Your Health is Kyorin's Mission

2021

ANNUAL REPORT

Year ended March 31, 2021

Kyorin

KYORIN Holdings, Inc.

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

Kyorin
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Kyorin
KYORIN Holdings, Inc.

Corporate Philosophy of the Kyorin Group

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

Corporate Message

Your Health is Kyorin's Mission

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 people's better health in any day and age.

Kyorin Legend

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.

CONTENTS

Editorial Policy

Annual Report 2021 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 non-financial 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 2020 (April 1, 2020 to March 31, 2021); some information also relates to fiscal 2021 activities.

Overview of HOPE100 Long-Term Vision

The Kyorin Group is working to realize its long-term vision, HOPE100, in 2023 to coincide with the centenary of the Group's core subsidiary, KYORIN Pharmaceutical Co., Ltd.
The overall vision comprises the **Statement and Five HOPEs.**

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

To Our Stakeholders

Minoru Hogawa
Representative Director and Chairman

Yutaka Ogihara
Representative Director, President and Chief Executive Officer

Striving to achieve continuous growth and the enhancement of corporate value through unique initiatives based on Kyorin's corporate philosophy

We would like to thank all our stakeholders for your ongoing support and understanding.

First, we would like to offer our deepest sympathy to all who have contracted COVID-19. We would also like to express our sincere gratitude to the frontline medical professionals working to prevent the spread of infections and bring the disease under control.

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 has formulated the HOPE100 long-term vision targeting 2023, the 100th anniversary of the founding of our core subsidiary, KYORIN Pharmaceutical Co., Ltd., as we work to achieve continuous growth and to enhance our corporate value over the medium to long term.

Through our business activities, we aim to become a globally recognized company by creating innovative new drugs and to engage in the comprehensive development of the new drugs business, the generic drugs business, and the infectious disease-related business with the aim of becoming a company that provides broad support for people's health. Under the statement "Realization of a growth trend through the pursuit of originality," included in the long-term vision's HOPE100–Stage 3– medium-term business plan (fiscal 2020–2023), we are striving to achieve performance targets through various business strategies and organizational strategies.

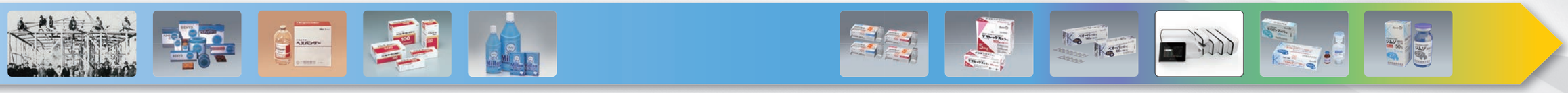
In addition, to fulfill our social responsibility as a company, we are strengthening our internal corporate governance structure and pursuing thorough compliance and work-style reforms, while also proactively working to address sustainability issues through our business activities.

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

August 2021

History of the Kyorin Group

Ninety-eight years have passed since the establishment of the Group's core subsidiary, KYORIN Pharmaceutical Co., Ltd., during which time we have been contributing to the treatment and prevention of disease and the maintenance and improvement of health. Looking ahead and following our corporate philosophy, we will seek to be recognized both within and outside as a company that supports sound and healthy lifestyles, under the HOPE100 long-term vision, as we approach the 100th anniversary of our founding.



1923 ⟶ 2021 ⟶ 2023

Vision

HOPE100 Long-Term Vision (FY2010–FY2023)

Product history

Infectious disease initiatives

KYORIN Pharmaceutical Co., Ltd. has long pursued basic research in infectious diseases. One infectious disease treatment it developed was a new quinolone agent, which led to the production of the world's first oral new quinolone synthetic antibacterial agent Norfloxacin (Baccidal). This preparation was licensed to Merck & Co. (U.S.A.) in 1980, and was sold in around 140 countries. This was followed by the development of Fleroxacin (Megalocin) and Gatifloxacin (Gatiflo), and the current sale of Lascufloxacin (as Lasvic Tablets and Lasvic IV drip infusion kits). In addition to therapeutic drugs, we have expanded into prevention and diagnosis and the field of infection countermeasures through products such as the multipurpose disinfectant cleaner Rubysta, the disinfectant brand Milton, and the proprietary microchannel-based genetic measurement device GeneSoC®. ▶P.18

- 1980 Norfloxacin, an antibacterial agent, was licensed to Merck & Co. (U.S.A.).
- 1982 Norfloxacin was licensed to Astra (Sweden) and Liade (Spain).
- 1983 Norfloxacin was licensed to American Home Products (U.S.A.).
- 1984 Baccidal, a broad-spectrum oral antibacterial agent, was launched.
- 1986 Fleroxacin, an antibacterial agent, was licensed to F. Hoffmann-La Roche (Switzerland).
- 1989 Baccidal Eyedrops, a broad-spectrum ophthalmic antibacterial agent, was launched.
- 1993 Megalocin, a long-acting new quinolone agent, was launched.
- 1996 Gatifloxacin was licensed to Bristol-Myers Squibb (U.S.A.).
- 1998 Milton, an effervescent disinfectant business, was acquired from P&G.
- 2000 Gatifloxacin eyedrops were licensed to Allergan (U.S.A.).
- 2002 Gatiflo, a broad-spectrum oral antibacterial agent, was launched.
- 2012 RUBYSTA, a multipurpose disinfectant cleaner, was launched.
- 2017 KYORIN Pharmaceutical Co., Ltd. acquired all of the outstanding shares of jTAS Inc., and carried out an absorption-type merger of jTAS (entry to diagnosis business).
- 2019 GeneSoC®, a microchannel-based genetic measurement device, was launched.
- 2020 Lasvic Tablets, an oral new quinolone antibacterial agent, was launched.
  Coronavirus detection reagent SARS-CoV-2 GeneSoC ER Kyorin was launched.
  Dedicated research reagent for the GeneSoC® microchannel-based genetic measurement device was launched.
- 2021 New quinolone injectable antibacterial agent Lasvic IV drip infusion kit was launched.
  Coronavirus detection reagent SARS-CoV-2 GeneSoC N2 Kyorin was launched.

Management-related events

- 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. Kyorin Yakuhin Co., Ltd. was organized as an independent marketing division.
- 1947 The Okaya Plant was started.
- 1967 The Nogi Plant was opened.
- 1977 Central Research Laboratories were opened.
- 1992 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 opened.
- 1996 The Research Center was established.
  Nisshin KYORIN Pharmaceutical Co., Ltd. established as a 50-50 joint venture with Nisshin Flour Milling Inc.
- 1999 Listed on the Tokyo Stock Exchange, Second Section.
- 2000 Listed on the Tokyo Stock Exchange, First Section.
- 2002 A subsidiary company, Kyorin Europe GmbH (Germany), was established.
- 2004 ActivX Biosciences, Inc. (U.S.A.) became a wholly owned subsidiary.
- 2005 The stock of Toyo Pharma Co., Ltd. (present KYORIN Rimedio Co., Ltd.) was acquired, making it into a subsidiary company.
- 2006 The Kyorin Group shifts to a holding company structure through a share exchange with KYORIN Co., Ltd.
  The Nogi Plant was closed.
- 2008 Nisshin KYORIN Pharmaceutical Co., Ltd. merged into KYORIN Pharmaceutical Co., Ltd.
- 2010 KYORIN Co., Ltd. changed its name to KYORIN Holdings, Inc.
- 2012 The Shiga Plant of MSD K.K. was acquired (conversion into subsidiary) and KYORIN Pharmaceutical Facilities Co., Ltd. (head office: Shiga Prefecture) was established.
- 2013 The Head Office was moved to Ochanomizu sola city in Kanda Surugadai.
- 2015 Establishment of the WATARASE Research Center of KYORIN Pharmaceutical Co., Ltd. through consolidation of the Drug Discovery Center (the former Central Research Laboratories) and the R&D Center (the former Research Center).
- 2016 The Okaya Plant was closed.
- 2017 KYORIN Rimedio Co., Ltd.'s Takaoka Pharmaceutical Technology Innovation Center, was established.
- 2018 New manufacturing subsidiary, KYORIN Pharmaceutical Group Facilities Co., Ltd. (head office: Tokyo), commenced operations.
- 2020 KYORIN Pharmaceutical Group Facilities Co., Ltd. and KYORIN Medical Supply Co., Ltd. merged.

Vision

- 1961 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.
- 1981 Mucodyne, a mucoregulant, was launched.
- 1989 Ketas, for bronchial asthma and cerebrovascular disorders, was launched.
- 1996 Pentasa, a treatment for ulcerative colitis and Crohn's disease, was launched.
- 2001 Kipres, a leukotriene receptor antagonist and bronchial asthma treatment medicine, was launched.
- 2007 Uritos, an overactive bladder drug, was launched.
- 2013 Flutiform, a combination drug for asthma treatment, was launched.
- 2015 FPR2 Agonist Program was licensed to Bristol-Myers Squibb Company (U.S.A.).
- 2016 Desalex, an antiallergic agent, was launched.
- 2018 Acquired the exclusive distribution rights in Japan for NASONEX®, a therapeutic agent for allergic rhinitis using a metered-dose manual pump spray unit, from MSD K.K.
  Beova, an overactive bladder drug, was launched.
- 2021 Interstitial cystitis therapeutic agent Zymso was launched.

HOPE100 Long-Term Vision (FY2010–FY2023)

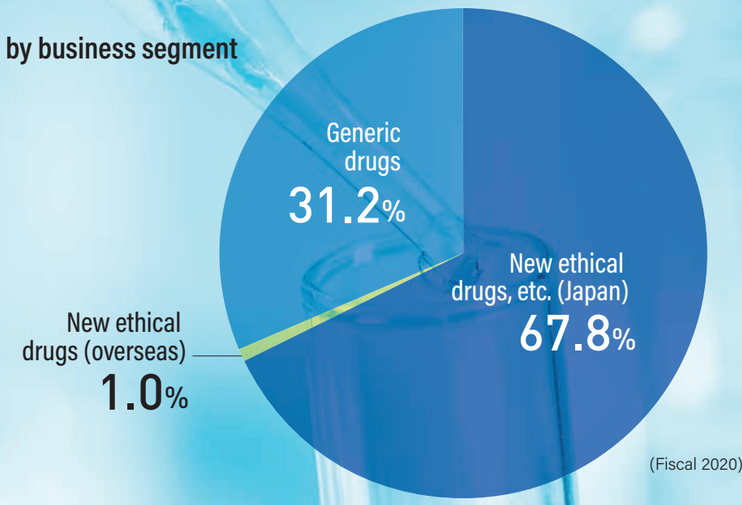
Corporate Vision for 2023

- Medium-Term Business Plan FY2010–FY2015 **Stage 1**
- Medium-Term Business Plan FY2016–FY2019 **Stage 2**
- Medium-Term Business Plan FY2020–FY2023 **Stage 3**

The Kyorin Group's Business

The Kyorin Group operates a pharmaceutical business organized under the holding company KYORIN Holdings Inc., focusing primarily on ethical drugs. Management resources for new drugs are concentrated in designated fields (respiratory, otolaryngology, and urology) based on a franchise customer (FC) strategy. The new ethical drugs, etc. business creates innovative new drugs, develops, manufactures, and sells pharmaceuticals, and also sells products related to environmental hygiene and the diagnosis of infectious diseases, as well as other products including over-the-counter drugs. We are also engaged in the in-house development, manufacturing, and sales of generic drugs.

Sales by business segment



(Fiscal 2020)

Primary Examples of New Ethical Drugs

Respiratory and Otolaryngology

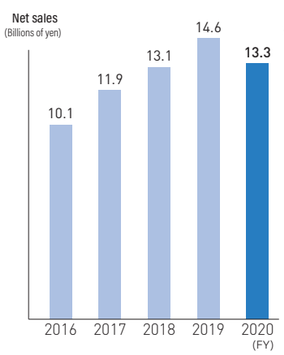
Flutiform

Combination drug for asthma treatment
General name: Fluticasone/Formoterol
Released : 2013

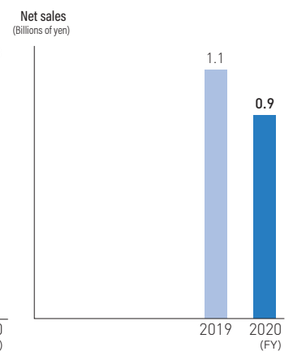
Lasvic

New quinolone synthetic antibacterial agent
General name: Lascufloxacin
Released : 2020 (75 mg tablet)
2021 (IV drip infusion kit)

ICS/LABA : ¥101 billion
Market share in FY2020 : 15%
*



Antibacterial agent (oral) : ¥63 billion
Market share in FY2020 : 2%
*



Urology

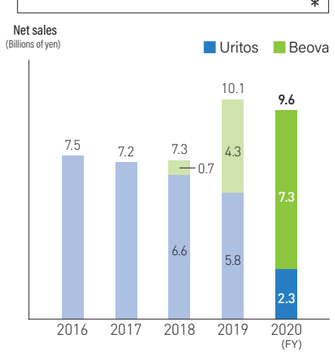
Uritos

Therapeutic agent for overactive bladder
General name: Imidafenacin
Released : 2007
Co-development and co-marketing with Ono Pharmaceutical Co., Ltd. (sold by Ono Pharmaceutical under the name Staybla)

Beova

Therapeutic agent for overactive bladder
General name: Vibegron
Released : 2018
Co-development and co-marketing with Kissei Pharmaceutical Co., Ltd.

OAB : ¥98 billion
Market share in FY2020 : 3% (Uritos)
9% (Beova)
*

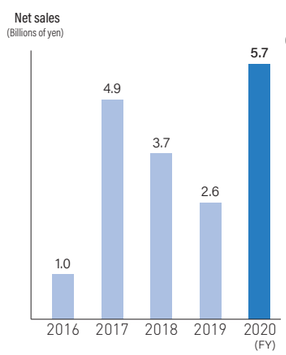


Otolaryngology

Desalex

Antiallergic agent
General name : Desloratadine
Released : 2016
Co-promotion with Kaken Pharmaceutical Co., Ltd., in field of dermatology

Antihistamine : ¥137 billion
Market share in FY2020 : 5%
*

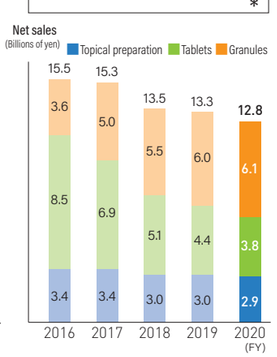


Other

Pentasa

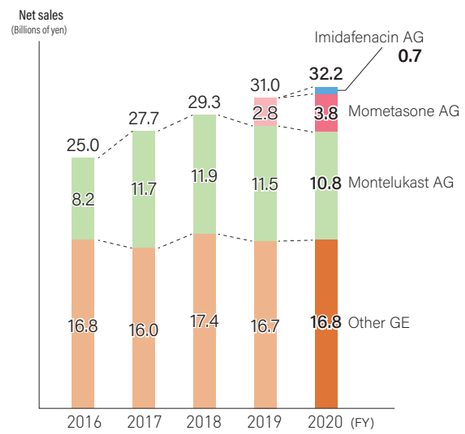
Ulcerative colitis and Crohn's disease treatment
General name : Mesalazine
Released : 1996 (250 mg tablet)
2015 (granules)

IBD : ¥45 billion
Market share in FY2020 : 33%
*



Generic Drugs

Providing a stable supply of high-quality new drugs and authorized generics, with the capability to carry out integrated development, manufacturing, and sales functions within the Group.



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Vision and Value Creation Process

The Kyorin Group strives to create value by addressing diversifying medical needs, while working to find solutions to social issues from an environmental, social, and governance (ESG) perspective, and sharing the results of those endeavors with all stakeholders. We believe the continuous implementation of this process for creating value will move us toward a sustainable society and achieve growth as a company, leading to enhanced corporate value.

Group-Related Social Issues

- Unmet medical needs
- Diversifying medical needs
- Combating infectious diseases
- Nurturing next-generation, work-style reform
- Social contribution

Invested capital

- Financial capital
- Manufacturing capital
- Intellectual capital
- Human capital
- Social and related capital
- Environmental capital

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

Business Activities

Drugs business

- New ethical drugs ▶P.20
- Generic drugs ▶P.28

Value Chain

- Drug Discovery ▶P.20
- Development ▶P.22
- Manufacturing ▶P.26
- Marketing ▶P.24

Reliability Assurance ▶P.29

Long-Term Vision HOPE100 Corporate Vision

Medium-Term Business Plan

Stage 1 (FY2010–FY2015)

Stage 2 (FY2016–FY2019)

Stage 3 (FY2020–FY2023) ▶P.16

Kyorin's strengths

- ▶Ability to discover novel drug compounds (original drug discovery capabilities)
- ▶Drug discovery competitiveness through alliances
- ▶Development potential (possession of know-how, personal connections, networks) for specific fields
- ▶A strong presence in specific fields
- ▶Ability to respond accurately through area management and a team structure
- ▶A manufacturing structure compatible with diverse needs
- ▶Efficient operation through equalized manufacturing balance and employee movement among plants
- ▶Stable supply of high-quality generic drugs (combining development, manufacturing, and sales functions)
- ▶Proactive pursuit of authorized generics business as a generics company affiliated with a manufacturer of new drugs

Environmental, Social, and Governance (ESG) Activities

Targeting sustainable social development and medium- to long-term increases in corporate value

- ESG Highlights ▶P.30
- Corporate Governance ▶P.32
- CSR Activities through Business Activities ▶P.38
- In harmony with the environment ▶P.44
- Co-existing in harmony with society ▶P.45

Value Provided by Kyorin

Society

- ▶Reducing the environmental burden
- ▶Contributing to the achievement of a sustainable society

Patients and medical professionals

- ▶Enhancing the quality of life (QOL)
- ▶Addressing unmet medical needs
- ▶Contributing to infectious disease countermeasures through prevention, diagnosis, and treatment

Employees

- ▶Creating workplace environments for career fulfillment
- ▶Developing employees' skills

Suppliers

- ▶Providing stable supplies and quality assurance
- ▶Procuring responsibly
- ▶Ensuring fair and free competition

Shareholders and investors

- ▶Providing stable returns to shareholders
- ▶Engaging in constructive dialogue

Striving to achieve continuous growth and enhance corporate value by fulfilling our social mission of contributing to people's health

Yutaka Ogihara
Representative Director, President and Chief Executive Officer

Q Please give us a summary of fiscal 2020.

A Business revenue and profit declined as a result of drug price revisions and other factors including the spread of coronavirus infections.

During fiscal 2020, the world faced an unprecedented crisis from the spread of coronavirus infections. Given this situation, the Kyorin Group continued to carry out its business activities as a company dedicated to life, recognizing a particular need to fulfill our social mission of providing a stable supply of pharmaceutical products.

In terms of manufacturing, we instituted thorough measures to prevent infection in plants and to ensure the safety of our employees, while strengthening our procurement and management of raw materials and ingredients. As a result, we could maintain a stable supply structure.

Although research and development saw effects on the progress of certain drug discovery projects, there were no major delays in the development schedule.

Marketing activities saw delays in market penetration for the new drugs group for reasons including restrained marketing activities by medical representatives (MRs), and sales were below our forecast. Marketing activities resumed to the extent possible after the lifting of the states of emergency, and we proactively engaged in new types of promotions including digital activities for medical institutions under continued calls for self-restraint.

Against this backdrop, the Group strove to revert to a growth trend under the HOPE100–Stage 3– medium-term business plan (fiscal 2020–2023) to achieve the HOPE100 long-term vision. Under the fiscal 2020 management policy of "accepting the challenge of pursuing originality," we embarked on proactive initiatives to accelerate the growth of the new drugs group, enhance the development pipeline, expand drug discovery projects, and improve our cost competitiveness.

Nevertheless, net sales declined from those of the previous year at the new ethical drugs, etc. (Japan) business, from the effects of NHI drug price revisions and the contraction of markets for main products in the Group's priority fields due to factors including the spread of coronavirus infections. On the other hand, sales at the generic drugs business rose, but consolidated net sales declined ¥7,079 million, or 6.4%, from those of the previous fiscal year, to ¥102,904 million.

In terms of profit, lower sales and a rise in the cost of sales ratio led to a ¥5,404 million decline in gross profit. Selling, general and administrative (SG&A) expenses were reduced ¥3,687 million (including a ¥1,283 million decrease in research and development expenses) through cost reduction initiatives and other factors including restrained marketing activities by MRs due to the spread of coronavirus infections, but operating income declined ¥1,717 million, or 22.9%, from that of the previous year, to ¥5,786 million. With extraordinary income of ¥1,929 million including a debt exemption gain due to the partial exemption of the repayment obligation for long-term debt to the Japan Science and Technology Agency (JST), net income declined 0.3% from that of the previous year, to ¥6,130 million.

Q Please tell us about the current business environment.

A With annual drug price revisions and the spread of coronavirus infections continuing, I believe the business environment will become even more challenging.

Negotiations among relevant cabinet ministers in December 2020, based on the government's policy for annual and off-year drug price revisions to control medical and pharmaceutical costs, have led to the implementation of annual NHI drug price revisions (as opposed to the previous policy of every two years) from fiscal 2021. The off-year revisions are to revise prices for items with "significant price deviations," and although the pharmaceutical industry requested that an average deviation rate of more than two times (16.0%) be considered appropriate, the criteria was set as items having a deviation rate of more than 5%. This will mean a significant increase in the number of items subject to drug price revisions. Going forward, a further acceleration in the pace of drug price reductions appears certain, and this will strongly impact our progress under Stage 3 and our corporate management. The effects will be particularly significant on long-listed products and generic drugs.

The Kyorin Group is therefore keenly aware that we need to accelerate the pace of growth for new drugs, expand the development pipeline, and work with even greater speed to create innovative new drugs, to achieve growth that will more than offset the negative developments.

I also believe that the effects from patients refraining from visiting physicians and thorough infection prevention measures stemming from the spread of coronavirus infections will continue to some degree and expect the ethical drugs market to remain flat or to contract. As the shift toward digital formats for MR activities to provide information will also accelerate, the Group will pursue stronger, original activities that fuse face-to-face meetings and digital formats.

Q Please update us on the progress of the HOPE100–Stage 3– medium-term business plan, which began with fiscal 2020.

A We are developing business strategies that align with coronavirus pandemic behavioral patterns.

Under the management policy for the first year of Stage 3 of "accepting the challenge of pursuing originality," we positioned the year as one whose success is measured by our ability to revert to a growth trend using main products including Flutiform, Desalex, Beova, and Lasvic. The prolonged spread of coronavirus infections, however, led to a contraction of the markets for ethical drugs in our priority fields, while self-restraint in MR activities delayed the market penetration of our main products, and results fell short of plans.

On the other hand, we made some progress in developing business strategies that align with coronavirus pandemic behavioral patterns.

In terms of "shifting to business based on the proposal of solutions and accelerating the growth of the new drugs group," we merged the former Healthcare Business Division into the Sales & Marketing Headquarters at KYORIN Pharmaceutical to begin solution-based marketing activities that integrate the ethical drugs business and the infection-related business, and pursued unique Kyorin initiatives with medical practitioners in the fields of prevention, diagnosis, and treatment of infectious disease. This approach will provide comprehensive solutions in the field of infectious disease to physicians, pharmacists, nurses, infection control teams (ICTs), and antimicrobial stewardship teams (ASTs) with products including Rubysta and Milton for prevention, GeneSoC® for diagnosis, and Lasvic for treatment. In addition, although the markets for major products like Flutiform, Desalex, and Lasvic contracted as a result of the coronavirus pandemic, proactive initiatives integrating face-to-face meetings and digital formats increased our share of each of those markets. Prescriptions for Beova greatly exceeded our initial sales plan and shipments are currently being adjusted. Subcontracted manufacturers are increasing facilities and working to launch new manufacturing sites, and we are facilitating steady production increases with the expectation that shipment adjustments will be fully completed during fiscal 2022.

With regard to "enhancing the pipeline to support medium-term growth," we have concluded a contract with ASKA Pharmaceutical Co., Ltd. for the joint development and sales of the enlarged prostate treatment AKP-009, marking a step forward in expanding the pipeline. Progress in "strengthening drug discovery capability to realize the creation of innovative new drugs" was generally as planned, with the approval for pediatric use of Flutiform, the release of the Lasvic Intravenous Drip Infusion Kit, and the approval for the manufacture and sales of Zymso® Intravesical Solution.

To "improve cost competitiveness," we have restructured the marketing organization at KYORIN Rimedio Co., Ltd. with a focus on drugstores and pharmacy chains, to make sales calls more efficient. We have also maintained a 100% success rate in our in-house development of generic products.

To "expand overseas revenue," we have concluded an out-licensing agreement with Otonomy, Inc. of the United States for a novel candidate compound created by KYORIN Pharmaceutical for sensorineural hearing loss and an asset purchase agreement with Priothera Limited of Ireland for the assignment of the immunomodulator KRP-203.

Q What are your management policies and initiatives for fiscal 2021?

A We will work to increase "speed" and "cost competitiveness" in our businesses under the management policy of "focusing on the pursuit of originality."

Considering the rapid shifts in our operating environment, we will not be able to achieve a growth trend with our previous speed and cost consciousness. I believe we need to continue repeatedly pursuing these efforts even more and to identify possibilities emerging from those results more quickly. We have therefore made "focusing on the pursuit of originality" our management policy for fiscal 2021, with business strategies focusing on "increasing 'speed' and 'cost competitiveness' in our businesses," through the following specific initiatives.

[Business strategies]

1 Shift to business based on the proposal of solutions and accelerate the growth of the new drugs group

We will accelerate to the greatest degree possible the integration of face-to-face meetings and digital formats in our medical marketing to step up our solution-based marketing at the infection-related business, while accelerating the growth of the new drugs group to maintain earnings that more than make up for the negative effects on sales and profit from drug price revisions.

2 Enhance pipeline to support medium-term growth

The lack of a pipeline for late-stage development is suggesting that the acquisition of in-licensed products to contribute to earnings growth over the short to medium term will be an important management issue. In April 2021, KYORIN Pharmaceutical concluded an agreement with MSD K.K. for exclusive distribution rights in Japan for the chronic cough treatment "Gefapixant" for which MSD has applied for the manufacture and marketing approval in Japan. As there are currently no approved treatments that have proven effective for refractory chronic cough or unexplained chronic cough, we expect "Gefapixant," to be a first-in-class drug. We will continue to strive to acquire drugs for our development pipeline to support the Group's growth.

3 Strengthen drug discovery capability to realize the creation of innovative new drugs

We are working to increase the speed of our evaluation and decision making on drug discovery themes. We will pursue discovery themes with a focus on the therapeutic target profile (TTP) and the target product profile (TPP), which serve as yardsticks for decisions. In April 2021, KYORIN Pharmaceutical began Phase I clinical trials on healthy adults in Britain of KRP-A218, a proprietary treatment for the rhinovirus infection that carries the risk of becoming aggravated, and we expect to out-license this product globally going forward. We are working to further strengthen our drug discovery capabilities with the aim of creating innovative new drugs.

4 Improve cost competitiveness

We recognize that in an increasingly challenging operating environment, generating profit is an important management issue. All divisions are working to thoroughly reduce costs.

5 Expand overseas revenue

We are building a solid track record in overseas out-licensing as we work to increase overseas revenue.

[Organization strategy]

Aim to be the No. 1 company for career fulfillment

Along with implementing work-style reforms that reflect changes in the external environment, we are introducing measures based on health management. We also thoroughly ensure that our corporate activities are consistent with our role as a company dedicated to life, based on legal and regulatory compliance and high ethics.

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

A We are working to resolve environmental problems and other social issues through our business activities.

We recognize that building relationships of trust with our stakeholders—patients and medical practitioners, shareholders and investors, employees, suppliers, and society—is essential for the enhancement of corporate value through continuous growth. Under the HOPE100 long-term vision, we are proactively working to create innovative new drugs that will be the source of the Group's value creation. In addition to contributing to people's health, we are prioritizing the themes of compliance and risk management, human resources management, environmental management, and social contribution activities. From an ESG perspective, we also consider it important to work proactively to address sustainability issues through activities based on the Sustainable Development Goals.

In terms of corporate governance, we are working to reinforce our management environment to gain the trust of society, with a focus on areas including expediting decision making, strengthening oversight functions for appropriate management, and maintaining transparency in corporate activities rooted in corporate ethics. To make the Board of Directors function more effectively, as of June 2021, independent outside directors make up one-third of the members. Offering advice based on their wealth of experience, they contribute to more active deliberation and stronger control. Our human resources management is based on the idea that our employees are the driving force

behind the Company's growth. We value our employees and are pursuing work-style reforms with the aim of making Kyorin "the leading company for career fulfillment."

Our corporate message of "Your Health is Kyorin's Mission" represents our strong commitment to contributing to people's health. In addition to providing value through our businesses dedicated to life, we aim to achieve a sustainable society by resolving social issues. We do not know when the completely unexpected coronavirus and the recent increased threat from virus variants will be brought under control, but the Kyorin Group recognizes that its ongoing efforts to control infectious disease will contribute significantly to society. During fiscal 2020, our GeneSoC® microchannel-based genetic measurement device received attention for the speed of its detection time, and we have released two reagents specifically for coronavirus detection. We will continue to make a unique contribution to the prevention, diagnosis, and treatment of infectious disease, covering coronavirus countermeasures and addressing issues related to the appropriate use of drugs, including the growing international problem of antimicrobial resistance (AMR).

By strengthening these ESG initiatives, the Kyorin Group is aiming for continuous growth and enhancement of corporate value going forward.

Q What measures are you implementing regarding the use of capital?

A We aim to raise capital efficiency through investment for growth and returns to shareholders, while maintaining a sound financial base.

Our basic policy regarding capital measures is to raise capital efficiency through investment for growth and returns to shareholders, while maintaining a sound financial base. In terms of returns to shareholders, we aim to pay a stable dividend, taking into account the dividend on equity (DOE) ratio. Given the dramatic changes taking place in the Group's external environment, from fiscal 2021, we anticipate increasing demand for funds for investment for growth, including the expansion of the development pipeline and capital expenditure, and have therefore lowered the DOE, the basis of shareholder returns. We are working to increase our business speed and cost competitiveness even further. I am certain that this approach will lead to future returns and I ask for shareholders' understanding on this point.

Q In conclusion, do you have a message for stakeholders?

A We will strive to fulfill our social mission of contributing to people's health and to enhance corporate value over the medium to long term.

Following our corporate philosophy, we have been engaged in businesses that contribute to life and health since our founding. In addition to pursuing the challenges of drug discovery in our priority research areas of fibrosis research and kinase research, we have raised our level of specialization through initiatives to establish a presence in designated fields centered on respiratory, otolaryngology, and urology. Going forward, we will continue to focus on areas where we can deploy Kyorin's strengths and pursue the challenge of evolving into a "company that supports sound and healthy lifestyles" by promoting the important theme of health for all people. In doing this, we will strive to achieve a sustainable society while also fulfilling our social mission of contributing to people's health and enhancing corporate value over the medium to long term.

I ask for the continued support of all our stakeholders.

Overview of HOPE100—Stage 3— Medium-Term Business Plan

The statement of the medium-term business plan HOPE100–Stage 3– is "Realization of a growth trend through the pursuit of originality." We aim to achieve performance targets through various business strategies and organizational strategies.

Vision in Stage 3

Aim to become a globally recognized company by creating innovative new drugs, while expanding the new drugs business, the GE business, and the infection-related business (prevention, diagnosis, and treatment of infections) through an integrated approach that provides broad support for people's health.

[Statement] Realization of a growth trend through the pursuit of originality

Strategy

Priority strategies	Priority items
1 Shift to business based on the proposal of solutions and accelerate the growth of new drugs groups	・Shift to business based on the proposal of solutions to problems by combining ethical drugs business and infection-related business and make Kyorin's unique contribution to healthcare workers. ・Accelerate the growth of new drugs groups as much as possible (Flutiform, Desalex, Beova, Lasvic, etc.). ・Streamline the healthcare business into business focused on infection-related fields.
2 Enhance pipeline to support medium-term growth	・Actively invest in enhancements of the pipeline that will contribute to business performance in the medium term by targeting mainly the three specialities (pneumology, otolaryngology, and urology) of franchise customers, infections, and rare and intractable diseases as domains for in-licensing.
3 Strengthen drug discovery capability to realize the creation of innovative new drugs	・Continue adding new layers to existing priority research domains and technologies and taking on new research domains and technologies. ・Pursue R&D based on clarification of healthcare value of new drug candidates. ・Achieve POC* ourselves, as a general rule, and aim for early global out-licensing. ・Increase diversity by actively acquiring drug discovery seeds.
4 Improve cost competitiveness	・Increase cost competitiveness of the GE business by improving the efficiency of the GE sales structure. ・Strengthen the ability to create new generics. ・Establish a manufacturing structure to achieve stable supply and low cost while also enabling expansion of subcontracted manufacturing.
5 Expand overseas revenue	・Expand overseas revenue through the promotion of global out-licensing. ・Steadily take steps toward direct entry into the Asian market.

*Proof of concept: Verification of the appropriateness of a development concept through clinical trials

Organization

Aim to be the leading company for career fulfillment	・Train and attract human resources to support our development as a next-generation company, aiming to be the leading company for career fulfillment.

Performance

Numerical targets (consolidated basis)

Growth potential: Net sales—CAGR of at least 5%
Profitability: Operating income before deduction of R&D expenses (operating income + R&D expenses)—at least 20% of net sales

Capital policy and shareholder returns

Maintaining a sound financial base while raising capital efficiency through investments for growth and returns to shareholders
Aiming for stable dividends, taking into account the dividend on equity (DOE) ratio

Message from Executive in Charge of Finance

Proactive investment for growth aims for long-term enhancement of corporate value

Capital policies and shareholder returns

- Raising capital efficiency through investment for growth and shareholder returns, while maintaining a sound financial base
- Aiming for stable dividends, taking into account the dividend on equity (DOE) ratio

Yoh Ito
Senior Corporate Officer
Director, Finance & Accounting

The fundamental financial strategy included in the HOPE100–Stage 3– medium-term business plan consists of two parts: (1) raising capital efficiency through investment for growth and shareholder returns, while maintaining a sound financial base; and (2) aiming for stable dividends, taking into account the DOE ratio.

The annual NHI drug price revisions being implemented from fiscal 2021 will severely affect the Kyorin Group's profit levels. To enhance corporate value over the long term in this environment, the continuous release of new drugs as profit drivers will become even more important. To do this, we have been increasing our investment in in-house research and development and in in-licensing products from other companies as we work to expand our development pipeline. In addition, we are investing capital to increase manufacturing capacity as needed, while at the same time working to reduce costs.

In May 2021, we announced that we would reduce our dividend as expressed by the DOE ratio for the fiscal year ending March 2022. The extremely large amount of investment required means that new drug development entails high risk for pharmaceutical manufacturers, and because earnings are subject to drastic fluctuations from factors like patent expiries, maintaining a sound financial base is essential to our existence. The Group's total shareholders' equity ratio stood at a healthy 74.6% as of March 31, 2021. I ask that shareholders understand that this reduction in the dividend is intended to allow for proactive investment for growth and the long-term enhancement of corporate value while maintaining a sound financial base. This investment for growth will also entail the use of externally procured funds when necessary, to address opportunities for long-term growth as appropriate.

[Research and Development Expenses]

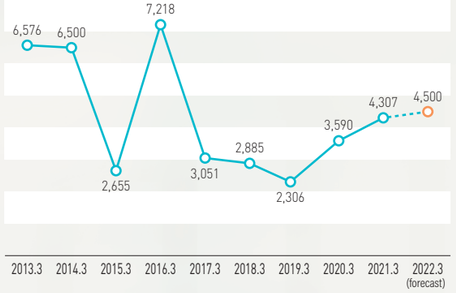
We are proactively investing to strengthen drug discovery capability to create innovative new drugs, while also in-licensing products to expand the pipeline to support our medium-term growth.

Research and development expenses (consolidated) (millions of yen)

[Capital investment]

We are investing capital to build an efficient manufacturing site that contributes to stable supplies of quality products and to expand our drug discovery and research and development facilities to build a business base for the medium to long term.

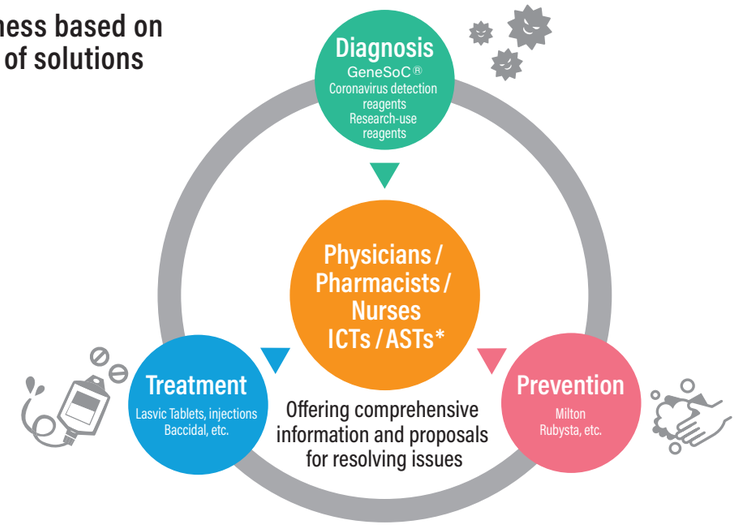
Capital expenditures (consolidated) (millions of yen)



TOPICS Initiatives to Control Infectious Diseases

The global threats posed by factors like antimicrobial resistance (AMR) and the spread of COVID-19 mean that there is greater demand than ever before for the prevention, diagnosis, and treatment of infectious diseases. The Kyorin Group has a proven track record in providing solutions to medical professionals in infection-related fields, offering comprehensive information and proposals for resolving issues related to infectious disease and infection control from a multifaceted perspective encompassing prevention, diagnosis, and treatment.

Shift to business based on the proposal of solutions



* ICTs: infection control teams; ASTs: antimicrobial stewardship teams

Contributing to the treatment of infectious diseases by raising awareness of appropriate procedures

Treatment

Lasvic

The Kyorin Group is cooperating with surveys and academic projects covering trends in drug-resistant bacteria and working with and providing support to infectious disease-related academic seminars and conferences to supply information to physicians, nurses, clinical technicians, and other members of ICTs and ASTs, to promote awareness of antimicrobial stewardship. As part of this program, two formulations of Lasvic—tablets and intravenous drip infusion kits—are contributing to the treatment of infectious diseases.

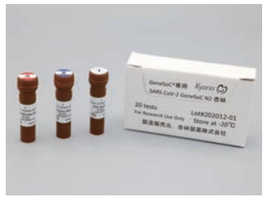
Identifies pathogenic microorganisms quickly, accurately, and easily and leads to appropriate use of antimicrobials

Diagnosis

GeneSoC®

Demand for detection equipment that accurately and quickly identifies pathogenic microorganisms in response to the coronavirus infections and antimicrobial resistance is currently growing.

The microchannel-based genetic measurement device GeneSoC® is a real-time PCR system that identifies pathogenic microorganisms quickly, accurately, and easily. We have released the SARS-CoV-2 GeneSoC ER Kyorin and the SARS-CoV-2 GeneSoC N2 Kyorin coronavirus detection reagents, and four research-use reagents to be used with the GeneSoC® system. Going forward, we are developing a smaller "GeneSoC® mini" and reagents for the simple extraction of nucleic acids with the aim of contributing further to quick detection at clinical sites, while also strengthening our business in pharmaceuticals for extracorporeal diagnosis.



Contributing to infection control at medical institutions

Prevention

Rubysta and Milton

Many types of microbes are present in medical institution environments, and in recent years we have learned that microbes are transmitted from person to person in these environments. Because much of this transmission is from environment surfaces to hands, it is important to keep environment surfaces clean in addition to disinfecting hands.

KYORIN Pharmaceutical Co., Ltd. is contributing to the control of infections with its lineup of the multipurpose disinfectant cleaner Rubysta and the disinfectant Milton, as infection countermeasure products in medical institutions.

Masahisa Fujita
Nurse certified in infection control, nurse practitioner
Deputy Director, Infection Control Office, Safety Management Division in Healthcare, Nippon Medical School Hospital

Nippon Medical School Hospital established an infection control team in 2003. Led by a nurse certified in infection control, the team includes physicians, pharmacists, and clinical technicians who work daily to control infections inside the hospital. In addition to our ongoing infection management, we are focusing on preventing the spread of coronavirus infections. This means that we have had to reconsider our usual infection management operations, and that reassessment created issues in terms of required time allocations and staffing adjustments. We are using Rubysta, which has a disinfection effect equivalent to 1,000 ppm sodium hypochlorite and the additional advantages of stability, little chlorine odor, and ease of preparation. It is widely used in places like emergency rooms and hematology wards, where the risk of infection is high. In the fields of obstetrics and pediatrics, we use Milton for immersion disinfection of tools and equipment. I hope that KYORIN Pharmaceutical will continue to provide these types of products and evidence to meet the needs of medical facilities.

Pharmaceutical Business

New Ethical Drugs

Drug Discovery

Koichiro Hagihara
Executive Director, Research and Development

With medical responses to health becoming increasingly diverse and complex, and new drug discovery more difficult than ever before, global pharmaceutical manufacturers are creating innovative new drugs, but many unmet medical needs still exist.

KYORIN Pharmaceutical supplements its proprietary drug discovery through open innovation with domestic and overseas pharmaceutical companies, academic institutions, and venture capital start-ups, in efforts to activate its drug discovery platform and to apply and cultivate new technologies, while also proactively seeking out and introducing external drug discovery themes in the pursuit of first-in-class drug discovery. Under the HOPE100–Stage 3– medium-term business plan, we are strengthening our drug discovery capabilities to create innovative new drugs, expanding our development pipeline to support medium-term growth, and putting maximum effort into efficient clinical trials, with the aim of enhancing corporate value.

During fiscal 2020, we carried out first-in-class drug discovery with a focus on our priority research domains of fibrosis and kinase research, including kinase research through closer cooperation between the WATARASE Research Center and ActivX Biosciences, Inc. (ActivX), based on our reorganized drug discovery structure, and we stepped up fibrosis research through our tie-up with the Department of Drug Discovery for Lung Diseases, which we established at Kyoto University. We were also able to out-license a new candidate compound for sensorineural hearing loss to Otonomy, Inc. of the United States, and KRP-A218, a proprietary treatment for rhinovirus infection that risks becoming aggravated, began Phase I clinical trials.

The spread of novel coronavirus infections had a negligible effect on KYORIN Pharmaceutical's Discovery Research Headquarters, but during fiscal 2021, we will continue to pay close attention to the safety and health of our employees while carrying out research and development activities, strengthening our drug discovery capabilities, which is the Group's most important priority, and striving to expand the development pipeline.

Strengths	Opportunities	Risks
● Working with the WATARASE Research Center and its disease model analytical technologies and low molecular weight drug discovery technologies, and ActivX in the United States, which has broad and quantitative kinase analysis technologies, we are able to identify targets and create novel compounds (Unique drug discovery capabilities) ● We are forming networks with academic institutions and venture capital start-ups in research areas including fibrosis, infectious diseases, and inflammation (pursuing open innovation)	● Using the low molecular weight drug discovery technologies we have developed over the years, we are not only acquiring multiple pharmacophores for newly identified discovery targets and pursuing optimal research with different basic structures, we are also pursuing simultaneous development with new modalities (nucleic acids, etc.), thereby diversifying the seeds to increase our likelihood of success	● Increased use of artificial intelligence in drug discovery could make low molecular weight drug discovery more efficient (through major cost reductions and shorter development periods), which could weaken our advantageous position in drug discovery ● Speed of ICT- and IoT-driven development at megapharmaceutical manufacturers

Initiatives under the HOPE100–Stage 3– Medium-Term Business Plan

Business strategy ▶ Strengthen drug discovery capability to create innovative new drugs

- Continue to add new layers to existing priority research domains and technologies and take on new research domains and technologies
- Pursue R&D based on clarification of healthcare value of new drug candidates
- Increase diversity by actively acquiring drug discovery seeds

Initiatives under the medium-term business plan

Continue to add new layers to existing priority research domains and technologies and take on new research domains and technologies

The WATARASE Research Center has technologies for analyzing disease models and low molecular weight drug discovery technologies, while ActivX has the KiNativ (broad and quantitative kinase analysis technology) platform. We have quantitatively and qualitatively reinforced our themes for initial-stage research and exploration in our priority research areas of fibrosis research and kinase research to make maximum use of the potential of these technologies and identify novel drug discovery targets. In fibrosis research, we are proactively working with academic institutions to explore candidate compounds that have pharmacological activity against identified discovery targets using iPS cells and human tissue, with a particular focus on creating innovative new drugs that act against targets that trigger fibrosis.

Pursuing open innovation

To supplement and build on KYORIN Pharmaceutical's proprietary drug discovery, we are proactively investigating external early-exploratory-stage drug discovery themes and candidate compounds, and using our evaluation technology platforms in areas including auditory function, bladder function, and infectious diseases to create a structure that can carry out speedy evaluations. This approach includes open innovation with academic institutions, venture capital start-ups, and domestic and overseas pharmaceutical companies, enabling us to approach drug discovery targets from various perspectives. We established the Department of Drug Discovery for Lung Diseases as a joint research program at the Graduate School of Medicine Kyoto University in fiscal 2017, and in fiscal 2020, extended for three years our program to integrate that academic institution's pathological research and basic research capabilities with KYORIN Pharmaceutical's drug discovery capabilities, to search for new targets for drug discovery. KYORIN Pharmaceutical is also pursuing joint research with the technology transfer company of the Hebrew University of Jerusalem to create new treatments in the respiratory field and is conducting joint research with the Microbial Chemistry Research Foundation's Institute of Microbial Chemistry to seek out antibacterial drugs effective against multidrug-resistant bacteria. We are also acquiring early-stage drug discovery seeds from outside the Group to build new platforms for drug discovery, which will increase and expand our drug discovery seeds, diversify disease areas and modalities, and disperse risks.

Initiatives for innovative new drug discovery

KYORIN Pharmaceutical applies selection and concentration in its research domains and themes. In the initial exploratory research stage, drug discovery activities emphasize therapeutic target profiles (TTP)* and scientific approaches toward them. After optimization research on leading compounds, decisions on whether to move forward are based on target product profiles (TPP). In addition, KYORIN Pharmaceutical uses the following three approaches in its drug discovery activities:

* KYORIN Pharmaceutical's approach to providing medical value: Propose and pursue themes with an awareness of specific symptoms (suffering) of specific patients (disease) and the relevant treatment being created.

●Search for novel targets

We are strengthening our early-exploration-stage research to search quickly for novel drug discovery targets and create innovative new drugs effective against those targets. To strengthen our early-stage drug discovery research both quantitatively and qualitatively, we are using humans (patients), disease model animal tissue or cells, and applying technologies including KiNativ and genome editing to enhance the quality of our target identification and validation. We are also stepping up our fibrosis research as a priority research area. Working with academic institutions with strengths in basic research, we are making maximum use of cutting-edge technologies like human disease-specific iPS cells for an enhanced level of drug discovery evaluation to select candidate compounds.

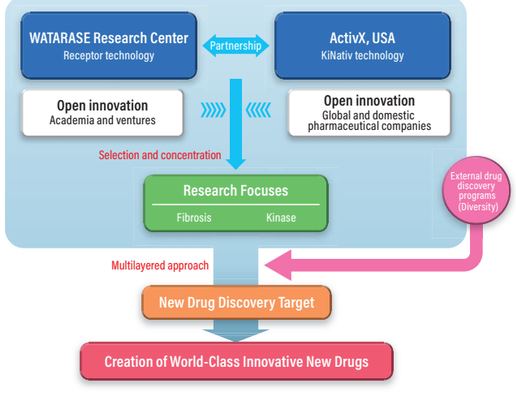
●Expand modalities

In addition to our existing low molecular weight drug discovery, we are using new technologies to explore compounds including medium molecular weight compounds and nucleic acid medicines, and building on our work on fusion protein formulations begun in January 2020 to pursue possibilities in new modalities and create new drugs with global potential that help address medical needs that cannot be met with low molecular weight drugs.

●Restructure drug discovery research centers

All research centers, covering early-exploration-stage research to research and development, have been consolidated at the WATARASE Research Center, which is carrying out drug discovery research with a structure that is effective and cooperative in the areas of pharmacology, chemistry, safety, and pharmacokinetics, as well as formulation and analysis. Experts in all these fields work in teams that cross organizational divisions to conduct research and complete development with greater quality and speed for drug discovery research that is consistent with global standards.

System for Continuous Creation of Innovative New Drugs



Pharmaceutical Business

New Ethical Drugs Development

Strengths

- Expertise, personal connections, and networks for product development in the fields of respiratory, otolaryngology, and urology (development capabilities in designated disease fields)

Opportunities

- An organizational structure that can carry out clinical trials effectively and promote the development of new drugs

Risks

- Significantly higher development costs from stricter standards for clinical trials and new drug approvals
- Increasingly severe effect on business viability from reform of the drug pricing system

Initiatives under the HOPE100 –Stage 3– Medium-Term Business Plan

Business strategy ▶ Enhance pipeline to support medium-term growth

Proactively invest in pipeline expansion to contribute to medium-term earnings through in-licensing for disease field including and peripheral to the three specialties of franchise customer fields (respiratory, otolaryngology, and urology), and infectious disease and rare and intractable diseases

In principle, achieve proof of concept (POC)* ourselves and aim for early global out-licensing

* Proof of concept: Confirmation of the effectiveness and safety to humans of candidate substances for new drugs in the research and development stage

Initiatives under the medium-term business plan

Expanding the pipeline to support growth

KYORIN Pharmaceutical, which considers the expansion of the pipeline to support medium-term growth an important management issue, is working to expand the development pipeline in its designated fields (respiratory, otolaryngology, and urology) as well as in infectious disease and in rare and intractable diseases.

During fiscal 2020, we acquired the benign prostatic hyperplasia treatment AKP-009 (in-licensed from ASKA Pharmaceutical Co., Ltd.). In terms of domestic development, the combination drug for asthma treatment Flutiform was approved for the additional indication of pediatric use, the injectable new quinolone antibacterial agent Lasvic Intravenous Drip Infusion Kit 150 mg was successfully launched, and we received approval for the manufacture and sales of the interstitial cystitis treatment Zymso Intravesical Solution 50%.

We also aim to roll out global licensing activities for proprietary compounds at an early date.

Products under development (As of May 11, 2021)

Phase Ⅲ – launch

Compound/Code	Target disease	Origin	Features	Stage
				Ph Ⅰ / Ph Ⅱ / Ph Ⅲ / NDA / Launch
Lasvic Intravenous Drip Infusion Kit 150 mg/ KRP-AM1977Y	Pneumonia, lung abscess, secondary infection of chronic respiratory disease	In-house	New quinolone injection developed to target lower respiratory tract infections 1. Highly distributed in lungs shows strong antibacterial activity against pathogenic bacteria for respiratory tract infections 2. Effective against both aerobic bacteria and anaerobic bacteria, and able to administer once a day 3. Effectiveness against aspiration pneumonia, pulmonary suppuration, and lung abscesses confirmed	Mar. 2021
Zymso Intravesical Solution 50%/KRP-116D	Interstitial cystitis	—	Dimethyl sulfoxide (DMSO), an unapproved and off-label drug with high medical needs	Apr. 2021

Note: Concluded an agreement with MSD K.K. for sales in Japan of chronic cough treatment Gefapixant Citrate (April 2021)

POC project (Ph Ⅰ–Ph Ⅱ)

Compound/Code	Target disease	Origin	Features	Stage
				Ph Ⅰ / Ph Ⅱ / Ph Ⅲ / NDA / Launch
KRP-R120	Interstitial lung disease (pulmonary sarcoidosis)	aTyr	Fusion protein drug that by binding to neuropilin-2 (NRP2) receptor has the action to suppress the excessive activation of immune cells, while being a potential first-in-class therapy to treat inflammatory diseases including pulmonary sarcoidosis	Jul. 2020 Ph Ⅰb/Ⅱa (aTyr in the U.S.A.)
KRP-A218	Rhinovirus infection that risks becoming aggravated	In-house	Antiviral drug to control viral replication within the body by targeting host molecules	Apr. 2021

Note: Development of Ad-SGE-REIC discontinued on the basis of difficulty realizing preconfigured product profiles (2nd quarter of FY2020)

In-licensed product

Compound/Code	Target disease	Origin	Features	Stage
				Ph Ⅰ / Ph Ⅱ / Ph Ⅲ / NDA / Launch
AKP-009	Benign prostatic hyperplasia	ASKA Pharmaceutical	Uses a novel androgen receptor modulator mode of action to shrink prostate as well as improve urinary function, and is expected to become a new therapeutic agent for benign prostatic hyperplasia	Dec. 2019 (ASKA Pharmaceutical)

Out-licensed product

Compound/Code	Licensee/Collaborative research	Target disease	Origin	Features	Stage
					Non-clinical / Ph Ⅰ / Ph Ⅱ / Ph Ⅲ / NDA
FPR2 agonist program	Bristol-Myers Squibb	Non-disclosure	In-house	FPR-2 agonists that mainly inhibit the migration of neutrophils and exhibit anti-inflammatory action	
KRP-203	Priothera	—	In-house	Sphingosine-1-Phosphate Receptor Agonist	
Compound for sensorineural hearing loss	Otonomy	Sensorineural hearing loss	In-house	New candidate compound for sensorineural hearing loss	

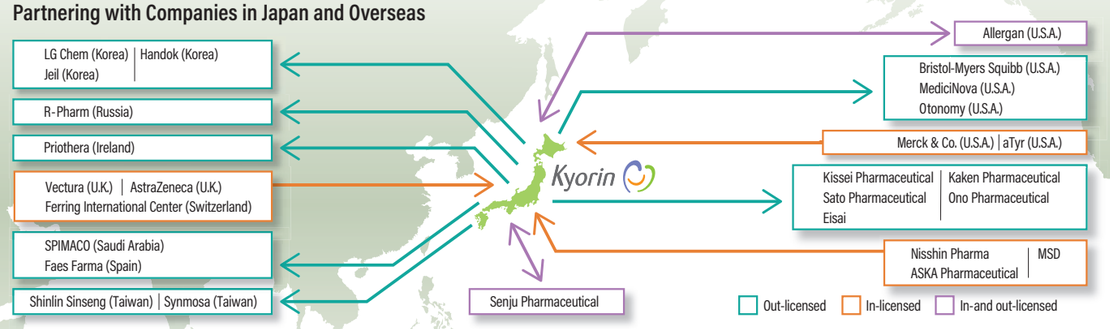
Promotion of proactive partnering activities

As per the business strategies in the HOPE100–Stage 3– medium-term business plan, KYORIN Pharmaceutical expanded its development pipeline by concluding an agreement with ASKA Pharmaceutical in September 2020 for the joint development and sales of a benign prostatic hyperplasia treatment (development code: AKP-009) and an agreement with MSD in April 2021 for the exclusive sales rights in Japan for the chronic cough treatment Gefapixant Citrate, for which MSD has applied for manufacturing and sales approval. Also, treatment of interstitial lung disease (pulmonary sarcoidosis, etc.) in Japan has progressed with the interstitial lung disease treatment KRP-R120, for which a licensing agreement was concluded with aTyr Pharma, Inc. of the United States in January 2020. Going forward, the Kyorin Group will continue its proactive partnering activities worldwide, with the aims of expanding the product pipeline to support medium-term growth and establishing a strong presence in our priority fields of respiratory, otolaryngology, and urology.

Promoting global out-licensing to increase overseas earnings

To maximize the value of its proprietary products, KYORIN Pharmaceutical is proactively engaged in out-licensing activities with global companies. In August 2020, a licensing agreement for a proprietary new candidate compound for sensorineural hearing loss was concluded with Otonomy of the United States, giving Otonomy exclusive global development, manufacturing, and sales rights for the compound. In October 2020, the intellectual property rights for the immunomodulator KRP-203 were sold to Priothera Limited, and in March 2021, a licensing agreement was concluded with Eisai Co., Ltd. related to the development and sales in four ASEAN countries of Vibegron, a therapeutic agent for overactive bladder (sales name in Japan: Beova). We are also currently working on overseas out-licensing of the new quinolone antibacterial agent Lascufloxacin (sales name in Japan: Lasvic).

Partnering with Companies in Japan and Overseas



Initiatives toward direct entry into Asia

In tandem with our licensing activities, we conducted market surveys and collected information on Southeast Asia, aiming to lay the foundation for a direct entry into overseas markets in the future, focusing on Asia. In 2017, we began selling our multipurpose disinfectant cleaner Rubysta through PT. Meiji Indonesian Pharmaceutical Industries (PT. Meiji Indonesia), a subsidiary of Meiji Seika Pharma Co., Ltd., and also concluded a licensing agreement for generic drug manufacturing technologies with the Vietnamese company BinhDinh Pharmaceutical and Medical Equipment JSC, and in 2019, we concluded an agreement giving generic drug sales rights to the Mongolian company Monospharm Trade Co., Ltd. Going forward, we will continue to consider directly entering overseas markets on the basis of locally collected information and move steadily in that direction.

Pharmaceutical Business

New Ethical Drugs Marketing

Masahide Sugibayashi
Executive Director, Sales & Marketing

Japan's ethical drug industry is undergoing structural market changes as a result of measures to reduce drug costs in line with the government's basic policy for reforming the drug pricing system. In this challenging market environment, the Kyorin Group has embarked on the HOPE100 –Stage 3– medium-term business plan. Fiscal 2020, the first year of the plan, was positioned as a period of renewed growth, and we strove to promote our new drugs group's products. Nevertheless, the novel coronavirus pandemic led to people refraining from visiting physicians, resulting in weak markets in KYORIN Pharmaceutical's priority fields, while restrained marketing activities by medical representatives meant that market penetration for new drugs was delayed. As a consequence, results for the year fell short of plans. At the same time, we developed and achieved a certain degree of success with new marketing styles in the field of infectious disease by going beyond treatment alone and providing total solutions that also include prevention and diagnosis. We also worked to meet current needs by supplementing and strengthening our marketing activities, which had previously consisted primarily of face-to-face interaction, by integrating digital technologies to provide information. We are confident that we have built a foundation for medical representative activities tailored to individual medical institutions and that we can anticipate accelerated growth in the new drugs group.

We expect novel coronavirus infections to continue to impact our marketing activities in fiscal 2021, but we have positioned the year as a period of turning around to a growth trend. With a shift to a solution-based approach in the field of infectious disease and the proactive development of activities that integrate digital technologies with face-to-face interaction, we will accelerate the growth of the new drugs group.

Strengths

- Strong presence and relationships of trust in designated fields (respiratory, otolaryngology, and urology) (franchise customer (FC) strategy)
- Product portfolio for continuous growth (full lineup of products for designated fields)
- Tailored responses to medical institutions through area management and team structure
- An infection-related business with products that contribute to prevention (Milton, Rubysta), diagnosis (GeneSoC®), and treatment (Lasvic) (solution-based approach)

Opportunities

- Lineup of patented products of the new drugs group to drive growth, including Flutiform, Desalex, Beova, and Lasvic, positioned for high sales growth
- With microchannel-based genetic measurement device GeneSoC®, which enables quick, accurate, and simple identification of pathogenic microorganisms, and development of diagnostic agents, the capability of offering protection and treatment as well as measures to address antimicrobial resistance (AMR) in the infection-related business

Risks

- Along with progress in control of medical representative visits and systems for them by appointment only, ways of providing information to physicians are shifting from traditional face-to-face interaction to internet-based methods, reducing opportunities for face-to-face meetings
- With the drastic overhaul of the drug pricing system, decline in sales of long-listed products will accelerate
- Ability to respond quickly to structural changes being sought in the domestic ethical drugs market

Initiatives under the HOPE100 –Stage 3– Medium-Term Business Plan

Business strategy ▶ Shift to business based on the proposal of solutions and accelerate growth of the new drugs group

Make a uniquely Kyorin contribution to medical practitioners by shifting to a solution-based approach that integrates the ethical drugs business and the infection-related business

Accelerate the growth of the new drugs group (Flutiform, Desalex, Beova, Lasvic, etc.) as much as possible

Consolidate healthcare businesses to focus on infection-related business and shift to solution-based approach

Initiatives under the medium-term business plan

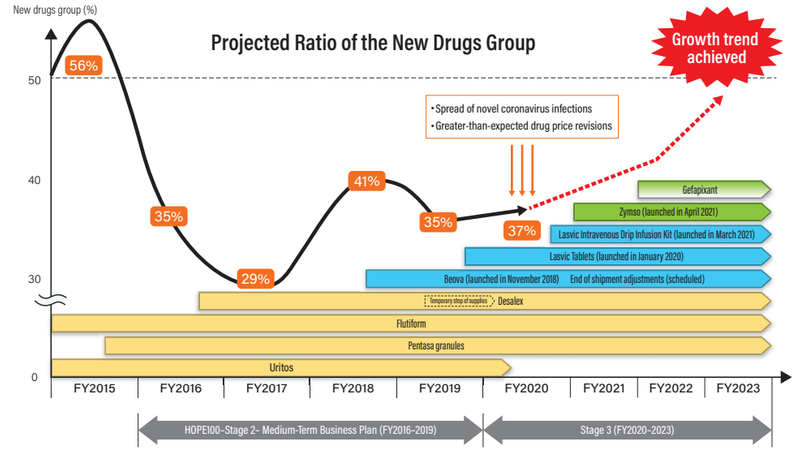
Shift in marketing style to solution-based approach

By engaging in solution-based activities that integrate the infection-related business with the new drugs business, we have begun making uniquely Kyorin contributions to medical practitioners. We aim to demonstrate Kyorin's originality by introducing Rubysta and Milton for prevention, GeneSoC® for diagnosis, and Lasvic for treatment to the doctors, pharmacists, and nurses of infection control teams (ICTs) and antimicrobial stewardship teams (ASTs) in particular, among medical practitioners, and by providing them comprehensive information. For details, please refer to "Topics: Initiatives to Control Infectious Diseases" on page 18.

Achieving a growth trend in the new drugs group

We see growth in Stage 3 driven by the new drugs group with the combination drug for asthma treatment Flutiform, the allergic disease treatment Desalex, the overactive bladder treatment Beova, and the new quinolone antibacterial agent Lasvic Tablets and Lasvic Intravenous Drip Infusion Kit. During fiscal 2020, the market for ethical drugs, our primary business area, contracted roughly 15% because of factors including drug price revisions and the novel coronavirus pandemic. Against this backdrop, sales of Flutiform decreased from those of the previous year, to ¥13.3 billion, but our market share grew to 15.5%. We are aiming for a 30% share by positioning the product as a first-choice asthma treatment on the basis of the utility of its aerosol formulations. As of the end of March 2021, Desalex's market share had recovered to the level prior to the temporary suspension of supplies (in December 2018). Going forward, we aim for Desalex to become the most prescribed drug in the field of otolaryngology and will also work toward increased prescriptions for internal medicine. Since the limit on the prescription period was lifted for Beova (in December 2019), the pace of prescriptions has been faster than forecast, leading to shipment adjustments. We apologize for any inconvenience caused, and as of now we expect to end these shipment adjustments during fiscal 2022. Lasvic was significantly affected by a contraction of the antibacterial market as a result of thorough novel coronavirus infection control measures. We launched the Lasvic Intravenous Drip Infusion Kit in March 2021, and with that and Lasvic Tablets we are aiming to contribute to the field of respiratory and otolaryngological infectious disease in fiscal 2021.

We see the effect from novel coronavirus infections continuing to some extent in fiscal 2021 but will put maximum effort into these Stage 3 growth drivers as we strive to achieve a growth trend.



Establishing a presence in the franchise customer fields

With the aim of establishing a presence in designated fields focusing on respiratory, otolaryngology, and urology, KYORIN Pharmaceutical has roughly 700 medical representatives engaged in activities to provide, gather, and transmit to medical practitioners information about the proper use of pharmaceutical products.

The marketing structure is a "team structure" comprising teams based on secondary medical districts (multiple medical representatives responsible for a designated area), using area management to cultivate an area as an entire team. Going forward, we will work to create a culture in which teams help one another and achieve their targets by refining our activities to address increasingly diverse medical needs swiftly and systematically.

Providing information using digital channels

The Guidelines for Prescription Drug Marketing Information Provision and the novel coronavirus pandemic have made it necessary to reform how information is provided to medical practitioners, in terms of both content and method. With the declarations of states of emergency, medical representatives have been forced to refrain from visiting medical institutions and having face-to-face interaction with medical practitioners. Given this situation, we have proactively developed activities for providing information using digital technologies. Taking a multifaceted approach to the use of digital media to provide, gather, and transmit information, we will work to optimize how we provide information, including using outside platforms in addition to our own media. We will also consolidate marketing data internally to enhance the quality of the information we provide to physicians. By supplementing and strengthening our marketing capabilities by integrating digital technologies with traditional face-to-face interaction, we will work to accelerate the growth of the new drugs group by developing medical representative activities tailored to each medical institution.

Pharmaceutical Business

Manufacturing

Michiro Onota
President and Chief Executive Officer
KYORIN Pharmaceutical Group Facilities Co., Ltd.

With unique manufacturing capabilities from having three plants as manufacturing centers, KYORIN Pharmaceutical Group Facilities is carrying out overall product optimization and appropriate capital investment to create a highly reliable manufacturing structure with an awareness of low-cost operations. During fiscal 2020, we did not offer training involving transfers between plants because of the spread of novel coronavirus infections. Instead, we switched to training specific to each plant, as we strove to raise the level of our good manufacturing practices (GMPs) even higher. We also worked to improve our structures for quality management and stable supplies by pursuing new technologies, which included photographing manufacturing operations and using this visualization to pass on technologies and analyze optimal actions. We will build on these activities to achieve stable supplies of high-quality products at low cost, and aim to expand our competitive manufacturing structure to allow for increased subcontracting from outside the Group.

Strengths

- Ability to meet diverse needs with mass-production technologies through labor saving and automation, the implementation of good manufacturing practices (GMPs) that meet global standards, and the flexibility to produce many types of products
- Equalized manufacturing balance across plants and made operations more efficient through staff exchanges across plants

Opportunities

- Growing need for subcontracted manufacturing for non-Japanese companies entering the Japanese market
- Ability to address growing demand for generic drugs

Risks

- Higher cost rates due to annual drug price revisions
- Effects on stable supplies caused by delays and interruptions in manufacturing and raw material procurement, and disruption of logistics functions due to natural disasters and other problems
- Increased cost of meeting expectations for higher levels of quality

Initiatives under the HOPE100 –Stage 3– Medium-Term Business Plan

Business strategy ▶ Enhance cost competitiveness

Establishing a manufacturing structure to achieve stable supply and low cost while also enabling expansion of subcontracted manufacturing

Initiatives under the medium-term business plan

Initiatives for greater cost competitiveness

KYORIN Pharmaceutical Group Facilities exchanges staff and shares information across plants to acquire technologies that lead to improvements in manufacturing. Going forward, we will work to raise the level of our GMPs, strengthen our manufacturing capabilities (capacity and efficiency), and use outside organizations to create a stable supply structure. We will also emphasize obtaining subcontracted manufacturing from outside the Group, with the aim of building a solid manufacturing base.

In April 2018, we consolidated our Group manufacturing functions and optimized manufacturing to overhaul our cost structure. Our initial goal for the restructuring effect was to achieve cost savings of ¥1 billion by fiscal 2023, but we met that target in fiscal 2020. We will continue to pursue low-cost operations going forward.

Initiatives to maintain quality

We are working in various ways to maintain quality and gain the trust of medical practitioners and patients. Initiatives include reciprocal GMP inspections among plants, strengthening data integrity (frameworks to ensure data completion, consistency, and accuracy), regular staff training and testing, and the use of video to standardize operations.

Initiative to establish a new manufacturing center

To meet growing demand for generic drugs and make it possible to accept subcontracted manufacturing, we are preparing to start construction on a new plant (Takaoka City, Toyama Prefecture) to increase our production capacity and raise productivity.

Overview of Plants

Noshiro Plant — Low-cost, high-volume manufacturing through automation

The Noshiro Plant uses automated transport of pharmaceutical ingredients and intermediate products, as well as robotic arms for labor saving. Automation makes it possible to manufacture large volumes at low cost with high productivity. In addition to new drugs, the facility is currently using these strengths to manufacture generic drugs in large volumes, focusing on tablets and capsules. The plant's advanced manufacturing activities have also been approved in GMP inspections carried out by overseas regulatory authorities and global companies headquartered overseas.

(Noshiro, Akita)

Plant certifications
Environmental management system: ISO 14001
Occupational health and safety management system: OHSAS 18001
OHSAS 18001 changed to ISO 45001 in August 2019

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 addition to manufacturing the Group's main products, the plant is unique for its high portion of manufacturing subcontracted from outside the Group, including for pharmaceutical products to be sold in Japan by overseas manufacturers. The plant is able to keep pace with the needs of the times, using the latest equipment for manufacturing that incorporates global GMP, with an awareness of issues including the prevention of cross contamination. Using its abundant experience and expertise gained from subcontracted manufacturing for global companies headquartered overseas, the facility is bolstering its manufacturing equipment and working aggressively to increase its manufacturing subcontracted from outside the Group.

(Koka, Shiga)

Plant certifications
Environmental management system: ISO 14001
Occupational health and safety management system: ISO 45001

Inami Plant — Manufacturing numerous types of products with focus on generic drugs

With a focus on generic drugs, the Inami Plant manufactures products in a variety of forms, including solid formulations taken internally, sterilized formulations for injections, eyedrops, and nose drops. Taking advantage of flexibility that enables it to manufacture many types of products, the facility handles various products that newly appear on the drug price list twice a year, manufacturing more than 200 products including those subcontracted from outside the Group. Through frequent visits from drug manufacturers ordering subcontracting, the facility has gained a wealth of expertise in providing a stable supply of high-quality products. In addition to investing in equipment for new pharmaceutical production, the facility is proactively pursuing improvement activities to raise productivity and working to reduce costs.

(Nanto, Toyama)

Plant certifications
Environmental management system: ISO 14001
Occupational health and safety management system: OHSAS 18001
OHSAS 18001 changed to ISO 45001 in August 2019

Supply chain management

The Kyorin Group addresses its supply chain comprehensively, to respond flexibly to changes in demand and create a structure that achieves more efficient manufacturing and stable supplies. Our supply chain management individually oversees (visualizes) every product from raw material procurement to manufacturing, warehousing, and shipment, in Japan and overseas. We are working to reduce risks that would affect stable supplies, including measures for shorter lead times from order to delivery and an increasing number of suppliers, to achieve a reliable, stable supply of products.

Pharmaceutical Business

Generic Drugs

Hiroshi Hashizume
Representative Director and President
KYORIN Rimedio Co., Ltd.

KYORIN Rimedio is the core company for the Kyorin Group's generic drugs business. Taking advantage of having development, manufacturing, and sales functions within the Group, we are proactively engaged in the field of authorized generics as a new drug-related generics company. Going forward, we will work to strengthen our generic drug development capabilities and steadily increase the number of products in development, while also making our marketing structure more efficient and our cost competitiveness stronger.

Strengths

- Development, manufacturing, and sales functions all within the Group
- Proactive pursuit of authorized generics as a new drug-related generics company

Opportunities

- Growing demand for generic drugs as population ages
- Patent expiries of major original drugs

Risks

- Reduced incentives to promote the use of generic drugs
- Weaker profitability due to annual drug price revisions

Initiatives under the HOPE100 –Stage 3– Medium-Term Business Plan

Business strategy ▶ Enhance cost competitiveness

Make the generics' marketing structure more efficient to enhance the generic business's cost competitiveness

Strengthen ability to create new generics

Initiatives under the medium-term business plan

Strengthen ability to create new generics

To provide generic drugs that can be used safely, KYORIN Rimedio has been carrying out pharmaceutical manufacturing and packaging from the perspectives of medical practitioners and patients, ensuring that products are easy to use in medical institutions and meet the needs of patients taking drugs. At the Takaoka Pharmaceutical Technology Innovation Center, which commenced full-scale operations in July 2017, we are working to enhance the quality and accelerate the speed of drug development to increase further the number of products in development, with the aim of becoming a generic drug company that provides attractive, unique generic drugs. During fiscal 2020, we launched nine ingredients with 17 products.

Address authorized generics

The Kyorin Group has achieved a certain degree of recognition for its steady market penetration using its ability to handle, within the Group, both original drugs and authorized generics that meet the diverse needs of medical practitioners and patients. We released Montelukast Tablets "KM," our authorized generic version of Kipres, in September 2016, followed by Mometasone Nasal 50μg "KYORIN," our authorized generic version of Nasonex, in August 2019, and Imidafenacin Tablets "KYORIN," OD tablets 0.1 mg, our authorized generic version of Uritos, in June 2020. We currently have gained more than a 50% share of their respective generic markets.

Make our marketing structure more efficient to enhance the business's cost competitiveness

KYORIN Rimedio has had its sales strength through a balanced approach using multiple sales channels, and going forward, it will build on that strength while also working to make its marketing structure more efficient, enhancing its sales capabilities and cost competitiveness through selection and concentration.

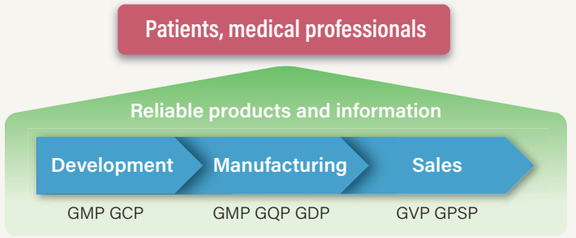
The Kyorin Group's Reliability Assurance System

In the wake of quality problems at generic drugs, including contamination by foreign substances, there is a need to further strengthen and enforce compliance and quality management systems for the manufacture and quality management of ethical drugs. The Kyorin Group believes that it is important to establish an ever-more meticulous reliability assurance system and to strictly control the quality of the drugs it handles. By promoting initiatives for the integrated assurance of the reliability of Kyorin products and by delivering high-quality, safe, and secure products to users, we aim to earn the trust of society at large.

Michiro Onota
Executive Director, Quality Assurance & Reliability
KYORIN Holdings, Inc.

Reliability assurance system

Our 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, we continuously need to provide products and information that are trusted by broad sectors of society, and we consider this 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 Division 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 safely.



GMP : Good Manufacturing Practice
GCP : Good Clinical Practice
GQP : Good Quality Practice
GDP : Good Distribution Practice
GVP : Good Vigilance Practice
GPSP: Good Post-Marketing Study Practice

Quality assurance

Quality assurance is carried out 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 Pharmaceutical Co., Ltd., 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.

ESG Highlights

By adhering to its corporate philosophy, the Kyorin Group aims to contribute to the sustainable development of society through activities in line with its Corporate Charter, earn the trust of all stakeholders, and enhance its corporate value over the medium to long term.

Corporate Charter

1. Contribute to sustainable economic growth and to the resolution of social issues
2. Fair business practices
3. Fair information disclosure and constructive dialogue with stakeholders
4. Relationships of trust with consumers and customers
5. Work-style reforms and improvement of work environments
6. Initiatives to tackle environmental issues
7. Co-exist with society and contribute to society's development
8. Comprehensive crisis management
9. Respect for human rights
10. Stringent implementation by Company officers of their responsibilities and the charter

Gaining the trust of our stakeholders

SDGs (Sustainable Development Goals)

The SDGs are a series of international goals targeted for achievement by 2030 adopted at the 2015 United Nations Summit. The Kyorin Group has incorporated these goals into its business practices and efforts to co-exist with society, and works to contribute to the realization of a sustainable society.

From an ESG (environmental, social, and governance) perspective, the Kyorin Group works to enhance its corporate value over the medium to long term by actively and proactively addressing sustainability issues (the sustainable development of society) through activities based on the Sustainable Development Goals (SDGs).

To achieve our long-term vision as a "company that supports sound and healthy lifestyles," we will contribute to people's health by developing and supplying reliable products and services useful to society. In addition, under our Corporate Charter, we will strive to create a vibrant society and respond to economic development by acting as a good corporate citizen and will strive to build a relationship of trust with our stakeholders.

ESG Initiatives

Governance

Corporate Governance ▶P.32
To realize sustained increases in corporate value, the Kyorin Group has recognized the strengthening and improvement of corporate governance as a key business issue, and implements initiatives to expedite decision making, to strengthen oversight functions for guaranteeing appropriate management, and to ensure transparent business activities rooted in corporate ethics.

Fair and Honest Business Activities ▶P.36
The Group strives to prevent all forms of corruption by maintaining high ethical standards, conducting business lawfully and fairly, and by complying with codes of conduct. It also maintains appropriate relationships with medical institutions and patient groups, and endeavors to build relationships of trust with suppliers and consumers.

Social

CSR through Business Activities ▶P.38
The Group positions contributing to society through the pharmaceutical business at the core of its CSR activities. As well as devoting itself to the sale, stable supply, and quality management (the Reliability Assurance System) of products arising from its research and development, the Group aims to provide relevant information and promote the appropriate use of pharmaceutical products to contribute to human health.

Initiatives to Respect Human Rights, Implement Work-Style Reforms, and Develop Human Resources ▶P.40
The Group respects the human rights of all people and acts in a highly ethical manner. To create in employees a sense of pride in their work, we aim to be a company that is trusted and "the leading company for career fulfillment" by working hand in hand with our fellow employees.

Living in Harmony with Society ▶P.45
We work to contribute to the development of a vibrant society and local economy by acting as a good corporate citizen and by donating to and supporting employee-led social activities.

Environment

In Harmony with the Environment ▶P.44
The Group works to protect the sustainable environment by preventing environmental pollution, reducing the environmental burden, and promoting measures to use resources more efficiently.

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 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 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 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 by 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 Groupwide 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 governance while securing 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. Following 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

Board of Directors

The Company's Board of Directors comprises nine directors, including three outside directors. The Board of Directors usually meets once a month, resolving legal matters, formulating and deciding important management policies and strategies, and overseeing business execution, etc.

Chairperson	: Yutaka Ogihara, Representative Director, President and Chief Executive Officer
Executive Directors	: Minoru Hogawa, Shigeru Ogihara, Michiro Onota, Koichiro Hagihara, Masahide Sugibayashi
Outside Directors	: Noriyuki Shikanai, Ken Shigematsu, Hiromi Watanabe

Board of Corporate Auditors

Following the Companies Act of Japan, Kyorin is a company with a board of corporate auditors, which comprises two statutory corporate auditors and three outside corporate auditors. The Board of Corporate Auditors has established a system to ensure that the exercise of authority for audits, etc., is carried out from an independent and objective standpoint through the timely and appropriate functioning of outside corporate auditors.

Chairperson	: Tomiharu Matsumoto, Senior Corporate Auditor
Senior Corporate Auditor	: Shugo Tamaki
Outside Corporate Auditors	: Masaji Obata, Takao Yamaguchi, Naohiro Kamei

Business execution system

To oversee business execution, we established a Management Committee, comprising the president and directors, which discusses and decides key operational matters concerning the Group.

Chairperson	: Yutaka Ogihara, Representative Director, President and Chief Executive Officer
Executive Directors	: Minoru Hogawa, Shigeru Ogihara, Michiro Onota, Koichiro Hagihara, Masahide Sugibayashi

In addition to the representative directors and the executive directors, who are engaged in ordinary business execution, we actively delegate authority to the corporate officers responsible for specific areas appointed as necessary, thus establishing a framework that allows prompt decision making and clarification of responsibility of business execution under the guidance and supervision of the Board of Directors. As of June 18, 2021, the Company had four corporate officers.

Committee on Remuneration and Nominations

Regarding remuneration and nomination of directors and corporate auditors, Kyorin has established the voluntary Committee on Remuneration and Nominations, mainly comprising independent outside directors, to seek appropriate advice in order to enhance the transparency of decision making.

Chairperson	: Yutaka Ogihara, Representative Director, President and Chief Executive Officer
Senior Corporate Auditor	: Tomiharu Matsumoto
Outside Directors	: Noriyuki Shikanai, Ken Shigematsu, Hiromi Watanabe

Corporate Governance System

Key Items	Description
Organizational design	Company with a board of corporate auditors
Number of directors (including outside directors)	9 (3)
Number of corporate auditors (including outside corporate auditors)	5 (3)
Number of the Board of Directors' meetings (held during fiscal 2020) (Average attendance rate of outside directors) (Average attendance rate of outside corporate auditors)	12 times (100%) (88.8%)
Number of the Board of Corporate Auditors' meetings (held during fiscal 2020) (Average attendance rate of outside corporate auditors)	11 times (90.9%)
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

Outside directors and outside corporate auditors

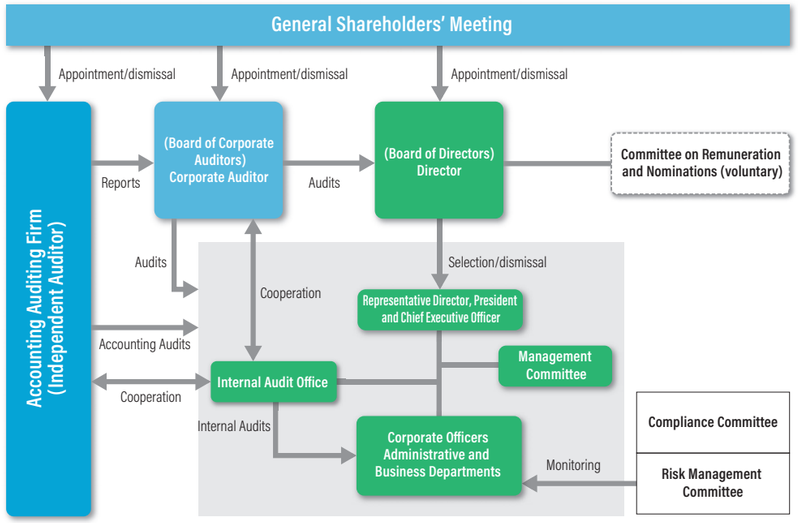
Kyorin has three outside directors and three outside corporate auditors.

We seek independent and objective advice from outside directors at Board of Directors' meetings, etc., and have established a highly effective management supervision system that maintains a distance from business execution. Noriyuki Shikanai uses his advanced expertise and abundant experience as an attorney to provide advice on corporate management, mainly from a legal perspective. Ken Shigematsu uses his abundant corporate experience and wide-ranging insight to provide advice on management in response to changes in the social environment. Hiromi Watanabe uses her wide-ranging insight as a physician to provide advice from the perspective of promoting women's participation in the workplace, an aspect of diversity.

Three outside corporate auditors are neutrally positioned and uncompromised by relationships with management or parties with special interests. All have considerable knowledge of corporate legal affairs, finance, or accounting, and perform a monitoring function with wide-ranging insight. Masaji Obata is well versed in corporate law as an attorney and has considerable knowledge of finance and accounting. Takao Yamaguchi has considerable knowledge of finance and accounting as a certified public accountant and a certified tax accountant. Naohiro Kamei is very familiar with finance and accounting from his work in the financial industry.

Kyorin selects outside directors and outside corporate auditors after reviewing the individuals' backgrounds and relationships with Kyorin, and from a standpoint independent from that of management, on the assumption that sufficient independence is ensured. All outside directors and outside corporate auditors fulfill the requirements as independent officers stipulated by the Tokyo Stock Exchange and have been reported as such to that body.

Corporate Governance and Management Structure (As of June 18, 2021)



Compensation of directors and corporate auditors

The Group's basic policy is to provide compensation that contributes to the enhancement of the Group's corporate value through sustainable and stable growth. Specifically, our compensation consists of two types: basic compensation, which is paid in cash, and stock options, which are paid in shares of the Company.

However, to ensure that outside directors are able to fully exercise their management oversight function, their compensation is limited to basic compensation, which is not linked to annual performance and does not include stock options.

The amounts of basic compensation and stock options are calculated in accordance with relevant decision-making policies, within the limits of the compensation approved by the General Shareholders' Meeting. The amounts are determined by the Representative Director, President and Chief Executive Officer, who is delegated by the Board of Directors, after the objectivity and transparency of the decision-making process have been confirmed by the voluntary Committee on Remuneration and Nominations, the majority of whose members are independent outside directors.

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 corporate auditor	Total compensation paid (Millions of yen)	Total paid by type of compensation (Millions of yen)		Number of applicable directors and corporate auditors (People)
		Basic compensation	Stock options	
Directors (Excluding outside directors)	235	230	5	7
Corporate auditors (Excluding outside corporate auditors)	33	33	—	2
Outside directors and corporate auditors	51	51	—	6

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. Following 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 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 for 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 by inspecting Group companies.

In order to ensure that audits are conducted effectively by corporate auditors, corporate auditors receive explanations on the content of accounting audits from the accounting auditing firm of the Company and exchange information with the firm. Corporate auditors also cooperate with the Internal Audit Office to have appropriate communication and to effectively perform the audits.

Under our adopted system, if executives or regular employees discover 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. We assign one auditing staff member to assist the duties of the corporate auditors, and the assignment is carefully checked by directors and corporate auditors to ensure independence.

Messages from Outside Directors

I feel that our outside directors are actively offering their views to management through the Board of Directors' meetings and are working diligently to strengthen governance. I myself use my legal knowledge and experience as an attorney to ensure the validity of decision making from the perspectives of governance and compliance. I will continue to provide advice and suggestions from an independent, external perspective to strengthen and enhance corporate governance at the Company.

Noriyuki Shikanai
Outside Director/Independent Director

The business environment in the pharmaceutical industry is undergoing major changes, such as medical system reforms including NHI drug price revisions and the digitization of healthcare. I am committed to providing advice on the future of the Company from a medium-term perspective, drawing on the knowledge I have gained in management. I will continue to make necessary suggestions to enhance the transparency of the Company's management and maintain the trust and meet the expectations of our stakeholders, taking into account global trends and sustainability.

Ken Shigematsui
Outside Director/Independent Director

In the HOPE100–Stage 3– medium-term business plan, the Company has defined activity to provide solutions in the field of infectious diseases as one pillar of its business and has reaffirmed the importance of the role it plays under the global spread of COVID-19. As a physician, I will continue to contribute to the further development of the Company by providing advice and suggestions from the perspective of promoting participation of women in the workplace, which is one aspect of diversity, as well as by supporting risk taking that creates unique value for the Company.

Hiromi Watanabe
Outside Director/Independent Director

Fair and Honest Business Activities

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

Compliance

Basic policy

An enterprise is required to promote the realization of a sustainable society through the creation of added value and employment that are useful to society and through autonomous and responsible actions based on fair and free competition. Following our corporate philosophy, the Kyorin Group conducts its activities in Japan and overseas based on a high standard of corporate ethics, in compliance with both the letter and the spirit of relevant laws, regulations, and international rules.

Corporate Charter and Compliance Guidelines

To ensure that the Kyorin Group's activities are based on a high standard of corporate ethics, we set up the KYORIN Holdings Corporate Charter and Compliance Guidelines in August 2006, then revised them in April 2019 to reflect our commitment to a sustainable society. In addition, we have established a system to promote compliance, including the Compliance Committee, which meets once a month.

Education and training

Internal training is held to ensure an understanding of 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 are reflected in the work performed by directors, corporate auditors and officers, and employees.
2. We have designated June and November "compliance enhancement months" and are working to ensure that compliance is thoroughly understood and practiced throughout the Group by implementing initiatives specified for each department and employee.

Internal whistleblowing system

The Kyorin Group has established a "Corporate Ethics Hotline" to accept inquiries, consultations, and reports regarding corporate ethics and responses to laws and regulations, etc. The Group also accepts whistleblower reports of suspected injustice or non-compliance via internal and external points of contact. We strictly maintain the confidentiality of whistleblowers, respect their privacy, and ensure that they are not disadvantaged. (Number of reports: 14 in fiscal 2020)

Initiatives related to transparency in relationships with medical institutions and other parties

The mission of a pharmaceutical company is to play an important role in "patient-focused medical care" as a valuable entity that contributes to the health and well-being of people around the world by continuously developing and providing a stable supply of good quality medicines. To fulfill this mission, partnerships with 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 funding to medical institutions, patient groups, and others on our website.

Risk management

Group companies have established the Risk Management Committee, which is held once a month to develop a management system that seeks to prevent the occurrence of risks and handle any risks that arise. The details of these meetings are regularly reported to the Management Committee. The Risk Management Committee oversees risk management initiatives across the entire Group, while also promoting activities to be implemented as necessary at respective divisions to build a structure to identify potential risks, reduce risks, and prevent risk events from occurring, and to minimize the damage from risk events that do occur unavoidably. If a problem arises, it will be reported to the corporate officer in charge in a timely manner. In the event of a natural disaster or other risk that could significantly impact business, a Contingency Measures Headquarters, headed by the president, will be established to manage the crisis.

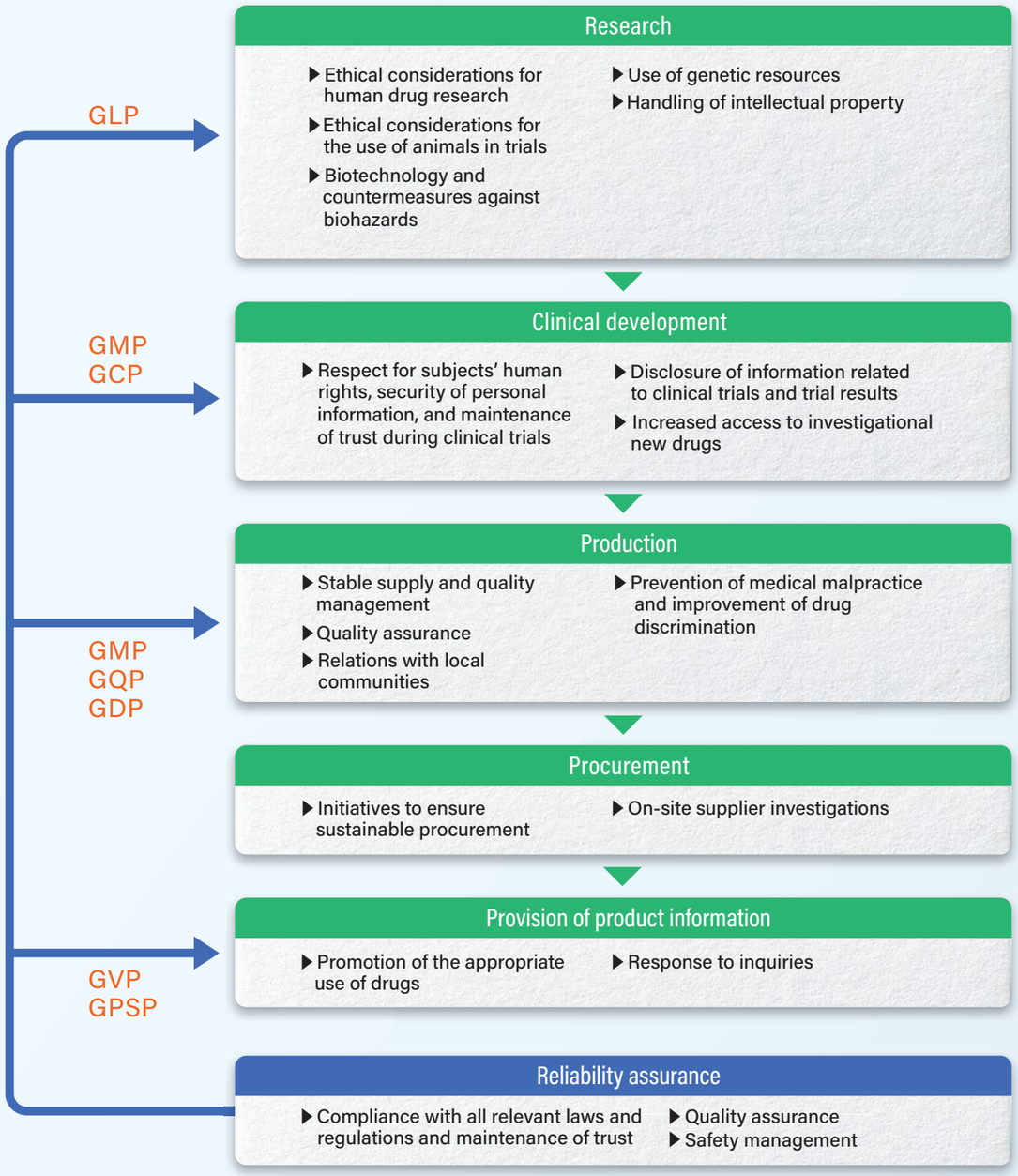
Business risks

The Kyorin Group is aware of risks that could significantly impact its operating results and financial position due to factors such as major revisions to relevant laws and regulations, medical system reforms, rapid changes in market conditions, and large-scale natural disasters. Among such risks, the following are those that may significantly impact investors' decisions. The Group is committed to addressing these risks in an organized and systematic manner, but the risks and uncertainties that may affect it are not limited to these.

Items/specific risks	Main responses
Risks related to research and development ● Delay or discontinuation of development due to unforeseen side effects or failure to achieve expected effects of development candidates	● Efficient research and development through the identification of priority research areas ● Collaboration with domestic and international pharmaceutical companies, academia, and venture companies (open innovation) in addition to proprietary drug discovery
Risks related to medical system reforms ● Unforeseen implementation of reforms to the NHI drug pricing system and medical systems	● Maximizing the spread of new ethical drugs ● Transformation of cost structures through consolidation of Group production functions and overall optimization
Risks related to stable supplies ● Delays or stoppages in manufacturing activities or procurement ● Product recalls due to quality problems, etc.	● Securing sufficient quantities of products and raw materials ● Securing important raw materials from multiple sources
Risks related to competition with other pharmaceutical products ● Competition with other companies' products ● Intensifying entry of generic drugs	● Establishment of a strong presence in specific fields, particularly respiratory, otolaryngology, and urology ● Developing business utilizing the Group's unique characteristics, including the launch of authorized generics
Risks related to IT security and information management ● Business interruptions and information leaks due to inadequate systems, computer viruses, cyberattacks, etc.	● Introducing security software and implementing regular backups ● Thoroughly familiarizing employees with various information management regulations and providing ongoing education
Risks related to intellectual property rights ● Business discontinuation or disputes due to infringement of intellectual property rights by third parties or infringements of patents or other intellectual property rights of other companies' products	● Strict management of intellectual property rights, etc. ● Ongoing monitoring to check for infringements by third parties
Risks related to litigation ● Litigation related to intellectual property rights, product liability (Product Liability Act), environmental protection, labor, etc.	● Responding after being advised by and consulting with experts
Risks related to alliances ● Impact on business results, etc., due to dissolving alliances	● Maintaining and developing ongoing alliances by improving relationships with business partners based on their sales strategies and R&D trends
Risks related to large-scale disasters, etc. ● Natural disasters, accidents, and pandemics such as influenza and novel coronavirus diseases ● Further contraction of the pharmaceutical market, delays in research and development schedules, and difficulties procuring raw materials due to the unexpected spread of novel coronavirus infections	● Preparation of response manuals and implementation of drills to prepare for large-scale disasters, etc. ● As a countermeasure against novel coronavirus infections, continuing business while taking into consideration the health of our employees by implementing measures such as telecommuting, staggered work hours, and refraining from sales activities
Risks related to fluctuations in financial markets ● Fluctuations in foreign exchange rates, interest rate levels, and stock market conditions	● Diversified investments, etc.
Risks related to the occurrence of side effects ● Restriction of use or discontinuation of sales due to unexpected side effects after a market launch	● Provision and collection of information that contributes to the proper use of pharmaceuticals, etc.
Risks related to environmental issues ● Violations of related laws and regulations due to accidents, etc. ● Temporary closure of facilities due to environmental pollution, etc., and countermeasures and legal liabilities	● Compliance with relevant laws and regulations and creation of high voluntary standards ● Integration of the environmental management system and the occupational health and safety management system to promote EHS activities throughout the Group

CSR through Business Activities

By following its corporate philosophy, the Kyorin Group is committed to proactively addressing sustainability issues through its pharmaceutical business of developing and providing useful and safe products and services to society. Throughout this process (from research and development through the disclosure of product information), KYORIN Pharmaceutical Co., Ltd., the core subsidiary of the Kyorin Group, is committed to respecting human rights and abiding by all relevant laws and regulations including the Act on Pharmaceuticals and Medical Devices.



GLP: Good Laboratory Practice, pharmaceutical safety-related standards for non-clinical trials; GCP: Good Clinical Practice, standards for pharmaceutical clinical trials; GMP: Good Manufacturing Practice, standards for production management and product quality management of pharmaceuticals and other items; GQP: Good Quality Practice, standards for product quality management of pharmaceuticals and other items; GDP: Good Distribution Practice, standards for proper distribution of pharmaceuticals; GVP: Good Vigilance Practice, standards for post-production marketing safety management of pharmaceuticals and other items; GPSP: Good Post-Marketing Study Practice, standards for post-production marketing survey and study practices of pharmaceuticals

Main initiatives (KYORIN Pharmaceutical Co., Ltd.)

Research

Ethical considerations for human drug research

The company conducts research on humans and research that obtains or applies materials derived from humans with their full consent and in line with the Declaration of Helsinki*, and the relevant laws, regulations, and guidelines of each country. It also conducts ethical education and training for researchers into bioethics and genome research and clinical research, and endeavors to respect the human rights and protect the personal information of research participants. It has created a human tissue research ethics investigation committee, which includes outside experts, to inspect the ethicality and scientific validity of research plans impartially and fairly.

*The Declaration of Helsinki is a set of ethical principles regarding human experimentation that governs doctors and other professionals involved in medical research.

Ethical considerations for the use of animals in trials

To conduct appropriate animal trials from a scientific perspective while taking into consideration the protection and welfare of animals, the company promotes strict adherence to the 3R principles—refinement (reduction of animal distress), replacement (substitution of animal experiments with alternatives), and reduction (decrease in the number of laboratory animals used)—and has established rules based on various policies to protect animals.

Clinical development

Respect for subjects' human rights, security of personal information, and maintenance of trust during clinical trials

The company conducts clinical trials in line with the Declaration of Helsinki* and relevant laws and regulations governing clinical trials of pharmaceuticals, including good clinical practice (GCP), while fully taking into consideration the human rights and personal information of trial subjects. Its clinical trial plans are approved after inspection for ethicality and scientific validity by internal and external committees. Moreover, it must give sufficient explanation of items such as the objectives of trials and the methods used, the expected merits and demerits, and compensation in case of damage to the health of subjects, and confirmation is needed that subjects understand the details and have given their consent to participate. In addition, checks are made to ensure that employees involved in trials have been properly educated and trained, that trial institutions respect GCP, and that trials are conducted appropriately.

Disclosure of information related to clinical trials and trial results

The company strives to use clinical trial databases to publicly disclose and improve the transparency of the clinical trial plans that it leads. Going forward, the company will promote the creation of appropriate data access environments for those involved in utilizing clinical trial data, including researchers, and promote the disclosure of information that is useful in scientific progress and innovation.

Production

Stable supply

The pharmaceutical supply chain includes a wide variety of diverse items, including raw materials, intermediates, and pharmaceutical ingredients, and is supported by a large number of suppliers in Japan and overseas. To maintain a stable supply, it is essential to strengthen ties with individual suppliers and ensure close alliances and information sharing. The company has created a stable supply structure based on demand forecasts for each region of the world and the unified management of inventory information and supply plans, making it possible to globally manage every stage of the process from ingredients manufacturing to supply of finished products. Moreover, as one of its risk-hedging policies, it strives to identify multiple alternative suppliers to supplement existing suppliers and different types of transportation routes.

Procurement

On-site supplier investigations

When selecting a new supplier, we begin transactions only after confirming through an on-site investigation that the supplier has measures in place for legal and regulatory compliance, labor safety, and environmental protection. For existing suppliers, we make regular visits to preserve and improve product quality and maintain a stable supply. In addition, we conduct risk assessments of work environments (including ones to prevent employee exposure to chemical substances) and take measures to reduce waste and lessen the environmental burden from wastewater and exhaust emissions.

Provision of product information

Promotion of the appropriate use of drugs

Mistakes in the use of drugs can damage a patient's health, while side effects can also occur even when drugs are used correctly. The company's medical representatives (MRs) work to accurately and swiftly provide information on appropriate product usage to allow medical professionals to use drugs more effectively and safely. In addition, we collect, analyze, and review information on efficacy and safety gleaned from the use of our drugs and transmit the results to medical professionals.

Response to inquiries

To promote the safe and effective use of drugs, the company believes it has a responsibility to respond to inquiries from patients and medical professionals by providing highly reliable drug information that is both fair and impartial. With this understanding, it has established the Drug Information Center to handle various questions. The center responded to around 23,000 inquiries in fiscal 2020.

Initiatives to Respect Human Rights, Implement Work-Style Reforms, and Develop Human Resources

As a company dedicated to life, the Kyorin Group has high ethical standards, a strong sense of responsibilities, and a powerful sense of mission. We aim to develop human resources who contribute to both the Company and society by performing their roles. To make this possible, we believe that it is important to create working environments and systems in which all employees enjoy good physical and mental health, are able to live up to their full potential, and work with peace of mind. As a good corporate citizen, we strive to maintain smooth communication and to contribute to society through our business activities as we also actively take on sustainability challenges.

Yasuyuki Shimokawa,
Corporate Officer, General Manager of
General Affairs & Human Resources Department

Basic stance

The Kyorin Group believes it is important for employees to respect the human rights of all people and to act with high ethical standards. To that end, we endeavor to create work environments that respect the diversity, character, and individuality of each and every employee, where they can work in health and safety. At the same time, we aim to be a company that offers strong career fulfillment and encourages all employees to enhance their ethical values and personal growth. Our corporate actions are rooted in this basic stance.

Respect for human rights

The Kyorin Group is managed with respect for the human rights of all people, and our Compliance Guidelines clearly state, "Along with understanding international norms regarding universally recognized human rights, we will respect the values and character of each individual, and will not engage in any form of discrimination in any situation, regarding each individual as being equal with all others, regardless of position or function." 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.

Promoting organization: becoming "the leading company for career fulfillment"

The Group positions valuing employees and empowering people/organizations as the most important challenges under the HOPE100 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 promote the creation and appropriate operation of the human resources management system (hiring, assigning, training, evaluation, transfers, compensation, social welfare, etc.) at each Group company under the basic concepts of our human resources management system.

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 share a common understanding that they are partners for mutual benefit. As employees contribute to the Company's development, the Company will contribute to rich and rewarding lives for employees.

Employees

By carrying out their duties, contribute to achieving 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

Employees are considered assets (drivers of growth) of the Company, which values them and supports their growth.

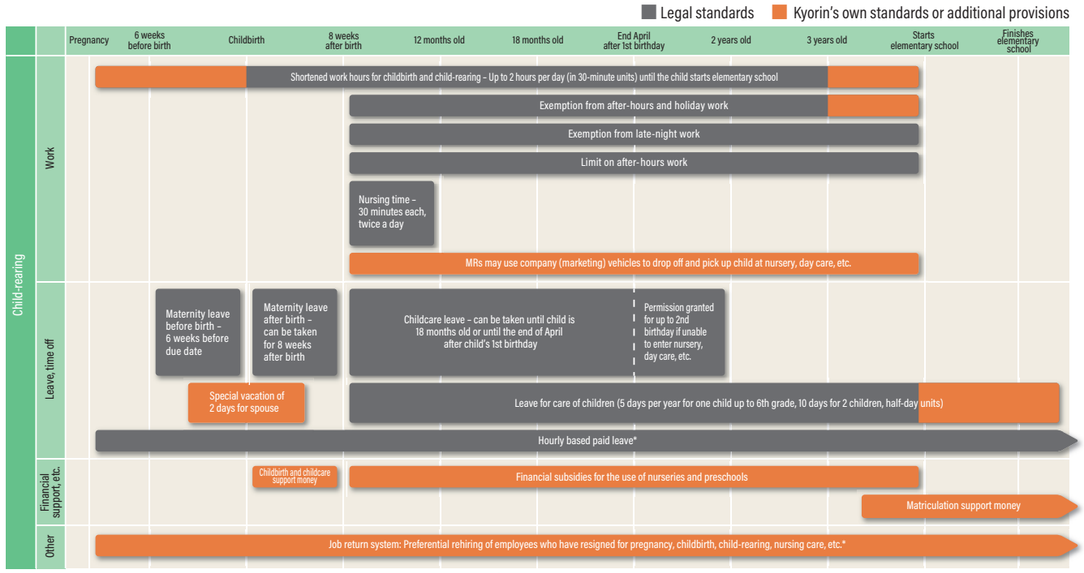
- Each employee is assigned duties that conform to abilities and work style.
- Each employee's contribution is comprehensively understood, and employees are evaluated and treated fairly and consistently.
- The Company provides a comfortable and rewarding work environment that fosters a "desire to work"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

Support for work-style reforms

In addition to carrying out measures to address issues regarding long working hours in accordance with the Related Acts to Promote Work Style Reform, we are also enabling new work styles, such as staggered work hours and working from home.

● 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.



* Hourly based paid leave and the job return system are also available for nursing care support

Nursing Care

- Expanded nursing care leave and breaks (186 days vs. legally stipulated 93 days)
- Support system for remote nursing care
- Nursing care seminars

A father and employee who took childcare leave

When my second child was born, I took one month of childcare leave. My parents live far away, as do my wife's parents, and the COVID-19 situation made it difficult to ask them for assistance. For that reason, we decided to use the Company's childcare-leave system to help us meet our childcare needs. After returning to work, I've been taking paid leave in hourly units, taking my older son to nursery school, picking him up, and playing an active role in caring for my children.

Keisuke Sato
Human Resources Group, General Affairs & Human Resources Department

● Promoting the use of paid leave

KYORIN Pharmaceutical Co., Ltd. proactively encourages the taking of paid leave, going over and above our legal obligations for paid leave under the Related Acts to Promote Work Style Reform (which requires companies to allow employees entitled to at least 10 days of annual paid leave to take five days, with the timing selected by the employee). We also promote the taking of three additional days of leave for employees to maintain a good work-life balance to maximize their capabilities. The paid-leave usage rate at KYORIN Pharmaceutical Co., Ltd. in fiscal 2020 was 57%.

Mid-career hiring

To create more diverse and flexible work styles in the Kyorin Group, we not only hire new graduates but also implement mid-career hiring, bringing in people with advanced skills and extensive experience. The percentage of full-time employees who were mid-career hires was 46% in fiscal 2018, 64% in fiscal 2019, and 45% in fiscal 2020.

Initiatives on disability hiring

As part of its social responsibilities, KYORIN Pharmaceutical Co., Ltd. strives to provide suitable work environments for employees with disabilities to enable them to give full play to their abilities and live independent lives like able-bodied people. We also endeavor to create work spaces that are easy for employees with disabilities to operate in, such as using apps for employees with impaired hearing. The hiring rate of persons with disabilities at KYORIN Pharmaceutical Co., Ltd. was 2.29% in fiscal 2020, which exceeds the legally mandated percentage.

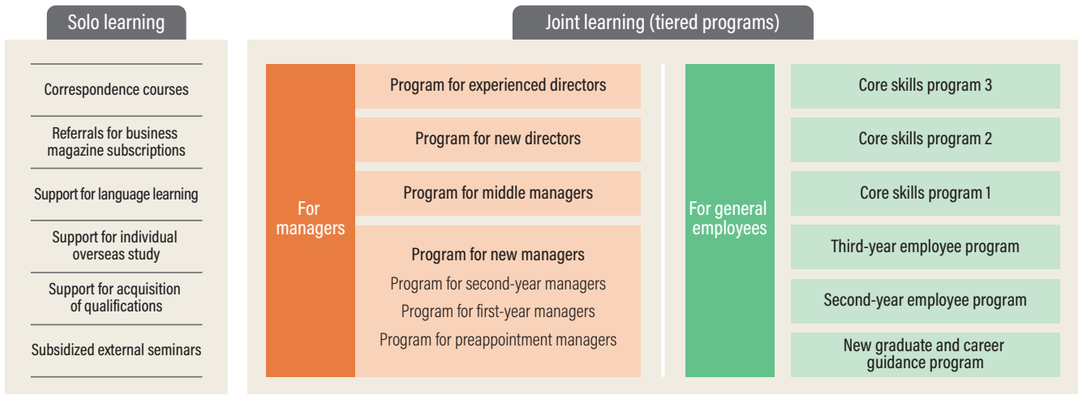
Job return system

KYORIN Pharmaceutical Co., Ltd. has created a job return system that provides opportunities for employees who still have a strong desire to work and are seen as vital by their colleagues to come back to their jobs. This system covers employees who have left the company due to various major life events such as marriage, the job transfer of a partner, pregnancy, childbirth, child-rearing, nursing care, volunteer activities, and overseas study.

Human resources development

KYORIN Pharmaceutical Co., Ltd. supports the growth of its employees by creating structured and systematic educational programs that provide opportunities for both solo learning (autonomous improvement of one's personality and abilities) and joint learning (mutual growth and support). The structure and mechanisms for solo learning include correspondence courses, referrals for business magazine subscriptions, support for language learning, individual overseas study, support for the acquisition of qualifications, and subsidized external seminars. In joint learning, we offer 12 different types of tiered programs ranging from new employee training to training for management. Functional training is provided by each department to give employees the knowledge and skills required in their roles.

Overall structure of solo learning/joint learning



Mental health

The Kyorin Group provides mental-health education to managers and employees. Our manager training includes 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 system for employees and their families to feel free to ask for 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.

Initiatives for Health Management

The KYORIN Group believes that our employees are the foundation of our corporate philosophy and long-term vision, and that their physical health and mental health are paramount. We have therefore enacted the Kyorin Group Health Declaration, with the aim of promoting Health Management®*.

* Health Management® is a registered trademark of the nonprofit organization Kenkokeiei.

The Kyorin Group Health Declaration —Your Health is Kyorin's Mission.—

As a company that supports sound and healthy lifestyles, the Kyorin Group views the health of its employees as a vital management issue, and is committed as an organization to promoting the health management of each and every employee.

1. To ensure that our employees and their families can live active lives, we pursue the maintenance of their sound physical and mental health by working hand in hand with a health insurance association.
2. We proactively support our employees' efforts to maintain and improve their health and to further their health awareness.
3. We implement measures to maintain and improve our employees' health and create safe and comfortable work environments as we aim to build business operations that allow us to fulfill our social mission of contributing to better health.

We strive to maintain and improve the health of our employees and their family members, to create a healthy and lively workplace culture where our employees can live up to their full potential, and to further increase their motivation and work satisfaction.

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

Health Management Promotion Structure

The Top Officer of this structure is the president of KYORIN Holdings, Inc., and the promotion officer is the general manager of the General Affairs & Human Resources Department. When sharing information with Group companies, we have a system in which industrial physicians, public health nurses, the KYORIN Health Insurance Association, and the secretariat work together to formulate health promotion measures and coordinate with health committees at individual companies to implement these measures.

In response to health challenges linked to solutions for business challenges, we assess the expected benefits of these measures, as well as the connections between specific activities involved in maintaining and promoting health, and support health management based on a health management strategy map.

Future initiatives

1. We will coordinate with health insurance associations to further implement health promotion measures.
2. We will achieve a 100% health examination participation rate and help employees maintain and improve their health.
3. We will implement measures aimed at improving employee lifestyle habits (smoking, alcohol consumption, exercise, sleep, and diet).
4. We will implement measures that cover everything from the prevention, early detection, and early response to mental health issues to supporting employees returning to work and preventing relapses.
5. We will conduct presenteeism* studies and verify the effectiveness of our health promotion measures.

*Working while sick. The state of being present at work but not performing as expected because of impaired mental or physical abilities due to illness, etc.

Lifestyle habit improvements

We have set numerical targets for 2023, using 2019 as our reference year, and are currently implementing improvements.

	2019 results (reference year)	2020 results	2023 targets
Percentage of employees who do not smoke	80.8%	81.2%	85%
Percentage of employees who drink appropriate amounts of alcohol*	73.3%	75.0%	80%

	2019 results (reference year)	2020 results	2023 targets
Percentage of employees who walk or engage in equivalent physical activities for one hour or more per day	44.8%	44.4%	55%
Percentage of employees who get sufficient sleep	63.5%	71.5%	75%

* Percentage of male employees who drink less than 40 g of alcohol per day and female employees who drink less than 20 g of alcohol per day

In Harmony with the Environment

Basic stance

The Kyorin Group's Charter of Corporate Conduct details the Group's understanding that "the tackling of environmental issues is a mission for all humankind and an imperative component of the very existence of corporations to which it remains voluntarily committed," and that as a company dedicated to life, it will always use its EHS activity to conduct business operations with due regard for their impact on the global environment and local communities.

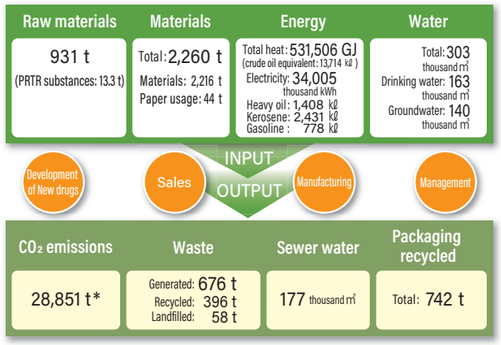
In all business operations, the Group promotes the effective use of our limited resources through energy and resource saving, waste reduction, and less use of substances that place a burden on the environment. It has established objectives and targets for these initiatives, reviews them as needed, and remains voluntarily and proactively committed to environmental protection and pollution prevention.

Environmental conservation initiatives

We are 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. KYORIN Pharmaceutical Group Facilities Co., Ltd. has obtained ISO 14001 certification, an international standard for environmental management systems, at all its plants.

In our efforts to combat global warming, we set a target of cutting CO_2 emissions from our head office, branches, research centers, and plants by a yearly average of 1.5% from the level of fiscal 2019 (27,477 tons) by fiscal 2023. In fiscal 2020, our CO_2 emissions were 27,041 tons, and we are steadily approaching our target.

KYORIN Group material flow (fiscal 2020)



*Emissions from the head office, branches, research centers, and plants, plus emissions from fuel used by sales vehicles, etc.

Introducing hybrid cars to reduce CO_2 emissions

The Kyorin Group 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 2021, all 916 vehicles used by the sales force met the standard for having low emission, and of these, 497 (approximately 54%) are hybrid vehicles, which were introduced in 2004. In addition, these vehicles adhere to the Ministry of the Environment's "Eco-Driving" guidelines regarding their impact on the environment and traffic safety.

Environmentally friendly R&D center

In May 2017, the ReHP* technology installed at KYORIN Pharmaceutical Co., Ltd.'s WATARASE Research Center was awarded an honorable mention in the Kanto chapter of the Japanese Association of Building Mechanical and Electrical Engineers' carbon-neutral category for construction equipment that contributes to achieving a low-carbon society. In addition, the Kanto Bureau of Economy, Trade and Industry conducted a document-based, on-site study of the center's energy conservation activities related to this system as well as its energy-saving promotion system, human resources development and education, and initiatives, and awarded it the Kanto Bureau of Economy, Trade and Industry Director's Award in the 2020 Awards for Excellence in Energy Management. During fiscal 2020, this system reduced electric power consumption by 46,446 kWh and CO_2 emissions by roughly 21 tons compared with conventional heat pumps for air conditioning and heating, for approximately 23% 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.

Reducing the environmental burden through solar power generation

In a move to lessen its environmental burden through the use of company-owned land, in fiscal 2013, KYORIN Pharmaceutical Co., Ltd. installed a facility for generating solar power, one form of renewable energy, in the town of Nogi in Tochigi Prefecture, and installed the second facility in fiscal 2017.

Living in Harmony with Society

Basic stance

The Kyorin Group's Charter of Corporate Conduct calls for it to "actively co-exist with society as a good corporate citizen and to contribute to society's development." The Kyorin Group is engaged in a variety of social contributions to achieve its goal of living in harmony with society. As a manufacturer of new drugs, we aim to contribute to society by developing and supplying useful pharmaceuticals (products and services including clearly superior drugs), while at the same time using our business activities to aid in the resolution and improvement of medical and welfare issues, issues faced by senior citizens, and environmental issues. We also engage in educational activities to support the health of young people. A healthy next generation will be able to power the creation and sustainable development of the highly livable and vibrant local communities that form the basis of our business activities. We pursue social contribution activities that are in keeping with our mission of being a company that supports sound and healthy lifestyles in a wide variety of ways.

Note: Due to the COVID-19 pandemic, the methods used to conduct some activities have been changed, and some activities have been cancelled.

Health education activities

Supporting hand-washing and gargling song

The Kyorin Group supported the "Goshigoshi Garagara Hand-Washing and Gargling Song" project, sung by the Otowa Yurikago Kai choir, by creating an original video for the song. Hand-washing and gargling are fundamental methods of preventing infection. Through this video, we hope to encourage children to have fun washing their hands and gargling, thus helping prevent the spread of COVID-19 and other infections.

URL : https://goshigara-kyorin.com/

Classroom visits

Since fiscal 2017, the Kyorin Group, as one activity embodying its corporate philosophy and contributing to society, has planned and organized visits to schools by employees to teach and demonstrate to elementary and junior high school students, who will lead the next generation, the correct ways of taking medicine and washing hands.

Work experience programs

Each Group facility offers internships, provides workplace tours and hands-on workshops for junior and senior high school students.

Supporting a hands-on science event for children

The Kyorin Group has supported the "Kyorin Group Presents the Great Adventure for the Body's Secrets" program since 2016, with the idea of supporting healthy lives for children, who will lead the next generation.

Contributing to local communities

Sponsoring sporting events

The Kyorin Group supported the Shimotsuke Soccer Workshop in Nogi for the 21st time in fiscal 2020 with the aim of providing local children an opportunity to think about and experience their own health management and improve their skills. In fiscal 2020, the workshop was held online due to the COVID-19 pandemic. Former J.League professional soccer player and current sports journalist Tetsuo Nakanishi gave tips on how to improve skills, explained training methods, and fielded questions from the participants.

Local cleanup activities

As a responsible member of the local community, the Group actively participates in cleanups of local districts, including the areas around its business facilities.

- Group companies (head offices, branches, plants, research centers): Cleanup activities around business facilities
- KYORIN Pharmaceutical Group Facilities Co., Ltd. Noshiro Plant: Clearing fallen leaves in front of government buildings
- KYORIN Pharmaceutical Group Facilities Co., Ltd. Shiga Plant: Sunflower Project environmental conservation activity

Donations to areas affected by natural disasters

As useful support for those affected by disasters, the Group provided relief goods.

- Support for recovery from heavy rains in southern Kumamoto in 2020: Environmental hygiene supplies (Milton), hand sanitizer (Noahtect), etc.
- Support for recovery from heavy rains in Yamagata in 2020: Environmental hygiene supplies (Rubysta, etc.)

First-aid and lifesaving courses for employees

KYORIN Pharmaceutical Co., Ltd.'s approximately 700 medical representatives receive first-aid training covering the necessity of first aid, CPR, the use of AEDs, and ways to stop bleeding. The same lessons were offered at each Group company's head office and at the WATARASE Research Center.

Ten-Year Consolidated Financial Highlights

KYORIN Holdings, Inc. and Its Consolidated Subsidiaries
Fiscal years ended March 31/As of March 31

Millions of yen

	3/2012	3/2013	3/2014	3/2015	3/2016	3/2017	3/2018*2	3/2019	3/2020	**3/2021**
Net sales	¥ 103,232	¥ 107,031	¥ 111,400	¥ 113,121	¥ 119,483	¥ 115,373	¥ 110,640	¥ 113,620	¥ 109,983	**¥ 102,904**
New ethical drugs, etc. (Japan)*1	92,561	94,535	97,562	96,612	98,430	89,584	79,639	83,456	77,535	**69,735**
New ethical drugs (Overseas)	2,015	2,400	1,849	1,032	5,586	764	3,339	830	1,490	**996**
Generic drugs	8,656	10,095	11,987	15,477	15,465	25,024	27,662	29,334	30,957	**32,172**
Operating income	14,464	17,948	17,607	14,737	19,636	10,413	8,822	8,972	7,503	**5,786**
Profit attributable to shareholders of KYORIN Holdings, Inc.	9,231	12,422	12,025	12,064	13,639	7,305	6,574	6,869	6,149	**6,130**
Net cash provided by operating activities	8,913	11,544	19,293	6,391	11,137	16,386	10,456	340	7,739	**5,189**
Net cash provided by (used in) investing activities	(4,926)	(7,187)	(2,477)	(1,364)	650	(13,142)	(6,038)	14,939	(2,943)	**(4,259)**
Net cash provided by (used in) financing activities	(7,412)	(5,132)	(3,704)	(5,233)	(2,245)	(5,721)	(3,735)	(27,315)	(5,117)	**(4,918)**
Free cash flow	3,987	4,357	16,816	5,027	11,787	3,244	4,418	15,279	4,796	**930**
R&D expenses	13,964	11,059	11,359	13,514	13,019	13,569	14,243	10,790	10,987	**9,703**
Capital expenditures	1,952	6,576	6,500	2,655	7,218	3,051	2,885	2,306	3,590	**4,307**
Depreciation and amortization	2,363	2,738	3,153	3,053	3,730	3,619	3,644	2,940	3,221	**3,564**
Total assets	145,673	154,968	169,378	183,383	197,825	192,668	196,736	173,034	171,160	**167,126**
Total net assets	118,201	129,099	137,821	148,600	157,049	157,837	163,297	123,395	122,710	**124,661**

Per Share Information

yen

Net assets	¥ 1,581.94	¥ 1,727.86	¥ 1,844.61	¥ 2,009.45	¥ 2,131.67	¥ 2,146.83	¥ 2,214.13	¥ 2,154.05	¥ 2,142.07	**¥ 2,175.52**
Basic profit	123.54	166.25	160.95	161.63	184.28	99.45	89.28	104.68	107.35	**106.99**
Cash dividends	45.00	50.00	52.00	52.00	58.00	58.00	58.00	75.00	75.00	**75.00**

Key Performance Indicators

Operating income margin (%)	14.0	16.8	15.8	13.0	16.4	9.0	8.0	7.9	6.8	**5.6**
Profit attributable to shareholders of KYORIN Holdings, Inc. / Net sales ratio (%)	8.9	11.6	10.8	10.7	11.4	6.3	5.9	6.0	5.6	**6.0**
R&D expenses / Net sales ratio (%)	13.5	10.3	10.2	11.9	10.9	11.8	12.9	9.5	10.0	**9.4**
Total shareholders' equity ratio (%)	81.1	83.3	81.4	81.0	79.4	81.9	83.0	71.3	71.7	**74.6**
ROE (%)	8.0	10.0	9.0	8.4	8.9	4.6	4.1	4.8	5.0	**5.0**
Consolidated payout ratio (%)	36.4	30.1	32.3	32.2	31.8	59.3	65.9	72.6	70.9	**71.1**
PER (times)	12.68	13.82	12.25	17.78	11.63	23.64	22.39	20.64	20.48	**18.02**

Non-Financial Information

Number of employees	2,297	2,444	2,452	2,445	2,420	2,382	2,348	2,297	2,271	**2,243**

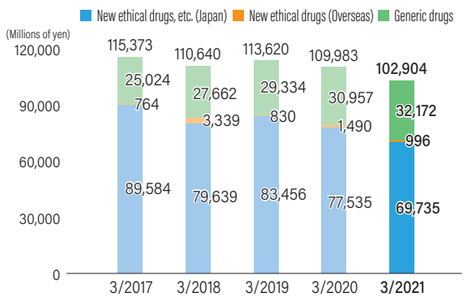
*1 From fiscal 2020 (ended March 31, 2021), reportable segments have been aggregated into a single segment. In conjunction with this, net sales categories have been changed and the previous new ethical drugs (Japan) and healthcare businesses have been combined into new ethical drugs, etc. (Japan).

*2 Figures shown are adjusted to retroactively apply certain revisions to accounting standards related to tax-effect accounting.

Performance Highlights

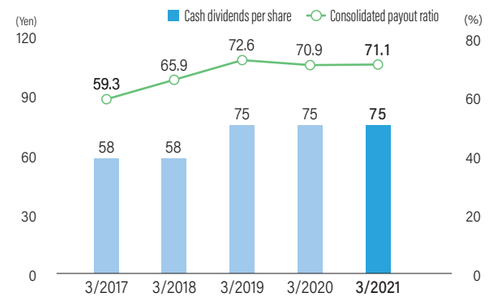
Financial Information

Net sales



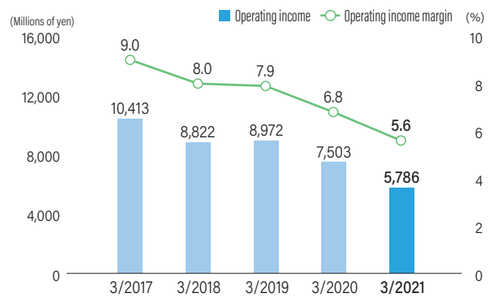
Due to factors such as drug price revisions and the COVID-19 pandemic, results for new ethical drugs, etc. (Japan) have decreased compared to those of the previous year, and overall net sales fell 6.4% year on year.

Cash dividends per share/Consolidated payout ratio



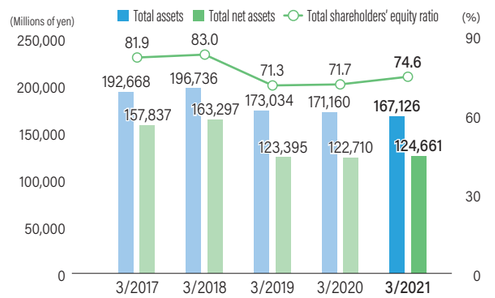
Regarding returns to shareholders, from fiscal 2018 (ended March 31, 2019), we have aimed to maintain stable dividends, while taking into consideration the dividend on equity (DOE) ratio.

Operating income/Operating income margin



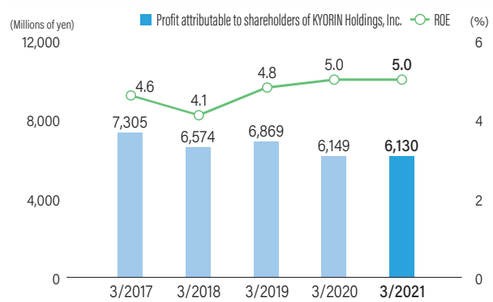
Operating income fell ¥1,717 million year on year, and the operating income margin was 5.6%, due primarily to a decrease in gross profit resulting from lower sales and a rising cost of sales ratio.

Total assets/Total net assets/Total shareholders' equity ratio



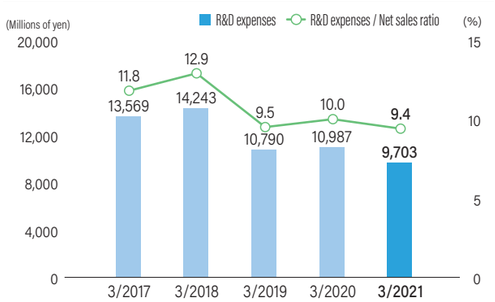
Total assets fell ¥4,034 million compared to those of a year earlier. Total net assets rose ¥1,951 million mainly due to an increase of ¥1,769 million in retained earnings. As a result, the total shareholders' equity ratio was 74.6%, a 2.9 percentage-point increase from that of the previous fiscal year.

Profit attributable to shareholders of KYORIN Holdings, Inc./ROE



We are striving to improve ROE by accelerating the growth of the new drugs group. During fiscal 2018 (ended March 31, 2019), we purchased ¥40.8 billion in treasury shares.

R&D expenses/R&D expenses/Net sales ratio

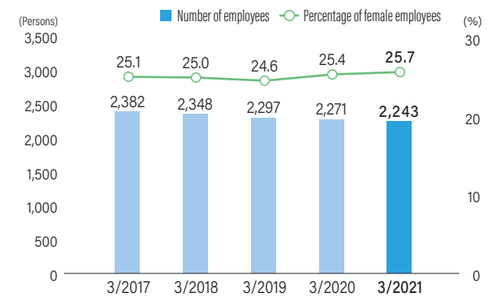


The standards of research and development expenses change depending on the progress of the development stage. We will continue to invest in research and development, and enhance our development pipeline to improve long-term corporate value.

Non-Financial Information

Human Resources

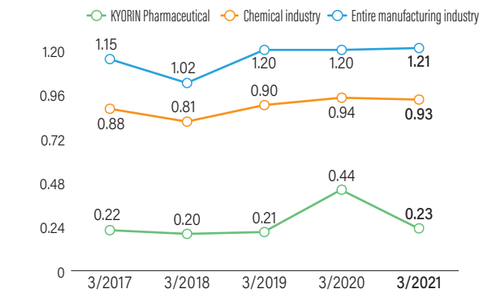
Number of employees/Percentage of female employees



We had 2,243 employees in fiscal 2020 (ended March 31, 2021), 25.7% of whom were women.

Rate of work accidents

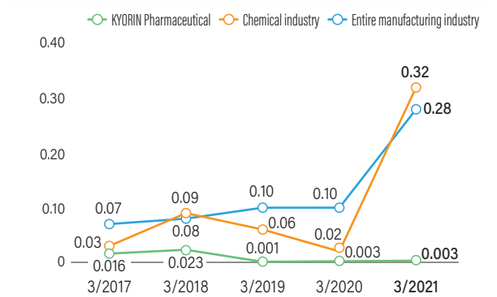
Frequency of accidents: Number of deaths and injuries due to work accidents (excluding accidents while commuting) / Total work hours x 1,000,000



We are working to improve health and safety levels by implementing measures aimed at having zero work accidents, promoting employee health, and creating comfortable work environments.

Severity of work accidents

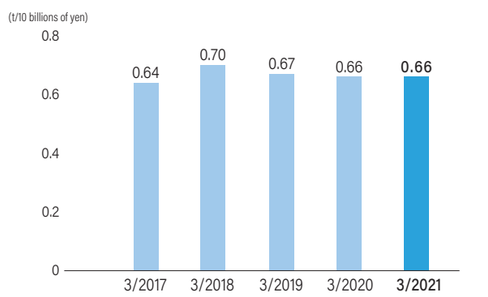
Magnitude of accidents: Number of lost work days (excluding accidents while commuting) / Total work hours x 1,000



Through measures to prevent work accidents, we have reduced both the work accident rate and the severity rate, indicators of the frequency and severity of work accidents, to levels below those of the chemical industry and the manufacturing industry overall.

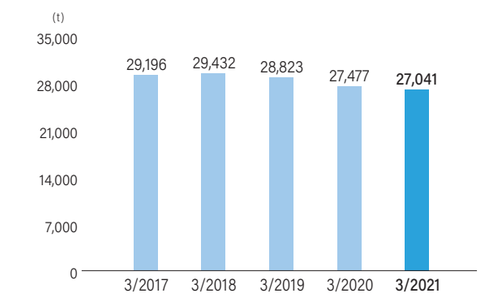
Environment

Waste volume in relation to sales



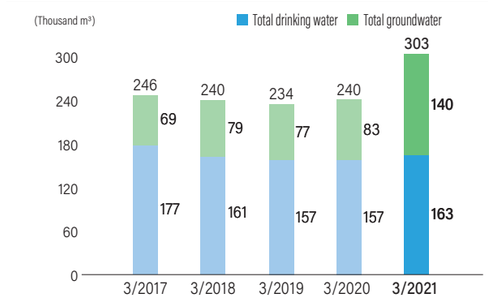
To realize a recycling-oriented society, we are practicing the 3Rs of reducing, reusing, and recycling waste.

CO_2 emissions from the head office, branches, factories, and research laboratories



In comparison to the 27,477 tons of CO_2 emissions in fiscal 2019, we aim to reduce our CO_2 emissions 6% by fiscal 2023 (an annual average reduction of 1.5% or more). In fiscal 2020, we had CO_2 emissions of 27,041 tons, and we are steadily approaching our target.

Volume of water used



To effectively utilize our precious water resources, we are implementing measures such as reducing water usage, thereby lowering our environmental impact. Our use of groundwater rose in fiscal 2020 due to changes in water quality.

Directors, Corporate Auditors, and Corporate Officers (As of June 18, 2021)

Executive Directors

Minoru Hogawa
Representative Director, Chairman
KYORIN Pharmaceutical Co., Ltd.
Representative Director, Chairman

December 1976	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 Management Planning Department, in charge of Accounting of KYORIN Holdings, Inc.
April 2010	Executive Director, Senior Executive Officer, 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, in charge of Finance & Accounting Department of KYORIN Holdings, Inc.
June 2012	Senior Managing Director, General Manager of Management Planning Department, in charge of Finance & Accounting Department of KYORIN Holdings, Inc.
June 2015	Representative Director, President and Chief Executive Officer, in charge of Auditing Office of KYORIN Holdings, Inc.
June 2017	Representative Director, President and Chief Executive Officer of KYORIN Pharmaceutical Co., Ltd.
June 2019	Representative Director, Chairman of KYORIN Holdings, Inc. (current)
June 2019	Representative Director, Chairman of KYORIN Pharmaceutical Co., Ltd. (current)

Yutaka Ogihara
Representative Director, President and Chief Executive Officer
Auditing

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.
June 2016	Senior Executive Director of KYORIN Pharmaceutical Co., Ltd.
April 2019	Senior Executive Director, Management Strategy Office, in charge of Information System Management Department of KYORIN Holdings, Inc.
June 2019	Representative Director, President and Chief Executive Officer of KYORIN Holdings, Inc. (current)
June 2019	Executive Director of KYORIN Pharmaceutical Co., Ltd. (current)

Shigeru Ogihara
Senior Managing Director
KYORIN Pharmaceutical Co., Ltd.
Representative Director, President and Chief Executive Officer

April 1979	Joined Kyorin Yakuhin Co., Ltd.
June 2009	Corporate Officer of KYORIN Pharmaceutical Co., Ltd.
June 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 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.
June 2016	Senior Executive Director, in charge of Intellectual Property Department of KYORIN Holdings, Inc.
June 2017	Senior Executive Director, in charge of Intellectual Property Department and Research and Development of KYORIN Holdings, Inc.
June 2019	Senior Managing Director of KYORIN Holdings, Inc. (current)
June 2019	Representative Director, President and Chief Executive Officer of KYORIN Pharmaceutical Co., Ltd. (current)

Michiro Onota
Executive Director
Quality Assurance & Reliability
KYORIN Pharmaceutical Group Facilities Co., Ltd.
President and Chief Executive Officer

April 1985	Joined 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.
April 2018	President and Chief Executive Officer of KYORIN Pharmaceutical Group Facilities Co., Ltd. (current)
June 2018	Executive Director of KYORIN Pharmaceutical Co., Ltd. (current)
June 2019	Executive Director, in charge of Generic Drugs Business of KYORIN Holdings, Inc.
June 2021	Executive Director, in charge of Quality Assurance & Reliability of KYORIN Holdings, Inc. (current)

Koichiro Hagihara
Executive Director
Intellectual Property
Research and Development

April 1983	Joined Nisshin Flour Milling Inc.
April 1998	Dispatched to Nisshin KYORIN Pharmaceutical Co., Ltd.
October 2008	Joined KYORIN Pharmaceutical Co., Ltd.
April 2013	Corporate Officer, General Manager of Discovery Research Department of KYORIN Pharmaceutical Co., Ltd.
April 2016	Senior Corporate Officer, Head of Clinical Development Center, General Manager of Discovery Research Management Department of KYORIN Pharmaceutical Co., Ltd.
April 2017	Senior Corporate Officer, Deputy General Manager of Discovery Research Headquarters, Head of Clinical Development Center of KYORIN Pharmaceutical Co., Ltd.
June 2018	Executive Director, in charge of Legal Department and Clinical Development of KYORIN Holdings, Inc.
June 2018	Executive Director, Deputy General Manager of Discovery Research Headquarters, Head of Clinical Development Center of KYORIN Pharmaceutical Co., Ltd.
June 2019	Executive Director, in charge of Intellectual Property Department and Research and Development of KYORIN Holdings, Inc. (current)
April 2021	Executive Director, General Manager of Discovery Research Headquarters of KYORIN Pharmaceutical Co., Ltd. (current)

Masahide Sugibayashi
Executive Director
Legal
Sales & Marketing
Healthcare Business

April 1981	Joined Kyorin Yakuhin Co., Ltd.
April 2006	General Manager of Saitama-Chiba Branch, Sales & Marketing Headquarters of KYORIN Pharmaceutical Co., Ltd.
April 2009	General Manager of Tokyo Branch I, Sales & Marketing Headquarters of KYORIN Pharmaceutical Co., Ltd.
April 2010	Corporate Officer, General Manager of Tokyo Branch, Sales & Marketing Headquarters of KYORIN Pharmaceutical Co., Ltd.
April 2012	Corporate Officer, Head of Sales & Marketing Headquarters of KYORIN Pharmaceutical Co., Ltd.
April 2013	Senior Corporate Officer, Head of Sales & Marketing Headquarters of KYORIN Pharmaceutical Co., Ltd.
April 2015	General Manager of General Affairs & Human Resources Department of KYORIN Holdings, Inc.
April 2015	Senior Corporate Officer, General Manager of Human Resources Department of KYORIN Pharmaceutical Co., Ltd.
April 2017	Senior Corporate Officer, Head of Sales & Marketing Headquarters of KYORIN Pharmaceutical Co., Ltd.
June 2018	Executive Director, Head of Sales & Marketing Headquarters of KYORIN Pharmaceutical Co., Ltd. (current)
June 2019	Executive Director, in charge of Legal Department, Sales & Marketing, and Healthcare Business of KYORIN Holdings, Inc. (current)

Noriyuki Shikanai
Outside Director

October 1971	Passed the National Bar Examination
April 1974	Registered with Daini Tokyo Bar Association
March 1977	Established Shikanai Law Office (currently Kyobashi Law Office) (current)
October 2002	Councilor of Keio University (current)
October 2010	Trustee of Keio University (current)
April 2012	Auditor of J. F. Oberlin University
June 2013	Outside Director of KYORIN Holdings, Inc. (current)

Ken Shigematsu
Outside Director

April 1971	Joined Mitsukoshi, Ltd.
March 1999	Executive Officer, General Manager of Product Planning Division, Sales Headquarters of Mitsukoshi, Ltd.
May 2002	Director, Executive Officer, Deputy General Manager of Sales Headquarters of Mitsukoshi, Ltd.
March 2004	Director, Managing Executive Officer, General Manager of Merchandising Headquarters of Mitsukoshi, Ltd.
March 2005	Director, Managing Executive Officer, Store Manager of Mitsukoshi Ginza of Mitsukoshi, Ltd.
April 2008	Managing Executive Officer of Isetan Mitsukoshi Holdings Ltd. Director of Mitsukoshi, Ltd.
April 2009	Director, Senior Managing Executive Officer, Special Appointive Officer of Mitsukoshi, Ltd.
April 2010	Senior Managing Executive Officer of Isetan Mitsukoshi Holdings Ltd. Representative Director, President and Chief Executive Officer of Nagoya Mitsukoshi Ltd.
October 2011	Representative Director, President and Chief Executive Officer of Endo Manufacturing Co., Ltd.
October 2015	Representative Director, President and Chief Executive Officer of MFSJ Co., Ltd.
June 2017	Outside Director of KYORIN Holdings, Inc. (current)

Hiromi Watanabe
Outside Director

April 1972	Joined Internal Medicine Department of Tokyo Women's Medical University Hospital
April 1998	Assistant Professor of Internal Medicine, School of Nursing of Tokyo Women's Medical University
April 2007	Professor and Dean of Medical Science, College of Nursing of Shukutoku University
April 2010	Member of the Board of Daijo Shukutoku Gakuen
April 2011	Professor of Medical Science, College of Nursing and Nutrition of Shukutoku University
November 2014	President of Tokyo Branch of Japan Medical Women's Association (current)
April 2016	Professor of Graduate School of Nursing Division of Nursing of Shukutoku University
April 2018	Neurology Department of Yokufukai Hospital of Total Health and Medical Care Center for Seniors (social welfare corporation) (current)
June 2018	Member of the Board of 3.11 Fund for Children with Thyroid Cancer (NPO) (current)
June 2019	Outside Director of KYORIN Holdings, Inc. (current)
April 2021	Member of the Board of Daijo Shukutoku Gakuen (current)

Senior Corporate Auditors

Tomiharu Matsumoto

Shugo Tamaki

Outside Corporate Auditors

Masaji Obata

Takao Yamaguchi

Naohiro Kamei

Senior Corporate Officer

Yoh Ito

Corporate Officers

Hiroshi Hashizume

Yasuyuki Shimokawa

Morio Yanagishima

Major Activities of Outside Directors and Outside Corporate Auditors (Year ended March 31, 2021)

Position	Name	Major Activities	Attendance at Meetings
Outside Directors	Noriyuki Shikanai	Utilizing his high degree of specialization and abundant experience as an attorney, he makes suggestions and offers appropriate advice on corporate management, mainly from a legal perspective.	Attended 12 out of 12 Board of Directors' meetings
	Ken Shigematsu	Utilizing his abundant experience and wide-ranging insight in corporate management, he makes suggestions and offers appropriate advice on management in response to changes in the social environment.	Attended 12 out of 12 Board of Directors' meetings
	Hiromi Watanabe	Utilizing her wide-ranging insight in a medical setting as a physician, she makes suggestions and offers appropriate advice from the perspective of promoting women's participation in the workplace, which is one aspect of diversity.	Attended 12 out of 12 Board of Directors' meetings
Outside Corporate Auditors	Masaji Obata	He makes comments as necessary based mainly on his specialist understanding as an attorney.	Attended 10 out of 12 Board of Directors' meetings and 9 out of 11 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 10 out of 11 Board of Corporate Auditors' meetings
	Naohiro Kamei	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 11 out of 11 Board of Corporate Auditors' meetings

Financial Analysis

Industry Trends in Japan

The Japanese pharmaceutical industry remained sluggish during fiscal 2020 due to the impact of measures to curtail medical expenses and drug costs, such as the drug price revisions (an industrywide average 4.38% in April 2020) implemented in line with the NHI drug pricing system reform, and fewer medical consultations due to the spread of COVID-19.

Given this situation, the Kyorin Group promoted a shift toward growth to achieve the Group's HOPE100 long-term vision. Under the HOPE100–Stage 3–medium-term business plan (fiscal 2020–2023) and under the management policy of "Accept the challenge of pursuing originality" for fiscal 2020, the Kyorin Group worked aggressively to accelerate the growth of new drugs group, enhance the development pipeline, expand drug discovery projects, and improve cost competitiveness.

Consolidated Operating Results

As for consolidated net sales for fiscal 2020, the ethical drugs market, which is the Kyorin Group's main focus had negative growth due to drug price revisions (the 2% range for KYORIN Pharmaceutical Co., Ltd. in April 2020) and the spread of COVID-19. While domestic sales of new ethical drugs, etc., were lower than those of the previous year, sales of generic drugs rose. However, on a consolidated basis, net sales declined ¥7,079 million, or 6.4%, from those of the previous year, to ¥102,904 million.

In terms of profit, lower sales and a rise in the cost of sales ratio resulted in a ¥5,404 million decrease in gross profit from that of the previous year. On the other hand, SG&A expenses declined ¥3,687 million (including a ¥1,283 million decrease in R&D expenses) due to efforts to reduce costs and refraining from MR activities with medical institutions due to the spread of COVID-19, while operating income declined ¥1,717 million, or 22.9%, to ¥5,786 million. Profit attributable to shareholders of KYORIN Holdings, Inc. declined 0.3%, to ¥6,130 million, as debt exemption gain etc., of ¥1,073 million was recorded as extraordinary income due to the partial exemption of the repayment obligation for long-term debt to JST (Japan Science and Technology Agency).

Assets, Liabilities, and Net Assets

As of March 31, 2021, current assets had decreased ¥3,031 million from those of the previous fiscal year-end, with increases in securities, merchandise and finished goods, work in process, raw materials and supplies, and other current assets, and decreases in cash and deposits, and notes and accounts receivable. Fixed assets decreased ¥1,002 million, with an increase in property, plant and equipment and a decrease in investment securities. As a result, total assets decreased ¥4,034 million from those of the previous fiscal year-end, to ¥167,126 million.

Total liabilities decreased ¥5,985 million from those of the previous fiscal year-end, to ¥42,464 million, a reflection of decreases in notes and accounts payable, accrued income taxes, and long-term debt.

Net assets increased ¥1,951 million from those of the previous fiscal year-end, to ¥124,661 million, including an increase in retained earnings.

As a result, the shareholders' equity ratio at the fiscal year-end was 74.6%, a 2.9 percentage-point increase from that of the previous fiscal year-end.

Cash Flows

Operating activities during fiscal 2020 generated net cash of ¥5,189 million, with major items including ¥8,352 million in profit before income taxes, depreciation and amortization of ¥3,564 million, a debt exemption gain of ¥1,073 million, a ¥7,001 million decrease in notes and accounts receivable, a ¥5,284 million increase in inventories, a ¥2,791 million decrease in notes and accounts payable, a ¥2,048 million decrease in other cash flows from operating activities, and ¥1,899 million in income taxes paid.

Investing activities used net cash of ¥4,259 million, primarily a reflection of ¥4,067 million in outlays for the purchase of property, plant and equipment, ¥1,057 million in outlays for the purchase of intangible assets, ¥1,407 million in outlays for the purchase of investment securities, and ¥1,641 million of proceeds from sale and redemption of investment securities.

Financing activities used net cash of ¥4,918 million, with major items including ¥4,347 million paid as cash dividends.

As a result, cash and cash equivalents at the end of fiscal 2020 totaled ¥26,476 million, a ¥4,033 million decrease from that of the previous fiscal year-end.

Outlook for Fiscal 2021

The operating environment for the Group's core ethical drugs business is expected to be even more challenging, as various policies are implemented to curtail medical expenses and drug costs. Against this backdrop, the Kyorin Group will work aggressively to accelerate the growth of the new drugs group, expand the development pipeline, speed up drug creation, and enhance our cost competitiveness under the HOPE100 – Stage 3 – medium-term business plan (fiscal 2020–2023), started in fiscal 2020 to achieve the HOPE100 long-term vision, with "Focusing on the pursuit of originality" as the management policy for fiscal 2021.

In terms of net sales for fiscal 2021, with regard to new ethical drugs, etc., (domestic), although we anticipate sales growth for our main products, we forecast a large decrease in sales of long-listed products due to the effect of the drug price revisions implemented in April 2021 (the 6% range for KYORIN Pharmaceutical Co., Ltd.). With regard to generic drugs, we anticipate sales growth due to the expansion of prescriptions for our main products and contributions from new generic drugs listed in fiscal 2021. In light of these expectations, we expect net sales for new ethical drugs, etc., (domestic) of ¥68,600 million, new ethical drugs (overseas) of ¥800 million, and generic drugs of ¥33,100 million.

In terms of profits, we forecast a decline in gross profit due to an increase in the cost of sales ratio. However, we expect a decline in SG&A expenses due to efforts to reduce costs, despite recording an up-front payment from the conclusion of an agreement for sales of a drug in Japan for the treatment of chronic coughing. As a result, we forecast operating income of ¥3,300 million.

We plan to apply the "Accounting Standard for Revenue Recognition" from the beginning of fiscal 2021, and the consolidated earnings forecast for fiscal 2021, disclosed recently incorporates these changes.

Accordingly, the amount of changes and the rate of changes from the actual results of those of the previous fiscal year, before the application of the relevant standard, etc., are not stated.

Although we have factored in to some extent the impact of the spread of COVID-19 on business results, uncertain environmental changes are still expected. We will therefore closely follow developments going forward. Should a revision to our forecasts be deemed necessary, we will promptly release such information.

Business Risks

The Group promotes its operations within the framework of pharmaceutical administration, in compliance with legal regulations regarding pharmaceutical development, production, and distribution in Japan, such as the Pharmaceutical and Medical Device Act, as well as various regulatory frameworks of other countries. However, we are aware of the existence of risks that could materially affect our business performance and financial condition, due to various factors including substantial changes in relevant laws, healthcare system reforms, drastic changes in the market environment, and large-scale natural disasters.

Among such risks, those that could materially affect the decisions of investors are described below. 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.

The forward-looking statements contained therein represent the Group's judgment as of March 31, 2021.

1. Risks Associated with R&D

Ethical drug development requires substantial R&D investment over lengthy periods, and the success rate for bringing a drug development candidate to market as a pharmaceutical product is low. KYORIN Pharmaceutical Co., Ltd., the Company's subsidiary, has clarified its priority research areas and has been making efforts to expand its pipeline, by engaging in proprietary drug discovery through cooperation with the WATARASE Research Center and ActivX Biosciences, Inc., in addition to R&D based on open innovation with pharmaceutical companies, academic institutions, and venture start-ups in Japan and overseas. However, should development be delayed or terminated due to the emergence of unforeseeable side effects, a failure to achieve intended clinical results, or other reasons, our business performance and financial condition could be materially affected.

2. Risks Associated with Healthcare System Reforms

Japan's healthcare system, including NHI drug prices, is being revised. In terms of sales, the Group is working to increase the ratio of new pharmaceuticals by maximizing their availability, while in terms of production, it is engaged in initiatives including reforms of the cost structure through a consolidation of its production functions and Groupwide optimization. However, should greater-than-expected NHI drug price revisions be made or changes to the NHI system occur, our business performance and financial condition could be materially affected.

3. Risks Associated with Stable Supply

The supply of certain products and raw materials to the Group depends on having specific business partners. The Group has secured a certain amount of products and raw materials to ensure a stable supply of its products, and has been striving to secure multiple suppliers of its essential raw materials. However, should manufacturing activities or procurement be delayed or terminated due to unforeseeable circumstances, the stable supply of our products could be adversely affected. Furthermore, while our pharmaceutical products are manufactured within various regulatory frameworks, should quality-related or other problems occur, and recalling our products become necessary, our business performance and financial condition could be materially affected.

4. Risks Associated with Competition from Other Drugs

In the new drugs business, the Group has been concentrating its management resources in the specific fields of respiratory, otolaryngology, and urology, and working to enhance its presence there by giving priority to activities that provide information to doctors specializing in these fields. In addition, in the generic drugs business, the Group has been engaged in business development that makes the most of its characteristics by proactively pursuing the market launch of authorized generics. However, should competition from peer products in these fields intensify and the entry of generic drugs after the patent expiration of the original drugs increase, our business performance and financial condition could be materially affected.

5. Risks Associated with IT Security and Information Management

Given that numerous IT systems are utilized in business operations, the Group strives to establish IT security measures and a framework for information management by implementing security software and periodic data back-ups, and establishing various information management rules and thoroughly communicating them to our employees. However, should unforeseeable business disruptions or leakages of information occur due to factors such as system faults, computer viruses, or cyberattacks, and society's trust in the Group become seriously weakened, our business performance and financial condition could be materially affected.

6. Risks Associated with Intellectual Property Rights

The Group strictly manages its intellectual property rights and continuously pays close attention to any infringements by third parties. However, should a third party exploit the Group's technologies and infringe on our intellectual property rights in our market or in a related market, or should the Group's business activities infringe on the patents of another company or otherwise violate its intellectual property rights, the Group could become involved in legal disputes and have to terminate some business operations, and our business performance and financial condition could be materially affected.

7. Risks Associated with Lawsuits

The Group, on the advice of experts, manages the litigation risks that occur in its business activities both in Japan and overseas, including those associated with intellectual property rights such as patents, violations of the Product Liability Act, environmental protection issues, and labor disputes. However, should such lawsuits be brought against the Group, our business performance and financial condition could be materially affected.

8. Risks Associated with Alliances

The Group promotes strategic alliances to make efficient use of external capital. Through tie-up agreements with other pharmaceutical companies inside and outside Japan, the subsidiary allocates sales rights for some of its products and collaborates in sales, R&D, and other activities. In addition, the Group strives to maintain and develop ongoing alliance relationships, enhancing these relationships in light of the sales strategies and R&D trends of the tie-up partners. However, should these alliance relationships be ended, our business performance and financial condition could be materially affected.

9. Risks Associated with Large-Scale Disasters

The Group prepares various manuals and conducts drills to prepare for large-scale and other disasters. However, should natural disasters beyond our expectations such as earthquakes or typhoons, accidents such as fires, or pandemics such as influenza or COVID-19 occur, these events could result in the closure of plants and the suspension of operations at KYORIN Pharmaceutical Group Facilities Co., Ltd., the Company's production subsidiary, the Group's suppliers, or other locations. While the Group has secured a certain amount of inventory to ensure a stable supply, should such plant closings or suspensions extend for a lengthy period, our business performance and financial condition could be materially affected.

10. Risks Associated with Volatility in the Financial Markets

The Group's business performance and financial condition could be materially affected during import and export transactions due to fluctuations in exchange rates. In addition, should fluctuations occur in the amounts of pension assets, retirement benefit obligations, the valuation of shares held, etc., due to fluctuations in exchange rates, in interest rate levels, or on the stock market, our business performance and financial condition could be materially affected.

11. Risks Associated with Side Effects

Clinical trials in the development phase of ethical drugs are conducted on only a limited number of subjects. Therefore, should unforeseeable side effects occur after the launch of a drug, its usage could be restricted or, in some cases, its sale could be discontinued, and our business performance and financial condition could be materially affected.

12. Risks Associated with Environmental Issues

The Group strives to not only comply with relevant laws and regulations but also to achieve even higher voluntary standards in terms of the environment, health, and safety. It also promotes Groupwide EHS activities that integrate the environmental management system and the industrial safety and hygiene management system. However, should a violation of relevant laws or regulations occur due to unexpected accidents or other events in business operations, our business performance and financial condition could be materially affected.

(Impact of the COVID-19 pandemic)

The Kyorin Group has implemented measures such as working from home, staggered work hours, and self-restraint in sales activities. For work like that done by production divisions that must be performed in offices, we are taking measures to ensure employees' health. However, if the pace or the number of COVID-19 infections exceeds forecasts, further contracting the markets for our main products, delays in schedules of research and development, difficulties in procuring raw materials, or any other problem occurs, our business performance and financial condition could be materially affected. Furthermore, even if the COVID-19 pandemic is brought under control, its impact may remain for some time.

Consolidated Balance Sheet

KYORIN Holdings, Inc. and Consolidated Subsidiaries
As of March 31

Assets	Millions of yen		Thousands of U.S. dollars (Note 3)
	2021	2020	2021
Current assets:			
Cash and cash in banks *(Notes 4 and 11)*	¥ 27,445	¥ 31,925	$ 247,878
Notes and accounts receivable *(Note 11)*	40,446	47,449	365,300
Short-term investments *(Notes 5 and 11)*	3,399	993	30,699
Inventories:			
Merchandise and finished goods	19,545	17,913	176,526
Work in process	7,293	6,190	65,869
Raw materials and supplies	11,730	9,179	105,943
Other	4,203	3,446	37,961
Less allowance for doubtful accounts	(37)	(40)	(334)
Total current assets	114,027	117,058	1,029,868
Property, plant and equipment:			
Land	2,872	2,104	25,939
Buildings and structures	32,958	32,391	297,670
Machinery and vehicles	25,173	23,511	227,357
Leased assets	860	926	7,767
Construction in progress	457	915	4,128
Other	9,685	9,120	87,473
Less accumulated depreciation and impairment loss	(48,113)	(46,248)	(434,547)
Property, plant and equipment, net	23,896	22,721	215,824
Investments and other assets:			
Investment securities *(Notes 5 and 11)*	23,645	25,868	213,557
Long-term loans	0	3	0
Deferred tax assets *(Note 13)*	343	714	3,098
Other	5,258	4,838	47,489
Less allowance for doubtful accounts	(44)	(44)	(397)
Total investments and other assets	29,203	31,380	263,755
Total assets	¥167,126	¥171,160	$1,509,447

Liabilities and net assets	Millions of yen		Thousands of U.S. dollars (Note 3)
	2021	2020	2021
Current liabilities:			
Notes and accounts payable *(Note 11)*	¥ 6,985	¥ 9,776	$ 63,087
Short-term bank loans *(Notes 6 and 11)*	10,300	10,400	93,027
Lease obligations *(Note 6)*	137	141	1,237
Accrued income taxes *(Note 13)*	476	1,414	4,299
Accrued bonuses to employees	2,206	2,334	19,924
Reserve for sales returns	23	25	208
Other	7,277	7,235	65,724
Total current liabilities	27,407	31,328	247,534
Long-term liabilities:			
Long-term debt *(Notes 6 and 11)*	11,036	12,514	99,675
Lease obligations *(Note 6)*	409	538	3,694
Deferred tax liabilities *(Note 13)*	293	201	2,646
Provision for stock-based payments	—	36	—
Liability for retirement benefits *(Notes 12)*	2,584	3,140	23,338
Other	733	690	6,620
Total long-term liabilities	15,057	17,121	135,992
Net assets:			
Shareholders' equity *(Note 7)*:			
Common stock, no par value:			
Authorized–297,000,000 shares in 2021 and 2020			
Issued–64,607,936 shares in 2021 and 2020	700	700	6,322
Capital surplus	4,752	4,752	42,919
Retained earnings	132,557	130,788	1,197,227
Treasury stock, at cost:			
7,305,913 shares in 2021			
7,321,870 shares in 2020	(17,671)	(17,706)	(159,601)
Total shareholders' equity	120,339	118,534	1,086,877
Accumulated other comprehensive income:			
Unrealized holding gain on other securities	6,639	6,922	59,962
Translation adjustments	(40)	36	(361)
Retirement benefits liability adjustments	(2,275)	(2,782)	(20,547)
Total accumulated other comprehensive income	4,322	4,176	39,035
Total net assets	124,661	122,710	1,125,912
Total liabilities and net assets	¥167,126	¥171,160	$1,509,447

See notes to consolidated financial statements.

Consolidated Statement of Income

KYORIN Holdings, Inc. and Consolidated Subsidiaries
For the year ended March 31, 2021

	Millions of yen		Thousands of U.S. dollars (Note 3)
	2021	2020	2021
Net sales	¥102,904	¥109,983	$929,408
Cost of sales	51,276	52,950	463,114
Gross profit	51,627	57,032	466,284
Selling, general and administrative expenses *(Note 8)*	45,841	49,528	414,026
Operating income	5,786	7,503	52,258
Other income (expenses):			
Interest and dividend income	420	428	3,793
Interest expense	(68)	(75)	(614)
Equity in gains of affiliates	49	19	443
Foreign exchange gain	129	106	1,165
Gain (loss) on sales and retirement of property, plant and equipment, net *(Note 9)*	342	(24)	3,089
Gain on sales of investment securities *(Note 5)*	488	104	4,408
Debt exemption gain *(Note 10)*	1,073	—	9,691
Subsidy income	86	108	777
Other, net	44	85	397
Other income, net	2,566	752	23,176
Profit before income taxes	8,352	8,255	75,434
Income taxes *(Note 13)*:			
Current	1,847	2,085	16,682
Deferred	374	20	3,378
Total income taxes	2,222	2,106	20,069
Profit	6,130	6,149	55,365
Profit attributable to shareholders of KYORIN Holdings, Inc.	¥ 6,130	¥ 6,149	$ 55,365

See notes to consolidated financial statements.

Consolidated Statement of Comprehensive Income

KYORIN Holdings, Inc. and Consolidated Subsidiaries
For the year ended March 31, 2021

	Millions of yen		Thousands of U.S. dollars (Note 3)
	2021	2020	2021
Profit	¥6,130	¥6,149	$55,365
Other comprehensive income (loss) *(Note 14)*:			
Unrealized holding loss on other securities	(305)	(1,982)	(2,755)
Translation adjustments	(77)	(19)	(695)
Retirement benefits liability adjustments	506	(451)	4,570
Share of other comprehensive income of affiliates accounted for using equity method	23	(21)	208
Total other comprehensive income (loss)	146	(2,474)	1,319
Comprehensive income	¥6,276	¥3,674	$56,684
Total comprehensive income attributable to:			
Shareholders of KYORIN Holdings, Inc.	¥6,276	¥3,674	$56,684
Non-controlling interests	—	—	—

See notes to consolidated financial statements.

Consolidated Statement of Changes in Net Assets

KYORIN Holdings, Inc. and Consolidated Subsidiaries
For the year ended March 31, 2021

Millions of yen

		Shareholders' equity					Accumulated other comprehensive 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, 2019	64,607,936	¥700	¥4,752	¥128,999	¥(17,707)	¥116,744	¥8,925	¥ 56	¥(2,331)	¥6,651	¥123,395
Cash dividends	—	—	—	(4,361)	—	(4,361)	—	—	—	—	(4,361)
Profit attributable to shareholders of KYORIN Holdings, Inc.	—	—	—	6,149	—	6,149	—	—	—	—	6,149
Purchase of treasury stock	—	—	—	—	(0)	(0)	—	—	—	—	(0)
Disposals of treasury stock	—	—	—	—	1	1	—	—	—	—	1
Other changes	—	—	—	—	—	—	(2,003)	(19)	(451)	(2,474)	(2,474)
Net changes during the year	—	—	—	1,788	1	1,789	(2,003)	(19)	(451)	(2,474)	(684)
Balance as of April 1, 2020	64,607,936	700	4,752	130,788	(17,706)	118,534	6,922	36	(2,782)	4,176	122,710
Cash dividends	—	—	—	(4,361)	—	(4,361)	—	—	—	—	(4,361)
Profit attributable to shareholders of KYORIN Holdings, Inc.	—	—	—	6,130	—	6,130	—	—	—	—	6,130
Purchase of treasury stock	—	—	—	—	(0)	(0)	—	—	—	—	(0)
Disposals of treasury stock	—	—	—	—	36	36	—	—	—	—	36
Other changes	—	—	—	—	—	—	(282)	(77)	506	146	146
Net changes during the year	—	—	—	1,769	35	1,804	(282)	(77)	506	146	1,951
Balance as of March 31, 2021	64,607,936	¥700	¥4,752	¥132,557	¥(17,671)	¥120,339	¥6,639	¥(40)	¥(2,275)	¥4,322	¥124,661

Thousands of U.S. dollars (Note 3)

		Shareholders' equity					Accumulated other comprehensive 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, 2020	64,607,936	$6,322	$42,919	$1,181,250	$(159,917)	$1,070,574	$62,518	$ 325	$(25,126)	$37,717	$1,108,291
Cash dividends	—	—	—	(39,388)	—	(39,388)	—	—	—	—	(39,388)
Profit attributable to shareholders of KYORIN Holdings, Inc.	—	—	—	55,365	—	55,365	—	—	—	—	55,365
Purchase of treasury stock	—	—	—	—	(0)	(0)	—	—	—	—	(0)
Disposals of treasury stock	—	—	—	—	325	325	—	—	—	—	325
Other changes	—	—	—	—	—	—	(2,547)	(695)	4,570	1,319	1,319
Net changes during the year	—	—	—	15,977	316	16,293	(2,547)	(695)	4,570	1,319	17,621
Balance as of March 31, 2021	64,607,936	$6,322	$42,919	$1,197,227	$(159,601)	$1,086,877	$59,962	$(361)	$(20,547)	$39,035	$1,125,912

See notes to consolidated financial statements.

Consolidated Statement of Cash Flows

KYORIN Holdings, Inc. and Consolidated Subsidiaries
For the year ended March 31, 2021

	Millions of yen		Thousands of U.S. dollars (Note 3)
	2021	2020	2021
Operating activities			
Profit before income taxes	¥ 8,352	¥ 8,255	$ 75,434
Depreciation and amortization	3,564	3,221	32,189
Decrease in allowance for doubtful accounts	(3)	(5)	(27)
(Decrease) increase in accrued bonuses to employees	(125)	94	(1,129)
Decrease in asset for retirement benefits	186	199	1,680
Decrease in liability for retirement benefits	(11)	(106)	(99)
Equity in gains of affiliates	(49)	(19)	(443)
Interest and dividend income	(420)	(428)	(3,793)
Interest expense	68	75	614
(Gain) loss on sales and retirement of property, plant and equipment, net	(342)	24	(3,089)
Gain on sales of investment securities, net	(488)	(104)	(4,408)
Debt exemption gain	(1,073)	—	(9,691)
Decrease in notes and accounts receivable	7,001	5,185	63,232
Increase in inventories	(5,284)	(7,863)	(47,724)
Decrease in notes and accounts payable	(2,791)	(1,664)	(25,208)
Increase (decrease) in consumption taxes payable	195	(101)	1,761
Other, net	(2,048)	2,129	(18,497)
Subtotal	6,728	8,892	60,766
Interest and dividend received	428	436	3,866
Interest paid	(68)	(75)	(614)
Income taxes paid	(1,899)	(1,513)	(17,151)
Net cash provided by operating activities	5,189	7,739	46,866
Investing activities			
Payments for time deposits	(622)	(954)	(5,618)
Proceeds from withdrawal of time deposits	1,020	622	9,212
Purchase of property, plant and equipment	(4,067)	(2,624)	(36,732)
Proceeds from sales of property, plant and equipment	368	26	3,324
Purchase of intangible assets	(1,057)	(593)	(9,547)
Purchase of investment securities	(1,407)	(100)	(12,708)
Proceeds from sales and redemption of investment securities	1,641	804	14,821
Other, net	(134)	(123)	(1,210)
Net cash used in investing activities	(4,259)	(2,943)	(38,466)
Financing activities			
Decrease in short-term bank loans, net	—	(10,000)	—
Repayments of lease obligations	(142)	(118)	(1,283)
Proceeds from long-term debt	0	10,180	0
Repayments of long-term debt	(428)	(832)	(3,866)
Net increase in treasury stock	(0)	(0)	(0)
Cash dividends	(4,347)	(4,346)	(39,261)
Net cash used in financing activities	(4,918)	(5,117)	(44,418)
Effects of exchange rate changes on cash and cash equivalents	(43)	(22)	(388)
Decrease in cash and cash equivalents	(4,033)	(343)	(36,425)
Cash and cash equivalents at beginning of year	30,509	30,914	275,551
Decrease in cash and cash equivalents due to the exclusion of consolidation	—	(61)	—
Cash and cash equivalents at end of year *(Note 4)*	¥26,476	¥30,509	$239,126

See notes to consolidated financial statements.

Notes to the Consolidated Financial Statements

KYORIN Holdings, Inc. and Consolidated Subsidiaries
For the year ended March 31, 2021

1. Basis of Presentation of Consolidated Financial Statements

The accompanying consolidated financial statements of KYORIN Holdings, Inc. (the "Company") and consolidated subsidiaries are 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 2020 consolidated financial statements to conform to the 2021 presentation. These reclassifications have no effect on consolidated profit and net assets. Amounts of less than one million yen have been rounded down to the nearest million yen, and amounts less than one thousand U.S. dollars have been rounded down to the nearest thousand U.S. dollars, in the presentation of the accompanying consolidated financial statements. As a result, the totals in yen and U.S. dollars do not necessarily agree with the sum of the individual amounts.

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 financial statements on an equity basis. As of March 31, 2021, the numbers of consolidated subsidiaries and affiliates accounted for by the equity method were five and one (six and one in 2020), respectively. KYORIN Medical Supply Co., Ltd., which was a consolidated subsidiary in the previous fiscal year, was merged with KYORIN Pharmaceutical Group Facilities Co., Ltd. as a surviving company as of April 1, 2020. Accordingly, KYORIN Medical Supply Co., Ltd. was excluded from the scope of consolidation. As of March 31, 2021, the number of unconsolidated subsidiaries was one. The Company deconsolidated Kyorin USA, Inc., which resolved to dissolve and has insignificant effect on the consolidated financial statements of the Company. 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 significant decline in the value of such investments, the Company has written down the investments.

Among the consolidated subsidiaries, Kyorin Europe GmbH and ActivX Biosciences, Inc. close their account books 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 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 net assets, are translated into yen at the exchange rates in effect at the balance sheet date. The components of net assets are translated at their historical exchange rates. Differences arising from the translation are presented as translation adjustments, which appear as a component of net assets in the accompanying consolidated balance sheet.

(c) Cash and Cash Equivalents

Cash and cash equivalents consist of cash on hand, deposits with banks withdrawable on demand, and short-term investments that are readily convertible into cash and subject to an insignificant risk of any changes in their value and 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, and 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. Inventories with lower profitability are written down to their net realizable value. Supplies except for samples are stated by the last purchase price method.

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

Depreciation of property, plant and equipment is calculated by the straight-line method based on the estimated useful lives of the respective assets. The useful lives of property, plant and equipment are summarized as follows:

Buildings and structures	3 to 50 years
Machinery and vehicles	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 a useful life of three to five years.

(g) Leases

Leased assets are 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 expensed as incurred.

(i) Income Taxes

Deferred tax assets and liabilities are determined on the basis of differences between financial reporting and the tax bases of the assets and liabilities and are measured using the effective tax rates and laws that 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 the 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 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 employees in the year such gain or loss occurs (10 years).

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

(k) 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 dividends and resolution of the ordinary general shareholders' meeting for other appropriations (see Note 7).

(l) Application of Tax Effect Accounting Related to the Transition from the Consolidated Taxation System to the Group Tax Sharing System

The Company and its domestic consolidated subsidiaries applied the consolidated taxation system from the year ended March 31, 2021.

With regard to items reviewed on the basis of the transition to the group tax sharing system and on the basis of the non-consolidated taxation system accompanying the transition to the group tax sharing system under the "Act for Partial Amendment to the Income Tax Act, etc." (Act No. 8 of 2020), the Company and its domestic consolidated subsidiaries did not apply Paragraph 44 of "Implementation Guidance on Tax Effect Accounting" (Accounting Standards Board of Japan ("ASBJ") Guidance No. 28, issued on February 16, 2018), due to the treatment pursuant to Paragraph 3 of the "Practical Solution on the Treatment of Tax Effect Accounting for the Transition from the Consolidated Taxation System to the Group Tax Sharing System" (ASBJ Practical Issues Task Force ("PITF") No. 39, March 31, 2020), and recorded the amounts of deferred tax assets and liabilities in accordance with the rules of the tax act before the amendments.

(m) Significant Accounting Estimates

Recoverability of deferred tax assets

(1) The amounts of deferred tax assets and liabilities recorded for the year ended March 31, 2021 were ¥343 million ($3,098 thousand) and ¥293 million ($2,646 thousand), respectively. The amount of deferred tax assets before offsetting against deferred tax liabilities was ¥4,322 million ($39,035 thousand).

(2) With respect to deductible temporary differences, recoverability of deferred tax assets is judged using taxable income based on future profitability, tax planning, etc.

Taxable income is estimated mainly on the basis of business plans that incorporate market prices (distribution prices), etc. The global spread of the novel coronavirus, which became apparent in the latter half of fiscal 2019, caused a contraction of the ethical drugs market due to fewer medical examinations and a delay in the market penetration of the new drugs group due to reduced activities by medical representatives (MRs), which affected the Group's business activities. When accounting estimates are made, it is extremely difficult to accurately measure and predict the future spread and end of the pandemic. Accordingly, on the assumption that recognized events and trends will continue until the end of the year ending March 31, 2022, future taxable income is estimated on the basis of business plans that incorporate such impacts.

The timing of when taxable income incurs and its amount may be affected by the external environment surrounding the ethical drugs business, which is the core of the Group, the future course of the novel coronavirus, and future changes in uncertain economic conditions. If the actual timing and amount of taxable income are different from estimates, deferred tax assets recorded in the consolidated financial statements for the year ended March 31, 2021 may be reversed.

(n) Accounting Standard Issued but Not Yet Effective

"Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, revised on March 31, 2020)
"Implementation Guidance on Accounting Standard for Revenue Recognition" (ASBJ Guidance No. 30, revised on March 26, 2021)

(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. As IFRS 15 became 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 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 the benefits of maintaining consistency with IFRS 15, and to add alternative accounting treatments to the extent that they do not impair comparability in cases where common practices and others in Japan should be considered.

(2) Date of application

From the beginning of the fiscal year ending March 31, 2022

(3) Effect of application

As the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, revised on March 31, 2020; hereinafter the "Revenue Recognition Accounting Standard"), etc., became applicable from the beginning of fiscal year starting on or after April 1, 2021, the Group will apply the Revenue Recognition Accounting Standard, etc., from the beginning of the year ending March 31, 2022 and recognize revenue as the amount it expects to receive in exchange for its goods or services when customers obtain control of the goods or services that are promised to be transferred.

The Group earns revenue from sales of pharmaceuticals and other products, as well as royalty income and service revenue based on contracts, etc., that allow third parties to research and develop, manufacture, sell, and use the Group's products and technologies.

Revenue from sales of pharmaceuticals and other products is recognized when performance obligations are satisfied by transferring control of pharmaceuticals and other products to customers. For sales of pharmaceuticals and other products in Japan, the Group plans to recognize revenue at the time of shipment in accordance with Paragraph 98 of the Implementation Guidance on Accounting Standard for Revenue Recognition, because the period from the time of shipment to the time when control of the pharmaceuticals and other products is transferred to customers is a normal period.

In addition, considerations for sales incentives, etc., paid to distributors were previously accounted for as selling, general and administrative expenses. With respect to certain sales incentives, etc., the method will be changed to reduce such incentives from transaction prices. Furthermore, for sales with expected reruns of products, a reserve

for sales returns was previously recorded based on an amount equivalent to gross profit. However, the method will be changed not to recognize revenue at the time of sales, in accordance with provisions regarding variable considerations.

Royalty income and service revenue include upfront payments, development milestone income, sales milestone income, and royalty income based on licensing agreements (granting or transferring rights to research and develop, manufacture, and sell pharmaceuticals and other products to third parties based on patents and know-how), as well as service revenue from evaluations of research and development and royalty income from the licensing of such evaluation technologies. With respect to income such as upfront payments, development milestone income, and sales milestone income based on licensing agreements, if performance obligations are satisfied at a point in time, the income is recognized as sales revenue when development and sales rights are granted, or when contractually specified milestones are achieved. If performance obligations are satisfied over time, the consideration is recorded as a contract liability. Upfront payments and milestone income are recognized as sales revenue over time, such as an expected contract period, in accordance with the method of measuring progress regarding satisfaction of performance obligations determined for each contract. Income related to sales royalties where the consideration received for licensing of intellectual property is based on net sales or usage is recognized as sales revenue when customers' sales revenue, etc., is generated, or performance obligations are satisfied, whichever is later.

With respect to the application of the Revenue Recognition Accounting Standard, etc., in accordance with the transitional treatment prescribed in the proviso of Paragraph 84 of the Revenue Recognition Accounting Standard, the cumulative effect of retroactively applying the new accounting policies prior to the beginning of the year ending March 31, 2022, will be added to or deducted from retained earnings at the beginning of the year ending March 31, 2022, and the new accounting policies will be applied from the beginning balance.

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

"Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 30, issued on July 4, 2019)
"Accounting Standard for Measurement of Inventories" (ASBJ Statement No. 9, revised on July 4, 2019)
"Accounting Standard for Financial Instruments" (ASBJ Statement No. 10, revised on July 4, 2019)
"Implementation Guidance on Accounting Standard for Fair Value Measurement" (ASBJ Guidance No. 31, issued on July 4, 2019)
"Implementation Guidance on Disclosures about Fair Value of Financial Instruments" (ASBJ Guidance No. 19, revised on March 31, 2020)

(1) Overview

The ASBJ promoted an initiative to enhance comparability of the requirements between Japanese accounting standards and international accounting standards, primarily in the areas of guidance on the fair values of financial instruments and their disclosures, and issued the "Accounting Standard for Fair Value Measurement," etc., considering the circumstance where the IASB and FASB have prescribed almost the similar detailed guidance (IFRS 13 "Fair Value Measuerment," issued by IASB, and Accounting Standard Codification Topic 820 "Fair Value Measuerment," issued by FASB).

The ASBJ's fundamental policies adopted for developing the "Accounting Standard for Fair Value Measurement," etc., are, in principle, to implement all the requirements of IFRS 13 from the viewpoint of enhancing the comparability of the financial statements of domestic and overseas companies by prescribing unified measurement methods, and also to prescribe exceptional treatments for individual matters so that comparability would not be impaired while the accounting practices that have conventionally been adopted in Japan are taken into account.

(2) Date of application

From the beginning of the fiscal year ending March 31, 2022

(3) Effect of application

The effect of applying the "Accounting Standard for Fair Value Measurement," etc., on the consolidated financial statements is currently unknown.

(o) Changes in Presentation

Application of the "Accounting Standard for Disclosure of Accounting Estimates"

The "Accounting Standard for Disclosure of Accounting Estimates" (ASBJ Statement No. 31, issued on March 31, 2020) has been applied to the consolidated financial statements for the year ended March 31, 2021, and notes on significant accounting estimates are described in the consolidated financial statements.

However, in such notes, matters related to the previous fiscal year are not disclosed in accordance with the transitional treatment prescribed in the proviso of Paragraph 11 of the accounting standard.

(p) Additional Information

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, introduced 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 the "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, on the basis of the share delivery rules prescribed by KYORIN Pharmaceutical in advance.

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

Introduction of the ESOP Plan is expected to contribute to employees' work motivation by increasing interest in improvement of business performance and the Company's share price. In addition, various stakeholders including shareholders are expected to 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, 2021 and 2020, the carrying amounts of the treasury shares were ¥1,624 million ($14,668 thousand) and ¥1,645 million, respectively, and the total numbers of treasury shares were 745 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, "Group Directors").

The Company is accounting for the Plan in line with the guidelines set out in the "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 arrangement whereby the Company's shares are acquired through a trust with 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 on the basis of the stock benefit rules for directors prescribed by the Company and its subsidiaries.

The Company adopted a Board Benefit Trust system when introducing the Plan. In principle, Group Directors will 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, 2021 and 2020, the carrying amounts of the treasury shares were ¥208 million ($1,879 thousand) and ¥224 million, respectively, and the total numbers of treasury shares were 92 thousand shares and 99 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 ¥110.72 = U.S.$1.00, the approximate rate of exchange on March 31, 2021. 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, 2021 and 2020 for the consolidated statements of cash flows consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2021	2020	2021
Cash and cash in banks	¥27,445	¥31,925	$247,878
Time deposits with a maturity over three months	(968)	(1,416)	(8,743)
Cash and cash equivalents	¥26,476	¥30,509	$239,126

5. Short-Term Investments and Investment Securities

Information regarding marketable securities classified as other securities as of March 31, 2021 and 2020 is as follows:

Marketable other securities

	Millions of yen			Thousands of U.S. dollars		
	2021			2021		
	Acquisition cost	Carrying value	Unrealized gain (loss)	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their acquisition cost:						
Equity securities	¥ 8,525	¥18,387	¥9,862	$ 76,996	$166,068	$89,072
Debt securities:						
Government bonds	1,300	1,300	0	11,741	11,741	0
Corporate bonds	—	—	—	—	—	—
Other bonds	—	—	—	—	—	—
Subtotal	9,825	19,688	9,862	88,737	177,818	89,072
Securities whose carrying value does not exceed their acquisition cost:						
Equity securities	2,008	1,607	(400)	18,136	14,514	(3,613)
Debt securities:						
Government bonds	4,100	4,099	(0)	37,030	37,021	(0)
Corporate bonds	—	—	—	—	—	—
Other bonds	—	—	—	—	—	—
Subtotal	6,108	5,707	(400)	55,166	51,544	(3,613)
Total	¥15,933	¥25,395	¥9,461	$143,904	$229,362	$85,450

	Millions of yen		
	2020		
	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their acquisition cost:			
Equity securities	¥ 8,652	¥18,755	¥10,102
Debt securities:			
Government bonds	900	900	0
Corporate bonds	—	—	—
Other bonds	—	—	—
Subtotal	9,552	19,655	10,103
Securities whose carrying value does not exceed their acquisition cost:			
Equity securities	2,034	1,858	(175)
Debt securities:			
Government bonds	3,100	3,098	(1)
Corporate bonds	—	—	—
Other bonds	1,000	993	(6)
Subtotal	6,134	5,950	(184)
Total	¥15,686	¥25,605	¥ 9,919

Unlisted securities and other non-marketable securities are not included in the above schedules as their fair market values are extremely difficult to determine. The amounts of these securities were ¥968 million ($8,743 thousand) and ¥640 million as of March 31, 2021 and 2020, respectively.

Sales amounts of securities classified as other securities and the related aggregate gain and loss for the years ended March 31, 2021 and 2020 are summarized as follows:

	Millions of yen		Thousands of U.S. dollars
	2021	2020	2021
Proceeds from sales	¥648	¥200	$5,853
Gains on sales	495	0	4,471
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, 2021 and 2020 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2021	2020	2021
Short-term bank loans	¥10,100	¥10,100	$91,221
Current portion of long-term debt	200	300	1,806
Current portion of lease obligations	137	141	1,237
Total	¥10,437	¥10,541	$94,265

The average interest rates applicable to short-term bank loans outstanding as of March 31, 2021 and 2020 are 0.3% and 0.3%, respectively.

Long-term debt and lease obligations as of March 31, 2021 and 2020 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2021	2020	2021
Long-term debt due through 2027 at average interest rate of 0.3% and 0.2% in 2021 and 2020, respectively	¥11,237	¥12,814	$101,490
Lease obligations due through 2030 in 2021 and 2020	546	679	4,931
Current portion of long-term debt and lease obligations due within one year	(337)	(441)	(3,044)
Total	¥11,446	¥13,052	$103,378

The annual maturities of long-term debt and lease obligations are summarized as follows:

Year ending March 31,	Millions of yen	Thousands of U.S. dollars
2022	¥ 337	$ 3,044
2023	321	2,899
2024	307	2,773
2025	10,263	92,693
2026	228	2,059

7. Shareholders' Equity

Japanese companies are 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 a 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 the two-year 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 and the purchase of treasury stock. The limitation is defined as the amount available for distribution to 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 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 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 by 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 shareholders, which is determined by a 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, 2021 and 2020 were ¥9,703 million ($87,635 thousand) and ¥10,987 million, respectively.

9. Gain or Loss on Sales and Retirement of Property, Plant and Equipment, Net

Significant components of the gain or loss on sales and retirement of property, plant and equipment, net for the years ended March 31, 2021 and 2020 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2021	2020	2021
Gain:			
Machinery and vehicles	¥ 0	¥ 19	$ 0
Land	366	—	3,306
Other	0	0	0
	¥367	¥ 19	$3,315
Loss:			
Buildings and structures	¥ (12)	¥ (7)	$ (108)
Machinery and vehicles	(9)	(2)	(81)
Other	(3)	(34)	(27)
	(25)	(43)	(226)
Total	¥342	¥(24)	$3,089

10. Debt Exemption Gain

A debt exemption gain was recorded due to exemption from an obligation to repay a long-term debt from the Japan Science and Technology Agency (National Research and Development Agency).

11. Financial Instruments

(a) Investment Policy of Financial Instruments

The Company and its consolidated subsidiaries mainly operate funds by highly secured financial instruments such as deposits and highly rated bonds, ensuring 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 of customers. The Company and its consolidated subsidiaries, in accordance with internal rules, keep track of adverse financial conditions of customers in the early stage to mitigate the bad debt by monitoring major customers' credit conditions periodically and managing the due date and balance per 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 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 of issuers. The Company and its consolidated subsidiaries regularly review the fair value and issuers' financial conditions 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.

Bank loans and debts are mainly used for the operating fund and fund for capital investments.

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

Carrying values, fair values, and their differences of financial instruments as of March 31, 2021 and 2020 are as follows:

	Millions of yen			Thousands of U.S. dollars		
	2021			2021		
	Carrying value	Fair value	Difference	Carrying value	Fair value	Difference
Cash and cash in banks	¥27,445	¥27,445	¥ —	$247,878	$247,878	$ —
Notes and accounts receivable	40,446	40,446	—	365,300	365,300	—
Short-term investments and investment securities	25,395	25,395	—	229,362	229,362	—
Total assets	¥93,287	¥93,287	¥ —	$842,549	$842,549	$ —
Notes and accounts payable	¥ 6,985	¥ 6,985	¥ —	$ 63,087	$ 63,087	$ —
Short-term bank loans	¥10,300	¥10,300	¥ —	$ 93,027	$ 93,027	$ —
Long-term debt	¥11,036	¥11,034	¥ (2)	$ 99,675	$ 99,657	$ (18)
Total liabilities	¥28,322	¥28,320	¥ (2)	$255,798	$255,780	$ (18)

	Millions of yen		
	2020		
	Carrying value	Fair value	Difference
Cash and cash in banks	¥ 31,925	¥ 31,925	¥ —
Notes and accounts receivable	47,449	47,449	—
Short-term investments and investment securities	25,605	25,605	—
Total assets	¥104,980	¥104,980	¥ —
Notes and accounts payable	¥ 9,776	¥ 9,776	¥ —
Short-term bank loans	¥ 10,400	¥ 10,400	¥ —
Long-term debt	¥ 12,514	¥ 12,512	¥ (2)
Total liabilities	¥ 32,691	¥ 32,689	¥ (2)

Unlisted securities and others of ¥1,649 million ($14,893 thousand) and ¥1,255 million, whose fair values are extremely difficult to determine as of March 31, 2021 and 2020, respectively, are not included in the above tables.

The 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 time.

Short-term investments and Investment securities

The 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 counterparty financial institutions. See Note 5, Short-Term Investments and Investment Securities, for securities by classification.

Notes and accounts payable and Short-term bank loans

The carrying value is deemed as the fair value since these are scheduled to be settled in a short time.

Long-term debt

The fair value of long-term debt is determined by discounting the amount of the total principal and interest at the interest rate assumed when new, similar loans are made.

The redemption schedule for monetary receivables and securities with maturities subsequent to March 31, 2021 is as follows:

	Millions of yen			
	2021			
	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	¥ 27,445	¥ —	¥ —	¥ —
Notes and accounts receivable	40,446	—	—	—
Short-term investments and investment securities:				
Other securities with maturities:				
Government bonds	3,400	2,000	—	—
Other	—	—	—	—
Total	¥ 71,291	¥ 2,000	¥ —	¥ —

	Thousands of U.S. dollars			
	2021			
	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	$247,878	$ —	$ —	$ —
Notes and accounts receivable	365,300	—	—	—
Short-term investments and investment securities:				
Other securities with maturities:				
Government bonds	30,708	18,064	—	—
Other	—	—	—	—
Total	$643,885	$18,064	$ —	$ —

12. 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.

Certain domestic consolidated subsidiaries apply a simplified method in calculating the retirement benefit obligation.

Defined benefit plans

(1) The changes in the retirement benefit obligation for the years ended March 31, 2021 and 2020 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2021	2020	2021
Retirement benefit obligation at the beginning of the year	¥36,211	¥35,500	$327,050
Service cost	1,210	1,196	10,928
Interest cost	181	177	1,635
Actuarial gain or loss	(58)	1,031	(524)
Retirement benefits paid	(1,870)	(1,694)	(16,889)
Retirement benefit obligation at the end of the year	¥35,673	¥36,211	$322,191

(2) The changes in plan assets for the years ended March 31, 2021 and 2020 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2021	2020	2021
Plan assets at the beginning of the year	¥33,249	¥33,315	$300,298
Expected return on plan assets	664	666	5,997
Actuarial gain or loss	155	(22)	1,400
Contributions paid by the employer	982	985	8,869
Retirement benefits paid	(1,870)	(1,694)	(16,889)
Plan assets at the end of the year	¥33,181	¥33,249	$299,684

(3) The changes in liability (asset) for retirement benefits for consolidated subsidiaries applying the simplified method for the years ended March 31, 2021 and 2020 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2021	2020	2021
Liability (asset) for retirement benefits at the beginning of the year	¥178	¥212	$1,608
Retirement benefit costs	132	113	1,192
Retirement benefits paid	—	(51)	—
Contributions to the plans	(107)	(95)	(966)
Transfer due to a change from the simplified method to the principle method	(58)	—	(524)
Decrease due to changes in the plans	(53)	—	(479)
Liability (asset) for retirement benefits at the end of the year	¥ 92	¥178	$ 831

(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, 2021 and 2020 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2021	2020	2021
Funded defined benefit obligation	¥36,189	¥36,611	$326,852
Plan assets	(33,609)	(33,586)	(303,549)
	2,579	3,024	23,293
Unfunded retirement benefit obligation	4	115	36
Net liability (asset) for retirement benefits	¥ 2,584	¥ 3,140	$ 23,338
Liability for retirement benefits	¥ 2,584	¥ 3,140	$ 23,338
Net liability (asset) for retirement benefits	¥ 2,584	¥ 3,140	$ 23,338

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

(5) The components of retirement benefit costs for the years ended March 31, 2021 and 2020 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2021	2020	2021
Service costs	¥1,210	¥1,196	$10,928
Interest costs	181	177	1,635
Expected return on plan assets	(664)	(666)	(5,997)
Amortization of actuarial loss	529	430	4,778
Amortization of prior service costs	(12)	(27)	(108)
Retirement benefit costs based on the simplified method	132	113	1,192
Retirement benefit costs	¥1,375	¥1,224	$12,419

(6) Prior service costs and actuarial gain or loss included in other comprehensive income (before tax effect) for the years ended March 31, 2021 and 2020 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2021	2020	2021
Prior service costs	¥ 12	¥ 27	$ 108
Actuarial gain or loss	(742)	622	(6,702)
Total	¥(730)	¥650	$(6,593)

(7) Unrecognized prior service costs and unrecognized actuarial loss included in accumulated other comprehensive income (before tax effect) as of March 31, 2021 and 2020 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2021	2020	2021
Unrecognized prior service costs	¥ (49)	¥ (61)	$ (443)
Unrecognized actuarial loss	3,330	4,072	30,076
Balance at the end of the year	¥3,280	¥4,011	$29,624

(8) Plan assets

The breakdown of plan assets is as follows:

	2021	2020
Domestic equity securities	2.5%	3.4%
Foreign debt securities	48.2	51.4
Foreign equity securities	6.6	4.9
General account	16.8	16.7
Short-term assets	3.6	4.4
Other	22.3	19.2
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

	2021	2020
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 ¥306 million ($2,764 thousand) and ¥295 million to the defined contribution plans for the years ended March 31, 2021 and 2020, respectively.

13. Income Taxes

Significant components of deferred tax assets and liabilities as of March 31, 2021 and 2020 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2021	2020	2021
Deferred tax assets:			
Liability for retirement benefits	¥1,059	¥1,274	$ 9,565
Accrued bonuses to employees	659	697	5,952
Allowance for doubtful accounts	24	27	217
Accrued enterprise tax	39	53	352
Loss on retirement of inventories	359	164	3,242
Loss on devaluation of investment securities	149	149	1,346
Loss on retirement of property, plant and equipment	38	38	343
Amortization of deferred assets	661	514	5,970
Loss on closure of plant	—	602	—
Other	1,394	1,608	12,590
Subtotal	4,384	5,130	39,595
Valuation allowance	(62)	(62)	(560)
Total deferred tax assets	4,322	5,068	39,035
Deferred tax liabilities:			
Reserve for reduction entry of property, plant and equipment	(1,022)	(1,091)	(9,230)
Unrealized holding gain on other securities	(2,902)	(3,037)	(26,210)
Prepaid pension cost	(259)	(313)	(2,339)
Other	(87)	(112)	(786)
Total deferred tax liabilities	(4,271)	(4,554)	(38,575)
Net deferred tax assets	¥ 50	¥ 513	$ 452

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, 2021 and 2020 is as follows:

	2021	2020
Statutory tax rate	30.6%	30.6%
Entertainment expenses and others that are not tax deductible permanently	0.4	1.2
Inhabitants' per capita taxes	1.3	1.2
Tax credits for research and development expenses	(4.7)	(6.0)
Valuation allowance	(0.1)	0.1
Internal profit elimination	(0.0)	(0.4)
Dividend income that is not taxable permanently	(1.0)	(0.8)
Effect of tax audit	—	0.1
Other	0.1	(0.5)
Effective tax rate	26.6%	25.5%

14. Comprehensive Income

Reclassification adjustments and income tax effects on other comprehensive income (loss) for the years ended March 31, 2021 and 2020 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2021	2020	2021
Unrealized holding gain (loss) on other securities:			
Gain (loss) arising during the year	¥ 47	¥(2,856)	$ 424
Reclassification adjustments	(488)	(0)	(4,408)
Before income tax effects	(440)	(2,856)	(3,974)
Income tax effects	134	874	1,210
Unrealized holding loss on other securities	(305)	(1,982)	(2,755)
Translation adjustments:			
Adjustments arising during the year	(77)	(19)	(695)
Retirement benefit liability adjustments:			
Gain (loss) arising during the year	213	(1,053)	1,924
Reclassification adjustments	516	403	4,660
Before income tax effects	730	(650)	6,593
Income tax effects	(223)	199	(2,014)
Retirement benefit liability adjustments	506	(451)	4,570
Share of other comprehensive income of affiliates accounted for using equity method:			
Gain (loss) arising during the year	23	(21)	208
Total other comprehensive income (loss)	¥146	¥(2,474)	$1,319

15. Segment Information

(Matters Concerning Changes in Reportable Segments)

The Group has changed its reportable segments to a single segment by consolidating the former two reportable segments of the "Ethical Pharmaceutical Business" and the "Consumer Healthcare Business" into the "Pharmaceutical Business."

From the year ended March 31, 2021, under the new medium-term business plan "HOPE100–Stage 3– (FY2020–FY2023)," the Group has concentrated the Consumer Healthcare Business on the infection-related field and promoted its integration with the Ethical Pharmaceutical Business. In line with this, the Group reviewed its business management classification and omitted the disclosure of reportable segments from the year ended March 31, 2021.

(Related Information)

(a) Information by Product and Service

Information by product and service is omitted for the years ended March 31, 2021 and 2020, since former reportable segments were changed to a single segment from the year ended March 31, 2021.

(b) Information by Geographical Area

(1) Sales

Information about sales by geographical area is omitted for the years ended March 31, 2021 and 2020, since domestic sales were more than 90% of net sales on the consolidated statement of income.

(2) Property, plant and equipment

Information about property, plant and equipment by geographical area is omitted for the years ended March 31, 2021 and 2020, since property, plant and equipment in Japan constituted more than 90% of property, plant and equipment on the consolidated balance sheet.

(c) Information by Major Customer for the Years Ended March 31, 2021 and 2020

	Millions of yen	
	2021	
Name of customer	Sales amount	Related segments
Alfresa Holdings Corporation	¥18,280	—
MEDIPAL HOLDINGS CORPORATION	16,405	—
SUZUKEN CO., LTD.	15,046	—
Toho Pharmaceutical Co., Ltd.	11,454	—

	Thousands of U.S. dollars	
	2021	
Name of customer	Sales amount	Related segments
Alfresa Holdings Corporation	$165,101	—
MEDIPAL HOLDINGS CORPORATION	148,167	—
SUZUKEN CO., LTD.	135,892	—
Toho Pharmaceutical Co., Ltd.	103,450	—

	Millions of yen	
	2020	
Name of customer	Sales amount	Related segments
Alfresa Holdings Corporation	¥20,242	—
SUZUKEN CO., LTD.	17,372	—
MEDIPAL HOLDINGS CORPORATION	16,889	—
Toho Pharmaceutical Co., Ltd.	13,098	—

As the Group is using a single segment, information about related segments is omitted.

(d) Information about Amortization and Unamortized Balance of Goodwill by Reportable Segment

There was no unamortized balance of goodwill as of March 31, 2021 and 2020.

16. Amounts per Share

Amounts per share for the years ended March 31, 2021 and 2020 are as follows:

	Yen		U.S. dollars
	2021	2020	2021
Basic profit	¥ 106.99	¥ 107.35	$ 0.97
Cash dividends	75.00	75.00	0.68
Net assets	2,175.52	2,142.07	19.65

Basic profit per share was computed on the basis of 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, 2021 and 2020.

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

The amount per share of net assets is computed on the basis of the net assets attributable to common shareholders 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 excluded from the calculation of the amount of profit per share were 843,761 and 854,090 for the years ended March 31, 2021 and 2020, respectively.

The numbers of these treasury shares at the end of the fiscal year excluded from the calculation of net assets per share were 837,508 and 853,887 as of March 31, 2021 and 2020, respectively.

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Independent Auditor's Report

The Board of Directors
KYORIN Holdings, Inc.

Opinion

We have audited the accompanying consolidated financial statements of KYORIN Holdings, Inc. and consolidated subsidiaries (the Group), which comprise the consolidated balance sheet as of March 31, 2021, and the consolidated statements of income, comprehensive income, changes in net assets, and cash flows for the year then ended, and notes to the consolidated financial statements.

In our opinion, the accompanying consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Group as of March 31, 2021, and its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with accounting principles generally accepted in Japan.

Basis for Opinion

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

Key Audit Matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the consolidated financial statements of the current period. These matters were addressed in the context of the audit of the consolidated financial statements as a whole, and in forming the auditor's opinion thereon, and we do not provide a separate opinion on these matters.

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Revenue recognition of royalty income	
Description of Key Audit Matter	Auditor's Response
The Group's consolidated net sales for the year ended March 31, 2021 were ¥102,904 million, part of which comprised of royalty income. Royalty income is income from contracts that allow third parties to manufacture, sell, and use the Group's products and technologies. Royalty income primarily consists of four types: upfront payment, development milestone, sales milestone, and royalty on net sales. Upfront payment, development milestone, and sales royalties are recognized as revenue at one point in time considering the contract details, and sales royalties are recognized over certain period corresponding to the contents of the customer's sales report. With regard to contracts that permit manufacturing and sale of products and use of technology, the terms and conditions are unique depending on the individual contract, and some of them are complicatedly stipulated. In addition, upfront payment, development milestone, and sales milestone occur non-recurringly, and the amount of each transaction, including royalty on net sales, has a large impact on profits of the Group. Accordingly we have decided that revenue recognition of royalty income is a key audit matter.	We conducted the following procedures to ensure that revenue recognition of royalty income was recorded properly. ・We understood the internal controls related to the revenue recognition process of royalty income, evaluated the design of controls, and tested the operations of controls for effectiveness. ・For transactions of high monetary importance, we observed contracts, internal approval materials, customer's report, etc. in order to understand the terms and conditions and their economic substance and inquired the person in charge of the company. ・Regarding upfront payment, development milestone and sales milestone, the appropriateness of measurement of revenue and the timing of revenue recognition was evaluated by vouching with the terms and conditions of the contract and the fact of cash receipts. ・Regarding sales royalties the appropriateness of the measurement of revenue and the timing of revenue recognition was evaluated by vouching with the customer's report and the fact of cash receipts.

Responsibilities of Management, the Corporate Auditor and the Board of Corporate Auditors for the Consolidated Financial Statements

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

In preparing the consolidated financial statements, management is responsible for assessing the Group's ability to continue as a going concern and disclosing, as required by accounting principles generally accepted in Japan, matters related to going concern.

The Corporate Auditor and the Board of Corporate Auditors are responsible for overseeing the Group's financial reporting process.

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Auditor's Responsibilities for the Audit of the Consolidated Financial Statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

As part of an audit in accordance with auditing standards generally accepted in Japan, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion.
- Consider internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances for our risk assessments, while the purpose of the audit of the consolidated financial statements is not expressing an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation in accordance with accounting principles generally accepted in Japan.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with the Corporate Auditor and the Board of Corporate Auditors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the Corporate Auditor and the Board of Corporate Auditors with a statement that we have complied with the ethical requirements regarding independence that are relevant to our audit of the financial statements in Japan, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

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

Interest Required to Be Disclosed by the Certified Public Accountants Act of Japan

Our firm and its designated engagement partners do not have any interest in the Group which is required to be disclosed pursuant to the provisions of the Certified Public Accountants Act of Japan.

Convenience Translation

The U.S. dollar amounts in the accompanying consolidated financial statements with respect to the year ended March 31, 2021 are presented solely for convenience. Our audit also included the translation of Japanese yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made on the basis described in Note 3 to the consolidated financial statements.

Ernst & Young ShinNihon LLC
Tokyo, Japan

June 21, 2021

春日 淳志

Atsushi Kasuga
Designated Engagement Partner
Certified Public Accountant

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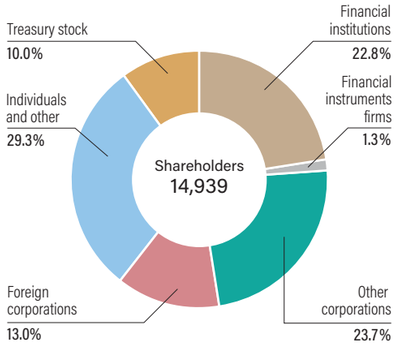
Corporate Overview and Stock Information (As of March 31, 2021)

Head Office	KYORIN Holdings, Inc. 6, Kanda Surugadai 4-chome, Chiyoda-ku, Tokyo 101-8311 Phone: +81-3-3525-4700 URL: https://www.kyorin-gr.co.jp/en/
Establishment	1958
Common Stock	¥700 million
Outstanding Shares	64,607,936
Shareholders	14,939
Listing	Tokyo Stock Exchange, First Section (Securities code: 4569)
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
Mykam Co., Ltd.	8.32%
The Master Trust Bank of Japan, Ltd. (Trust Account)	8.16%
Custody Bank of Japan, Ltd. (Trust Account)	5.53%
Kyorin Group Stock Ownership Association	3.46%
Banrina Co., Ltd.	3.35%
Archans Co., Ltd.	3.35%
Yutaka Ogihara	3.21%
Mariko Ogihara	3.02%
KAKEN PHARMACEUTICAL CO., LTD.	2.75%
Akira Ogihara	2.74%

Major Shareholders

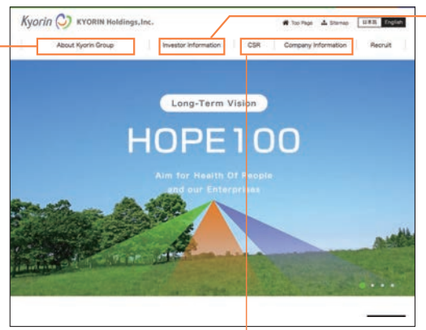


Website Information

Homepage ▶ https://www.kyorin-gr.co.jp/en/

Please visit the Kyorin Group website for the latest information about the Group and earnings-related material.

1 About the Kyorin Group
- President's Message
- Corporate Philosophy, LongTerm Vision
- History of the Kyorin Group
- Overview of the Kyorin Group, Value Creation Process
- Overview of Group Business, etc.



2 Investor information

Medium-Term Business Plan, Products under Development, Financial Information, IR Library, Stock Information, etc.

3 CSR, Company Information, etc.

Overview of Group Companies

KYORIN Pharmaceutical Co., Ltd.

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.

Capital: ¥4,317 million
Percentage of ownership: 100%
Head office : 6, Kanda Surugadai 4-chome, Chiyoda-ku, Tokyo 101-8311
Operations : Drug discovery, development, and sales of ethical drugs and sales of over-the-counter drugs, etc.

KYORIN Holdings, Inc.

KYORIN Rimedio Co., Ltd.

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 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 products to the market.

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

KYORIN Pharmaceutical Group Facilities Co., Ltd.

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 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.

Capital : ¥350 million
Percentage of ownership : 100%
Head office : 6, Kanda Surugadai 4-chome, Chiyoda-ku, Tokyo 101-8311
Operations : Subcontracted manufacturing of ethical drugs

KYORIN Pharmaceutical Co., Ltd. Subsidiaries

Kyorin Europe GmbH
Capital : €50,000
Percentage of ownership : 100%
Head office : Kaiserstrasse 8, 60311 Frankfurt am Main, Germany
Operations : Evaluation of other companies' technologies, etc.; research, analysis, and negotiation of partner licenses; work related to clinical trials; and collection of information related to drug discovery

ActivX Biosciences, Inc.
Capital : US$1
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.