6,229	27,317	23,102	(292)	1,252	24,061	51,379
Balance as of March 31, 2018	74,947,628	\$6,587	\$44,716	\$1,435,419	\$(23,581)	\$1,463,150	\$95,050	\$ 781	\$(22,368)	\$73,473	\$1,536,624

# **Consolidated Statement of Cash Flows**

KYORIN Holdings, Inc. and Consolidated Subsidiaries For the year ended March 31, 2018

			Thousands of
		Millions of yen	U.S. dollars (Note 3)
	2018	2017	2018
Operating activities			
Profit before income taxes	¥ 9,061	¥ 9,716	\$ 85,264
Depreciation and amortization	3,644	3,619	34,290
Decrease in allowance for doubtful accounts	(16)	(67)	(151)
Decrease in accrued bonuses to employees	(293)	(561)	(2,757)
(Decrease) increase in accrued retirement benefits for directors and corporate auditors	(16)	3	(151)
Decrease (increase) in asset for retirement benefits	586	(1,326)	5,514
Increase in liability for retirement benefits	61	21	574
Equity in gains of affiliates	(28)	(23)	(263)
Increase in provision for loss on guarantees	428	_	4,027
Interest and dividend income	(398)	(374)	(3,745)
Interest expense	24	29	226
Losses on sales and retirement of property, plant and equipment, net	51	135	480
Gain on sales of investment securities, net	_	(3)	_
Gain on sales of shares of subsidiaries and affiliates	(576)	_	(5,420)
(Increase) decrease in notes and accounts receivable	(1,842)	2,102	(17,333)
Decrease in inventories	901	3,286	8,478
Decrease in notes and accounts payable	(834)	(634)	(7,848)
(Decrease) increase in consumption taxes payable	(912)	945	(8,582)
Other, net	1,889	2,935	17,775
Subtotal	11,729	19,804	110,370
Interest and dividend received	405	381	3,811
Interest paid	(24)	(29)	(226)
Income taxes paid	(1,655)	(3,769)	(15,574)
Net cash provided by operating activities	10,456	16,386	98,391
Investing activities			
Payments for time deposits	(768)	(1,443)	(7,227)
Proceeds from withdrawal of time deposits	722	1,079	6,794
Purchase of property, plant and equipment	(3,387)	(2,208)	(31,872)
Proceeds from sales of property, plant and equipment	91	89	856
Purchase of intangible assets	(486)	(437)	(4,573)
Purchase of investment securities	(7,099)	(16,600)	(66,802)
Proceeds from sales and redemption of investment securities	5,000	6,403	47,050
Purchase of shares of subsidiaries resulting in change in scope of consolidation	(399)	-	(3,755)
Proceeds from sales of shares of subsidiaries resulting in change	(555)		(0,: 00)
in scope of consolidation	434	_	4,084
Other, net	(146)	(26)	(1,374)
Net cash used in investing activities	(6,038)	(13,142)	(56,818)
Financing activities			
Decrease in short-term bank loans, net	(245)	(600)	(2,305)
Repayments of lease obligations	(104)	(116)	(979)
Proceeds from long-term debt	1,712	916	16,110
Repayments of long-term debt	(1,297)	(1,153)	(12,205)
Net decrease (increase) in treasury stock	524	(445)	4,931
Cash dividends	(4,325)	(4,322)	(40,698)
Net cash used in financing activities	(3,735)	(5,721)	(35,146)
Effects of exchange rate changes on cash and cash equivalents	(210)	(65)	(1,976)
Increase (decrease) in cash and cash equivalents	471	(2,543)	4,432
Cash and cash equivalents at beginning of year	42,499	45,043	399,915
Cash and cash equivalents at end of year (Note 4)	¥42,971	¥42,499	\$404,357
	, 0 . 1	,	Ţ.J.,007

### **Notes to Consolidated Financial Statements**

KYORIN Holdings, Inc. and Consolidated Subsidiaries For the year ended March 31, 2018

#### 1. Basis of Presentation of Consolidated Financial Statements

The accompanying consolidated financial statements of KYORIN Holdings, Inc. (the "Company") and its domestic subsidiaries have been prepared in accordance with accounting principles generally accepted in Japan ("Japanese GAAP"), 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.

Certain reclassifications have been made in the 2017 consolidated financial statements to conform to the 2018 presentation. These reclassifications have no effect on consolidated profit and net assets.

#### 2. Summary of Significant Accounting Policies

(a) Basis of Consolidation and Accounting for Investments in Unconsolidated Subsidiaries and Affiliates
The accompanying consolidated financial statements include the accounts of the Company and significant
companies controlled directly or indirectly by the Company. Companies over which the Company exercises
significant influence in terms of their operating and financial policies are included in the consolidated balance
sheets on an equity basis. All significant inter-company balances and transactions are eliminated in consolidation.

Investments in subsidiaries and affiliates, which are not consolidated or accounted for by the equity method, are carried at cost or less. Where there has been a permanent decline in the value of such investments, the Company has written down the investments.

Among the consolidated subsidiaries, Kyorin USA, Inc., Kyorin Europe GmbH, and ActivX Biosciences, Inc. close their books of account at December 31 for financial reporting purposes. Their financial statements are used for preparing the consolidated financial statements, and necessary adjustments are made to the consolidated financial statements for any significant transactions between their balance sheet date (December 31) and the consolidated balance sheet date (March 31).

#### (b) Foreign Currency Translation

The revenue and expense accounts of the foreign consolidated subsidiaries are translated into yen at the average rates of exchange in effect during the year. The balance sheet accounts, except for the components of shareholders' equity, are translated into yen at the exchange rates in effect at the balance sheet date. The components of shareholders' equity are translated at their historical exchange rates. Translation adjustments are presented as a component of net assets in the accompanying consolidated balance sheets.

#### (c) Cash and Cash Equivalents

Cash and cash equivalents consist of cash on hand, deposit with banks withdrawable on demand, and short-term investments which are readily convertible into cash and are subject to an insignificant risk of any changes in their value and which were purchased with original maturities of three months or less.

#### (d) Short-Term Investments and Investment Securities

Securities other than equity securities issued by subsidiaries and an affiliate are classified into other securities. Marketable securities classified as other securities are carried at fair value with changes in unrealized gain or loss, net of the applicable income taxes, directly included in net assets. Non-marketable securities classified as other securities are stated at cost. Cost of securities sold is determined by the moving average method.

#### (e) Inventories

Merchandise and finished goods, work in process, raw materials, and some supplies (samples) are mainly stated at cost determined by the gross average method. These inventories with lower profitability are written down to their net realizable value. Supplies except for samples are stated at the last purchase price method.

#### (f) Depreciation and Amortization (Except for Leased Assets)

Depreciation of property, plant and equipment is calculated by the declining-balance method at rates based on the estimated useful lives of the respective assets. For buildings (excluding accompanying facilities) acquired on or after April 1, 1998 and facilities attached to buildings and other non-building structures

acquired on or after April 1, 2016, the straight-line method is used. The useful lives of property, plant and equipment are summarized as follows:

Buildings and structures 3 to 50 years

Machinery and vehicle 4 to 17 years

Intangible assets are amortized by the straight-line method over their estimated useful lives. Computer software for internal use is capitalized and amortized by the straight-line method over the useful life of five years.

#### (g) Leases

Leased assets are initially accounted for at their acquisition costs and depreciated over the lease term by the straight-line method with no residual value. All finance leases are accounted for in the same manner as sales transactions.

#### (h) Research and Development Expenses

Research and development expenses are charged to income as incurred.

#### (i) Income Taxes

Deferred tax assets and liabilities are determined based on the differences between financial reporting and the tax bases of the assets and liabilities and are measured using the effective tax rates and laws which will be in effect when the differences are expected to reverse.

#### (j) Accounting Method for Retirement Benefits

The retirement benefit obligation is calculated by allocating the estimated retirement benefit amount to period of service on the benefit formula basis.

Prior service cost is amortized as incurred by the straight-line method over the average remaining years of service of the employees in the year such cost occurs (10 years).

Actuarial gain or loss is amortized from the year following the year in which such gain or loss is recognized primarily by the straight-line method over the average remaining years of service of the employees in the year such gain or loss occurs (10 years).

Unrecognized actuarial loss and unrecognized prior service costs are, after adjusting for tax effects, recorded as retirement benefits liability adjustments under accumulated other comprehensive income in net assets.

#### (k) Accrued Retirement Benefits for Directors and Corporate Auditors

Directors and corporate auditors of certain consolidated subsidiaries are customarily entitled to lump-sum payments under their respective unfunded retirement benefit plans. Accrued retirement benefits for these directors and corporate auditors have been estimated in an amount required under the assumption that all directors and corporate auditors retired at the balance sheet date based on their policy.

#### (I) Appropriation of Retained Earnings

Appropriation of retained earnings with respect to a given financial period is made by resolution of the board of directors' meeting for dividend and resolution of the ordinary general shareholders' meeting for other appropriations (see Note 7).

#### (m) Accounting Standard Issued but Not Yet Effective

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

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

#### (1) Overview

The International Accounting Standards Board ("IASB") and the Financial Accounting Standards Board of the United States of America ("FASB") jointly developed a comprehensive accounting standard for revenue recognition and issued "Revenue from Contracts with Customers" (IFRS 15, issued by the IASB and Topic 606, issued by the FASB) in May 2014. Considering that IFRS 15 has become applicable from fiscal years beginning on or after January 1, 2018 and Topic 606 from fiscal years beginning after December 15, 2017, the ASBJ developed a comprehensive accounting standard for revenue recognition and issued it together with implementation guidance.

The ASBJ's basic policy in developing the accounting standard for revenue recognition was to establish accounting standards as a starting point in accordance with basic principles of IFRS 15 from the viewpoint of comparability of financial statements, which is one of benefits of maintaining consistency with IFRS 15, and to add alternative accounting treatments to the extent they do not impair comparability in cases where common practices and others in Japan should be considered.

#### (2) Date of application

The Company is considering the date of application.

#### (3) Effect of application

The effect of applying the "Accounting Standard for Revenue Recognition," etc. on the consolidated financial statements is currently under assessment.

#### (n) Additional Information

#### Trust-Based Employee Shareholding Incentive Plan

At a meeting of the Board of Directors held on February 2, 2015, the Company resolved to introduce a trustbased employee shareholding incentive plan (hereinafter, the "Plan") to provide additional incentive for improving the Company's corporate value, primarily by enhancing employee welfare and benefits, raising employee awareness of the stock price and improving work motivation. The Plan will steadily supply the Company's shares to the employee shareholding association, and distribute the returns generated by management of trust assets to employees.

The Company is accounting for the Plan in line with the guidelines set out in "Practical Solution on Transactions of Delivering the Company's Own Stock to Employees etc. through Trusts" (PITF No. 30, March 26, 2015).

#### (1) Outline of transactions

The Plan is an incentive plan designed to return the economic benefits of an appreciation in the Company's stock price to all employees who join the Kyorin Pharmaceutical Group Shareholding Association (hereinafter, the "Shareholding Association").

Under the Plan, the Company shall enter into a stock benefit trust (Employee Shareholding Association Distribution Type) agreement where the Company is the settlor and Mizuho Trust & Banking Co., Ltd. (hereinafter, "Mizuho Trust & Banking") is the trustee (Hereinafter, the trust based on the agreement shall be referred to as the "Trust."). Furthermore, Mizuho Trust & Banking shall enter into an agreement with Trust & Custody Services Bank, Ltd. to re-entrust the management of trust assets, such as the Company's shares, with Trust & Customer Services Bank (Trust Account E) (hereinafter, "Trust Account E") as the trustee.

Trust Account E will acquire the Company's shares from the markets in the amounts expected to be acquired by the Shareholding Association during the prescribed stock acquisition period, after borrowing the acquisition funds from a bank. Until the trust account finishes, the shares will be periodically sold to the Shareholding Association. If a significant amount of realized gains on sale of shares remain within the trust assets of the Trust following the sale of the shares to the Shareholding Association by Trust Account E, these gains will be distributed as residual assets to Shareholding Association members who satisfy the eligibility requirements for beneficiaries. Moreover, the Company provides guarantees for the loans undertaken to acquire its shares. Therefore, if there is a residual loan balance equivalent to a realized loss on the sale of these shares due to a decline in the Company's stock price, the Company shall repay this residual loan balance based on the guarantee agreement.

#### (2) Company shares remaining in trust

Treasury shares remaining in the Trust are presented as treasury stock in net assets with carrying value in the Trust (excluding ancillary expenses). As of March 31, 2018 and 2017, the carrying amounts of the treasury shares were ¥306 million (\$2,879 thousand) and ¥968 million, respectively, and the total numbers of treasury shares were 107 thousand shares and 338 thousand shares, respectively.

#### (3) Carrying amounts of debt recorded through the application of the gross price method

The carrying amounts of debt recorded through the application of the gross price method were ¥749 million (\$7,048 thousand) and ¥1,269 million as of March 31, 2018 and 2017, respectively.

#### Employee Stock Delivery Trust (the "J-ESOP")

At a meeting of the Board of Directors held on February 23, 2016, the Company resolved that KYORIN Pharmaceutical Co., Ltd. ("KYORIN Pharmaceutical"), a subsidiary of the Company introduces an incentive plan referred to as the Employee Stock Delivery Trust (the "J-ESOP") (hereinafter, the "ESOP Plan") under which the Company's shares will be delivered to employees of KYORIN Pharmaceutical.

The Company is accounting for the Plan in line with the guidelines set out in "Practical Solution on Transactions of Delivering the Company's Own Stock to Employees etc. through Trusts" (PITF No. 30, March 26, 2015).

#### (1) Outline of transactions

Under the ESOP Plan, the Company's shares will be delivered to eligible employees of KYORIN Pharmaceutical who satisfy certain requirements, based on the share delivery rules prescribed by KYORIN Pharmaceutical in advance.

KYORIN Pharmaceutical will award its employees a set number of points based on business performance and his or her personal contribution and deliver or pay the Company's shares and cash to its employees who attained rights to receive such delivery or payment under certain conditions. The Trust will acquire the Company's shares to be delivered including future delivery portion using the entrusted money, and separately manage as trust assets.

Through introduction of the ESOP Plan, it is expected to contribute to employees' work motivation, by increasing interest in improvement of business performance and the Company's share price. In addition, it is expected that various stakeholders including shareholders will receive shared benefits from improvement in the Company's corporate value.

#### (2) Company shares remaining in trust

Treasury shares remaining in the Trust are presented as treasury stock in net assets with carrying value in the Trust (excluding ancillary expenses). As of March 31, 2018 and 2017, the carrying amounts of the treasury shares were ¥1,645 million (\$15,479 thousand) and ¥1,645 million, respectively, and the total numbers of treasury shares were 754 thousand shares and 754 thousand shares, respectively.

#### Performance-Linked Stock Compensation Plan

At the 58th Ordinary General Meeting of Shareholders held on June 24, 2016, the Company resolved to introduce a performance-linked stock compensation plan (hereinafter, the "Plan") for directors (excluding outside directors) of KYORIN Holdings, Inc. and KYORIN Pharmaceutical (hereinafter, the "Group Directors").

The Company is accounting for the Plan in line with the guidelines set out in "Practical Solution on Transactions of Delivering the Company's Own Stock to Employees etc. through Trusts" (PITF No. 30, March 26, 2015).

#### (1) Outline of transactions

The Plan is a stock-based compensation plan whereby the Company's shares are acquired through a trust with the funds contributed by the Company, and the Company's shares and the amount of cash equivalent to the Company's shares at their fair value (hereinafter, the "Company's Shares, etc.") are paid to eligible Group Directors based on the stock benefit rules for directors prescribed by the Company and its subsidiary.

The Company adopts a Board Benefit Trust system when introducing the Plan. In principle, the Group Directors shall receive the Company's Shares, etc. on a certain date during the trust period set out by the stock benefit rules for directors or upon their retirement, whichever is earlier.

#### (2) Company shares remaining in trust

Treasury shares remaining in the Trust are presented as treasury stock in net assets with carrying value in the Trust (excluding ancillary expenses). As of March 31, 2018 and 2017, the carrying amounts of the treasury shares were ¥226 million (\$2,127 thousand) and ¥226 million, respectively, and the total numbers of treasury shares were 100 thousand shares and 100 thousand shares, respectively.

#### 3. U.S. Dollar Amounts

The translation of yen amounts into U.S. dollar amounts is included solely for convenience, as a matter of arithmetic computation only, at the rate of ¥106.27 = U.S.\$1.00, the approximate rate of exchange on March 31, 2018. The translation should not be construed as a representation that yen have been, could have been, or could in the future be, converted into U.S. dollars at the above or any other rate.

#### 4. Cash and Cash Equivalents

Cash and cash equivalents as of March 31, 2018 and 2017 for the consolidated statements of cash flows consisted of the following:

		Millions of yen	Thousands of U.S. dollars
	2018	2017	2018
Cash and cash in banks	¥44,117	¥43,619	\$415,141
Short-term investments	_	_	_
Time deposits with a maturity over three months	(1,145)	(1,120)	(10,774)
Cash and cash equivalents	¥42,971	¥42,499	\$404,357

#### 5. Short-Term Investments and Investment Securities

Information regarding marketable securities classified as other securities as of March 31, 2018 and 2017 is as follows:

Marketable other securities

		1	Millions of yen	Thousands of U.S. do		
			2018			2018
	Acquisition cost	Carrying value	Unrealized gain (loss)	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their acquisition cost:						
Equity securities	¥10,747	¥25,242	¥14,495	\$101,129	\$237,527	\$136,398
Debt securities:						
Government bonds	500	501	1	4,705	4,714	9
Corporate bonds	_	_	_	_	_	_
Other bonds	_	_	_	_	_	_
Subtotal	11,247	25,744	14,496	105,834	242,251	136,407
Securities whose carrying value does not exceed their acquisition cost:						
Equity securities	8	8	(0)	75	75	(0)
Debt securities:						
Government bonds	23,499	23,477	(21)	221,125	220,918	(198)
Corporate bonds	_	_	_	_	_	_
Other bonds	1,000	987	(12)	9,410	9,288	(113)
Subtotal	24,508	24,473	(35)	230,620	230,291	(329)
Total	¥35,756	¥50,217	¥14,461	\$336,464	\$472,542	\$136,078

		1	Millions of yen
			2017
	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their acquisition cost:			
Equity securities	¥ 8,744	¥19,927	¥11,183
Debt securities:			
Government bonds	5,501	5,508	6
Corporate bonds	_	_	_
Other bonds	_	_	_
Subtotal	14,246	25,436	11,189
Securities whose carrying value does not exceed their acquisition cost:			
Equity securities	2,012	1,780	(231)
Debt securities:			
Government bonds	16,400	16,382	(17)
Corporate bonds	_	_	_
Other bonds	1,000	980	(19)
Subtotal	19,412	19,143	(268)
Total	¥33,658	¥44,579	¥10,921

Unlisted securities and other non-marketable securities are not included in the above schedules as their fair market values are extremely difficult to be determined. The amounts of these securities were ¥493 million (\$4,639 thousand) and ¥493 million as of March 31, 2018 and 2017, respectively.

Sales amounts of securities classified as other securities and the related aggregate gain and loss for the years ended March 31, 2018 and 2017 are summarized as follows:

		Millions of yen	Thousands of U.S. dollars
	2018	2017	2018
Proceeds from sales	¥-	¥3	\$-
Gains on sales	_	3	_
Losses on sales	_	_	_

#### 6. Short-Term Bank Loans, Long-Term Debt and Lease Obligations

Short-term bank loans and the current portion of long-term debt and lease obligations as of March 31, 2018 and 2017 consisted of the following:

		Millions of yen	Thousands of U.S. dollars
	2018	2017	2018
Short-term bank loans	¥ 125	¥ 630	\$1,176
Current portion of long-term debt	832	691	7,829
Current portion of lease obligations	99	98	932
Total	¥1,056	¥1,419	\$9,937

The average interest rates applicable to short-term bank loans outstanding as of March 31, 2018 and 2017 are 0.5% and 0.4%, respectively.

Long-term debt (excluding long-term debt related to a trust-based employee shareholding incentive plan) and lease obligations as of March 31, 2018 and 2017 consisted of the following:

		Millions of yen	Thousands of U.S. dollars
	2018	2017	2018
Long-term debt, due through 2027 at average interest rate of 0.4% and 0.4% in 2018 and 2017, respectively	¥4,745	¥4,321	\$44,650
Lease obligations due through 2030 in 2018 and 2017	510	576	4,799
Current portion of long-term debt and lease obligations due within one year	(931)	(789)	(8,761)
Total	¥4,324	¥4,108	\$40,689

Interest expenses related to a trust-based employee shareholding incentive plan (see Note 2 (n)) are excluded from the calculation of the average interest rate applicable to long-term debt because interest expenses on such debt are not recorded as interest expense in the consolidated statement of income.

Long-term debt from Japan Science and Technology Agency (National Research and Development Agency), amounting to ¥792 million (\$7,453 thousand) and ¥490 million as of March 31, 2018 and 2017, respectively, bears no interest.

The annual maturities of long-term debt (excluding long-term debt related to a trust-based employee shareholding incentive plan and long-term debt from Japan Science and Technology Agency (National Research and Development Agency)) and lease obligations are summarized as follows:

Year ending March 31,	Millions of yen	Thousands of U.S. dollars
2019	¥931	\$8,761
2020	918	8,638
2021	382	3,595
2022	275	2,588
2023	258	2,428

The annual maturities of long-term debt from Japan Science and Technology Agency (National Research and Development Agency) are excluded from the above table because authorization date of success in development and other matters are not determinable.

The annual maturities of long-term debt related to a trust-based employee shareholding incentive plan are excluded from the above table because its repayment amount is variable.

#### 7. Shareholders' Equity

Japanese companies have been subject to the Companies Act of Japan (the "Companies Act"). The significant provisions in the Companies Act that affect financial and accounting matters are summarized below:

#### (a) Dividends

Under the Companies Act, companies can pay dividends at any time during the fiscal year in addition to the year-end dividend upon resolution at the shareholders' meeting. The board of directors may declare dividends (except for dividends-in-kind) if the company has prescribed so in its articles of incorporation for companies that meet certain criteria such as:

- (1) having the board of directors,
- (2) having independent auditors,
- (3) having a board of corporate auditors, and
- (4) the term of service of the directors is prescribed as one year rather than two years of normal term by its articles of incorporation.

The Companies Act permits companies to distribute dividends-in-kind (non-cash assets) to shareholders subject to a certain limitation and additional requirements.

Semiannual interim dividends may also be paid once a year upon resolution by the board of directors if the articles of incorporation of the company so stipulate. The Companies Act also provides certain limitations on the amounts available for dividends or the purchase of treasury stock. The limitation is defined as the amount available for distribution to the shareholders, but the amount of net assets after dividends must be maintained at no less than ¥3 million.

#### (b) Increases/Decreases and Transfer of Common Stock, Reserve and Surplus

The Companies Act requires that an amount equal to 10% of dividends must be appropriated as a legal reserve (a component of retained earnings) or as additional paid-in capital (a component of capital surplus) depending on the equity account charged upon the payment of such dividends until the total of aggregate amount of legal reserve and additional paid-in capital equals 25% of the common stock. Under the Companies Act, the total amount of additional paid-in capital and legal reserve may be reversed without limitation. The Companies Act also provides that common stock, legal reserve, additional paid-in capital, other capital surplus and retained earnings can be transferred among the accounts under certain conditions upon resolution of the shareholders.

#### (c) Treasury Stock and Stock Option

The Companies Act also provides for companies to purchase treasury stock and dispose of such treasury stock by resolution of the board of directors. The amount of treasury stock purchased cannot exceed the amount available for distribution to the shareholders, which is determined by specific formula. Under the Companies Act, stock acquisition rights, which were previously presented as a liability, are now presented as a separate component of net assets. The Companies Act also provides that companies can purchase both treasury stock acquisition rights and treasury stock. Such treasury stock acquisition rights are presented as a separate component of net assets or deducted directly from stock acquisition rights.

#### 8. Research and Development Expenses

Research and development expenses included in general and administrative expenses for the years ended March 31, 2018 and 2017 were ¥14,243 million (\$134,027 thousand) and ¥13,569 million, respectively.

#### Gain on Sales and Retirement of Property, Plant and Equipment, Net

Significant components of the gain on sales and retirement of property, plant and equipment, net for the years ended March 31, 2018 and 2017 are as follows:

Thousands of

		U.S. dollars	
	2018	2017	2018
Gain:			
Buildings and structures	¥ —	¥ —	\$ -
Machinery and vehicle	_	_	_
Land	50	44	470
Other	0	_	0
	¥ 50	¥ 44	\$ 470
Loss:			
Buildings and structures	¥ (40)	¥ (73)	\$(376)
Machinery and vehicle	(27)	(6)	(254)
Other	(35)	(100)	(329)
	(102)	(180)	(960)
Total	¥ (51)	¥(135)	\$(480)

#### 10. Financial Instruments

#### (a) Investment Policy of Financial Instruments

The Company and its consolidated subsidiaries mainly operate funds by the highly secured financial instruments such as deposits and highly rated bonds, ensuring the security and liquidity. The Company and its consolidated subsidiaries use bank loans as the prime source of financing, and no derivatives are used.

#### (b) Details of Financial Instruments, Associated Risks and Risk Management

Operating receivables such as notes and accounts receivable are exposed to credit risk. The Company and its consolidated subsidiaries, in accordance with internal rules, keep track of the adverse financial conditions of the customers in the early stage to mitigate the bad debt by monitoring the major customers' credit conditions periodically and managing the due date and balance per each customer. The Company and its consolidated subsidiaries mitigate foreign currency risk by utilizing foreign currency deposits for operating receivables denominated in foreign currencies and settling payables denominated in the same currencies through the deposits.

Short-term investments and investment securities mainly consist of highly rated bond securities and equity securities of companies with business relationships and are exposed to market risk and credit risk. The Company and its consolidated subsidiaries regularly review the fair value and issuers' financial condition to mitigate the risks.

Operating payables such as notes and accounts payable are mainly due within six months. Certain operating payables are denominated in foreign currencies.

Short-term bank loans are mainly used to finance operating capital, and long-term debts are used to finance fund for the introduction of a trust-based employee shareholding incentive plan, fund for the introduction of the Employee Stock Delivery Trust (the "J-ESOP") and funding support for development expenses from Japan Science and Technology Agency (National Research and Development Agency).

Operating payables and loans and debts are exposed to liquidity risk. The Company and its consolidated subsidiaries manage the risk by preparing and updating the cash management plan periodically.

#### (c) Supplemental Information on Fair Value of Financial Instruments

As well as the values based on market prices, fair values of financial instruments include values, which are reasonably calculated in case market prices do not exist. As the calculation of those values includes variable factors, those values may vary in case different assumptions are applied.

Carrying values, fair values, and their differences of financial instruments as of March 31, 2018 and 2017 are as follows:

		1	Millions of yen		Thousands	of U.S. dollars
			2018			2018
	Carrying value	Fair value	Difference	Carrying value	Fair value	Difference
Cash and cash in banks	¥ 44,117	¥ 44,117	¥—	\$ 415,141	\$ 415,141	\$-
Notes and accounts receivable	47,862	47,862	_	450,381	450,381	_
Short-term investments and investment securities	50,217	50,217	_	472,542	472,542	_
Total assets	¥142,197	¥142,197	¥—	\$1,338,073	\$1,338,073	\$-
Notes and accounts payable	¥ 10,266	¥ 10,266	¥-	\$ 96,603	\$ 96,603	\$-
Total liabilities	¥ 10,266	¥ 10,266	¥—	\$ 96,603	\$ 96,603	\$-

		N	Millions of yen
			2017
	Carrying value	Fair value	Difference
Cash and cash in banks	¥ 43,619	¥ 43,619	¥—
Notes and accounts receivable	46,192	46,192	_
Short-term investments and investment securities	44,579	44,579	_
Total assets	¥134,392	¥134,392	¥—
Notes and accounts payable	¥ 11,157	¥ 11,157	¥—
Total liabilities	¥ 11,157	¥ 11,157	¥—

Unlisted securities and others of ¥1,097 million (\$10,323 thousand) and ¥1,075 million whose fair values are extremely difficult to determine as of March 31, 2018 and 2017, respectively, are not included in the above tables.

Calculation method of fair value of financial instruments and information about securities are as follows:

#### Cash and cash in banks and Notes and accounts receivable

The carrying value is deemed as the fair value since it is scheduled to be settled in a short period of time.

#### Short-term investments and Investment securities

Fair value of equity securities is based on the price on stock exchanges and that of bonds is based on the price on bond markets or the price presented by the counterparty financial institutions. Please see Note 5, Short-Term Investments and Investment Securities, for securities by classification.

#### Notes and accounts payable

The carrying value is deemed as the fair value since it is scheduled to be settled in a short period of time.

The redemption schedule for monetary receivables and securities with maturities subsequent to March 31, 2018 is as follows:

				Millions of yen
				2018
	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
Cash and cash in banks	¥44,117	¥ –	¥—	¥—
Notes and accounts receivable	47,862	_	_	_
Short-term investments and investment securities:				
Other securities with maturities:				
Government bonds	600	23,400	_	_
Bonds	_	_	_	_
Other	_	1,000	_	_
Total	¥92,580	¥24,400	¥—	¥—

				2018
	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
Cash and cash in banks	\$415,141	\$ -	\$-	\$-
Notes and accounts receivable	450,381	_	_	_
Short-term investments and investment securities:				
Other securities with maturities:				
Government bonds	5,646	220,194	_	_
Bonds	_	_	_	_
Other	_	9,410	_	_
Total	\$871,177	\$229,604	\$-	\$-

#### 11. Retirement Benefit Plans

The Company and its consolidated subsidiaries have defined benefit pension plans, defined contribution pension plans, and annuity in advance retirement severance plans, and certain domestic consolidated subsidiaries adopt lump-sum retirement plans.

Certain consolidated subsidiaries have adopted the simplified method in calculating the retirement benefit obligations.

#### Defined benefit plans

(1) The changes in the retirement benefit obligation for the years ended March 31, 2018 and 2017 are as follows:

		Millions of yen	Thousands of U.S. dollars
	2018	2017	2018
Retirement benefit obligation at the beginning of the year	¥34,704	¥34,478	\$326,564
Service cost	1,165	1,160	10,963
Interest cost	173	172	1,628
Actuarial loss	436	157	4,103
Retirement benefits paid	(1,420)	(1,264)	(13,362)
Prior service costs	228	_	2,145
Increase due to change from simplified method			
to principle method	479	_	4,507
Retirement benefit obligation at the end of the year	¥35,767	¥34,704	\$336,567

(2) The changes in plan assets for the years ended March 31, 2018 and 2017 are as follows:

		Millions of yen	U.S. dollars
	2018	2017	2018
Plan assets at the beginning of the year	¥33,441	¥31,784	\$314,680
Expected return on plan assets	668	635	6,286
Actuarial gain or loss	(82)	330	(772)
Contributions paid by the employer	959	1,954	9,024
Retirement benefits paid	(1,420)	(1,264)	(13,362)
Increase due to change from simplified method			
to principle method	389	_	3,660
Plan assets at the end of the year	¥33,955	¥33,441	\$319,516

(3) The changes in liability (asset) for retirement benefits for consolidated subsidiaries applying the simplified method for the years ended March 31, 2018 and 2017 are as follows:

		Millions of yen	Thousands of U.S. dollars
	2018	2017	2018
Liability (asset) for retirement benefits at the beginning of the year	¥303	¥350	\$2,851
Retirement benefits costs	128	53	1,204
Retirement benefits paid	(22)	(17)	(207)
Contributions to the plans	(69)	(83)	(649)
Decrease due to exclusion from consolidation	(20)	_	(188)
Decrease due to change from simplified method to principle method	(128)	_	(1,204)
Liability (asset) for retirement benefits at the end of the year	¥191	¥303	\$1,797

(4) The reconciliation between the liabilities recorded in the consolidated balance sheet and the balances of defined benefit obligations and plan assets as of March 31, 2018 and 2017 are as follows:

		Millions of yen	Thousands of U.S. dollars
	2018	2017	2018
Funded defined benefit obligation	¥35,911	¥35,095	\$337,922
Plan assets	(34,162)	(33,941)	(321,464)
	1,749	1,153	16,458
Unfunded retirement benefit obligation	253	413	2,381
Net liability (asset) for retirement benefits	¥ 2,002	¥ 1,567	\$ 18,839
Liability for retirement benefits	¥ 2,136	¥ 1,676	\$ 20,100
Asset for retirement benefits	(133)	(109)	(1,252)
Net liability (asset) for retirement benefits	¥ 2,002	¥ 1,567	\$ 18,839

The above table includes defined benefit plans applying the simplified method.

(5) The components of retirement benefits costs for the years ended March 31, 2018 and 2017 are as follows:

		Thousands of U.S. dollars	
	2018	2017	2018
Service costs	¥1,165	¥1,160	\$10,963
Interest costs	173	172	1,628
Expected return on plan assets	(668)	(635)	(6,286)
Amortization of actuarial loss	980	1,020	9,222
Amortization of prior service costs	(39)	(67)	(367)
Retirement benefits costs based on the simplified method	128	53	1,204
Decrease due to change from simplified method to principle method	(38)	_	(358)
Retirement benefits costs	¥1,699	¥1,704	\$15,988

(6) Prior service costs and actuarial gain or loss included in other comprehensive income (before tax effect) for the years ended March 31, 2018 and 2017 are as follows:

		Millions of yen	Thousands of U.S. dollars
	2018	2017	2018
Prior service costs	¥ 268	¥ 67	\$ 2,522
Actuarial gain or loss	(461)	(1,194)	(4,338)
Total	¥(192)	¥(1,126)	\$(1,807)

(7) Unrecognized prior service costs and unrecognized actuarial loss included in accumulated other comprehensive income (before tax effect) as of March 31, 2018 and 2017 are as follows:

		Millions of yen	Thousands of U.S. dollars
	2018	2017	2018
Unrecognized prior service costs	¥ (136)	¥ (405)	\$ (1,280)
Unrecognized actuarial loss	3,563	4,024	33,528
Balance at the end of the year	¥3,426	¥3,618	\$32,239

#### (8) Plan assets

The breakdown of plan assets is as follows:

	2018	2017
Domestic debt securities	-%	41.3%
Domestic equity securities	5.7	5.7
Foreign debt securities	24.0	6.0
Foreign equity securities	10.7	12.5
General account	10.5	7.5
Short-term assets	22.9	_
Other	26.2	27.0
Total	100.0%	100.0%

In determining the long-term expected rate of return on plan assets, the Company and its consolidated subsidiaries consider the current and projected asset allocations, as well as current and future long-term rates of return for various categories of plan assets.

#### (9) Actuarial assumptions

	2018	2017
Discount rate	0.5%	0.5%
Expected rate of return on plan assets	2.0%	2.0%

#### Defined contribution plans

The Company and its consolidated subsidiaries contributed ¥296 million (\$2,795 thousand) and ¥306 million to the defined contribution plans for the years ended March 31, 2018 and 2017, respectively.

12. 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 U.S. dollars
2018	2017	2018
¥1,187	¥1,233	\$11,170
719	818	6,766
28	34	263
91	44	856
249	230	2,343
125	506	1,176
830	838	7,810
_	121	_
906	193	8,525
586	814	5,514
_	176	_
131	_	1,233
1,160	1,088	10,916
6,016	6,102	56,611
(185)	(225)	(1,741)
5,831	5,876	54,870
(1,232)	(1,330)	(11,593)
(4,428)	(3,344)	(41,667)
(573)	(749)	(5,392)
(126)	(3)	(1,186)
(6,360)	(5,427)	(59,848)
¥ (529)	¥ 449	\$ (4,978)
	¥1,187 719 28 91 249 125 830 — 906 586 — 131 1,160 6,016 (185) 5,831  (1,232) (4,428) (573) (126) (6,360)	2018       2017         ¥1,187       ¥1,233         719       818         28       34         91       44         249       230         125       506         830       838         —       121         906       193         586       814         —       176         131       —         1,160       1,088         6,016       6,102         (185)       (225)         5,831       5,876         (1,232)       (1,330)         (4,428)       (3,344)         (573)       (749)         (126)       (3)         (6,360)       (5,427)

Taxes on income consist of corporate, inhabitants and enterprise taxes. A reconciliation of the statutory tax rate to the effective tax rate for the years ended March 31, 2018 and 2017 are as follows:

	2018	2017
Statutory tax rate	30.9%	30.9%
Entertainment expenses and others that are not tax deductible permanently	1.4	1.6
Inhabitants' per capita taxes	1.1	1.0
Tax credits for research and development expenses	(6.2)	(3.4)
Valuation allowance	1.3	(3.4)
Internal profit elimination	(0.1)	(0.9)
Other	(0.9)	(1.0)
Effective tax rate	27.4%	24.8%

#### 13. Comprehensive Income

Reclassification adjustments and income tax effects on other comprehensive income for the years ended March 31, 2018 and 2017 are as follows:

		Millions of yen	Thousands of U.S. dollars
	2018	2017	2018
Unrealized holding gain (loss) on other securities:			
Gain arising during the year	¥3,540	¥(3,934)	\$33,311
Reclassification adjustments	_	(3)	_
Before income tax effects	3,540	(3,937)	33,311
Income tax effects	(1,083)	1,205	(10,191)
Unrealized holding gain (loss) on other securities	2,456	(2,732)	23,111
Translation adjustments:			
Adjustments arising during the year	(31)	(45)	(292)
Retirement benefits liability adjustments:			
Gain (loss) arising during the year	(747)	173	(7,029)
Reclassification adjustments	940	953	8,845
Before income tax effects	192	1,126	1,807
Income tax effects	58	(344)	546
Retirement benefits liability adjustments	133	781	1,252
Share of other comprehensive income of affiliates accounted for using equity method:			
Gain (loss) arising during the year	(0)	5	(0)
Total other comprehensive income	¥2,557	¥(1,990)	\$24,061

#### 14. Segment Information

#### (a) Overview of Reportable Segments

The Company's reportable segments are those for which separate financial information is available and regular examination by the board of directors is performed in order to decide how resources are allocated among the Company and evaluate their performance.

The Company has two reportable segments, the Ethical Pharmaceutical Business and the Consumer Healthcare Business, which are classified based on similarities in terms of products and services.

The Ethical Pharmaceutical Business mainly produces, sells, and purchases ethical drugs and generic drugs. The Consumer Healthcare Business mainly produces, sells, and purchases environmental hygiene products and over-the-counter drugs.

(b) Method of Calculating Net Sales, Profit (Loss), Assets and Other Items by Reportable Segment Accounting policies of the reportable segments are consistent to those described in Note 2, Summary of Significant Accounting Policies.

Segment profit is based on operating income.

Inter-segment transactions are based on prevailing market price.

#### (c) Information about Net Sales, Profit (Loss), Assets and Other Items by Reportable Segment

(c) illioithalion about Net Sales, Front					Millions of yen
					2018
			ortable segment		
	Ethical Pharmaceutical Business	Consumer Healthcare Business	Total	Adjustments	Consolidated
Net sales:					
Sales to third parties	¥104,703	¥5,937	¥110,640	¥ –	¥110,640
Inter-segment sales or transfers	14	0	14	(14)	_
Total	¥104,718	¥5,937	¥110,655	¥ (14)	¥110,640
Segment profit (loss)	¥ 8,260	¥ 187	¥ 8,447	¥ 375	¥ 8,822
Segment assets	¥164,079	¥9,493	¥173,572	¥24,778	¥198,350
Other items:					
Depreciation and amortization	¥ 3,285	¥ 52	¥ 3,338	¥ 306	¥ 3,644
Investments in affiliates accounted for using equity method	603	_	603	_	603
Increase in property, plant and equipment and intangible assets	3,413	29	3,443	98	3,541
				Thousand	ds of U.S. dollars
					2018
		Rep	ortable segment		
	Ethical Pharmaceutical Business	Consumer Healthcare Business	Total	Adjustments	Consolidated
Net sales:					
Sales to third parties	\$ 985,255	\$55,867	\$1,041,122	\$ -	\$1,041,122
Inter-segment sales or transfers	132	0	132	(132)	_
Total	\$ 985,396	\$55,867	\$1,041,263	\$ (132)	\$1,041,122
Segment profit (loss)	\$ 77,727		\$ 79,486	\$ 3,529	\$ 83,015
Segment assets	\$1,543,982	\$89,329	\$1,633,311	\$233,161	\$1,866,472
Other items:					
Depreciation and amortization	\$ 30,912	\$ 489	\$ 31,411	\$ 2,879	\$ 34,290
Investments in affiliates accounted for using equity method	5,674	_	5,674	_	5,674
Increase in property, plant and equipment and intangible assets	32,116	273	32,399	922	33,321
					Millions of yen
					2017
		Rep	ortable segment		
	Ethical Pharmaceutical Business	Consumer Healthcare Business	Total	Adjustments	Consolidated
Net sales:					
Sales to third parties	¥109,566	¥5,807	¥115,373	¥ –	¥115,373
Inter-segment sales or transfers	38	0	38	(38)	_
Total	¥109,604	¥5,807	¥115,412	¥ (38)	¥115,373
Segment profit (loss)	¥ 10,106		¥ 10,104	¥ 308	¥ 10,413
Segment assets	¥161,023	. ,	¥168,636	¥24,031	¥192,668
Other items:					
Depreciation and amortization Investments in affiliates accounted	¥ 3,236	¥ 58	¥ 3,294	¥ 324	¥ 3,619
for using equity method Increase in property, plant and	581	_	581	_	581
II IOI OGOO II I DI ODOI LVI DIGI IL GI IG					

- 1. "Adjustments" for "Segment profit (loss)" of ¥375 million (\$3,529 thousand) and ¥308 million for the years ended March 31, 2018 and 2017, respectively, were mainly eliminations of inter-segment transactions.
- 2. "Adjustments" for "Segment assets" of ¥24,778 million (\$233,161 thousand) and ¥24,031 million as of March 31, 2018 and 2017, respectively, were the Company's assets and offset of inter-segment receivables and payables.
- 3. "Adjustments" for "Depreciation and amortization" of ¥306 million (\$2,879 thousand) and ¥324 million for the years ended March 31, 2018 and 2017, respectively, were depreciation of property, plant and equipment and intangible assets of the Company.
- 4. "Adjustments" for "Increase in property, plant and equipment and intangible assets" of ¥98 million (\$922 thousand) and ¥98 million for the years ended March 31, 2018 and 2017, respectively, were increase in property, plant and equipment and intangible assets of the Company.
- "Segment profit (loss)" is adjusted to operating income disclosed in the accompanying consolidated statements of income.

(Related Information)

#### (a) Information by Product and Service

Information by product and service is omitted since the classification by product and service was the same as the reportable segment for the years ended March 31, 2018 and 2017.

#### (b) Information by Geographical Area

#### (1) Sales

Information about sales by geographical area is omitted for the years ended March 31, 2018 and 2017, since domestic sales were more than 90% of net sales on the consolidated statements of income.

#### (2) Property, plant and equipment

Information about property, plant and equipment by geographical area is omitted for the years ended March 31, 2018 and 2017, since property, plant and equipment in Japan constituted more than 90% of property, plant and equipment on the consolidated balance sheets.

#### (c) Information by Major Customer for the Years Ended March 31, 2018 and 2017

		A A'U'
		Millions of yen
		2018
Name of customer	Sales amount	Related segments
Alfresa Holdings Corporation	¥19,562	Ethical Pharmaceutical Business, Consumer Healthcare Business
SUZUKEN CO., LTD.	17,344	Ethical Pharmaceutical Business, Consumer Healthcare Business
MEDIPAL HOLDINGS CORPORATION	16,248	Ethical Pharmaceutical Business, Consumer Healthcare Business
Toho Pharmaceutical Co., Ltd.	13,351	Ethical Pharmaceutical Business, Consumer Healthcare Business
		Thousands of U.S. dollars
		2018
Name of customer	Sales amount	Related segments
Alfresa Holdings Corporation	\$184,078	Ethical Pharmaceutical Business, Consumer Healthcare Business
SUZUKEN CO., LTD.	163,207	Ethical Pharmaceutical Business, Consumer Healthcare Business
MEDIPAL HOLDINGS CORPORATION	152,894	Ethical Pharmaceutical Business, Consumer Healthcare Business
Toho Pharmaceutical Co., Ltd.	125,633	Ethical Pharmaceutical Business, Consumer Healthcare Business

		Millions of yen
		2017
Name of customer	Sales amount	Related segments
Alfresa Holdings Corporation	¥20,561	Ethical Pharmaceutical Business, Consumer Healthcare Business
SUZUKEN CO., LTD.	18,251	Ethical Pharmaceutical Business, Consumer Healthcare Business
MEDIPAL HOLDINGS CORPORATION	16,867	Ethical Pharmaceutical Business, Consumer Healthcare Business
Toho Pharmaceutical Co., Ltd.	15,076	Ethical Pharmaceutical Business, Consumer Healthcare Business

(d) Information about Amortization and Unamortized Balance of Goodwill by Reportable Segment There was no unamortized balance of goodwill as of March 31, 2018 and 2017.

#### 15. Contingent Liabilities

Contingent liabilities as of March 31, 2018 and 2017 are as follows:

		Millions of yen	Thousands of U.S. dollars
	2018	2017	2018
Guarantors of indebtedness of employees	¥6	¥7	\$56

#### 16. Amounts per Share

Amounts per share for the years ended March 31, 2018 and 2017 are as follows:

	Yen		U.S. dollars
	2018	2017	2018
Basic profit	¥ 89.28	¥ 99.45	\$ 0.84
Cash dividends	58.00	58.00	0.55
Net assets	2,214.13	2,146.83	20.83

Basic profit per share was computed based on the profit attributable to common shareholders of KYORIN Holdings, Inc. and the weighted average number of shares of common stock outstanding during the year. Diluted profit per share is omitted because no potentially dilutive shares were outstanding during the years ended March 31, 2018 and 2017.

Cash dividends per share represent the cash dividends applicable to the year.

The amount per share of net assets is computed based on the net assets attributable to common share-holders of KYORIN Holdings, Inc. and the number of shares of common stock outstanding at the year-end.

The treasury shares remaining in trust and recorded as treasury stock in shareholders' equity are included in the treasury shares excluded from the calculation of the average number of shares during the fiscal year, which is used to calculate the amount of profit per share. Furthermore, these treasury shares are included in the number of treasury shares excluded from the total number of issued shares at the end of the fiscal year, which is used to calculate net assets per share.

The average numbers of treasury shares during the fiscal year that were excluded from the calculation of the amount of profit per share were 1,068,358 and 1,255,816 for the years ended March 31, 2018 and 2017, respectively.

The numbers of these treasury shares at the end of the fiscal year that were excluded from the calculation of net assets per share were 961,700 and 1,193,500 as of March 31, 2018 and 2017, respectively.

#### 17. Subsequent Events

#### Merger and Demerger among Wholly Owned Subsidiaries of the Company

Based on the resolution at a meeting of the Board of Directors held on December 19, 2017, the Company had KYORIN Pharmaceutical Group Facilities Co., Ltd. (Chiyoda-ku, Tokyo), a consolidated subsidiary of the Company, acquire the Noshiro Plant (Noshiro, Akita) of KYORIN Pharmaceutical Co., Ltd., a consolidated subsidiary of the Company, and the Production Division (Nanto, Toyama) of KYORIN Rimedio Co., Ltd., a consolidated subsidiary of the Company, through an absorption-type company demerger and acquire KYORIN Pharmaceutical Facilities Co., Ltd. (Koka, Shiga), a consolidated subsidiary of the Company, through an absorption-type merger effective as of April 1, 2018.

#### 1. Purpose of the absorption-type demerger and the absorption-type merger

One of the priority strategies of the Group's medium-term business plan (2016–2019), HOPE 100 Stage 2, is "Enhanced low cost structure: Reform of the cost structure through optimization within the Group" and the Group has been conducting the overall optimization of production operations through collaborations between its Group companies. The Group is aiming at leveling of capacity utilization and the efficient use of assets, and the building of a competitive Group production structure for consistently providing high-quality products at low cost by consolidating the production functions.

#### 2. Outline of the absorption-type demergers

(1) Outline of the companies involved in the absorption-type demergers

	Demerged companies		Successor company
1. Name	KYORIN Pharmaceutical Co., Ltd.	KYORIN Rimedio Co., Ltd.	KYORIN Pharmaceutical Group Facilities Co., Ltd. (Newly established in October 2017)
2. Head office	6, Kanda Surugadai 4-Chome Chiyoda-ku, Tokyo	287-1, Shimocho, Moroe-Cho, Kanazawa- City, Ishikawa	6, Kanda Surugadai 4-Chome Chiyoda-ku, Tokyo
3. Representative	Minoru Hogawa	Hiroshi Hashizume	Michiro Onota
4. Business description	Manufacture and sales of prescription medicine	Manufacture and sales of prescription medicine	Manufacture and sales of prescription medicine
5. Year of establishment	1940	1947	2017
6. Closing date	March 31	March 31	March 31

#### (2) Date of the demergers

April 1, 2018

#### (3) Legal form of the demergers

Absorption-type demerger with KYORIN Pharmaceutical Co., Ltd. and KYORIN Rimedio Co., Ltd. as the demerged companies and KYORIN Pharmaceutical Group Facilities Co., Ltd. (Chiyoda-ku, Tokyo) as the successor company

#### (4) Outline of the accounting treatment

The Company applied the accounting treatment stipulated by the Accounting Standard for Business Combinations (ASBJ Statement No. 21, September 13, 2013) and the Guidance on Accounting Standard for Business Combinations and Accounting Standard for Business Divestitures (ASBJ Guidance No. 10, September 13, 2013) for the transaction under common control.

#### 3. Outline of the absorption-type merger

(1) Outline of the companies involved in the absorption-type mergers

	Surviving company	Absorbed company
1. Name	KYORIN Pharmaceutical Group Facilities Co., Ltd. (Newly established in October 2017)	KYORIN Pharmaceutical Facilities Co., Ltd.
2. Head office	6, Kanda Surugadai 4-Chome Chiyoda-ku, Tokyo	1-4 Sasagaoka, Mizukuchi-cho, Koka, Shiga
3. Representative	Michiro Oonota	Kei Takahashi
4. Business description	Manufacture and sales of prescription medicine	Manufacture and sales of prescription medicine
5. Year of establishment	2017	2012
6. Closing date	March 31	March 31

#### (2) Date of the merger April 1, 2018

#### (3) Legal form of the merger

Absorption-type merger with KYORIN Pharmaceutical Group Facilities Co., Ltd. (Chiyoda-ku, Tokyo) as the surviving company and KYORIN Pharmaceutical Facilities Co., Ltd. (Koka, Shiga) as the absorbed company

#### (4) Outline of the accounting treatment

The Company applied the accounting treatment stipulated by the Accounting Standard for Business Combinations (ASBJ Statement No. 21, September 13, 2013) and the Guidance on Accounting Standard for Business Combinations and Accounting Standard for Business Divestitures (ASBJ Guidance No. 10, September 13, 2013) for the transaction under common control.

## **Independent Auditor's Report**



Ernst & Young ShinNihon LLC
Hibiya Kokusal Bidg
2-2-3 Uchisalwal-cho, Chiyoda-ku
Tokyo, Japan 100-0011

Erls +91 3 3503 1100
Fax: +81 3 3503 1197
www.shinnihon.or.jp

#### Independent Auditor's Report

The Board of Directors KYORIN Holdings, Inc.

We have audited the accompanying consolidated financial statements of KYORIN Holdings, Inc. and its consolidated subsidiaries, which comprise the consolidated balance sheet as at March 31, 2018, and the 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

Enset & young Shirtihon LLC

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.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of KYORIN Holdings, Inc. and its consolidated subsidiaries as at March 31, 2018, and their consolidated financial performance and cash flows for the year then ended in conformity with accounting principles generally accepted in Japan.

#### Convenience Translation

We have reviewed the translation of these consolidated financial statements into U.S. dollars, presented for the convenience of readers, and, in our opinion, the accompanying consolidated financial statements have been properly translated on the basis described in Note 3.

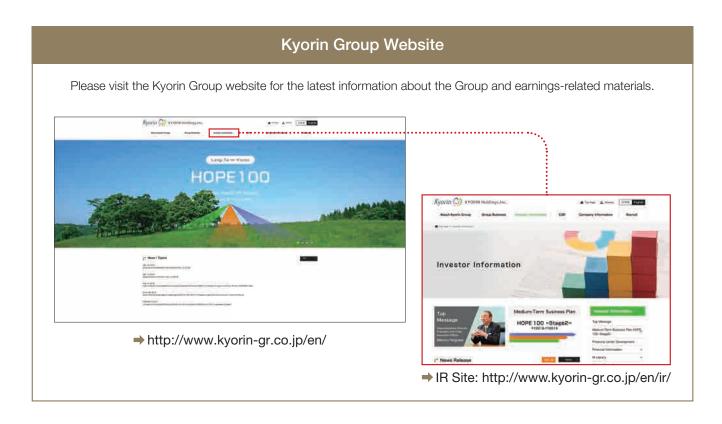
June 25, 2018

A member film of Erns: 8 Young Global Limites

# Corporate Overview/Stock Information (As of March 31, 2018)

Head Office	KYORIN Holdings, Inc.			
	6, Kanda Surugadai 4-chome, Chiyoda-ku, Tokyo 101-8311			
	Phone: +81-3-3525-4700			
	URL: http://www.kyorin-gr.co.jp/en/			
Establishment	1958			
Common Stock	¥700 million			
Outstanding Shares	74,947,628			
Shareholders	8,349			
Listing	Tokyo Stock Exchange, First Section			
Transfer Agent	Mizuho Trust & Banking Co., Ltd.,			
	2-1, Yaesu 1-chome, Chuo-ku, Tokyo 103-0028			
	Phone: +81-3-3278-8111			
Major Shareholders	Percentage of shares held			
	TEIJIN LIMITED	19.17%		
	Mykam Co., Ltd.	5.14%		
	The Master Trust Bank of Japan, Ltd.			
	(Trust Account)	3.21%		
	Japan Trustee Services Bank, Ltd.			
	(Trust Account)	2.97%		
	Banrina Co., Ltd.	2.60%		
	Archans Co., Ltd.	2.60%		
	Yutaka Ogihara	2.49%		
	Kyorin Group Stock Ownership Association	2.40%		
	Mariko Ogihara	2.35%		
	Hiroko Ogihara	2.33%		

### Major Shareholders 17.5% 26.7% 1.3% Shareholders 8,349 15.4% 39.0% 17.5% Financial institutions Financial instruments firms 1.3% Other corporations 39.0% 15.4% Foreign corporations 26.7% Individuals and other



#### The Kyorin Group

#### Consolidated Subsidiaries

#### KYORIN Pharmaceutical Co., Ltd.



¥4,317 million Percentage of ownership: 100% Head office: 6, Kanda Surugadai 4-chome, Chiyoda-ku, Tokyo 101-8311

Operations: Drug discovery business, manufacture and sales of drugs (ethical drugs, over-the-counter drugs and others)

With a corporate vision of aiming to be "a pharmaceutical manufacturer that is trusted by patients and medical professionals, and is recognized for its presence in society," KYORIN Pharmaceutical works to establish its presence in the specific fields of respiratory, otolaryngology and urology, and create innovative new drugs that can be deployed on a global level.

#### KYORIN Rimedio Co., Ltd



Capital: ¥1,200 million Percentage of ownership: 100% Head office: 287-1, Shimocho Moroe-cho, Kanazawa-shi, Ishikawa 920-0017 Operations: Manufacture and sales of drugs (generic drugs, over-the-counter

drugs and others)

As the Kyorin Group subsidiary responsible for the generic drugs business, KYORIN Rimedio aims to become "a highly reliable generic drug manufacturer." To contribute to the health of patients, and recognizing critical social issues in reducing healthcare costs and helping to maintain social security infrastructure, KYORIN Rimedio will continue to ensure a stable supply of high-quality products and information, as it works to deliver distinctive generic drugs to the market.

#### KYORIN Medical Supply Co., Ltd.



Capital: ¥488 million Percentage of ownership: 100%

Head office: 6F Niikura Building, 2-11, Kanda Tsukasamachi 2-chome, Chiyoda-ku,

Tokyo 101-0048

Operations: Environmental hygiene, sales promotion, planning and production of advertising

KYORIN Medical Supply handles the environmental hygiene business, which is being positioned as one of the core operations of the Kyorin Group's healthcare business. The company is also involved in a wide range of communications businesses, focusing on the planning and production of pharmaceutical-related advertising, and contributes to society as a member of a corporate group that aims to support healthy lifestyles.

#### KYORIN Pharmaceutical Group Facilities Co., Ltd.







Capital: ¥350 million Percentage of ownership: 100% Head office: 6, Kanda Surugadai 4-chome, Chiyoda-ku, Tokyo 101-8311 Operations: Manufacture, sales, imports, and exports of prescription medicines

As a new pharmaceutical manufacturing subsidiary, KYORIN Pharmaceutical Group Facilities was created through the merger of KYORIN Pharmaceutical's Noshiro Plant, KYORIN Rimedio's Manufacturing Division, and the former KYORIN Pharmaceutical Facilities (Koka City, Shiga Prefecture), and commenced full-scale operations on April 1, 2018. By consolidating the Group's manufacturing functions, the company provides a stable supply of high-quality, low-cost pharmaceuticals, and aims to be an independent pharmaceutical manufacturing subcontractor that is relied upon by other companies both inside and outside the Kyorin Group.

#### KYORIN Pharmaceutical Co., Ltd. Subsidiaries

#### Kyorin USA, Inc.

Capital: US\$500,000 Percentage of ownership: 100%

Head office: 500 Frank W. Burr Boulevard, Teaneck, New Jersey 07666, United States Operations: Research and analysis of other companies' technologies and collection of

information concerning clinical trials

#### Kyorin Europe GmbH

Capital: €50,000

Percentage of ownership: 100%

Head office: Kaiserstrasse 8, 60311 Frankfurt am Main, Germany

Operations: Research and analysis of other companies' technologies and collection of

information concerning clinical trials

#### ActivX Biosciences, Inc.

Percentage of ownership: 100%

Head office: 11025 N. Torrey Pines Rd., La Jolla, California 92037, United States

Operations: Discovery and evaluation of candidate compounds

#### **Equity-Method Affiliate**

#### Nippon Rika Co., Ltd.

Capital: ¥411 million Percentage of ownership: 29.9%

Head office: 2-2, Nihonbashi Honcho 4-chome, Chuo-ku,

Tokyo 103-0023

Operations: Production and sales of pharmaceuticals, reagents,

intermediates, and other products



#### Disclaimer Regarding Forward-Looking Statements

Statements made in this annual report with respect to KYORIN Holdings, Inc.'s forecasts, plans, strategies and other statements other than those of historical facts are forward-looking statements about the future performance of the Company and its consolidated subsidiaries and are based on management's rational assumptions and beliefs in light of information currently available. As a consequence, readers should understand that, for a variety of reasons, actual results could differ materially from projections presented in this report. Key factors that could impact our results include, but are not limited to, economic conditions, social trends, competition from rival companies, laws and regulations, uncertainties in drug development and exchange rate fluctuations.



6, Kanda Surugadai 4-chome, Chiyoda-ku, Tokyo 101-8311, Japan Corporate Communication, President's Office TEL +81-3-3525-4707 URL http://www.kyorin-gr.co.jp/en/



