





2023



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## 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

#### Editorial Policy

This report is being published as an Integrated Report, comprehensively including non-financial information such as management strategies, business overviews, and accounts of sustainability activities in addition to the information included in the previously issued annual reports.

We hope that this report will deepen the understanding of shareholders, investors, and a wide range of other stakeholders about the Kyorin Group's activities.

Please visit our corporate website for more detailed information.

[Detailed information]

Information for shareholders and investors:

https://www.kyorin-pharm.co.jp/en/ir/ Information on corporate governance:

https://www.kyorin-pharm.co.jp/en/company/governance.shtml

Information on sustainability:

https://www.kyorin-pharm.co.jp/en/sustainability/

#### Scope of coverage

Period covered: Fiscal 2022 (April 2022–March 2023) \*Some fiscal 2023 activities are reported.

Organizations covered: KYORIN Pharmaceutical Co., Ltd. and its Group companies

#### Reference guidelines, etc.

- The IFRS Foundation's international integrated reporting framework
- Global Reporting Initiative's (GRI) sustainability reporting standards
- ISO 26000 guidance on social responsibility
- Ministry of Economy, Trade and Industry's Guidance for Collaborative Value Creation 2.0
- Ministry of the Environment's Environmental Reporting Guidelines 2018, etc.

#### Disclaime

This report contains performance forecasts, goals and plans, and other forward-looking statements related to the Group. These statements draw 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 and unknown risks and uncertainties. Therefore, due to various factors that may occur, the actual performance, progress/success/failure of developments, and other insights may differ significantly from the description. It also contains information about medicines (including those under development), but the description is not for the purpose of advertising or medical advice.

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#### 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 Legen

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.

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**Minoru Hogawa**Representative Director, Chairman

Yutaka Ogihara

Representative Director,

President and Chief Executive Officer

# Pursuing a new long-term vision based on a new business structure, for growth as a company and for a sustainable society, to fulfill our social mission of contributing to better health

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

To strengthen our business promotion functions and increase management efficiency, and with fiscal 2023 marking the 100th anniversary of our founding, we have transformed our business structure from a pure holding company structure to a business holding company structure and changed our trade name to "KYORIN Pharmaceutical Co., Ltd."

Management of the Kyorin Group is currently being greatly affected by drastic changes in our external operating environment. At the same time, a look at our internal environment shows that we are creating new drugs that are expected to become growth drivers, and we believe we have entered a period of growth. Against this backdrop, we concluded the HOPE100 long-term vision one year ahead of schedule and launched the new long-term vision "Vision 110" and the medium-term business plan "Vision 110 –Stage1–" in April 2023.

Going forward, we will vigorously pursue the long-term vision "Vision 110," based on our corporate philosophy, and work earnestly to achieve both corporate growth and a sustainable society.

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

August 2023



The Kyorin Group marked the 100th anniversary of our founding on June 16, 2023.

We would like to express our sincere gratitude to the stakeholders who have supported us during that time. Over the next 100 years, we will aim to make even greater strides.

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## **Kyorin Group's** 100-Year History

#### Management-related events

1931 Kyorin Chemical Laboratory was established.

1940 Kyorin Chemical Laboratory was renamed KYORIN Pharmaceutical

1947

Kyorin Yakuhin Co., Ltd. was organized.



Toyo Shinyaku Sha



The Okaya Plant was



1962 Kyorin Chemical

1960



1970

1980

1990

KYORIN Pharmaceutical Co., Ltd. and Kyorin Yakuhin Co., Ltd. were merged.



was opened.

## 1996

Nisshin KYORIN Pharmaceutical Co., Ltd. was established.

#### 1998 Milton was acquired.

1999 Listed on Second Section of the Tokyo

Stock Exchange

2000

Transferred listing to First Section of the Tokyo Stock Exchange.

Kyorin USA, Inc. was established (dissolved in March 2020).

## 2002

Kyorin Europe GmbH was March 2023).

ActivX Biosciences, Inc. became a wholly owned subsidiary (dissolved in March 2023).

Toyo Pharma Co., Ltd. (present KYORIN Rimedio Co., Ltd.) was acquired, and generic drugs business entered.

1995-2009

MIC plan

Shifted to pure holding company structure.

2010

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

Net sales reached ¥100 billion. Trade name changed to KYORIN Holdings, Inc.

KYORIN Pharmaceutical Group Facilities Co., Ltd. was established.



WATARASE Research Center was established.

2010-2022

HOPE100

KYORIN Pharmaceutical Co., Ltd. carried out an absorption-type merger of jTAS (entry to diagnosis business).

#### ${\sf Takaoka\ Pharmaceutical\ Technology\ Innovation\ Center\ was\ established}.$

2021

was launched.

2022

Lyfnua was

launched.

KYORIN Pharmaceutical Group Facilities

2023

Transferred to Prime

Market of the Tokyo Stock

100th anniversary

Co., Ltd., shift to

to KYORIN

business holding

Merger by absorption of

KYORIN Pharmaceutical

company structure, and

change of trade name

Pharmaceutical Co.,

2022

Exchange.

2023

2020

## Strategy/ Concept

#### Founding-1994

Building a corporate foundation with research and development, manufacturing, and sales functions

With the aim of contributing to people's health, KYORIN Pharmaceutical was established as Toyo Shinyaku Sha in 1923 and began manufacturing and selling injection-type medicines. During the 1960s, we built a structure for the research and development of new drugs, and since then, we have continued to contribute to people's health through the research and development, manufacture, and sales of original, new medicines. We marked the 100th anniversary of the Group's founding in 2023 and will continue to grow as a company that makes a wide-ranging contribution to people's health.



launched. Deamelin-S was launched.



1961 Behyd was







1971 Cholexamin was

1970



1981 Mucodyne was launched.

1980

1980 Norfloxacin was licensed to Merck & Co.



1996

Pentasa was launched

Gatifloxacin was

licensed to Bristol-Myers Squibb.

1989 Ketas was launched





1984

Baccidal was

1993

# healthcare-contributing force

Aiming to be an original and significant Aiming to be recognized both within and outside as a company that supports sound and healthy lifestyles

## Vision 110

Lasvic IV drip infusion kit

2023-



2007 Uritos was launched.



Milton was launched



Kipres was



Gatiflo was launched.



2001



2019

GeneSoC was

launched.

2018 Beova was

2016 Desalex was launched.

2013



Rubysta was



Fiscal 2023 net sales (forecast)



¥116.2 billion



Megalocin was launched. 2010 2023 2020

**Product history** 

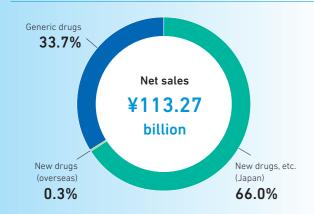
1923

1960

#### Overview of the Kyorin Group

The Kyorin Group, which comprises the business holding company KYORIN Pharmaceutical Co., Ltd. and subsidiaries KYORIN Rimedio Co., Ltd. and KYORIN Pharmaceutical Group Facilities Co., Ltd., is engaged in a pharmaceutical products business primarily consisting of ethical drug products. The new drugs business creates original, new drugs and develops, manufactures, and sells other pharmaceutical products, and also sells products related to environmental hygiene and the diagnosis of infectious disease, as well other products including general pharmaceuticals. The generic drugs business develops, manufactures, and sells proprietary generic drugs and, working with the new drugs business, strives to provide a stable supply of high-quality, highly reliable products.

#### Net sales breakdown (fiscal 2022)



#### Operating profit

¥5,123 million

Profit attributable to owners of parent

¥4,723 million

Total assets

¥176,045 million

Net assets

¥125,461 million

Basic earnings per share

¥82.44

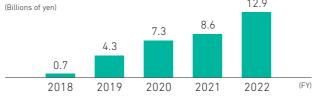
#### Beova



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

Overactive bladder treatment market: ¥89 billion Market share in fiscal 2022: 16.7%

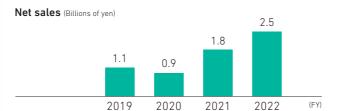
## Net sales (KYORIN Pharmaceutical sales portion)





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

#### Oral antibacterial agent market: ¥60.5 billion Market share in fiscal 2022: 4.0%



#### Environmental hygiene products

#### Milton

Disinfectant for baby bottles and bottle nipples Hand disinfectant Disinfectant spray



#### Rubysta

Multipurpose disinfectant

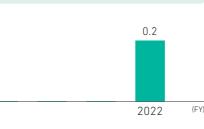
## **Primary Examples of New Drugs**

#### Lyfnua

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

Estimated number of patients (estimate based on morbidity rate) Number of refractory cough patients: approx. 2.5 million, including 0.4-0.5 million with refractory chronic cough

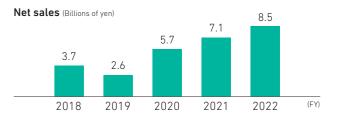
#### Net sales (Billions of yen)



#### Desalex

Antiallergic agent General name: Desloratadine Released: 2016

#### Antihistamine market: ¥122 billion Market share in fiscal 2022: 8.1%



## Flutiform



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

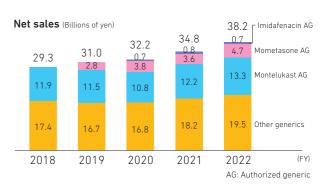
#### ICS/LABA combination drug market: ¥85.6 billion Market share in fiscal 2022: 16.0%



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## **Generic Drugs**





## General medical devices, pharmaceuticals for in vitro diagnostics, etc.



#### GeneSoC

Research-use devices Research-use reagents General medical devices Pharmaceuticals for in vitro diagnostics

# Message from the President Yutaka Ogihara Representative Director, President and Chief Executive Officer Pursuing new challenges based on the long-term vision "Vision 110," we will build a foundation for continuous growth

# One hundred years after our founding, the Kyorin Group's unchanging mission is to "contribute to better health"

The Kyorin Group marked the 100th anniversary of our founding in June 2023. Hiroshi Ogihara, Kyorin's founder and my grandfather, decided to go into business to help many sick people at the same time by manufacturing and selling medicines. He founded Toyo Shinyaku Sha, the predecessor of KYORIN Pharmaceutical Co., Ltd., in Omori-ku, Tokyo (part of today's Ota-ku, Tokyo), in 1923. That was the beginning of the Kyorin Group. Established as Tokyo was recovering from the Great Kanto Earthquake, the company has continued through the Taisho, Showa, Heisei, and Reiwa periods, though that path has by no means been smooth. We therefore made steady progress one step at a time through the efforts of my predecessors and approached our 100th anniversary with deep emotion. I would like to express our sincere gratitude to everyone who has assisted and supported the Kyorin Group to date.

The idea of wanting "to contribute to better health" goes back to the time of the Kyorin Group's founding and continues today in our corporate philosophy of "fulfilling our mission of cherishing life and benefiting society by contributing to better health" and our corporate message of "Your Health is Kyorin's Mission."

The slogan for our 100th anniversary is "Wishing you good health for the next 100 years." That time frame, which is neither a goal nor a checkpoint, instead expresses a new starting line and incorporates our strong desire to contribute anew to people's health for the next 100 years. The Group's senior management, myself included, will use this opportunity to work even harder toward the Kyorin Group's continuous growth and development as we enter this next stage.



## Transforming the Group's structure and formulating a new longterm vision and a new medium-term business plan in fiscal 2023

In fiscal 2023, the 100th anniversary of our founding, and as a response to the drastic changes the Kyorin Group is currently experiencing, we have transformed the Group's structure with the aims of strengthening our business promotion functions and increasing management efficiency. Specifically, we have absorbed our main operating company, KYORIN Pharmaceutical Co., Ltd., into KYORIN Holdings, Inc., shifting from a pure holding company structure to a business holding company structure, and changed our trade name to "KYORIN Pharmaceutical Co., Ltd."

Over the past few years, our external operating environment has seen a further strengthening of measures to hold down expenses for medical treatment and medicines, including through annual NHI drug price revisions (mid-year revisions). Also, the spread of coronavirus infections unexpectedly caused people to refrain from seeking medical treatment, making the environment even more challenging. At the same time, despite this external environment, we believe our internal environment has entered a period of growth, with new drugs expected to drive growth in place and new businesses including diagnostics being on track.

Against this backdrop, we formulated the new long-term vision "Vision 110" and the new medium-term business plan "Vision 110 – Stage 1–" and began operating under them in April 2023.

## Review of the medium-term business plan "HOPE100 -Stage 3-"

The medium-term business plan "HOPE100 -Stage 3-," which concluded in fiscal 2022, set targets to be achieved through five business strategies and an organizational strategy. A review of these initiatives shows that in one of the business strategies, "shift to business based on the proposal of solutions and accelerate the growth of the new drugs group," we set a target of having new drugs account for at least 50% of net sales, and during the period covered by the plan, we launched a succession of new drugs including the Lasvic IV drip infusion kit, Zymso, and Lyfnua. However, because of factors including a market contraction caused by the COVID-19 pandemic, we were unable to achieve sizeable growth in main products, and the ratio of new drugs in fiscal 2022 fell short of our target, at 42.0%. For "enhancing the pipeline to support medium-term growth," we concluded four inlicensing contracts, but our current development pipeline cannot be considered sufficient. To "strengthen drug discovery capability to realize the creation of innovative new drugs," our proprietary KRP-A218 began clinical trials in the United Kingdom in fiscal 2021. At the same time, after outlicensing the agonist FPR2 to Bristol-Myers Squibb Company of the United States, we were expecting it to become a major out-licensed product, but unfortunately the development right was returned as part of BMS's development strategy. For "improving cost competitiveness," we have developed and launched an annual average of six ingredients as generics newly added to the drug price list, as planned. To "expand overseas revenue," we successfully concluded five out-licensing agreements including those for Vibegron and Lascufloxacin. Regarding our target of a "compound annual growth rate (CAGR) for net sales of at least 5%," we finished the plan with a rate of 1%, and for "operating

#### Long-term vision



#### Vision for 110th anniversary

#### Our goal

A company that contributes broadly to people's health by comprehensively developing healthcare-related businesses, with a core focus on the new drugs business, which continuously provides high-value new drugs that meet medical needs

profit before deduction of R&D expenses of at least 20% of net sales," we reached 14.2%. We take these results very seriously and will aim for continuous growth under the new long-term vision.

# Proactively pursuing the medium-term business plan "Vision 110 -Stage1-"

The long-term vision "Vision 110" sets out our blueprint for the next 10 years, through the 110th anniversary of our founding. In addition to incorporating the concept and DNA of creating high-value new drugs to contribute to people's health, which we have achieved since our founding, the new long-term vision clarifies the issues we have faced to date and draws a new corporate image.

The new vision sets a goal of being "a company that contributes broadly to people's health by comprehensively developing healthcare-related businesses, with a core focus on the new drugs business, which continuously provides high-value new drugs that meet medical needs" and divides the period covered into three segments (Stage 1: fiscal 2023–25; Stage 2: fiscal 2026–29; Stage 3: fiscal 2030–32). The statement for the medium-term business plan "Vision 110 –Stage1–" is "transforming to a business structure to realize Vision 110." Against the backdrop of an extremely challenging business environment, this is the objective we definitely want to achieve.

We will pursue the following five initiatives under Stage 1.

# Strengthening drug discovery capability to create high-value new drugs that meet medical needs

renovated our organizational structure to pursue new initiatives by establishing a new Innovation Research Laboratory to strengthen the functions of our disease research and drug discovery technologies, and a new Research Planning Department to formulate overall drug discovery themes and expand cooperation with external organizations. In addition to strengthening basic technology, we will pursue new, high-value themes and the creation of high-value new drugs drugs that address medical needs. Regarding drug discovery technologies, in addition to small molecule drug discovery,

we will use nucleic acid drug discovery and new external technologies. In disease research, we will

focus on the fields of fibrosis, immune and inflammatory disorders, and other diseases.

We will pursue innovation in drug discovery under a new drugs discovery strategy. For this, we have



## 2 Expanding development pipeline through in-licensing

Expansion of the development pipeline is an urgent issue for the Kyorin Group. We have established a new Business Development Headquarters to significantly strengthen our acquisition of in-licensed products and accelerate our evaluation and acquisition of in-licensed products. In addition to expanding our modalities and disease areas for in-licensing and proactively developing a wide range of in-licensing activities, we will step up investment and hiring with a target of acquiring at least six in-licensing products during Stage 1. In addition, in the field of otolaryngology, we are moving forward with development of the KRP-DT123 tinnitus treatment and steadily pursuing DTx (digital therapeutics) development.

## Maximizing the ratio of new drugs

Growth in new drugs is the driver of higher sales and profit, and we aim to accelerate as much as possible the growth of new drugs and maximize their market penetration. We envision the combined sales of five new drug products growing to roughly ¥20 billion by fiscal 2025 and will work to accelerate their market penetration for rapid growth. At the same time, we will continuously strengthen our quality and supply chain management to offer a stable supply of high-quality pharmaceuticals. In addition, as we handle new modalities, we will build quality control structures and supply chains as appropriate to deal with them.

# 4 Promoting healthcare-related businesses that have synergies with the new drugs business

For the continuous growth of the generic drugs business, we are increasing our development capabilities for generics newly added to the drug price list and accelerating growth with a focus on additional listings. Also, we intend to strengthen Groupwide production capacity and offer stable supplies when the Takaoka Plant, currently under construction, commences full-capacity operations, while lowering production costs. In the infection-related business, we will promote popularization of the diagnostics business and the Rubysta and Milton product lines. We also intend to strengthen our reliability assurance system to support comprehensive business development.

## Building a sustainable corporate foundation

We will promote cost optimization Groupwide in response to changes in the business environment. To bolster human capital, we will revise our human resources system, introduce measures to enhance career fulfillment, and work on human resources development, while promoting health management and striving to maintain and improve employees' health. In areas including the environment, compliance, and governance, we will pursue measures appropriate for a TSE Prime Market-listed company. For reducing CO<sub>2</sub> emissions, for example, we have set a clear target to be achieved by fiscal 2030. We will steadily pursue these initiatives to build a sustainable corporate base that addresses social issues and the needs of the times.

#### ■ Performance target for fiscal 2025

We have set the following numerical performance targets for growth potential and profitability.

- Growth potential: Net sales CAGR At least 2.0%
- Profitability: Operating profit before deduction of R&D expenses (operating profit + R&D expenses) At least 16.0%

Our basic capital policy is to improve capital efficiency through investment for growth and shareholder returns, while maintaining a sound financial base with an ongoing awareness of the cost of capital and return on capital.

For returns to shareholders, we will maintain a stable dividend, taking into consideration the dividend on equity (DOE) ratio.

# Aiming for growth by implementing new measures in fiscal 2023, the first year under the new medium-term business plan "Vision 110 –Stage1-"

Fiscal 2023 is important as the first year under the new medium-term business plan. Our management policy is the "reform of business structure and growth from new initiatives." In addition to accelerating growth driven by new drugs, we will address the urgent issue of expanding the development pipeline. I believe the Kyorin Group exists to create high-value new drugs that address medical needs and to contribute to better health. While continuously pursuing the challenge of drug discovery and innovation is important from a long-term perspective, significant time and costs are required for the results of drug discovery to materialize. We also recognize that it will be difficult to have a sufficient development pipeline going forward with proprietary drugs alone. Therefore, until we have a full lineup of in-house products, we will proactively pursue a wide range of in-licensing activities while investing and increasing personnel to significantly strengthen in-licensing capabilities, with a primary focus on expanding the development pipeline. At the same time, now that we have a full lineup of new drugs to drive growth, we will strive to accelerate growth and raise profitability while continuing to improve cost competitiveness, as we step up measures to build a solid corporate base with a sense of speed.



# Proactively addressing sustainability issues through our business activities

Acting on our corporate philosophy, the Kyorin Group is proactively addressing sustainability issues (for the continuous development of both the Company and society) through business activities based on our Corporate Charter, an approach that we believe will lead to enhanced corporate value over the medium to long term. Therefore, under our long-term vision and medium-term business plan, our business development includes strengthening our financial base, effectively using human capital and other resources, and enhancing corporate governance.

The Company's Board of Directors has six members, including three outside directors, and in principle meets monthly to pass resolutions on legally required matters, formulate and decide important management issues and strategies, and oversee operational execution. Calls to strengthen the business management structure have been growing recently. As a means to enhance corporate governance, in fiscal 2023, we designated chief X officers (CxOs) from among directors and corporate officers in key operational areas to confer with the Management Committee on important matters related to the Company's and Group companies' operational execution.

For matters related to sustainability, we have identified 10 important issues to be addressed as materiality through our medium- to long-term business activities from the perspectives of "value creation (issues directly connected to our business activities)" and "a foundation to support value creation (issues related to the foundation of our business activities)." We will focus on addressing these issues under the long-term vision "Vision 110" and the medium-term business plan "Vision 110 –Stage1-."

Environmental consideration in our business activities, including responses to climate change, is a particularly important materiality, and following our basic policy on sustainability, we carry out business activities with constant awareness of their effect on the global environment and the environments of local communities. We have established an Environmental Committee, chaired by the corporate officer in charge of General Affairs, to implement and promote environmental measures including ones addressing climate change, as a structure to examine environmental measures. The committee identifies and evaluates risks and opportunities related to climate change and comprehensively considers how to respond, with initiatives addressing climate-related issues part of the management strategy. Specifically, we have set a target of reducing CO<sub>2</sub> emissions 46% from the fiscal 2015 level by fiscal 2030, as we pursue the challenge of achieving carbon neutrality by 2050.



Reflecting our founder's idea that "a business is as good as its people" and believing that employee growth is the driving force that supports the strengthening of our business, we are working to enhance our human capital. We also consider it important for all employees to respect the human rights of all people and to act with high ethical consideration. We therefore maintain workplace environments where the diversity, character, and individual characteristics of all employees are respected, where their health is taken into consideration, and where they can work comfortably and safely. Enhancing human capital means prioritizing employees and invigorating people and organizations. We recognize this as an important issue for producing results by excuting our business strategy. The Kyorin Group is working to optimize operations with a basic policy for human resources management that views employees and the Company as partners who continue to fulfill the responsibilities expected of each other over the long term and achieve mutual benefits (with employees contributing to the Company, and the Company enriching employees' lives and contributing to their self-fulfillment). To promote work-style reforms and the active participation of female employees, we have set a target of having women hold 15% of management positions by 2030 and are implementing plans to have male employees use at least 50% of their authorized childcare leave by fiscal 2025.

# Valuing our founding spirit as we strive to enhance medium- to long-term corporate value

The Company policy and Company motto of the Kyorin Group spell out our founding spirit, *Honryo*, which covers the Company's mission and purpose, employees' mental attitudes, and standards of conduct. With fiscal 2023 being the 100th anniversary of our founding, we are returning to our origin with a new starting point for the next 100 years by instilling our *Honryo* founding spirit internally and as the basis of our business activities. The Kyorin Group places the highest priority on "health," an important theme for all people. Going forward, we will aim to be a company that contributes to people's health, while making every effort to achieve the long-term vision "Vision 110" with unshakeable conviction as we strive to enhance corporate value over the medium to long term.

I ask for the continued support of all our stakeholders.

#### **Value Creation Process**

Following our corporate philosophy that states "Kyorin continues to fulfill its mission of cherishing life and benefiting society by contributing to better health," the Kyorin Group is carrying out business activities aligned with our newly formulated long-term vision, medium-term business plan, and designated materialities (important issues). With a new drugs business that continuously provides high-value new drugs to meet diverse medical needs as our core business, we are comprehensively

developing health-related businesses to realize corporate growth and address social issues, while also striving to create value by sharing the successes of those efforts with all stakeholders. Through this ongoing value creation process, we aim to achieve a sustainable society and enhance corporate value.

#### Social value External Corporate Philosophy Kyorin continues to fulfill its mission of cherishing life and benefiting society by contributing to better health. provided by Kyorin environment Social environment Long-Term Vision "Vision 110" **Invested capital** Decreasing birthrate Meet medical needs through and aging population the creation and sale of new Growing geopolitical drugs (enhance quality of life **Products and services** Medium-Term Business Plan "Vision 110 -Stage1-" (2023-2025) meet unmet medical needs) · Calls for companies to Human capital · Promote activities based on the address sustainabilityproposal of solutions to help Business strategies related issues · Employees who will resolve issues at medical facilities Cultivation of the next drive arowth Provide stable supply of Performance Numerical targets (consolidated basis) generation Comfortable working high-quality pharmaceuticals 1. Strengthening drug discovery capability to create high-value new drugs that meet medical needs New drugs targets Net sales CAGR Progress in work-style through compliance with systems and 2. Expansion of development pipeline through in-licensing reforms relevant laws and risk environments, respect Operating profit before deduction of R&D expenses management for human rights 3. Maximization of the ratio of new drugs Medical environment · Provide, collect, and transmit (Operating profit + R&D expenses) 4. Promoting healthcare-related businesses that have synergies with the new drugs business information to promote Promotion of measures · Capital policy and shareholder returns appropriate use of to curtail medical care Intellectual capital 5. Building a sustainable corporate foundation pharmaceutical products and pharmaceutical · Contribute to community- Technologies, costs amid tight public based healthcare Generic drugs **Business activities** finances for medical expertise and organization for new Suppliers drug discovery · Advances toward Pharmaceutical business Value chain · Coordinate with suppliers and individualized medical care and fields of share information to create Drug discovery P.26 Development P.26 Manufacturing P.32 Marketing P.30 New drugs \_\_\_\_\_P.26 stable supply structure specialization Manufacturing Research-use devices/ Procure responsibly In-licensing P.28 Increasing needs for general medical devices • Ensure fair and free competition diagnostics and Generic drugs P.34 Reliability assurance P.36 Human resources P.50 Corporate governance P.60 Production structure Pharmaceuticals for in prevention in addition that provides a stable to treatment vitro diagnostics supply of high-quality • Changes in ways • Promote environmental Kyorin's strengths (top section) and weaknesses (bottom section) products information should be conservation initiatives to provided to medical reduce environmental impact · Research capabilities and use of open innovation for fibrosis and immunity and inflammatory disorders • Strong presence in designated fields (respiratory, otolaryngology, and urology) facilities · Create a vibrant society by Social and related Digital transformation • Development capabilities in designated fields (knowledge, expertise and experience, personal connections and networks) • Manufacturing structure able to address diverse needs contributing to local Environmental (DX) in medical care communities and promoting hygiene products public awareness of health • Insufficient experience and inadequate R&D pipeline in new modalities Pharmaceutical Various partnerships Need to strengthen corporate foundation (enhancement, training, effective use of human Relationships of trust environment · Limited investment in R&D capital, and cost optimization) with stakeholders Increasing · Address employee welfare sophistication and and work-style reforms to difficulty of drug **Environmental** Kyorin's sustainability discovery capital workplaces Diversification and Provide opportunities for Addressing sustainability issues P.42 Materiality P.22 increased complexity Resources used based training and education of drug discovery on environmental Create workplace Value creation Foundation to support value creation • Sustainability in business activities P.45 modalities management system environments for career Materiality directly connected to Materiality related to foundation of business activities • Fair and honest business activities P.48 Increasing desire for business activities 4. Enhance human capital assurance of • Enhancing human capital P.50 5. Promote work-style reforms that respect diverse values pharmaceutical Financial capital 1. Create high-value new products that • Living in harmony with society P.54 manufacturers' 6. Promote health management meet medical needs • Disclose information promptly reliability Solid financial base • In harmony with the environment P.56 7. Perform environmentally friendly business activities 2. Maximize value of products and appropriately Increasing calls for 8. Ensure thorough compliance • Corporate governance P.60 3. Provide a stable supply of highstable supply of quality pharmaceutical products 9. Strengthen corporate governance pharmaceuticals · Engage in constructive dialogue 10. Strengthen relationships with stakeholders

Reinvest to enhance corporate value

KYORIN Pharmaceutical Co., Ltd. | Integrated Report 2023

The Kyorin Group formulated the long-term vision "Vision 110" with a view 10 years into the future, when we will mark the 110th anniversary of our founding. We will pursue business strategies toward attaining our goal of being "a company that contributes broadly to people's health by comprehensively developing healthcare-related businesses, with a core focus on the new drugs business, which continuously provides high-value new drugs that meet medical needs."

#### Long-term vision



#### Vision for 110th anniversary

#### Our goal

A company that contributes broadly to people's health by comprehensively developing healthcare-related businesses, with a core focus on the new drugs business, which continuously provides high-value new drugs that meet medical needs

#### Term

10 years: Fiscal 2023-2032

#### Medium-term business plan

#### Stage1

Fiscal 2023–2025

#### Stage2

Fiscal 2026-2029

#### Stage3

Fiscal 2030-2032

The period covered by the long-term vision "Vision 110" is divided into three stages, and we are working to achieve the targets of those stages.

#### Medium-term business plan

Transforming the business structure to realize Vision 110



The Statement for the Vision 110 -Stage1- is "transforming the business structure to realize Vision 110." We will pursue the following five business strategies to reach our performance targets and improve support and evaluations from stakeholders.

- 1 Strengthening drug discovery capability to create high-value new drugs that meet medical needs
- 2 Expansion of development pipeline through in-licensing
- 3 Maximization of the ratio of new drugs
- 4 Promoting healthcare-related businesses that have synergies with the new drugs business
- 5 Building a sustainable corporate foundation

#### Strategic image of medium-term business plan Stage 1 (Fiscal 2023–2025) Stage 2-3 Strengthen the drug discovery capability to create high-value new drugs **Drug discovery** that meet medical needs Pursue drug innovation through new drug discovery strategies Reorganization Creation of new drugs from long-term perspective

#### New drugs business

**business** 

In-licensing

## Expansion of development pipeline through in-licensing

- Significantly strengthen in-licensing capability
- Promote DTx development

estment of resources Enhancement of development pipeline

## Maximization of the ratio of new drugs

- Marketing, SCM, Maximize the expansion of new drugs Reliability
  - Ensure the stable supply of high-quality drugs



## Driving force of revenue Maximization of profitability

assurance

## Healthcarerelated

- Generic drugs business
- Achieve sustainable growth in the generic drugs business Strengthen production capacity for pharmaceuticals and reduce manufacturing costs



Other business

Promote infectious disease-related business



	Performance targets for fiscal 2025		
Perforr	nance targets (consolidated	basis)	Capital policy and shareholder returns
Growth potential	Net sales CAGR	At least 2%	Our capital policy is to improve capital efficiency through investment for growth and shareholder returns,
Profitability	Operating profit before deduction of R&D expenses (operating profit + R&D expenses)	At least 16%	while maintaining a sound financial base. Regarding shareholder returns, we will continue stable dividends, taking into account the dividend on equity (DOE) ratio.

1 Strengthening drug discovery capability to create high-value new drugs that meet medical needs

#### Pursue drug innovation through new drug discovery strategies

- In addition to drug discovery targeting diseases with low drug effectiveness, use new technologies to create drugs for existing treatments that have issues
- > Integrate drug discovery technologies and disease research to create high-value, new drugs
- > Regarding drug discovery technologies, use nucleic acid drug discovery and new external technologies in addition to small molecule drug discovery
- > Regarding disease research, focus on lung fibrosis, immune and inflammatory disorders, and other diseases

## 2 Expanding development pipeline through in-licensing

#### Significant strengthening of in-licensing capabilities

- > Expand the scope of modalities and therapeutic areas for potential in-licensing, engage in wide-ranging in-licensing activities
- > Increase investment in capital and human resources

#### DTx development

- > Steadily pursue development of medical-use apps in field of otolaryngology
- 3 Maximizing the ratio of new drugs

#### Maximization of new drug penetration

Increase impact of detailed information through in-person meetings, accelerate growth of new drugs to maximum extent possible

#### Stable supply of high-quality pharmaceutical products

- > Strengthen procurement and management of products, raw materials, etc. (supply chain management)
- > Strengthen quality management in accordance with GQP\*
- > Build quality control structures and supply chains for new modalities as appropriate

## 4 Promoting healthcare-related businesses that have synergies with the new drugs business

#### Achieve sustainable growth in the generic drugs business

- > Enhance the capability of generic drugs development and accelerate growth business
- > Strive to ensure stable supply by enhancement of manufacturing and SCM structure
- > Develop low-cost system throughout business environment

# Strengthen production capacity for pharmaceutical products and reduce manufacturing costs

- > Maximize manufacturing capability by ensuring reliable operation at Takaoka Plant and optimizing each plant
- Improve reliability and maintain stable manufacturing by raising the level of GMP\*2
- > Cost reduction by improvement activities

#### Promote infectious disease-related business

- > Develop diagnostics business for future with enhancement in IVD\*3 area
- > Spread Rubysta and Milton brands

# Strengthen reliability assurance structure to support comprehensive business development

- > Strengthen pharmaceutical-related legal and regulatory compliance structure
- > Quickly and accurately address environmental changes involving reliability assurance

#### 5 Building a sustainable corporate foundation

#### Improve cost competitiveness

> Cost optimization throughout business environment

#### Enhance human capital

- > Human resources development for people leading Vision 110
- > Revision of human resources system to improve career fulfillment
- > Promote work-style reforms to meet diverse values
- > Promote initiatives for health management and work to maintain and promote employee health

#### Respond to environmental issues, compliance, governance, etc.

- > Set target of cutting CO2 emissions by 2030 and commit proactively to reach it
- > Abide by all laws, regulations, codes of conduct, and the spirit thereof and act with high ethical standards for thorough compliance
- > Strengthen corporate governance
- > Appropriate actions to stakeholders

<sup>\*1</sup> GQP: Good Quality Practice

<sup>\*2</sup> GMP: Good Manufacturing Practice

<sup>\*3</sup> IVD: Pharmaceuticals for In Vitro Diagnostics

### Materiality

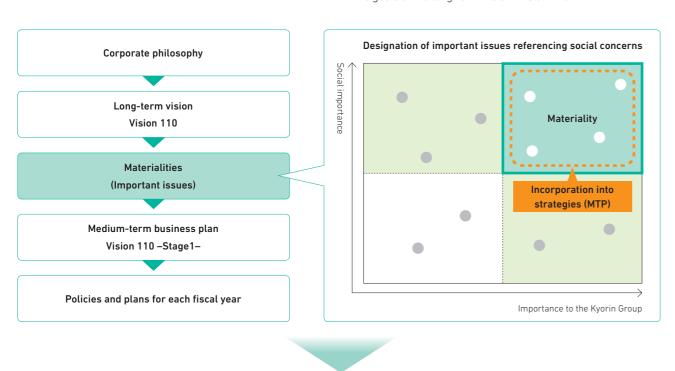
Under the new long-term vision "Vision 110 (fiscal 2023–32)" to realize our corporate philosophy, the Kyorin Group aims to be "a company that contributes broadly to people's health by comprehensively developing healthcare-related businesses, with a core focus on the new drugs business, which continuously provides high-value new drugs that meet medical needs." To achieve this goal, we need to create both social value and economic value, and consider it important to grow as a company and also contribute to realizing a sustainable society. We have formulated a basic policy for addressing sustainability issues, have designated materialities (important issues), and will appropriately address them.

#### Basic policy on sustainability

As per our corporate philosophy, the Kyorin Group is proactively addressing sustainability issues for society's continuous development through business activities based on our Corporate Charter, as we work to enhance corporate value over the medium to long term.

#### Designation of materiality

Using a matrix with one axis representing social importance and the other axis standing for importance to the Group, we have designated 10 items as materiality from among the various issues related to sustainability. We will place a priority on addressing these issues from the perspective of "value creation (issues directly connected to business activities)" and the perspective of a "base to support value creation (issues related to a base for business activities)" as we work to achieve the goals of the long-term vision "Vision 110."



Value creation materiality

- Creating high-value products that meet medical needs
- Maximizing value of products
- $\bullet$  Providing a stable supply of high-quality pharmaceutical products

Base to support value creation materiality

- Enhancing human capital
- Promoting work-style reforms that respect diverse values
- Promoting health management
- Carrying out environmentally friendly business activities
- Ensuring thorough compliance
- $\bullet \ \mathsf{Strengthening} \ \mathsf{corporate} \ \mathsf{governance} \\$
- $\bullet \ {\it Strengthening relationships with stakeholders}\\$

#### 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.

#### Materiality

матегіа	,			
		Materiality	KPI	Related SDGs
	V;	Creating high-value products that meet medical needs	Clinical development milestones     Number of in-licensed products	
	Value creation	Maximizing value of products	Ratio of new drugs     Sales of main products	3 monthstating 9 according to the state of t
	ation	Providing a stable supply of high- quality pharmaceutical products	Number of stockouts     Number of product recalls     On-track progress at Takaoka Plant (qualitative)	
		Enhancing human capital	Main scores from job satisfaction surveys     Appropriate operation and improvement of human resources system (qualitative)	
Corporate philosophy	8	Promoting work-style reforms that respect diverse values	Percentage of management positions filled by women  Percentage of male employees taking childcare leave  Percentage of employees with disabilities	5 ments  S mints when an an an annual services convenience conveni
hilosoph	ase to su	Promoting health management	Percentage of employees undergoing health examinations and stress checks	
¥	Base to support value creation	Carrying out environmentally friendly business activities	• Percentage reduction of CO <sub>2</sub> emissions	7 superiors 12 monoral mentions of the control of t
	ion	Ensuring thorough compliance	Number of significant compliance violations	
		Strengthening corporate governance	Appropriate response to Corporate Governance     Code (qualitative)	16 MAN READS
		Strengthening relationships with stakeholders	Stronger engagement with investors (qualitative)	

KYORIN Pharmaceutical Co., Ltd. 1 Integrated Report 2023

#### Message from Executive in Charge of Finance

Managing with a constant awareness of the cost of capital and return on capital, while working to increase capital efficiency through proactive investment for growth and shareholder returns

Yasuji Kurose

Corporate Officer CStO & CFO
Director of Corporate Planning, in charge of Product
Strategy and Finance & Accounting



As the Kyorin Group's CFO, I believe my role is to invest proactively for the future while maintaining a sound financial base, and to continuously enhance both corporate value and shareholder value.

Two fundamental ways of thinking underpin our financial strategy under the medium-term business plan "Vision 110 –Stage1–": (1) increase capital efficiency through investment for growth and shareholder returns, with a constant awareness of the cost of capital and return on capital, while maintaining a sound financial base; and (2) maintain a stable dividend, taking into account the dividend on equity (DOE) ratio. The medium-term business plan also sets numerical targets for growth and profitability at a compound annual growth rate of at least 2% for net sales and operating profit before deduction of R&D expenses (operating profit + R&D expenses) of at least 16%.

Regarding the financial base, the large investment required for new drug development at a pharmaceutical company carries significant risks, and business results are significantly affected by factors like the expiry of patents. Therefore, I believe that maintaining a solid financial base is essential for the Company's continued existence. As of March 31, 2023, the Kyorin Group's total shareholders' equity ratio was a healthy 71.3%, and we will proactively

Shareholders' equity ratio



invest for growth while maintaining this sound position. As we make investments for growth, we will procure funds externally as needed to seize medium- to long-term growth opportunities when they arise.

For the cost of capital and return on capital, the Tokyo Stock Exchange is requesting that companies with a price-book value ratio (PBR) of less than 1x carry out management with an awareness of the cost of capital and return on capital. The Kyorin Group's return on equity (ROE) for fiscal 2022 was 3.8%, which I do not view as sufficient. Under the medium-term business plan, we will strive for a continuously higher return on capital by maximizing the ratio of new drugs and improving our cost competitiveness.



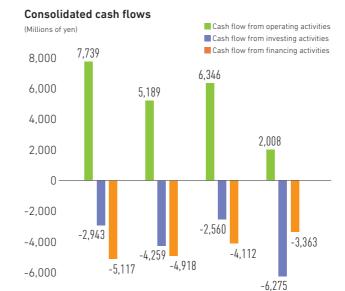
Regarding investment for growth, we are working proactively to strengthen our drug discovery capabilities, expand our development pipeline through in-licensing, and increase production capacity through capital expenditures. We are forecasting R&D expenses of ¥9.6 billion in fiscal 2023, a ¥1.3 billion decrease from the previous year's level, which in part reflects a falloff in the wake of advances made in the development pipeline through fiscal 2022. Since our results forecast for fiscal 2023 does not include acquisition

costs for new in-licensed products, R&D expenses could be significantly higher depending on in-licensed items. We are also forecasting capital expenditures of ¥5.9 billion in fiscal 2023, which includes ¥5.0 billion planned for new facilities, including construction expenses for the Takaoka Plant. We will work continuously to maximize production capacity, maintain stable production, and reduce manufacturing costs. Other planned capital expenditures break down as ¥0.5 billion for administrative and sales equipment and ¥0.4 billion for research equipment.

Regarding shareholder returns, despite a drastically changing operating environment, we will maintain a stable dividend level, taking DOE into consideration and preserving a balance between financial soundness and investment for growth. For fiscal 2022, the dividend per share was ¥52, and the DOE ratio was 2.4%.

We maintain cross shareholdings to develop and preserve transactional and business relationships that are deemed to contribute to the Group's sustainable growth and enhance corporate value. If the significance of these shareholdings is determined to have diminished, however, we intend to reduce those shareholdings as appropriate, through dialogue with the issuer. During fiscal 2023, we reduced the number of issuers in which we hold cross shareholdings by two, in the amount of ¥1,897 million (compared with the balance sheet amount as of April 1, 2022). We will continue to appropriately reduce our cross shareholdings from the standpoint of capital efficiency.

Drastic changes in the external environment, including annual NHI drug price revisions, are significantly affecting



3/2021

3/2022

3/2023





#### Capital expenditures



the Kyorin Group's net sales and profit levels. We believe that maximizing the new drugs ratio and enhancing our cost competitiveness are of the greatest importance for achieving our targets for growth and profitability in this environment. In terms of maximizing the ratio of new drugs, we expect sales to grow in fiscal 2023 with new drugs that are expected to drive growth in place and markets for main products that had contracted during the COVID-19 pandemic to recover. We are planning for sales of five new drugs to boost net sales roughly \u20 billion by fiscal 2025, the final year of the medium-term business plan, and are aiming for a new drugs ratio of at least 50%. To enhance our cost competitiveness, all divisions Groupwide are implementing thorough cost reductions as we work to decrease the consolidated ratio of SG&A to net sales (excluding R&D expenses).

Recognizing the importance of proactively investing for growth while maintaining a sound financial base and managing with a constant awareness of the cost of capital and return on capital, we aim to achieve the medium-term business plan to continuously enhance both corporate value and shareholder value.

-8,000

3/2020

#### **New Drugs Business**

# **Drug Discovery and Development**

#### Changing environment (internal and external)

- Increasing sophistication and difficulty of drug discovery
- Diversification and complexity of drug discovery modalities and basic technologies
- Evolution and proliferation of digital technologies
- Expansion of the healthcare field with the entry of companies from different industries
- Growing concern about social security costs and moves to curb them

#### **Opportunities**

- Development of basic research technologies to increase drug discovery research opportunities
- Acceleration of research through activation of open innovation
- Use of big data and AI to streamline R&D
- Increase in new treatment options thanks to digital technologies
- Increasing importance of drugs with superior medical economy

#### Risks

- Increased use of AI in drug discovery making small molecule drug discovery more efficient (through major cost reductions and shorter development periods), which could weaken our drug discovery advantage
- Megapharmaceutical manufacturers deploying digital technology to increase speed of development
- Further rise in development costs due to stricter clinical trials and stricter approval of new drugs
- Market contraction due to reform of drug pricing system and its impact on business viability

Medium-term business plan

Vision 110 -Stage1- initiatives

#### **Business strategy**

Strengthening drug discovery capability to create high-value new drugs that meet medical needs

#### ■ Pursue drug innovation through new drug discovery strategies

- Engage in drug discovery using novel technologies for existing treatments that have issues, in addition to drug discovery for diseases where drug contribution is low
- Combine drug discovery technologies and disease research to create new high-value drugs
- Drug discovery technologies: Deploy nucleic acid drug discovery and new external technologies, in addition to small molecule drug discovery
- Disease research: Focus on fibrosis, immune and inflammatory disorders, and other diseases



Junichi Ishiyama

Corporate Officer CSO Senior Director of Discovery Research HQs In charge of Intellectual Property

Drug discovery has become increasingly sophisticated and challenging in recent years due to the emergence of various modalities for diverse medical needs. In this environment, the Group urgently needs to pursue drug discovery programs that will progress to the clinical stage. Under the medium-term business plan "Vision 110 -Stage1-," we will use a new drug discovery strategy to take on the challenge of drug discovery innovation, with the aim of "strengthening drug discovery capability to create high-value new drugs that meet medical needs." By combining promising drug discovery targets identified from disease research with the latest drug discovery technologies, we will create new drugs with clinical significance. In addition to small molecule drug discovery, which is our specialty, we will actively utilize nucleic acid drug discovery and new external technologies as new modalities to create new drugs with higher value. For this, we will incorporate superior external technologies with our own technologies and ideas. We will also improve the expertise of our researchers and broaden their perspectives through collaboration with external organizations. In these and other ways, we will work to develop human resources who will play key roles in realizing the long-term vision "Vision 110."

In fiscal 2023, we will strive to initiate and promote high-value research projects and strengthen our drug discovery technologies. At the same time, we will promote multiple development projects based on our development strategy to maximize value and achieve new milestones.

## Initiatives under the medium-term business plan

# Pursue drug discovery innovation through new drug discovery strategies

#### > New drug discovery strategies

In the Group's core business of new drugs, the continuous creation of new drugs is difficult. To address this issue, we need to pursue drug discovery programs and formulate exit strategies for progressing to clinical trials, and we have strengthened our organizational functions to this end.

By combining drug discovery technologies and disease research (drug discovery targets), we will take on the challenge of "drug discovery innovation" to create new value. In the past, we focused on diseases where drug contribution is low (unmet medical needs) and concentrated on drug discovery for those diseases. Under Vision 110 –Stage1–, however, we will work on drug discovery that creates clinical significance by deploying new technologies for existing treatments that have issues.

We have identified fibrosis, immune and inflammatory disorders, and other diseases as our focus areas for drug

discovery research and are working to create and promote new drug discovery programs by advancing disease research in these areas.

## Strengthen collaboration with external organizations and establish research projects

In research on fibrosis, we collaborated with the Department of Drug Discovery for Lung Diseases at the Kyoto University Graduate School of Medicine to build a unique pulmonary fibrosis model and launch a new research project focusing on triggers of fibrosis. We are also collaborating with academia to strengthen our target verification technology. In other areas, we are exploring opportunities for joint research with domestic companies, international companies, and academia. In drug discovery technology, meanwhile, we will build a foundation in nucleic acid drug discovery and utilize external technologies, in addition to reinforcing our capabilities in small molecule drug discovery, one of our strengths. By incorporating not only our own technologies and ideas but also superior external technologies, we will create new drugs with higher value.

Pursuing value creation, we will select and focus on research projects while formulating and verifying exit strategies. In the initial exploratory research stage, our drug discovery activities emphasize target therapeutic profiles (TTPs) and scientific approaches to them. After optimization research into leading compounds, we base our decisions on whether to move forward on target product profiles (TPPs).

#### > Expand development pipeline through in-licensing and formulate development and medical strategies to maximize value

We will strengthen cooperation with relevant departments to speed up evaluation and acquisition of candidates for in-licensing. For development candidates, we will formulate highly distinctive development strategies while being always attentive to novel clinical evaluation methods and therapeutic strategies. Regarding the licensing agreement concluded in January 2020 with U.S.-based aTyr Pharma, Inc. for KRP-R120: efzofitimod (genetic recombination), a fusion protein formulation, we started Phase III multiregional clinical trials in September 2022. Those trials are progressing well.

In November 2022, we concluded an agreement with SUSMED, Inc. for the joint development and marketing of KRP-DT123, a therapeutic application in the field of otolaryngology, a priority area for Kyorin. In this field, we contribute to medical care by providing patients new treatment options based on approaches different from pharmaceuticals. We plan to start specific clinical research using KRP-DT123 to treat tinnitus in fiscal 2023.

As we expand our development pipeline, including for in-licensed products, we expect to diversify modalities and pursue global development. To address them, we will develop our own strategies and strengthen our regulatory function.

#### Development of new research themes

New targets

Known targets: Creating value through technological innovation

Focus areas

 $\bullet \ \mathsf{Fibrosis} \ \bullet \ \mathsf{Immune/inflammatory} \ \mathsf{disorders} \ \bullet \ \mathsf{Others}$ 



#### Strengthen basic technology

Small molecule drugs: Continuous technological enhancement

Nucleic acid medicines: Establishment of basic technology

New technology (Open innovation)

Drug discovery capability to create high-value new drugs that meet medical needs

#### Development pipeline

Code	Stage	Target disease	Mechanism	Remarks
KRP-R120	Ph3	Interstitial lung disease (pulmonary sarcoidosis)	Neuropilin-2 (NRP2) receptor agonist	Origin: aTyr Pharma
KRP-A218	Ph1	Rhinovirus infection that risks becoming severe	PI4KB inhibitor	Origin: In-house
KRP-114VP	Ph1	Overactive bladder	$oldsymbol{eta}$ 3 adrenergic agonist	Origin: Merck Additional pediatric indication for Beova®
AKP-009	Ph2a (conducted by ASKA Pharmaceutical)	Benign prostatic hyperplasia	Novel androgen receptor modulator	Origin: ASKA Pharmaceutical
DTx				
Code	Stage	Target disease	Remarks	
KRP-DT123	Specific clinical research to be conducted	Tinnitus	Therapeutic application (joint development with SUSMED)	

#### **New Drugs Business**

## In-Licensing

#### Changing environment (internal and external)

- Growing needs for diagnosis and prevention in addition to treatment
- · Advances in digital transformation in medicine
- Increasing sophistication and difficulty of drug discovery
- Diversification and complexity of drug discovery modalities
- Depleted development pipeline
- Strong financial base

#### **Opportunities**

- Expansion of technological innovation through open innovation
- Increase in opportunities to collaborate with partners from different industries
- Significant increase in capital and personnel
- Portfolio of therapeutic drugs and products related to diagnosis and prevention
- Growing value of innovative new drugs for rare and intractable diseases

#### Risks

- Surging investments in in-licensing contracts
- Earlier-than-normal recruitment by megapharmaceutical manufacturers
- Lack of human resources with multiple perspectives

Medium-term business plan
Vision 110 -Stage1- initiatives

#### **Business strategy**

Expanding development pipeline through in-licensing

#### ■ Significantly strengthen our ability to acquire in-licensed products

- Expand modalities and disease areas targeted for in-licensing and pursue wide-ranging in-licensing activities
- Increase in-licensing investments and boost investments in organizational reforms and human resources

#### ■ Promote development of digital therapeutics (DTx)

• Develop a therapeutic application in the field of otolaryngology



**Takaaki Kaji**Corporate Officer CBDO
Senior Director of Business
Development HQs

To rebuild the foundation of our core new drugs business and put it on a growth trajectory, we must urgently expand our development pipeline. In fiscal 2023, our newly established Business Development Headquarters will work with the Licensing Department and the Alliance Department to swiftly introduce a development pipeline. By stabilizing our existing alliances and creating new businesses, we will generate stable earnings and create new business opportunities, thereby fostering the sustainable growth of our new drugs business.

Under Vision 110 –Stage1–, we have set a guideline for expected sales based on our business strategy "expanding the development pipeline through in-licensing" while being conscious of medium- to long-term profits. Our aim is to secure six or more in-licensed items. We recognize that the efforts of the Business Development Headquarters will be truly appreciated only when in-licensed products are commercialized and generate profits, and will continue working proactively to achieve those goals.

In fiscal 2023, we will acquire at least one in-licensed product in the late-stage development phase and at least one in-licensed product in the early-stage development phase. Those acquisitions will enable us to expand our development pipeline, which is our most important priority.

## Initiatives under the medium-term business plan

# Search and evaluate through organizational reforms and deployment of personnel

To achieve the objectives of Stage 1, we must work closely with relevant departments to promote speedy and accurate evaluations since we are always searching and evaluating aspects of multiple projects in progress. With this in mind, we established the Licensing Department (licensing activities) and the Alliance Department (contract negotiations and management of alliances) under the Business Development Headquarters and will provide personnel for those entities to the maximum extent possible. To strengthen the headquarters function, we will step up collaboration within the headquarters and develop human resources. At the same time, we will activate our organization to enable onestop in-licensing services, ranging from exploration to evaluation, negotiation of terms and conditions, and conclusion of contracts. By building a system of collaboration with relevant departments to allow speedy responses, we will work Companywide to achieve our performance targets.

#### Expand in-licensing target modalities and disease fields

To broaden our development pipeline, we need to expand target modalities and disease fields and pursue in-licensing initiatives in a wide range of areas. In addition to small molecule drug discovery, where we have been actively engaged, we will work to quickly secure development candidates that will enable us to demonstrate our strengths in new modalities and disease fields outside the franchise customer (FC) field (respiratory, otolaryngology, and urology), as well as in-licensed products with viable commercial prospects.

#### Promote DTx development

Amid advances in recent years in digital transformation (DX) in the medical field, we have also taken on the challenge of engaging in R&D on digital therapeutics (DTx). In November 2022, we concluded an agreement with SUSMED, Inc. to conduct joint R&D and sales related to DTx as software for medical devices. In collaboration with relevant departments, the Business Development Headquarters will steadily develop a therapeutic application in the field of otolaryngology (target disease: tinnitus). It will also gather information on the development of new therapeutic applications in a wide range of fields.

#### Pursue proactive partnering activities

Under the medium-term business plan "Vision 110

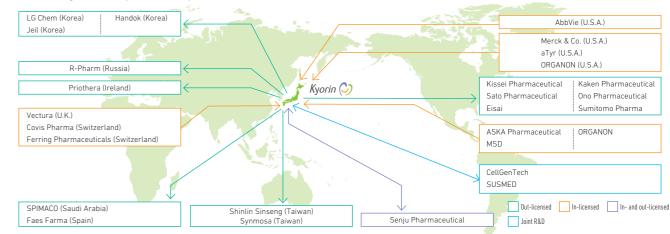
-Stage1-," KYORIN Pharmaceutical's Alliance Department and Licensing Department will work closely with other relevant departments to pursue proactive partnering activities. In line with the business strategy of the medium-term business plan, we have expanded our development pipeline in various ways. In September 2020, for example, we concluded an agreement with ASKA Pharmaceutical Co.,

Ltd. for the joint development and sales of AKP-009, a benign prostatic hyperplasia treatment, and in April 2021, we signed an agreement with MSD K.K. for the exclusive distribution rights in Japan for Lyfnua (launched in April 2022), a treatment for intractable chronic cough. Regarding the licensing agreement concluded in January 2020 with U.S.-based aTyr Pharma, Inc. for KRP-R120 (interstitial lung disease treatment), we decided to conduct multiregional clinical trials with aTyr Pharma and started Phase 3 clinical trials in Japan in September 2022. In June 2022, we signed an agreement with CellGenTech, Inc. for the joint development of a genetically modified human adipocyte as an in-licensed product in its early-stage development phase for the treatment of Fabry disease.

## Promote global out-licensing activities to increase overseas earnings

Under our medium-term business plan, we will continue to aggressively pursue out-licensing activities with global companies to maximize the value of drugs discovered inhouse. We have already made good progress under the previous medium-term business plan. In October 2020, for example, we concluded an agreement for the transfer of intellectual property rights for the immunomodulator KRP-203 to Ireland-based Priothera Limited. In March 2021, we signed a licensing agreement with Eisai Co., Ltd. for the development and sales in four ASEAN countries of the overactive bladder treatment Vibegron (sales name in Japan: Beova). In March 2023, we signed a licensing agreement with Sumitomo Pharma Co., Ltd. for the development, manufacture, and sales of Vibegron in Taiwan and elsewhere. Going forward, we will continue to actively pursue worldwide partnering activities to expand our product pipeline, which will support medium-term growth and bolster overseas earnings.

#### Partnering with companies in Japan and overseas



#### **New Drugs Business**

## Marketing

#### Changing environment (internal and external)

- Government measures to curb medical and drug costs in response to tightened healthcare funding
- Growing need for diagnosis and prevention in addition to treatment
- Changes in the way information is provided to the medical field (introduction of quidelines, etc.)
- Advances in DX in medical care (treatment)

#### Opportunities

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

#### Risks

- Increasing restrictions on medical representative (MR) visits and use of appointment-only systems, making it difficult to meet with physicians and exchange information
- Accelerating decline in sales of long-listed products due to overhaul of the drug pricing system
- Structural changes in the domestic ethical drugs market

Medium-term business plan
Vision 110 -Stage1- initiatives

#### **Business strategy**

Maximizing the ratio of new drugs

#### **■** Emphasize proliferation of new drugs

 Promote in-person meetings with physicians to increase the impact of medical details and accelerate the growth of new drugs

#### Noriaki Tamura



Corporate Officer CCO
Senior Director of Sales &
Marketing HQs
In charge of Information
System Management and
In Vitro Diagnostics
Business

In the pharmaceutical market, we see the emergence of an innovation-friendly environment conducive to the creation of pioneering new drugs. However, conditions are changing dramatically as the government actively introduces measures to control drug costs and reduce the nation's financial burden. In this environment, the Group considers growth through the proliferation of new drugs an important issue and has set "maximizing the ratio of new drugs" as a business strategy under Vision 110 -Stage1-. For this, we will adopt an activity model that delivers results by increasing the impact of medical details based on visits to medical institutions for in-person meetings with physicians, then deployment of digital channels to provide information. Through solution-based marketing activities, meanwhile, we will help resolve issues and meet the diverse needs and circumstances of medical practitioners and patients.

In fiscal 2023, the first year of our medium-term business plan, we aim to accelerate the proliferation of new drugs (five mainstay products, etc.) launched under the previous plan and thus enter a growth trajectory.

## Initiatives under the medium-term business plan

#### Promote solution-based marketing activities

Given restrictions on meetings with medical practitioners, we believe it is important to visit medical institutions directly to provide detailed information that leaves an impact. This is done through in-person meetings where we provide various kinds of pharmaceutical information and obtain orders for prescriptions. To this end, we provide all MRs with training in detail skills that will help them offer solutions and improve their abilities. Starting with the patient, we formulate hypothetical scenarios to gain an understanding of the patient's current needs, then draw up a plan and propose a suitable drug formulation from our range of products. In infectious diseases, we will continue to introduce Milton and Rubysta for infection control (prevention) at medical institutions. GeneSoC for identification (diagnosis) of pathogenic microorganisms, and Lasvic for appropriate use (treatment) of antimicrobials. We will also engage in solution-based marketing activities to provide comprehensive information. In respiratory and otolaryngology diseases, we are working to enhance our product lineup, which includes Lyfnua (chronic cough treatment), Lasvic (new quinolone antibacterial agent), Desalex (antiallergic agent), and Flutiform (combination drug for asthma treatment). We will also propose prescriptions for each disease and provide information that helps resolve issues and meet the needs of medical practitioners, while promoting the expanded use of our products.

#### Provide information through digital channels

With the COVID-19 pandemic having partially restricted MRs' visits to medical institutions 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." With this in mind, we visit medical institutions for in-person meetings with physicians, then deploy digital channels to increase the impact of the information we gather, thus enhancing our marketing capabilities. We will continue to analyze market data amassed internally to grasp the needs of medical practitioners as we engage in high-quality information-provision activities.

#### Enter a growth trajectory for new drugs

To enter a growth trajectory, we need to focus on proliferating new drugs to accelerate our growth. We have set the ratio of new drugs (sales of new drugs as a percentage of total ethical drug sales) as a performance indicator (target value of 50% or more) and are working to maximize proliferation to this end. In fiscal 2023, we will aim to increase the ratio of new drugs by ceaselessly promoting prescriptions for Lasvic, Lyfnua, Desalex, and Flutiform, as well as Beova, an overactive bladder (OAB) treatment whose shipment limits were ended in fiscal 2022.

We apologize for the inconvenience caused to medical practitioners by the limitations we placed on shipments of Beova. The situation was caused by a greater-than-expected increase in prescriptions after the prescription period limit was lifted. We subsequently made a concerted effort to increase production capacity and ended the limitations in August 2022. With a steady increase in new prescriptions, we are aiming for the top share of the OAB market. Meanwhile, in

April 2022, we launched Lyfnua, the world's first drug for treating chronic cough. Going forward, we will work to establish a solid market position by promoting understanding of the product's features, especially among respiratory specialists. In fiscal 2023, we will also exploit the removal of restrictions on the prescription period to achieve market penetration as soon as possible. Meanwhile, the market for Lasvic shrank due to the promotion of its appropriate use against antimicrobial resistance (AMR), as well as rigorous measures to prevent infectious diseases. We expect the market to recover to some degree as the COVID-19 pandemic subsides. Looking ahead, we will emphasize the features of Lasvic and grow it into the top-selling product in the oral antibacterial agent market. As for Desalex, we increased sales and market share through focused efforts on otolaryngology and internal medicine. Since it is a drug that is both effective and easy to use, we will continue targeting Desalex to be the No. 1 prescription in the field of otolaryngology. For Flutiform, we will emphasize its usefulness as an aerosol formulation to increase its share on a volume basis (in the low single-digit range).

#### Establish a presence in designated fields

Adhering to an FC strategy that concentrates resources in designated fields centering on respiratory, otolaryngology, and urology, we aim to establish a presence in those fields by having roughly 650 MRs provide and collect information on the appropriate use of pharmaceuticals and convey that information to medical practitioners. For marketing, we have adopted a "team structure," with teams based in secondary medical districts (where multiple MRs are responsible for a designated area), using an area management strategy in which teams cultivate their own areas. Going forward, we will work to create a framework for teams to assist each other and achieve their targets by refining our activities to address increasingly diverse medical needs swiftly and systematically.

Product	States aimed for	Goal at FY2025
Beova®	First-line treatment for OAB	• 50% patient share
Lasvic®	First-choice antibacterial agent for elderly or patients with underlying disease in respiratory infection	40% share in new quinolone market in FY2025 for tablets/iv
Lyfnua®	Only treatment for chronic cough	• FY2025 approx. 10,000 of GP approx. 2,000 of HP
<b>Desalex</b> ®	Effective and easy-to-use drug	• Sales of 10 billion yen in FY2025
Fultiform®	Aerosol for patients with weak inspiration	Sustainable growth on volume basis to FY2025 with CAGR of low single digit %

## New Drugs Business and Generic Drugs Business

## Manufacturing

#### Changing environment (internal and external)

- Increasing demand for pharmaceutical companies to ensure reliability
- Rising manufacturing costs
- Changes in manufacturing technologies

#### Opportunities

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

#### Risks

- Annual drug price revisions that translate to higher cost of sales ratio
- Higher raw material prices due to increasing crude oil prices and logistics costs
- Delays and suspension of manufacturing activities and raw materials procurement due to pandemics, natural disasters, unstable social situations, etc.

Medium-term business plan
Vision 110 -Stage1- initiatives

**Business strategy** 

## Strengthening production capacity for drugs and reduce manufacturing costs

- Maximize production capacity through reliable operation of Takaoka Plant and overall optimization of other plants
- Improve reliability and maintain stable production by raising the GMP level
- Reduce costs through continuous improvement activities

We have a manufacturing structure that ensures stable supplies of highly reliable products underscored by a commitment to low-cost operations. For this, we draw on our three production facilities to achieve overall optimization of all manufactured products and appropriate capital investment. As a result, we reached our cost reduction targets and increased production volume at each plant. However, business conditions are changing dramatically, characterized by stricter quality requirements, rising manufacturing costs, and more sophisticated manufacturing technologies. In response, we must take new measures to maintain a stable supply of high-quality products. Under the medium-term business plan "Vision 110 - Stage 1-," one of our business strategies is to "strengthen production capacity for drugs and reduce manufacturing costs." By strengthening our product supply capacity and raising the GMP\*1 level, we aim to achieve low-cost production and a stable supply of high-quality products, increase subcontracted manufacturing contracts from outside the Kyorin Group, and establish a competitive manufacturing structure.

## Initiatives under the medium-term business plan

## Establish a new manufacturing structure by constructing the Takaoka Plant

In line with the increase in our pharmaceutical manufacturing volume, we need to strengthen our production and supply capacity. With this in mind, we are building a new plant in Takaoka City, Toyama Prefecture. The new facility will increase the production of tablets (oral solid formulations) and further raise the GMP level. It will also streamline various processes and improve manufacturing efficiency, thus assuring stable supplies and low-cost manufacturing. In addition, it will reduce our environmental impact by actively utilizing renewable energy sources. The new plant is scheduled to start operations in April 2024, enabling us to quickly realize stable supplies and lower costs through a four-plant system.

#### Improve reliability and maintain product quality

In recent years, quality requirements for products have become more stringent. In response, we are working to maintain quality through various approaches, including cross-facility reciprocal audits of GMPs, reinforcement of data integrity (framework ensuring data is complete, consistent, and accurate), regular training and testing of employees, and the use of video to teach standardized operations. In these ways, we are working relentlessly to provide products that earn the confidence of medical practitioners and patients.

## Increase production efficiency to improve cost competitiveness

We are working to establish a manufacturing structure that ensures stable supplies of new and generic drugs and low-cost production. During the production process, we utilize various practices to improve manufacturing quality, including enhancing production techniques and acquiring new technologies. Going forward, we will strive to improve production efficiency by appropriately deploying resources and improving processes to ensure low-cost operations and increases in production volume. In these ways, we will solidify our structure to improve cost competitiveness.

#### Overall optimization of our manufacturing system

Aiming to maximize our manufacturing capacity, we are pursuing an optimal combination of manufacturing items and sites by taking advantage of the characteristics of each of our three plants. The Noshiro Plant produces not only new drugs, mainly tablets and capsules, but also generics in large volumes. The Shiga Plant actively engages in subcontracted manufacturing. It has a high ratio of manufacturing subcontracted from outside the Group, including the manufacture of pharmaceutical products to be sold in Japan by foreign pharmaceutical companies. The Inami Plant mainly handles generic drugs but also manufactures solid formulations taken internally and eyedrops. All three plants are working to raise GMP levels and maintain and improve quality-control systems, while establishing PIC/S\*2 GMP compliance and building a supply system for both domestic and overseas markets. We will continue making aggressive capital investments, including those at the Takaoka Plant, to further improve productivity and ensure reliability.

#### Supply chain management (SCM)

In light of changing business conditions, we have established a system to ensure stable product supplies. We centrally manage and visualize suppliers' inventory information and the supply plans for all regions around the world to address demand forecasts for each product. This setup enables us to globally manage every stage, from the manufacture of pharmaceutical ingredients to the supply of products. Looking ahead, we will strive to build an even stronger supply chain to flexibly address changing business conditions.

Our 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 providing stable supplies without interruption in the procurement chain, we consider it imperative to strengthen relationships with individual suppliers by working closely and sharing information with them. Several challenges have emerged in the past few years, including geopolitical risks, exchange rate fluctuations, rising raw material prices due to rising energy costs and semiconductor shortages, and a logistics problem in 2024. Nevertheless, the Kyorin Group will continuously strive to ensure stable product supplies by reducing various risks through production planning and inventory coordination with internal manufacturers and external subcontracted manufacturers, while developing multiple and alternative suppliers and improving logistics efficiency.

\*1 GMP: Initialism for good manufacturing practice, a standard for the manufacture, management, and quality control of pharmaceutical products

\*2 PIC/S: Pharmaceutical Inspection Co-operation Scheme



Noshiro Plant Location: Noshiro, Akita

Plant certifications

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



Shiga Plant Location: Koka, Shiga

Plant certifications

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



Inami Plant Location: Nanto, Toyama

Plant certifications

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



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#### **Generic Drugs Business**

## **Generic Drugs**

#### Changing environment (internal and external)

- Government measures to curb medical and drug costs in response to tight healthcare finances
- Growing demand for pharmaceutical companies to ensure reliability

#### Opportunities

- Increased demand for generic drugs due to promotion of measures to contain drug costs
- Patent expiries of major original drugs
- Increasing demand for high-quality products

#### Risks

- Reduced incentives to promote use of generic drugs
- · Weaker profitability due to annual drug price revisions
- Soaring prices of raw materials and energy

Medium-term business plan
Vision 110 -Stage1- initiatives

#### **Business strategy**

#### Achieving sustainable growth of the generic drugs business

- Maintain strong capability to develop new generic products and leverage such products to accelerate growth
- Strengthen production and procurement systems, including those outside the Group, to ensure stable supplies
- Build a low-cost structure resilient to changing business conditions

a company with a strong business presence and employees who play active roles and take pride in their work. Business conditions for our company remain challenging, evidenced by annual drug price revisions, widespread supply concerns triggered by quality problems at some companies, and rising costs due to high prices and soaring energy costs. To ensure stable supplies, we are strengthening our product supply capacity, mainly through the transfer of manufacturing and the commissioning of the Takaoka Plant, which is currently under construction. To address future changes in this environment, we will take on the challenge of entering new fields, spearheaded by the Takaoka Pharmaceutical Technology Innovation Center, and further reinforce our development capabilities.

Deploying its unique strengths, KYORIN Rimedio aims to be

## Initiatives under the medium-term business plan

## Maintain and strengthen our capability to create new generics and accelerate growth

To provide generic drugs that can be used safely, KYORIN Rimedio manufactures pharmaceuticals and provides 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. To address changing business conditions, we will enhance our in-house development capabilities by strengthening our expertise, human resources, and organizational functions, with a view toward taking on challenges in new fields. In addition to small molecule compounds, these include highly pharmacologically active drugs, anticancer drugs, and formulations in niche areas. Going forward, we will advance our business to become a high-profile generic drugs company. In fiscal 2022, we launched eight new products with four ingredients.

# Strengthen production and procurement systems to ensure stable supplies

Quality problems at some companies have sparked widespread concern about supply stability and are yet to be resolved. In response, the entire Group is working to optimize production and ordering plans. We will strive to increase product procurement volumes, including using external resources, to ensure stable supplies.

## Establish a low-cost structure resilient to changing business conditions

KYORIN Rimedio has always been strong on the sales side thanks to its multifaceted, well-balanced sales channels.

Going forward, we will leverage this strength while improving efficiency by reforming our sales structure, increasing sales, and improving cost competitiveness through a strategy of selection and concentration.

#### Address authorized generics

The Kyorin Group has achieved a certain degree of market recognition for selling both original drugs and authorized generics that meet the diverse needs of medical practitioners and patients. We currently sell Montelukast Tablets "KM" (our authorized generic version of Kipres), Mometasone Nasal 50µg "KYORIN" (our authorized generic version of Nasonex), and Imidafenacin Tablets "KYORIN" OD tablets 0.1mg (our authorized generic version of Uritos). All three products have gained a share of 50% or higher in their respective generic markets.

#### Takaoka Pharmaceutical Technology Innovation Center Strengthen in-house capability to develop new generic products robustly

The Takaoka Pharmaceutical Technology Innovation Center was established in July 2017 to strengthen our capability to develop new generic products, the foundation of our generic drugs business. The facility has all the capabilities needed to obtain patent application data, ranging from patent searches and planning strategies for development items to evaluations of pharmaceutical ingredients, formulation design, and quality evaluation, as well as conduct clinical trials and measure drug concentrations. To further improve the quality of these capabilities and accelerate drug development, we promote open innovation through joint development with other companies and the use of Toyama Prefecture's industry-academia-government collaboration system. At the same time, we work to revitalize communication through organizational restructuring that includes assigning researchers with different specialties to the same department.

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#### Aspirations for Vision 110 -Stage1-

We will enhance the quality of our drug development and accelerate its process by increasing the expertise of researchers and activating communication among the center's staff to strengthen our human resources and organizational functions. We will consider taking on challenges not only in small molecule compounds but also in new areas, such as highly pharmacologically active drugs, anticancer drugs, and formulations in niche areas. We will work to further broaden our product lineup to offer attractive generics.

#### Takaoka Plant

## Provide high-quality products that meet market demand

Construction of the Takaoka Plant is one of the Kyorin Group's most important projects. Scheduled to start operations in April 2024, the plant will be the Group's main facility for manufacturing generics. We regard this as a priority project directly related to the growth of the generic drugs business handled by KYORIN Rimedio. Quality problems with ethical drugs, such as contamination by foreign substances, have led to shortages in the supply of generics and become a social problem. By commissioning the Takaoka Plant, we aim to strengthen our generic manufacturing capacity and build a production system that reliably meets market demand.

The Takaoka Plant will have an annual production capacity of roughly 2 billion tablets (solid formulations taken internally), which is more than twice that of the Inami Plant, which primarily manufactures generic drugs. Going forward, we will further expand our manufacturing system by swiftly engaging in full-scale production and increasing overall production volumes, including those at existing plants.



#### Raise GMP levels to increase reliability

The Takaoka Plant will raise the GMP level. With this in mind, we will further strengthen and solidify compliance with laws and regulations related to manufacturing and quality control, as well as our quality control structure, to ensure stable supplies of safe and reliable products.

Thinking of the environment, we have designed the plant to significantly reduce CO<sub>2</sub> emissions compared with those at existing production facilities. We will also reduce the environmental impact by actively using clean energy sources like liquefied natural gas (LNG) and renewable energy like hydroelectric power. In addition, we will strive to achieve stable supplies and low-cost production by saving labor in various operations and by improving manufacturing efficiency.



Hiroshi Hashizume

Corporate Officer Representative Director and President of KYORIN Rimedio Co., Ltd.

## **Reliability Assurance**

#### Changing environment (internal and external)

- · Growing calls for pharmaceutical companies to ensure reliability
- Diversification and increasing complexity of drug discovery modalities

#### **Opportunities**

- Growing demand to supply high-quality products
- Establishment of quality and safety management systems in new modalities

#### Risks

- Tighter regulations at home and abroad
- Quality issues in domestic and international supply chains

Medium-term business plan Vision 110 -Stage1- initiatives

**Business strategy** 

#### Strengthening reliability assurance system to support comprehensive business development

- Strengthen our legal compliance system for pharmaceutical matters
- Promote prompt and reliable responses to changes in the environment surrounding reliability assurance

Regulations and society's demands for product reliability have become even more severe in recent years, requiring companies to further enhance their quality and safety assurance systems. Meanwhile, the Kyorin Group is making progress in the diagnostics business, therapeutic applications, and new businesses, in addition to pharmaceuticals. Amid drastically changing conditions both internally and externally, we will respond flexibly and swiftly to realize the long-term vision "Vision 110." Abiding by laws and regulations, we will provide high-quality products, earn greater trust by ensuring effectiveness and safety, and contribute broadly to people's health.

#### Reliability assurance system

To ensure the stable supply of high-quality products, the about products' efficacy, safety, and quality.

#### **Quality assurance**

The Kyorin Group has a quality policy for both ensuring

For pharmaceuticals, we have established a system to

Group complies with the Good Quality Practice (GQP) and Good Vigilance Practice (GVP) standards for pharmaceuticals. In the diagnostics business, we have established a system that conforms to the Quality Management System (QMS) standard for manufacturing and managing medical devices and in vitro diagnostics and quality control. Our Quality Assurance & Reliability Division, which plays a central role in this process, is independent of the R&D, manufacturing, and sales divisions. It engages in unified product reliability assurance initiatives to provide products and information that patients and medical practitioners can use with confidence. In addition, we promote proper use of our products and assure their reliability by faithfully and promptly responding to aftersales inquiries from patients and medical practitioners

product quality and providing stable supplies. We are strengthening operation of our manufacturing centers through management of quality risk based on scientific

supply high-quality products based on GMP standards in cooperation with Group plants and other facilities from the development stage. We have also set up a distribution system that conforms to Good Distribution Practice (GDP) standards for pharmaceutical products. After launches, we conduct quality assurance in compliance with GQP standards to ensure the quality and stable supply of products, from development and manufacture to distribution.

#### **KYORIN Pharmaceutical's Quality Policy**

"Kyorin continues to fulfill its mission of cherishing life and benefiting society by contributing to better health." Following this corporate philosophy, we provide high-quality products that are trusted by patients and medical practitioners.

- We engage in appropriate quality-related activities in compliance with relevant laws, regulatory requirements, and internal standards.
- We practice quality risk management based on scientific knowledge to ensure product reliability.
- We strive to raise employee awareness of quality and foster a quality-driven culture with ongoing education.
- We work closely with subcontracted manufacturers and suppliers to ensure stable supplies of high-quality products.
- We listen and respond sincerely to patients, medical practitioners, and others and actively strive to improve product quality.

For in vitro diagnostics and medical devices (diagnostics business), we are committed to providing high-quality products by practicing quality assurance in compliance with QMS standards across all stages, from design and development to sales. To maintain product quality and ensure integrity during the distribution process, we have established a GDP-compliant distribution system. Under this system, which includes on-site inspections, we confirm that quality control is performed properly at storage and

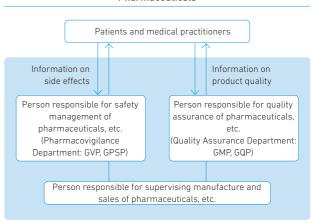
#### Safety management

distribution companies.

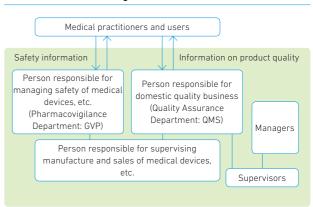
Drugs can be effective for treating patients (benefits) but can also have adverse side effects (risks). Therefore, during the development phase, we collect and manage safety information on investigational new drugs and appropriately monitor and evaluate changes in the safety profile of those drugs. After a product is launched, moreover, side effects unforeseen during the development phase may become apparent. For this reason, 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 the medical community, with the balance taken into account. The Kyorin Group formulates risk management plans and collects and manages safety information by individual product. We also conduct drugmonitoring activities for pharmaceuticals and medical devices in compliance with GVP standards to ensure their safety and proper use. In addition, we conduct postlaunch investigations to collect and evaluate information on the safety and efficacy of pharmaceuticals in compliance with Good Post-marketing Study Practice (GPSP) standards.

#### Manufacturing and Sales Structure

#### **Pharmaceuticals**



#### In vitro diagnostics/medical devices



# Katsuhiro Hamada

Corporate Officer Senior Director of Quality Assurance & Reliability HQs

KYORIN Pharmaceutical Co., Ltd. | Integrated Report 2023 KYORIN Pharmaceutical Co., Ltd. | Integrated Report 2023

## Marked the 100th anniversary of our founding

The Kyorin Group marked the 100th anniversary of its founding on June 16, 2023. With the concept "thanks for the past and taking a leap forward in the future with health as the core," we held various events and an advertising campaign to express our gratitude to all stakeholders and to look ahead to advances over the next 100 years.

#### Logo

The "100" logo is designed with a right-side upward inclination to express the sense of further growth. The addition on the final "0" is a new leaf to symbolize health and future growth. The logo also suggests ripe apricots. The color gradation symbolizes time flowing toward the future and the continuation of growth.

#### Slogan

Our slogan, "Wishing you good health for the next 100 years," expresses the idea that the 100th anniversary is neither a goal nor a checkpoint but a new starting line. The slogan incorporates the message that we will further contribute to people's health.



# 健康への願いを 次の100年へ。 Anniversary おかげさまで、創業100周年

## Newspaper advertisement

We placed newspaper advertisements on June 16, the anniversary of our founding. Beneath a picture of sequoia trees, which are the largest terrestrial organisms and grow for more than 2,000 years, the message expresses the Group's concept of contributing to people's health while continuing to grow.

#### 100th-anniversary events

 In April, we launched a special anniversary website and, in June, released the commemorative 100th Anniversary History video, which looks back on our 100 years of history. These presentations are sending our message to people inside and outside the Group.

https://www.kyorin-pharm.co.jp/100th/ (Japanese only)

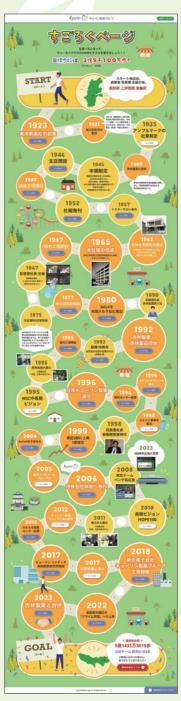


 Anniversary ceremonies and receptions were held for employees on July 14. The events were dispersed across five locations nationwide and held as in-person gatherings, which were difficult to arrange during the COVID-19 pandemic. The ceremonies looked back at 100 years of history and shared memories, pledging to make a leap forward over the next 100 years.





A History Walking Relay to the Future event was held for all employees to participate in a journey and recall memories from the time of our founding through 2023.
 The event aimed to have every employee walk 6,000 steps in one day, for a combined target of 391 million steps. (In Japanese, "3" and "9" are pronounced san and kyu, and "1 million" is written as 100 man, for Thank You 100 years.)



KYORIN Pharmaceutical Co., Ltd. | Integrated Report 2023

## SPECIAL FEATURE

## **Our Challenges**

Since our founding, the Kyorin Group has maintained the concept of "contributing to better health." All employees are boldly taking on the challenge with an awareness of and the desire to be part of the effort, aiming to achieve the long-term vision "Vision 110" that looks toward our 110th anniversary.



# Aiming to spur innovation that has value for nationts

The Innovation Research Laboratory, which was newly established to verify and create research targets directly linked to drug discovery, is working to strengthen basic drug discovery technologies and quickly identify valuable drug discovery themes. As various changes in the external business environment raise the level of difficulty in drug discovery, we are building on our proprietary pathological research and basic technologies developed to date while proactively accessing new external technologies and promising drug targets to spur innovation. All members are contributing to discovering new, high-value drugs that meet medical needs, aiming to become a company that contributes widely to people's health.



# Licensing activities that broaden perspectives, pursue challenges, and evolve

Licensing plays the important role of expanding the development pipeline through in-licensing. To fully carry out this role, we need to swiftly and appropriately evaluate asset values by responding to changes in and the diversification of business partners, modalities, and the development environment. We also need to promote internal and external agreements and decision making through appropriate proposals and negotiations to continuously pursue the challenge of creating new business opportunities. We will fulfill our role by working as a team to broaden perspectives and strengthen our ability to gather information, while sharing viewpoints based on a variety of evidence from stakeholders' different perspectives, making evaluations and proposals from in-depth examinations, and repeatedly revising and developing them as appropriate.



#### Aiming to be an MR who contributes to patients' health

MRs provide information to medical practitioners that contributes to the appropriate use of pharmaceutical products. In carrying out our activities, MRs think about individual patients going about their daily lives with good health and smiles on their faces, share problems that arise with medical practitioners, and propose solutions using appropriate prescriptions of Kyorin's products. When one MR receives useful information, the MR shares it with the team and uses feedback from team members to provide medical practitioners information that addresses patients' needs. Working as a team, we MRs are engaged in activities that enable us to contribute to the health of as many patients as possible.



#### Ensuring pharmaceutical products that give peace of mind

The Quality Control Department performs the tests and inspections needed to manufacture pharmaceutical products. In addition to the products themselves, the work covers many types of raw materials and packaging. Because the pharmaceutical industry environment is changing by the day, it is important to continue pursuing even higher GMP levels by meeting the latest regulatory requirements. Under the long-term vision "Vision 110," as the department responsible for quality, we will strengthen the quality control foundation to optimize our structure for compiling data, creating manuals, and operating testing equipment, to ensure that each individual test is accurate. We also emphasize training younger staff members to establish a superior quality control structure and quality culture.



# Gaining trust by ensuring quality and a stable supply of generic drugs

In addition to gaining the trust of patients and medical practitioners by providing safe and reliable pharmaceutical products, the Quality

Assurance Department plays the important role of overseeing manufacturing sites to prevent problems and ensure stable supplies. The pharmaceutical industry is facing problems in terms of quality and supply interruptions, and we are the department making improvements to prevent these problems. We perform our jobs with a sense of responsibility, making it a point to exchange views internally on rules, regulations, and other issues daily. Through these ongoing efforts, we are working to instill a strong awareness of quality and strengthen our reliability assurance system to support the pharmaceutical business.

Realizing
Vision 110 through
the ideas of
individual
employees



#### Interacting with "people" to enhance human capital

Human Resources, where I work, is responsible for energizing people and organizations through activities including the hiring, training, assigning, evaluation, compensation, and treatment of human resources, to achieve our management strategies. We emphasize the spirit in the phrase "a business is as good as its people," thinking that is unchanged since our founding, and continuously interact with "people" while rebuilding systems to conform to the times. As a project leader, I am working to enhance human capital by implementing a human resources system oriented toward employees' "autonomy" and "growth." We are also promoting work-style reforms by creating systems that allow all employees to pursue career paths that personally suit them and making every effort to maximize employees' job satisfaction and performance.

### Addressing Sustainability Issues

Under the newly formulated long-term vision "Vision 110," the Kyorin Group has determined that working to resolve sustainability issues (for the continuous development of society and the Company) through business activities based on our Corporate Charter will lead to the medium- to long-term enhancement of corporate value.

To achieve the objectives of the long-term vision, we will strive to carry out fair and honest business activities in compliance with laws and regulations including the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the "Act on Pharmaceuticals and Medical Devices"), while respecting the human rights of all people. We will also seek to create workplace environments comfortable for employees and take environmental considerations into account in our business activities.

We will carry out our social mission of contributing to better health by developing and providing useful and safe products and services, while contributing to economic development and realizing a dynamic society through activities as a good corporate citizen.

As we pursue these objectives, we will need the cooperation, collaboration, and partnership of all our stakeholders. We will work to deepen our relationships with stakeholders and gain their trust and empathy by providing value in various ways including dialogue (engagement).



Yasuyuki Shimokawa Corporate Officer CHRO In charge of Human Resources, General Affairs, and Legal and Corporate Compliance

#### **Corporate Charter**

- 1 Contribute to sustainable economic growth and to the resolution of social issues
- 2 Rigorous and scientific research and development
- 3 Promotion of appropriate use of drugs
- 4 Relationships of trust with medical professionals, patients, etc.
- 5 Fair business practices
- 6 Thorough information management
- 7 Fair information disclosure and constructive dialogue with stakeholders
- 8 Work-style reforms and improvement of work environments
- 9 Initiatives to tackle environmental issues
- 10 Co-exist with society and contribute to society's development
- 11 Comprehensive crisis management
- 12 Respect for human rights
- 13 Stringent implementation by Company officers of their responsibilities and the charter

## Relationships with stakeholders Patients and their families Medical Local professionals communities Corporate philosophy Suppliers Shareholders and business and investors partners **Employees**

#### 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.

#### SUSTAINABLE GOALS

















#### Engaging in dialogue with stakeholders and providing value

We believe that activities to create both social value and economic value are needed to achieve the long-term vision "Vision 110" and that dialogue (engagement) with all stakeholders involved in the process to realize that vision is essential. All Group employees are working as one to meet the requests and expectations of all stakeholders through various activities including dialogue.

Stakeholders	Stakeholders' requests and our response (value provided)	Main venues for dialogue and frequency
Patients and their families	<ul> <li>Provide information related to drug safety and effectiveness</li> <li>Support patients' groups</li> <li>Provide a stable supply of products, etc.</li> </ul>	<ul> <li>Drug Information Center (FY2022 inquiries: approx. 23,500)</li> <li>Websites for promoting awareness of diseases (as needed)</li> </ul>
Medical professionals	<ul> <li>Provide information related to the appropriate use of ethical drugs</li> <li>Provide a stable supply and ensure quality of investigational new drugs and products</li> </ul>	<ul> <li>Communication with MRs, Medical Affairs Department, and clinical research associates (as needed)</li> <li>Release of medical information on websites, at academic conferences, etc., for medical professionals (as needed)</li> </ul>
Employees	<ul> <li>Provide opportunities and venues for self-fulfillment and personal development</li> <li>Create comfortable workplace environments and provide job satisfaction</li> <li>Compensate appropriately</li> </ul>	<ul> <li>Websites (intranet) for employees (as needed)</li> <li>Individual meetings (twice annually)</li> <li>Internal training (as needed)</li> <li>Internal whistleblowing system, structure</li> <li>Employee surveys (awareness surveys)</li> </ul>
Pharmaceutical wholesalers and suppliers	Create value in cooperation with Group companies	<ul> <li>Activities by MRs and distributor sales staff (as needed)</li> <li>Briefings, etc. (as needed)</li> </ul>
Joint research partners and joint development partners	Create successful research outcomes and innovation Create new value through integration with Group capabilities Develop medical applications from cuttingedge research results	Daily operations (as needed)
Shareholders and investors	<ul> <li>Provide timely and appropriate information and have communication</li> <li>Provide benefits from continuous enhancement of corporate value</li> <li>Pay a stable dividend</li> </ul>	<ul> <li>General shareholders' meeting (annually)</li> <li>Results briefings (twice annually), press conferences (as needed)</li> <li>IR activities (IR staff: 20 to 30 times annually), management meetings (several times annually)</li> </ul>
Local communities	Carry out activities that contribute to society, make donations Protect the environment Create employment	<ul> <li>Cleanup activities (twice annually)</li> <li>Seasonal events (twice annually)</li> <li>Facility tours (2 to 5 times annually)</li> </ul>

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## Sustainability in Business Activities/Gaining Social Trust

#### Sustainability issues and initiatives

Following our corporate philosophy, the Kyorin Group addresses sustainability issues proactively. In accordance with our Corporate Charter, which was formulated based on corporate ethics and the compliance at the root of all our corporate activities, we will contribute to realizing a sustainable society by fulfilling our social responsibilities through our activities, with the new drugs business as our core.

#### Sustainability issues and initiatives

Correlation with SDGs

#### Sustainability in Business Activities/Gaining Social Trust

We believe that contributing to society through our business activities leads to fulfilling our social responsibility. In addition to traditional areas ranging from research and development to product sales, stable supplies, and quality management (reliability assurance), we aim to contribute to people's health by providing appropriate information and promoting proper use of pharmaceuticals.

#### Fair and Honest Business Activities

We strive to maintain high ethical standards, conduct business lawfully and fairly, comply with codes of conduct, and prevent legal violations. We have also created a structure to appropriately manage business-related risks.

#### **Enhancing Human Capital**

Reflecting our founder's idea that a business is as good as its people and believing that human resources growth is the driving force that underpins strengthening the business, we are working to enhance our human capital. The Group is managed to enable all employees to respect the human rights of all people and act with high ethical standards.

#### Living in Harmony with Society

Acting as a good corporate citizen, we contribute to creating a vibrant society and developing local economies through activities in which employees participate and by making donations.

#### In Harmony with the Environment

We are working to preserve a sustainable environment through measures including preventing environmental pollution, reducing our environmental burden, and promoting the effective use of resources.









#### **Corporate Governance**

Bolstering corporate governance is regarded as an important management issue to continuously enhance corporate value. Our initiatives include expediting decision making, strengthening appropriate management oversight functions, and maintaining transparency in corporate activities based on corporate ethics.



## Drug discovery and clinical development to create new drugs with high value

#### Research (Drug discovery)

- Ethical considerations for human drug research
- Ethical considerations for the use of animals in experiments
- 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

#### 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 our core areas for research and development, we are working proactively to protect intellectual property and concentrating our investment in acquisition of intellectual property rights to create 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.

## 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. 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.

# Stable supply of high-quality drugs (supply chain, quality assurance, product information)

Procurement (SCM)

Initiatives to ensure sustainable

• On-site supplier investigations

procurement

## Technological development and manufacturing

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

#### Stable supply and quality management

The Company contributes to medical care by providing customers a stable supply of high-quality products that comply with laws, regulatory requirements, and internal guidelines. By closely cooperating with Group company KYORIN Pharmaceutical Group Facilities and other manufacturing locations, we work to continuously improve good manufacturing practices (GMPs) for pharmaceuticals and other products while observing good distribution practices (GDPs) for pharmaceuticals, as we strive to provide a stable supply of high-quality pharmaceutical products.

#### 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), we strive to maintain the quality of products by guaranteeing quality in accordance with good quality practices (GQPs) for pharmaceuticals and other products including confirmation that each product is made 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. We are also aiming to build an even more resilient supply chain to respond flexibly to recent changes in business conditions.

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. With the appearance in recent years of geopolitical risk, exchange rate fluctuations, high costs for raw materials for reasons including higher energy prices and shortages of semiconductors, and the "2024 problem" in logistics (a projected shortage of drivers in Japan as a result of new overtime regulations taking effect), the Kyorin Group is working continuously to mitigate these various risks and maintain stable supplies through initiatives including coordinating production plans and inventories with internal and external subcontractors, diversifying and cultivating alternative suppliers, and making logistics more efficient.

#### 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.

# Providing product information and building relationships of trust with patients and medical professionals

#### Provision of product information

- Promotion of the appropriate use of drugs
- Responding to drug inquiries

## Initiatives for patients and medical professionals

- Public website for medical professionals and patients
- Providing information about disease
- Supporting the Department of Drug Discovery Medicine
- Supporting the Medical Education Project

#### 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 our 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.

We are continuously working to improve our response to pharmaceutical product-related inquiries by using objective, accurate, and the most up-to-date data to provide consistent, appropriate, and correct information. 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.

Number of inquiries: Approximately 23,500 (fiscal 2022)

#### Public website for medical professionals and patients

We strive to meet the information needs of medical professionals by posting product-related information, the latest academic information, and other information useful in daily medical care on Kyorin Medical Bridge and other websites for medical professionals. We also strive to increase patient adherence to guidelines by providing information on how to take medicine properly, information about disease, and other information on websites for patients.

#### Providing information about disease

We assist medical professionals in creating disease information tools for informed consent from patients, with the aims of helping patients correctly understand disease and improving their quality of life (QOL).

#### Supporting the Department of Drug Discovery Medicine

We helped establish and support the Department of Drug Discovery Medicine at the Kyoto University Graduate School of Medicine to cultivate innovative human resources for Japan's drug discovery in the post-genome era through cooperation between industry and academia.

#### Supporting the Medical Education Project

We contribute to the improvement of quality in medical care by creating educational opportunities for medical professionals and improving their knowledge and skills through support for the Medical Education Project, planned and managed by the Japanese Society of Otorhinolaryngology—Head and Neck Surgery, Inc.

#### Reliability assurance initiatives

We have established a detailed reliability assurance system for the products we handle and aim to gain the trust of wide segments of society by ensuring compliance with relevant laws and regulations, assuring reliability, guaranteeing quality, and pursuing safety management.

#### 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 work to propose various policies and raise awareness, promote compliance and risk management, and prevent legal and regulatory violations.

#### 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 formulated the KYORIN Pharmaceutical Corporate Charter and Compliance Guidelines in August 2006. These were revised in April 2019 to reflect our commitment to a sustainable society and again in April 2023 to reflect the Group's restructuring and changes in the business environment including legal revisions and social developments. In addition, we have established a system to promote compliance, including the Compliance Committee, which meets once a month.

#### Education and training

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

- (1) Focusing on departments responsible for compliance and each division's compliance promotion managers, Companywide level-specific training (newly hired employees, newly appointed managers, etc.) and functional training are held to teach corporate ethics and compliance, and efforts are made to ensure that an understanding and consideration of compliance are reflected in the work performed by directors, corporate auditors and officers, and employees.
- (2) We have designated June and November as twice-yearly "compliance enforcement months" and are working to ensure that compliance is thoroughly understood and practiced through initiatives designated 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.

Whistleblowing reports: eight (fiscal 2022)

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

The mission of a pharmaceutical company is to contribute to the health and welfare of people around the world through ongoing research and the development of high-value new drugs that address medical needs and by providing stable supplies of those drugs. 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.

Against this backdrop, the Kyorin Group has established the Guidelines for Transparency of Relationships between Corporate Activities and Medical Institutions, etc., and the Guidelines on Collaboration with Patient Groups and Transparency of Their Activities. 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 carries out its business in compliance with the Act on Pharmaceuticals and Medical Devices and other relevant laws and regulations of Japan and other countries. However, we recognize the following risks with the possibility of substantial impacts 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. We are addressing these risks organizationally and systematically. However, the risks and uncertainties that could affect the Group are not limited to these.

Main responses	Potential risks
Risks related to research and development  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	Delay or discontinuation of development due to unforeseen side effects or failure to achieve expected effects of development candidates
Risks related to medical system reforms  • Maximizing the spread of new drugs  • Transformation of cost structures through consolidation of Group production functions and overall optimization	Unforeseen implementation of reforms to the NHI drug pricing system and medical insurance systems
Risks related to stable supplies  Securing specific amounts of products and raw materials Securing important raw materials from multiple sources	Delays or stoppages in manufacturing activities or procurement     Product recalls due to quality problems, etc.
Risks related to alliances • Improving relationships with business partners based on their sales strategies and R&D trends	• Impact on business results, etc., due to dissolving alliances
Risks related to IT security and information management  Introducing security software and implementing regular backups Thoroughly familiarizing employees with various information management regulations and providing ongoing education	Business interruptions and information leaks due to inadequate systems, computer viruses, cyberattacks, etc.
Risks related to competition with other pharmaceutical products  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	Competition with other companies' products     Intensifying entry of generic drugs
Risks related to intellectual property rights  Strict management of intellectual property rights  Ongoing monitoring to check for infringements by third parties	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
Risks related to litigation • Response based on advice of experts, etc.	Litigation related to intellectual property rights, product liability     (Product Liability Act), environmental protection, labor, etc.
Risks related to the occurrence of side effects     Providing and collecting information that contributes to using pharmaceutical products properly	Restriction of use or discontinuation of sales due to unexpected side effects after a market launch
Risks related to environmental issues  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  Establishment of Environmental Committee to conduct business activities that take into account environmental impact at Group level	Violations of related laws and regulations due to accidents, etc. Introduction of environmental taxes, changes in procurement or operating costs, etc., associated with transition to a decarbonized society Changes at business locations and in procurement, operations, etc., due to damage from irregular weather or changes in weather patterns
Risks related to large-scale disasters, etc.     Preparation of response manuals and implementation of drills to prepare for large-scale disasters, etc.     Stable supply system through maintenance of specific amounts of product inventories, etc.	Closure of factories, cessation of operations, etc., at manufacturing subsidiaries or suppliers
Risks related to fluctuations in financial markets  Risk-hedging measures, diversified investment, etc.	• Losses from import/export transactions, valuation losses on pension assets, retirement benefit obligations, equity holdings, etc.

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#### **Enhancing Human Capital**

#### **Basic stance**

Reflecting our founder's idea that "a business is as good as its people" and believing that human resources growth is the driving force that underpins strengthening the business, we are working to enhance our human capital. We believe it is important for employees to respect the human rights of all people and to act with high ethical standards. We are therefore working to create workplace environments where each employee's diversity, character, and individuality are respected, where employees' health is taken into account, and where employees can work comfortably and safely.

#### 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.

#### **Human resources management**

As we enhance human capital, we recognize that to achieve our business strategies it is important to place importance on employees and energize people and organizations. The Kyorin Group's basic policy underlying our human resources management system views the Company and its employees as partners who, by continuously fulfilling the

responsibilities expected of each other over the long term, realize mutual benefits (with employees contributing to the Company's development, and the Company enriching employees' lives and contributing to their self-fulfillment). We are creating frameworks (systems, standards, guidelines, etc.) for hiring, position assignments, growth (training), evaluations, transfers, compensation, welfare, and other benefits, and promoting their appropriate operation based on this policy.

In the Survey on Employee Satisfaction carried out annually at each Group company, we aim for higher scores in major areas while incorporating the opinions of the human resources management system that surface in the survey to review and improve the system.

#### Promoting work-style reforms with respect for diverse values

In accordance with the Act on the Arrangement of Related Acts to Promote Work Style Reform, we are making efforts to rectify long working hours and accommodate diverse work styles. As part of these efforts, we seek to create workplace environments that make it easy to balance work and family life by supporting employees throughout their various life stages including times they need to provide childcare or nursing care, while creating environments that provide employees with full lives backed by a healthy family life.

#### Support for employees' childcare and nursing care

We have in place a system for employees who need to provide childcare or nursing care. In recognition of these efforts, in 2021, we received Kurumin Certification as a "company that supports child rearing" under the Act on Advancement of Measures to Support

Raising Next-Generation Children. We are

also aiming to have at least 50% of male

employees take childcare leave (by fiscal 2025). Percentage of employees taking childcare leave (consolidated basis, fiscal 2022)

> Note: Calculated as number of employees taking childcare leave (including employees and employees whose spouses gave birth in fiscal 2021 and previous years) divided by number of employees and employees whose spouses gave birth in fiscal 2022

Men:

Women: 107.4%

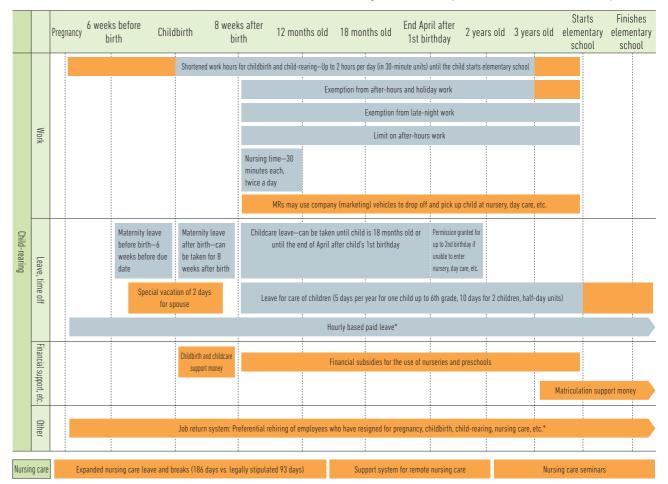
32.3%

#### 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 Act on the Arrangement of 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.

Percentage of allotted paid | 74.2% leave taken (consolidated basis, fiscal 2022)

Legal standards Kyorin's own standards or additional provisions



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

#### "Partners for mutual benefits over the long term"

By continuously fulfilling the responsibilities expected of each other over the long term, the Company and its employees are partners who realize mutual benefits (with employees contributing to the Company's development, and the Company enriching employees' lives and contributing to their self-fulfillment).

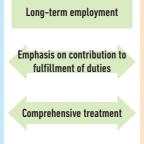
#### Employees

Contribute to achieving the Company's (organization's) goals and objectives through autonomy, growth, and performance of their duties

Perform tasks and carry out duties proactively and with initiative

Take initiative to maintain and enhance their own humanity and ability to carry out their duties

Cooperate with co-workers for the success of the organization



Self-reliance and cooperation

#### Company

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

Each employee is assigned duties that conform to ability 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.

#### Job return system

The Company 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.

#### Mid-career hiring

In addition to hiring new graduates, we hire mid-career people with advanced skills and extensive experience to create more diverse and flexible work styles. We work to eliminate concerns about things like unequal opportunities for promotion and strive to assign the right person to the right position.

Percentage of full-time employees	42%
who are mid-career hires	
(consolidated basis, fiscal 2022)	
Percentage of managers who are mid-career hires	26.1%
(consolidated basis, fiscal 2022)	

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## **Initiatives for Health Management**

#### Initiatives on disability hiring

As one of its social responsibilities, the Company 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.

2.43%

#### Percentage of employees with disabilities

(KYORIN Pharmaceutical, fiscal 2022)

#### Human resources development

The Company 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 managers. Functional training is provided by each department to give employees the knowledge and skills required in their roles.

¥60.000

#### Amount spent on training per employee

(KYORIN Pharmaceutical, fiscal 2022)

The Company 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 work together to help the employee recover, return to work, and prevent a relapse.

Percentage of employees taking leave for mental health

Percentage of those returning to work

(consolidated basis fiscal 2022)

#### Promoting women's active participation

Through initiatives related to promoting women's active participation, we are creating workplace environments in which female employees can fully use their capabilities and play active roles. Our goal is to have women fill 15% of management positions by 2030.

Percentage of women in management positions (consolidated basis, fiscal 2022)

Pay difference between male and female employees

(KYORIN Pharmaceutical, fiscal 2022)

8.5%

All employees: 68.4% Full-time employees: 72.4% Part-time and contract

#### Mental health

0.75%

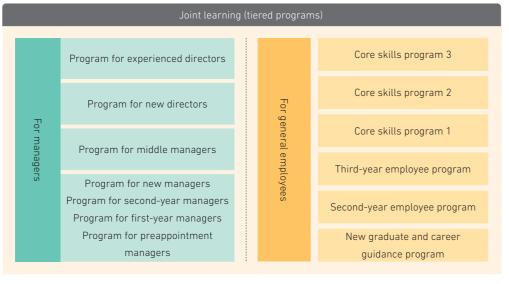
52.9%

employees: 46.7%

#### Overall structure of solo learning/joint learning



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The Kyorin Group believes that the health of each employee, both mental and physical, is essential for realizing our corporate philosophy and achieving our long-term vision, and on June 16, 2020, we formulated the Kyorin Group Health Declaration to promote Health Management.®\* We aim to create workplace environments in which all employees are motivated to promote their own health and approach their work enthusiastically. In recognition of these efforts, the Company has been designated as one of the Certified

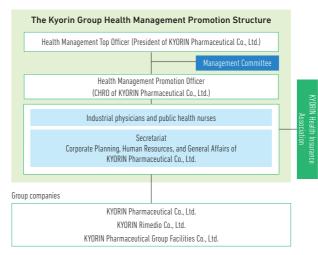
Health & Productivity Management Outstanding Organizations (large corporate sector) for five consecutive years, since 2019.

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

健康経営優良法人

#### **Health Management Promotion Structure**

The top officer of this structure is the president of KYORIN Pharmaceutical Co., Ltd., and the promotion officer is the CHRO of KYORIN Pharmaceutical Co., Ltd. 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.



#### **Major 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 2025, using 2019 as our reference year, and are currently implementing improvements.

	2019 results (reference year)	2020 results	2021 results	2022 results	2025 targets
Percentage of employees who do not smoke	80.6%	81.3%	82.3%	82.5%	85%
Percentage of employees who drink appropriate amounts of alcohol*	73.4%	74.6%	73.6%	70.1%	80%
Percentage of employees who walk or engage in equivalent physical activities for one hour or more per day	45.0%	44.8%	44.0%	44.8%	55%
Percentage of employees who get sufficient sleep	64.8%	72.8%	69.1%	67.2%	75%

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

#### The Kyorin Group Health Declaration

(Established on June 16, 2020)

#### —Your Health is Kyorin's Mission—

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.

### 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." 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). 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 were changed, and some activities were cancelled.



Classroom visi



Teach Me—Doctors Explain the Great Adventure for the Karada-no-Himitsu



Course for the general public



Website for patients with ulcerative colitis and Crohn's disease

#### 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 business facility offers internships and provides workplace tours and hands-on workshops for junior and senior high school students.

#### Supporting a hands-on science event for children

The Kyorin Group has supported the "Kyorin Group Presents the Great Adventure for the Karada-no-Himitsu (the Body's Secrets)" program since 2016, with the idea of supporting healthy lives for children, who will lead the next generation. Suspended in 2020 to prevent the spread of COVID-19, this event was restarted in 2023 on an even larger scale as the Ultimate Great Adventure for the Karada-no-Himitsu. Also, in fiscal 2018, we launched the event-linked website Teach Me—Doctors Explain the Great Adventure for the Karada-no-Himitsu, which provides videos for children from kindergarten through lower elementary school ages describing the body's workings and explaining diseases to deepen their interest and motivate them to learn more. URL: https://www.kyorin-pharm.co.jp/karada/ (Japanese only)

#### Course for the general public

In June 2023, we held a course for the general public on concerns about prolonged coughing and how to deal with it to help the general public better understand the disease.

#### Websites for patients with ulcerative colitis and Crohn's disease

We have set up the websites "Guide to Ulcerative Colitis and Crohn's Disease" and "Intractable Disease Subsidy System for Patients with Ulcerative Colitis or Crohn's Disease," which provide useful information on the diseases and subsidy programs for patients and their families.

#### Milton brand official account

In July 2022, we launched an official Instagram account for the Milton brand to provide product information and also to distribute useful information to people raising children or about to have children with online seminars like Mini-Classroom for Parents at Home through a tie-up with Benesse's Tamahiyo service.

Milton brand official account: https://www.instagram.com/milton\_official.jp/

#### Contributing to local communities

#### Sponsoring sports events

We support the Shimotsuke Soccer Workshop in Nogi sports event, which was held in fiscal 2022 for the 22nd time, to provide local children an opportunity to think about and experience their own health management and improve their skills. Led by former J-League player and current sports journalist Tetsuo Nakanishi, the fiscal 2022 event was held outdoors for the first time in three years, and many children showed impressive strength and stamina in their playing. Donations were also collected at the event to support the local community, and soccer balls were donated to the town of Nogi in Tochigi Prefecture.

#### 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
- Noshiro Plant: Clearing away fallen leaves around government buildings, cleanup activities in Nakashima Park at Noshiro Port, and cleanup activities at the Kaneyu, a former Japanese-style restaurant
- Inami Plant: Cleanup activities at Zuisenji Temple
- Shiga Plant: Participation in "Sunflower Project" and the "Make Lake Biwa Beautiful" environmental conservation activities

#### Donations to areas affected by natural disasters

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

- Support for those affected by heavy rains in the Hokuriku region in August 2022: Environmental hygiene supplies (Rubysta)
- Support for those affected by heavy rains in Aomori Prefecture in August 2022: Environmental hygiene supplies (Rubysta, Milton)

#### First-aid and lifesaving courses for employees

Group employees including roughly 650 Kyorin medical representatives received training on the need for first aid, CPR, the use of AEDs, and ways to stop bleeding.





Shimotsuke Soccer Workshop



Soccer ball donation ceremony



Cleanup at Zuisenji Temple

#### In Harmony with the Environment

#### **Basic stance**

The Kyorin Group's Charter of Corporate Conduct details our 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." Business activities that take into account climate change and other environmental considerations are one example of our materiality.

Following our basic policy on sustainability, the Group promotes reduced use of environmentally harmful materials and the effective use of the world's limited resources through energy and resource conservation, waste reduction, and enhanced chemical substance management in all our business activities. By setting and constantly reviewing objectives and targets for these initiatives, we are voluntarily and proactively committed to protecting the environment and preventing pollution.

#### **Environmental management structure**

The Group has established an Environmental Committee, chaired by the corporate officer in charge of General Affairs, to implement and promote environmental measures, including ones addressing climate change, as a structure to consider environmental measures at the Group level. Led by General Affairs, the committee, which comprises directors, corporate auditors, and corporate officers for management strategies and the plants and research centers doing business related to the environment in local communities, considers and reviews responses to environmental issues (vision, targets, road maps, etc.). In coordination with environmental, health, and safety (EHS) activities, the committee identifies and evaluates risks and opportunities related to climate change and comprehensively compiles additional measures that it

proposes to the Management Committee, with the resulting decisions reported to the Board of Directors.

#### Promoting environmental management

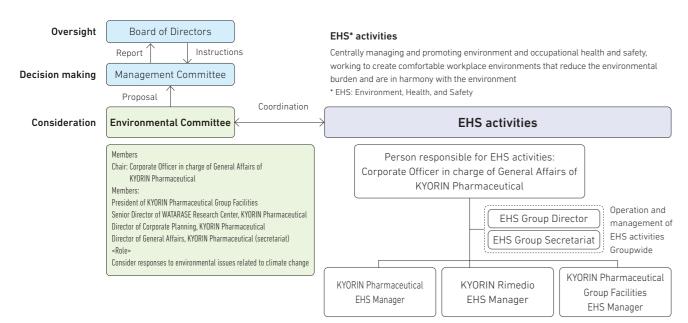
We are promoting the effective use of the world's limited resources and have set targets to protect the environment under the important themes of preventing global warming, protecting resources, and living in harmony with the natural environment. All Group plants have obtained ISO 14001 certification, an international standard for environmental management systems. We will maintain and continue these measures going forward.

Regarding climate change, we will promote the reduction of CO<sub>2</sub> emissions for preventing global warming. We also evaluate and address climate change risks and earnings opportunities by referencing the framework of the Task Force on Climate-related Financial Disclosures (TCFD) and are promoting expanded disclosure related to the effects of climate change on our businesses.

## Analysis of risks and earnings opportunities related to climate change

The effects on the Kyorin Group's business and management from global warming and climate change themselves, as well as changes to the business environment from long-term policy related to climate change, are broken down as physical risks and earnings opportunities caused by climate change and transition risks to a decarbonized society, and undergo a scenario analysis.

The scenario analysis is carried out by referencing documents and materials including the Intergovernmental Panel on Climate Change's (the IPCC's) Fifth Assessment Report's RCP 2.6 (2°C scenario) and RCP 8.5 (4°C scenario).



#### 2°C 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.	<ul> <li>Further promote activities to reduce CO<sub>2</sub> emissions</li> <li>Shift to electric power generated from renewable energy sources</li> <li>Reduce number of vehicles for sales force and switch to hybrid vehicles and electric vehicles</li> <li>Efficiently use the EHS management system</li> </ul>
·	Installation of equipment and machinery	<ul> <li>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.</li> </ul>	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	<ul> <li>Delays in the Company's introduction of climate change countermeasures could erode investor confidence and negatively affect the share price.</li> <li>Insufficient disclosure of information could reduce share price.</li> </ul>	Disclose timely and appropriate information including status of climate change countermeasures     Participate in external surveys

#### 4°C Scenario

#### Physical Risks

Segment	Event	Risks	Response policy
Acute risk	Direct damage from unusual weather (typhoons, heavy rains, etc.)	<ul> <li>Localized heavy rains, large typhoons, etc., could cause flooding, halt operations, and necessitate repair expenses at research, manufacturing, and logistics centers.</li> <li>In addition to Group facilities, supply chain disruptions (affecting materials procurement and shipment logistics) could occur.</li> </ul>	<ul> <li>Consider and implement equipment plans that envision water damage, etc.</li> <li>Carry out drills that envision emergencies</li> <li>Appropriately manage inventories</li> <li>Secure multiple suppliers of materials</li> </ul>
Chronic risk	Changes in location of centers, procurement, and operations from changes in climate patterns, higher temperatures, rising 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 physical 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

#### **Earnings Opportunities**

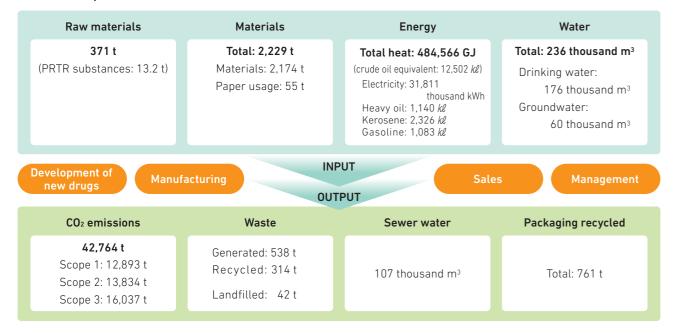
Segment	Event	Earnings opportunity	Response policy
Market changes	Changes in disease trends	<ul> <li>Increases in infectious disease from rising temperatures could increase the Company's business opportunities.</li> <li>Demand and scope of appropriate use of our products for the prevention, diagnosis,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

#### Moving toward carbon neutrality

Vision: The tackling of environmental issues is a mission for all humankind. We are voluntarily pursuing the challenge of "carbon neutrality by 2050" as an imperative component for the very existence of corporations.

2030 target: Reduce CO2 emissions 46% in fiscal 2030 vs. fiscal 2015

#### KYORIN Group material flow (fiscal 2022)



#### CO<sub>2</sub> emissions (Scope 1, 2, and 3)

The Kyorin Group strives to expand the scope of coverage to calculate CO2 emissions throughout its supply chains.



#### **Specific initiatives**

#### Introducing low-emission cars to reduce CO<sub>2</sub> emissions

The Kyorin Group is reducing the number of vehicles used by its sales force and proactively introducing low-emission cars, hybrid cars, and other environmentally friendly vehicles to prevent global warming. As of March 2023, all 861 vehicles used by the sales force met the standard for having low emission, and of these, 389 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.



Low-emission car

#### Environmentally friendly head office and R&D center

The head office (Ochanomizu sola city) has reduced its CO<sub>2</sub> 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 the WATARASE Research Center was awarded an honorable mention in the Kanto chapter of the Japanese Association of



WATARASE Research Center

Building Mechanical and Electrical Engineers' carbonneutral 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 2022, this system reduced electric power consumption 69,158 kWh and CO<sub>2</sub> emissions roughly 32 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, the Company 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.

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#### **Corporate Governance**

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

#### Basic policy on corporate governance

The most important management goal for the Company 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 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.

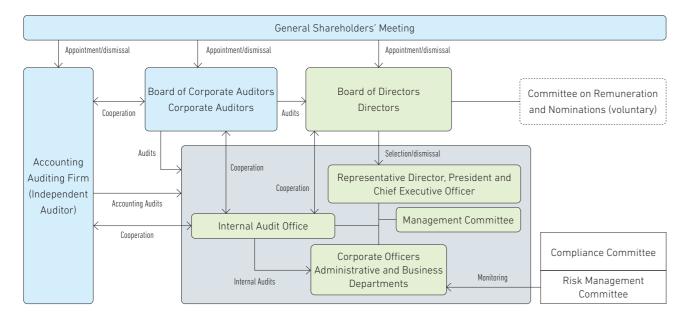
The Company has appointed three outside directors to further strengthen supervision of the business execution of directors and to further enhance the transparency and fairness of management.

The Company 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 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), we appoint compliance and risk management promotion officers for every Kyorin Group company. We have established a Groupwide compliance and risk management system administered by the Compliance Committee and Risk Management Committee. We have established guidelines for each Group 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 meet with their management before deciding important issues. The Internal Audit Office conducts audits of each Group company based on internal audit guidelines. Following the results of these audits, the heads of departments that oversee the operations of Group companies issue instructions or warnings and provide appropriate guidance.

#### Corporate governance structure



#### **Corporate governance system**

#### **Board of Directors**

The Company's Board of Directors comprises six 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, Michiro Onota
Outside Directors: Noriyuki Shikanai, Ken Shigematsu,
Hiromi Watanabe

#### Business execution system (Management Committee)

To oversee business execution, we established a Management Committee comprising internal directors and chief X officers (CxOs) that discusses and decides key operational matters about the Company and Group companies.

Chairperson: Yutaka Ogihara, Representative Director,
President and Chief Executive Officer
Executive Directors: Minoru Hogawa, Michiro Onota
Chief X Officers (CxOs): Yasuyuki Shimokawa, Yasuji
Kurose, Takaaki Kaji, Noriaki
Tamura, Junichi Ishiyama

In addition to the representative directors and the internal 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 30, 2023, the Company had 13 corporate officers.

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

Following the Companies Act of Japan, the Company 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 (voluntary)

For the remuneration and nomination of directors and corporate auditors (including succession planning), the Company 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 (As of June 30, 2023)

Key items	Description
Organizational design	Company with a board of corporate auditors
Number of directors (including outside directors)	6 (3)
Number of corporate auditors (including outside corporate auditors)	5 (3)
Number of the Board of Directors' meetings (held during fiscal 2022)	13
(Average attendance rate of outside directors)	(100%)
(Average attendance rate of outside corporate auditors)	(97%)
Number of the Board of Corporate Auditors' meetings (held during fiscal 2022)	13
(Average attendance rate of outside corporate auditors)	(97%)
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 (voluntary)
Accounting auditing firm	Ernst & Young ShinNihon LLC

#### Outside directors and outside corporate auditors

The Company 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 wideranging 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, an attorney, is well versed in corporate legal affairs and has considerable knowledge of legal matters.

The Company has established criteria for determining the independence of outside directors and outside corporate auditors, and selects candidates on the premise that they have sufficient independence to perform their duties as outside officers independent of the Company's management. 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, Inc.

#### 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 at the General Shareholders' Meeting. The amounts are determined by the representative director, president and chief executive officer, who is delegated that authority by the Board of Directors, after the objectivity and transparency of the decision-making process have been confirmed by examining whether any arbitrary decisions were made as well as the statistical data used as a reference, 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 (Fiscal 2022)

Discount of the second of the	Total compensation	Total paid by type (Millions	Number of applicable	
Director or corporate auditor	paid (Millions of yen)	Basic compensation	Stock options	directors and corporate auditors (People)
Directors (Excluding outside directors)	181	173	8	6
Corporate auditors (Excluding outside corporate auditors)	33	33	_	3
Outside directors or corporate auditors	49	49	_	8

<sup>\*</sup> Includes one director and one corporate auditor who retired on June 24, 2022.

#### Internal audits and audits conducted by corporate auditors

Internal audits are conducted by the Internal Audit Office, which is staffed by six employees who report directly to the president and is independent from other sections. Following yearly auditing plans, the Internal Audit Office regularly assesses and evaluates the effectiveness and efficiency of the legal compliance and internal control systems in the Company 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 audit divisions 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.

#### 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		0	0	0			
	Yutaka Ogihara		0	0				
	Michiro Onota		0	0				
	Noriyuki Shikanai	Outside Independent				0		Attorney
	Ken Shigematsu	Outside Independent	0					
	Hiromi Watanabe	Outside Independent		0			0	Medical Doctor
	Tomiharu Matsumoto			0		0		
	Kenji Akutsu		0	0				
Corporate auditors	Takao Yamaguchi	Outside Independent			0			Certified Public Accountant
	Yukio Ikemura	Outside Independent	0		0			
	Kensuke Morita	Outside Independent				0	0	Attorney

#### **Messages from Outside Directors**



Noriyuki Shikanai
Outside Director/
Independent Officer

As an outside director, I am engaged in management supervision from the perspective of shareholders, focusing on Kyorin's corporate governance and compliance. I also offer opinions to enhance corporate value from a social perspective, including views on initiatives to address the UN's Sustainable Development Goals.

The COVID-19 pandemic has caused the general public to pay closer attention to the approval system for ethical drugs. Against this backdrop, we are constantly discussing how the Company's business activities can contribute to society. Today, the ways people interact with each other in their social lives and in corporate activities are changing greatly, while at the same time companies cannot ignore the development of generative AI for the next generation. I believe that proactively introducing generative AI can increase a company's management efficiency for growth as a company that can contribute even more to society. As an attorney, I have been in a position to offer objective advice to a wide range of companies and will proactively offer advice and recommendations to Kyorin's management, referencing my experience with the management of other companies.



Ken Shigematsu
Outside Director/
Independent Officer

The long-term vision "Vision 110," formulated on the 100th anniversary of Kyorin's founding, includes a major transformation and a major challenge. The transformation is from a pure holding company structure to a business holding company structure with KYORIN Pharmaceutical as the core company, for a management structure more closely aligned with the Group's businesses. In addition, the designation of chief X officers with clear authority and responsibilities in key operational areas has created a business management structure that can function with greater mobility than in the past. The challenge lies in the Company's future business direction. In research and development, we are shifting investment to human capital and the development pipeline to achieve our targeted portfolio, while on the manufacturing side, construction of the Takaoka Plant is on track to begin operations, which will create a production structure that dramatically improves productivity and advances toward decarbonization.

The Board of Directors is discussing issues to continuously enhance corporate value over a medium-term time frame while closely following today's business developments. The Committee on Remuneration and Nominations (voluntary) makes its decisions based not only on business results but also by fully evaluating processes and effectively makes impartial and exacting decisions. As an independent outside director, I supervise management objectively while offering advice as necessary on areas including management strategy, capital policies, and compliance.

I ask for the continued support of shareholders.

#### **Messages from Outside Directors**



**Hiromi Watanabe**Outside Director/
Independent Officer

The Japanese government has set a target for companies listed on the Tokyo Stock Exchange's Prime Market of "raising the percentage of female officers from 11.4% as of 2022 to at least 30% by 2030." The intention is not only to shine a light on minorities but also to use the ideas, sensitivities, and special characteristics of women to create boards that address gender issues and other aspects of diversity. Nevertheless, Japan ranked 125th of 146 countries in the World Economic Forum's Global Gender Gap Report 2023 and 123rd in the Economic Participation and Opportunity category, in part because of the small number of women in management positions.

Even if companies establish internal programs for workers to support childcare and nursing care, it will still be difficult for employees to continue their careers if those programs are not fully utilized. On the 100th anniversary of Kyorin's founding, the internal Project for Women's Active Participation, which looks 10 years into the future, was launched. The project is collecting and sharing a wide range of information and has begun proposing policies to train newly hired employees, confirm career plans, and support the return to work and continuation of careers. These issues concern not only women but also the work styles of male employees of all ages. We recognize that these are urgent issues for the Company as a whole. As a female independent outside director, I will make every effort to support participation by women with a view toward the Company's future from a medium- to long-term perspective.

As a medical doctor, I offer advice on a range of issues in the belief that one of my important roles is to represent the positions of medical workplaces and the actual perspectives of patients.

## Ten-Year Consolidated Financial Highlights

(Fiscal years ended March 31/As of March 31)

Millions of yen

	3/2014	3/2015	3/2016	3/2017	3/2018*2	3/2019	3/2020	3/2021	3/2022*3	3/2023
Net sales	111,400	113,121	119,483	115,373	110,640	113,620	109,983	102,904	105,534	113,270
New drugs, etc. (Japan)*1	97,562	96,612	98,430	89,584	79,639	83,456	77,535	69,735	69,725	74,770
New drugs (Overseas)	1,849	1,032	5,586	764	3,339	830	1,490	996	1,033	308
Generic drugs	11,987	15,477	15,465	25,024	27,662	29,334	30,957	32,172	34,775	38,190
Operating profit	17,607	14,737	19,636	10,413	8,822	8,972	7,503	5,786	5,007	5,123
Profit attributable to owners of parent	12,025	12,064	13,639	7,305	6,574	6,869	6,149	6,130	3,932	4,723
Net cash provided by operating activities	19,293	6,391	11,137	16,386	10,456	340	7,739	5,189	6,346	2,008
Net cash provided by (used in) investing activities	(2,477)	(1,364)	650	(13,142)	(6,038)	14,939	(2,943)	(4,259)	(2,560)	(6,275)
Net cash used in financing activities	(3,704)	(5,233)	(2,245)	(5,721)	(3,735)	(27,315)	(5,117)	(4,918)	(4,112)	(3,363)
Free cash flow	16,816	5,027	11,787	3,244	4,418	15,279	4,796	930	3,786	(4,267)
R&D expenses	11,359	13,514	13,019	13,569	14,243	10,790	10,987	9,703	8,897	10,903
Capital expenditures	6,500	2,655	7,218	3,051	2,885	2,306	3,590	4,307	3,624	5,252
Depreciation and amortization	3,153	3,053	3,730	3,619	3,644	2,940	3,221	3,564	3,714	3,840
Total assets	169,378	183,383	197,825	192,668	196,736	173,034	171,160	167,126	171,924	176,045
Total net assets	137,821	148,600	157,049	157,837	163,297	123,395	122,710	124,661	124,507	125,461
Per Share Information										
Net assets (Yen)	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	2,189.40
Basic profit (Yen)	160.95	161.63	184.28	99.45	89.28	104.68	107.35	106.99	68.62	82.44
Cash dividends (Yen)	52.00	52.00	58.00	58.00	58.00	75.00	75.00	75.00	52.00	52.00
Key Performance Indicators										
Operating profit margin (%)	15.8	13.0	16.4	9.0	8.0	7.9	6.8	5.6	4.7	4.5
Profit attributable to owners of parent / Net sales ratio (%)	10.8	10.7	11.4	6.3	5.9	6.0	5.6	6.0	3.7	4.2
R&D expenses / Net sales ratio (%)	10.2	11.9	10.9	11.8	12.9	9.5	10.0	9.4	8.4	9.6
Total shareholders' equity ratio (%)	81.4	81.0	79.4	81.9	83.0	71.3	71.7	74.6	72.4	71.3
ROE (%)	9.0	8.4	8.9	4.6	4.1	4.8	5.0	5.0	3.2	3.8
Consolidated payout ratio (%)	32.3	32.2	31.8	59.3	65.9	72.6	70.9	71.1	76.9	64.0
PER (times)	12.25	17.78	11.63	23.64	22.39	20.64	20.48	18.02	25.90	20.67
Non-Financial Information										
Number of employees	2,452	2,445	2,420	2,382	2,348	2,297	2,271	2,243	2,222	2,138
	<del></del>									

<sup>\*1</sup> 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 drugs (Japan) and healthcare businesses have been combined into new drugs, etc. (Japan).

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<sup>\*2</sup> Figures shown are adjusted to retroactively apply certain revisions to accounting standards related to tax-effect accounting.

<sup>\*3</sup> 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**



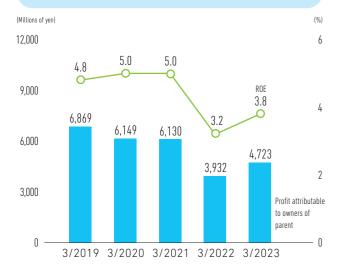
Although affected by drug price revisions and the COVID-19 pandemic, sales of new drugs, etc. (Japan) surpassed those of the previous fiscal year due to growth in sales of main products such as Beova and Desalex. Sales of generic drugs also rose. The result was an overall sales increase of ¥7,735 million over those of the previous fiscal year.

#### Operating profit, Operating profit margin



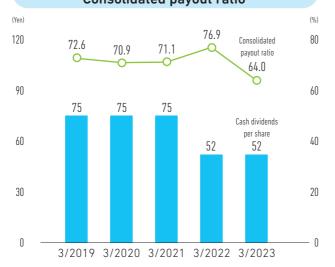
Gross profit increased ¥726 million over that of the previous fiscal year due to sales expansion, but selling, general and administrative expenses increased ¥610 million (including increased R&D expenses of ¥2,005 million), resulting in an operating profit of ¥5,123 million, an increase of ¥115 million

#### Profit attributable to owners of parent, ROE



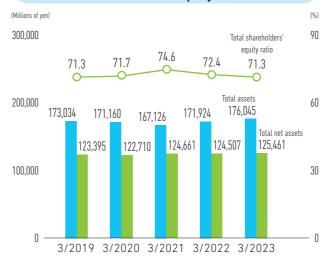
Profit figures surpassed those of the previous fiscal year, and ROE was 3.8%. The Company aims to increase profit and improve ROE by maximizing the ratio of new drugs and through cost competitiveness.

#### Cash dividends per share, Consolidated payout ratio



Regarding returns to shareholders, we aim to pay stable dividends based on DOE. From fiscal 2021, 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 ¥4,121 million compared to those at the end of the previous fiscal year. Total net assets rose ¥953 million due to an increase in retained earnings, despite a decrease in valuation difference on available-for-sale securities and other factors. As a result, the total shareholders' equity ratio decreased 1.1 percentage points year on year, to 71.3%.

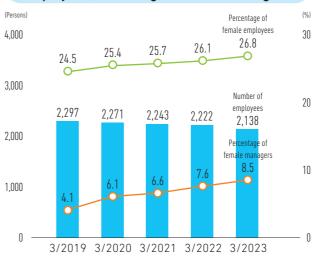
#### R&D expenses, R&D expenses/Net sales ratio



The expense level for research and development varies according to factors such as the progress of the development stage (phase of clinical trial). In fiscal 2022, R&D expenses increased ¥2,005 million over those of the previous fiscal year. We will invest in research and development to create high-value new drugs that meet medical needs and expand our development pipeline to improve corporate value.

#### Non-Financial Information

#### Number of employees, Percentage of female employees, Percentage of female managers



As of March 31, 2023, the entire Group had 2,138 employees, of whom 26.8% were female, and female managers made up 8.5% of all managers. We are working to create an environment in which female employees can demonstrate their talents and use them to the fullest.

### Employee turnover rate



As of April 1, the percentage of employees who left for personal reasons during fiscal 2022 was 3.9% for the entire Group.

#### **Non-Financial Information**

#### Employment rate of persons with disabilities



3/2019 3/2020 3/2021 3/2022 3/2023

As of March 31, 2023, the employment rate of persons with disabilities was 2.33% for the Group as a whole. We are working to create a comfortable work environment that allows people with disabilities to fully demonstrate their talents.

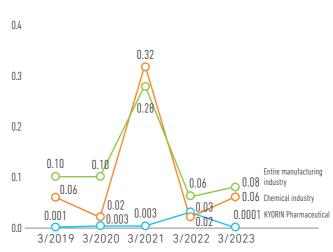
#### Usage rate of annual paid leave



3/2019 3/2020 3/2021 3/2022 3/2023

The usage rate of annual paid leave during fiscal 2022 was 74.2% for the entire Group. We regularly promote taking paid leave to enable employees to maintain a good work-life balance to maximize their capabilities.

# Severity of work accidents



Due to our efforts to prevent work accidents, the severity rate, which indicates the degree of severity of work accidents, is below the levels of the entire manufacturing industry and the chemical industry.

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

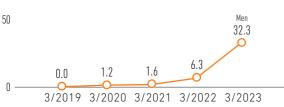
#### Waste volume in relation to sales



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

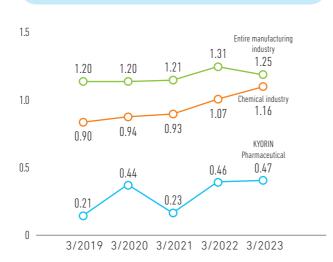
#### Usage rate of childcare leave





The childcare leave usage rate for the entire Group in fiscal 2022 was 107.4% for women and 32.3% for men. The denominator is the number of employees who gave birth to a child or whose spouses gave birth during the fiscal year. The numerator is the number of employees who took childcare leave (including those who had given birth or whose spouses had given birth in the previous fiscal year).

#### Rate of work accidents



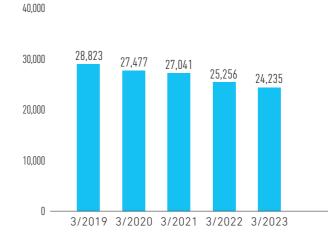
To improve the levels of health and safety, we are working to achieve zero work accidents, promote employee health, and create comfortable work environments. The rate of work accidents, which represents the frequency of occupational accidents, is below the level of the entire manufacturing industry and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

Frequency of accidents: Number of deaths and injuries due to work accidents

(excluding accidents while commuting)/Total work hours x

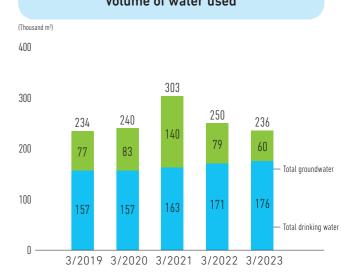
1.000.000

# CO<sub>2</sub> emissions from the head office, branches, factories, and research laboratories



We have set a target to reduce  $CO_2$  emissions 6% (1.5% per year on average) from the fiscal 2019 level by fiscal 2023 and achieved the target with 24,235 tons emitted in fiscal 2022. Currently, we have set a new target of a 46% reduction from the fiscal 2015 level by fiscal 2030 and are working on various measures.

## 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.

## Directors, Corporate Auditors, and Corporate Officers

(As of June 23, 2023)

#### **Executive Directors**



#### Minoru Hogawa

Representative Director, Chairman

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.

Executive Director, Management Strategy Office, General Manager of Management Planning Department. in charge of Accounting of the Company Executive Director, Senior Executive Officer, General Manager

of Management Planning Department, in charge of Finance & Accounting Department of the Company Senior Executive Director, General Manager of Management Planning Department, in charge of Senior Managing Director, General Manager of

Finance & Accounting Department of the Company Representative Director, President and Chief Executive Officer in charge of Auditing Office of the Company Officer of KYORIN Pharmaceutical Co., Ltd. Representative Director, Chairman of the Company

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



#### Yutaka Ogihara

Representative Director, President and Chief Executive Officer, in charge of Auditing

Joined KYORIN Pharmaceutical Co., Ltd. June 2011 Executive Director, President's Office, in charge of Corporate Communication Department and Information System Management Department of the Company Executive Director, President's Office of the Compan June 2016 Senior Executive Director, President's Office of the

June 2016 Senior Executive Director of KYORIN Pharmaceutical April 2019 Senior Executive Director, Management Strategy

Office, in charge of Information System Management Department of the Company

Officer, in charge of Auditing Office of the Company Executive Director of KYORIN Pharmaceutical Co., Ltd.
Representative Director, President and Chief Executive Officer in charge of Auditing of the Company (current)



#### Michiro Onota

Executive Director, CMO, in charge of SCM and Quality Assurance & Reliability Representative Director, President of KYORIN Pharmaceutical Group Facilities Co., Ltd.

Inined KYORIN Pharmaceutical Co., Ltd. Representative Director, President and Chief Executive Officer of KYORIN Rimedio Co., Ltd. June 2017 Executive Director of the Company

Representative Director, President of KYORIN Pharmaceutical Group Facilities Co., Ltd. (current) Executive Director of KYORIN Pharmaceutical Co., Ltd. June 2019 Executive Director, in charge of Generic Drugs Business June 2021 Executive Director, in charge of Quality Assurance &

Reliability of the Company Executive Director, CMO, in charge of SCM and Quality Anril 2023

Ken Shigematsu

May 2002

March 2004

March 2005

October 2015

Outside Director/Independent Officer

Holdings Ltd.

Director of Mitsukoshi, Ltd.

Officer of MES LCo. Ltd. Outside Director of the Company (current)

Joined Mitsukoshi, Ltd.

Executive Officer, General Manager of Product Planning Division, Sales Headquarters of Mitsukoshi, Ltd.

Director, Executive Officer, Deputy General Manager of

Director, Managing Executive Officer, General Manager

of Merchandising Headquarters of Mitsukoshi, Ltd. Director, Managing Executive Officer, Store Manager of Mitsukoshi Ginza of Mitsukoshi, Ltd.

Managing Executive Officer of Isetan Mitsukoshi

Director, Senior Managing Executive Officer, Special Annointive Officer of Mitsukoshi, Ltd. Senior Managing Executive Officer of Isetan Mitsukoshi

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

Officer of Endo Manufacturing Co., Ltd. Representative Director, President and Chief Executive

Sales Headquarters of Mitsukoshi, Ltd.



### 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)

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 the Company (current)



Hiromi Watanabe Outside Director/Independent Officer

Joined Internal Medicine Department of Tokyo Women's

Medical University Hospital 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

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 April 2016 Professor of Graduate School of Nursing Division of Nursing

of Shukutoku University Neurology Department of Yokufukai Hospital of Total Health and Medical Care Center for Seniors (social welfare corporation) (current) Member of the Board of 3.11 Fund for Children with Thyroid

Cancer (NPO) (current) Outside Director of the Company (current) Member of the Board of Daijo Shukutoku Gakuen (current) April 2021 October 2021 Deputy Director of Shimotakaido Station Clinic ENT Plus+

\*The KYORIN Pharmaceutical Co., Ltd. listed in the career summary of each officer refers to the former KYORIN Pharmaceutical Co., Ltd., which merged with the Company on

#### **Senior Corporate Auditors**

### Tomiharu Matsumoto Kenji Akutsu

#### **Outside Corporate Auditors/ Independent Officers**

Takao Yamaguchi Yukio Ikemura Kensuke Morita

#### **Corporate Officers**

#### Yasuyuki Shimokawa

In charge of Human Resources, General Affairs, and Legal & Compliance

Corporate Officer CStO & CFO

Director of Corporate Planning, in charge of Product Strategy and Finance & Accounting

#### Takaaki Kaji

Senior Director of Business Development HQs

#### Junichi Ishiyama

Senior Director of Discovery Research HOs, in charge of Intellectual Property

#### Hiroshi Hashizume

Representative Director and President of KYORIN Rimedio Co., Ltd.

Corporate Officer

#### Yasuji Kurose

Corporate Officer CBDO

## Noriaki Tamura

Corporate Officer CCO Senior Director of Sales & Marketing HQs, in charge of Information System Management and I Vitro Diagnostics Business

Corporate Officer CSO

#### Kei Takahashi

Senior Corporate Officer Senior Director of SCM HQs

#### Tetsuo Tatsumi

Director of Tokyo Branch

#### Tokutaro Yasue

Senior Director of WATARASE Research Center

#### Director of CMC Research Laboratory

Makoto Yanai

#### Deputy Senior Director of Business Development HQs

Katsuhiro Hamada

Senior Director of Quality Assurance & Reliability HQs

Yoshinobu Hashimoto

Senior Director of Corporate Planning and Promotion Compliance of KYORIN Rimedio Co., Ltd.

#### Kiyoo Uehara

Director of General Affairs

## Major activities of outside directors and outside corporate auditors (Fiscal 2022)

Position	Name	Major activities	Attendance at meetings
	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 13 out of 13 Board of Directors' meetings
Outside Directors	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 13 out of 13 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 13 out of 13 Board of Directors' 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 13 out of 13 Board of Directors' meetings and 13 out of 13 Board of Corporate Auditors' meetings
Outside Corporate Auditors	Yukio Ikemura	He contributes appropriately to ensure accurate decision making by the Board of Directors. In addition, at meetings of the Board of Corporate Auditors, he offers suitable comments based on his experience and insight.	Attended 9 out of 9 Board of Directors' meetings* and 10 out of 10 Board of Corporate Auditors' meetings*
	Kensuke Morita	He makes comments as necessary based mainly on his specialist understanding as an attorney.	Attended 8 out of 9 Board of Directors' meetings* and 9 out of 10 Board of Corporate Auditors' meetings*

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## Financial Analysis

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

The Japanese ethical drugs industry maintained a low single-digit growth rate in the domestic ethical drugs market during fiscal 2022 due to the ongoing promotion of measures to curtail drug costs, such as the drug price revisions implemented in April 2022 in line with the NHI drug price system reform, while the number of medical consultations by patients impacted by COVID-19 normalized.

In this operating environment, the Kyorin Group set a management policy of "realization of a growth trend through the pursuit of originality" under the HOPE100 –Stage 3–medium-term business plan (fiscal 2020–2023), with the aim of achieving the Group's HOPE100 long-term vision. The main points of this strategy with relation to increasing the speed of business are (1) accelerate the growth of the new drugs group, (2) enhance the pipeline, and (3) increase the speed of drug discovery.

#### **Consolidated Operating Results**

For consolidated net sales for fiscal 2022, sales of new drugs, etc. (Japan) exceeded those of the previous fiscal year due to the growth of new drugs, driven by vigorous efforts to promote awareness of our products, despite the impact of drug price revisions (the 8% range for former KYORIN Pharmaceutical Co., Ltd.) and COVID-19. Sales of generic drugs also rose, and overall net sales totaled ¥113,270 million, a year-on-year increase of ¥7,735 million (7.3%), reaching the Group's consolidated performance target.

Regarding profit, despite the cost of sales ratio rising as a result of drug price revisions, etc., gross profit rose ¥726 million year on year due to increased sales. Furthermore, SG&A expenses excluding R&D expenses fell ¥1,395 million year on year (with R&D expenses rising ¥2,005 million), due to the absence of an upfront payment recorded the previous year for an agreement related to the introduction of a product and cost reduction measures. Operating profit rose ¥115 million year on year (2.3%), to ¥5,123 million. Profit attributable to owners of parent rose ¥791 million year on year (20.1%), to ¥4,723 million, due to extraordinary income of ¥881 million in gain on insurance related to storage products

damaged by a fire at the Nishinihon delivery center, ¥401 million in income of compensation for damages, and ¥685 million in gain on sale of investment securities, although extraordinary loss of ¥716 million was also recorded in the dissolution of ActivX Biosciences, Inc., a subsidiary of the former KYORIN Pharmaceutical Co., Ltd.

#### Assets, Liabilities, and Net Assets

As of March 31, 2023, current assets rose ¥2,654 million, with increases in accounts receivable and raw materials and supplies, despite a decrease in cash and deposits. Fixed assets rose ¥1,467 million, with increases in property, plant and equipment and intangible assets, despite a decrease in investment securities. As a result, total assets rose ¥4,121 million from those of the previous fiscal year-end, to ¥176,045 million.

Total liabilities rose ¥3,167 million from those of the previous fiscal year-end, to ¥50,584 million, due to increases in notes and accounts payable and in income taxes payable despite a decrease in other current liabilities.

Net assets rose \$953 million from those of the previous fiscal year-end, to \$125,461 million, due to an increase in retained earnings.

As a result, equity ratio at the fiscal year-end was 71.3%, a 1.1 percentage-point decrease from that of the previous fiscal year-end.

#### **Cash Flows**

Operating activities generated net cash of ¥2,008 million, primarily ¥6,906 million in profit before income taxes, ¥3,840 million in depreciation and amortization, a ¥5,621 million increase in notes and accounts receivable, a ¥5,809 million increase in inventories, a ¥2,866 million increase in notes and accounts payable, ¥3,050 million in proceeds from insurance income, and ¥2,065 million in income taxes paid.

Investing activities used net cash of ¥6,275 million, primarily ¥6,330 million in purchase of property, plant and equipment, ¥3,075 million in purchase of intangible assets, and ¥3,193 million in proceeds from the sale and redemption of investment securities.

Financing activities used net cash of ¥3,363 million, primarily ¥3,015 million paid as cash dividends.

As a result, cash and cash equivalents at the end of fiscal 2022 totaled ¥18,816 million, a ¥7,472 million decrease from that of the previous fiscal year-end.

#### Outlook for Fiscal 2024

The external environment surrounding the ethical drugs business included some unexpected events such as further promotion of measures to curtail medical expenses and drug costs including annual NHI drug price revisions (midyear revisions) and the reluctance of patients to visit medical institutions due to the COVID-19 pandemic. These events have significantly affected management of the Kyorin Group. On the other hand, we believe our internal environment has entered a period of growth with the launch of new drugs expected to become growth drivers and new businesses, such as the diagnostics business, being on track.

Under these circumstances, for fiscal 2023, the 100th anniversary of our founding, we have renovated the Group structure. At the same time, after concluding the HOPE100 long-term vision (fiscal 2010–2023) one year ahead of schedule, we decided to formulate and launch the new long-term vision "Vision 110" (fiscal 2023–2032) and the new medium-term business plan "Vision 110 –Stage1–" (fiscal 2023–2025). The new medium-term business plan reads "transforming to a business structure to realize Vision 110." For this, the Group will promote five business strategies to reach performance targets and improve support and evaluations from stakeholders.

The management policy for fiscal 2023, the first year of Vision 110, is growth by "reform of business structure and growth from new initiatives." We will actively work to reform our drug discovery systems, expand the development pipeline, maximize the expansion of sales growth in new drugs, and improve cost competitiveness, thereby achieving growth in the Group's business performance.

We forecast increased net sales of new drugs, etc. (Japan) during the next consolidated fiscal year due to expected sales growth for new drugs such as our core products Beova, an overactive bladder therapeutic agent, and Lyfnua, a chronic cough treatment, despite the impact of the drug price revisions in April 2023 (the 7% range for KYORIN Pharmaceutical Co., Ltd.). For generic drugs, we forecast a decrease in sales of authorized generics, although we anticipate an increase in sales of our main products, products newly listed in June 2023, and those to be listed in December 2023. As a result, we forecast ¥79,100 million in net sales of new drugs, etc. (Japan), ¥400 million in net sales of generic drugs, and consolidated net sales of ¥116,200 million.

Regarding profit, we forecast an increase in gross profit due to increased revenue and a lower cost of sales ratio resulting from a rise in the ratio of new drugs, despite the effect of drug price revisions. On the other hand, despite an expected rise in SG&A expenses (with year-on-year R&D expenses decreasing ¥1,300 million), we forecast operating profit of ¥6,000 million and profit attributable to owners of parent of ¥4,900 million due to an increase in gross profit.

#### **Business Risks**

The Group promotes its operations within the framework of pharmaceutical administration, in compliance with legal regulations regarding pharmaceutical research and 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, 2023.

#### 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. The Company has clarified its priority research areas and has been making efforts to expand its pipeline through R&D based on open innovation with domestic and overseas pharmaceutical companies, academic institutions, and venture start-ups, in addition to engaging in proprietary drug discovery at the WATARASE Research Center. 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 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.

# 5. Risks Associated with IT Security and Information

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 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 expiry of the original drugs increase, our business performance and financial condition could be materially affected.

#### 7. 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.

#### 8. 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.

#### 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 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 its critical issues. As a result, it has established the Environmental Committee to consider the impact of Groupwide business activities on the environment. 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.

### 11. 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.

#### 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.

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## **Consolidated Balance Sheet**

KYORIN Pharmaceutical Co., Ltd. and Consolidated Subsidiaries
As of March 31

		Millions of yen	Thousands of U.S. dollars (Note 3)
	2023	2022	2023
Assets			
Current assets:			
Cash and cash in banks (Notes 4 and 11)	¥ 19,394	¥ 26,994	\$ 145,230
Notes receivable (Note 11)	1,816	1,521	13,599
Accounts receivable (Note 11)	45,475	40,154	340,535
Contract assets	9	_	67
Short-term investments (Notes 5 and 11)	_	500	_
Inventories:			
Merchandise and finished goods	19,074	19,038	142,834
Work in process	9,079	7,742	67,987
Raw materials and supplies	19,872	15,437	148,809
Other	4,349	5,029	32,567
Less allowance for doubtful accounts	(41)	(39)	(307)
Total current assets	119,030	116,376	891,343
Property, plant and equipment:			
Land	2,830	2,872	21,192
Buildings and structures	33,950	33,791	254,231
Machinery and vehicle	26,341	25,940	197,252
Leased assets	757	840	5,669
Construction in progress	4,760	1,326	35,645
Other	9,213	9,855	68,991
Less accumulated depreciation and impairment loss	(52,019)	(50,293)	(389,539)
Property, plant and equipment, net	25,834	24,334	193,455
Investments and other assets:			
Investment securities (Notes 5 and 11)	22,979	25,703	172,076
Long-term loans	_	0	_
Deferred tax assets (Note 13)	1,316	783	9,855
Other	6,913	4,764	51,767
Less allowance for doubtful accounts	(29)	(38)	(217)
Total investments and other assets	31,179	31,213	233,481
Total assets	¥176,045	¥171,924	\$1,318,294

		Millions of yen	Thousands of U.S. dollar
	2023	2022	2023
Liabilities and net assets			
Current liabilities:			
Notes and accounts payable (Note 11)	¥ 13,762	¥ 10,896	\$ 103,055
Short-term bank loans (Notes 6 and 11)	10,300	10,300	77,130
Lease obligations (Note 6)	134	147	1,003
Accrued income taxes (Note 13)	2,027	530	15,179
Accrued bonuses to employees	2,182	2,295	16,340
Other	6,576	8,011	49,244
Total current liabilities	34,983	32,182	261,966
Long-term liabilities:			
Long-term debt (Notes 6 and 11)	10,636	10,836	79,647
Lease obligations (Note 6)	207	341	1,550
Deferred tax liabilities (Note 13)	_	175	_
Provision for stock-based payments	466	343	3,490
Liability for retirement benefits (Note 12)	3,721	2,885	27,864
Other	568	652	4,253
Total long-term liabilities	15,600	15,234	116,819
Net assets:			
Shareholders' equity (Note 7):			
Common stock, no par value:			
Authorized–297,000,000 shares in 2023 and 2022	700	700	5040
Issued-64,607,936 shares in 2023 and 2022	700	700	5,242
Capital surplus	4,752	4,752	35,585
Retained earnings	134,396	132,710	1,006,410
Treasury stock, at cost:			
7,304,066 shares in 2023	(.=)	( )	
7,306,000 shares in 2022	(17,666)	(17,671)	(132,290
Total shareholders' equity	122,182	120,491	914,947
Accumulated other comprehensive income:	F (0F	4.040	
Unrealized holding gain on other securities	5,695	6,268	42,646
Translation adjustments	340	110	2,546
Retirement benefits liability adjustments	(2,756)	(2,362)	(20,638
Total accumulated other comprehensive income  Total net assets	3,278	4,016	24,547
	125,461	124,507	939,501

See notes to consolidated financial statements.

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## **Consolidated Statement of Income**

KYORIN Pharmaceutical Co., Ltd. and Consolidated Subsidiaries For the year ended March 31, 2023

		Millions of yen	Thousands of U.S. dollars (Note 3)
	2023	2022	2023
Net sales	¥113,270	¥105,534	\$848,210
Cost of sales	63.102	56.093	472.533
Gross profit	50,167	49,441	375,670
Selling, general and administrative expenses (Note 8)	45,043	44,433	337,300
Operating profit	5,123	5,007	38,363
Other income (expenses):			
Interest and dividend income	465	411	3,482
Interest expense	(66)	(66)	(494)
Equity in (losses) gains of affiliates	(0)	25	(0)
Foreign exchange gain	78	98	584
Loss on sales and retirement of property, plant and	(15)	(32)	(112)
equipment, net (Note 9)	(10)	(32)	(112)
Gain on sales of investment securities (Note 5)	683	_	5,115
Loss on devaluation of investment securities (Note 5)	(9)	(320)	(67)
Gain on insurance	881	_	6,597
Compensation income for damages	401	_	3,003
Impairment loss (Note 10)	(257)	_	(1,925)
Loss on liquidation of subsidiaries and associates	(605)	_	(4,530)
Subsidy income	34	36	255
Other, net	194	56	1,453
Other income, net	1,783	209	13,352
Profit before income taxes	6,906	5,216	51,715
Income taxes (Note 13):			
Current	2,462	1,630	18,436
Deferred	(279)	(346)	(2,089)
Total income taxes	2,182	1,284	16,340
Profit	4,723	3,932	35,368
Profit attributable to shareholders of KYORIN Pharmaceutical Co., Ltd.	¥ 4,723	¥ 3,932	\$ 35,368

See notes to consolidated financial statements.

# **Consolidated Statement of Comprehensive Income**

KYORIN Pharmaceutical Co., Ltd. and Consolidated Subsidiaries For the year ended March 31, 2023

		Millions of yen	Thousands of U.S. dollars (Note 3)
	2023	2022	2023
Profit	¥4,723	¥3,932	\$35,368
Other comprehensive income (loss) (Note 14):			
Unrealized holding loss on other securities	(578)	(393)	(4,328)
Translation adjustments	229	151	1,715
Retirement benefits liability adjustments	(394)	(86)	(2,950)
Share of other comprehensive income of affiliates	5	21	37
accounted for using equity method		21	
Total other comprehensive loss	(737)	(306)	(5,519)
Comprehensive income	¥3,986	¥3,625	\$29,849
Total comprehensive income attributable to:			
Shareholders of KYORIN Pharmaceutical Co., Ltd.	¥3,986	¥3,625	\$29,849
Non-controlling interests	_	_	_
See notes to consolidated financial statements.			

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

KYORIN Pharmaceutical Co., Ltd. and Consolidated Subsidiaries For the year ended March 31, 2023

										Mil	lions of yen
					Shareho	lders' equity	Acc	umulated oth	ner compreher	nsive income	
	Number of shares issued (Common stock)	Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Unrealized holding gain (loss) on other securities	Translation adjustments	Retirement benefits liability adjustments	Total accumulated other comprehensive income	Total net assets
Balance as of April 1, 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 Pharmaceutical Co., Ltd.	_	-	_	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 April 1, 2022	64,607,936	700	4,752	132,710	(17,671)	120,491	6,268	110	(2,362)	4,016	124,507
Cash dividends	_	_	_	(3,023)	_	(3,023)	-	_	-	_	(3,023)
Profit attributable to shareholders of KYORIN Pharmaceutical Co., Ltd.	-	-	-	4,723	-	4,723	-	-	-	-	4,723
Change in scope of consolidation	-	-	-	(13)	-	(13)	-	-	-	-	(13)
Purchase of treasury stock	_	_	_	_	(0)	(0)	_	_	_	_	(0)
Disposals of treasury stock	_	_	_	-	4	4	-	_	_	-	4
Other changes	_	_	_	_	_	-	(572)	229	(394)	(737)	(737)
Net changes during the year	_	_	_	1,686	4	1,690	(572)	229	(394)	(737)	953
Balance as of March 31, 2023	64,607,936	¥700	¥4,752	¥134,396	¥(17,666)	¥122,182	¥5,695	¥340	¥(2,756)	¥3,278	¥125,461

	_								Thousan	ds of U.S. dol	lars (Note 3)
					Shareho	lders' equity	Aco	cumulated oth	er compreher	nsive income	
	Number of shares issued (Common stock)	Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Unrealized holding gain (loss) on other securities	Translation adjustments	Retirement benefits liability adjustments	Total accumulated other comprehensive income	Total net assets
Balance as of April 1, 2022	64,607,936	\$5,242	\$35,585	\$ 993,785	\$(132,327)	\$902,284	\$46,937	\$ 824	\$(17,688)	\$30,073	\$932,357
Cash dividends	_	_	_	(22,637)	_	(22,637)	_	_	_	_	(22,637)
Profit attributable to shareholders of KYORIN Pharmaceutical Co., Ltd.	-	-	-	35,368	_	35,368	_	_	_	-	35,368
Change in scope of consolidation	-	-	-	(97)	_	(97)	_	-	-	-	(97)
Purchase of treasury stock	_	_	_	_	(0)	(0)	_	_	_	_	(0)
Disposals of treasury stock	_	_	_	_	30	30	_	_	_	_	30
Other changes	_	_	_	_	_	_	(4,283)	1,715	(2,950)	(5,519)	(5,519)
Net changes during the year	_	_	_	12,625	30	12,655	(4,283)	1,715	(2,950)	(5,519)	7,136
Balance as of March 31, 2023	64,607,936	\$5,242	\$35,585	\$1,006,410	\$(132,290)	\$914,947	\$42,646	\$2,546	\$(20,638)	\$24,547	\$939,501

See notes to consolidated financial statements.

### **Consolidated Statement of Cash Flows**

KYORIN Pharmaceutical Co., Ltd. and Consolidated Subsidiaries For the year ended March 31, 2023

To the year chaca march of, 2020			
		Millions of yen	Thousands of U.S. dollars (Note 3)
	2023	2022	2023
Operating activities			
Profit before income taxes	¥ 6,906	¥ 5,216	\$ 51,715
Depreciation and amortization	3,840	3,714	28,755
Impairment loss	257	_	1,925
Decrease in allowance for doubtful accounts	(6)	(3)	(45)
(Decrease) increase in accrued bonuses to employees	(121)	83	(906)
Increase in provision for stock-based payments	122	343	914
Decrease in asset for retirement benefits	201	127	1,505
Increase in liability for retirement benefits	66	48	494
Equity in losses (gains) of affiliates	0	(25)	0
Interest and dividend income	(465)	(411)	(3,482)
Interest expense	66	66	494
Loss on sales and retirement of property, plant and		0.0	440
equipment, net	15	32	112
(Gain) loss on sales of investment securities, net	(683)	0	(5,115)
Loss on devaluation of investment securities	9	320	67
Gain on insurance	(881)	_	(6,597)
Proceeds from compensation for damages	(401)	_	(3,003)
Loss on liquidation of subsidiaries and associates	605	_	4,530
Increase in notes and accounts receivable	(5,621)	(1,226)	(42,092)
Increase in inventories	(5,809)	(3,633)	(43,500)
Increase in notes and accounts payable	2,866	3,910	21,462
Increase (decrease) in consumption taxes payable	219	(35)	1,640
Other, net	(973)	(1,287)	(7,286)
Subtotal	216	7,240	1,617
Interest and dividend received	473	420	3,542
Interest paid	(66)	(66)	(494)
Proceeds from insurance income	3,050	_	22,840
Compensation received for damage	401	_	3,003
Income taxes paid	(2,065)	(1,248)	(15,464)
Net cash provided by operating activities	2,008	6,346	15,037
Investing activities			
Payments for time deposits	(622)	(622)	(4,658)
Proceeds from withdrawal of time deposits	810	946	6,066
Purchase of property, plant and equipment	(6,330)	(2,444)	(47,402)
Proceeds from sales of property, plant and equipment	100	0	749
Purchase of intangible assets	(3,075)	(246)	(23,027)
Purchase of investment securities	(100)	(3,407)	(749)
Proceeds from sales and redemption of investment securities	3,193	3,400	23,910
Other, net	(251)	(185)	(1,880)
Net cash used in investing activities	(6,275)	(2,560)	(46,990)
Financing activities			
Repayments of lease obligations	(147)	(143)	(1,101)
Repayments of long-term debt	(200)	(200)	(1,498)
Net increase in treasury stock	(0)	(0)	(0)
Cash dividends	(3,015)	(3,767)	(22,578)
Net cash used in financing activities	(3,363)	(4,112)	(25,183)
Effects of exchange rate changes on cash and cash equivalents	241	139	1,805
Decrease in cash and cash equivalents	(7,388)	(186)	(55,324)
Cash and cash equivalents at beginning of year	26,289	26,476	196,862
Decrease in cash and cash equivalents resulting from	(84)	_	(629)
exclusion of subsidiaries from consolidation			
Cash and cash equivalents at end of year (Note 4)	¥18,816	¥26,289	\$140,902

See notes to consolidated financial statements.

#### Notes to Consolidated Financial Statements

KYORIN Pharmaceutical Co., Ltd. and Consolidated Subsidiaries For the year ended March 31, 2023

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

The accompanying consolidated financial statements of KYORIN Pharmaceutical Co., Ltd. (the "Company") and consolidated subsidiaries (the "Group") 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 2022

consolidated financial statements to conform to the 2023 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, 2023, the numbers of consolidated subsidiaries and affiliates accounted for by the equity method were four and one (five and one in 2022), respectively. As of March 31, 2023, the number of unconsolidated subsidiaries was two. The Company deconsolidated Kyorin USA, Inc. and Kyorin Europe GmbH, which resolved to dissolve in March 2020 and March 2023, respectively, and became unconsolidated subsidiaries because they have insignificant effects on the consolidated financial statements of the Company. Both companies were in the process of liquidation as of the consolidated balance sheet date. 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, ActivX
Biosciences, Inc. closes its account books at December 31
for financial reporting purposes. Its 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 its balance sheet date (December 31) and the
consolidated balance sheet date (March 31). Previously, the
financial statements of Kyorin Europe GmbH as of

December 31 were also used for preparing the consolidated financial statements. However, due to the resolution for dissolution in March 2023, Kyorin Europe GmbH was in the process of liquidation as of the consolidated balance sheet date. To reflect the financial position and operating results after the resolution for dissolution, the 15 months from December 31, 2021 to March 31, 2023 were included in the scope of consolidation for the year ended March 31, 2023.

#### (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 4 to 50 years

Machinery and vehicle 4 to 17 years

Intangible assets are amortized by the stra

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).

#### (I) Application of the Group Tax Sharing System

The Company and its domestic consolidated subsidiaries have applied the group tax sharing system.

#### (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, 2023 and 2022 were as follows:

			I nousands of
		Millions of yen	U.S. dollars
	2023	2022	2023
Deferred tax assets	¥1,316	¥ 783	\$ 9,855
Deferred tax liabilities	_	175	_
(Deferred tax assets before offsetting against deferred tax liabilities)	4,897	4,628	36,671

(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 market growth rate trends due to implementation of annual drug price revisions implemented in line with basic policies of the NHI drug pricing system reforms and further promotion of measures to curtail medical expenses and drug costs, and cost increases in raw materials, energy, etc. affected the Group's business activities. Such effects have been incorporated into the business plans, which are the basis for estimating future taxable income, in light of external information, etc. available at the end of the year ended March 31, 2023.

The timing of when taxable income incurs and its amount may be affected by changes in the external environment surrounding the ethical drugs business, which is the core of the Group. 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, 2023 may be reversed.

#### (o) Changes in Accounting Policies

# Application of the Implementation Guidance on Accounting Standard for Fair Value Measurement

The Group has applied the "Implementation Guidance on Accounting Standard for Fair Value Measurement" (Accounting Standards Board of Japan ("ASBJ") Guidance No. 31, issued on June 17, 2021; hereinafter the "Fair Value Measurement Guidance"), from the beginning of the year ended March 31, 2023 and prospectively apply new accounting policies stipulated by the Fair Value Measurement Guidance in accordance with the transitional treatment provided in Paragraph 27–2 of the Fair Value Measurement Guidance. The application of the implementation guidance has no effect on the consolidated financial statements.

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

- "Accounting Standard for Current Income Taxes" (ASBJ Statement No. 27, revised on October 28, 2022)
- "Accounting Standard for Presentation of Comprehensive Income" (ASBJ Statement No. 25, revised on October 28, 2022)

### "Guidance on Accounting Standard for Tax Effect Accounting" (ASBJ Guidance No. 28, revised on October 28, 2022)

#### (1) Overview

In February 2018, ASBJ issued ASBJ Statement No. 28, "Partial Amendments to Accounting Standard for Tax Effect Accounting," etc. (hereinafter, "ASBJ Statement No. 28, etc."), which completed the transfer of implementation guidance on tax effect accounting from the Japanese Institute of Certified Public Accountants to ASBJ. However, in the course of the deliberations, the following two issues were to be discussed again after the release of ASBJ Statement No. 28, etc., and they were discussed and released:

- The classification of tax expense (taxation on other comprehensive income)
- Tax effect on sales of equity securities issued by subsidiaries, etc. (equity securities issued by subsidiaries or affiliates) when the group taxation regime is applied

#### (2) Date of application

From the beginning of the fiscal year ending March 31, 2025

#### (3) Effect of application

The effect of applying the "Accounting Standard for Current Income Taxes," etc. 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"), which was a subsidiary of the Company, introduced an incentive plan referred to as the Employee Stock Delivery Trust (the "J-ESOP," hereinafter, the "ESOP Plan") under which the Company's shares are delivered to employees of KYORIN Pharmaceutical.

The Company accounts 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 are delivered to eligible employees of KYORIN Pharmaceutical who satisfy certain requirements, on the basis of the share delivery rules prescribed by KYORIN Pharmaceutical in advance.

KYORIN Pharmaceutical awards its employees a set number of points on the bases of business performance

and their personal contribution and delivers or pays the Company's shares and cash to employees who attain rights to receive such delivery or payment under certain conditions. The Trust acquires the Company's shares to be delivered including future delivery portion using the entrusted money, and separately manages 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, 2023 and 2022, the carrying amounts of the treasury shares were ¥1,621 million (\$12,139 thousand) and ¥1,624 million, respectively, and the total numbers of treasury shares were 743 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 and KYORIN Pharmaceutical (hereinafter, "Group Directors").

The Company accounts 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's 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, 2023 and

2022, the carrying amounts of the treasury shares were ¥208 million (\$1,558 thousand) and ¥208 million, respectively, and the total numbers of treasury shares were 91 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 ¥133.54 = U.S.\$1.00, the approximate rate of exchange on March 31, 2023. 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, 2023 and 2022 for the consolidated statements of cash flows consisted of the following:

		Millions of yen	Thousands of U.S. dollars
	2023	2022	2023
Cash and cash in banks	¥19,394	¥26,994	\$145,230
Time deposits with a maturity over three months	(578)	(704)	(4,328)
Cash and cash equivalents	¥18,816	¥26,289	\$140,902

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

Information regarding marketable securities classified as other securities as of March 31, 2023 and 2022 is as follows: Marketable other securities

			Millions of yen		Thou	sands of U.S. dollars
			2023			2023
	Acquisition	Carrying	Unrealized	Acquisition	Carrying	Unrealized
	cost	value	gain (loss)	cost	value	gain (loss)
Securities whose carrying value exceeds their acquisition cost:						
Equity securities	¥8,518	¥16,560	¥8,041	\$63,786	\$124,008	\$60,214
Debt securities:						
Government bonds	_	_	_	_	_	_
Corporate bonds	_	_	_	_	_	_
Other bonds	_	_	_	_	_	_
Subtotal	8,518	16,560	8,041	63,786	124,008	60,214
Securities whose carrying value does not exceed their acquisition cost:						
Equity securities	13	11	(1)	97	82	(7)
Debt securities:						
Government bonds	5,000	4,981	(18)	37,442	37,300	(135)
Corporate bonds	_	_	_	_	_	_
Other bonds	_	_	_	_	_	_
Subtotal	5,013	4,993	(19)	37,539	37,390	(142)
Total	¥13,531	¥21,553	¥8,021	\$101,325	\$161,397	\$60,064

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			Millions of yen
			2022
	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their acquisition cost:			
Equity securities	¥ 8,521	¥17,549	¥9,027
Debt securities:			
Government bonds	_	_	_
Corporate bonds	_	_	_
Other bonds	_	_	_
Subtotal	8,521	17,549	9,027
Securities whose carrying value does not exceed their acquisition cost:			
Equity securities	2,012	1,875	(136)
Debt securities:			
Government bonds	5,400	5,386	(13)
Corporate bonds	_	_	_
Other bonds	_	_	_
Subtotal	7,412	7,261	(150)
Total	¥15,933	¥24,811	¥8,877

Unlisted securities and other non-marketable securities are not included in the above schedules. The amounts of these securities were ¥709 million (\$5,309 thousand) and ¥673 million as of March 31, 2023 and 2022, respectively.

Sales amounts of securities classified as other securities and the related aggregate gain and loss for the years ended March 31, 2023 and 2022 are summarized as follows:

			11100301103 01
		Millions of yen	U.S. dollars
	2023	2022	2023
Proceeds from sales	¥2,689	¥—	\$20,136
Gains on sales	685	_	5,130
Losses on sales	1	_	7

In the years ended March 31, 2023 and 2022, impairment loss on securities of ¥9 million (\$67 thousand) (¥9 million (\$67 thousand) of unlisted securities classified as other securities that are not measured at fair value) and ¥320 million (¥320 million of unlisted securities classified as other securities that are not measured at fair value) were

recognized, respectively.

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, 2023 and 2022 consisted of the following:

		U.S. dollars	
	2023	2022	2023
Short-term bank loans	¥10,100	¥10,100	\$75,633
Current portion of long-term debt	200	200	1,498
Current portion of lease obligations	134	147	1,003
Total	¥10,434	¥10,447	\$78,134

The average interest rates applicable to short-term bank loans outstanding as of March 31, 2023 and 2022 are 0.3% and 0.3%, respectively.

Long-term debt and lease obligations as of March 31, 2023 and 2022 consisted of the following:

		Millions of yen	U.S. dollars
	2023	2022	2023
Long-term debt due through 2027 at average interest rate of 0.3% and 0.3% in 2023 and 2022, respectively	¥10,836	¥11,036	\$81,144
Lease obligations due through 2030 in 2023 and 2022	341	489	2,554
Current portion of long-term debt and lease obligations due within one year	(334)	(348)	(2,501)
Total	¥10,843	¥11,177	\$81,197

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

Year ending March 31,	Millions of yen	U.S. dollars
2024	¥ 334	\$ 2,501
2025	10,285	77,018
2026	229	1,715
2027	197	1,475
2028	85	637

#### 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,

2023 and 2022 were ¥10,903 million (\$81,646 thousand) and ¥8,897 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, 2023 and 2022 are as follows:

		Thousands of U.S. dollars	
	2023	2022	2023
Gain:			
Buildings and structures	¥ 0	¥ —	\$ 0
Machinery and vehicles	0	_	0
Other	10	0	75
	¥ 10	¥ 0	\$ 75
Loss:			
Buildings and structures	¥(13)	¥(11)	\$ (97)
Machinery and vehicles	(5)	(2)	(37)
Other	(6)	(18)	(45)
	¥(25)	¥(32)	\$(187)
Total	¥(15)	¥(32)	\$(112)

#### 10.Impairment Loss

For the year ended March 31, 2023, the Group recognized an impairment loss on the following assets:

Location	Use	Type of assets
KYORIN Pharmaceutical Group Facilities Co., Ltd. Noshiro-shi, Akita Prefecture	Dormitory	Buildings and structures, land
ActivX Biosciences, Inc. U.S.A.	Assets for business use	Buildings and structures, other

At KYORIN Pharmaceutical Group Facilities Co., Ltd., a consolidated subsidiary of the Company, a dormitory that has been idle was written down to its recoverable amount, and the amount of decrease was recorded in other expenses as an impairment loss of ¥147 million (\$1,101 thousand). The impairment loss consists of ¥104 million (\$779 thousand) of buildings and structures and ¥42 million (\$315 thousand) of land. The recoverable amount of the assets is calculated based on the appraisal value by a real estate appraiser.

Due to the decision on the policy to dissolve ActivX

Biosciences, Inc., a consolidated subsidiary of the Company, the carrying amount was written down to its recoverable amount, and the amount of decrease was recorded in other expenses as an impairment loss of ¥110 million (\$824 thousand). The impairment loss consists of ¥23 million (\$172 thousand) of buildings and structures and ¥87 million (\$651 thousand) of other. The recoverable amount of the assets is measured based on net realizable value. The net realizable value is calculated based on the estimated amount of sale.

#### 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, 2023 and 2022 are as follows:

	Millions of yen				Tho	usands of U.S. dollars
			2023			2023
	Carrying value	Fair value	Difference	Carrying value	Fair value	Difference
Notes receivable	¥ 1,816	¥ 1,816	¥—	\$ 13,599	\$ 13,599	\$ —
Accounts receivable	45,475	45,475	_	340,535	340,535	_
Short-term investments and investment securities	21,553	21,553	_	161,397	161,397	_
Total assets	¥68,845	¥68,845	¥—	\$515,538	\$515,538	\$ -
Notes and accounts payable	¥13,762	¥13,762	¥—	\$103,055	\$103,055	\$ —
Short-term bank loans	10,300	10,300	_	77,130	77,130	_
Long-term debt	10,636	10,634	(2)	79,647	79,632	(15)
Total liabilities	¥34,699	¥34,697	¥(2)	\$259,840	\$259,825	\$(15)

			Millions of yen		
	Carrying value	Fair value	Difference		
Notes receivable	¥ 1,521	¥ 1,521	¥ —		
Accounts receivable	40,154	40,154	_		
Short-term investments and investment securities	24,811	24,811	_		
Total assets	¥66,487	¥66,487	¥ —		
Notes and accounts payable	¥10,896	¥10,896	¥ —		
Short-term bank loans	10,300	10,300	_		
Long-term debt	10,836	10,834	(2)		
Total liabilities	¥32,033	¥32,030	¥(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 ¥1,425 million (\$10,671 thousand) and ¥1,392 million as of March 31, 2023 and 2022, respectively.

The redemption schedule for monetary receivables and securities with maturities subsequent to March 31, 2023 is as follows:

Millions of ven

				2023
	Due in one year or less		Due after five years through ten years	Due after ten years
Cash and cash in banks	¥19,394	¥ —	¥—	¥—
Notes receivable	1,816	_	_	_
Accounts receivable	45,475	_	_	_
Short-term investments and investment securities:				
Other securities with maturities:				
Government bonds	_	5,000	_	_
Other	_	_	_	_
Total	¥66,686	¥5,000	¥—	¥—

			Tho	ousands of U.S. dollars
				2023
	Due in one year or less		Due after five years through ten years	Due after ten years
Cash and cash in banks	\$145,230	\$ —	\$—	\$—
Notes receivable	13,599	_	_	_
Accounts receivable	340,535	_	_	_
Short-term investments and investment securities:				
Other securities with maturities:				
Government bonds	_	37,442	_	_
Other	_	_	_	_
Total	\$499,371	\$37,442	\$—	\$—

				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	¥—	¥—

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, 2023 and 2022 are as follows:

						Millions of yen
						2023
	Due in one year or less		Due after two years through three years	Due after three years through four years	Due after four years through five years	Due after five years
Short-term bank loans	¥10,100	¥ —	¥ —	¥ —	¥ —	¥ —
Long-term debt	200	10,200	200	173	61	_
Lease obligations	134	85	29	23	23	44
Guarantee deposits received	172	_	_	_	_	_
Total	¥10,606	¥10,285	¥229	¥197	¥85	¥44

					Tho	usands of U.S. dollars
						2023
	Due in one year or less		Due after two years through three years	Due after three years through four years	Due after four years through five years	Due after five years
Short-term bank loans	\$75,633	\$ -	\$ -	\$ —	\$ -	\$ —
Long-term debt	1,498	76,382	1,498	1,295	457	_
Lease obligations	1,003	637	217	172	172	329
Guarantee deposits received	1,288	_	_	_	_	_
Total	\$79,422	\$77,018	\$1,715	\$1,475	\$637	\$329

						Millions of yen
						2022
	Due in one year or less		Due after two years through three years	Due after three years through four years	Due after 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

## Fair value information by level within the fair value hierarchy $% \left( 1\right) =\left( 1\right) \left( 1\right) \left($

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
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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, 2023 and 2022 are as follows:

				Millions of yen			Thousand	ds of U.S. dollars
				2023				2023
	Fair value						Fair value	
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Short-term investments and investment securities	¥21,553	¥—	¥—	¥21,553	\$161,397	\$—	\$—	\$161,397
Total assets	¥21,553	¥—	¥—	¥21,553	\$161,397	\$—	\$—	\$161,397

					Millions of yen
					2022
					Fair value
	Leve	l 1	Level 2	Level 3	Total
Short-term investments and investment securities	¥24,8	11	¥—	¥—	¥24,811
Total assets	¥24,8	11	¥—	¥—	¥24,811

Financial instruments other than those recorded in the consolidated balance sheet at fair value as of March 31, 2023 and 2022 are as follows:

	Millions of yen						Thousand	ds of U.S. dollars
				2023				2023
				Fair value				Fair value
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Notes receivable	¥—	¥ 1,816	¥—	¥ 1,816	\$—	\$ 13,599	\$—	\$ 13,599
Accounts receivable	_	45,475	_	45,475	_	340,535	_	340,535
Total assets	¥—	¥47,291	¥—	¥47,291	\$—	354,134	\$—	\$354,134
Notes and accounts payable	¥—	¥13,762	¥—	¥13,762	\$—	\$103,055	\$—	\$103,055
Short-term bank loans	_	10,300	_	10,300	_	77,130	_	77,130
Long-term debt	_	10,634	_	10,634	_	79,632	_	79,632
Total liabilities	¥—	¥34,697	¥—	¥34,697	\$—	\$259,825	\$—	\$259,825

				Millions of yen
				2022
			1	Fair value
	 Level 1	Level 2	Level 3	Total
Notes receivable	¥—	1,521	¥—	1,521
Accounts receivable	_	40,154	_	40,154
Total assets	¥—	41,676	¥—	41,676
Notes and accounts payable	¥—	10,896	¥—	10,896
Short-term bank loans	_	10,300	_	10,300
Long-term debt	_	10,834	_	10,834
Total liabilities	¥—	32,030	¥—	32,030

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 Group has 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, 2023 and 2022 are as follows:

		Millions of yen			
	2023	2022	2023		
Retirement benefit obligation at the beginning of the year	¥35,174	¥35,673	\$263,397		
Service cost	1,095	1,121	8,200		
Interest cost	175	178	1,310		
Actuarial gain or loss	(494)	(114)	(3,699)		
Retirement benefits paid	(1,441)	(1,683)	(10,791)		
Retirement benefit obligation at the end of the year	¥34,510	¥35,174	\$258,424		

(2) The changes in plan assets for the years ended March 31, 2023 and 2022 are as follows:

		Millions of yen		
	2023	2022	2023	
Plan assets at the beginning of the year	¥32,369	¥33,181	\$242,392	
Expected return on plan assets	647	663	4,845	
Actuarial gain or loss	(1,590)	(707)	(11,907)	
Contributions paid by the employer	891	915	6,672	
Retirement benefits paid	(1,441)	(1,683)	(10,791)	
Plan assets at the end of the year	¥30,876	¥32,369	\$231,212	

(3) The changes in liability (asset) for retirement benefits for consolidated subsidiaries applying the simplified method for the years ended March 31, 2023 and 2022 are as follows:

			Thousands of
		Millions of yen	U.S. dollars
	2023	2022	2023
Liability for retirement benefits at the beginning of the year	¥79	¥ 92	\$592
Retirement benefits costs	76	97	569
Contributions to the plans	(67)	(110)	(502)
Liability for retirement benefits at the end of the year	¥88	¥ 79	\$659

(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, 2023 and 2022 are as follows:

		Millions of yen	U.S. dollars
	2023	2022	2023
Funded defined benefit obligation	¥35,118	¥35,755	\$262,977
Plan assets	(31,403)	(32,875)	(235,158)
	3,715	2,879	27,819
Unfunded retirement benefit obligation	6	5	45
Net liability for retirement benefits	¥ 3,721	¥ 2,885	\$ 27,864
Liability for retirement benefits	¥ 3,721	¥ 2,885	\$ 27,864
Net liability for retirement benefits	¥ 3,721	¥ 2,885	\$ 27,864

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

(5) The components of retirement benefits costs for the years ended March 31, 2023 and 2022 are as follows:

		Thousands of U.S. dollars	
	2023	2022	2023
Service costs	¥1,095	¥1,121	\$ 8,200
Interest costs	175	178	1,310
Expected return on plan assets	(647)	(663)	(4,845)
Amortization of actuarial loss	554	493	4,149
Amortization of prior service costs	(26)	(25)	(195)
Retirement benefits costs based on the simplified method	76	97	569
Retirement benefits costs	¥1,227	¥1,202	\$ 9,188

(6) Prior service costs and actuarial gain or loss included in other comprehensive income (before tax effect) for the years ended March 31, 2023 and 2022 are as follows:

			Thousands of
		Millions of yen	U.S. dollars
	2023	2022	2023
Prior service costs	¥ 26	¥ 25	\$ 195
Actuarial gain or loss	541	98	4,051
Total	¥568	¥124	\$4,253

(7) Unrecognized prior service costs and unrecognized actuarial loss included in accumulated other comprehensive income (before tax effect) as of March 31, 2023 and 2022 are as follows:

			Thousands of
		Millions of yen	U.S. dollars
	2023	2022	2023
Unrecognized prior service costs	¥2	(23)	\$15
Unrecognized actuarial loss	3,970	3,428	29,729
Balance at the end of the year	¥3,973	¥3,405	\$29,751

#### (8) Plan assets

The breakdown of plan assets is as follows:

	2023	2022
Domestic equity securities	4.0%	3.7%
Foreign debt securities	36.3	46.9
Foreign equity securities	5.9	4.5
General account	28.7	19.0
Short-term assets	1.3	3.1
Other	23.8	22.8
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

	2023	2022
Discount rate	Mainly 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 ¥283 million (\$2,119 thousand) and ¥295 million to the defined contribution plans for the years ended March 31, 2023 and 2022, respectively.

#### 13.Income Taxes

Significant components of deferred tax assets and liabilities as of March 31, 2023 and 2022 are as follows:

Significant components of deferred tax assets and traditities as of Marc	0 ., 2020 aa 202		Thousands of
		Millions of yen	U.S. dollars
	2023	2022	2023
Deferred tax assets:			
Liability for retirement benefits	¥ 1,316	¥ 1,124	\$ 9,855
Accrued bonuses to employees	668	685	5,002
Allowance for doubtful accounts	23	23	172
Accrued enterprise tax	78	28	584
Loss on retirement of inventories	345	246	2,583
Loss on devaluation of investment securities	245	245	1,835
Loss on retirement of property, plant and equipment	51	38	382
Amortization of deferred assets	1,093	816	8,185
Other	1,328	1,481	9,945
Subtotal	5,151	4,691	38,573
Valuation allowance	(253)	(62)	(1,895)
Total deferred tax assets	4,897	4,628	36,671
Deferred tax liabilities:			
Reserve for reduction entry of property, plant and equipment	(887)	(953)	(6,642)
Unrealized holding gain on other securities	(2,473)	(2,728)	(18,519)
Prepaid pension cost	(170)	(232)	(1,273)
Other	(49)	(105)	(367)
Total deferred tax liabilities	(3,580)	(4,020)	(26,808)
Net deferred tax assets	¥ 1,316	¥ 608	\$ 9,855

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, 2023 and 2022 are as follows:

	2023*	2022
Statutory tax rate		30.6%
Entertainment expenses and others that are not tax deductible permanently		0.6
Inhabitants' per capita taxes		2.0
Tax credits for research and development expenses		(7.1)
Valuation allowance		0.0
Dividends income that is not taxable permanently		(1.1)
Other		(0.4)
Effective tax rate		24.6%

<sup>\*</sup>Notes are omitted because the difference between the statutory tax rate and the effective tax rate is less than 5.0% of the statutory tax rate.

Accounting treatment of corporate and local income taxes or tax effect accounting related to these taxes

From the year ended March 31, 2023, the Company and its domestic consolidated subsidiaries have applied the group tax sharing system. In addition, the Company and its domestic consolidated subsidiaries have performed

accounting treatment of corporate and local income taxes or tax effect accounting related to these taxes and disclosure in accordance with the "Practical Solution on the Accounting and Disclosure Under the Group Tax Sharing System" (PITF No. 42, August 12, 2021).

#### 14.Comprehensive Income

Reclassification adjustments and income tax effects on other comprehensive income (loss) for the years ended March 31, 2023 and 2022 are as follows:

		Millions of yen	Thousands of U.S. dollars
	2023	2022	2023
Unrealized holding gain (loss) on other securities:			
Loss arising during the year	¥ (149)	¥(888)	\$(1,116)
Reclassification adjustments	(683)	320	(5,115)
Before income tax effects	(833)	(568)	(6,238)
Deferred tax	255	174	1,910
Unrealized holding loss on other securities	(578)	(393)	(4,328)
Translation adjustments:			
Adjustments arising during the year	229	151	1,715
Retirement benefits liability adjustments:			
Loss arising during the year	(1,095)	(592)	(8,200)
Reclassification adjustments	527	468	3,946
Before income tax effects	(568)	(124)	(4,253)
Deferred tax	174	38	1,303
Retirement benefits liability adjustments	(394)	(86)	(2,950)
Share of other comprehensive income of affiliates accounted for using equity method:			
Gain arising during the year	5	21	37
Total other comprehensive loss	¥ (737)	¥(306)	\$(5,519)

#### 15. Revenue Recognition

Information on the disaggregation of revenue from contracts with customers for the years ended March 31, 2023 and 2022 is as follows:

			Thousands of
		Millions of yen	U.S. dollars
	2023	2022	2023
Sales of pharmaceuticals and other products	¥108,526	¥101,147	\$812,685
Royalty income and service revenue	4,743	4,387	35,517
Revenue from contracts with customers	¥113,270	¥105,534	\$848,210
Net sales to external customers	¥113,270	¥105,534	\$848,210

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, 2023, which is expected to be recognized from the year ending March 31, 2024 onward, is as follows:

- (1) The Group has no balances of contract liabilities. In addition, there is no revenue recognized in the year ended March 31, 2023 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, 2023 and 2022, 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, 2023 and 2022, 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, 2023 and 2022, 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, 2023 and 2022, 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, 2023 and 2022

Name of customer

Sales amount Related segments

Alfresa Holdings Corporation

MEDIPAL HOLDINGS CORPORATION

SUZUKEN CO., LTD.

Toho Pharmaceutical Co., Ltd.

		Thousands of U.S. dollars
		2023
Name of customer	Sales amount	Related segments
Alfresa Holdings Corporation	\$146,151	_
MEDIPAL HOLDINGS CORPORATION	136,244	_
SUZUKEN CO., LTD.	125,812	_
Toho Pharmaceutical Co., Ltd.	98,016	_

		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	_

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, 2023 and 2022.

#### 17. Amounts per Share

Amounts per share for the years ended March 31, 2023 and 2022 are as follows:

		1011	0.0. 001.01
	2023	2022	2023
Basic profit	¥ 82.44	¥ 68.62	\$ 0.62
Cash dividends	52.00	52.00	0.39
Net assets	2,189.40	2,172.83	16.40

Basic profit per share was computed on the basis of the profit attributable to common shareholders of KYORIN Pharmaceutical Co., Ltd. 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, 2023 and 2022.

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 Pharmaceutical Co., Ltd. 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.

US dollars

The average numbers of treasury shares during the fiscal year that were excluded from the calculation of the amount of profit per share were 836,270 and 837,508 for the years ended March 31, 2023 and 2022, 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 835,443 and 837,508 as of March 31, 2023 and 2022, 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 KYORIN Pharmaceutical Co., Ltd., which was its wholly owned subsidiary, as the resolving company by absorption with the effective date of April 1, 2023, and entered into the merger agreement on May 11, 2022. The merger was effective as of April 1, 2023.

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

- (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 was changed from KYORIN Holdings, Inc. to KYORIN Pharmaceutical Co., Ltd. on April 1, 2023.
- (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 accounts 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). This has no effect on the consolidated financial statements.

#### Relocation of Head Office

At the meeting of the Board of Directors held on April 26, 2023, the Company resolved to relocate its head office and entered into a lease agreement on May 11, 2023 to move into the building where the head office to be relocated.

Outline of relocation of head office is as follows:

 Location of new head office
 1-3-7 Otemachi, Chiyoda-ku, Tokyo (8th to 10th floors, NIKKEI building)

- (2) Scheduled date of relocation May 2024
- (3) Purpose of relocation To promote flexible working style in light of internal and external changes in environment, and to achieve more efficient management.
- (4) Effects on business results for the fiscal year ending March 31, 2024 Expenses arising from the relocation of the head office is under close examination.



### Independent Auditor's Report

The Board of Directors KYORIN Pharmaceutical Co., Ltd.

#### **Opinion**

We have audited the accompanying consolidated financial statements of KYORIN Pharmaceutical Co., Ltd. and its consolidated subsidiaries (the Group), which comprise the consolidated balance sheet as at March 31, 2023, 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, 2023, 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, 2023 were ¥113,270 million, of which royalty income and service revenue were 4,743 million yen, part of which comprised of royalty income.	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,		

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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.

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 of 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.

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# 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.

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- 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, 2023 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.

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Ernst & Young ShinNihon LLC Tokyo, Japan

August 31, 2023

Ryo Kayama

Ryo Kayama

Designated Engagement Partner

Certified Public Accountant

Atsushi Kasuga
Designated Engagement Partner
Certified Public Accountant

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## **Corporate Overview and Stock Information**

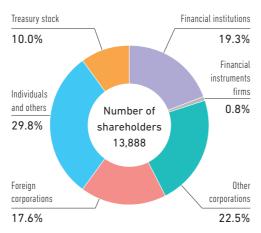
(As of March 31, 2023)

Head Office	KYORIN Pharmaceutical Co., Ltd. 6, Kanda Surugadai 4-chome, Chiyoda-ku, Tokyo 101-8311 Phone: +81-3-3525-4700	
Main business	Manufacture, sales, and procurement of pharmaceuticals	
Establishment	1958	
Common Stock	¥700 million	
Outstanding Shares	64,607,936	
Shareholders	13,888	
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	
	Percentage of shares held	
Major Shareholders	The Master Trust Bank of Japan, Ltd. (Trust Account) Mykam Co., Ltd. Custody Bank of Japan, Ltd. (Trust Account) Kyorin Group Stock Ownership Association	8.32% 5.29% 3.83%
	Banrina Co., Ltd. Archans Co., Ltd. Yutaka Ogihara	3.35% 3.35% 3.22%
	Mariko Ogihara KAKEN PHARMACEUTICAL CO., LTD.	3.02% 2.75%

Akira Ogihara



#### Major Shareholders



#### **Website Information**

2.74%

### https://www.kyorin-pharm.co.jp/en/

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



# **Group Companies**

### KYORIN Rimedio Co., Ltd.

Capital: ¥1,200 million

Percentage of ownership: 100%

Head office: 287-1, Shimocho Moroe-cho, Kanazawa-shi, Ishikawa 920-0017 Operations: Manufacture, sales, and procurement of pharmaceuticals



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

# KYORIN Pharmaceutical Group Facilities Co., Ltd.

Capital: ¥350 million

Percentage of ownership: 100%

Head office: 6, Kanda Surugadai 4-chome, Chiyoda-ku, Tokyo 101-8311 Operations: Manufacturing and testing of pharmaceuticals







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

## **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

 $\label{thm:continuous} \mbox{Operations: Production and sales of pharmaceuticals, reagents, intermediates,} \\ \mbox{and other products}$ 

Contact point for inquiries about this report

Public Relations & IR Group, Corporate Planning +81-3-3525-4707

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