Your Health is Kyorin's Mission

2022

ANNUAL REPORT

Year ended March 31, 2022

KYORIN Holdings, Inc.

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.

C O N T E N T S

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

Editorial Policy

Annual Report 2022 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 2021 (April 1, 2021 through March 31, 2022); some information also relates to fiscal 2022 activities.

Disclaimer

This report contains performance forecasts, goals and plans, and other forward-looking statements related to the Group.
These statements are based on the judgment of the Group's assumptions and outlooks based on the information and forecasts available at the time of preparation of this material, and contain known or unknown risks and uncertainties. Therefore, due to various factors that may occur, the actual performance, progress/success/failure of the development, and other insights may differ significantly from the description. It also contains informationabout medicines (including those under development), but the description is not for the purpose of advertising or medical advice.

Aiming to achieve the HOPE100 long-term vision and become a globally recognized company by creating innovative new drugs

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

Since our founding in 1923, the Kyorin Group has been developing a pharmaceutical business for people's health, based on our corporate philosophy of "Kyorin continues to fulfill its mission of cherishing life and benefiting society by contributing to better health." To achieve this philosophy, we are currently operating under the HOPE100 long-term vision with a view toward 2023, the 100th anniversary of our founding, and striving to achieve the targets contained in the HOPE100—Stage 3— medium-term business plan, the culmination of HOPE100, under the statement "Realization of a growth trend through the pursuit of originality."

Against this backdrop, we have decided to renovate our Group structure to a business holding company structure and change our name to KYORIN Pharmaceutical Co., Ltd. from April 2023. By focusing our strength on the new drugs business as the Group's core business, we aim to become a globally recognized company by creating innovative new drugs, as we strive for continuous growth and enhancement of corporate value over the next 100 years.

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

July 2022

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**.

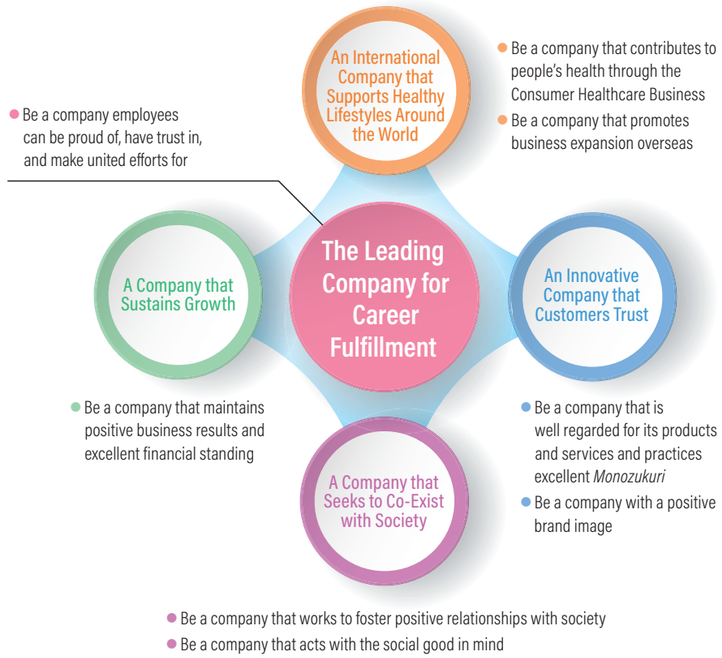
Long-Term Vision

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



History of the Kyorin Group

Ninety-nine years have passed since the establishment of the Group's core subsidiary, KYORIN Pharmaceutical Co., Ltd. During this time, we have contributed to patients' treatment primarily through the research and development, manufacture, and sales of new drugs. Under the HOPE100 long-term vision, formulated in fiscal 2010, we have been responding to people's diversifying needs by developing a broad range of businesses under the umbrella of the KYORIN Pharmaceutical Group, covering the prevention and treatment of disease and the maintenance and improvement of health. Under the HOPE100—Stage 3— medium-term business plan, we are currently pursuing a new drugs business, a generic drugs business, and an infection-related business (the prevention, diagnosis, and treatment of infectious diseases), with the aim of becoming a globally recognized company by creating innovative new drugs.

1923 → **2022** --→ **2023**

HOPE100 Long-Term Vision (FY2010–FY2023)

Medium-Term Business Plan Stage 1 FY2010–FY2015

Medium-Term Business Plan Stage 2 FY2016–FY2019

Medium-Term Business Plan Stage 3 FY2020–FY2023

Product history

Infectious disease initiatives

- 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 mucoregulating drug, 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. Beova, an overactive bladder drug, was launched.
- 2021 Interstitial cystitis therapeutic agent Zymso was launched.
- 2022 Cough treatment Lyfnua was launched.

- 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.

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. 22

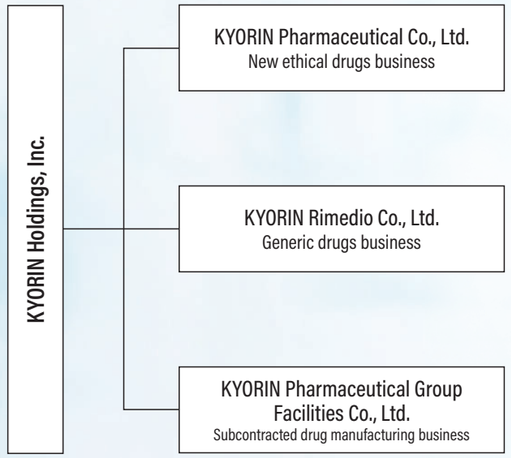
- 2012 Rubysta, a multipurpose disinfectant cleaner, was launched.
- 2017 KYORIN Pharmaceutical Co., Ltd. acquired all of the outstanding shares of jTAS Inc. and carried out an absorption-type merger of jTAS (entry to diagnosis business).
- 2019 GeneSoC, a microchannel-based genetic measurement device, was launched.
- 2020 Lasvic Tablets, an oral new quinolone antibacterial agent, was launched. 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. Compact Real Time PCR System GeneSoC mini was launched.
- 2022 GenSoC SARS-CoV-2 N2 Detection Kit was launched as in vitro diagnostics. Co-promotion of antiviral drug Lagevrio was begun.

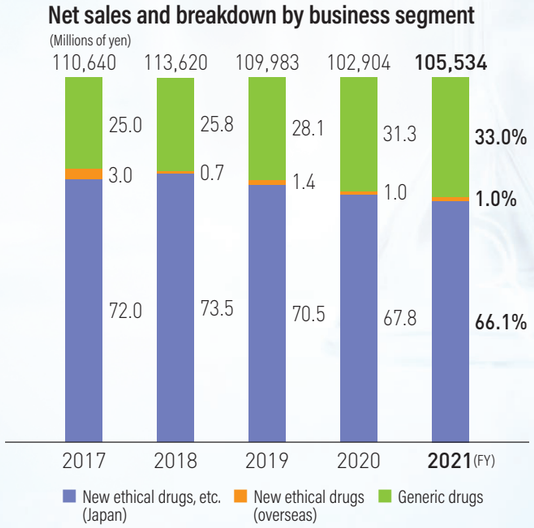
Management-related events

- 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 opened.
- 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. was 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 Kyorin Europe GmbH (Germany) was established.
- 2004 ActivX Biosciences, Inc. (U.S.A.) became a 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.
- 2022 Listed on the Tokyo Stock Exchange, Prime Market. Resolution was passed and merger agreement was concluded for absorption-type merger of KYORIN Pharmaceutical (effective April 2023).

The Kyorin Group's Business

The Kyorin Group operates pharmaceutical businesses with KYORIN Holdings, Inc. as the holding company and KYORIN Pharmaceutical (main business: new ethical drugs), KYORIN Rimedio (generic drugs), and KYORIN Pharmaceutical Group Facilities (subcontracted drug manufacturing) as the main operating companies, with ethical drugs as its core business. Management resources at the new ethical drugs business are concentrated in specific fields (respiratory, otolaryngology, and urology) based on a franchise customer (FC) strategy, for the creation of innovative new drugs and pharmaceutical development, manufacture, and sales, along with sales of products related to environmental hygiene and the diagnosis of infectious disease in the infection-related field. The generic drugs business engages in proprietary development, manufacture, and sales of generic drugs. By coordinating with the new drugs business, we strive to provide a stable supply of high-quality, highly reliable products.





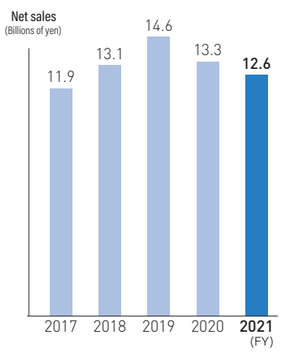
Primary Examples of New Ethical Drugs

Respiratory and Otolaryngology

Flutiform

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

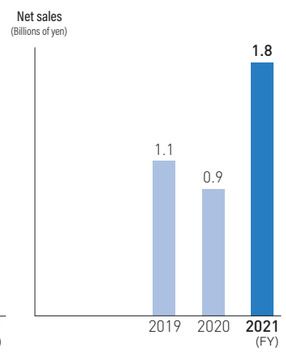
ICS/LABA: ¥90 billion
Market share in FY2021: 16%*



Lasvic

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

Antibacterial agent (oral): ¥62 billion
Market share in FY2021: 3%*



Lyfnua

Cough treatment
General name: Gefapixant citrate
Released: 2022
Concluded agreement with MSD K.K. for exclusive distribution rights in Japan

Mechanism

P2X3 receptor and P2X2/3 receptor subtype antagonist

First-year sales activities

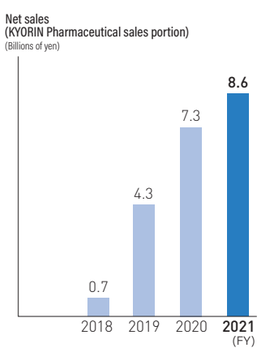
Aiming to establish position by promoting understanding of product's properties, especially among respiratory specialist physicians

Urology

Beova

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

OAB: ¥93 billion
Market share in FY2021: 10%*

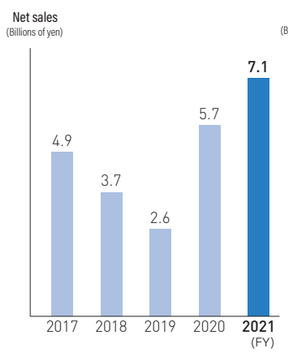


Otolaryngology

Desalex

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

Antihistamine: ¥126 billion
Market share in FY2021: 7%*

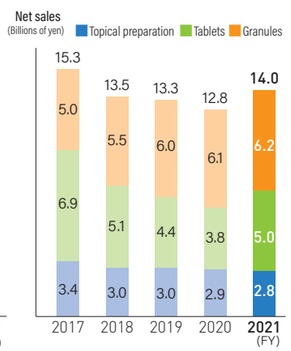


Other

Pentasa

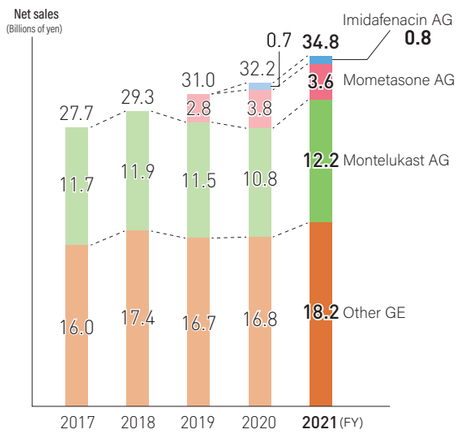
Ulcerative colitis and Crohn's disease treatment
General name: Mesalazine
Released: 1996 (250 mg tablet)
2015 (granules)

IBD: ¥47 billion
Market share in FY2021: 34%*



Generic Drugs

We are working to provide a stable supply of high-quality products using our strengths to handle new drugs, authorized generics (AG), and generic drugs, as well as the integrated development, manufacturing, and sales functions within the Group.



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Value Creation Process

The Kyorin Group strives to pursue business activities to create value based on our corporate philosophy by working to address diversifying medical needs and other social issues and sharing those achievements with all stakeholders. By continuing this value creation process, we aim to achieve a sustainable society and enhance corporate value.

Needs of society

- Responses to unmet medical needs
- Responses to diversifying medical needs
- Contributions to prevention and treatment of infectious diseases
- Stable supply of high-quality pharmaceuticals
- Nurturing next generation
- Promotion of work-style reform
- Addressing climate change
- Strengthening of corporate governance

Corporate Philosophy

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

Invested capital (input)

Human capital
Employees as driving force of growth
Structure for ease of work (human resources management system)

Intellectual capital
Technologies, expertise, and organizational structure for new drug discovery

Manufacturing capital
Manufacturing structure for stable supply of products

Social and related capital
Various partnerships
Relationships of trust with stakeholders

Environmental capital
Resources used, based on environmental management system

Financial capital
Solid financial base

HOPE100 Long-Term Vision (FY2010–FY2023)

Medium-Term Business Plan Stage 3 (FY2020–FY2023)

Strategy

1. Shift to business based on the proposal of solutions and accelerate the growth of new drugs group
2. Enhance pipeline to support medium-term growth
3. Strengthen drug discovery capability to realize the creation of innovative new drugs
4. Improve cost competitiveness
5. Expand overseas revenue

Organization

Aim to be the leading company for career fulfillment

Performance

- Numerical targets (consolidated basis)
- Capital policy and shareholder returns

Business activities

Pharmaceutical business

- New ethical drugs P. 24
- Generic drugs P. 32

Value chain

Drug discovery P. 24 → Development P. 26 → Manufacturing P. 30 → Marketing P. 28

Reliability assurance P. 33

Products and services (output)

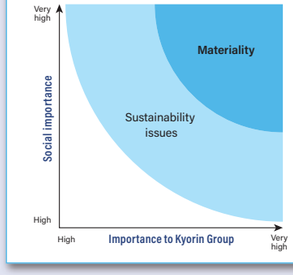
- New ethical drugs
- Generic drugs
- Diagnosis-related products
- Environmental hygiene-related products

Kyorin's strengths

- Pursuing open innovation in research areas including fibrosis, infectious diseases, and inflammation
- Development potential (possession of know-how, personal connections, networks) for specific fields
- Strong presence in specific fields
- Manufacturing structure able to address diversifying needs
- Integrated generic drug development, manufacturing, and sales functions within the Group

Kyorin's sustainability

Materiality: P. 10



- Creation of innovative new drugs
- Stable supply of products
- Maintenance of product reliability and safety
- Provision of appropriate drug information
- Promotion of diversity and inclusion
- Thorough compliance
- Protection of personal information and confidential information
- Environmentally friendly business activities
- Strengthening of corporate governance

Addressing Sustainability Issues: P. 34

- Sustainability in Business Activities P. 36
- Respect for Human Rights and Human Resources Management P. 38
- Fair and Honest Business Activities P. 42
- Living in Harmony with Society P. 44
- In Harmony with the Environment P. 45
- Corporate Governance P. 47

Value provided by Kyorin

Patients and medical professionals

- Meet medical needs through the creation and sale of innovative new drugs (enhance quality of life, meet unmet medical needs)
- Promote activities based on the proposal of solutions to help resolve issues at medical facilities
- Provide stable supply of high-quality pharmaceuticals through compliance with relevant laws and risk management
- Provide and gather information to promote appropriate use of pharmaceutical products
- Contribute to community-based health care

Suppliers

- Coordinate with suppliers and share information to create stable supply structure
- Procure responsibly
- Ensure fair and free competition

Society

- Promote environmental preservation initiatives to reduce environmental impact
- Create a vibrant society by contributing to local communities and promoting public awareness of health

Employees

- Address employee welfare and work-style reforms to provide comfortable workplaces
- Provide opportunities for training and education
- Create workplace environments for career fulfillment

Shareholders

- Disclose information promptly and appropriately
- Provide stable shareholder returns
- Engage in constructive dialogue

Reinvest to enhance corporate value

Materiality

To realize the Kyorin Group's corporate philosophy, we have formulated the HOPE100 long-term vision with the aim of evolving into a "company that supports sound and healthy lifestyles" with strong, continuous growth. To achieve this goal, along with our growth as a company, we consider it important to contribute to achieving a sustainable society. We have formulated a basic policy for our initiatives related to sustainability, designated issues in terms of materiality, and are addressing these issues appropriately.

Basic policy on sustainability

Following our corporate philosophy, "Kyorin continues to fulfill its mission of cherishing life and benefiting society by contributing to better health," the Kyorin Group is working proactively and positively to address sustainability issues (for society's continuous development) through business activities based on our Corporate Charter, with the aim of medium- to long-term enhancement of corporate value.

Designation of materiality

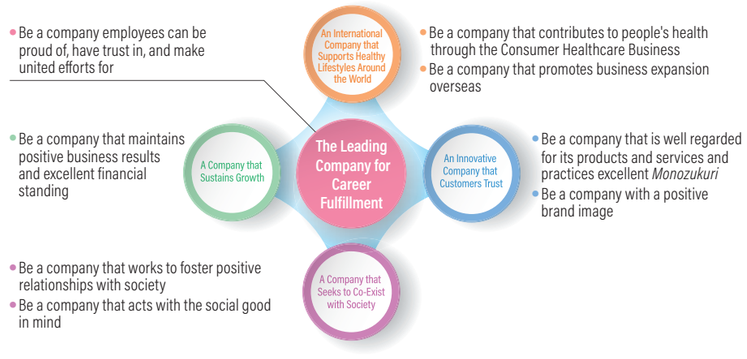
The HOPE100 long-term vision outlines an overall image to which the Kyorin Group aspires (the Five HOPEs). To achieve this vision, we have designated nine priority issues to be addressed in terms of materiality from among our core business issues related to sustainability, from perspectives including human resources, corporate governance, and the environment.

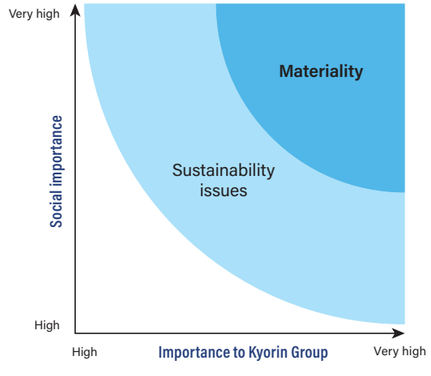
Corporate Philosophy
Kyorin continues to fulfill its mission of cherishing life and benefiting society by contributing to better health.

Long-Term Vision
HOPE100 (Aim for **H**ealth **O**f **P**eople and our **E**nterprises)

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





Materiality

- Creation of innovative new drugs
- Stable supply of products
- Maintenance of product reliability and safety
- Provision of appropriate drug information
- Promotion of diversity and inclusion
- Thorough compliance
- Protection of personal information and confidential information
- Environmentally friendly business activities
- Strengthening of corporate governance

Process for designating materiality

Materiality is designated by the following process, based on the Kyorin Group's forward-looking environmental outlook and analysis and referral to various principles and guidelines.

These issues are continuously reviewed in light of environmental changes, the Kyorin Group's business activities, and demands of society.

1. Identification of issues
Issues are identified based on various principles and guidelines (including ISO 26000, the UN's Sustainable Development Goals, and the materiality map for the healthcare industry formulated by the Sustainability Accounting Standards Board).

2. Narrowing down of issues
Identified issues are narrowed down in light of the Group's corporate philosophy, long-term vision, etc.

3. Assignment of priority
Issues of particularly high priority are identified using a matrix with two axes—importance to society and importance to the Group.

4. Designation of materiality
Issues identified as important for materiality are deliberated by the Management Committee and resolved by the Board of Directors.

Main initiatives

Corporate philosophy / HOPE100 long-term vision

Five HOPEs	Materiality	Initiatives related to materiality	Related SDGs
The leading company for career fulfillment	• Promotion of diversity and inclusion	• Respect the human rights of all people • Promote the cultivation of employees' career fulfillment and create opportunities for human resources development • Employ women and mid-career hires and appoint them to management positions • Proactively introduce systems for childcare and nursing care	5, 8
An international company that supports healthy lifestyles around the world	• Creation of innovative new drugs • Stable supply of products • Maintenance of product reliability and safety • Provision of appropriate drug information	• Clarify priority research fields for efficient research and development • Create proprietary drugs and partner with domestic and overseas pharmaceutical companies, academia, and venture companies (open innovation) • Observe regulations related to good manufacturing practices, etc. • Create detailed reliability assurance system • Comply with laws and regulations in research, development, and manufacturing • Promote supply chain management • Secure sufficient amounts of raw materials and diversify suppliers of raw materials • Provide training on pharmaceutical-related information and related laws, regulations, etc. • Swiftly collect and report information on side effects • Observe guidelines related to providing pharmaceutical-related sales information	3, 9, 12, 17
An innovative company that customers trust	• Environmentally friendly business activities	• Address effects of climate change (reduce CO_2 emissions) • Promote in-house environmental management system (ISO 14001 certification, etc.) • Reduce waste materials, environmentally harmful materials, etc.	7, 12, 13, 15
A company that seeks to co-exist with society	• Thorough compliance • Protection of personal information and confidential information	• Instill Corporate Charter and Compliance Guidelines (ongoing employee training) • Establish and manage Compliance Committee • Thoroughly familiarize employees with various information management regulations and provide ongoing education • Appropriately manage authority of access to various types of information, etc.	16
A company that sustains growth	• Strengthening of corporate governance	• Accelerate decision making, strengthen oversight function for appropriate management, and maintain transparency in corporate activities • Establish Committee on Remuneration and Nominations • Carry out internal audits in coordination with management	

Wielding Kyorin's unique competitive strengths to achieve a growth trend

Q Please give us a summary of fiscal 2021.

A Despite an adverse business environment, we created an internal structure to respond to changes and proactively pursued business.

In terms of the business environment in fiscal 2021, although the COVID-19 pandemic is continuing from the previous year with no end in sight, the ethical drugs market recovered from the contraction caused by patients refraining from visiting medical institutions and achieved overall growth. The Kyorin Group's major product markets, including our priority respiratory and otolaryngology areas, are recovering but continue to trail the prepandemic pace.

The commencement in fiscal 2021 of annual revisions as part of the overhaul of the drug pricing system has also been a major operational change. Greater-than-anticipated reductions to the prices of many products, mainly long-listed products and generics, have had a major impact on the Group's business results.

Against this adverse business environment, I believe that in fiscal 2021 we proactively developed our unique competitive strengths to achieve a growth trend.

Specifically, during fiscal 2021, the second year under the HOPE100–Stage 3– medium-term business plan, we pursued six implementation programs as priority business strategic points to increase our speed and cost competitiveness under the management policy of "focusing on the pursuit of originality."

With regard to "shifting to business based on the proposal of solutions and accelerating the growth of the new drugs group," we integrated information provision activities using digital channels with traditional in-person meetings for comprehensive development to supplement and strengthen our marketing base. In terms of shifting to a business based on providing solutions, we have expanded our product lineup in the infection-related areas of prevention, diagnosis, and treatment, and made unique approaches to medical practitioners. In treatment, we began co-promotion with MSD K.K. in January 2022 of the COVID-19 treatment Lagevrio. The new drugs group has seen a slower pace of growth because of the effect of the pandemic and drug price revisions but has expanded its main product lineup in priority areas (respiratory, otolaryngology, and urology), and growth is accelerating further.

We recognize "enhancing the pipeline to support medium-term growth" as a pressing issue for the Kyorin Group and proactively worked to address it. Having received manufacturing and marketing approval, we launched the interstitial cystitis treatment Zymso. We also obtained exclusive distribution rights from MSD K.K. for the chronic cough treatment Lyfnua as an in-licensed product in late-stage development. For further expansion, we proactively explored candidates for in-licensing not only in our priority areas (respiratory, otolaryngology, and urology), but also in the areas of infection and rare and intractable disease.

To "strengthen drug discovery capability to realize the creation of innovative new drugs," we have increased the speed of our evaluation and decision making on drug discovery programs and revised priorities of programs and allocation of resources accordingly. In terms of the progress of product development, the interstitial lung disease treatment KRP-R120 has completed Phase 1 clinical trials in Japan, and with Phase 1b/2a trials being conducted in the United States by aTyr Pharma, Inc. of the United States, the out-licenser, showing favorable results, we are considering carrying out multiregional clinical trials. We have also begun Phase 1 clinical trials of our proprietary rhinovirus infection treatment KRP-A218 in the United Kingdom. In terms of open innovation, we concluded a collaboration research agreement in March 2022 with Lumen Bioscience, Inc. of the United States to obtain a new development candidate toward clinical study using spirulina genetic protein engineering technology. With regard to out-licensed products, development of the agonist FPR2, which had been expected to become a major out-licensed product, handled by Bristol-Myers Squibb Company of the United States, the licensee, was halted due to strategic reasons and unfortunately the development right was returned. We will explore other out-licensing opportunities going forward.

With regard to "improving cost competitiveness," all divisions at all Group companies have made comprehensive cost reductions as planned. In addition, our social mission as a pharmaceutical company is to provide a stable supply of drugs, and we are working to fulfill this mission through thorough COVID-19 infection prevention measures and reinforcement of our procurement and management of raw materials and ingredients. At the same time, by making a Companywide effort to address supply pressures and limited shipments caused by a fire at the Nishinihon Delivery Center of KYORIN Pharmaceutical Co., Ltd. and a sudden surge in demand for ethical drug products, we were able to

maintain a stable supply without being significantly impacted.

To “expand overseas revenue,” we are proactively pursuing out-licensing to generate earnings at an early date and have successfully out-licensed the new quinolone synthetic antibacterial agent Lascufloxacin to a Chinese company.

With the “aim to be the leading company for career fulfillment,” we strove to create flexible and comfortable workplace environments. We have reviewed our work structure and introduced working from home and staggered work shifts as flexible work-style choices to enable employees to use their time effectively and perform their work efficiently.

Q How would you evaluate the Group’s business performance in fiscal 2021?

A Business revenue increased but profit decreased year on year. Still, we exceeded our initial forecast.

On a consolidated basis in fiscal 2021, net sales rose to ¥105.5 billion, while operating profit declined to ¥5.0 billion year on year. In terms of sales, the new drugs group saw growth in main products including the antiallergic agent Desalex, the therapeutic agent for overactive bladder Beova, and the new quinolone synthetic antibacterial agent Lasvic. In addition, quality problems that appeared at certain generic pharmaceutical companies led to unstable supplies of products. As a result, sales of long-listed drugs such as the ulcerative colitis and Crohn’s disease treatment Pentasa and the mucoregulator Mucodyne were higher than projected. Generics also made a contribution, including the authorized generic version of the bronchial asthma and allergic rhinitis treatment Kipres and other generics newly added to the drug price list during fiscal 2021. In terms of profit, drug price revisions came in at the 6% level at KYORIN Pharmaceutical Co., Ltd., causing a 3.4 percentage-point rise in the cost rate, which resulted in a ¥2.2 billion decline in gross profit. Selling, general and administrative (SG&A) expenses decreased on thorough Companywide cost reduction efforts, but operating profit declined roughly ¥0.8 billion on the increase in the cost rate. We expect the cost rate to improve on growth in new drugs going forward.

Net sales were ¥2.9 billion higher than our initial forecast, resulting in gross profit that was higher than projected. With SG&A expenses in line with our projections, operating profit was higher than forecast.

Q What are your management policies and specific initiatives for fiscal 2022?

A We will enhance the speed of our business to realize a growth trend.

Even though the current business environment is very challenging, I am convinced that more than anything else, we need to realize a growth trend. Against this backdrop, we set our management policy for fiscal 2022, which is the same as our Stage 3 statement—Realization of a growth trend through the pursuit of originality—. We will work to turn around to an underlying trend of medium- to long-term revenue and profit growth.

The main point in the pursuit of our business strategy is to enhance the speed of our business. By further accelerating the growth of the new drugs group, we will offset the negative effects of drug price revisions and achieve this year’s business forecast. With regard to candidates for in-licensing from other companies, which I consider particularly crucial to our medium-term growth trend, we aim to evaluate candidates quickly and acquire multiple products. We will also invest more proactively to expand our development pipeline. To strengthen our drug discovery capability, I personally have been focusing on a sense of speed. We will further accelerate the speed of evaluation and decision making on drug discovery themes to move forward in creating innovative new drugs.

Fiscal 2022 management policy

Realization of a growth trend through the pursuit of originality

Business strategy in fiscal 2022

Increase the speed of our business

(1) Accelerate the growth of the new drugs group

Accelerate the growth of the new drugs group to offset the negative effects of drug price revisions

(2) Enhance pipeline

Increase the speed of evaluation and acquisition of in-licensed products essential to growth

(3) Increase the speed of drug discovery

Increase the speed of evaluation of drug discovery programs and decision making

In other words, fiscal 2022 will see an awareness of speed in all areas, and we will pursue the following five implementation programs.

Fiscal 2022 implementation programs

1. Shift to business based on the proposal of solutions and accelerate the growth of the new drugs group
2. Enhance the pipeline to support medium-term growth
3. Strengthen drug discovery capability to realize the creation of innovative new drugs
4. Strengthen the growth potential of the generic drugs business and secure a stable supply
5. Construct a sustainable corporate base

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

In our solutions-based marketing, we are vigorously promoting activities at medical institutions that integrate digital channels with in-person meetings. In the area of infectious disease, we will continue to provide medical practitioners with solutions that entail prevention, diagnosis, and treatment. For prevention, we will promote Milton and Rubysta, and for treatment we will position Lasvic and Lagevrio as our core agents for the treatment of infectious disease. For diagnosis, we will promote the GeneSoC mini and the GeneSoC-use PCR pretreatment kit, released during fiscal 2021, and the COVID-19 detection kit for extracorporeal diagnosis, released in April 2022, while also working toward the development and sales of new laboratory reagents and in vitro diagnosis products for respiratory and sexually transmitted infection. We aim to achieve at an early date more than ¥10 billion in sales of infection-related products for prevention, diagnosis, and treatment.

With regard to accelerating the growth of the new drugs group, in April 2022, we released the cough treatment Lyfnua. As the only treatment for refractory chronic cough, this will present patients with a new choice. We have enhanced our product lineup in the respiratory and otolaryngology fields to a level that no competitor can match. For coughing, which can be caused by various diseases, I believe we will be able to provide new, original solutions by introducing products in line with target diseases. We also forecast that the restrictions on shipments of Beova will end in August 2022. I apologize to medical practitioners for the substantial and lengthy inconvenience that this has caused. As we approach this resumption, we have been making all-out efforts to increase our overall production capacity through measures including increasing facilities at our subcontracted manufacturers and commencing

operations with new subcontractors. By accelerating the growth of the new drugs group to the greatest extent possible, we aim to offset the negative effects of drug price revisions and achieve our targets.

2 Enhance the pipeline to support medium-term growth

With regard to a development pipeline that will drive the Stage 3 “realization of a growth trend,” we recognize that the early acquisition of in-licensed products that will contribute to medium- and long-term earnings growth is an important management issue. We aim to acquire at least one in-licensed product in late-stage development and one in early-stage development, including ones for rare diseases. In fiscal 2022, we have acquired an exclusive license to develop and commercialize cellular and tissue-based products for patients with the rare and intractable Fabry disease from CellGenTech Inc. We will work to expand our development pipeline quickly by further increasing the speed of our evaluation and acquisition of in-licensing candidates.

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

To strengthen our drug discovery capability, we will select and focus on research fields and programs. In KYORIN Pharmaceutical Co., Ltd.’s priority fibrosis research area, we have successfully constructed and analyzed a novel in vitro pulmonary fibrosis model through joint research with the Department of Drug Discovery for Lung Diseases at the Kyoto University Graduate School of Medicine and identified multiple drug discovery targets related to fibrosis. With regard to the introduction of new modalities and technologies, we have begun collaborating with

domestic and overseas companies to discover nucleic acid drugs. To strengthen our drug discovery capability to create innovative new drugs, we are increasing the speed of our evaluation and decision making on drug discovery programs, while also pursuing drug discovery programs using the yardsticks of target therapeutic profile (TTP) and target product profile (TPP).

4 Strengthen the growth potential of the generic drugs business and secure a stable supply

Recent problems related to the quality and safety of generic drug products have reduced trust in the generic drugs industry, and we take very seriously the major social uncertainty this has caused. Given our mission of providing patients with a stable supply of high-quality, safe generic drug products, the Kyorin Group is stepping up its efforts to assure reliability with respect to our manufacturing management and quality control. During fiscal 2022, we will work to maintain our 100% success rate for products developed in-house being added to the drug price list, while also closely coordinating our sales plans and production plans to achieve growth from increased sales of newly listed products and priority products. In addition, with the increase in pharmaceutical production volume, we are proceeding with the construction of the Takaoka Plant as planned to strengthen our supply capacity.

5 Construct a sustainable corporate base

While fully recognizing the adverse external environmental changes and the Kyorin Group's position that are continuing in fiscal 2022, we are implementing thorough cost controls Companywide and working to reduce unnecessary expenses and decrease manufacturing costs. In particular, we will further increase the speed of our market promotion of the new drugs group, expansion of the development pipeline, and strengthening of our drug discovery capability to achieve our fiscal 2022 targets. We are also striving to become the leading company for career fulfillment by considering introducing new measures to improve operational efficiency and productivity as work-style reform initiatives, while also systematically developing more specific measures for health management. In addition, as a company listed on the TSE Prime Market, we are continuing to address relevant sustainability issues from an environmental, social, and governance (ESG) perspective.

Q Please tell us more about your initiatives to address sustainability issues.

A In addition to continuing to contribute to people's health, we are working to resolve environmental and other social issues through our business activities.

The Kyorin Group's basic policy is "by adhering to its corporate philosophy, the Kyorin Group aims to address sustainability issues proactively and flexibly through business activities in line with its Corporate Charter to enhance its corporate value over the medium to long term." To achieve this goal, we have formulated a matrix with the importance of social issues and their importance to the Kyorin Group as the two axes, based on the Kyorin Group's business risks, opportunities, current situation, issues, and analysis of the future operational outlook. From the matrix, we identified nine material issues as being of particularly high priority that should be focused on. Specific initiatives were selected based on their relevance to the corporate vision outlined in the HOPE100 long-term vision (Five HOPEs). This means placing importance on contributing to society through our pharmaceutical business, including innovative new drug discovery, product quality assurance, and the stable supplies that are particularly crucial for a pharmaceutical company, operating our businesses while taking into account environmental considerations, ensuring thorough compliance, and strengthening governance.

To enhance the Kyorin Group's corporate value and achieve sustainable growth, maintaining proactive communication and building relationships of trust with all stakeholders—including patients, medical practitioners, shareholders, investors, employees, suppliers, and local communities—are indispensable.

Our corporate message of "Your Health is Kyorin's Mission" expresses our strong desire to contribute to people's health. In addition to providing value through our businesses, as a company tied to human life, the Kyorin Group aims to resolve sustainability issues through relationships of trust with all stakeholders to achieve sustainable growth for the Kyorin Group and a sustainable society.

Q Please tell us about the background behind the Kyorin Group's restructuring planned for April 2023.

A The restructuring is intended to achieve our corporate vision of being "a globally recognized company through the creation of innovative new drugs."

Stage 3 clearly stated our corporate vision of being "a globally recognized company through the creation of innovative new drugs." Amid the drastic changes in our business environment, we need to quickly improve our business promotion function and management efficiency to achieve our corporate vision. To accomplish these goals, we have determined that a transition from the current pure holding company structure to a business holding company structure is strategically appropriate to strengthen the core new drugs business. Along with positioning new drugs as our core business, we will comprehensively develop the generic drugs business, the infection-related business, and the subcontracted drug manufacturing business with the aim of contributing to people's health by providing new value to patients and medical practitioners.

The restructuring is scheduled to take effect on April 1, 2023, and we are currently making preparations for the new organization. We intend to change the holding company name to KYORIN Pharmaceutical Co., Ltd. for a smooth transition for KYORIN Pharmaceutical Co., Ltd.'s current businesses including the new drug discovery and pharmaceutical businesses.

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

A We will strive to enhance corporate value over the medium to long term through Kyorin's unique contributions.

June 2022 marked the 99th anniversary of the Kyorin Group's founding. Since our founding, we have earnestly pursued business activities based on our corporate philosophy: "Kyorin continues to fulfill its mission of cherishing life and benefiting society by contributing to better health." We will reach our 100th anniversary in 2023. Going forward, we will keep striving to create innovative new drugs and keep developing businesses in areas where we can demonstrate Kyorin's strengths to raise our competitiveness even further. Thinking first and foremost about "health," an important theme for all people around the world, we will work to achieve a sustainable world by fulfilling our social mission to the greatest extent possible and enhance corporate value over the medium to long term with a view toward the next 100 years.

I ask for the continued support of our stakeholders going forward.

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

HOPE100 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.

Specific form of a "company that supports sound and healthy lifestyles," as targeted in Stage 3

With the goal of becoming a globally recognized company by creating innovative new drugs, we aim to become a company that broadly supports people's health and engages in the comprehensive development of the new drugs business, the generic drugs business, and the infection-related business (prevention, diagnosis, and treatment of infectious disease).

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.

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 group	• 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 group 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 (respiratory, 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: Confirmation of the effectiveness and safety to humans of candidate substances for new drugs in the research and development stage

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 profit before deduction of R&D expenses (operating profit + 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

Information

Regarding the absorption-type merger of KYORIN Pharmaceutical Co., Ltd. and change of our name

Effective April 1, 2023, KYORIN Holdings, Inc. will change from a pure holding company structure to a business holding company structure by reorganizing the Group through the absorption-type merger of KYORIN Pharmaceutical Co., Ltd., our main operating company, and changing our name to KYORIN Pharmaceutical Co., Ltd.

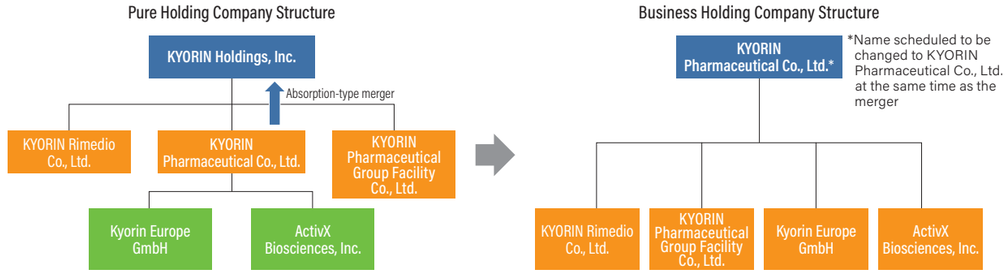
Purposes of the merger

The business environment surrounding the Group features not only a higher degree of difficulty in new drug creation and enormous R&D investment is required but also drug price revisions implemented for a wide range of products annually, which is expected to affect the management of the Group greatly.

In view of such rapid changes in the environment and our current corporate situation, the Company will renovate the Group structure in 2023, when the Company celebrates its 100th anniversary, in order to improve its business promotion function and management efficiency.

With the renovation to a business holding company structure centered on KYORIN Pharmaceutical Co., Ltd., the new drug business will be placed at the core of the group management and strongly promoted, while the generic drug business, infection-related business, and subcontracted drug manufacturing business will be developed in a complex manner. The Company will build a system to make a leap forward for the next 100 years.

Merger scheme



Proactive investment for growth aims to enhance medium- to long-term corporate value and shareholder value

Yoh Ito
Senior Corporate Officer
Director, Finance & Accounting

Capital policy 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**

As the Kyorin Group's executive in charge of finance, I recognize that my role is to continuously enhance corporate value and shareholder value by investing proactively for the future while maintaining a sound financial position.

The fundamental thinking underpinning our financial strategy under 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. Annual drug price revisions are having a major negative impact on the Group's profit levels. To enhance long-term corporate value in this environment, nothing is more important than continuously developing and bringing to market the new drugs that are the source of our profit. We therefore intend to expand our development pipeline by stepping up investment in proprietary research and development and investment in the acquisition of in-licensed products from other companies. In addition, we will work to increase sales of products of the highly profitable new drugs group, while also investing extensively in manufacturing equipment to boost our production capacity as necessary and simultaneously improve cost efficiency, aiming to increase both sales and profit.

The current medium-term business plan forecasts achieving sustainable growth as a performance target. The specific targets are for average annual growth in net sales of at least 5% and for operating profit before deduction of research and development expenses (operating profit + R&D expenses) to correspond to at least 20% of net sales. In fiscal 2020, however, the start of Stage 3 coincided with an increase of COVID-19 infections, causing the ethical drugs market to contract as patients refrained from visiting medical institutions, leaving us unable to achieve our targets for growth and profitability. In fiscal 2022, we are forecasting sales growth driven by growth from recovering markets at the new drugs group. We are confident that a turnaround to a growth trend should emerge.

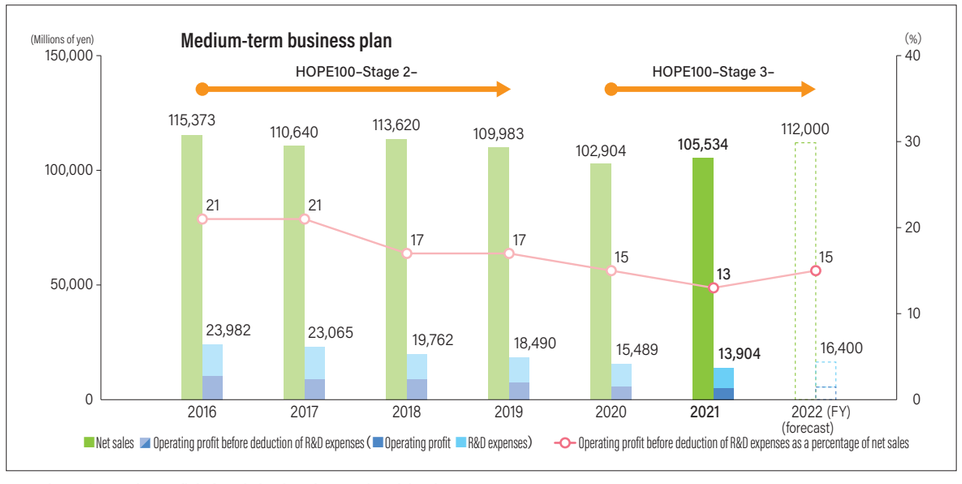
With the expansion of the development pipeline in fiscal 2022, we expect research and development expenses to increase ¥2.0 billion from those of the previous year, to ¥10.9 billion. However, this figure could rise if we are able to acquire new in-licensed products before the end of the fiscal year. In addition, we have decided to increase our pharmaceutical supply capacity by building a new plant (the Takaoka Plant) in Toyama Prefecture at an investment amount of roughly ¥10 billion, with construction scheduled to start in September 2022. Of the ¥5.0 billion slated for capital expenditures, we expect ¥3.9 billion to be related to the new facility.

With regard to returns to shareholders, annual drug price revisions have significantly changed our operating environment. To maintain a balance between financial soundness and investment for growth, in fiscal 2021, we lowered the level of our baseline DOE ratio and intend to pay a dividend at the same level this year. In terms of internal reserves, we plan to invest in pillars for growth, proactively using these investments to strengthen our growth potential and develop future businesses by investing in areas including the drug discovery and development that are crucial for a pharmaceutical company, as well as for product in-licensing, new business acquisitions, and capital investment.

In terms of cross shareholdings, we hold shares that we have determined will contribute to maintaining and strengthening long-term business relationships, the Group's sustainable growth, and enhancement of its corporate value. However, if the significance of holdings is deemed to have diminished, we intend to reduce those shareholdings as appropriate, based on dialogue with the issuers of those shares.

Pharmaceutical companies need to invest heavily in new drug development, which carries high risks, and factors like patent expiries significantly affect business results, making a sound financial base essential to our survival. The Kyorin Group's total shareholders' equity ratio stood at a healthy 72.4% as of March 31, 2022. We aim to invest proactively for growth and enhance corporate value and shareholder value over the long term while maintaining this sound financial base. When investing for growth, we will procure funds from outside sources as necessary to seize long-term growth opportunities when they arise. I ask for your continued support.

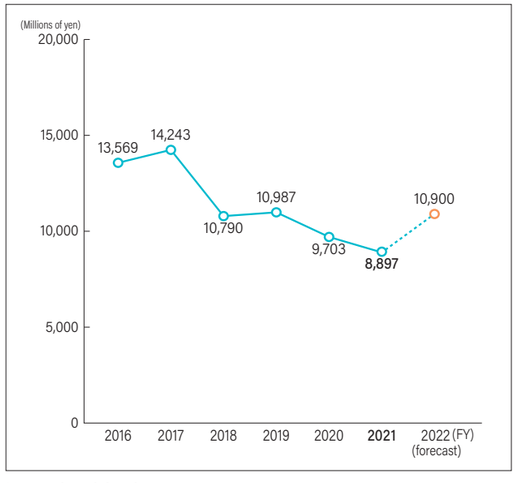
Net sales and operating profit before deduction of research and development expenses



Net sales and operating profit before deduction of research and development expenses

Annual drug price revisions and the pandemic are significantly influencing net sales and operating profit. However, we are forecasting sales and profit growth in fiscal 2022 as we expand the lineup of our new drugs group and are expecting restrictions on shipments of a main product to end. We anticipate operating profit before deduction of R&D expenses to reach ¥16,400 million, corresponding to roughly 15% of net sales.

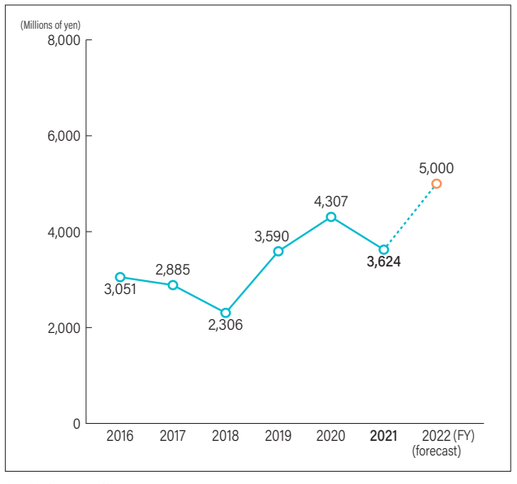
Research and development expenses (consolidated)



Research and development expenses

We are investing proactively to strengthen our drug discovery capabilities to create innovative new drugs and also to acquire in-licensed products to expand our development pipeline to support medium-term growth. We expect research and development expenses to increase during fiscal 2022 as the development pipeline evolves.

Capital expenditures (consolidated)



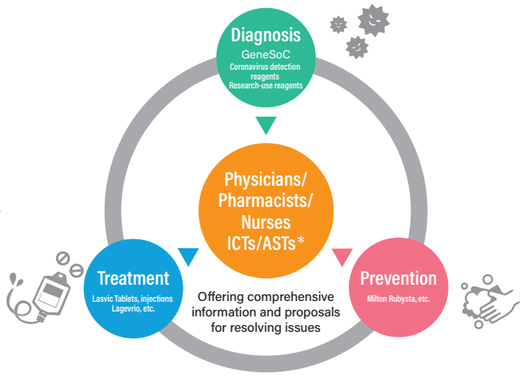
Capital expenditures

We are making capital expenditures to build a business platform for the medium to long term, including the construction of an efficient production facility to contribute to quality improvement and stable supplies, and the enhancement of equipment and facilities for drug discovery and drug research and development. Construction of the new production facility, the Takaoka Plant (investment amount of roughly ¥10 billion), is scheduled to start in September 2022.

Topics Shift to Business Based on the Proposal of Solutions

Providing solutions in the field of infectious diseases

With the global threat of antimicrobial resistance (AMR) and the spread of COVID-19 becoming global threats, the need for countermeasures to infectious disease is greater than ever. The Kyorin Group has a proven track record in providing solutions to medical professionals in infection-related fields, offering information and proposals for resolving issues related to infectious disease and infection control from a multifaceted perspective encompassing prevention, diagnosis, and treatment.



* ICTs: infection control teams
ASTs: antimicrobial stewardship teams

Treatment

Contributing to the treatment of infectious diseases by promoting appropriate use of antibacterial drugs

Lasvic

KYORIN Pharmaceutical Co., Ltd. cooperates on surveys and academic projects covering trends in drug-resistant bacteria, working with and supporting infectious disease-related academic seminars and conferences by providing information on the appropriate use of antibacterial drugs to physicians, nurses, and other members of ICTs and ASTs, including clinical technicians. Our efforts include contributing to the treatment of infectious diseases with two types of our proprietary new quinolone antibacterial agent Lasvic tablets and intravenous drip infusion kit.

Treatment

Contributing to treatment of COVID-19 infections

Lagevrio

In response to the spread of COVID-19 infections, KYORIN Pharmaceutical Co., Ltd. concluded a co-promotion agreement with MSD K.K. and is pursuing activities to provide information about the oral antiviral drug Lagevrio. By offering a new treatment option in the form of an antiviral agent that can be taken at home, we are contributing to the treatment of COVID-19.

Prevention

Contributing to infection control at medical institutions

Rubysta and Milton

Because much of the transmission of microbes 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.

Diagnosis

Identifies pathogenic microorganisms quickly, accurately, and easily to help stop the spread of infections and promotes the appropriate use of antimicrobials

GeneSoC

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

During fiscal 2021, KYORIN Pharmaceutical Co., Ltd. released the lightweight, compact, general medical device Compact Real Time PCR system GeneSoC mini and the GeneSoC PCR Preprocessing Kit reagent for RNA extraction, and in April 2022, the GeneSoC SARS-CoV-2 N2 Detection Kit, in vitro diagnostics to detect coronavirus nucleic acid. By developing and selling research-use reagents for areas including respiratory infection and sexually transmitted disease as well as pharmaceuticals for in vitro diagnostics, we are contributing to the diagnosis of infectious disease and appropriate use of antimicrobials.

Expanding product lineup in the respiratory and otolaryngology fields

In line with its franchise customer strategy, KYORIN Pharmaceutical Co., Ltd. has been expanding its product lineup in the priority fields of respiratory and otolaryngology. By providing medical professionals with a broad range of information and proposals to resolve issues for treating patients suffering from diseases in these fields, we aim to be a company trusted by various people in medical care and a company recognized for its presence in society.

Products

Bronchial asthma	Allergic rhinitis	Refractory chronic cough
Flutiform/Kipres	Desalex/Kipres/Nasonex	Lyfnua
Acute bronchitis, bronchial asthma (expectorant)	COPD	Respiratory/ otolaryngological infection
Mucodyne	Eklira	Lasvic

MR activities
- Providing information
- Promoting appropriate use

Digital channels
- Emails providing information
- Online meetings, briefings, and meetings

Kyorin → Medical professionals → Patients

Support tools
- Tools to promote awareness of disease
- Doctor Salon
- Drug Information Center
- Website

Support tools
- Tools to promote awareness of disease
- Website
- Drug Information Center

New product

Contributing to treatment of chronic cough with world's first selective P2X3 receptor antagonist

Lyfnua

Lyfnua, the world's first drug effective against refractory chronic cough, was released in April 2022. Refractory chronic cough is resistant to the specific treatment of the primary disease, and chronic cough can also exist when the primary disease cannot be identified. Lyfnua offers a new treatment option to patients suffering from refractory chronic cough.

New Ethical Drugs: Drug Discovery

Koichiro Hagihara
Executive Director, Research and Development

KYORIN Pharmaceutical Co., Ltd. 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 programs 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 2021, we continued to focus on our priority research domains of fibrosis and kinase research. As a result, we successfully identified several drug discovery targets and built disease models. We also promoted the introduction of new technologies through joint research with companies in Japan and overseas. We will continue to carry out proactive research and development activities during fiscal 2022 to strengthen our drug discovery capabilities—the Group's top priority—and expand our development pipeline.

Strengths

- Disease model analytical technologies and small molecule drug discovery technologies (WATARASE Research Center)
- Kinase analysis technologies (ActivX)
- Tie-ups with academic institutions and venture capital start-ups (promotion of open innovation) in research areas including fibrosis, infectious disease, and inflammation

Opportunities

- Develop basic research technologies to increase drug discovery research opportunities
- Develop disease research through advances in diagnostic technologies
- Change in global awareness regarding threat of infectious diseases
- Step up open innovation to accelerate research
- Speed up use of digital technologies

Risks

- Increased use of artificial intelligence in drug discovery could make small molecule 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

KYORIN Pharmaceutical Co., Ltd.'s WATARASE Research Center has technologies for analyzing disease models and small molecule 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 working with academic institutions to proactively explore drug candidate compounds that have pharmacological activity against drug discovery targets identified by using iPS cells and human tissue as we strive to create innovative new drugs by adding new layers to research domains and technologies. We are also working with companies in Japan and overseas by using multiple modalities including nucleic acid drug discovery and small molecule drug discovery, with the aim of uncovering new fibrosis treatments.

Pursuing open innovation

To supplement and build on KYORIN Pharmaceutical Co., Ltd.'s proprietary drug discovery, we are proactively investigating external early-exploratory-stage drug discovery programs 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 Kyoto University Graduate School of Medicine in fiscal 2017 and are integrating that academic institution's pathological research and basic research capabilities with KYORIN Pharmaceutical Co., Ltd.'s drug discovery capabilities to search for new drug discovery targets. This tie-up with academia has produced results such as successfully building a fibrosis disease model and identifying drug discovery targets that trigger fibrosis. As a next stage in fibrosis research, we will build a patient-tiered research structure and basic structure to create new drugs to treat fibrosis. With regard to venture capital start-ups, we have accelerated the introduction of new technologies through the conclusion of a collaborative research agreement with Lumen Bioscience, Inc. of the United States that aims to obtain new development candidates using Lumen's spirulina genetic protein engineering technology, and in Japan, through a collaborative development agreement with the biotech venture CellGenTech, Inc. for the development of pharmaceuticals using genetically modified human adipocytes. We are also acquiring early-stage drug discovery seeds from outside the Kyorin 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 Co., Ltd. applies selection and concentration in its research domains and themes. In the initial exploratory research stage, drug discovery activities emphasize target therapeutic 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 Co., Ltd. undertakes drug discovery activities utilizing three approaches:

* KYORIN Pharmaceutical Co., Ltd.'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

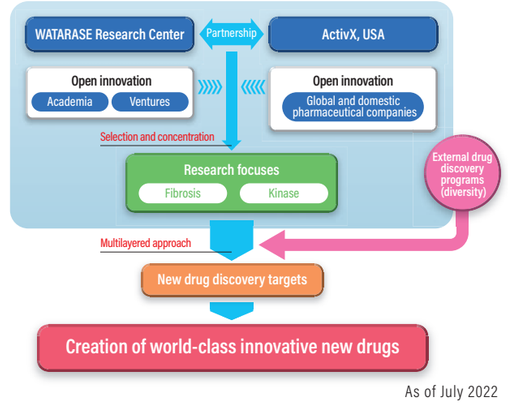
We are strengthening our early-exploration-stage research to quickly seek out novel drug discovery targets and create innovative new drugs effective against those targets. To strengthen our early-stage drug discovery research both quantitatively and qualitatively, we are using humans (patients) and disease model animal tissue or cells, and applying genetic study research technologies and information analysis technologies 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 small molecule drug discovery, we are using new technologies to explore compounds including mid-size molecule and nucleic acid medicines. Through our development of the fusion protein formulation (KRP-R120), in-licensed from aTyr Pharma, Inc. of the United States in January 2020, we are pursuing possibilities in new modalities and working to create new drugs with global potential that help address medical needs that cannot be met with small molecule 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.



As of July 2022

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)
- Development strategy with cooperation by drug discovery, marketing, and strategic planning divisions

Opportunities

- Increase overseas clinical trials and multiregional clinical trials
- Raise precision of test subject selection through development of diagnostic technologies
- Use digital technologies to realize efficient operations
- Use early approval and other systems to provide treatment opportunities more quickly
- Promote development by creating and using an ecosystem and coordinating across it with other industries, academic institutions, etc.

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 fields 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 Co., Ltd., 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 2021, we began Phase 1 clinical trial of KRP-A218, a treatment for rhinovirus that risks becoming aggravated. Phase 1 clinical trial of the interstitial lung disease (pulmonary sarcoidosis) treatment KRP-R120 was completed, and we are now considering multiregional clinical trials with the out-licenser, aTyr Pharma, Inc. of the United States. In April 2022, we launched Lyfnua, a selective P2X3 receptor antagonist for the treatment of intractable chronic cough.

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

Products under development (As of May 11, 2022)

Phase 3–launch

Product name/General name	Target disease	Origin	Features	Stage
				Ph1 Ph2 Ph3 NDA Launch
Lyfnua/ Gefapixant citrate	Intractable chronic cough	MSD	World's first selective P2X3 receptor antagonist	Apr. 2022

POC project (Phase 1–Phase 2)

Compound/Code	Target disease	Origin	Features	Stage
				Ph1 Ph2 Ph3 NDA Launch
KRP-R120	Interstitial lung disease (pulmonary sarcoidosis)	aTyr Pharma	Fusion protein drug that by binding to neuropilin-2 (NRP2) receptor acts to suppress the excessive activation of immune cells, while being a potential first-in-class therapy to treat inflammatory diseases including pulmonary sarcoidosis	Consider starting international joint clinical trials
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

In-licensed product

Compound/Code	Target disease	Origin	Features	Stage
				Ph1 Ph2 Ph3 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
					Ph1 Ph2 Ph3 NDA Launch
KRP-203	Priothera	—	In-house	Sphingosine-1-Phosphate Receptor Agonist	

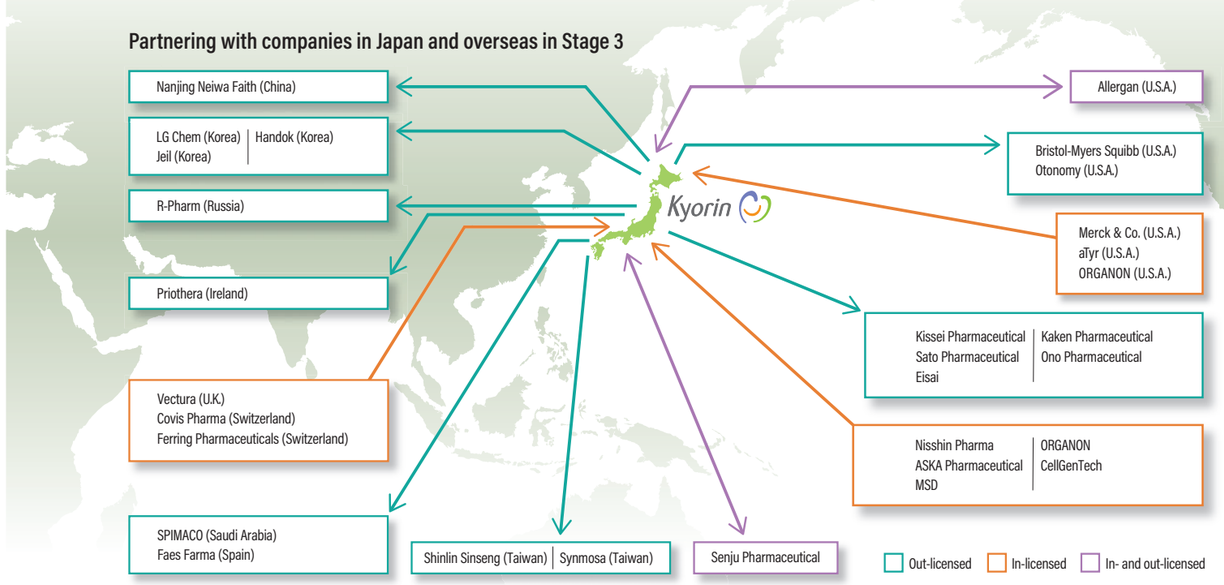
Promotion of proactive partnering activities

In line with the business strategy contained in the HOPE100–Stage 3– medium-term business plan, KYORIN Pharmaceutical Co., Ltd. expanded its development pipeline in September 2020 with the conclusion of an agreement with ASKA Pharmaceutical Co., Ltd. for the joint development and sales of the benign prostate treatment AKP-009, and in April 2021 completed an agreement with MSD K.K. for the exclusive distribution rights in Japan of Lyfnua. In regard to the licensing agreement concluded in January 2020 with aTyr Pharma, Inc. for KRP-R120, Phase 1 clinical trial in Japan has ended, and we are considering moving on toward development with the next phase of testing (multiregional clinical trials). We have also begun joint development with Lumen Bioscience, Inc. of the United States and CellGenTech, Inc. 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 Co., Ltd. is proactively engaged in out-licensing activities with global companies. In October 2020, we concluded an agreement for the transfer of intellectual property rights for the immunomodulator KRP-203 to the Irish company Priothera Limited, and in March 2021, a licensing agreement with Eisai for the development and sales in four ASEAN countries of the overactive bladder treatment Vibegron (sales name in Japan: Beova). The company also concluded a licensing agreement related to the new quinoline oral antibacterial agent Lascufloxacin (sales name in Japan: Lasvic) with the Chinese company Nanjing Neiwa Faith Co., Ltd. in March 2022, granting it exclusive development and commercialization rights in China.

Partnering with companies in Japan and overseas in Stage 3



New Ethical Drugs: Marketing

Morio Yanagishima
Executive Director, Sales & Marketing

The Kyorin Group's business strategies under the HOPE100–Stage 3– medium-term business plan include a shift to solution-based pharmaceutical marketing and the accelerated growth of the new drugs group. On the basis of these strategies, we are proactively pursuing our business activities. In terms of solution-based marketing activities that help resolve issues by addressing the needs and situations of medical practitioners and patients, we are working in particular to expand our product lineup from the standpoint of the prevention, diagnosis, and treatment of infectious disease and comprehensively providing information. Against the backdrop of the coronavirus pandemic, we are proactively using digital channels in addition to our core in-person meetings to realize two-way communication with medical practitioners.

During fiscal 2022, we launched Lyfnua in April and expect restricted shipments of Beova to end in August. By pursuing solution-based marketing and providing information through integrated digital channels, we aim to accelerate awareness of the new drugs group and achieve a growth trend.

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, Lagevrio) (solution-based approach)

Opportunities

- Expanded lineup of patented new drugs group (Flutiform, Desalex, Beova, Lasvic, Lyfnua, etc.)
- Increased testing demand in response to the COVID-19 pandemic
- Expectations for development of new testing methods through technological innovation
- Increased demand for high-quality products

Risks

- With increased restrictions on MR visits and use of appointment-only systems, difficulty in providing information to physicians and decrease in opportunities to meet with them
- With the drastic overhaul of the drug pricing system, decline in sales of long-listed products will accelerate
- Structural changes 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 as much as possible (Flutiform, Desalex, Beova, Lasvic, etc.)

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

Initiatives under the medium-term business plan

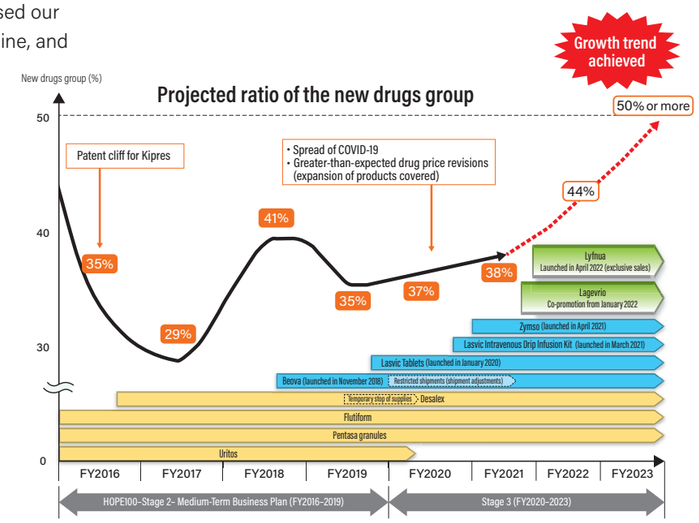
Promotion of solution-based marketing activities

Since fiscal 2020, we have been providing comprehensive information and carrying out solution-based marketing activities for infectious disease by introducing medical practitioners to Milton and Rubysta for prevention, GeneSoC for diagnosis, and Lasvic for treatment. We made efforts to provide a wider range of information during fiscal 2021 with the release of the GeneSoC mini genetic analysis device and the expansion of our infection-related product lineup including co-promotion with MSD K.K. of the new oral antiviral drug Lagevrio for the treatment of COVID-19. We will continue to work to make a uniquely Kyorin contribution going forward by providing information that offers solutions to the needs of medical practitioners and by promoting awareness of our products. In the respiratory field, one of our FC areas, we expanded our product lineup with the release in April 2022 of Lyfnua, the world's only selective P2X3 receptor antagonist for intractable chronic cough. For more details, please refer to "Topics: Shift to Business Based on the Proposal of Solutions" on pages 22-23.

Achieving a growth trend in the new drugs group

To achieve a growth trend, we consider it important to accelerate growth with an emphasis on the new drugs group to increase its ratio of net sales.

During fiscal 2021, the market for Flutiform contracted as a result of drug price revisions and the spread of competitor products, and sales declined from those of the previous year, to ¥12.6 billion, but the product's market share increased to 16%. Going forward, we will work to increase the volume of prescriptions by noting the usefulness of an aerosol formulation, with the aim of achieving a 30% share on a volume basis. For Desalex, we focused our activities on otolaryngology and internal medicine, and both sales and market share grew. Going forward, we aim for it to be the mostcommon prescription in otolaryngology, as a formulation that is both effective and easy to use. We have been restricting shipments of Beova because of a greater-than-anticipated increase in prescriptions. We sincerely apologize to medical practitioners for this inconvenience, are making every effort to increase production of stable supplies, and expect the restrictions to end in August 2022. Going forward, we aim to be able to supply three times the fiscal 2021 sales volume and are promoting the product to the greatest extent possible. Lasvic has seen significant results from the promotion of its appropriate use in terms of antimicrobial resistance (AMR) and the contraction of the antimicrobial market as thorough infection control measures have been strengthened. We expect the market to trend flat going forward but will continue to promote the product's special features for growth into the top-selling product in the oral antimicrobial market. We are also working to establish a position for Lyfnua and during fiscal 2022 will strive to promote understanding of the product's special features with an emphasis on respiratory specialists.



Establishing a presence in designated fields

Following an FC strategy that concentrates resources on designated fields centering on respiratory, otolaryngology, and urology, KYORIN Pharmaceutical Co., Ltd. aims to establish a presence in these fields with roughly 700 medical representatives (MRs) providing and collecting information on the appropriate use of pharmaceuticals and conveying that information to medical practitioners.

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

With the COVID-19 pandemic having partially restricted MRs' visits to medical facilities and in-person meetings with medical practitioners, we have made progress digitalizing our activities to provide pharmaceutical information. The Kyorin Group considers two-way communication with medical practitioners important for MRs to fulfill their original role: "To achieve appropriate use of pharmaceuticals and contribute to medical care by providing, collecting, and conveying pharmaceutical information," and we are working to complement and strengthen our marketing capabilities by integrating digital technologies into MRs' core in-person meetings. We will continue to make proactive use of digital tools, while also consolidating the market data amassed internally to analyze the needs of medical practitioners, to carry out high-quality activities for providing information.

Manufacturing

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

Having three plants as manufacturing centers gives the Kyorin Group unique capabilities for overall optimization of all manufactured products and appropriate capital investment, establishing a manufacturing structure that provides stable supplies of highly reliable products with an awareness of low-cost operations. During fiscal 2021, we discussed current issues in greater depth from various perspectives to maintain product quality through enhanced good manufacturing practices (GMPs), to continue to provide stable supplies through increased manufacturing capacity and to reduce costs by pursuing process improvements and the acquisition of technologies. As a result, our emphasis on quality and approach to legal compliance became instilled in manufacturing sites, and we also achieved a degree of success in terms of product supplies and cost reductions. At the same time, the need to further increase manufacturing capacity became evident, and in addition to adding equipment at existing facilities, we decided to construct a new plant. We will also continue working to increase manufacturing efficiency and reform work styles, directly leading to high-quality manufacturing activities. Going forward, we will further pursue these measures to provide stable supplies of high-quality products at a low cost, increase our subcontracted manufacturing from outside the Kyorin Group, and establish a competitive manufacturing structure.

Strengths

- Mass-production technologies through labor savings and automation
- Use of GMPs that conform to global standards
- Flexibility to manufacture a variety of products
- Manufacturing structure able to address diverse needs

Opportunities

- Growing need for subcontracted manufacturing for foreign companies entering the Japanese market
- Response to demand from growth of generic products
- Increased requests for supply of high-quality products

Risks

- Annual drug price revisions that translate to higher cost rates
- Higher raw material prices from higher crude oil prices and logistics costs
- Delays and suspension of manufacturing activities and raw material procurement due to pandemic, natural disasters, etc.

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 is building a manufacturing structure that will provide stable supplies of new drugs and generic drugs at a low cost, under a core strategy of “enhancing cost competitiveness.” We are creating a stable supply structure by incorporating acquired technologies that will improve our manufacturing activities, raising the level of our GMPs, strengthening manufacturing capabilities (capacity and efficiency), and using outside facilities.

Initiative to establish a new manufacturing center

To increase the Kyorin Group’s pharmaceutical production volume, it has become necessary to increase our product supply capacity, and we are therefore building the Takaoka Plant with an investment of approximately ¥10 billion. The new facility’s annual production capacity will be roughly 2 billion tablets (solid formulations taken internally), which is more than twice that of the Inami Plant. In addition to being a facility that will further raise the level of our GMPs, we believe the streamlining of various operations and higher manufacturing efficiency can realize stable supplies with low-cost manufacturing. Construction is scheduled to begin in September 2022 and end in October 2023, with the commencement of operations targeted for April 2024.

Initiatives to maintain quality

We are working to maintain quality through a variety of approaches, including cross-facility reciprocal audits of GMPs, the strengthening of data integrity (a framework to ensure data is complete, consistent, and accurate), regular training and testing of employees, and the use of video to teach standardized operations, as we make a maximum effort to provide products that earn the confidence of medical practitioners and patients.

Overview of Plant

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

Location: Noshiro, Akita

The Noshiro Plant consists of a pharmaceutical ingredient manufacturing plant for products developed by KYORIN Pharmaceutical Co., Ltd. and a formulation plant for ethical drugs. The formulation plant uses automated transport of pharmaceutical ingredients and intermediate products, and robotic arms for labor savings, automation that facilitates mass production with high productivity and low costs. 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.

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

Shiga Plant — Focusing on subcontracted manufacturing incorporating global GMPs

Location: Koka, Shiga

In addition to producing the Kyorin Group’s main products, the Shiga Plant, which was a manufacturing base for a foreign pharmaceutical manufacturer for many years, is unique for its high amount of manufacturing subcontracted from outside the Group, including pharmaceutical products to be sold in Japan by foreign pharmaceutical manufacturers. Since its establishment, the plant has used manufacturing equipment that incorporates global GMPs with an awareness of issues including the prevention of cross contamination. The introduction of this cutting-edge equipment enables manufacturing that keeps pace with the needs of the times. The plant is using its extensive experience and expertise in subcontracting from overseas global companies as it works proactively to increase manufacturing subcontracted from outside the Kyorin Group.

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

Location: Nanto, Toyama

The strength of the Inami Plant, which primarily manufactures generic drugs, lies in flexibility that makes it possible to manufacture drugs in a variety of forms, including solid formulations taken internally, and sterilized formulations for injections, eye drops, and nose drops. The plant currently manufactures more than 200 products, including those subcontracted from outside the Kyorin Group. Frequent visits from drug manufacturers ordering subcontracting give the plant a wealth of expertise in providing a stable supply of high-quality products. In response to the growth in demand for generic drugs in recent years, the plant is proactively investing in equipment, while also focusing on improving processes to raise productivity and enhance reliability even further.

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

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. Supply chain management includes the creation of supplier maps and checklists by region inside and outside Japan for all products to allow visualization of supply chains, from raw material procurement to manufacturing, warehousing, and shipment, as well as to shorten lead times from order to delivery, reduce supply risks, and maintain certain, stable supplies through the diversification of suppliers.

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 Kyorin Group, we are proactively engaged in the field of authorized generics as a new drug-related generics company. The recent emergence of quality issues at certain generic drug companies has led to uncertainties in supplies, bringing to light the issues of responsibility for quality assurance and stable supplies in the generic drug industry. At KYORIN Rimedio, we are continuously working to comply with relevant laws and regulations and bolster corporate governance, with the aim of further strengthening our quality control structure. Going forward, we will provide information as appropriate for the peace of mind of patients and medical practitioners, while diligently carrying out our mission of offering a stable supply of high-quality products.

Strengths	Opportunities	Risks
● Development, manufacturing, and sales functions all within the Kyorin Group ● Proactive pursuit of authorized generics as a new drug-related generics company	● Growing demand for generic drugs as population ages ● Patent expiries of major original drugs ● Increasing demand for high-quality products	● 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 2021, we launched five ingredients with nine products.

Address authorized generics

The Kyorin Group has achieved a certain degree of recognition in the market for its sales of 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 acquired 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 generic drugs' marketing structure more efficient, enhancing its sales capabilities and cost competitiveness through selection and concentration.

The Kyorin Group's Reliability Assurance System

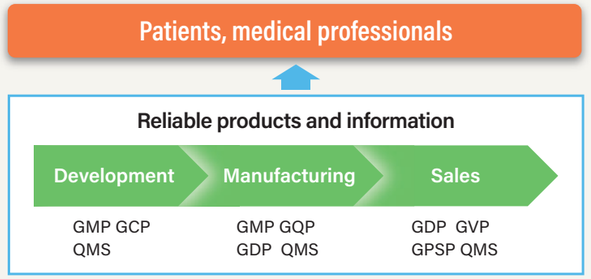
The pharmaceutical industry is being called on to further strengthen its legal compliance and quality control structures related to manufacturing and quality management, while also maintaining and strengthening stable supplies. The Kyorin Group believes that it is important to establish an ever-more 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 the Kyorin Group's 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

One aim under the long-term vision is to be "an innovative company that customers trust." 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, 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
QMS: Quality Management System

Quality assurance

The Kyorin Group has a quality policy for both ensuring product quality and providing stable supplies. We are strengthening operation of our manufacturing centers through management of quality risk based on scientific evidence.

For pharmaceuticals, we are building a structure to supply high-quality products based on GMPs with Kyorin Group plants and other facilities from the development stage, while also striving to ensure product quality and provide stable supplies by assuring quality through GQPs after sales. For extracorporeal diagnosis-use drugs and devices (diagnostics business), we are working to provide stable supplies of superior products through quality assurance using QMSs from the design and development stages through sales. In addition, after-sales inquiries regarding quality collected from patients and medical professionals are given the highest priority and 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 about benefits and risks after a product is launched, and to quickly provide appropriate information to medical facilities, with the balance taken into account. The Kyorin Group formulates risk management plans and collects and manages safety information on an individual product basis. We strive to ensure safety and promote proper use by carrying out drug-monitoring activities based on GVPs. Post-manufacturing surveillance is carried out adhering to GPSPs 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.

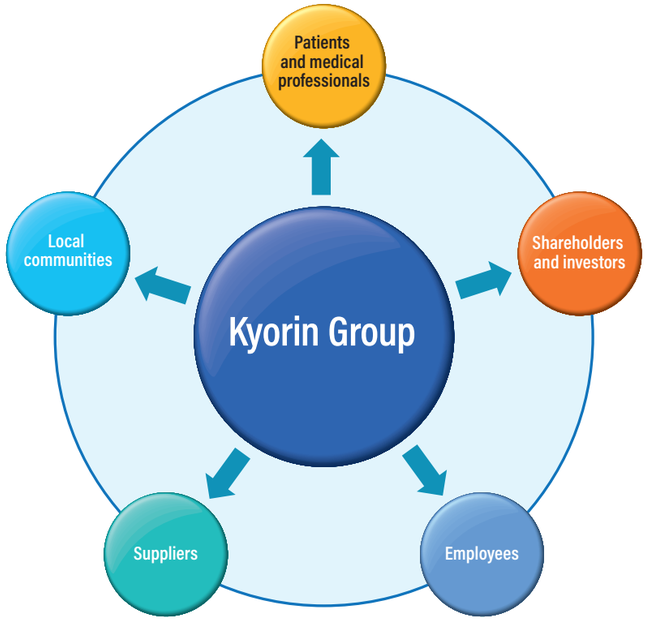
Addressing Sustainability Issues

Following our corporate philosophy, the Kyorin Group is proactively addressing sustainability issues. In accordance with our Corporate Charter, which was formulated based on our corporate philosophy and compliance—the source of all our business activities—we are fulfilling our social responsibility while also contributing to society's continuous development through corporate activities with ethical drugs as our core business. Going forward, we will continue to work to deepen dialogue with all the Group's stakeholders and gain their trust and understanding.

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

Relationships with 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.

Proactively addressing sustainability issues according to a basic policy

We believe that proactively addressing sustainability issues (for society's continuous development) through business activities based on our Corporate Charter will lead to the enhancement of the Kyorin Group's corporate value over the medium to long term. Our specific responses are activities derived from the UN Sustainable Development Goals (SDGs) from an environmental, social, and governance (ESG) perspective.

To achieve our long-term vision of becoming a company that supports sound and healthy lifestyles, we are fulfilling our social responsibility with the ethical drugs business as the Group's core business, respecting the human rights of people involved in all our businesses from research and development to manufacturing and sales, and providing product information, while complying with the Act on Pharmaceuticals and Medical Devices and other relevant laws and regulations, through fair and honest business activities. We are also working to create comfortable work environments for employees, strengthening measures to minimize the environmental impact of our business activities, and promoting harmonization with the environment and living in harmony with society. By developing and providing useful, safe products and services, we are fulfilling our social mission of contributing to people's health, while also acting as a good corporate citizen to help realize a vibrant society and economic development.

Sustainability issues and initiatives	SDGs
Sustainability in Business Activities ▸P. 36 The Kyorin Group sees contributing to society through our ethical drugs business as a way to fulfill our social responsibility. 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.	S Social
Respect for Human Rights and Human Resources Management ▸P. 38 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.	
Fair and Honest Business Activities ▸P. 42 The Group strives to prevent all forms of corruption by maintaining high ethical standards, conducting business lawfully and fairly, and 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.	
Living in Harmony with Society ▸P. 44 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.	
In Harmony with the Environment ▸P. 45 The Group works to protect the sustainable environment by preventing environmental pollution, reducing the environmental burden, and promoting measures to use resources more efficiently.	E Environmental
Corporate Governance ▸P. 47 To realize sustained increases in corporate value, the Kyorin Group has recognized the 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.	G Governance

Sustainability in Business Activities

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 and the appropriate use of drugs), KYORIN Pharmaceutical Co., Ltd., the core subsidiary of the Kyorin Group, is committed to respecting the human rights of all people and abiding by all relevant laws and regulations including the Act on Pharmaceuticals and Medical Devices.

Research (Drug discovery)

- Ethical considerations for human drug research
- Ethical considerations for the use of animals in trials
- Biotechnology and countermeasures against biohazards
- Use of genetic resources
- Handling of intellectual property

Clinical development

- Respect for subjects' human rights, security of personal information, and maintenance of trust during clinical trials
- Disclosure of information related to clinical trials and trial results
- Increased access to investigational new drugs

Technological development and manufacturing

- Quality management
- Quality assurance
- Stable supply
- Prevention of medical malpractice and improvement of drug discrimination
- Relations with local communities

Procurement (SCM)

- Initiatives to ensure sustainable procurement
- On-site supplier investigations

Provision of product information

- Promotion of the appropriate use of drugs
- Responding to drug inquiries
- Public website for medical professionals and patients

Initiatives for patients and medical professionals

- Providing information via Doctor Salon
- Providing information about disease
- Supporting the Department of Drug Discovery Medicine
- Supporting the Medical Education Project financially

Reliability assurance

- Compliance with all relevant laws and regulations and maintenance of trust
- Quality assurance
- Safety management

▶P. 33

Main initiatives (KYORIN Pharmaceutical Co., Ltd.) *Partial excerpts and descriptions

Research (Drug discovery)

▶Ethical considerations for human drug research

The company conducts research on humans, obtains human-derived test materials and information, and carries out research using those materials with the consent of participants through appropriate responses in accordance with the Declaration of Helsinki* and the relevant laws, regulations, and guidelines of each country. Researchers also undergo ethical education and training related to bioethics, genome research, and clinical research, and the company strives to respect the human rights and protect the personal information of the people who cooperate in this research. Also, in line with the Ethical Guidelines for Medical and Biological Research Involving Human Subjects, the company has created a research ethics investigation committee, which includes outside experts, to impartially and fairly inspect the ethicality and scientific validity of research plans.

*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 experiments

Animal experiments are essential in the research and development of drugs to promote human health. The company has an internal committee that inspects all experiments from the perspective of 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)—based on the Act on Welfare and Management of Animals (animal welfare legislation) and the "Basic Policies for the Conduct of Animal Experimentation in the Institutions under the Ministry of Health, Labour and Welfare" to ensure that animal experiments are carried out appropriately from a scientific perspective that considers the animals' welfare. Regular independent inspections are also done to confirm that the conditions related to the raising of laboratory animals and animal experiments are in regulatory compliance. Surveys are conducted and certification is obtained from the Japan Pharmaceutical Information Center's Center for Accreditation of Animal Experimentation Institutions, a third-party organization, based on guidance from the Ministry of Health, Labour and Welfare.

▶Handling of intellectual property

The protection of intellectual property is important for maintaining competitiveness while meeting unmet medical needs, and the company has formulated internal guidelines for handling intellectual property. In addition to the proactive protection of intellectual property in the main areas of research and development, any intellectual property right that is no longer of use is appropriately released, to focus investment on more effective intellectual property rights and build an intellectual property portfolio that contributes to business continuity. The company is also putting effort into intellectual property landscape activities based on an analysis of patent information, to share intellectual property information with research divisions and contribute to building a future research and development pipeline.

Clinical development

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

The company carries out clinical trials in line with the Declaration of Helsinki and relevant laws and regulations governing clinical trials of pharmaceuticals, including good clinical practice (GCP), with full consideration given to protecting the human rights and personal information of trial subjects, to confirm that candidate substances for new drugs are effective and safe. Its clinical trial plans are approved after inspection for ethicality and scientific validity by internal and external committees. Moreover, clinical trials are carried out after the subjects are fully informed about items including the objectives of clinical trials and their methods, anticipated merits and demerits, and compensation in the event of damage to their health. Confirmation that subjects understand the details and have given their consent to participate is required. In addition, employees involved in clinical trials receive education and training, and clinical trial institutions are monitored to ensure that the clinical trials are appropriately carried out in compliance with GCP. The company also strives to manage clinical trial data properly to ensure that the subjects' privacy is protected. In addition, it regularly confirms that clinical trials done externally are carried out in conformity with the same standards.

▶Disclosure of information related to clinical trials and trial results

The company is working to improve transparency by disclosing clinical trial plans and results. Plans for clinical trials led by the company are posted on a clinical trial database available to the general public. Going forward, the company will promote the creation of an environment for appropriate access to clinical trial data by researchers and others who might use that data, disclosing information to maximize the value of clinical trial data and playing a role in the advancement of science and promotion of innovation. Information disclosure methods are currently being reviewed, and the policy for the disclosure of clinical trial data will be released when it is finalized.

Technological development and manufacturing

▶Quality assurance

The company believes that it must continuously provide products and information widely trusted by society. That is its highest priority. The company is focused on centrally monitoring all operations related to reliability assurance, from development to sales, complying with relevant laws and regulations, and maximizing the continuation of trust. The Quality Assurance & Reliability HQs, which plays a central role in this effort, is independent from research and development, manufacturing, and sales divisions, and works to provide products and information that can be used by patients and medical professionals with peace of mind.

At the development stage, the quality of investigational new drugs is assured based on standards related to their manufacturing management and quality control (investigational new drug GMPs). After sales (after manufacture and sales), the company strives to ensure quality through compliance with standards to guarantee the excellence of products manufactured and sold (GQPs) including the confirmation that each product is produced with appropriate equipment according to a designated procedure manual. Quality inquiries from patients and medical professionals after sales are acknowledged and answered sincerely and swiftly.

▶Stable supply

With the increase in global products and diversification of modalities, supply chains are becoming increasingly complex. Given these changes, the company has built a structure for stable supplies that makes it possible to visualize and centrally manage demand forecasts, inventory information, and supply plans for all regions around the world. This structure enables global management from the manufacture of pharmaceutical ingredients to the supplying of products.

The pharmaceutical supply chain, which encompasses a wide variety of items including raw materials, intermediates, and pharmaceutical ingredients, is supported by numerous suppliers in Japan and overseas. To continue to provide stable supplies without interruption in the procurement chain, the company considers it imperative to strengthen relationships with individual suppliers by working closely together and sharing information. As another risk hedge, it is striving to secure multiple alternative suppliers in addition to existing suppliers and various types of alternative transport routes. Stable supplies are also being strengthened with the promotion of compliance in logistics, including imports and exports.

To achieve even more stable supplies, appropriate warehousing standards and procurement plans are formulated for individual products. For products that fluctuate because of seasonal factors or sudden popularity, the company strives to carry out flexible procurement while monitoring changes daily in close cooperation with internal marketing divisions.

Procurement (SCM)

▶Initiatives to ensure sustainable procurement

The company considers it important to fulfill its social responsibility by striving to provide stable supplies of products through optimal supply chain management and asks suppliers for cooperation based on their own social responsibility. The company carries out sustainable procurement with a strong sense of ethics, in compliance with both the letter and the spirit of laws, regulations, and international rules in Japan and overseas, while promoting environmental awareness including reducing the use of chemical substances and waste.

▶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. We regularly visit suppliers with whom we have business relationships to continuously maintain and enhance product quality and stable supplies. We also carry out risk evaluations in areas like work environments (including measures to prevent employees from being exposed to chemical substances), measures to reduce waste, and measures to lessen the environmental impact of wastewater and exhaust emissions from manufacturing activities. When on-site investigations identify items needing correction, we propose improvements, request an improvement plan, and follow up on the improvement status.

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. In those cases, 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. We also collect information from medical facilities that use our proprietary products about the products' effectiveness and safety, and pass on the results of the analysis and evaluation of that information to medical professionals. Given the company's MRs' mission of contributing to better health, MRs act with a strong sense of ethics and work in strict compliance with relevant laws and regulations, guidelines, industry rules, and internal guidelines, including KYORIN Pharmaceutical Co., Ltd.'s Corporate Charter.

▶Responding to drug inquiries

The company feels a responsibility to provide highly reliable drug information that is both fair and impartial in response to inquiries from patients and medical professionals. By fulfilling this responsibility, the company promotes the appropriate use of products that are safe and effective. With this understanding, it established the Drug Information Center to answer various inquiries, roughly 24,000 during fiscal 2021.

The company also aims to provide consistent, appropriate, and accurate information in reply to inquiries about pharmaceutical information and is continuously working to improve its responses. These efforts allow the company to answer inquiries concisely, swiftly, and accurately, and are also useful for analyzing the needs of patients and medical professionals and managing product life cycles. The company uses a global medical information system to provide high-quality responses to inquiries from patients and medical professionals.

Respect for Human Rights and Human Resources Management

Message from executive in charge

Under our HOPE100 long-term vision, the Kyorin Group, aiming to be "a company that supports sound and healthy lifestyles," has designated a specific overall vision toward which the Group aspires named the Five HOPEs, whose central element is to be "the leading company for career fulfillment." We are creating work environments and systems that are both physically and mentally beneficial for all employees, allowing them to display their talents to the fullest, with the aim of being a company in which employees have pride, confidence, and solidarity. Another of the Five HOPEs is to be "a company that seeks to co-exist with society," meaning that we will operate in compliance with laws, regulations, and standards, showing a strong sense of ethics and responsibility, while working proactively to contribute to society and address sustainability issues including global environmental problems.

Yasuyuki Shimokawa
Corporate Officer, Director of General Affairs & Human Resources Department, in charge of Promotion Compliance & External Relations

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 those ends, 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 strategy to become "the leading company for career fulfillment"

The Kyorin 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 co-workers. 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 co-workers for the success of the organization.

Company

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

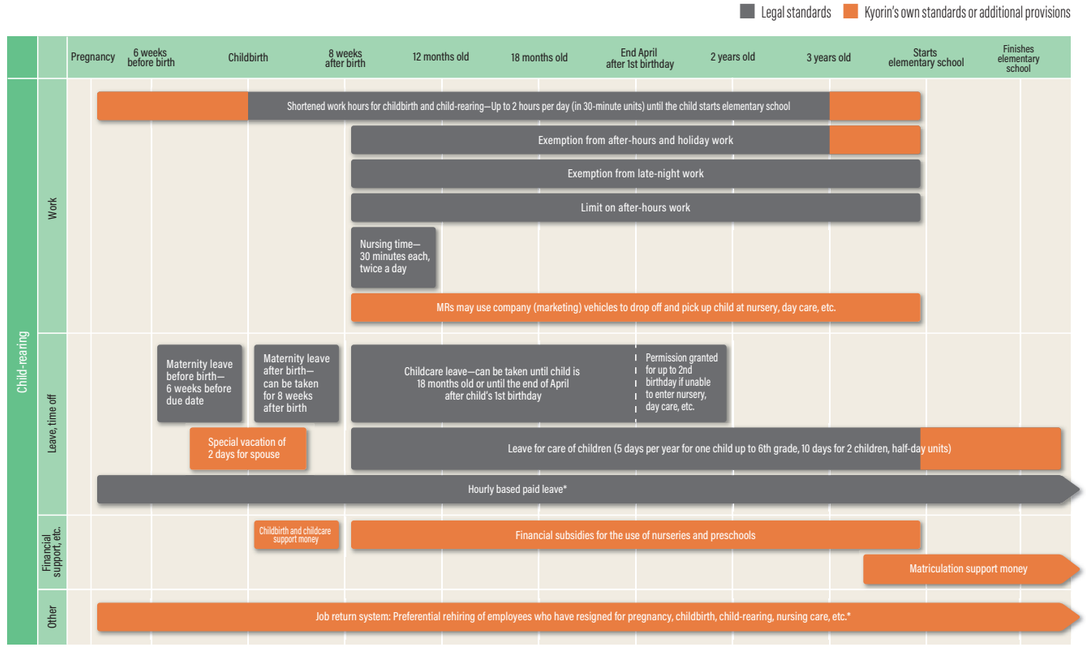
- Each employee is assigned duties that conform to abilities and work style.
- Each employee's contribution is comprehensively understood, and employees are evaluated and treated fairly and consistently.
- The Company provides a comfortable and rewarding work environment that fosters a "desire to work"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

Support for work-style reforms

Given changes within and outside the Kyorin Group, the Group is promoting autonomous and flexible work styles to invigorate employees and organizations, with the aim of continuously enhancing corporate value. 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 times they need to provide childcare or nursing care, to create environments that make it easier to balance work lives and family lives, while also striving to maintain an environment where employees, backed by a healthy home life, can feel fulfilled in their work. In recognition of these efforts, in 2021, KYORIN Pharmaceutical Co., Ltd. received Kurumin Certification as a "company that supports child rearing" under the Act on Advancement of Measures to Support Raising Next-Generation Children. During fiscal 2021, the rate of eligible employees taking childcare leave was 100% for women and 5.9% for men.



*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

Promoting the use of paid leave

The Kyorin Group proactively encourages the taking of paid leave, going beyond 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 regularly promote taking vacation and consecutive days off to enable employees to maintain a good work-life balance to maximize their capabilities. KYORIN Pharmaceutical Co., Ltd. promotes taking three additional days of leave. The paid-leave usage rate at the Group in fiscal 2021 was 66.8%.

● 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.

● Promoting active participation by women

In line with the Act on the Promotion of Female Participation and Career Advancement in the Workplace, the Kyorin Group is creating work environments that allow female employees to demonstrate their talents and use them to the fullest. As of the end of fiscal 2021, the rate of female management positions was 7.6% (with the fiscal 2030 target set at 15%).

● 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 rate of full-time employees who were mid-career hires was 61.9% in fiscal 2019, 57.6% in fiscal 2020, and 20.7% in fiscal 2021.

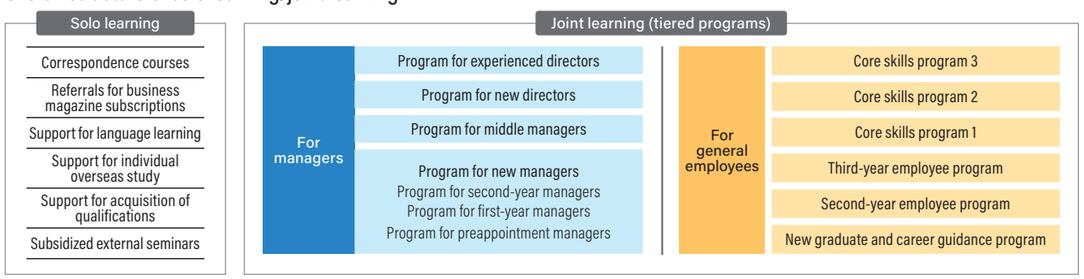
● Initiatives on disability hiring

As one 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 by using apps for employees with impaired hearing. The hiring rate of persons with disabilities at KYORIN Pharmaceutical Co., Ltd. was 2.36% in fiscal 2021, which exceeds the legally mandated percentage.

● 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. Expenditures for employee training during fiscal 2021 were ¥46,000 per employee.

Overall structure of solo learning/joint learning



● Mental health

The Kyorin Group provides mental health education for 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. The rate of employees taking leave for mental health during fiscal 2021 was 0.6% and the rate of those who returned to work was 33.3%.

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—

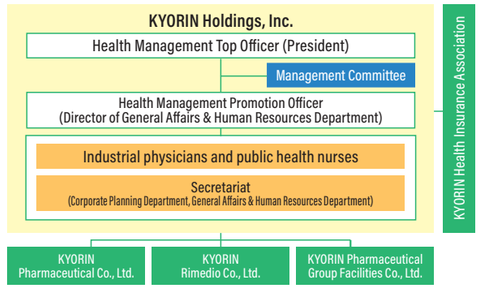
As a company that supports sound and healthy lifestyles, the Kyorin Group views the health of its employees as a vital management issue, and is committed as an organization to promoting the health management of each and every employee.

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 director 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 to 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.

In acknowledgment of these activities, the Company has been recognized as one of the "Certified Health & Productivity Management Outstanding Organizations (large corporate sector)" for the four consecutive years since 2019.

2022 健康経営優良法人 Health and productivity

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 the support of employees returning to work and the prevention of 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*2 results (reference year)	2020*2 results	2021 results	2023 targets
Percentage of employees who do not smoke	80.6%	81.3%	82.3%	85%
Percentage of employees who drink appropriate amounts of alcohol*1	73.4%	74.6%	73.6%	80%

	2019*2 results (reference year)	2020*2 results	2021 results	2023 targets
Percentage of employees who walk or engage in equivalent physical activities for one hour or more per day	45.0%	44.8%	44.0%	55%
Percentage of employees who get sufficient sleep	64.8%	72.8%	69.1%	75%

* 1 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
* 2 Figures announced last year (results for fiscal 2019 and fiscal 2020) have been revised to reflect changes in calculation methods.

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 has a Compliance Committee and a Risk Management Committee, which adopt various measures to publicize and promote compliance and risk management.

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 offcers, 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. There were 13 reports during fiscal 2021.

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 superior 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 disclose information about funding to medical institutions, patient groups, and others on our website.

Risk management

The Kyorin 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 operates its businesses in compliance with the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices and other laws and regulations of Japan covering areas including pharmaceutical development, manufacturing, and sales, as well as the various regulations of other countries. Nevertheless, we are aware of the risk of a substantial impact on our operating results and financial position from factors including major revisions to relevant laws and regulations, medical system reforms, drastic changes in market conditions, and large-scale natural disasters. The Group is committed to addressing these risks in an organized and systematic manner, but the risks and uncertainties that could 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 dispute arising from infringement on intellectual property rights by third parties or the Group's infringement on intellectual property rights of other companies	● 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 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 large-scale disasters, etc. ● Natural disasters, accidents, and pandemics such as influenza and novel coronavirus disease ● 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 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 ● Introduction of environmental taxes, changes in procurement or operating costs, etc., associated with transition to a decarbonized society	● 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 environmental, health, and safety (EHS) activities throughout the Group ● Business activities that take into consideration environmental effects, including the reduction of environmentally harmful materials
Risks related to fluctuations in financial markets ● Fluctuations in foreign exchange rates, interest rate levels, and stock market conditions	● Diversified investments, etc.

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

● Classroom visits

One activity that embodies the Kyorin Group's corporate philosophy and contributes to society is to visit elementary and junior high school classrooms nationwide, which we have done since fiscal 2017, to teach and demonstrate to the children representing the next generation the correct ways of taking medicine and washing their hands. In response to the COVID-19 pandemic, online classroom visits were added in fiscal 2021.

● Work experience programs

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

● 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/

● 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 with the aim of providing local children an opportunity to think about and experience their own health management and improve their skills.

● 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
Cleanup activities around Nakashima Park at Noshiro Port
Inami Plant: Cleanup activities at Zuisenji Temple
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 August 2021: Environmental hygiene supplies (Rubysta, etc.), hand sanitizer (Noahtect), 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.

In Harmony with the Environment

Basic stance

The Kyorin Group's Charter of Corporate Conduct details the Kyorin 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." The Group always conducts its business operations with due regard for their impact on the global environment and local communities, through measures to address climate change and EHS and other activities.

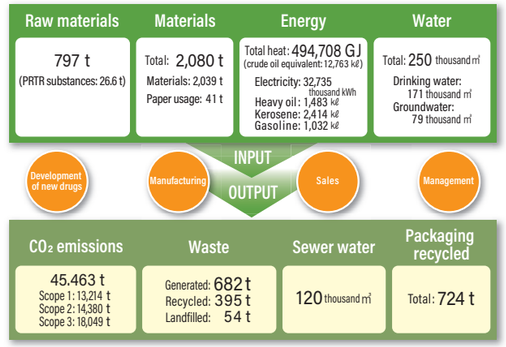
In all business operations, the Group promotes the effective use of the world's limited resources through energy and resource conservation, waste reduction, and decreased use of environmentally harmful materials by such means as enhanced chemical substance management. We have established objectives and targets for these initiatives, review them as necessary, and remain voluntarily and proactively committed to protecting the environment and preventing pollution.

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 promote effective use of limited resources. 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 2021, our CO_2 emissions were 25,256 tons, and we are steadily approaching our target.

KYORIN Group material flow (fiscal 2021)



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 2022, all 889 vehicles used by the sales force met the standard for having low emission, and of these, 434 (approximately 49%) 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 head office and R&D center

The head office (Ochanomizu sola city) has reduced its CO_2 emissions with the change in September 2021 to renewable energy sources for all its electric power consumption.

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 2021, this system reduced electric power consumption 78,557 kWh and CO_2 emissions roughly 35 tons compared with conventional heat pumps for air conditioning and heating, for approximately 33% 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.

Disclosure of climate change-related information

Among the various issues related to sustainability, the Kyorin Group has designated "environmentally friendly business activities" as one of materiality and is working to preserve the environment through measures including addressing climate change. The Group also evaluates climate change risks and earnings opportunities by referencing the Task Force on Climate-related Financial Disclosures (TCFD) framework and addresses them while pursuing expanded disclosure, based on TCFD recommendations, of the effect of climate change on our businesses.

● Analysis of risks and earnings opportunities related to climate change

The effects on the Kyorin Group's businesses and management from global warming and climate change themselves, as well as changes to the business environment from long-term policy direction related to climate change, are broken down as physical risks and earnings opportunities caused by the transition risks to a decarbonized society and climate change. Those risks and opportunities were the subjects of a scenario analysis carried out with reference to documents and materials including the Intergovernmental Panel on Climate Change's (IPCC) Fifth Assessment Report's RCP2.6 (2℃ scenario) and RCP8.5 (4℃ scenario).

2℃ Scenario **Transition Risks**

Segment	Event	Risks	Response policy
Policies, laws and regulations	Introduction of an environmental (carbon) tax	• The introduction of an environmental (carbon) tax on greenhouse gas emissions related to research, manufacturing, and marketing could increase costs.	• Further promote activities to reduce CO_2 emissions • Consider transition to electric power generated from renewable energy sources • Consider reduction in number of vehicles for sales force and replacement with hybrid vehicles and electric vehicles • Efficiently use the EHS management system
	Installation of equipment and machinery	• The replacement of existing equipment with new models that can operate with renewable energy as a result of newly enacted laws and regulations could increase costs.	• Systematically upgrade equipment to energy-saving models and machinery
Market	Changes in procurement/ operational costs	• Increasing the percentage of electric power generated from renewable energy sources could raise the cost of electric power procurement. • Responses to transition risks by suppliers and logistics subcontractors could increase manufacturing and logistics costs.	• Secure electric power generated from renewable energy sources • Install highly efficient machinery • Cooperate with suppliers, logistics subcontractors, and others to reduce logistics costs
Evaluation	Assessment from investors	• Delays in the Company's introduction of climate change countermeasures could erode investor confidence and negatively affect the share price. Insufficient information disclosure could also cause the share price to fall.	• Disclose timely and appropriate information including status of climate change countermeasures • Participate in external surveys

4℃ Scenario **Physical Risks**

Segment	Event	Risks	Response policy
Acute risk	Direct damage from unusual weather (typhoons, heavy rains, etc.)	• Localized heavy rains, large typhoons, etc., could cause flooding, halt operations, and necessitate repair expenses at research, manufacturing, and logistics centers. In addition to Group facilities, supply chain disruptions (affecting materials procurement and shipment logistics) could occur.	• Consider and implement equipment plans that envision water damage, etc. • Carry out drills that envision emergencies • Appropriately manage inventories • Secure multiple suppliers of materials
Chronic risk	Changes in location of centers, procurement, and operations from changes in climate patterns, higher temperatures, sea levels, etc.	• Several research and manufacturing centers are located near rivers, and sea levels are rising due to higher temperatures. Flood susceptibility countermeasures in response to changes in climate patterns and reviews of locations could increase costs. • Responses to transition risks by suppliers and logistics subcontractors could lead to higher market prices and increase manufacturing and logistics costs. • Air-conditioning temperature management in manufacturing, warehousing, and logistics in response to higher temperatures could increase costs.	• Consider and implement equipment plans that envision water damage, etc. • Appropriately manage inventories • Consider optimizing locations from a business continuity planning (BCP) perspective • Secure multiple suppliers of materials • Improve energy efficiency

4℃ Scenario **Earnings Opportunities**

Segment	Event	Earnings opportunity	Response policy
Market changes	Changes in disease trends	• Increases in infectious disease from rising temperatures could increase the Company's business opportunities. Demand and scope of appropriate use of our products for the diagnosis, prevention, and treatment of infectious disease could increase and expand.	• Shift to business based on the proposal of solutions • Establish presence in franchise customer fields • Proactively invest in pipeline expansion

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 as an important management issue.

Basic policy on corporate governance

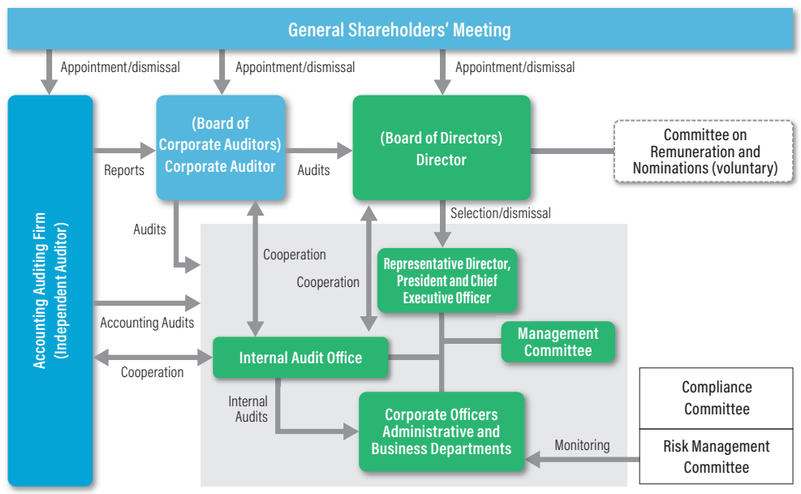
The most important management goal for KYORIN Holdings, Inc. is to continue raising shareholder value. To achieve this goal requires fostering a management environment that enables us to build trust with the general public. Therefore, having given better corporate governance a high priority, we seek 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 Holdings, Inc. 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 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 structure (As of June 30, 2022)



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, Morio Yanagishima
Outside Directors: Noriyuki Shikanai, Ken Shigematsu, Hiromi Watanabe

● Business execution system (Management Committee)

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, Morio Yanagishima

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 24, 2022, the Company had four corporate officers.

● Board of Corporate Auditors

Following the Companies Act of Japan, KYORIN Holdings, Inc. 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 outside corporate auditors exercise authority for audits, etc., from an independent and objective standpoint.

Chairperson: Tomiharu Matsumoto, Senior Corporate Auditor
Senior Corporate Auditor: Kenji Akutsu
Outside Corporate Auditors: Takao Yamaguchi, Yukio Ikemura, Kensuke Morita

● Committee on Remuneration and Nominations

For the remuneration and nomination of directors and corporate auditors (including succession planning), KYORIN Holdings, Inc. has established a Committee on Remuneration and Nominations (voluntary), the majority of whose members are independent outside directors detached from management, thereby maintaining independence and objectivity from the functions of the Board of Directors regarding remuneration and nominations.

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 2021) (Average attendance rate of outside directors) (Average attendance rate of outside corporate auditors)	12 times (100%) (94.4%)
Number of the Board of Corporate Auditors' meetings (held during fiscal 2021) (Average attendance rate of outside corporate auditors)	12 times (94.4%)
Term of office of directors	1 year
Adoption of the corporate officer system	Yes
Voluntary Committee of the Board of Directors	Committee on Remuneration and Nominations
Accounting auditing firm	Ernst & Young ShinNihon LLC

Outside directors and outside corporate auditors

KYORIN Holdings, Inc. 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.

Takao Yamaguchi has considerable knowledge of finance and accounting as a certified public accountant and a certified tax accountant.

Yukio Ikemura has considerable knowledge of corporate management gained from his many years of experience as an officer and employee in various industries.

Kensuke Morita is well versed in corporate legal affairs as an attorney, and as a university professor he also has considerable knowledge of business science.

KYORIN Holdings, Inc. selects outside directors and outside corporate auditors after reviewing the individuals' backgrounds and relationships with KYORIN Holdings, Inc., 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 of independence criteria stipulated by the Company and have been reported as independent officers to the Tokyo Stock Exchange.

Compensation of directors and corporate auditors

The Kyorin Group's basic policy is to provide compensation that contributes to the enhancement of the Kyorin 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)	181	181	—	7
Corporate auditors (Excluding outside corporate auditors)	33	33	—	2
Outside directors or 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 internal 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 Kyorin 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 each department, office, and Group company.

To ensure that audits are conducted effectively, the Company's accounting auditing firm explains the content of the accounting audits to the corporate auditors, exchanges information with them, and also cooperates with the Internal Audit Office to ensure appropriate communication and effective performance of audits.

Under our adopted system, if executives or regular employees discover that an executive officer or employee is acting in contravention of laws, 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.

Messages from Outside Directors

As an outside director, I supervise the Company's governance and management from the perspective of shareholders and from the viewpoint of compliance, and also offer opinions to enhance the Company's corporate value as a socially responsible entity, through initiatives such as the SDGs. As an attorney, I provide advice and recommendations from an objective standpoint to various companies, and I actively offer my advice and suggestions on the management of the Company, while referring to how companies in other industries are managed.

Noriyuki Shikanai
Outside Director/Independent Officer

On the 100th anniversary of the Company's founding in 2023, we will establish a new Group management structure and begin anew, with a view toward the next medium-term business plan. This year will be an important time of preparation for that purpose, and the Board of Directors will deepen discussions about the future direction of the Company. I will continue to make necessary suggestions by drawing on my past management experience and knowledge to establish unique businesses that contribute to society, while improving our corporate value by remaining fully aware of sustainability, maintaining the trust of our stakeholders, and meeting their expectations.

Ken Shigematsu
Outside Director/Independent Officer

I have been an outside director at the Company for three years. Although this is a different world from the medical and educational fields where I have worked in my career, I find similarities in the Group's business, in that we support people's desire to live the way they feel they should live, be who they want to be, and remain healthy. In many respects, the world has been undergoing a major transition over the past several years. Thinking of the next 100 sustainable years, I intend to make suggestions in light of current circumstances in the medical field and actively support the development of human resources to ensure diversity, especially the development of female employees who boldly take on challenges.

Hiromi Watanabe
Outside Director/Independent Officer

Messages from New Outside Corporate Auditors

My name is Yukio Ikemura. I was elected as an outside corporate auditor at the annual general shareholders' meeting in June 2022.

People often say that "common sense at a company is not common in the world." When you have worked for the same company for a long time, you become accustomed to the company's way of doing things and no longer have any misgivings. This is not necessarily a bad thing. However, while companies may sometimes have a good culture, sometimes changes are necessary.

Having worked in completely different industries (including banking, manufacturing, and real estate management companies), I believe that what is required of me is to perform audit work properly from such an external perspective and to express my opinions as necessary. I will do my best to make a contribution, and I look forward to working with everyone at the Company.

Yukio Ikemura
Outside Corporate Auditor/Independent Officer

My name is Kensuke Morita. I was elected as an outside corporate auditor at the annual general shareholders' meeting in June 2022.

Following the Company's corporate philosophy of "Kyorin continues to fulfill its mission of cherishing life and benefiting society by contributing to better health," the Company has been in the pharmaceutical business for 100 years, and its purpose and mission will not fade as we move into the future. I take very seriously our history and tradition, as well as the fruits of our predecessors' unrelenting efforts, and I am deeply humbled by the need to live up to the expectations of the Company's current and future stakeholders. I will conclude my remarks by assuring you that I will utilize the wisdom and experience gained through more than 30 years as an attorney and 10 years in university education to faithfully conduct audits on fraudulent and illegal activities.

Kensuke Morita
Outside Corporate Auditor/Independent Officer

Skills matrix of the Company's directors and corporate auditors

The Company's Board of Directors consists of diverse individuals with various skills (knowledge, experience, etc.) to ensure that the Board of Directors appropriately performs its decision-making and management supervision functions and maintains a more transparent governance structure in accordance with the Company's medium- to long-term management direction and business strategy. The skills possessed by individual directors and corporate auditors are as follows.

	Name	Attributes	Corporate management	Healthcare business	Finance & accounting	Legal	Academic experts	Major qualifications, etc.
Directors	Minoru Hogawa		○	○	○			
	Yutaka Ogihara		○	○				
	Shigeru Ogihara		○	○				Pharmacist
	Michiro Onota		○	○				
	Koichiro Hagihara			○		○		
	Morio Yanagishima			○				
	Noriyuki Shikanai	Outside Independent				○		Attorney
	Ken Shigematsu	Outside Independent	○					
	Hiromi Watanabe	Outside Independent		○			○	Medical Doctor
Corporate auditors	Tomiharu Matsumoto			○		○		
	Kenji Akutsu		○	○				
	Takao Yamaguchi	Outside Independent			○			Certified Public Accountant
	Yukio Ikemura	Outside Independent	○					
	Kensuke Morita	Outside Independent				○	○	Attorney

Ten-Year Consolidated Financial Highlights (Fiscal years ended March 31/As of March 31)

Millions of yen

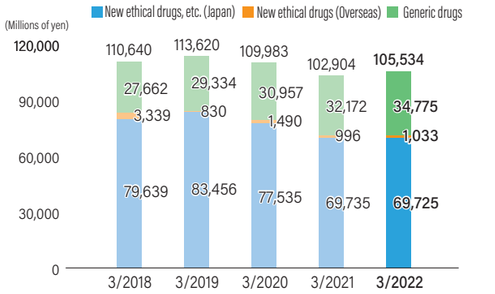
	3/2013	3/2014	3/2015	3/2016	3/2017	3/2018*2	3/2019	3/2020	3/2021	3/2022*3
Net sales	107,031	111,400	113,121	119,483	115,373	110,640	113,620	109,983	102,904	**105,534**
New ethical drugs, etc. (Japan)*1	94,535	97,562	96,612	98,430	89,584	79,639	83,456	77,535	69,735	**69,725**
New ethical drugs (Overseas)	2,400	1,849	1,032	5,586	764	3,339	830	1,490	996	**1,033**
Generic drugs	10,095	11,987	15,477	15,465	25,024	27,662	29,334	30,957	32,172	**34,775**
Operating profit	17,948	17,607	14,737	19,636	10,413	8,822	8,972	7,503	5,786	**5,007**
Profit attributable to shareholders of KYORIN Holdings, Inc.	12,422	12,025	12,064	13,639	7,305	6,574	6,869	6,149	6,130	**3,932**
Net cash provided by operating activities	11,544	19,293	6,391	11,137	16,386	10,456	340	7,739	5,189	**6,346**
Net cash provided by (used in) investing activities	(7,187)	(2,477)	(1,364)	650	(13,142)	(6,038)	14,939	(2,943)	(4,259)	**(2,560)**
Net cash used in financing activities	(5,132)	(3,704)	(5,233)	(2,245)	(5,721)	(3,735)	(27,315)	(5,117)	(4,918)	**(4,112)**
Free cash flow	4,357	16,816	5,027	11,787	3,244	4,418	15,279	4,796	930	**3,786**
R&D expenses	11,059	11,359	13,514	13,019	13,569	14,243	10,790	10,987	9,703	**8,897**
Capital expenditures	6,576	6,500	2,655	7,218	3,051	2,885	2,306	3,590	4,307	**3,624**
Depreciation and amortization	2,738	3,153	3,053	3,730	3,619	3,644	2,940	3,221	3,564	**3,714**
Total assets	154,968	169,378	183,383	197,825	192,668	196,736	173,034	171,160	167,126	**171,924**
Total net assets	129,099	137,821	148,600	157,049	157,837	163,297	123,395	122,710	124,661	**124,507**
Per Share Information										
Net assets (Yen)	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	**2,172.83**
Basic profit (Yen)	166.25	160.95	161.63	184.28	99.45	89.28	104.68	107.35	106.99	**68.62**
Cash dividends (Yen)	50.00	52.00	52.00	58.00	58.00	58.00	75.00	75.00	75.00	**52.00**
Key Performance Indicators										
Operating profit margin (%)	16.8	15.8	13.0	16.4	9.0	8.0	7.9	6.8	5.6	**4.7**
Profit attributable to shareholders of KYORIN Holdings, Inc. / Net sales ratio (%)	11.6	10.8	10.7	11.4	6.3	5.9	6.0	5.6	6.0	**3.7**
R&D expenses / Net sales ratio (%)	10.3	10.2	11.9	10.9	11.8	12.9	9.5	10.0	9.4	**8.4**
Total shareholders' equity ratio (%)	83.3	81.4	81.0	79.4	81.9	83.0	71.3	71.7	74.6	**72.4**
ROE (%)	10.0	9.0	8.4	8.9	4.6	4.1	4.8	5.0	5.0	**3.2**
Consolidated payout ratio (%)	30.1	32.3	32.2	31.8	59.3	65.9	72.6	70.9	71.1	**76.9**
PER (times)	13.82	12.25	17.78	11.63	23.64	22.39	20.64	20.48	18.02	**25.90**
Non-Financial Information										
Number of employees	2,444	2,452	2,445	2,420	2,382	2,348	2,297	2,271	2,243	**2,222**

*1 From the beginning of 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.
*3 From the beginning of fiscal 2021, the "Accounting Standards for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020), etc., have been applied.

Performance Highlights

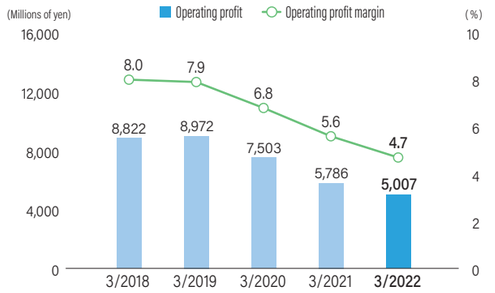
Financial Information

Net sales



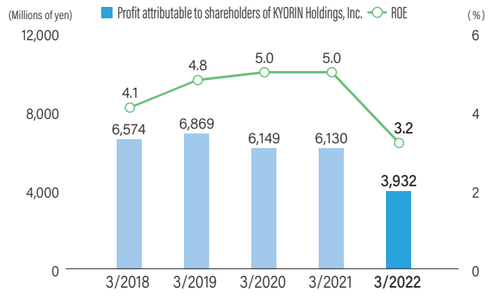
Although affected by factors such as drug price revisions and the COVID-19 pandemic, sales of our new drugs and some long-listed products grew, while results for new ethical drugs, etc., (Japan) were flat. Sales of generic drugs increased, and overall sales topped those of the previous year, to ¥105,534 million.

Operating profit/Operating profit margin



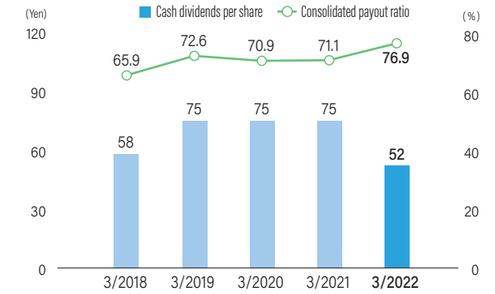
Despite the increase in net sales, operating profit decreased ¥778 million year on year, and the operating profit margin was 4.7%, due to an increase in the cost of sales ratio and a decrease in gross profit as a result of drug price revisions and an increase in the percentage of generic drugs sold.

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



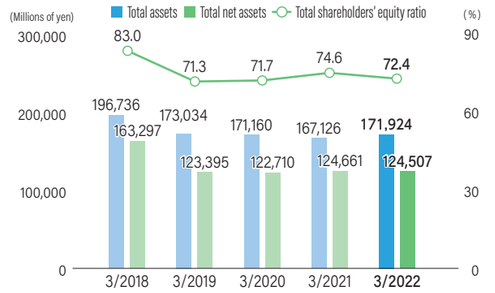
Profit decreased and ROE declined compared to figures for the previous fiscal year. Going forward, we will accelerate the growth of new drugs in order to increase profit and improve ROE. During fiscal 2018 (ended March 31, 2019), we purchased ¥40.8 billion in treasury shares.

Cash dividends per share/Consolidated payout ratio



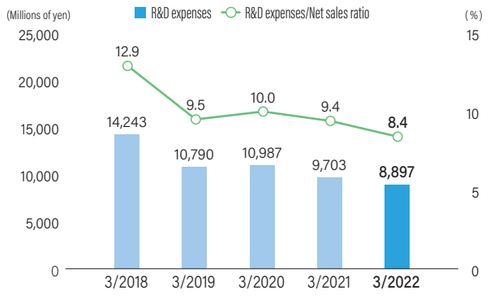
Regarding returns to shareholders, we aim to pay stable dividends based on DOE from fiscal 2018 (ended March 31, 2019). From fiscal 2021 (ended March 31, 2022), we have lowered the level of DOE and set the annual dividend at ¥52 (including a year-end dividend of ¥32), taking into account changes in the business environment and the growing demand for funds for growth investment.

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



Total assets increased ¥4,797 million compared to those at the end of the previous fiscal year. Total net assets decreased ¥154 million, due to a decline in valuation difference on available-for-sale securities, despite an increase in retained earnings. As a result, the total shareholders' equity ratio decreased 2.2 percentage points year on year, to 72.4%.

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

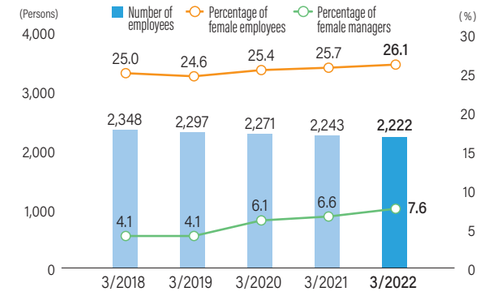


Research and development expenses decreased ¥805 million from those of the previous fiscal year. The expense level for research and development changes depending on factors such as the progress of the development stage (phase of clinical trial). We will continue to invest a certain amount in research and development, enhance our development pipeline, and create new drugs to improve long-term corporate value.

Non-Financial Information

Human Resources

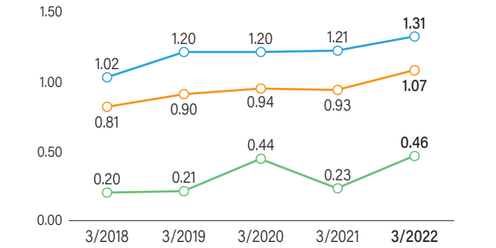
Number of employees/Percentage of female employees/ Percentage of female managers



In fiscal 2021 (ended March 31, 2022), we had 2,222 employees, 26.1% of them women and 7.6% of them female managers.

Rate of work accidents

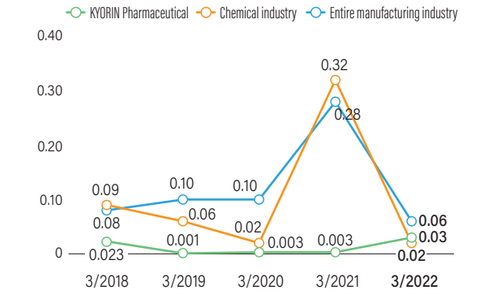
Frequency of accidents: Number of deaths and injuries due to work accidents (excluding accidents while commuting)/Total work hours x 1,000,000



To improve the levels of health and safety, we are working to achieve zero work accidents, promote employee health, and create comfortable work environments. The rate of work accidents, which represents the frequency of occupational accidents, is below the level of the entire manufacturing industry and that of the chemical industry.

Severity of work accidents

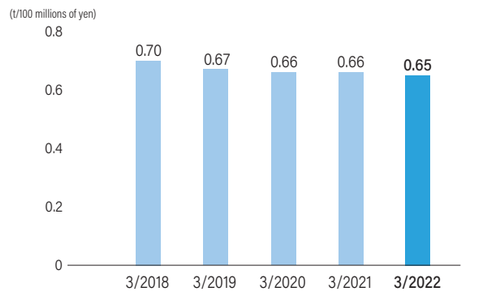
Magnitude of accidents: Number of lost work days (excluding accidents while commuting)/Total work hours x 1,000



Due to measures to prevent work accidents, the severity rate, which expresses the degree of severity of work accidents, is below the level of the entire manufacturing industry.

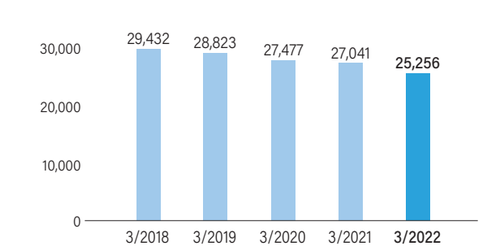
Environment

Waste volume in relation to sales



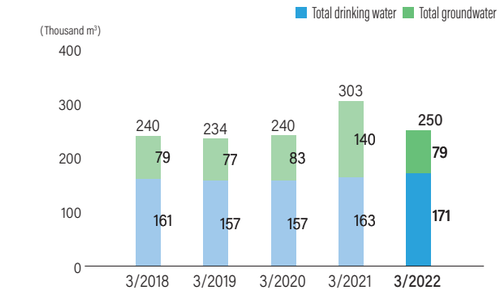
We are promoting the 3Rs of reducing, reusing, and recycling waste, as part of efforts to realize a recycling-oriented society.

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



With regard to CO_2 emissions, we have set a target of reducing our CO_2 emissions by 6% by fiscal 2023 (an annual average reduction of 1.5% or more) and are engaged in various measures to that end. In comparison to the 27,477 tons of CO_2 emissions in fiscal 2019, we had CO_2 emissions of 25,256 tons in fiscal 2021 and 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. Note that our use of groundwater rose in fiscal 2020 due to changes in water quality in the areas around our plants.

Directors, Corporate Auditors, and Corporate Officers (As of June 24, 2022)

Executive Directors

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

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

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,
in charge of Quality Assurance & Reliability
President and Chief Executive Officer of KYORIN Pharmaceutical Group Facilities Co., Ltd.

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,
in charge of Intellectual Property,
Legal, and 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.
April 2021 Executive Director, General Manager of Discovery Research Headquarters of KYORIN Pharmaceutical Co., Ltd. (current)
June 2022 Executive Director, in charge of Intellectual Property Department, Legal Department, and Research and Development of KYORIN Holdings, Inc. (current)

Morio Yanagishima
Executive Director,
General Manager of Product Strategy,
in charge of Sales & Marketing and Healthcare Business

April 1982 Joined Kyorin Yakuhin Co., Ltd.
April 2016 Corporate Officer, General Manager of Tokyo Branch, Sales & Marketing Headquarters of KYORIN Pharmaceutical Co., Ltd.
April 2017 Corporate Officer, General Manager of Marketing & Product Planning, General Manager of Product Planning, Sales & Marketing Headquarters of KYORIN Pharmaceutical Co., Ltd.
April 2019 Corporate Officer, Deputy General Manager of Sales & Marketing Headquarters, General Manager of Marketing & Product Planning of KYORIN Pharmaceutical Co., Ltd.
June 2019 Executive Director, Deputy General Manager of Sales & Marketing Headquarters, General Manager of Marketing & Product Planning of KYORIN Pharmaceutical Co., Ltd.
April 2021 Executive Director, General Manager of Product Strategy of KYORIN Pharmaceutical Co., Ltd.
April 2021 Corporate Officer, General Manager of Product Strategy of KYORIN Holdings, Inc.
June 2021 Corporate Officer, General Manager of Product Strategy, in charge of Corporate Planning of KYORIN Holdings, Inc.
June 2021 Executive Director, General Manager of Product Strategy, in charge of Promotion Compliance, Corporate Planning of KYORIN Pharmaceutical Co., Ltd.
June 2022 Executive Director, General Manager of Product Strategy, in charge of Sales & Marketing and Healthcare Business of KYORIN Holdings, Inc. (current)
June 2022 Executive Director, General Manager of Product Strategy, in charge of Promotion Compliance, Sales & Marketing Headquarters, and In Vitro Diagnostics Business of KYORIN Pharmaceutical Co., Ltd. (current)

Noriyuki Shikanai
Outside Director/Independent Officer

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/Independent Officer

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/Independent Officer

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)
October 2021 Deputy Director of Shimotakaido Station Clinic ENT Plus+ (current)

Senior Corporate Auditors

Tomiharu Matsumoto

Kenji Akutsu

Outside Corporate Auditors/ Independent Officers

Takao Yamaguchi

Yukio Ikemura

Kensuke Morita

Senior Corporate Officer

Yoh Ito

Corporate Officers

Hiroshi Hashizume

Yasuyuki Shimokawa

Yasuji Kurose

Major activities of outside directors and outside corporate auditors (Fiscal 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, and fully performs his role mainly in deciding important management matters of the Company and Group companies and supervising business execution.	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, and fully performs his role mainly in deciding important management matters of the Company and Group companies and supervising business execution.	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, and fully performs her role mainly in deciding important management matters of the Company and Group companies and supervising business execution.	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 12 out of 12 Board of Directors' meetings and 12 out of 12 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 12 out of 12 Board of Directors' meetings and 12 out of 12 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 10 out of 12 Board of Directors' meetings and 10 out of 12 Board of Corporate Auditors' meetings

* Masaji Obata and Naohiro Kamei retired from their positions as outside corporate auditors at the annual general shareholders' meeting held on June 24, 2022.

Financial Analysis

Industry Trends in Japan

The Japanese pharmaceutical industry maintained a low single-digit growth rate in the domestic ethical drugs market during fiscal 2021 due to the impact of measures to curtail medical expenses and drug costs, such as the drug price revisions 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 "Focusing on the pursuit of originality" for fiscal 2021, the Kyorin Group worked aggressively to accelerate the growth of the new drugs group, enhance the development pipeline, speed up drug discovery, and improve cost competitiveness.

Consolidated Operating Results

As for consolidated net sales for fiscal 2021, the ethical drugs market for respiratory, otolaryngology, and other fields, which is the Kyorin Group's main focus, had negative growth due to drug price revisions (the 6% range for KYORIN Pharmaceutical Co., Ltd.) and the spread of COVID-19. Under those circumstances, sales of new ethical drugs, etc., (domestic) remained flat compared to those of the previous fiscal year due mainly to a decrease in sales of out-licensed products and lump-sum payments related to those products, despite growth in the new drugs group as a result of efficient product promotion and increased sales of major long-listed products due to the impact of product supply concerns stemming from quality issues at some generic drug companies. However, sales of generic drugs rose, and overall net sales totaled ¥105,534 million, exceeding the ¥102,904 million result for the previous fiscal year.

In terms of profit, despite higher sales than those of the previous fiscal year, a rise in the cost of sales ratio due to drug price revisions and other impacts resulted in ¥49,441 million in gross profit, down from ¥51,627 million for the previous fiscal year. On the other hand, SG&A expenses declined to ¥44,433 million (including ¥8,897 million of R&D expenses, compared with ¥9,703 million for the previous fiscal year) from ¥45,841 million for the previous fiscal year due to efforts to reduce costs, despite the recording of an up-front payment for an agreement related to the introduction of the treatment for cough "Lyfnua® Tablets 45 mg (gefapixant citrate)." As a result, operating profit was ¥5,007 million, compared with ¥5,786 million for the previous fiscal year, and profit attributable to shareholders of KYORIN Holdings, Inc. was ¥3,932 million, compared with ¥6,130 million for the previous fiscal year.

For the previous fiscal year, debt exemption gain, etc., of ¥1,073 million was recorded as extraordinary income due to the exemption of part of the repayment obligation for long-term debt to JST (Japan Science and Technology Agency).

Assets, Liabilities, and Net Assets

As of March 31, 2022, current assets had increased ¥2,349 million from those of the previous fiscal year-end, with increases in accounts receivable and raw materials and supplies, and a decrease in securities. Fixed assets increased ¥2,447 million, with increases in property, plant and equipment and investment securities, and a decrease in intangible assets. As a result, total assets increased ¥4,797 million from those of the previous fiscal year-end, to ¥171,924 million.

Total liabilities increased ¥4,951 million from those of the previous fiscal year-end, to ¥47,416 million, a reflection of increases in notes and accounts payable and other current liabilities.

Net assets decreased ¥154 million from those of the previous fiscal year-end, to ¥124,507 million, including an increase in retained earnings and a decrease in valuation difference on available-for-sale securities.

As a result, the shareholders' equity ratio at the fiscal year-end was 72.4%, a 2.2 percentage-point decrease from that of the previous fiscal year-end.

Cash Flows

Operating activities during fiscal 2021 generated net cash of ¥6,346 million, with major items including ¥5,216 million in profit before income taxes, depreciation and amortization of ¥3,714 million, a ¥1,226 million increase in notes and accounts receivable, a ¥3,633 million increase in inventories, a ¥3,910 million increase in notes and accounts payable, and ¥1,248 million in income taxes paid.

Investing activities used net cash of ¥2,560 million, primarily a reflection of ¥2,444 million in outlays for the purchase of property, plant and equipment, ¥3,407 million in outlays for the purchase of investment securities, and ¥3,400 million in proceeds from the sale and redemption of investment securities.

Financing activities used net cash of ¥4,112 million, with major items including ¥3,767 million paid as cash dividends.

As a result, cash and cash equivalents at the end of fiscal 2021 totaled ¥26,289 million, a ¥186 million decrease from that of the previous fiscal year-end.

Outlook for Fiscal 2023

The operating environment for the domestic 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 strive to increase speed in its business by working aggressively in three areas: accelerating the growth of the new drugs group, expanding the development pipeline, and speeding up drug creation under the HOPE100—Stage 3— medium-term business plan (fiscal 2020–2023), started in fiscal 2020 to achieve the HOPE100 long-term vision, with "Realization of a growth trend through the pursuit of originality" as the management policy for fiscal 2022.

In terms of net sales for fiscal 2022, with regard to new ethical drugs, etc., (domestic), although the drug price revisions implemented in April 2022 (the 8% range for KYORIN Pharmaceutical Co., Ltd.) had effects, we forecast an increase in sales of new ethical drugs, etc., (domestic) because we anticipate sales growth for the new drugs group mainly through removal of limited shipping (shipping adjustments) of our main product Beova, the overactive bladder drug, and the launch of Lyfnua, for the treatment of cough. With regard to generic drugs, we also anticipate sales growth due to the expansion of sales of our main products and contributions from new generic drugs listed in June and December 2022. In light of this thinking, we expect net sales for new ethical drugs, etc., (domestic) of ¥74,500 million, new ethical drugs (overseas) of ¥700 million, and generic drugs of ¥36,700 million, and we expect consolidated net sales of ¥112,000 million.

In terms of profit, we forecast higher gross profit due to increased revenue and a lower cost of sales ratio resulting from a stronger performance by the new drugs group, despite the drug price revisions. However, we expect a rise in SG&A expenses due to an increase in R&D expenses (increase of ¥2,000 million from that of the previous fiscal year), despite aggressive efforts to reduce costs. As a result, we forecast operating profit of ¥5,500 million and profit attributable to shareholders of KYORIN Holdings, Inc. of ¥4,500 million.

Although we have factored in to some extent the impact of the spread of COVID-19 on business results, uncertain environments 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, 2022.

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., a subsidiary of the Company, 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 backups, 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 infringe on our intellectual property rights, or should the Group's business activities infringe on the intellectual property rights of another company, the Group could encounter legal disputes and business discontinuation 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 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.

10. 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.

11. 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. In particular, the Group views climate change countermeasures as one of our critical issues and conducts business activities in consideration of their impact on the environment, including the reduction of environmentally hazardous substances. 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.

12. 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.

(Impact of the COVID-19 pandemic)

Various factors including fewer visits to medical institutions and restrictions on information services due to the continuing spread of COVID-19 infections could materially affect the Group's business performance and financial condition. The Group is promoting work-style reforms such as working from home and staggered work hours, while taking measures to ensure employees' health. In our sales activities, while self-restraining from MR activities to medical institutions, the Group is aggressively engaged in information service activities utilizing digital channels in multiple aspects. However, if the pace or the number of COVID-19 infections exceeds forecasts, our business performance and financial condition could be materially affected.

Consolidated Balance Sheet

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

	Millions of yen		Thousands of U.S. dollars *(Note 3)*
Assets	2022	2021	2022
Current assets:			
Cash and cash in banks *(Notes 4 and 11)*	¥ 26,994	¥ 27,445	$ 220,521
Notes and accounts receivable *(Note 11)*	—	40,446	—
Notes receivable *(Note 11)*	1,521	—	12,425
Accounts receivable *(Note 11)*	40,154	—	328,029
Short-term investments *(Notes 5 and 11)*	500	3,399	4,085
Inventories:			
Merchandise and finished goods	19,038	19,545	155,527
Work in process	7,742	7,293	63,246
Raw materials and supplies	15,437	11,730	126,109
Other	5,029	4,203	41,083
Less allowance for doubtful accounts	(39)	(37)	(319)
Total current assets	116,376	114,027	950,707
Property, plant and equipment:			
Land	2,872	2,872	23,462
Buildings and structures	33,791	32,958	276,048
Machinery and vehicle	25,940	25,173	211,911
Leased assets	840	860	6,862
Construction in progress	1,326	457	10,832
Other	9,855	9,685	80,508
Less accumulated depreciation and impairment loss	(50,293)	(48,113)	(410,857)
Property, plant and equipment, net	24,334	23,896	198,791
Investments and other assets:			
Investment securities *(Notes 5 and 11)*	25,703	23,645	209,975
Long-term loans	0	0	0
Deferred tax assets *(Note 13)*	783	343	6,397
Other	4,764	5,258	38,918
Less allowance for doubtful accounts	(38)	(44)	(310)
Total investments and other assets	31,213	29,203	254,987
Total assets	¥171,924	¥167,126	$1,404,493

	Millions of yen		Thousands of U.S. dollars *(Note 3)*
Liabilities and net assets	2022	2021	2022
Current liabilities:			
Notes and accounts payable *(Note 11)*	¥ 10,896	¥ 6,985	$ 89,012
Short-term bank loans *(Notes 6 and 11)*	10,300	10,300	84,143
Lease obligations *(Note 6)*	147	137	1,201
Accrued income taxes *(Note 13)*	530	476	4,330
Accrued bonuses to employees	2,295	2,206	18,748
Reserve for sales returns	—	23	—
Other	8,011	7,277	65,444
Total current liabilities	32,182	27,407	262,903
Long-term liabilities:			
Long-term debt *(Notes 6 and 11)*	10,836	11,036	88,522
Lease obligations *(Note 6)*	341	409	2,786
Deferred tax liabilities *(Note 13)*	175	293	1,430
Provision for stock-based payments	343	—	2,802
Liability for retirement benefits *(Note 12)*	2,885	2,584	23,568
Other	652	733	5,326
Total long-term liabilities	15,234	15,057	124,451
Net assets:			
Shareholders' equity *(Note 7)*:			
Common stock, no par value:			
Authorized—297,000,000 shares in 2022 and 2021			
Issued—64,607,936 shares in 2022 and 2021	700	700	5,718
Capital surplus	4,752	4,752	38,820
Retained earnings	132,710	132,557	1,084,143
Treasury stock, at cost:			
7,306,000 shares in 2022			
7,305,913 shares in 2021	(17,671)	(17,671)	(144,359)
Total shareholders' equity	120,491	120,339	984,323
Accumulated other comprehensive income:			
Unrealized holding gain on other securities	6,268	6,639	51,205
Translation adjustments	110	(40)	899
Retirement benefits liability adjustments	(2,362)	(2,275)	(19,296)
Total accumulated other comprehensive income	4,016	4,322	32,808
Total net assets	124,507	124,661	1,017,131
Total liabilities and net assets	¥171,924	¥167,126	$1,404,493

See notes to consolidated financial statements.

Consolidated Statement of Income

KYORIN Holdings, Inc. and Consolidated Subsidiaries
For the year ended March 31, 2022

	Millions of yen		Thousands of U.S. dollars *(Note 3)*
	2022	2021	2022
Net sales	¥105,534	¥102,904	$862,135
Cost of sales	56,093	51,276	458,239
Gross profit	49,441	51,627	403,897
Selling, general and administrative expenses *(Note 8)*	44,433	45,841	362,985
Operating profit	5,007	5,786	40,904
Other income (expenses):			
Interest and dividend income	411	420	3,358
Interest expense	(66)	(68)	(539)
Equity in gains of affiliates	25	49	204
Foreign exchange gain	98	129	801
(Loss) gain on sales and retirement of property, plant and equipment, net *(Note 9)*	(32)	342	(261)
Gain on sales of investment securities *(Note 5)*	–	488	–
Loss on devaluation of investment securities *(Note 5)*	(320)	–	(2,614)
Debt exemption gain *(Note 10)*	–	1,073	–
Subsidy income	36	86	294
Other, net	56	44	457
Other income, net	209	2,566	1,707
Profit before income taxes	5,216	8,352	42,611
Income taxes *(Note 13)*:			
Current	1,630	1,847	13,316
Deferred	(346)	374	(2,827)
Total income taxes	1,284	2,222	10,489
Profit	3,932	6,130	32,122
Profit attributable to shareholders of KYORIN Holdings, Inc.	¥ 3,932	¥ 6,130	$ 32,122

See notes to consolidated financial statements.

Consolidated Statement of Comprehensive Income

KYORIN Holdings, Inc. and Consolidated Subsidiaries
For the year ended March 31, 2022

	Millions of yen		Thousands of U.S. dollars *(Note 3)*
	2022	2021	2022
Profit	¥3,932	¥6,130	$32,122
Other comprehensive income (loss) *(Note 14)*:			
Unrealized holding loss on other securities	(393)	(305)	(3,211)
Translation adjustments	151	(77)	1,234
Retirement benefits liability adjustments	(86)	506	(703)
Share of other comprehensive income of affiliates accounted for using equity method	21	23	172
Total other comprehensive income (loss)	(306)	146	(2,500)
Comprehensive income	¥3,625	¥6,276	$29,614
Total comprehensive income attributable to:			
Shareholders of KYORIN Holdings, Inc.	¥3,625	¥6,276	$29,614
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, 2022

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, 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 April 1, 2021	64,607,936	700	4,752	132,557	(17,671)	120,339	6,639	(40)	(2,275)	4,322	124,661
Cash dividends	–	–	–	(3,779)	–	(3,779)	–	–	–	–	(3,779)
Profit attributable to shareholders of KYORIN Holdings, Inc.	–	–	–	3,932	–	3,932	–	–	–	–	3,932
Purchase of treasury stock	–	–	–	–	(0)	(0)	–	–	–	–	(0)
Other changes	–	–	–	–	–	–	(371)	151	(86)	(306)	(306)
Net changes during the year	–	–	–	152	(0)	152	(371)	151	(86)	(306)	(154)
Balance as of March 31, 2022	64,607,936	¥700	¥4,752	¥132,710	¥(17,671)	¥120,491	¥6,268	¥110	¥(2,362)	¥4,016	¥124,507

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, 2021	64,607,936	$5,718	$38,820	$1,082,894	$(144,359)	$983,081	$54,236	$ (327)	$(18,585)	$35,308	$1,018,389
Cash dividends	–	–	–	(30,872)	–	(30,872)	–	–	–	–	(30,872)
Profit attributable to shareholders of KYORIN Holdings, Inc.	–	–	–	32,122	–	32,122	–	–	–	–	32,122
Purchase of treasury stock	–	–	–	–	(0)	(0)	–	–	–	–	(0)
Other changes	–	–	–	–	–	–	(3,031)	1,234	(703)	(2,500)	(2,500)
Net changes during the year	–	–	–	1,242	(0)	1,242	(3,031)	1,234	(703)	(2,500)	(1,258)
Balance as of March 31, 2022	64,607,936	$5,718	$38,820	$1,084,143	$(144,359)	$984,323	$51,205	$ 899	$(19,296)	$32,808	$1,017,131

See notes to consolidated financial statements.

Consolidated Statement of Cash Flows

KYORIN Holdings, Inc. and Consolidated Subsidiaries
For the year ended March 31, 2022

	Millions of yen		Thousands of U.S. dollars *(Note 3)*
	2022	2021	2022
Operating activities			
Profit before income taxes	¥ 5,216	¥ 8,352	$ 42,611
Depreciation and amortization	3,714	3,564	30,341
Decrease in allowance for doubtful accounts	(3)	(3)	(25)
Increase (decrease) in accrued bonuses to employees	83	(125)	678
Increase (decrease) in provision for stock-based payments	343	(36)	2,802
Decrease in asset for retirement benefits	127	186	1,037
Increase (decrease) in liability for retirement benefits	48	(11)	392
Equity in gains of affiliates	(25)	(49)	(204)
Interest and dividend income	(411)	(420)	(3,358)
Interest expense	66	68	539
Loss (gain) on sales and retirement of property, plant and equipment, net	32	(342)	261
Loss (gain) on sales of investment securities, net	0	(488)	0
Loss on devaluation of investment securities	320	—	2,614
Debt exemption gain	—	(1,073)	—
(Increase) decrease in notes and accounts receivable	(1,226)	7,001	(10,016)
Increase in inventories	(3,633)	(5,284)	(29,679)
Increase (decrease) in notes and accounts payable	3,910	(2,791)	31,942
(Decrease) increase in consumption taxes payable	(35)	195	(286)
Other, net	(1,287)	(2,011)	(10,514)
Subtotal	7,240	6,728	59,145
Interest and dividend received	420	428	3,431
Interest paid	(66)	(68)	(539)
Income taxes paid	(1,248)	(1,899)	(10,195)
Net cash provided by operating activities	6,346	5,189	51,842
Investing activities			
Payments for time deposits	(622)	(622)	(5,081)
Proceeds from withdrawal of time deposits	946	1,020	7,728
Purchase of property, plant and equipment	(2,444)	(4,067)	(19,966)
Proceeds from sales of property, plant and equipment	0	368	0
Purchase of intangible assets	(246)	(1,057)	(2,010)
Purchase of investment securities	(3,407)	(1,407)	(27,833)
Proceeds from sales and redemption of investment securities	3,400	1,641	27,776
Other, net	(185)	(134)	(1,511)
Net cash used in investing activities	(2,560)	(4,259)	(20,913)
Financing activities			
Repayments of lease obligations	(143)	(142)	(1,168)
Proceeds from long-term debt	—	0	—
Repayments of long-term debt	(200)	(428)	(1,634)
Net increase in treasury stock	(0)	(0)	(0)
Cash dividends	(3,767)	(4,347)	(30,774)
Net cash used in financing activities	(4,112)	(4,918)	(33,592)
Effects of exchange rate changes on cash and cash equivalents	139	(43)	1,136
Decrease in cash and cash equivalents	(186)	(4,033)	(1,519)
Cash and cash equivalents at beginning of year	26,476	30,509	216,290
Cash and cash equivalents at end of year *(Note 4)*	¥26,289	¥26,476	$214,762

See notes to consolidated financial statements.

Notes to Consolidated Financial Statements

KYORIN Holdings, Inc. and Consolidated Subsidiaries
For the year ended March 31, 2022

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 2021 consolidated financial statements to conform to the 2022 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, 2022, the numbers of consolidated subsidiaries and affiliates accounted for by the equity method were five and one (five and one in 2021), respectively. As of March 31, 2022, 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, deposit 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. Securities other than equity securities, etc. without market prices that are 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. Equity securities, etc. without market prices that are 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 vehicle	4 to 17 years

Intangible assets are amortized by the straight-line method over their estimated useful lives. Computer software for internal use is capitalized and amortized by the straight-line method over the useful life of 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 enacted 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 adjusting 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 Deferred Tax Accounting Related to the Transition from the Consolidated Taxation System to the Group Tax Sharing System

The Company and its domestic consolidated subsidiaries have applied the consolidated taxation system.

From the year ending March 31, 2023, the Company and its domestic consolidated subsidiaries will transition from the consolidated taxation system to the group tax sharing system. However, 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 do not apply Paragraph 44 of "Implementation Guidance on Deferred Tax 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 Deferred Tax 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 record the amounts of deferred tax assets and liabilities in accordance with the rules of the tax act before the amendments.

From the beginning of the year ending March 31, 2023, the Company and its domestic consolidated subsidiaries will apply the "Practical Solution on the Accounting and Disclosure Under the Group Tax Sharing System" (PITF No. 42, August 12, 2021), which provides for accounting treatment and disclosure of corporate and local income taxes and deferred tax accounting in the case where a group tax sharing system is applied.

(m) Significant Revenue and Expense Recognition Standards

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. The Group recognizes 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.

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 recognizes 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.

Transaction prices are calculated based on considerations promised in contracts with customers, less sales rebates, etc.

For considerations for sales incentives, etc., paid to distributors, the Group reduces certain sales incentives, etc., from transaction prices.

In addition, for sales with expected reruns of products, the Group does not 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 the 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.

The Group receives considerations for performance obligations generally within one year after satisfying the performance obligations in accordance with payment terms prescribed separately, and such considerations do not contain a significant financing component.

(n) Significant Accounting Estimates

Recoverability of deferred tax assets

(1) The amounts of deferred tax assets and liabilities recorded for the years ended March 31, 2022 and 2021 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2022	2021	2022
Deferred tax assets	¥ 783	¥ 343	$ 6,397
Deferred tax liabilities	175	293	1,430
(Deferred tax assets before offsetting against deferred tax liabilities)	4,628	4,322	37,807

(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, 2023, future taxable income is estimated on basis of the 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, 2022 may be reversed.

(o) Changes in Accounting Policies

Application of the Accounting Standard for Revenue Recognition, etc.

The Group has applied the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, revised on March 31, 2020; hereinafter the "Revenue Recognition Accounting Standard"), etc., from the beginning of the year ended March 31, 2022 and recognizes 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.

Accordingly, while 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 has been 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 has been changed not to recognize revenue at the time of sales, in accordance with provisions regarding variable considerations.

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 ended March 31, 2022, is added to or deducted from retained earnings at the beginning of the year ended March 31, 2022, and the new accounting policies are applied from the beginning balance.

As a result, for the year ended March 31, 2022, net sales decreased by ¥966 million ($7,892 thousand) and selling, general and administrative expenses decreased by ¥966 million ($7,892 thousand), while there is no change in operating profit, ordinary profit, and profit before income taxes. There is no effect on the beginning balance of retained earnings.

"Notes and accounts receivable" presented under "Current assets" in the consolidated balance sheet for the previous fiscal year are included in "Notes receivable" and "Accounts receivable" for the year ended March 31, 2022. However, no reclassification has been made to reflect the new presentation method for the previous fiscal year in accordance with the transitional treatment prescribed in Paragraph 89-2 of the Revenue Recognition Accounting Standard. In addition, notes on "Revenue Recognition" for the previous fiscal year is not disclosed in accordance with the transitional treatment prescribed in Paragraph 89-3 of the Revenue Recognition Accounting Standard.

Application of the Accounting Standard for Fair Value Measurement, etc.

The Group has applied the "Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 30, issued on July 4, 2019; hereinafter the "Fair Value Measurement Standard"), etc., from the beginning of the year ended March 31, 2022 and prospectively apply new accounting policies stipulated by the Fair Value Measurement Standard, etc., in accordance with the transitional treatment provided in Paragraph 19 of the Fair Value Measurement Standard and Paragraph 44-2 of the "Accounting Standard for Financial Instruments" (ASBJ Statement No. 10, revised on July 4, 2019). The application of the accounting standard, etc., has no effect on the consolidated financial statements.

In addition, the Group include notes on fair value information by level within the fair value hierarchy in the notes on "Financial Instruments." However, such notes related to the previous fiscal year are not disclosed in accordance with the transitional treatment provided in Paragraph 7-4 of the "Implementation Guidance on Disclosures about Fair Value of Financial Instruments" (ASBJ Guidance No. 19, revised on July 4, 2019).

(p) Accounting Standard Issued but Not Yet Effective

"Implementation Guidance on Accounting Standard for Fair Value Measurement" (ASBJ Guidance No. 31, revised on June 17, 2021)

(1) Overview

The revision of "Implementation Guidance on Accounting Standard for Fair Value Measurement" (ASBJ Guidance No. 31) on June 17, 2021 was as revised and released, as it was considered at the time of release on July 4, 2019 that a certain period of time would be required for discussions with related parties, etc., to consider the "fair value measurement of investment trusts," and that a certain amount of consideration would also be required for notes on the fair value of "investments in partnerships, etc., in which the net amount of equity is recorded on the balance sheet," taking approximately one year after the release of the "Accounting Standard for Fair Value Measurement."

(2) Date of application

From the beginning of the fiscal year ending March 31, 2023

(3) Effect of application

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

(q) 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 introduces an incentive plan referred to as the Employee Stock Delivery Trust (the "J-ESOP," hereinafter, the "ESOP Plan") under which the Company's shares will be delivered to employees of KYORIN Pharmaceutical.

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

(1) Outline of transactions

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

KYORIN Pharmaceutical will award its employees a set number of points on the bases 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 portion 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, 2022 and 2021, the carrying amounts of the treasury shares were ¥1,624 million ($13,267 thousand) and ¥1,624 million, respectively, and the total numbers of treasury shares were 745 thousand shares and 745 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 subsidiary.

The Company adopts 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, 2022 and 2021, the carrying amounts of the treasury shares were¥208 million ($1,699 thousand) and ¥208 million, respectively, and the total numbers of treasury shares were 92 thousand shares and 92 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 ¥122.41 = U.S.$1.00, the approximate rate of exchange on March 31, 2022. 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, 2022 and 2021 for the consolidated statements of cash flows consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2022	2021	2022
Cash and cash in banks	¥26,994	¥27,445	$220,521
Time deposits with a maturity over three months	(704)	(968)	(5,751)
Cash and cash equivalents	¥26,289	¥26,476	$214,762

5. Short-Term Investments and Investment Securities

Information regarding marketable securities classified as other securities as of March 31, 2022 and 2021 is as follows:

Marketable other securities

	Millions of yen			Thousands of U.S. dollars		
	2022			2022		
	Acquisition cost	Carrying value	Unrealized gain (loss)	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their acquisition cost:						
Equity securities	¥ 8,521	¥17,549	¥9,027	$ 69,610	$143,362	$73,744
Debt securities:						
Government bonds	—	—	—	—	—	—
Corporate bonds	—	—	—	—	—	—
Other bonds	—	—	—	—	—	—
Subtotal	8,521	17,549	9,027	69,610	143,362	73,744
Securities whose carrying value does not exceed their acquisition cost:						
Equity securities	2,012	1,875	(136)	16,437	15,317	(1,111)
Debt securities:						
Government bonds	5,400	5,386	(13)	44,114	44,000	(106)
Corporate bonds	—	—	—	—	—	—
Other bonds	—	—	—	—	—	—
Subtotal	7,412	7,261	(150)	60,551	59,317	(1,225)
Total	¥15,933	¥24,811	¥8,877	$130,161	$202,688	$72,519

	Millions of yen		
	2021		
	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their acquisition cost:			
Equity securities	¥ 8,525	¥18,387	¥9,862
Debt securities:			
Government bonds	1,300	1,300	0
Corporate bonds	—	—	—
Other bonds	—	—	—
Subtotal	9,825	19,688	9,862
Securities whose carrying value does not exceed their acquisition cost:			
Equity securities	2,008	1,607	(400)
Debt securities:			
Government bonds	4,100	4,099	(0)
Corporate bonds	—	—	—
Other bonds	—	—	—
Subtotal	6,108	5,707	(400)
Total	¥15,933	¥25,395	¥9,461

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 ¥673 million ($5,498 thousand) and ¥968 million as of March 31, 2022 and 2021, respectively.

Sales amounts of securities classified as other securities and the related aggregate gain and loss for the years ended March 31, 2022 and 2021 are summarized as follows:

	Millions of yen		Thousands of U.S. dollars
	2022	2021	2022
Proceeds from sales	¥ —	¥648	$ —
Gains on sales	—	495	—
Losses on sales	—	—	—

In the year ended March 31, 2022, impairment loss on securities of ¥320 million ($2,614 thousand) (¥320 million ($2,614 thousand) of unlisted securities classified as other securities that are not measured at fair value) was recognized.

The impairment loss was recognized for the amount deemed necessary, taking into consideration the recoverability of the actual value of the equity securities and other factors.

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, 2022 and 2021 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2022	2021	2022
Short-term bank loans	¥10,100	¥10,100	$82,510
Current portion of long-term debt	200	200	1,634
Current portion of lease obligations	147	137	1,201
Total	¥10,447	¥10,437	$85,344

The average interest rates applicable to short-term bank loans outstanding as of March 31, 2022 and 2021 are 0.3% and 0.3%, respectively.

Long-term debt and lease obligations as of March 31, 2022 and 2021 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2022	2021	2022
Long-term debt due through 2027 at average interest rate of 0.3% and 0.3% in 2022 and 2021, respectively	¥11,036	¥11,237	$90,156
Lease obligations due through 2030 in 2022 and 2021	489	546	3,995
Current portion of long-term debt and lease obligations due within one year	(348)	(337)	(2,843)
Total	¥11,177	¥11,446	$91,308

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
2023	¥ 348	$ 2,843
2024	334	2,729
2025	10,285	84,021
2026	229	1,871
2027	197	1,609

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 of normal term by its articles of incorporation.

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

Semiannual interim dividends may also be paid once a year upon resolution by the board of directors if the articles of incorporation of the company so stipulate. The Companies Act also provides certain limitations on the amounts available for dividends 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, 2022 and 2021 were ¥8,897 million ($72,682 thousand) and ¥9,703 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, 2022 and 2021 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2022	2021	2022
Gain:			
Machinery and vehicles	¥ —	¥ 0	$ —
Land	—	366	—
Other	0	0	0
	¥ 0	¥367	$ 0
Loss:			
Buildings and structures	¥(11)	¥ (12)	$ (90)
Machinery and vehicles	(2)	(9)	(16)
Other	(18)	(3)	(147)
	(32)	(25)	(261)
Total	¥(32)	¥342	$(261)

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 bad debt by monitoring the 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 the deposits.

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

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

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 the calculation of fair values of financial instruments 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, 2022 and 2021 are as follows:

	Millions of yen			Thousands of U.S. dollars		
	2022			2022		
	Carrying value	Fair value	Difference	Carrying value	Fair value	Difference
Notes receivable	¥ 1,521	¥ 1,521	¥ —	$ 12,425	$ 12,425	$ —
Accounts receivable	40,154	40,154	—	328,029	328,029	—
Short-term investments and investment securities	24,811	24,811	—	202,688	202,688	—
Total assets	¥66,487	¥66,487	¥ —	$543,150	$543,150	$ —
Notes and accounts payable	¥10,896	¥10,896	¥ —	$ 89,012	$ 89,012	$ —
Short-term bank loans	10,300	10,300	—	84,143	84,143	—
Long-term debt	10,836	10,834	(2)	88,522	88,506	(16)
Total liabilities	¥32,033	¥32,030	¥ (2)	$261,686	$261,662	$ (16)

	Millions of yen		
	2021		
	Carrying value	Fair value	Difference
Notes and accounts receivable	¥40,446	¥40,446	¥—
Short-term investments and investment securities	25,395	25,395	—
Total assets	¥65,842	¥65,842	¥—
Notes and accounts payable	¥ 6,985	¥ 6,985	¥—
Short-term bank loans	10,300	10,300	—
Long-term debt	11,036	11,034	(2)
Total liabilities	¥28,322	¥28,320	¥(2)

"Cash and cash in banks" are omitted because their carrying value is deemed as the fair value since they are scheduled to be settled in a short time.

Equity securities, etc. without market prices are not included in "Short-term investments and investment securities" in the above tables. These financial instruments recorded in the consolidated balance sheet are unlisted securities and others of ¥1,392 million ($11,372 thousand) as of March 31, 2022. Unlisted securities and others of ¥1,649 million, whose fair values are extremely difficult to determine as of March 31, 2021, are not included in the above tables.

The redemption schedule for monetary receivables and securities with maturities subsequent to March 31, 2022 is as follows:

	Millions of yen			
	2022			
	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	¥26,994	¥ —	¥ —	¥ —
Notes receivable	1,521	—	—	—
Accounts receivable	40,154	—	—	—
Short-term investments and investment securities:				
Other securities with maturities:				
Government bonds	500	4,900	—	—
Other	—	—	—	—
Total	¥69,170	¥ 4,900	¥ —	¥ —

	Thousands of U.S. dollars			
	2022			
	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	$220,521	$ —	$ —	$ —
Notes receivable	12,425	—	—	—
Accounts receivable	328,029	—	—	—
Short-term investments and investment securities:				
Other securities with maturities:				
Government bonds	4,085	40,029	—	—
Other	—	—	—	—
Total	$565,068	$40,029	$ —	$ —

	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	¥ —	¥ —

Scheduled repayments of corporate bonds, long-term debt, lease obligations and other interest-bearing liabilities after the consolidated balance sheet date as of March 31, 2022 and 2021 are as follows:

	Millions of yen					
	2022					
	Due in one year or less	Due after one year through two years	Due after two years through three years	Due after three years through four years	Due afte four years through five years	Due after five years
Short-term bank loans	¥10,100	¥ —	¥ —	¥ —	¥ —	¥ —
Long-term debt	200	200	10,200	200	173	61
Lease obligations	147	134	85	29	23	67
Guarantee deposits received	182	—	—	—	—	—
Total	¥10,630	¥334	¥10,285	¥229	¥197	¥129

	Thousands of U.S. dollars					
	2022					
	Due in one year or less	Due after one year through two years	Due after two years through three years	Due after three years through four years	Due afte four years through five years	Due after five years
Short-term bank loans	$82,510	$ —	$ —	$ —	$ —	$ —
Long-term debt	1,634	1,634	83,327	1,634	1,413	498
Lease obligations	1,201	1,095	694	237	188	547
Guarantee deposits received	1,487	—	—	—	—	—
Total	$86,839	$2,729	$84,021	$1,871	$1,609	$1,054

	Millions of yen					
	2021					
	Due in one year or less	Due after one year through two years	Due after two years through three years	Due after three years through four years	Due afte four years through five years	Due after five years
Short-term bank loans	¥10,100	¥ —	¥ —	¥ —	¥ —	¥ —
Long-term debt	200	200	200	10,200	200	235
Lease obligations	137	121	107	62	28	89
Guarantee deposits received	225	—	—	—	—	—
Total	¥10,663	¥321	¥307	¥10,263	¥228	¥325

Fair value information by level within the fair value hierarchy

The fair value of financial instruments is classified into the following three levels according to the observability and materiality of inputs used to measure fair value.

Level 1 fair value: Fair value measured using observable inputs, i.e., quoted prices in active markets for assets or liabilities that are the subject to the measurement

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

Level 3 fair value: Fair value measured using unobservable inputs

If multiple inputs that are significant to the fair value measurement are used, the fair value measurement is categorized in its entirety in the level of the lowest level input that is significant to the entire measurement.

Financial instruments recorded in the consolidated balance sheet at fair value as of March 31, 2022 are as follows:

	Millions of yen				Thousands of U.S. dollars			
	Fair value				Fair value			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Short-term investments and investment securities	¥24,811	¥—	¥—	¥24,811	$202,688	$—	$—	$202,688
Total assets	¥24,811	¥—	¥—	¥24,811	$202,688	$—	$—	$202,688

Financial instruments other than those recorded in the consolidated balance sheet at fair value as of March 31, 2022 are as follows:

	Millions of yen				Thousands of U.S. dollars			
	Fair value				Fair value			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Notes receivable	¥—	¥ 1,521	¥—	¥ 1,521	$—	$ 12,425	$—	$ 12,425
Accounts receivable	—	40,154	—	40,154	—	328,029	—	328,029
Total assets	¥—	¥41,676	¥—	¥41,676	$—	$340,462	$—	$340,462
Notes and accounts payable	¥—	¥10,896	¥—	¥10,896	$—	$ 89,012	$—	$ 89,012
Short-term bank loans	—	10,300	—	10,300	—	84,143	—	84,143
Long-term debt	—	10,834	—	10,834	—	88,506	—	88,506
Total liabilities	¥—	¥32,030	¥—	¥32,030	$—	$261,662	$—	$261,662

The description of valuation techniques and inputs used in the fair value measurements is as follows:

Notes and accounts receivable

The carrying value is deemed as the fair value since they are scheduled to be settled in a short time. Their fair value is classified as Level 2.

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 the counterparty financial institutions. Their fair value is classified as Level 1.

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 period of time. Their fair value is classified as Level 2.

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 in case new, similar loans are borrowed. Their fair value is classified as Level 2.

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, 2022 and 2021 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2022	2021	2022
Retirement benefit obligation at the beginning of the year	¥35,673	¥36,211	$291,422
Service cost	1,121	1,210	9,158
Interest cost	178	181	1,454
Actuarial gain or loss	(114)	(58)	(931)
Retirement benefits paid	(1,683)	(1,870)	(13,749)
Retirement benefit obligation at the end of the year	¥35,174	¥35,673	$287,346

(2) The changes in plan assets for the years ended March 31, 2022 and 2021 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2022	2021	2022
Plan assets at the beginning of the year	¥33,181	¥33,249	$271,064
Expected return on plan assets	663	664	5,416
Actuarial gain or loss	(707)	155	(5,776)
Contributions paid by the employer	915	982	7,475
Retirement benefits paid	(1,683)	(1,870)	(13,749)
Plan assets at the end of the year	¥32,369	¥33,181	$264,431

(3) The changes in liability (asset) for retirement benefits for consolidated subsidiaries applying the simplified method for the years ended March 31, 2022 and 2021 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2022	2021	2022
Liability for retirement benefits at the beginning of the year	¥92	¥178	$752
Retirement benefits costs	97	132	792
Contributions to the plans	(110)	(107)	(899)
Transfer due to a change from the simplified method to the principle method	—	(58)	—
Decrease due to changes in the plans	—	(53)	—
Liability for retirement benefits at the end of the year	¥79	¥ 92	$645

(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, 2022 and 2021 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2022	2021	2022
Funded defined benefit obligation	¥35,755	¥36,189	$292,092
Plan assets	(32,875)	(33,609)	(268,565)
	2,879	2,579	23,519
Unfunded retirement benefit obligation	5	4	41
Net liability for retirement benefits	¥ 2,885	¥ 2,584	$ 23,568
Liability for retirement benefits	¥ 2,885	¥ 2,584	$ 23,568
Net liability for retirement benefits	¥ 2,885	¥ 2,584	$ 23,568

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

(5) The components of retirement benefits costs for the years ended March 31, 2022 and 2021 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2022	2021	2022
Service costs	¥1,121	¥1,210	$9,158
Interest costs	178	181	1,454
Expected return on plan assets	(663)	(664)	(5,416)
Amortization of actuarial loss	493	529	4,027
Amortization of prior service costs	(25)	(12)	(204)
Retirement benefits costs based on the simplified method	97	132	792
Retirement benefits costs	¥1,202	¥1,375	$9,819

(6) Prior service costs and actuarial gain or loss included in other comprehensive income (before tax effect) for the years ended March 31, 2022 and 2021 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2022	2021	2022
Prior service costs	¥ 25	¥ 12	$ 204
Actuarial gain or loss	98	(742)	801
Total	¥124	¥(730)	$1,013

(7) Unrecognized prior service costs and unrecognized actuarial loss included in accumulated other comprehensive income (before tax effect) as of March 31, 2022 and 2021 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2022	2021	2022
Unrecognized prior service costs	¥ (23)	¥ (49)	$ (188)
Unrecognized actuarial loss	3,428	3,330	28,004
Balance at the end of the year	¥3,405	¥3,280	$27,816

(8) Plan assets

The breakdown of plan assets is as follows:

	2022	2021
Domestic equity securities	3.7%	2.5%
Foreign debt securities	46.9	48.2
Foreign equity securities	4.5	6.6
General account	19.0	16.8
Short-term assets	3.1	3.6
Other	22.8	22.3
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

	2022	2021
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 ¥295 million ($2,410 thousand) and ¥306 million to the defined contribution plans for the years ended March 31, 2022 and 2021, respectively.

13. Income Taxes

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

	Millions of yen		Thousands of U.S. dollars
	2022	2021	2022
Deferred tax assets:			
Liability for retirement benefits	¥1,124	¥1,059	$9,182
Accrued bonuses to employees	685	659	5,596
Allowance for doubtful accounts	23	24	188
Accrued enterprise tax	28	39	229
Loss on retirement of inventories	246	359	2,010
Loss on devaluation of investment securities	245	149	2,001
Loss on retirement of property, plant and equipment	38	38	310
Amortization of deferred assets	816	661	6,666
Other	1,481	1,394	12,099
Subtotal	4,691	4,384	38,322
Valuation allowance	(62)	(62)	(506)
Total deferred tax assets	4,628	4,322	37,807
Deferred tax liabilities:			
Reserve for reduction entry of property, plant and equipment	(953)	(1,022)	(7,785)
Unrealized holding gain on other securities	(2,728)	(2,902)	(22,286)
Prepaid pension cost	(232)	(259)	(1,895)
Other	(105)	(87)	(858)
Total deferred tax liabilities	(4,020)	(4,271)	(32,840)
Net deferred tax assets	¥ 608	¥ 50	$4,967

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, 2022 and 2021 are as follows:

	2022	2021
Statutory tax rate	30.6%	30.6%
Entertainment expenses and others that are not tax deductible permanently	0.6	0.4
Inhabitants' per capita taxes	2.0	1.3
Tax credits for research and development expenses	(7.1)	(4.7)
Valuation allowance	0.0	(0.1)
Dividends income that is not taxable permanently	(1.1)	(1.0)
Other	(0.4)	0.1
Effective tax rate	24.6%	26.6%

14. Comprehensive Income

Reclassification adjustments and income tax effects on other comprehensive income (loss) for the years ended March 31, 2022 and 2021 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2022	2021	2022
Unrealized holding gain (loss) on other securities:			
Gain (loss) arising during the year	¥(888)	¥ 47	$(7,254)
Reclassification adjustments	320	(488)	2,614
Before income tax effects	(568)	(440)	(4,640)
Deferred tax	174	134	1,421
Unrealized holding loss on other securities	(393)	(305)	(3,211)
Translation adjustments:			
Adjustments arising during the year	151	(77)	1,234
Retirement benefits liability adjustments:			
Gain (loss) arising during the year	(592)	213	(4,836)
Reclassification adjustments	468	516	3,823
Before income tax effects	(124)	730	(1,013)
Deferred tax	38	(223)	310
Retirement benefits liability adjustments	(86)	506	(703)
Share of other comprehensive income of affiliates accounted for using equity method:			
Gain arising during the year	21	23	172
Total other comprehensive income (loss)	¥(306)	¥146	$(2,500)

15. Revenue Recognition

Information on the disaggregation of revenue from contracts with customers for the year ended March 31, 2022 is as follows:

	Millions of yen	Thousands of U.S. dollars
Sales of pharmaceuticals and other products	¥101,147	$826,297
Royalty income and service revenue	4,387	35,839
Revenue from contracts with customers	¥105,534	$862,135
Net sales to external customers	¥105,534	$862,135

Useful information in understanding revenue from contracts with customers is as disclosed in "Notes to Consolidated Financial Statements, 2. Summary of Significant Accounting Policies, *(m) Significant Revenue and Expense Recognition Standards*."

Information regarding the relationship between the satisfaction of performance obligations under contracts with customers and cash flows arising from such contracts, as well as the amount and timing of revenue from contracts with customers that existed at the end of the year ended March 31, 2022, which is expected to be recognized from the year ending March 31, 2023 onward, is as follows:

(1) The Group has no balances of contract assets or contract liabilities. In addition, there is no revenue recognized in the year ended March 31, 2022 from performance obligations that were satisfied (or partially satisfied) in previous fiscal years.

(2) The Group has no significant transactions with an initially expected contract term of more than one year. In addition, there are no significant amounts of consideration arising from contracts with customers that are not included in the transaction price.

16. Segment Information

Segment information is omitted for the years ended March 31, 2022 and 2021, since the Group operates in a single segment.

(Related Information)

(a) Information by Product and Service

Information by product and service is omitted for the years ended March 31, 2022 and 2021, since the Group operates in a single segment.

(b) Information by Geographical Area

(1) Sales

Information about sales by geographical area is omitted for the years ended March 31, 2022 and 2021, 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, 2022 and 2021, 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, 2022 and 2021

	Millions of yen	
	2022	
Name of customer	Sales amount	Related segments
Alfresa Holdings Corporation	¥18,603	—
MEDIPAL HOLDINGS CORPORATION	17,464	—
SUZUKEN CO., LTD.	16,523	—
Toho Pharmaceutical Co., Ltd.	11,863	—

	Thousands of U.S. dollars	
	2022	
Name of customer	Sales amount	Related segments
Alfresa Holdings Corporation	$151,973	—
MEDIPAL HOLDINGS CORPORATION	142,668	—
SUZUKEN CO., LTD.	134,981	—
Toho Pharmaceutical Co., Ltd.	96,912	—

	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	—

As the Group operates in 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, 2022 and 2021.

17. Amounts per Share

Amounts per share for the years ended March 31, 2022 and 2021 are as follows:

	Yen		U.S. dollars
	2022	2021	2022
Basic profit	¥ 68.62	¥ 106.99	$ 0.56
Cash dividends	52.00	75.00	0.42
Net assets	2,172.83	2,175.52	17.75

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, 2022 and 2021.

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 that were excluded from the calculation of the amount of profit per share were 837,508 and 843,761 for the years ended March 31, 2022 and 2021, respectively.

The numbers of these treasury shares at the end of the fiscal year that were excluded from the calculation of net assets per share were 837,508 and 837,508 as of March 31, 2022 and 2021, respectively.

18. Significant Subsequent Event

Absorption-Type Merger of a Consolidated Subsidiary

At the meeting of the Board of Directors held on May 11, 2022, the Company resolved to conduct an absorption-type merger (hereinafter, the "Merger") with the Company as the surviving company and its wholly owned subsidiary, KYORIN Pharmaceutical Co., Ltd. as the resolving company by absorption with the effective date of April 1, 2023, and entered into the merger agreement on May 11, 2022.

Outline of the business combination is as follows:

(1) Name of company to be acquired and its business
Name of company to be acquired: KYORIN Pharmaceutical Co., Ltd.
Business: Manufacture, sales, and purchases of pharmaceuticals and other products

(2) Date of execution of merger agreement
May 11, 2022

(3) Date of business combination
April 1, 2023 (scheduled)

(4) Legal form of business combination
An absorption-type merger, with the Company as the surviving company and KYORIN Pharmaceutical Co., Ltd. being dissolved

(5) Name of company after the combination
KYORIN Pharmaceutical Co., Ltd.
The trade name will be changed from KYORIN Holdings, Inc. to KYORIN Pharmaceutical Co., Ltd. on April 1, 2023, subject to approval of the proposal to amend the Articles of Incorporation at the 64th Annual General Meeting of Shareholders held on June 24, 2022, and the Merger becoming effective.

(6) Other matters concerning the outline of the transaction
In view of rapid changes in the business environment surrounding the Group and the situation of the Company, the Company has decided to conduct the Merger in order to improve its business promotion function and management efficiency.

With respect to accounting treatments, the Company will account for the transaction as a transaction under common control, in accordance with the "Accounting Standard for Business Combinations" (ASBJ Statement No. 21, revised on January 16, 2019) and the "Implementation Guidance on Accounting Standard for Business Combinations and Accounting Standard for Business Divestitures" (ASBJ Guidance No. 10, revised on January 16, 2019).

Reduction of Legal Capital Surplus

At the meeting of the Board of Directors held on May 11, 2022, the Company resolved to propose to decrease the amount of legal capital surplus to the 64th Annual General Meeting of Shareholders held on June 24, 2022.

The Company will decrease the amount of legal capital surplus pursuant to Article 448, Paragraph 1 of the Companies Act and transfer it to raise other capital surplus in order to realize flexible implementation of its capital policy.

Details of reduction of legal capital surplus are as follows:

(1) Amount of legal capital surplus to be reduced
The Company plans to reduce the amount of legal capital surplus by ¥30,000,000,000 ($245,078 thousand) from ¥39,185,282,976 ($320,115 thousand), and the amount will come to ¥9,185,282,976 ($75,037 thousand).

(2) Method of reduction of legal capital surplus
The Company plans to reduce legal capital surplus and transfer that amount to other capital surplus.

The schedule for reduction of legal capital surplus is as follows:

(1) Date of resolution by the Board of Directors: May 11, 2022
(2) Date of resolution by the annual general meeting of shareholders: June 24, 2022
(3) Public notice on creditors' statements of objection: June 27, 2022 (scheduled)
(4) Deadline for creditors' statements of objection: July 27, 2022 (scheduled)
(5) Effective date: August 31, 2022 (scheduled)

Building a better working world

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 its consolidated subsidiaries (the Group), which comprise the consolidated balance sheet as at March 31, 2022, 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 at March 31, 2022, and its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with accounting principles generally accepted in Japan.

Basis for Opinion

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

Key Audit 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.

Revenue recognition of royalty income	
Description of Key Audit Matter	**Auditor's Response**
As stated in Note 15.Revenue Recognition, the Group's consolidated net sales for the year ended March 31, 2022 were ¥105,534 million, of which royalty income and service revenue were 4,387 million yen, part of which comprised of royalty income. Royalty income is income from contracts that allow third parties to manufacture and sell the Group's products and use its technologies. Royalty income primarily consists of four types: upfront payment, development milestone, sales milestone, and royalty on net sales. If performance obligations are satisfied at a point in time considering the contract details, upfront payment, development milestone and sales milestone are recognized as net sales when development and sales rights are granted, or when the contractually specified milestones are achieved, and sales royalties are recognized as net sales when customers' net sales etc. is generated, or performance obligations are satisfied, whichever is later. 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 primarily 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 and 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, we obtained the contract to confirm the appropriateness of revenue recognition by fulfilling performance obligations at a point in time, measurement of revenue and the timing of revenue recognition by verifying the consistency between the contents of the contract and the performance obligations recognized by the Group and comparing the time of fulfillment of performance obligation with the fact of cash receipts. ・Regarding royalty on net sales, we obtained the customer's report and verified the appropriateness of the measurement of revenue and the timing of revenue recognition by comparing the timing of occurrence of customers' net sales, etc. with the time of fulfillment of performance obligation.

Other Information

The other information comprises the information included in the Annual Report that contains audited consolidated financial statements but does not include the consolidated financial statements and our auditor's report thereon. Management is responsible for preparation and disclosure of the other information. The Corporate Auditor and the Board of Corporate Auditors are responsible for overseeing the Group's reporting process of the other information.

Our opinion on the consolidated financial statements does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the consolidated financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the consolidated financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

Ernst & Young ShinNihon LLC

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.

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.

Ernst & Young ShinNihon LLC

- 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 consolidated 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.

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, 2022 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

Ernst & Young ShinNihon LLC
Tokyo, Japan

August 12, 2022

香山 良

Ryo Kayama
Designated Engagement Partner
Certified Public Accountant

春日 厚志

Atsushi Kasuga
Designated Engagement Partner
Certified Public Accountant

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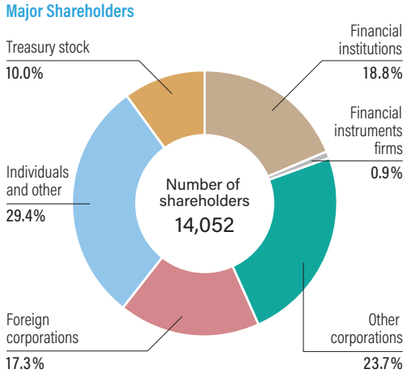
Corporate Overview and Stock Information (As of March 31, 2022)

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	14,052
Listing	Tokyo Stock Exchange (Securities code: 4569)
Transfer Agent	Mizuho Trust & Banking Co., Ltd. 1-3-3, Marunouchi, Chiyoda-ku, Tokyo 100–8241 Phone: +81-3-6627–8000

Major Shareholders

	Percentage of shares held
The Master Trust Bank of Japan, Ltd. (Trust Account)	11.01%
Mykam Co., Ltd.	8.32%
Custody Bank of Japan, Ltd. (Trust Account)	4.48%
Kyorin Group Stock Ownership Association	3.66%
Banrina Co., Ltd.	3.35%
Archans Co., Ltd.	3.35%
Yutaka Ogihara	3.22%
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/

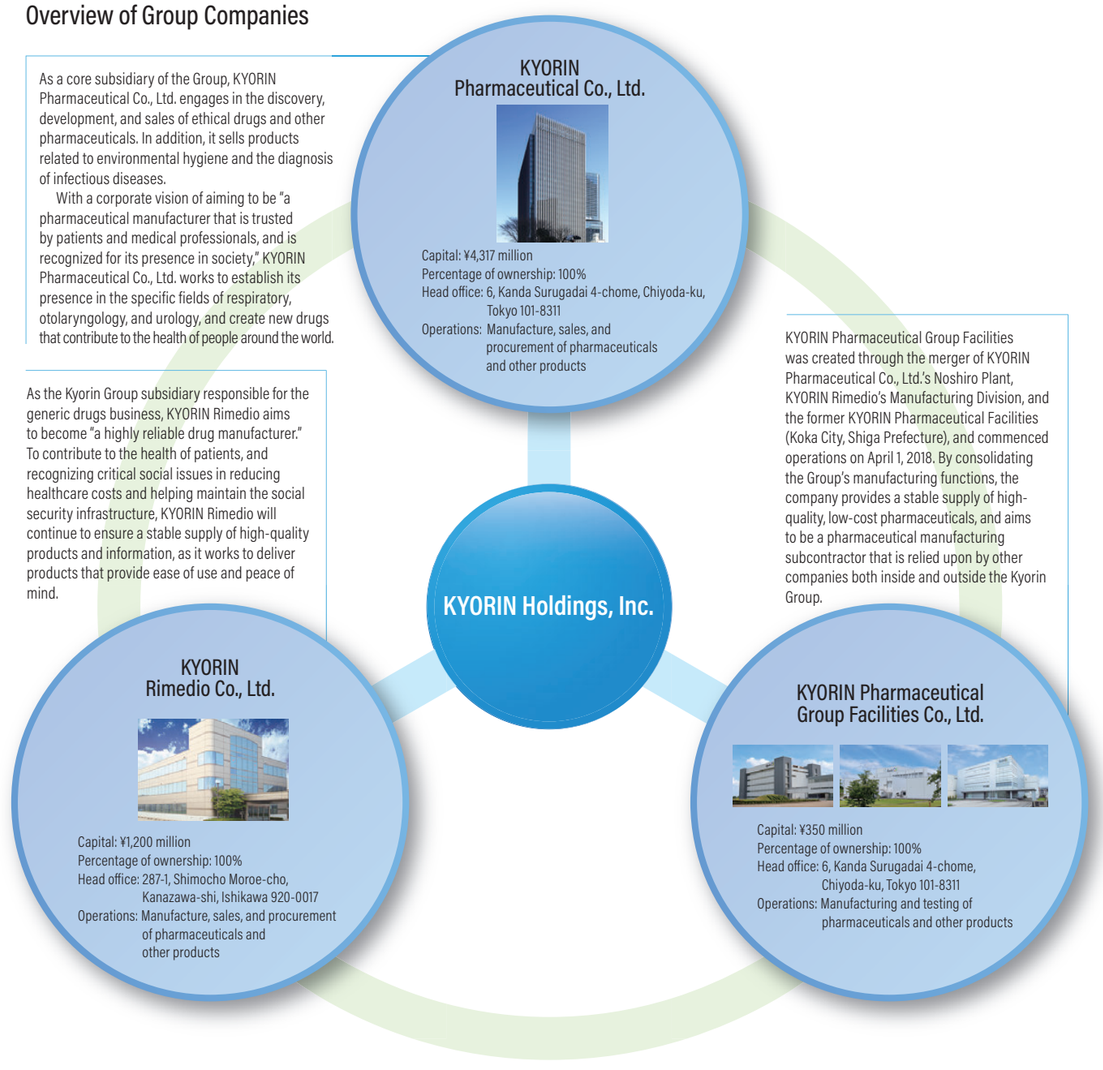
Please visit the Kyorin Group website for the latest information about the Group and earnings-related material.

1 About the Kyorin Group
President's Message
Corporate Philosophy
Long-Term 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. 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; research, analysis, and negotiation of partner licenses

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

Contact point for inquiries about this report Public Relations & IR Group, Corporate Planning Division +81-3-3525-4707