KYOWA KIRIN

Annual Report 2020

For the year ended December 31, 2020

Life-changing

Kyowa Kirin Co., Ltd.

Contents

Editorial Policy

We have published this integrated report to help investors understand the Kyowa Kirin Group's management vision, strategies, operating conditions and future vision, referencing the IIRC International Integrated Reporting Framework and Guidance for Collaborative Value Creation released by Japan's Ministry of Economy, Trade and Industry.

Environment
Social
Governance
Guidance for Collaborative Value Creation

Annual Report (PDF version)
https://ir.kyowakirin.com/en/library/annual.html

Kyowa Kirin Website
https://www.kyowakirin.com/

Financial Results
https://ir.kyowakirin.com/en/library/earnings.html

Sustainability
https://www.kyowakirin.com/sustainability/

ESG Data
https://www.kyowakirin.com/sustainability/esg_data/

Concerning the Scope of This Report

The scope of this report is Kyowa Kirin Co., Ltd. and its consolidated subsidiaries in Japan and overseas. Environmental data is annotated for the convenience of readers. The reporting period includes calendar year 2020, and 2021 in part.

This report is intended to inform shareholders/investors of information related to the Company's business in a fair manner.
Though it may include information concerning pharmaceutical products (including products under development), it is not for the purpose of promoting, advertising or medical advice.

Performance Forecasts

Forecasts contained in this report are assumptions based on reasonable judgments and information available at the time. Actual results may differ significantly due to a variety of factors.

Company Names

In this report, group companies are abbreviated as follows: Kyowa Kirin Co., Ltd. (Kyowa Kirin).

Numerical Data

The sum of the breakdown may not equal the total due to rounding.

INTRODUCTION

OUR PHILOSOPHY

The Kyowa Kirin Group companies strive to contribute to the health and wellbeing of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

CORE VALUES

Innovation

Transform lives with passion and excitement.
Challenge the status quo in all of our work.

Commitment to Life

Work for the most precious presence on this planet.
Create value for patients, caregivers, healthcare professionals, and customer.

Integrity

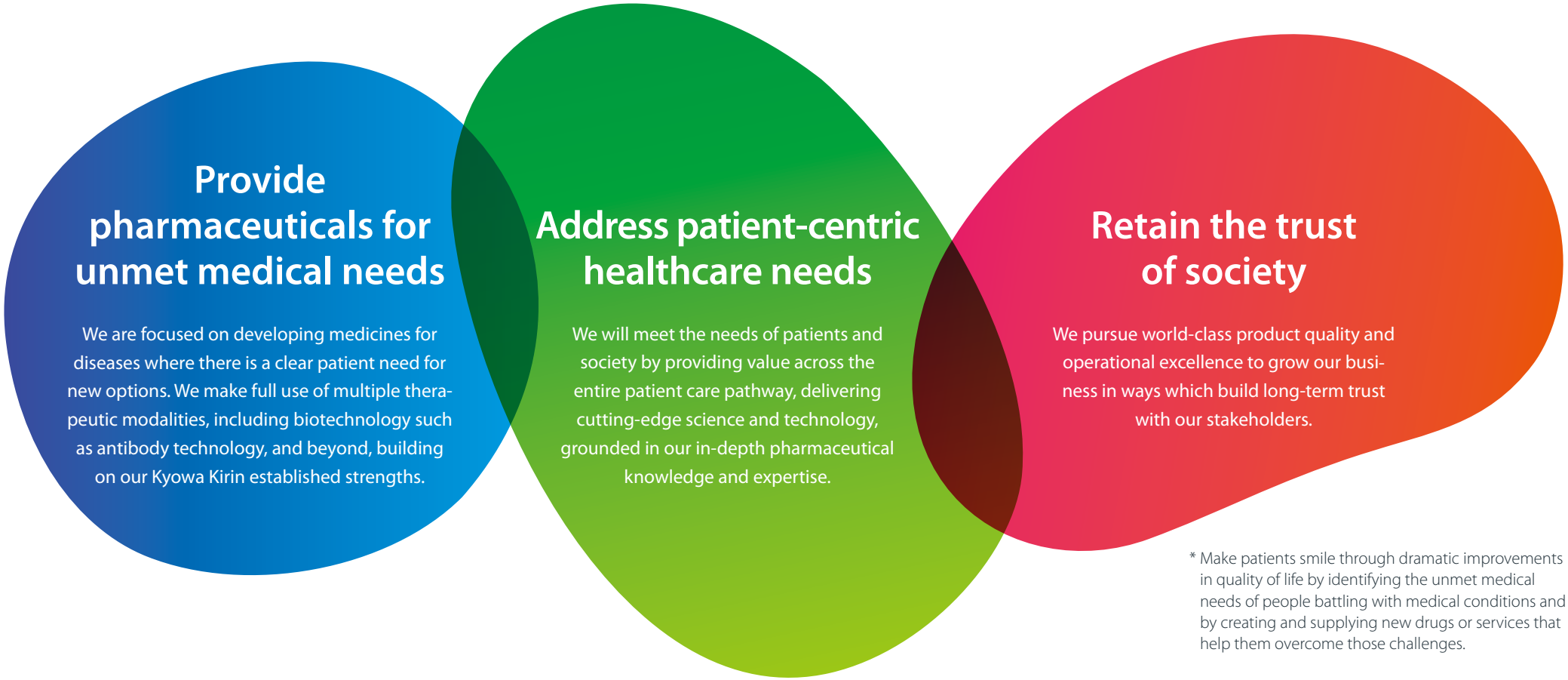
Do the right things. Be sincere and ethical consistently.
Make a better world through good business practices.

Teamwork/Wa

One for all, all for one.
Work in diverse teams and respect each other.
Go beyond boundaries and collaborate with stakeholders.

Our New Vision toward 2030

Kyowa Kirin will realize the successful creation and delivery of life-changing value* that ultimately makes people smile, as a Japan-based Global Specialty Pharmaceutical company built on the diverse team of experts with shared passion for innovation.

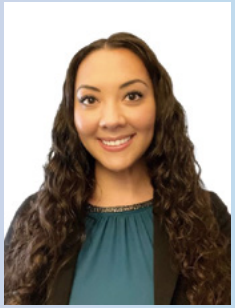


* Make patients smile through dramatic improvements in quality of life by identifying the unmet medical needs of people battling with medical conditions and by creating and supplying new drugs or services that help them overcome those challenges.

How Our People Are Working to Realize the Group Vision

In innovative new drug research, we need to utilize diverse drug discovery modalities and deepen our expertise in disease science. Both are major challenges, but we will pursue new opportunities by utilizing Kyowa Kirin's strengths, centered on its proprietary antibody technologies.

Akifumi Kato, Ph.D.
Modality Research Laboratories 1, Research Unit,
R&D Division
Kyowa Kirin Co., Ltd.



As a compliance professional, it is important to me to work at a company committed to integrity. It is very exciting to be part of a growing company with a great culture and clear mission and values, and it is fulfilling to know that all of our work has such a profound impact as we meet the needs of our patients.

Kristina Jordan
Manager, Compliance Operations
Kyowa Kirin, Inc.

My passion lies in helping others, and it's a great privilege to work for Kyowa Kirin, a company fully committed to patients and community, giving something back to society and bringing our company values to life.

Rishi Vadukul
Patient Diagnostic Liaison, Northern Cluster Rare Disease Business Unit
Kyowa Kirin International plc

Rising to the Challenge: Realizing the New Vision for the Group

Every day, I'm motivated by the fact that the pharmaceuticals we make bring smiles to patients around the world. Targeting further progress, we're harnessing digital technologies to establish even more robust production processes to support the manufacture of pharmaceuticals that win and retain the trust of patients and healthcare professionals.

Chiaki Inaba
Process Engineering, Manufacturing, Takasaki Plant,
Production Division
Kyowa Kirin Co., Ltd.

We continue to seek out and select the best approach from limitless possibilities. That thinking has been an unwavering part of Kyowa Kirin's drug development activities. Ultimately, we're aiming to bring smiles to the faces of patients. Motivated by that responsibility, we will continue to work on driving dramatic changes in medical care, and in patients' lives.

Jun Kinoshita
Clinical Development Group 1 & Asia-Pacific Development Group, Clinical Development Center, Development Unit,
R&D Division
Kyowa Kirin Co., Ltd.

There is no perfect person, only a perfect team. To develop successful relationships with all stakeholders throughout our value chain, streamline clinical trials and product development, whilst improving operational efficiency, the digital team and I continue to pursue 'Change & Challenge' with our 'Patient Centric' concept.

Zhu Xian Lin
Head of Digital Marketing Team
Kyowa Kirin China Pharmaceutical Co., Ltd.

Message from President

What motivates us? Bringing a smile to the faces of people battling disease

Since the merger in 2008, our overriding goal has been to transform Kyowa Kirin into a Japan-based Global Specialty Pharmaceutical Company (GSP). During the FY2016-2020 Medium Term Business Plan, we implemented four key strategies to make the leap forward as a GSP, achieving encouraging results. We launched three global strategic products in the US and Europe and made steady progress with clinical trials for next-generation products in our development pipeline. We also continued to broaden and deepen our research pipeline.

Kyowa Kirin has just started its journey as a GSP, but we still face a number of challenges. To guide us in the next phase, we have formulated a new vision for the Kyowa Kirin Group through to 2030. The vision is to create and deliver life-changing value that ultimately makes people smile, as a Japan-based GSP built on a diverse team of experts with a shared passion for innovation. To realize the vision, we have developed the FY2021-2025 Medium Term Business Plan, which has three key strategies: provide pharmaceuticals for unmet medical needs, address patient-centric healthcare needs, and retain the trust of society. Additionally, we will focus on training personnel, improving the Group's organizational capabilities and strengthening our digital platforms to give us the capacity to steadily implement the strategies and generate further growth after the plan completes five years from now.

Our world is facing an unprecedented crisis due to the COVID-19 pandemic. However, new vaccines, the crucial tool to help us beat the pandemic, have been developed at unparalleled speed, and new medications are also in development. The progress we are seeing in the medical field has raised hopes that we can control this new disease. The crisis has demonstrated again the crucial role our industry plays in supporting societies and economies worldwide. It has also underscored the importance of ensuring stable, reliable supplies of high-quality medicines, particularly when conditions are unpredictable.

As a pharmaceutical company with significant corporate social responsibilities, Kyowa Kirin is more committed than ever to meeting the needs of stakeholders and continuing to contribute to society. I hope we can count on your continued support in the months and years ahead.

Masashi Miyamoto, Ph.D.
Representative Director of the Board,
President and Chief Executive Officer

Overview of New Medium Term Business Plan

In February 2021, the Kyowa Kirin Group announced a new Medium Term Business Plan for the period 2021 to 2025.

The plan sets out the strategies for the next five years to achieve our qualitative and quantitative goals in 2025 and our longer-term vision for the Group.

We also adjusted the Group's material issues (materiality), aiming to generate growth while also satisfying the demands and expectations of society.

Philosophy

New Vision

To be in 2025

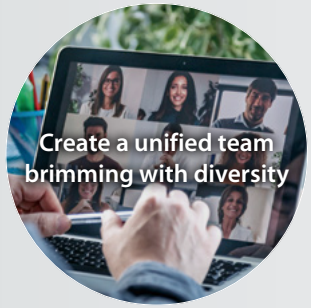
- Maximize the value of global products
- Establish framework to ensure stable global supplies
- Build a drug pipeline to drive growth beyond 2025
- Launch services that go beyond pharmaceuticals
- Foster a corporate culture suited to global business development

Strategy

- Address patient-centric healthcare needs
- Provide pharmaceuticals for unmet medical needs
- Retain the trust of society
- Reinforce human resources and structures that support the creation of Life-changing value

ROE	**10%** or higher
Revenue growth rate	**CAGR 10%** or higher
R&D expense ratio	Targeting **18-20%** to support **active investment**
Core operating profit ratio	**25%** or higher by FY2025
Dividend payout ratio	**Sustained dividend hikes** with **40%** (based on core EPS)

Kyowa Kirin's Materiality



CSV* management = Contribute to the Health and Well-Being of People

Contribute to the SDGs

* In our management philosophy, we are committed to creating new value by capitalizing on the Kyowa Kirin Group's strengths in life sciences and technologies with the aim of contributing to the health and well-being of people around the world. What we mean by "new value" is value that can be shared with society, or in other words, "Creating Shared Value (CSV)."
We practice CSV management aimed at realizing improved corporate value through the creation of both social and economic value by addressing social issues.

Medium- to Long-term Outlook

We aim to accelerate growth through 2030 by developing next-generation global products and maximizing the value of existing global strategic products – the Group's growth drivers today.

We are also targeting sustained growth beyond 2030 by expanding our pipeline and establishing new drug discovery technologies.

2025 → 2030

FY2021-2025 MTBP

- Strengthen the global business foundation to support further leaps
- Accelerate growth as a Global Specialty Pharmaceutical Company (GSP)
- Strive to create new value beyond pharmaceuticals

2026-2030

- Become a GSP trusted even more by patients
- Create new drugs that offer Life-changing value
- Enhance ability to create new value

Reinforce and Maintain Human Resources and Structures that Support the Creation of Life-changing Value

Maximize the Value of G3B

POTELIGEO (mogamulizumab)
CRYSVITA
NOURIANZ (istradefylline) tablets

Accelerate Growth by Next-generation Global Products

KHK4083
KW-6356
ME-401

Generate Sustained Growth and Achieve Our New Vision for Kyowa Kirin

Expand Sales of Global Strategic Products to Drive Growth

Generate Revenue from Existing Products and the Launch of New Local Products

Special Discussion

Akira Morita
Outside Director and Chair of the Board

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Masashi Miyamoto, Ph.D.
Representative Director, President and Chief Executive Officer

In February 2021, the Kyowa Kirin Group embarked on a new phase of growth with the launch of its latest Medium Term Business Plan, which covers the FY2021-FY2025 period. In this section, CEO Masashi Miyamoto sits down for a special discussion with Outside Director Akira Morita to talk about the Group's current position and its strategy going forward.

Theme 1 Changes in society caused by COVID-19 and the impact on Kyowa Kirin

Miyamoto: The COVID-19 pandemic is spurring dramatic change in society. Those changes are particularly evident in the medical field, where growing use of socially distanced communication and non-contact medical examinations are leading to shifts in patient behavior.

A product supplied by the Kyowa Kirin Group is subject to new guidelines aimed at reducing the number of hospital visits for drug administration in order to balance the risk of infection with the benefits of receiving treatment. Other restrictions on our business activities, such as limits on visits to medical institutions, mean we are unable to promote new products properly. To mitigate the risk of infection and operate under pandemic restrictions, we continue to distribute information online and use email, web conferencing apps and other digital tools to communicate with medical professionals.

With socially distanced environments likely to become the new normal, a key challenge for the Group will be how we adapt to these new conditions. That presents opportunities, as well as risks. One area of opportunity is digital technology. By harnessing digital tools in our new non-contact world, we have the potential to reduce costs for certain business activities, even if they typically required significant resources and investment in the past. For a company like ours, which is relatively small compared with the Big Pharma players, that makes it easier for us to expand on the global stage – a clear opportunity for Kyowa Kirin. However, we face major risks if the Group is too slow to introduce digital systems amid the broader shift to digitization.

Morita: I agree. With society changing rapidly due to the pandemic, implementing digital transformation (DX) is now of paramount importance to all companies, not just pharmaceutical firms. We have to actively harness digital technology to create innovative systems and services ahead of our competitors.

A key element of DX will be gathering, storing and utilizing information as digital data. A prime example of that approach is Israel's COVID-19 vaccine rollout program. Israel uses its citizen ID scheme to manage individual health records, providing detailed insights into who has received the vaccine and when. The authorities then analyze the data to help them keep the virus under control.

Pharmaceutical companies in particular also need to actively utilize big data resources and introduce AI technologies, which will help to significantly reduce clinical study costs and speed up new drug development. That of course has major benefits for patients.

Theme 2

Reviewing the FY2016-2020 Medium Term Business Plan

Miyamoto: We made significant progress during the FY2016-2020 Medium Term Business Plan, including launching three global strategic products and expanding our sales areas. The main factor behind the success of the three new drugs was their underlying capability. In other words, we used our unique strengths to develop drugs that satisfy unmet medical needs.

The achievement was also driven by the passion of our research teams, which launched the original development projects and persevered for around 20 years, motivated by a desire to find treatments for conditions that other companies showed no interest in. Kyowa Kirin was formed in 2008 through the merger of two companies that were both trying to establish a solid foundation of pharmaceutical business. Both companies had thoughts that they had to take a completely different approach from other veteran pharmaceutical companies to survive in the industry, creating the conditions for independent-minded researchers to take root in our organization. Many times, development of the three global strategic products was almost halted, but a key factor behind their eventual success was the strong determination of employees who created the drugs to ensure they were ultimately delivered to patients.

Morita: I was appointed Outside Director in 2019, which coincided with the start of Kyowa Kirin's global push. My impression is that all directors and employees are highly motivated and upbeat at the moment, buoyed by the solid progress of the global strategic products. However, we need to turn our attention to the outside world, especially at times like these. The world's medical needs are constantly changing, and past results are no guarantee of future success. We need to make sure there is no mismatch between our business strategies and the operating environment. If necessary, we might have to adjust our past approaches and thinking. In that respect, I hope to continue providing advice to Mr. Miyamoto from an external standpoint.

Review of FY2016-2020 MTBP

Improvement of Global Competitiveness

- Results: Achieved strong growth, supported by our successful launch of global products in the US and Europe
- Issues: Reinforce sales channels in the US and Europe and global structures for quality, demand forecasting, and stable supplies

Creating Innovation

- Results: Progressed late-stage development compounds and reinforced research pipeline by combining in-house and external technologies
- Issues: Continue to strengthen the pipeline, and further reinforce drug discovery technologies to drive future growth

Continuous Improvement for Operational Excellence

- Results: Strengthened domestic products by focusing resources on priority categories and launched One Kyowa Kirin structure
- Issues: Rigorously enforce compliance, foster a corporate culture with high awareness of risk, and accelerate digital transformation (DX)

Contribution to Health and Well-being of People

- Results: Responded to society's needs for tighter control of medical expenses with launch of Nesp-AG and biosimilars
- Issues: Continue to provide solutions that address increasingly diverse medical needs

Theme 3

Key ideas behind our FY2021-2025 Medium Term Business Plan

Miyamoto: In February 2021, we published a new vision for the Group toward 2030, along with our latest Medium Term Business Plan. The key phrases in the vision are "life-changing value" and "make patients smile." Life-changing value in this context means value from the perspective of patients, their families and medical professionals, not Kyowa Kirin. Specifically, we want to bring a smile to the faces of patients by providing medicines and services

for diseases with no existing effective drugs and treatments in order to deliver improvements in quality of life. Our new vision is built around this objective.

Morita: All the outside directors endorsed the new vision. The main job of pharmaceutical companies is to help people overcome pain and suffering. To do that, they need to keep reinforcing their R&D capabilities, which also ultimately helps to generate profits. In that way, pharmaceutical companies create both social value and economic value. In Kyowa Kirin's new vision, that is expressed as "make people smile" and "create life-changing value," which I think describes exactly what pharmaceutical companies should do.

Miyamoto: Indeed. All our overseas Group companies also need to be fully on board with the vision to ensure it becomes a reality. To achieve that, the challenge for us is to keep creating revolutionary new products to sustain the momentum of our three global strategic products. What do you think our priority should be?

Morita: In my view, the pursuit of science should underpin everything we do, but as I mentioned earlier, harnessing the power of digital technology to make drug discovery more efficient will be key. By using AI to analyze various data from experimental trials, we will have more success in identifying new drug targets and dramatically accelerate the pace of drug development. Global pharma companies are already investing heavily in digital tools and technology. Kyowa Kirin is making progress in this area as well, illustrated by its tie-up with AI drug discovery technology firm InveniAI, but we have to do more.

Miyamoto: To ensure we continue to create a steady stream of innovative new drugs, we also have to understand patients better. For example, with anemia related to chronic kidney disease, progression is asymptomatic in most cases, so many patients do not notice they are getting worse, or even realize they have the condition. If small changes in their condition are identified, they can receive appropriate treatment, leading to dramatic improvements in quality of life – what we call "life-changing value." That approach will help us identify new unmet medical needs based on a deeper understanding of patients. We also see potential to improve the efficiency of drug development by gathering, organizing and analyzing large volumes of patient data, which can be used as evidence in drug development.

Theme 4 Reinforcing corporate governance

Miyamoto: Kyowa Kirin is a listed company, and so is its parent company. That means shareholders and investors look at the Group's governance and management transparency more closely than other companies. We are therefore putting considerable time and effort into strengthening corporate governance. As part of that, we appointed you, an outside director, as Chair of the Board in 2020. How was your first year in the role?

Morita: As Chair, my mission is to improve the effectiveness of the Board of Directors and guide the board in making the correct management decisions. I was initially a bit apprehensive about filling such a major role, but once the meetings began, my concerns disappeared, thanks to active board discussions backed by expert insights from both inside and outside directors.

Almost all board meetings in 2020 were conducted online due to the COVID-19 pandemic. In face-to-face meetings, we get more visual cues and a better idea of when people want to say something, which makes it easier to run meetings than in a virtual setting. However, after several online meetings, we are all getting used to the new approach, and discussions are increasingly as effective as during face-to-face meetings. Kyowa Kirin is also providing board members with more detailed information packages before meetings, reducing the time needed to go through each agenda item and facilitating in-depth discussions.

Miyamoto: I think the fact that you are the Chair and also an outside director is helping to create an environment where it is easier for external board members to express their opinions. For me, governance is about protecting the interests of minority shareholders and ensuring our independence as a company to avoid any conflicts of interest. For that reason, some directors are recused from discussions about certain agenda items. When we were discussing the sale of Kyowa Hakko Bio to our parent company Kirin Holdings, directors with concurrent posts at Kirin were asked to leave the meeting. And when there are very sensitive discussions from a governance perspective, there were some cases that inside directors like myself are sometimes recused, leaving only independent outside executives and third-party legal counsel.

Morita: Protecting minority interests is always at the front of my mind. Because Kyowa Kirin is a listed company with a listed parent, I aim to supervise the board closely from an outside perspective.

Theme 5 Engagement with stakeholders

Miyamoto: We place importance on dialogue with stakeholders to ensure the public's demands and expectations are reflected in business management. In our dialogue in 2019, we received plenty of useful input and feedback, and we got a strong impression that stakeholders are really looking to us to drive innovation. Some stakeholders called on us to set R&D KPIs and strengthen our strategic approach in research, because building an R&D platform will be vital to innovation. We took that advice on board by adopting the ratio of R&D expenses to revenue as a new KPI for our new Medium Term Business Plan.

Morita: Indeed. We have to focus on the issues faced by society today and consider how to provide value to all stakeholders. This will need to be a key approach for business leaders going forward. Climate change in particular is something that companies have to tackle seriously. Awareness of climate change has not been that high in Japan, partly because of a relatively modest impact so far, but from a global perspective, environmental issues are the biggest risk facing society over the next ten to twenty years.

Miyamoto: As part of the Kirin Group Environmental Vision 2050, we are targeting net-zero CO_2 emissions across our entire value chain by 2050. While that might seem like a long way in the future, we have already started work, because our vision will only be an empty promise if we do not move forward systematically. Due to the nature of our business, Kyowa Kirin's direct CO_2 emissions are lower than a typical manufacturing company, but our R&D centers and plants use large amounts of electricity. To address that issue, we plan to put the infrastructure in place to switch to renewable energy.

Morita: I want to see Kyowa Kirin actively disclose information about its ESG non-financial targets and initiatives to foster a deeper and broader understanding of what we are doing in the ESG sphere. Communication is becoming increasingly important to win and retain the trust of multiple stakeholder groups.

Miyamoto: I agree. By sharing information, we can tackle and solve issues together with stakeholders. I believe that will become a key reason why companies are valued by society, supporting sustained growth in corporate value.

Thank you for your time today.

Materiality

Identifying material issues to address during the Medium Term Business Plan from 2021

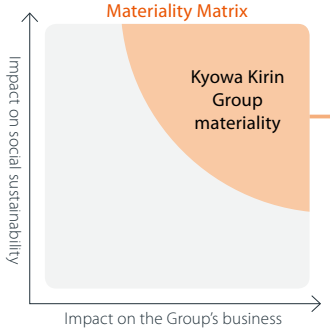
By identifying priority issues that the Group needs to address from both a social and business perspective, we aim to help build a sustainable society while also growing our business.

STEP 1 List issues
- List issues to be discussed (competitor, sector and expert review, data analysis)

STEP 2 Assess impact on social sustainability and business
- Prioritize listed issues from a social perspective (media surveys, trend surveys)
- Prioritize listed issues from a business perspective (analysis of internal documents, hearings with management, internal workshops)

STEP 3 Identify materiality (material issues)
- Formulate a materiality matrix

STEP 4 Confirm validity and finalize
- Conduct dialogue with stakeholders
- Discuss and confirm materiality in internal meetings attended by management
- Embed materiality in the Medium Term Business Plan
- Finalize at Board of Directors meeting



Growth opportunities

Make as many people as possible smile
- Continuous innovation
- Patient support and advocacy
- Access to medicine

Growth foundations

Foster even greater trust in Kyowa Kirin
- Corporate governance
- Provide high-quality, safe products and services
- Supply chain management
- Proper use of products
- Responsible marketing and advertising
- Responsible research and development
- Anti-counterfeiting
- Transparency and disclosure
- Legal compliance and ethical business practices
- Tax compliance
- Anti-bribery and corruption
- Privacy and information security
- Reinforce risk management
- Respecting human rights
- Stakeholder engagement

Organizational culture and talent

Create a unified team brimming with diversity
- Diversity and inclusion
- Occupational health and safety
- Employee development and provide opportunities for employees to grow

Social foundations

Ensure a thriving global environment for future generations
- Climate change
- Biodiversity
- Reducing pollution
- Waste and resource use
- Water use
- Philanthropic activities
- Advancement of medical science

Related SDGs

Materiality

Stakeholder Dialogue

Experts participating in the dialogue (affiliations accurate as of October 2019)

Mr. Toshio Arima
Chairman of the Board, Global Compact Network Japan (GCNJ)

Mr. Toshihiko Fujii
Visiting Professor, Tama Graduate School of Business

Ms. Emi Onozuka
Vice President, Stewardship Responsibility Group, Portfolio Management, Goldman Sachs Asset Management Japan

Haruka Sakamoto, M.D., Ph.D.
Project Researcher, Department of Global Health Policy, Graduate School of Medicine, The University of Tokyo

Mr. Bruno Rossi
Executive Manager, SATORU GK

Facilitator

Mr. Keiichi Ushijima
EY Japan Climate Change and Sustainability Services (CCaSS) Leader

Kyowa Kirin participants

Nobuo Hanai, Ph.D.
Director, Chairman (as of October 2019)

Masashi Miyamoto, Ph.D.
Representative Director, President and CEO

Yutaka Osawa
Representative Director, Executive Vice President

Reflecting society's expectations and demands in the Medium Term Business Plan (October 2019)

As part of the process of defining material issues (materiality) for the Kyowa Kirin Group, we held dialogue sessions attended by experts from a wide range of fields in order to accurately identify society's expectations and demands on the Group and reflect them in our Medium Term Business Plan.

Extracts of Opinions

- Materiality can be defined as non-financial issues that have a high possibility of impacting future financial performance. Non-financial information is extremely important in showing how the Group uses internal resources as effectively as possible to support the continued development of new drugs.
- Corporate governance has a key role to play in managing the allocation of financial resources to support continuous innovation. Kyowa Kirin also needs to foster a culture that encourages the efficient and effective use of internal resources to address environmental and social issues.
- Society is looking to the global pharma sector to mitigate risks that could impact stable supplies of pharmaceuticals, based on an understanding of the issues and conditions unique to each country.
- Materiality is effective in understanding the issues we face, but we also need to be aware that the actual impact and importance of those issues varies considerably from country to country.
- The crux of the debate about access to medicine intersects with how people view the concept of well-being in each country, which can be established through dialogue with stakeholders in those countries. To understand what disadvantaged people in society need, we have to be more attuned with their values.
- As part of its expansion overseas, Kyowa Kirin needs to be conscious of its position as a corporate citizen. It needs to participate in industry associations as a corporate citizen and invest its resources effectively. I would like to see Kyowa Kirin become a driver of change through partnerships with other companies.
- We hope Kyowa Kirin continues to prioritize drug discovery, which is the source of its competitiveness.

Financial Strategy

Motohiko Kawaguchi
Executive Officer,
Director, Finance Department

Targeting sustained, long-term increases in ROE and dividends by boosting growth, innovation and profitability

Numerical guidance in the FY2021-2025 Medium Term Business Plan

In the FY2021-2025 Medium Term Business Plan, we are targeting sustainable growth beyond FY2025 and increased corporate value over the medium- to long-term. To measure progress, we are using return on equity (ROE) as a key performance indicator (KPI). Our aim is to achieve ROE of 10% or higher as early as possible (vs. ROE of 7% in 2020) so that ROE consistently exceeds the expected cost of capital. We also aim to increase ROE over the longer term.

To achieve our ROE objectives, we need to continuously increase the Group's growth potential, capability to innovate and profitability, and we have selected three KPIs to measure our progress in those areas: revenue growth rate, R&D expenses ratio and core operating profit ratio.

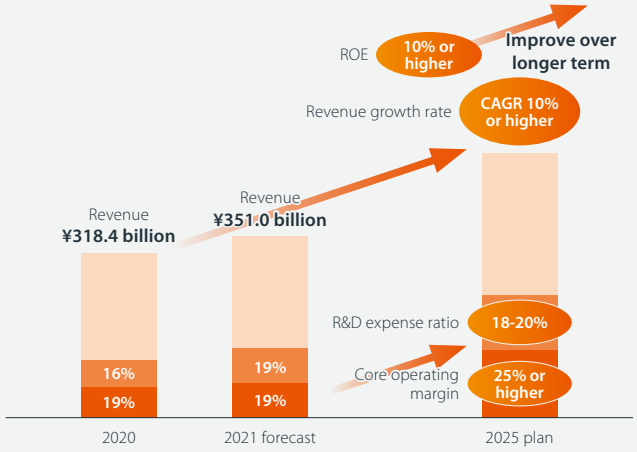
First, let's look at the revenue growth rate (growth potential benchmark). During the five years of the Medium Term Business Plan, we are targeting average annual top-line growth of 10% or higher. We aim to do that by implementing further steps to increase sales and maximize the value of existing global strategic products and by steadily rolling out the next-generation strategic products. Second, the R&D expenses ratio (capability to innovate benchmark). Our goal is to expand the drug pipeline to accelerate and drive the Group's growth beyond FY2025 by consistently and actively investing in research and development, aiming for an R&D expenses ratio target of 18-20% (vs. 16% in 2020). At the same time, we will work to improve profitability by reducing the selling, general and administrative expenses ratio through tighter cost control to achieve our third KPI, a core operating profit ratio (profitability benchmark) of 25% or higher (vs. 19% in 2020) by FY2025, the final year of the plan.

By implementing measures to achieve those three KPIs, we are targeting growth in core operating profit and core EPS that outpaces revenue growth in order to improve ROE over the medium- to long-term and support sustained increases in the dividend. Ultimately, our objective is to establish a stable earnings structure and generate continued growth as a Global Specialty Pharmaceutical Company (GSP).

Financial KPIs (Numerical guidance)

ROE	**10% or higher** (achieve target early / maintain or increase over the medium- to long-term)
Revenue growth rate	**CAGR*1 10% or higher**
R&D expenses ratio	**Targeting 18-20% to support active investment**
Core operating profit ratio*2	**25% or higher by 2025**
Dividend payout ratio	**Targeting sustained dividend hikes with 40%** (based on core EPS*3)

*1 Average growth rate over a five-year period, with FY2020 as the base year.
*2 Core operating profit: "Gross profit" – "Selling, general and administrative expenses" – "Research and development expenses" + "Share of profit (loss) of investments accounted for using equity method."
*3 "Core profit" ("Profit attributable to owners of parent" – "Other income and expenses" (excluding impact from applicable taxes)) ÷ average number of shares during fiscal year.



Cash allocation and investments in growth

In our five-year cash allocation plans in the FY2021-2025 Medium Term Business Plan, we assume the source of funds will be new operating cash flow of ¥800 billion or higher (before deduction of R&D expenses) generated during the plan's five years, as well as cash on hand of roughly ¥300 billion as of end-FY2020. In principle, our policy on cash allocation is to maintain a net cash position, while also ensuring sufficient financial flexibility by securing borrowing capacity and responsive fund-raising methods (commercial paper, commitment lines), in addition to cash on hand, to ensure access to sufficient funds for large-scale strategic investments if the need arises.

Our top priority for cash allocation is R&D, Strategic, and Capital investments to sustain growth beyond FY2025 and maximize corporate value. Over the plan's five years, we aim to invest roughly ¥400 billion in R&D and spend approximately ¥100 billion on capital investment, while taking a flexible and active stance on strategic investments.

R&D investment

The Kyowa Kirin Group has world-class R&D and drug discovery capabilities in the field of biopharmaceuticals. To further strengthen the Group's ability to innovate and sustain growth beyond 2025, we aim to continue investing heavily in R&D during the FY2021-2025 Medium Term Business Plan, based on an R&D expenses ratio of 18-20% (R&D investment as a percentage of revenue). In R&D activities, we will channel resources into the development of next-generation global strategic products such as KHK4083, KW-6356 and ME-401 to maximize the value of our pipeline. We also plan to invest heavily in areas that support innovation over the long term, such as multi-modality technology platforms that can create groundbreaking new treatments, aiming to consistently create new products that bring life-changing value to patients.

Strategic investment

In addition to internal R&D efforts, we will actively utilize external resources through strategic partnerships (in-licensing, tie-ups, etc.) and M&A to introduce drug discovery technologies and new compounds for our pipeline. And we are aiming to faster our sustained growth by expanding our global pipeline over the medium- to long-term, generating synergies with existing global strategic products, and increasing opportunities to create Only-one value. The Strategic Investment Review Committee, which is led by CEO Masashi Miyamoto, has been conducted roughly twice a month to actively discuss potential targets for strategic growth investments.

Capital Investment (CAPEX)

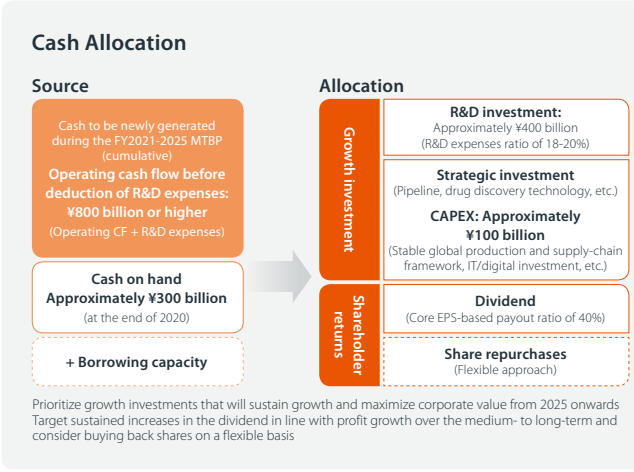
We will invest heavily to create a more competitive business structure to help us maximize the value of global strategic products. In particular, we will focus on establishing a robust quality assurance and production system that can reliably supply safe, high-quality pharmaceuticals to patients worldwide. We are also aware that we need to reinforce the Group's functions as it expands and develops globally. Specifically, we aim to rapidly establish a global business foundation that supports Kyowa Kirin's sustained growth as a GSP, which will mean investments to reinforce global governance and risk management systems and to build a platform that allows us to strategically utilize IT and digital tools.

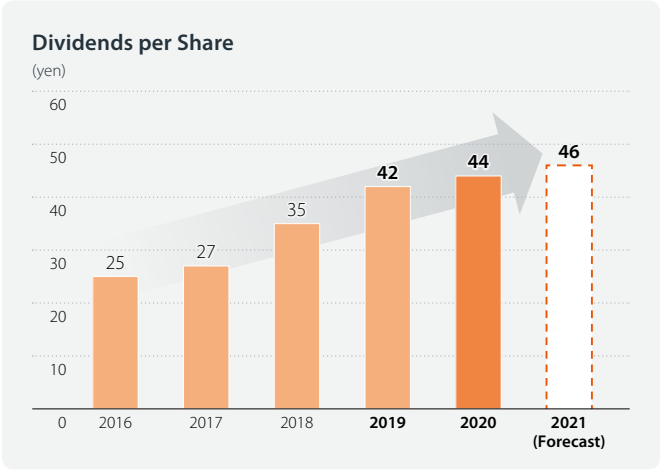
When evaluating the profitability of those potential investments or development projects, we use two quantitative standards: net present value (NPV) and expected present value (EPV). Both standards are based on the hurdle rate (by region), which reflects the expected cost of capital (WACC) for investors. In investment decisions, we focus on whether the investment will contribute to an increase in corporate value over the medium- to long-term by generating returns in excess of the cost of capital.

Shareholder returns

In the FY2021-2025 Medium Term Business Plan, we are targeting a consolidated dividend payout ratio of 40% based on core EPS, aiming to steadily increase returns for investors by raising the dividend in line with profit growth over the medium- to long-term. Based on that policy, we plan to raise the dividend to ¥46.00 per share for FY2021, a hike of ¥2.00 from FY2020 and the fifth consecutive year of increases. We will also flexibly consider buying back shares, taking into account the share price and other factors.

To generate sustained growth and maximize corporate value as a Japan-based GSP, we will enhance the Group's growth potential, capability to innovate and profitability in order to improve ROE over the medium- to long-term and support sustained increases in the dividend.





PERFORMANCE AND STRATEGY BY BUSINESS DIVISION

Kyowa Kirin has established three key strategies to achieve its vision toward 2030 for the Group.
All the Group's business divisions and function-based teams are working closely together to execute the strategies.

Strategy to Realize Our New Vision

- Maximize the value of global products
- Establish framework to ensure stable global supplies
- Build a drug pipeline to drive growth beyond 2025
- Launch services that go beyond pharmaceuticals
- Foster a corporate culture suited to global business development

Provide pharmaceuticals for unmet medical needs

- Maximize the value of G3B
- Continue to create groundbreaking new drugs

Address patient-centric healthcare needs

- Patient advocacy
- Provide value that goes beyond pharmaceuticals

Retain the trust of society

- Ensure stable supplies of high-quality pharmaceuticals
- Help to protect the global environment

Reinforce human resources and structures that support the creation of Life-changing value

- Cultivate human resources
- Strengthen organizations
- Build digital platforms

Research and Development

Research

Progress in FY2020

New value creation and future innovation with a focus on "Only-one value"

Guided by the key phrase – "Provide "Only-one value" to Patients. This is our Dream." the R&D Division continues to take on a wide range of challenges, aiming to create new development compounds for unmet medical needs and establish ground-breaking modality technologies that support the creation of new families of drugs for the Kyowa Kirin pipeline.

In FY2020 we made good progress with pipeline drug discovery using our in-house technologies and through partnerships with other companies.

We entered into a partnership with InveniAI to leverage its AI technology to identify novel targets for our next-generation antibody technology and explore new disease applications. We are also collaborating with Ardelyx, Inc. to create molecularly-targeted drugs based on targeting key molecules identified from Ardelyx's research, in addition to the licensing agreement with Ardelyx, Inc. for tenapanor (code name: KHK7791), a first-in-class phosphate absorption inhibitor. Furthermore, we have started an innovative collaboration in small molecule drug development with Axcelead Drug Discovery Partners Inc. The collaboration will allow us to build a novel small molecule drug discovery platform. Utilizing the platform, we aim to expand our R&D pipeline through the discovery of multiple innovative drug candidates.

These efforts illustrate how we are advancing "Technology-Driven Drug Discovery" through open innovation and collaboration with multiple external domestic and overseas R&D facilities, as well as our own R&D sites in Japan and the US, to establish new modality technologies and build a unique pipeline by harnessing those technologies.

Development

Progress in FY2020

Building a development system befitting a GSP and maximizing product value

In FY2020, the final year of the FY2016-2020 Medium Term Business Plan, we worked to maximize the value of our product lineup by further developing and expanding the reach of global strategic products already on the market.

One of those products, burosumab (marketed as Crysvita in the US and Europe) was approved for tumor-induced osteomalacia (TIO) in addition to the already approved indication of X-linked hypophosphatemia (XLH). Burosumab also received approval for the treatment of XLH in adolescents and adults in the EU and for FGF23-related hypophosphatemic rickets and osteomalacia in South Korea. We also submitted a marketing authorization application in the EU for istradefylline (code name: KW-6002) as an adjunctive treatment to levodopa-based regimens in adult patients with Parkinson's disease experiencing wearing-off symptoms. The application has been validated by the European Medicines Agency (EMA) and is now under review.

We also worked to maximize the value of existing products. Brodalumab (marketed as Lumicef in Japan) received approval in Japan for the treatment of ankylosing spondylitis and non-radiographic axial spondyloarthritis and was approved for the treatment of plaque psoriasis in China. Also in China, darbepoetin alfa (code name: KRN321) received approval for the treatment of renal anemia (patients on dialysis), and we submitted a new application for romiplostim (code name: AMG531) for the treatment of chronic idiopathic (immune) thrombocytopenic purpura. In Japan, we started a clinical study of an automated injection device for pegfilgrastim (code name: KRN125, marketed as G-Lasta in Japan). The device is designed to reduce the ambulant burden on patients, and contributes to reducing burden on healthcare professionals.

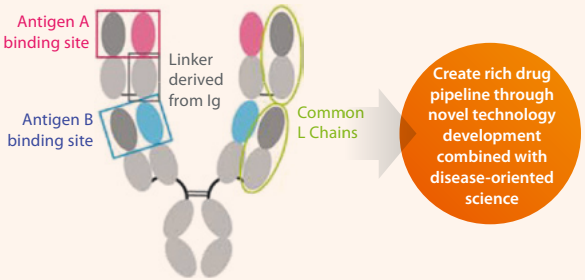
We also made solid progress with our development pipeline during FY2020. The results of a domestic phase II study of tenapanor (code name: KHK7791) in hyperphosphatemia patients on hemodialysis confirmed the drug's safety and efficacy, and we are now preparing to initiate a domestic phase III study. We also conducted a phase IIb study in Japan of KW-6356, a next-generation compound of istradefylline (marketed as Nouriast in Japan, Nourianz in the US), and we hope the data generated will support a broader label. The phase IIb study, which was conducted in patients with Parkinson's disease receiving treatment with levodopa-containing preparations, achieved the primary endpoint. In addition, we entered a global license, development, and commercialization agreement with MEI Pharma, Inc. to further develop and commercialize zandelisib (code name: ME-401). Under the agreement, we started a domestic phase II clinical study in patients with indolent B-cell non-Hodgkin's lymphoma (iNHL).

At Kyowa Kirin, we are using our virtual Global Development Organization (vGDO), an integrated development platform that brings together resources from different regions and teams, to accelerate the drug development process, launch multiple products, including new global strategic products, and implement product life-cycle management.

Next-generation Technology

Proprietary bispecific antibody technology

- Selection of linkers derived from Immunoglobulin (Ig) and the common sequence of L Chains
- Versatility equivalent to wild type IgG
- Unique biology based on bivalent x bivalent binding



Strategy to Realize Our New Vision

MID-TERM BUSINESS PLAN

Future Initiatives

Continue to create life-changing "Only-one value" to bring happiness to patients battling medical conditions

2025 goals for the R&D Division

1. For products to be launched in multiple regions, we will formulate and execute development plans that match the actual situation in each region and obtain approval for multiple products continuously.
2. Through the vGDO organization, we will ensure efficient operation of the global R&D function, consensus building, and highly transparent decision-making.
3. To provide "Only-one value" drug to patients, we will evolve and deepen research and development while fundamentally reviewing our human resource management system and organizational structure.

To achieve the above goals, we will expand the development pipeline – focusing on global strategic products and next candidates – and maximize the value of products and development compounds, by pursuing operational excellence across our global development organization and aiming to build a global R&D framework that maximizes product value. Also, to create life-changing value with overwhelming competitive advantages, we will harness next-generation antibody technology and multiple modalities to build a more competitive search pipeline and acquire groundbreaking drug discovery platform technologies, which will support our efforts to continue delivering "Only-one value" to patients battling with conditions that currently have no effective treatments. Moreover, we will establish a stronger organizational governance system suited to a GSP, as well as upskill human resources, reform our organizational culture and upgrade our IT platform to reinforce the global R&D structure.

To help us attain the 2025 goals, we will instill "Our R&D Spirits," as what each person in Global R&D should be and wants to be, based on Core Values of the Kyowa Kirin Group. By spreading the vision, we aim to motivate employees to take on new challenges while respecting independent thought and actions.

Our R&D Spirits

- **Be the Best in Science**
  （サイエンスで負けない）
- **Passion for Innovation**
  （イノベーションへの情熱）
- **Every Challenge, a Step to Success**
  （挑戦なくして成功なし）
- **This is me. This is our team.**
  （多様な個性が輝くチームになろう）

Next-generation Strategic Products

	Country / region*1	Indication*2	Approval year*3	Total addressable market*4	No. of patients*5
KHK4083	NA/EU/JP	Atopic dermatitis	2025/2026	★★★	16,000K
KW-6356	NA/EU/JP	Parkinson's disease	2025	★★★	3,500K
ME-401	NA/EU/JP	Follicular lymphoma Marginal zone lymphoma	2023	★★★	~800K
RTA 402	JP/Asia	Alport syndrome Diabetic kidney disease Autosomal dominant polycystic kidney disease (ADPKD)	2022 2023 2025	★★★	2,500K~
KHK7791	JP	Hyperphosphatemia under maintenance dialysis	2023	★☆☆	250K

*1 Products may not be approved/launched in all countries or regions shown in the table
*2 Indications may ultimately differ to expectations due to status of approvals from regulatory authorities
*3 Expected year of first approval
*4 Expected total addressable market based on the indications and countries/regions shown in the table, not projected sales or targets of the Company; ★ = less than ¥50bn, ★★ = ¥50-100bn, ★★★ = Over ¥100bn
*5 Total number of estimated patients in all countries/regions shown in the table.
Note: The size of the total addressable market and patient numbers are based on our estimates

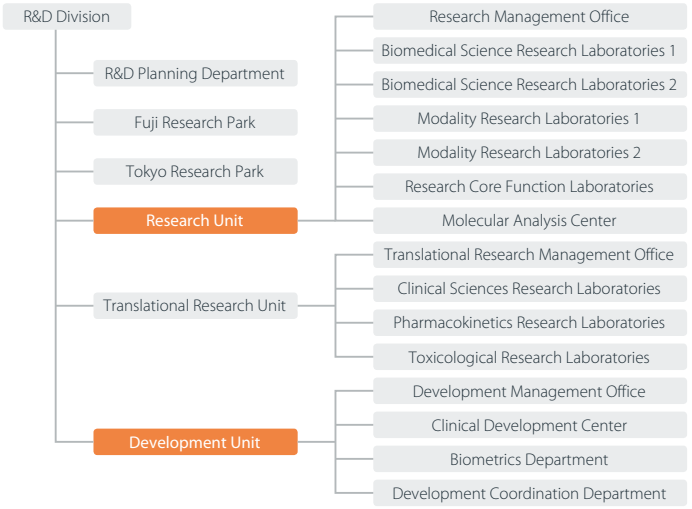
Our new R&D organization

We have established a Research Unit and a Development Unit as part of a radical overhaul of the Kyowa Kirin R&D Division. The new setup will help us to continuously launch products, as well as give us a stronger platform to create new products that support the Group's growth and build a globally competitive portfolio. Our aim is to harness the strengths we have built up so far and promote cooperation in the division to create a more flexible, responsive organization backed by faster decision-making.

The Research Unit will further accelerate the development of innovative drug discovery technology based on the progress and fusion of science while maintaining the disease intelligence and internal and external networks that have been cultivated so far as its strengths. In addition, we aim for more efficient and highly mobile management by making full use of external collaboration such as open innovation.

The Development Unit will pursue operational excellence in the global development organization, efficiently share development experience and expertise globally and regionally, and strategically train human resources. The goal is to reinforce management and operational functions to improve the speed and quality of global development.

Under this new structure, the Kyowa Kirin R&D Division aims to build a more competitive search pipeline and acquire groundbreaking drug discovery platform technologies and expand the development pipeline and maximize the value of the Group's products and development compounds.



Domestic Operations

Progress in FY2020

Contributing to healthcare with new drugs and expanded indications

We steadily deployed efforts for the launch of new products and the expansion of indication of existing products in 2020.

In June, Fentos Tape was approved for the additional indication of cancer pain relief for opioid analgesic naïve patients. In August, we launched Duvroq as a new class of treatment for renal anemia. Duvroq is an orally-convenient treatment option that avoids the administration challenges and cold storage requirements of existing injectable erythropoiesis-stimulating agents (ESA). Because Duvroq can be used by non-dialysis patients, as well as patients on dialysis, we expect the drug to become a highly convenient treatment option for many renal anemia patients right from launch. In September, Rituximab biosimilar (BS) received approval for the treatment of chronic idiopathic thrombocytopenic purpura and as a premedication for ibritumomab tiuxetan. In November, Rituximab BS also received approval for the treatment of acquired thrombotic thrombocytopenic purpura. In the same month, Lumicef was granted approval for the treatment of ankylosing spondylitis and non-radiographic axial spondyloarthritis. Meanwhile, Crysvita is now available to patients in Japan as a self-injection formulation that can be used at home. The new formulation is expected to improve patient quality of life (QOL) by saving time and alleviating the physical and financial burden for patients who currently have to visit hospital to receive the drug.

MID-TERM BUSINESS PLAN

Future Initiatives

Our vision for 2025

By advancing our digital strategy, we aim to diversify connections with customers and increase the efficiency and value of our interactions with them. To realize that goal, we will overhaul work practices in the Sales & Marketing Division, focusing on medical representatives (MR), to reinforce the foundations of our domestic operations.

Key Actions in Our New Medium Term Business Plan (2021)

Optimize channel mix in contacts with customers

- Achieve best mix of contact and non-contact channels
  Develop new operating model in chronic kidney disease (CKD) treatment area, extend to and test in other franchise areas
- Start implementing closed loop marketing (CLM)
- Enhance non-contact channels and content

Marketing platform DX: Reinforce data and analytics functions and structures

- Build data warehouse
- Start using SFA/CRM*
- Launch data governance system in Sales & Marketing Division

Work practice reforms

- Expand customer contact resources by realigning committees and over-hauling internal work processes
- Explore / implement rebuilding of head office and branch office functions
- Improve efficiency of MR activities by introducing SFA/CRM*
- Redefine our image of the model MR
- Overhaul education and training systems (including shift to digital tools)
- Build personnel training strategies and systems (including programs to enhance MR skills)
- Streamline and digitize work processes

*Sales force automation/customer relationship management: new marketing support systems

TOPIC

We have redefined our image of the model MR in response to expected changes in the pharmaceutical company operating environment. In addition to clearly setting out the skills required as model MRs, we plan to build a self-led training system aligned to the different stages of MR development.

Model MR

Highly ethical individuals who bring happiness to people with medical conditions by contributing to healthcare through the responsible collection and provision of medical information.

Skills and qualities of the model MR

TOPIC

We have signed a partnership with the Japan Kidney Association to raise patient awareness of kidney disease. Through the partnership, we have launched the DIAMOND Project (DIsease awareness Activities aiMed at Overcoming (Diabetic) kidNey Disease). The project is actively implementing a range of activities across Japan to raise awareness, such as seminars for the media, surveys to ascertain the level of public awareness, and seminars for medical professionals and government employees to increase awareness about the importance of strategies to tackle the disease and help people suffering from the condition.

DIAMOND Project
Collaborated by JKA & KKC

Overseas Operations

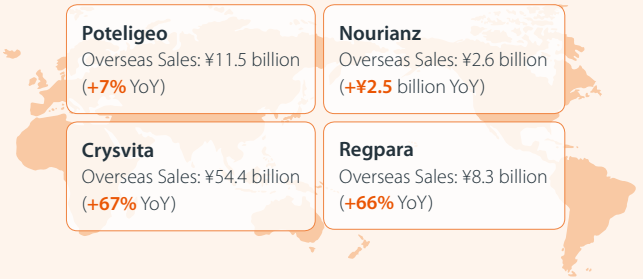
Progress in FY2020

Global strategic products steadily growing into key products

In FY2020, overseas revenue (excluding technology licensing revenue) totaled ¥134.2 billion, a second consecutive annual record, despite the tough business condition due to the COVID-19 pandemic.

In North America, Crysvita received FDA approval for the additional indication of tumor-induced osteomalacia (TIO), giving us the opportunity to contribute to the health of even more patients with Crysvita. US sales of Crysvita also grew steadily, reaching ¥42.4 billion. Sales of Nourianz, which was launched in the US in October 2019, totaled ¥2.6 billion. FY2020 sales figures for Crysvita and Nourianz highlight how the global strategic products, including Poteligeo, are growing into key products for Kyowa Kirin. In EMEA, the number of countries where Crysvita is available has increased since the product was launched in Germany in 2018. In 2020, we launched Crysvita in a further 8 countries. Also, in June 2020, we launched Poteligeo in Germany, the first country in Europe to get the product. Launch schedules have been delayed in some countries due to the COVID-19 pandemic, but sales are growing steadily and feedback is very positive in markets where the drug is now available. In Asia/Oceania, sales of all our products were also firm in FY2020, despite the pandemic. Sales of Regpara were particularly robust in China, reaching a record-high. The strong sales reflected rapid hospital uptake by being added to China's National Essential Drug List (NEDL) in 2018, as well as continued information provision activities through our proprietary digital platform, which has been in development since 2017. Going forward, we will continue to further develop our operations overseas to deliver medicines to as many in-need patients as possible.

Overseas flagship drug sales in FY2020



MID-TERM BUSINESS PLAN

Future Initiatives

Overseas expansion is driving Kyowa Kirin's dramatic growth

In our Medium Term Business Plan, covering the period through FY2025, our goal is to raise awareness of Kyowa Kirin as a Japan-based Global Specialty Pharmaceutical Company (GSP) focused on the key markets of North America, EMEA and Asia/Oceania. Backed by that greater visibility, we aim to expand our overseas operations to bring a smile to as many patients, family members and medical professionals as possible, while also driving Kyowa Kirin's dramatic growth.

To deliver three global strategic products rapidly to as many patients as possible, we are working to achieve unparalleled operational excellence by reinforcing the One Kyowa Kirin (OKK) management structure, which was first launched in 2019. Also, we will build good relationships with patient groups to maintain and strengthen patient advocacy.

OKK is a matrix management structure combining a regional organization based on four regions – Japan, North America, EMEA, and Asia/Oceania – and a functional organization based on the functions needed by a pharmaceutical company. By developing our regional businesses in line with local conditions, achieving certain global standards for each Group function, and executing product strategies that maximize value, we aim to respond to issues accurately and rapidly in both a local and global context while also improving efficiency in all work processes to drive further growth in overseas operations. Also, as our organization becomes more global, we plan to nurture talent, promote personnel exchanges and develop teams that are international but anchored by our corporate culture from Japan.

In North America, we forecast further growth through FY2025, with the market set to be the main area in the Group's overseas operations. We will reinforce the Group's business base in North America to prepare for independent sales operation of Crysvita, scheduled to start from 2023. In addition to that, we plan to step up engagement with patient advocacy groups such as the National Organization of Rare Disease (NORD), and also ensure as many patients as possible have access to Crysvita – a treatment for rare conditions. We also plan to launch a new patient ambassador program with the aim of letting real patients share their experiences with Poteligeo. Through their stories, we will raise disease awareness, educate new patients and answer questions about treatment, and build support for patients with a rare condition. We will not only raise awareness of the disease but also listen to patients and support them all along the treatment journey. Meanwhile, we aim to encourage appropriate use of Nourianz as a new drug with a novel mechanism of action.

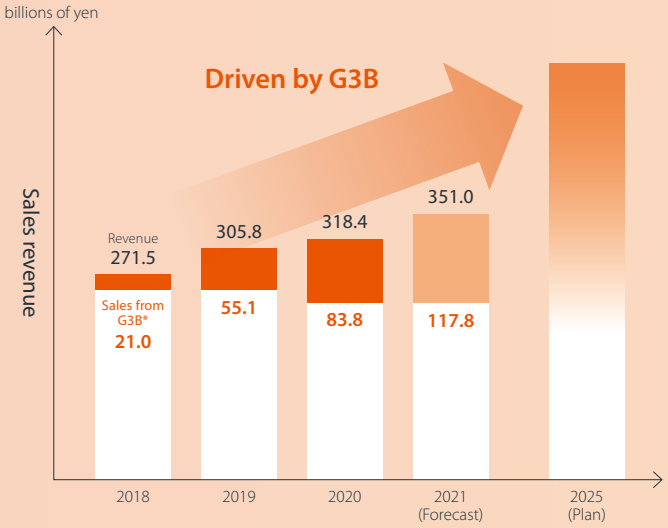
In EMEA, we plan to increase market penetration of Crysvita to establish it as our mainstay product in the region. We also aim to launch and drive uptake of Poteligeo in key markets. In particular, we will support patient needs to help ensure access to our medicines.

In Asia/Oceania, we will maintain and expand our position in the kidney and blood cancer fields and reinforce our business base across the region. We also plan to increase market penetration for Crysvita and launch Orkedia, a successor drug to Regpara which generated record-high revenue in China in FY2020.

Special Feature

Maximize the Value of Global Three Brands (G3B)

During the previous Medium Term Business Plan, we successfully launched three in-house developed global strategic products in markets worldwide, starting with North America and Europe. Sales of the three global strategic products are growing steadily and are now a key factor driving the Group's earnings. We are targeting even stronger growth by steadily maximizing the value of each product.



* Total sales generated by G3B (Crysvita, Poteligeo, Nouriast/Nourianz), including in Japan (sales from EAP not included)

Crysvita

(Burosumab, an anti-FGF23 fully human monoclonal antibody)

X-linked hypophosphatemia and tumor-induced osteomalacia

It binds to FGF23 overproduced in the blood due to a genetic abnormality and inhibits its action, and consequently, enhances renal tubular reabsorption of phosphate and increases phosphate blood levels.

Future Initiatives

Key Actions

- Expand commercialization territory
- Increase the treatment penetration rate
- Achieve smooth transition of North America business
- Expand indications

Ongoing Issues

- Identify the patient's treatment needs and establish the treatment evidence of the drug for those needs
- Convey the drug value appropriately to patients and physicians
- Provide appropriate treatments by raising disease awareness and diagnosis rates

Establish Crysvita as the standard treatment for XLH / unresectable TIO and contribute as a global leader in these therapeutic areas through the sustainable growth of the product

Poteligeo

(Mogamulizumab, an anti-CCR4 humanized antibody)

Relapsed or Refractory Mycosis Fungoides and Sézary Syndrome

Anticancer therapeutic antibody that binds to CCR4 on the surface of cells, exerting ADCC activity to eliminate attached cancer cells.

Key Actions

- Expand commercialization territory
- Dive deep into CTCL treatment

Ongoing Issues

- Collect and utilize clinical evidence
- Consider combination therapies with other treatments
- Support patients and their families by deepening understanding of the disease

In the global market, clarify the importance of treatment for appropriate early-stage CTCL patients and contribute through disease control; In Japan, establish its importance as a treatment for ATL which is indicated and commonly used

Nourianz

(Istradefylline, an Adenosine A_{2A} receptor antagonist)

Parkinson's disease

Istradefylline is a novel mechanism of action which selectively blocks the action of the adenosine A_{2A} receptor. The drug is recognized as being effective in reducing off time associated with use of levodopa/carbidopa to treat Parkinson's disease.

Key Actions

- Expand commercialization territory
- Broaden understanding the role of adenosine A_{2A} receptors in Parkinson's disease

Ongoing Issues

- Collect and utilize clinical evidence
- Establish positioning in the treatment paradigm
- Support patients and their families by deepening understanding of the disease

Collect clinical evidence, establish treatment positioning and develop a standard of care worldwide for wearing-off management in combination with levodopa

Maximizing the Value of Crysvita and Bringing a Smile to the Faces of Patients Worldwide

Crysvita, launched in 2018, has been significantly contributing for the treatment of patients worldwide with X-linked hypophosphataemia (XLH). Our main objective is to bring a smile to even more patients by maximizing the Crysvita's value and expanding its use to more countries. In this feature section, we talk to patients, healthcare professionals and employees with connections to Crysvita to provide a deeper understanding about the drug, which is set to become one of the Group's key products.

*We used to use David's photo however withdrew it because of the copyright expiring.

David
a patient living with XLH

It's made a big difference in my life

I was officially diagnosed with XLH when I was two years old and have lived with the disease my entire life. I have always had stiffness in my limbs and suffered from aches, fatigue and localized pain, which made it difficult to do many of the things I enjoy. I took standard treatments to help manage the symptoms, and I was able to enjoy sports like badminton and golf in my younger days, but eventually, it became harder for me and I had to give these activities up.

In 2016, I had the opportunity to join a clinical trial of Crysvita (burosumab). I was 50 years old at the time, and I saw my life improve after entering the trial as the product helped my stiffness and pain. I will never forget the day I played golf for the first time in decades with close friends from school. It was only nine holes, but I was able to walk the course, and I could enjoy the sport and felt so happy to be doing something I love and had been unable to do for so long.

I have two daughters who both have been diagnosed with XLH. My sincere hope is that not only my daughters but anyone living with XLH may have a chance to experience benefits of treatment, just as I have.

Results with treatment vary. Patients treated with Crysvita should be monitored by their physician for any allergic reactions, reactions at the site of injection, and calcium levels in the kidney. Common side effects include headache, fever, and diarrhea. For full safety information see respective country product website and Crysvita Product Label were marketed.

Special Discussion

In February, we had a chance to speak with Dr. Thomas Carpenter, Professor of Pediatrics (Endocrinology) and of Orthopaedics and Rehabilitation and Clinical Professor of Nursing; Director, Yale Center for X-Linked Hypophosphatemia (XLH) and Elizabeth Olear, Research Associate Pediatrics. Working together, they established a world-renowned XLH research center at Yale University, supported initially by an NIH-funded grant and currently involved in the care of ~100 patients from about 50 families. Through our discussion, we learned more about the experiences of patients and families affected by XLH, and treated with Crysvita (burosumab). Below are some excerpts of the conversation.

Director, Yale Center for X-Linked Hypophosphatemia (XLH)
Thomas Carpenter, MD

Research Associate Pediatrics
Elizabeth Olear

Describe how your practice has grown.

Dr. Carpenter (TC): We've grown the Center, in part, as adults diagnosed with XLH have children and bring them here for care. About 20 years ago, we established an NIH-funded center for X-Linked Hypophosphatemia and that has helped us establish a large cohort of patients for observational and clinical research.

Ms. Olear (EO): Once children start coming to Yale, they don't want to leave. Our family-centered approach allows for continuity of care across all of life's transitions. One of the things I love about endocrinology is that you have a lifelong relationship with your patients, and their families.

What concerns do you hear when a patient is first diagnosed?

TC: Everybody is a little different. With families that know they are carrying the mutation, they know what to expect and they want to make the diagnosis early. Many have heard us say, over and over, that early therapy is better for long-term outcomes, and they are eager to start treatment.

EO: For the de novo cases, it can be a difficult diagnosis to receive. Sometimes there's an immediate concern among parents about the lifelong aspects of the disorder.

TC: In situations where there's no family history, which we estimate may be more than 15%, we have to start education right away. These families are mostly worried about whether their child will have a persistent deformity and whether they will be able to actively participate in childhood activities.

How has the approval of Crysvita changed the conversation?

TC: There's more awareness about the disease. Once there's a therapeutic breakthrough available, people are motivated to start seeking help. Crysvita has led more people to seek care and treatment for XLH.

What's the feedback from patients?

TC: One of our patients described living with XLH as life-altering – affecting how you move and feel. With treatment, she's gained back mobility and is able to do the activities she enjoys.

Results from treatment are often more dramatic in adults because of the changes they notice. A patient who loves to garden shared, "I used to tire out from gardening after a short while due to stiffness. But one day I found myself in the garden until the sun set. It had been hours."

Results with treatment vary. Patients treated with Crysvita should be monitored by their physician for any allergic reactions, reactions at the site of injection, and calcium levels in the kidney. Common side effects include headache, fever, and diarrhea. For full safety information see respective country product website and Crysvita Product Label were marketed.

Emil D. Kakkis, M.D., Ph.D.
President, Chief Executive Officer and
Founder of Ultragenyx Pharmaceutical Inc.

Pressing Ahead with Ambition and Ingenuity

Working with Kyowa Kirin on Crysvita has been one of the most important programs of my career in rare diseases. We together have successfully treated a serious chronic bone disease at its underlying cause and changed the future of medicine for these patients for all time.

When a loved one is diagnosed with any rare disease, it can feel like a bolt of genetic lightning that instantly changes the family's future. They often learn shortly after their diagnosis that there are no good approved treatment options for them, and we are working every day to change this. Fortunately for patients and families living with XLH and TIO, they now have a globally approved therapeutic breakthrough in Crysvita. In the three years since Crysvita's initial approval, we have seen more and more people seek treatment for their disease, and it has been tremendous to see the difference this therapy has made in their lives, both young children and adults. In some families, we have heard from three generations getting treated together for the first time, changing their families' future.

During this extremely challenging pandemic year, we have also remained steadfast in ensuring that all XLH and TIO patients in the U.S. still have access to Crysvita, and we have stepped up our efforts to do whatever is needed to support our patients with our partner's support. I am proud of the dedication and creativity of our team to ensure that we meet this goal every day, and look forward to a successful year ahead with Crysvita.

Ultragenyx is a US biopharmaceutical company founded in 2010. The company's management team, including president Emil D. Kakkis MD, PHD, has a strong track-record in rare disease therapeutics. Ultragenyx has been a key Kyowa Kirin partner since entering into a collaboration and license agreement to develop and commercialize Crysvita in 2013.

Abdul Mullick, Ph.D.
EMEA Region Head
President, Kyowa Kirin International plc

Now that really made me smile!

This year, I will reach my three-year anniversary since joining the Kyowa Kirin Group. The time has flown by, and every day, I am reminded of the important role we have to play in supporting people living with rare and underserved diseases.

I joined the company because I believe in our vision and in the work we are doing to meet the needs of people across the world. I was especially attracted to the company purpose: to make people smile. This is such a unique purpose, and it says so much in just a few simple words. The impact of a smile, the ability to help someone to feel joy, peace, comfort, this is what we are doing at Kyowa Kirin.

Not a day goes by that I do not see the impact of our efforts. From our focus on making sure people can access our medicines, to supporting our employees through the last year of the pandemic and ensuring we all are taking care of each other, to driving forward our digital transformation that will position us for the future.

I recently received an email from someone living with XLH, whose two children are benefitting from our medicine for the genetic disease. She was excited to share that she was due to receive the medicine following the EMA approval of the adult indication and she wanted to thank us for all we are doing.

Tomohiro Sudo
Executive Officer, Director,
Global Product Strategy
Kyowa Kirin Co., Ltd.

Our Challenge Continues

After two decades of work going back to the start of basic research in 1998, we achieved the long-awaited launch of Crysvita in the US in April 2018 and in Germany the following month. Since then, we have worked to raise awareness of X-linked hypophosphataemia (XLH) among physicians and focused on accelerating Crysvita's global roll out by expanding indications. Our management team has also continued to drive the Group's transformation into a Global Specialty Pharmaceutical Company (GSP) with measures such as the One Kyowa Kirin (OKK) structure, launched in 2019 to support global expansion. That has helped us increase Crysvita's launch markets to 26 and deliver the drug to more than 3,000 patients. As a result, despite the unprecedented COVID-19 pandemic, global sales of Crysvita reached ¥58.2 billion in 2020, underscoring the contribution we are making to patients and the drug's growing momentum.

In line with that growth, we will work to realize Kyowa Kirin's Management Philosophy, Vision and Core Values, while also preparing for our next challenges, which are already appearing on the horizon. For example, we have to achieve a major step-change in global supply capacity and accelerate drug development to meet the expectations of Crysvita users worldwide. We will also tackle other issues in 2021, such as further improving the OKK structure to strengthen strategy execution centered on global strategic products.

Earlier this year we announced the new Medium Term Business Plan, taking us through to 2025. In 2021, the plan's first year, we're targeting global Crysvita sales of ¥82.7 billion. Our goal is to bring happiness to people battling with medical conditions. Guided by a shared commitment to that objective, we will work with colleagues worldwide to create and deliver life-changing value to patients everywhere by harnessing the power of our diverse team of experts with a passion for innovation.

Yosuke Okada
Senior Director, CRV Global Product Management Office
Kyowa Kirin International plc

Patient Happiness Is What Drives Us

In the UK, where I'm currently based, I have the opportunity to get direct feedback from EU patients who have been prescribed Crysvita to treat XLH. "I can play soccer again with my friends," and "I don't have to get ready to get off the train two stops ahead of time," are just a couple of the comments I've heard. That kind of feedback gives me the motivation to work even harder for people everywhere who need Crysvita.

Development of Crysvita started in the US and I joined the development project team in 2014. At that point, the plan was to use post-approval data from the US and Europe to support our new drug application in Japan. However, we instead decided to join an Ultragenyx's international phase 3 clinical study to deliver Crysvita to patients in markets outside the US and Europe more rapidly. It was an ambitious goal, but the team pulled together and joined the study, ultimately helping us to secure early approval for Crysvita in Japan after the US and Europe.

But our development work didn't end there. We still have plenty of work to do to bring smiles to the faces of patients and healthcare professionals, such as accelerating the launch of Crysvita in other markets, raising awareness of the drug and its benefits, developing easier-to-use formulations, and exploring the potential for additional indications. It's now three years since we launched Crysvita in the US and Europe, but every time we get positive feedback from patients, it motivates us to make our product even better. That feeling is the strength and driving force of our development team.

Takashi Shimada, Ph.D.
Vice President, Nephrology Head, Global Medical Affairs
Kyowa Kirin International plc

Crysvita Was Born Out of Our Frontier Mentality

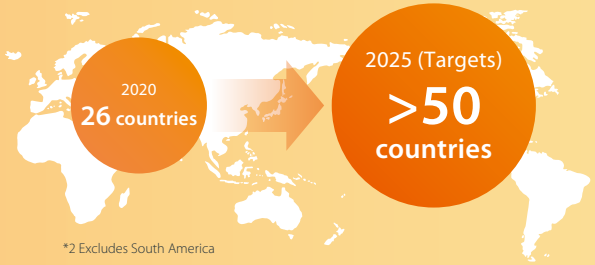
I was assigned to a research team at Kirin Brewery Co., Ltd. that helped get the Crysvita project off the ground. Today, with our long-held dream of launching Crysvita now a reality, I've looked back and asked myself how we succeeded in developing the world's first monoclonal antibody drug targeting fibroblast growth factor 23 (FGF23). I believe a key factor is the strong "frontier mentality" of everyone in the team. Our team was full of true professionals who had no qualms about reaching out to help colleagues, even if there was no direct connection with their own research, and our drug discovery research boldly targeted areas that other companies were not involved in, instead of using information from published studies and joint research. That environment, similar to what you would see in academia or startups, has been carried through to our research teams today.

Crysvita research started with the search for novel drug discovery targets. In other words, we were working almost completely in the dark, guided only by tentative theories. The ability to drive that kind of true innovation cannot be acquired overnight. I believe the key strengths of Kyowa Kirin's drug discovery are its expertise, experience and technologies, accumulated over many years, and a corporate culture that continues to cultivate researchers with the ability to create innovative products from scratch.

Number of patients*1 (global total)

*1 Excludes EAP patients and patients who have not started the reimbursement process

Number of launch countries*2



*2 Excludes South America

Manufacturing

Progress in FY2020

Ensuring stable supplies of high-quality pharmaceuticals

During 2020, we pushed ahead with preparations to upgrade our production framework and ensure stable supplies of pharmaceuticals, based on production plans for each product. Especially for our three global strategic products, we have developed manufacturing plans that facilitate production at multiple sites to ensure production capacity and inventories meet the requirements of our Business Continuity Plan (BCP), in line with long-term demand forecasts. In parallel with those efforts, we continued to work on installing new manufacturing equipment and IT and digital systems to support efficient manufacturing at all our production sites.

To establish supply networks to each country, we strategically applied for manufacturing and marketing approvals for multiple products in FY2020. After approval, we have progressively had periodic inspections from the regulatory authorities in each country.

Achieving high productivity

In biopharmaceuticals, production cells with high titers of target proteins result in higher productivity and are more likely to reduce manufacturing costs. We continued to achieve world-class levels of biopharmaceutical productivity in FY2020 after confirming performance at the lab level was reproduced at production scale for development products. We plan to apply our production cell technology to further improve productivity of bio-pharmaceuticals. For low-molecular-weight drugs, we will try to achieve high productivity by studying the introduction of next-generation manufacturing technology.

Developing drug formulations that benefit patients

We are progressively developing new formulations and devices for existing drugs to make them easier to use for patients, such as moving to prefilled syringes from vial formulations and developing automatic dosing devices that does not require patient visits to the hospital. In FY2020, submissions for approval were prepared as planned. We will continue to push ahead with development in line with plans to ensure patients see the benefits as soon as possible.

Biopharmaceutical drug substance production facility

Injectable formulation production facility

MID-TERM BUSINESS PLAN

Future Initiatives

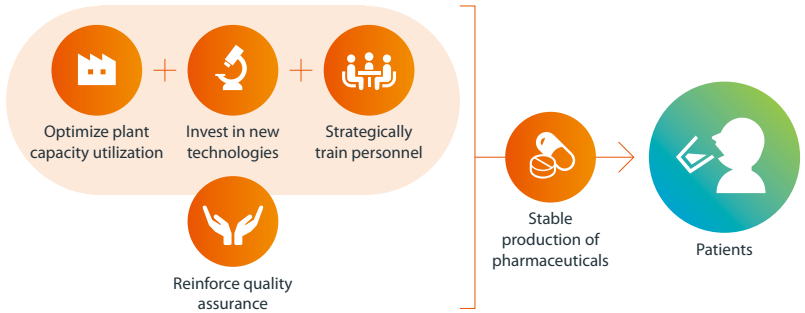
Supplying high-quality pharmaceuticals backed by stable plant operation

Ensuring stable supplies of high-quality pharmaceuticals to patients will remain one of the Production Division's most important tasks. To achieve that, we plan to optimize plant operations and improve efficiency by further optimizing plant capacity utilization and investing aggressively in technologies such as production technology, IT systems and automation.

In fundamental technology research, we plan to work closely with the R&D Division, other companies, universities and other partners in joint research to lift the level of existing proprietary technologies. We will also actively develop new production processes in line with development schedules for new-format large molecule drugs and small molecule drugs. With the Medium Term Business Plan also setting out a schedule for sustained drug development, we will continue to supply investigational drugs and submit regulatory applications in accordance with drug development plans.

Personnel development is also a crucial element of the Production Division's medium term business plan for 2021-2025. We will actively draw on the expertise of external consultants to put in place necessary training and education systems, allowing the division to conduct strategic program-based training and provide employees with a learning environment. Through those initiatives, we will continue to focus on creating active work environments for all employees involved in production.

Initiatives to support stable plant operations



Supply Chain Management (SCM)

Progress in FY2020

We launched a Global Supply Chain organization in 2019 and this year, we embarked on various new initiatives to further reinforce the organization.

Globalization of SCM function

In April 2020, we established a new Global Planning Group in the function. The new group has strengthened coordination between global SCM strategy and initiatives in each region and strengthened functions such as budget management monitoring and supply risk management. Specifically, we stepped up efforts to build a regional SCM organization in North America to support the growth of global products, and we worked to get a better understanding of increasingly complex distribution and logistics networks in the EU to help us identify opportunities for future optimization.

In pharmaceutical manufacturing, we rely on contract manufacturing organizations (CMOs) to supplement our own production capabilities and facilities. Therefore, we have created a CMO management framework to help build better strategic partnerships with CMOs in Japan and overseas.

Better Balancing of Demand & Supply

After launching a sales and operations planning (S&OP) in FY2019, we started to roll out the same mechanism at our domestic plants in FY2020, allowing us to better balance supply and demand from a profit margin perspective, in line with business plans.

We are also progressively digitizing planning operations. In FY2020, we launched a planning system that visualizes and systemizes supply-demand planning for three global strategic products. Using that know-how, we will continue to improve operational efficiency and system to ensure data integrity.

Although FY2020 was a tough year due to the COVID-19 pandemic that presented numerous challenges for managing supply chain, including a tight air freight capacity and rising air freight costs, we have mostly managed to maintain stable supply.

It was a year of the big environmental changes within Kyowa Kirin and in the outside world. However, we have initiated a variety of efforts for the future and processes for further leaps.

MID-TERM BUSINESS PLAN

Future Initiatives

Our vision for 2025

A creator of value by partnering with business & supply sites and implementing optimal solutions from an enterprise viewpoint by truly connected global teamwork (wa) & passion for life

Support the company's efforts to achieve financial goals by achieving reliable & stable supply, and maximizing product value with end to end supply chain optimization

An enhanced optimized global SCM function

Kyowa Kirin faces increasingly diverse market needs due to rising sales of global products and an increase in the number of countries where its products are sold. To meet those needs, we aim to enhance global SCM organization to allow us to have a better oversight and create synergies across regions. Specifically, we plan to look at allocating resources for key supply chain functionalities with good balance of centralization versus localization, clarify roles and responsibilities across regions, and define globally harmonized CMO management policy & processes.

We will also revisit logistics & distribution strategy for optimization within the EU and other regions as well.

Stable supply and risk management

One of the most important mission for the SCM function is to build a system that ensures stable supplies of products. In addition to supplying products under normal conditions, the system has to be robust enough to ensure patients can access our products during periods of instability, such as during dramatic shifts in geopolitical conditions and the kind of unexpected situation we are seeing now with COVID-19.

From a Business Continuity Plan (BCP) perspective, we are looking into implementing dual sourcing of strategic global products as well as setting up multiple storage locations to mitigate supply risks caused by natural disasters and pandemics.

Supply chain operational excellence

We will further strengthen alignment between SCM and product strategy, build closer ties with key stakeholders worldwide and continuously improve global S&OP processes.

We will also utilize the long-term demand forecast based on multiple scenarios and deepen discussions on the planned capacity utilization with our own manufacturing sites and CMOs.

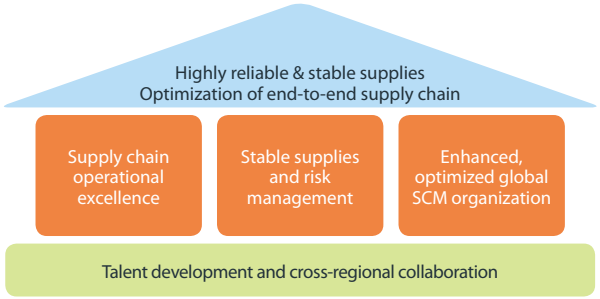
Additionally, we plan to visualize supply chain performance based on KPIs and utilize the data to manage and improve SCM.

Aiming to improve performance in the SCM function

Talent development

Upskilling workforce will be vital to implementing the various initiatives. Our goal is to raise the overall supply chain capability of the organization. We will use a talent review process to identify global talents and strategically develop them, create various opportunities for intentional collaboration cross-regionally and continue to utilize e-learning (Supply Chain Academy) to raise supply chain skills.

Ensuring stable supplies and optimizing supply chains with three initiatives, anchored by talent development



Medical Affairs

Progress in FY2020

Generating and disseminating scientific evidence tailored to each country and building systems to support those activities

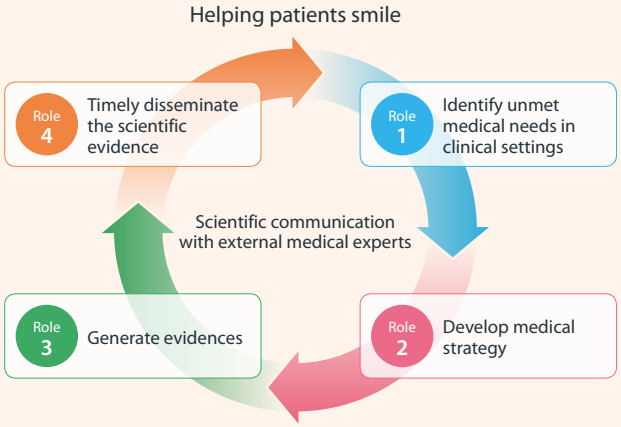
In recent years, Kyowa Kirin has launched a number of new products or expanded indications for its products in many countries and regions. Examples are burosumab, mogamulizumab, istradefylline, daprodustat, darbepoetin alfa, brodalumab and romiplostim (marketed in Japan as Crysvita, Poteligeo, Nouriast, Duvroq, Nesp, Lumicef, and Romiplate, respectively).

Medical Affairs is responsible for responding to enquiries from healthcare professionals about Kyowa Kirin's products and disease and for exchanging medical information with them. We have also initiated new clinical researches in collaboration with medical institutions to address unmet medical needs. Moreover, we have helped to provide medical information to healthcare professionals by active publication on clinical research data and other research outcomes at academic conferences and in medical journals.

We have put in place internal and external systems to expedite those activities. For example, on a global level, we have worked to provide medical information efficiently and rapidly to healthcare professionals by sharing FAQs, literatures and other information about our products across the Kyowa Kirin Group. In Japan, we set up a website called Kurukotsu Hiroba to provide information and raise awareness about rare disease, FGF23-related hypophosphatemic rickets and osteomalacia. We also introduced a web-based application system for investigator-initiated study to ensure transparency, and created a chatbot-based system to respond to enquiries timely.

The various roles of medical affairs

To help patients smile, Medical Affairs identifies unmet medical needs, generates evidences to address those needs, and disseminates the data to healthcare professionals, contributing to improvement of patient outcomes.



Kurukotsu Hiroba

Kurukotsu Hiroba website provides information about FGF23-related hypophosphatemic rickets/ osteomalacia and national medical expenses assistance programs, etc.

https://www.kurukotsu.com/

MID-TERM BUSINESS PLAN

Future Initiatives

Reinforcing global systems to support a more strategic approach

Under the new Medium Term Business Plan starting from 2021, Kyowa Kirin plans to launch more new drugs and expand indications in countries and regions worldwide. In Medical Affairs, we will generate new evidences that addresses unmet medical needs; through the provision of those data and scientific information exchange with healthcare professionals, we further identify unmet medical needs and we aim to contribute to help patients smile. In addition, to contribute to improve patient access to pharmaceuticals, we will step up efforts to address the growing needs of health economics and outcomes research (HEOR) and real-world evidence (RWE), which are increasingly important from the perspective of reimbursement in countries worldwide.

To ensure our contributions are more efficient, we plan to reinforce integration of global medical affairs; a global organization covering four regions (Japan, North America, EMEA, Asia/Oceania) will be involved in the decision-making such as clinical research and others. We also plan to strengthen global governance by conducting timely monitoring activities in each region. In addition, we aim to build a system for rapid information sharing, using digital technology to integrate data about our products worldwide and share information through a common global platform.

Another key initiative is to actively develop and manage our MA talent, who will play a vital role in reinforcing our global systems. Backed by a range of measures designed to realize our five-year vision, we will continue to work hard on making the Kyowa Kirin Group's medical affairs activities more strategic and efficient.

Pharmacovigilance (PV)

Progress in FY2020

Reinforcing the global pharmacovigilance (PV) organization

During the FY2016-2020 Mid-term Business Plan, we tackled the key challenge of building a global PV organization and establishing a single global safety database system to centrally manage all safety information gathered from markets worldwide. This work was integral to our efforts to secure manufacturing and marketing approval for three global strategic products in the US and Europe. In FY2020, we started full operation of the new global PV organization, which has four functions (compliance, operations, medical safety and planning) and covers four regions (Japan, North America, EMEA and Asia/Oceania). By strengthening our global PV quality management system, which supports pharmaceutical safety monitoring activities and is especially important for the global expansion, we have moved to a framework that allows us to conduct PV activities in compliance with regulations worldwide. Safety information gathered by the single global safety database system is being used on a global level for risk analysis, such as identifying risk signals in product data. In addition, we launched a program to encourage personnel exchanges between regions to enhance cooperation and actively rolled out projects to improve operational efficiency, while training and hiring the necessary personnel to reinforce the PV organization. In FY2020, the global COVID-19 pandemic forced us to change the way we work, but we were able to overcome any difficulties and continue appropriate PV activities by using innovative approaches, such as holding meetings and allocating duties while all our global staff were working from home.

Our Mission

Patient safety and appropriate use of our medicines is at the core of our business.

We carefully evaluate safety data, provide reports to regulatory authorities in each jurisdiction and ensure frontline medical staff have access to the right information.

MID-TERM BUSINESS PLAN

Future Initiatives

Contributing to the safety and happiness of patients worldwide

As part of the formulation process for the new five-year Mid-term Business Plan, which starts in FY2021, we gathered opinions from our PV staff worldwide to help us develop a new vision for PV activities – Global PV Vision 2025. The vision puts priority on the health of patients and sets out two key areas that we need to address to achieve that goal: utilize innovative technologies and actively share information. Ultimately, we have created a new vision that incorporates the aspirations of our employees to conduct safety monitoring activities that set an example for the industry. We will take the following steps to realize our vision.

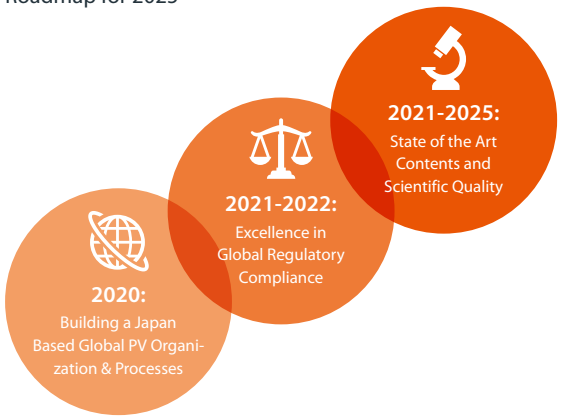
(1) Excellence in global regulatory compliance: We will continue to strengthen our systems to strive for the highest levels of compliance with pharmaceutical regulations in jurisdictions worldwide to help us increase the number of countries where Kyowa Kirin products are sold and developed. (2) Evolution of medical safety function: To increase the scientific quality and value to prescribers and patients of our risk-benefit information, we will actively work with partners in industry and academia and share expertise with other sectors to utilize new data and technology tools (real-world data, text mining, etc.) that help us predict and prevent adverse reactions. (3) Enhance operational function: We will work to improve operational efficiency by using innovative IT technologies such as robotic process automation, chat bots and automated translation.

All our activities are designed to contribute to the safety and happiness of patients worldwide. Through those activities, our employees will work with patients to learn, grow and lead the industry by example.

Global PV Vision 2025

Kyowa Kirin Global Pharmacovigilance will be an **industry leader** in **improving patient health** by **predicting and preventing adverse reactions** through **integrated innovative safety science methodologies** and **proactive communication of risk-benefit information** for our products.

Roadmap for 2025



Quality Assurance (QA)

Progress in FY2020

Strengthening of Global Quality Assurance

Global Quality Assurance (GQA) continues to strengthen and mature in full alignment with our Global Quality Roadmap to 2025 and One Kyowa Kirin. The Global Quality Roadmap to 2025 is a set of key strategic imperatives and actions that the company aims to achieve over the next 5 years. We continue to rapidly progress along our Quality Roadmap and are in the Foundational and Globalization phase with a firm focus on People, Process and Systems.

Notably, our enterprise/electronic Quality Management Systems (eQMS) investment is progressing according to plan. Once fully complete, (in 2022) this initiative will deliver a fully compliant eQMS platform for usage throughout Kyowa Kirin, including our manufacturing plants. Quality Management Systems such as deviations, corrective and preventive actions, training, document management, audits, supplier management, change controls, and more, will move from largely paper based processes to fully electronic and GxP compliant ways of working, and become globally harmonized.

Our quality governance processes are fully operational. This includes our Management Reviews, the Global Quality Assurance Committee, and our Global Product Council. Both of these very important management review meetings focus on the health of our QMS and also take deep dives into Product specific data with the ultimate goal to continuously improve.

Regarding organizational structure, the GQA function has been strengthened by the addition of a Global Research and Development dedicated QA department, whose main purpose is to support our rich development pipeline and oversee all aspects of R&D Quality. Additionally, we have successfully recruited a top talent for our previously open Japan Region QA Head position. This role has oversight of all aspects of quality in the Japan region. Our GQA organizational structure continues to ensure that our highest priority is always on patient safety, compliance and customer satisfaction.

MESSAGE

Head of Global QA
Jonathan Patroni

Message from Jonathan Patroni, Global QA Head

I firmly believe that in a Pharmaceutical Company, Quality is Everyone's Responsibly and without having the highest level of Quality and Compliance, our Patients, Caregivers and Regulators will not have trust in us.

We have established a clear vision, mission, and an agreed upon set of values that all employees live by. We continue to strengthen our GQA leadership because our talent and human capital are always a company's greatest assets. We continue to develop our processes and systems to rely on science-based approaches to decisions, ones that drive effective and sound risk management, demand robust data integrity, and promote an environment of preventing issues before they arise. Our ultimate goal as part of our Global Quality Roadmap to 2025 and One Kyowa Kirin is to achieve a Competitive Advantage and a World Class Quality System and Quality Culture.

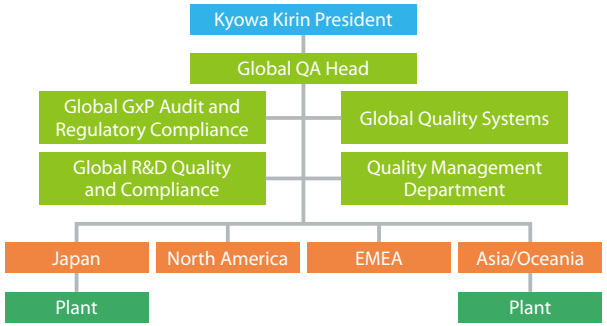
MID-TERM BUSINESS PLAN

Future Initiatives

Looking ahead

GQA has established very aggressive but realistic goals for 2021. First and foremost, we will continue to ensure that the highest quality medicines are available for our patients. We will continue executing our Global Quality Roadmap to 2025, preparing for and supporting market launches, new product approvals, and continue cultivating a positive Quality Culture mindset throughout the Company. Continuously improving is very important if we are going to achieve our ultimate Company goal of becoming a Global Specialty Pharmaceutical Company. As such, we will continue improving our processes, products and systems with rigor and determination. Importantly, we will deliver on our eQMS targets, complete all regional specific deliverables, and promote a flexible and learning-based organization with a keen focus on our people. With regard to our talent, we want the entire Quality organization to live by our Leadership Values and Principles which include Aspiring High, Thinking Broadly, Being Decisive, Acting with Integrity, and Executing Flawlessly. We will always endeavor to have the right person in the right role with clear development and succession plans in place. Finally, our GQA Vision continues to be unwavering in that we will ensure the highest quality medicines are available to our patients worldwide by designing and implementing an integrated global quality management system, we will embrace the new One Kyowa Kirin culture while adhering to global quality, safety and compliance standards.

Global QA Structure



Environment

Kyowa Kirin makes dedicated efforts to protect the global environment, which is key to business continuity, while promoting activities that are geared toward realizing a sustainable society.

Environmental Management

Based on the Kyowa Kirin Group Environmental Policy, the Kyowa Kirin Group has made a clear commitment to the environment in the conduct of its business activities. We are working actively to contribute to the sustainability of society by passing on a rich global environment to future generations with the goal of achieving the Kirin Group Environmental Vision 2050.

In addition to practicing CSV management by tackling social issues, the Kyowa Kirin Group has identified material issues (materiality) while also incorporating materiality into its Medium Term Business Plan. Moreover, among these materiality issues, we have especially positioned the SDGs related to "climate change (prevention of global warming)" and "preservation of water resources" as core issues of our environmental activities.

Key matters related to the Group's environmental management activities are discussed and decided by the Group CSR Committee, which is chaired by the Representative Director Executive Vice President, who also serves as chief executive officer for all environmental matters. Details are reported to the Board of Directors.

Daily environmental management activities are conducted in accordance with the ISO 14001 environmental management system. Effective from January 1, 2019, all domestic production and research sites have switched from third-party accreditation of compliance with ISO 14001 to self-declaration.

Response to Climate Change and Other Issues

Aspiring in Kirin Group Environmental Vision 2050 to work together to create a society that has overcome climate change, the Kirin Group is striving to realize net-zero greenhouse gas emissions from the entire value chain while at the same time reducing greenhouse gas emissions in conjunction with its stakeholders in a bid to take the lead in building a carbon-free society.

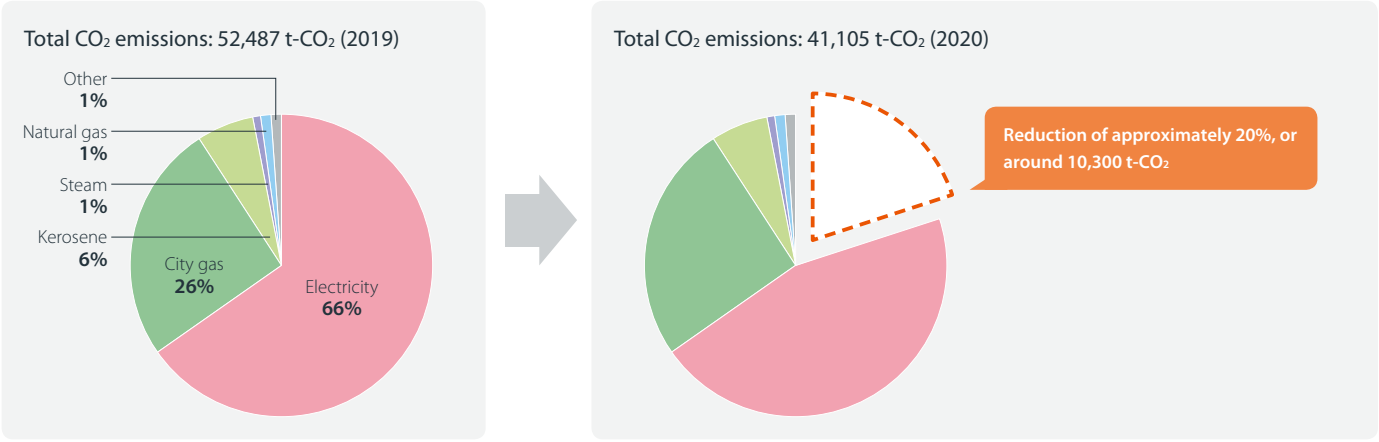
In addition to upholding the global goal of reducing CO_2 emissions for FY2030 (to 20% less than the FY2015 level*1) in collaboration with its parent company, Kirin Holdings Company, Limited, in accordance with the Science Based Targets (SBT) approach, the Kyowa Kirin Group has set individual per-unit energy consumption targets for each of its production and research sites while implementing measures to raise productivity. In FY2020, per-unit energy consumption declined 2.9% compared with the previous year (global target: 1% reduction year on year).

Meanwhile, Kyowa Kirin was the first pharmaceutical maker in Japan to introduce Aqua Premium*2, a 100% hydropower electricity supply service that generates zero CO_2 emissions at its Takasaki Plant from January 1, 2020, replacing 75% of the electricity used at the Takasaki Plant with hydroelectric power generation. Through the introduction of "Aqua Premium," about 23.4 million kWh of the Kyowa Kirin Group's annual electricity consumption of about 72.4 million kWh*3 has been replaced with renewable energy derived from hydropower. As a result, the Kyowa Kirin Group*3 reduced its annual CO_2 emissions by about 20%, equivalent to about 10,300 t-CO_2.

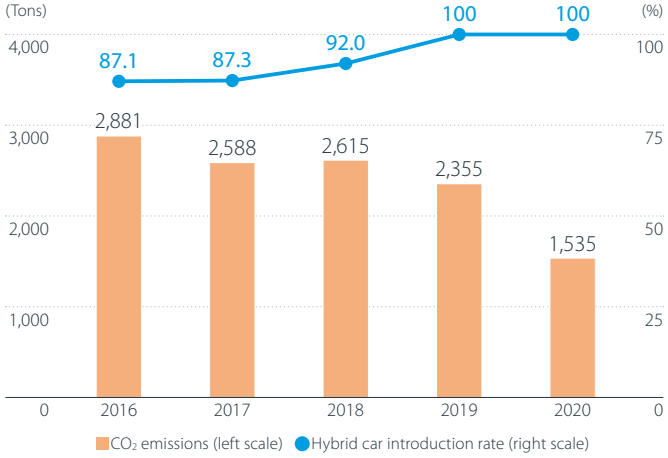
Furthermore, in Japan, the Kyowa Kirin Group has been replacing its commercial fleet with hybrid vehicles in phases since 2009. As of the end of FY2019, the hybrid car introduction rate of company-owned vehicles reached 100%, with the entire fleet switching to hybrid vehicles. This initiative is helping to further reduce CO_2 emissions generated by our sales activities.

*1 Target for the Kyowa Kirin Group and the Kyowa Hakko Bio Group.
*2 TEPCO Energy Partner, Incorporated
*3 Kyowa Kirin Group domestic and overseas production and research sites.

Reducing CO_2 Emissions through Renewable Energy (the Kyowa Kirin Group's CO_2 Emissions Ratio)



CO_2 Emissions from Commercial Vehicles and Hybrid Car Introduction Rate



Strategy to Realize Our New Vision

Task Force on Climate-Related Financial Disclosures (TCFD)

Kirin Holdings Company, Limited announced its support for the recommendations of the Task Force on Climate-Related Financial Disclosures (TCFD) before any other company in the food and beverage industry in Japan on behalf of the Kirin Group. Kirin Holdings has also conducted analyses of different scenarios, evaluated the resilience of business strategies with respect to climate change and published the results. Moreover, the Kyowa Kirin Group is working to disclose information in accordance with the TCFD recommendations. The impact of the transition to a carbon-free society or the progress of climate change on our business varies. Recognizing that many factors are intricately linked, we are sorting out these relationships, evaluating climate-related risks and opportunities and identifying key drivers (factors with high uncertainty that can have a decisive impact on business performance). In the meantime, we have developed several scenarios for future changes in society due to climate change.

In the future, we will conduct scenario analyses for these key drivers to quantify the business impact of each scenario, examine the response policy for business impact and the resilience of strategies, and disclose these results in sequence.

Biodiversity Preservation

As part of its activities to preserve ecosystems and ensure biodiversity, Kyowa Kirin has been working to protect water resources through its engagement in the Kirin Group's water-source preservation project since FY2007. The Takasaki and Ube plants carry out weeding, planting and tree thinning to create forest areas that provide water resources. The Takasaki Plant has entered into a three-party agreement with Gunma Prefecture and Kurabuchi Furusato Public Corporation, under which it engages in Takasaki Water Source Forest Conservation Activities to protect forest areas in Kurabuchi-machi, Takasaki City.

In addition, for the fourth year running, Kirin Holdings Company, Limited has been recognized as the highest Water Security A List company by CDP, an international non-profit organization that provides an environmental data disclosure system. CDP praised the Kirin Group, of which Kyowa Kirin is a member, for its efforts to protect water resources.

Kyowa Kirin business sites also work with various local communities to preserve ecosystems, including cleaning local streams and rivers and releasing young amago trout into rivers. The Fuji site continues to clean up a nearby river through Shizuoka Prefecture's River Friendship Program in collaboration with local government agencies.

The Kyowa Kirin Group is also taking steps to reduce its impact on ecosystems in procurement activities. Specifically, we are introducing internal envelopes, company pamphlets, cardboard product packaging and other items made from FSC® certified paper*4 to help protect the world's forests.

Kyowa Kirin complies with the Kirin Group's Guidelines on Access to Genetic Resources when seeking access to raw materials and specimens. Under the guidelines, any profits generated from their use are shared with the local communities that provide them.

Furthermore, to comply with the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Cartagena Act), we have put in place an internal committee to conduct proper management.

*4 Kyowa Kirin has acquired FSC® promotion license (FSC® N003037).

TOPIC

—Working in unison, the Group is actively contributing to the environment—

Forest activities to preserve water resources

Gunma Prefecture Environmental Award

Campaign to reduce the amount of rubbish around Mount Fuji

Use of FSC®-certified paper

A BUSINESS BASE TO SUPPORT STRATEGY EXECUTION

Commitment to Life

We are building a robust business base to support the continued creation of life-changing value that brings a smile to the faces of patients.

Human resources underpin the Group's growth

To drive growth and achieve our vision for the Group, we need to cultivate people who take the initiative and are open to change.

As the Company expands, clearly defining the role of each team and the employees helps them focus on their assigned roles. However, that approach does not foster independent thinkers who are open to new ideas. To achieve our vision for the Group, we need people who ask themselves what they can do to realize the vision and how they can contribute beyond their own team. As a company, we have an important role to play in developing that kind of person by accurately evaluating their performance and providing training programs and work experience to help them grow even more.

Diversity leads to sustainable growth

Kyowa Kirin's non-Japanese headcount is increasing as the Group becomes more international. Non-Japanese employees now account for roughly 25% of the total workforce. Female employees are also making dramatic advances, with women playing key roles in the Group's organizations and business activities. Women now fill more than 10% of managerial positions (as of December 31, 2020). These trends illustrate how diversity is gaining momentum across the Group.

However, a more diverse workforce does not necessarily translate into growth. The key point is how we harness diversity. One Kyowa Kirin is our matrix management structure that combines a regional organization and a functional organization. The structure is leading to more opportunities for diverse human resources to work together. Creating a culture that encourages open discussion and problem-solving is key to ensuring our diverse workforce

Yutaka Osawa
Representative Director of the Board,
Executive Vice President

There are many patients worldwide waiting for new treatments from Kyowa Kirin

achieves the Group's shared goals. That kind of approach will be particularly important in tackling the many issues faced by the Group in increasingly uncertain times, helping to support Kyowa Kirin's sustained growth.

Reinforcing information security

The COVID-19 pandemic is spurring digitization across our business operations. Internal and external communication methods are also changing dramatically, especially communication with overseas sites, with online meetings now held daily. However, the shift to digital systems is creating greater risks for information security. We are urgently working to mitigate those risks as a matter of priority. The ICT function is gathering and analyzing data on incidents reported by each region, issuing alerts to business sites in Japan and overseas and rapidly reinforcing IT infrastructure.

In our business, we handle highly sensitive information, so we have to quickly identify any unauthorized attempts to access information and prevent cyberattacks before they occur. We will continue to reinforce information security as a key management issue. In parallel, we will work to raise employee awareness about information security, using case studies of actual cyberattacks and other incidents to ensure our personnel know how to comprehensively protect themselves.

Building a global governance system

As part of efforts to build a stronger global governance system, senior management and the heads of each region (North America, EMEA and Asia/Oceania) hold regular meetings to discuss operational issues related to the One Kyowa Kirin structure. Representatives from each region submit reports and raise any issues, helping the Group formulate various initiatives and responses.

To drive improvements in internal audit activities, our head office is working closely with the team in the North America region to enhance our internal audit system that evaluates governance matters. We are also upgrading internal audit functions in EMEA and Asia/Oceania based on the One Kyowa Kirin structure.

Kyowa Kirin is growing rapidly as a global company. However, the capabilities of governance systems can fall behind during periods of rapid growth, presenting significant risks. At Kyowa Kirin, we understand that building a global governance system is vital to support the Group's future growth.

Conclusion

Every day, we are motivated by the fact that there are many patients worldwide waiting for new treatments from Kyowa Kirin. That motivation will drive our efforts to realize our new vision for the Group and achieve the targets in the new Medium Term Business Plan. Going forward, we will continue to reinforce the Group's business base to support all our employees as they work towards the shared goal of creating life-changing value that brings a smile to the faces of patients.

Human Resources

Talent Management Initiatives

Talent Management Policy

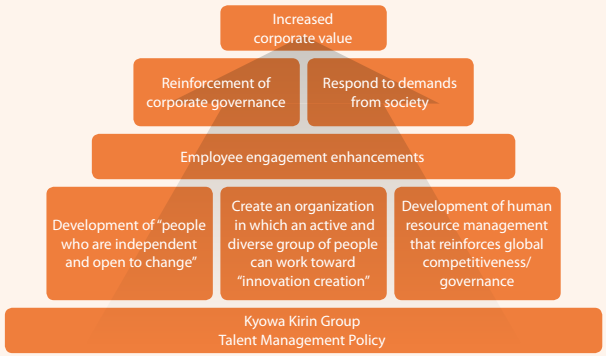
Considering its employees as the source of innovation, the Kyowa Kirin Group is striving to unleash the full potential of each and every employee to develop individuals and organizations that will tirelessly tackle reform and create new value. The policy clearly defines the relationship between the Group's employees and the companies they work for and our common global approach to developing the capabilities of our personnel.

We believe that the following three points are critically important for the Group to fulfill its corporate philosophy.

- Development of people who are independent and open to change
- Create an organization in which an active and diverse group of people can work toward innovation creation
- Development of human resource management that reinforces global competitiveness/governance

We are working to increase corporate value by increasing employee engagement through world-class human resource and organizational development.

Priority Initiatives Based on Talent Management Policy



Development of people who are independent and open to change

Global Succession Plan

We will commence efforts to discover, train, and select next-generation leader candidates who will lead the future of the One Kyowa Kirin structure, regardless of gender, age or nationality. Previously, we had been operating a human resource development system for each region, but from 2021 the plan is for human resource managers from the four regions (Japan, EMEA, North America, and Asia/Oceania) to gather and hold meetings for the purpose of exchanging information on human resources. At the meetings, we will list potential successors for important positions and formulate succession plans. By building a mechanism to build up a picture of and nurture leader candidates at the global level, we will build a pipeline of human resources who will tirelessly tackle reform and create new value.

Formulation of divisional human resource strategies

For each employee to have an overall company vision in mind, each corporate division also formulates a vision and a human resources strategy to achieve that vision. We would like this talent strategy to enable all employees within a division to understand the direction of change and put that change into practice.

By formulating personnel strategies using a common format and common indicators for each division, we will promote company-wide human resource strategies by having each division share its efforts with the others.

Human Resource Development Committee

Under its One Kyowa Kirin structure, Kyowa Kirin has commenced corporate culture reforms to accelerate globalization and promote management strategies for further growth. To promote this aspect, we have established a Human Resource Development Committee. Here, committee members are also selected from officers other than those in charge of human resources, and thorough discussions are held on human resource development and the personnel measures necessary to realize the Company's vision and the desired corporate culture. Specifically, the Company is aiming to develop human resources who will drive the realization of its vision and the transformation of its corporate culture as well as create ripple effects through initiatives.

TOPICS

Senior Manager Coaching

In 2020, we introduced senior manager coaching as a link to next-generation management human resource development, which is planned as a human resource development measure in line with business strategies and management plans, and the human resource development efforts in each division. We provide coaching geared toward all senior managers of the Kyowa Kirin Group with the aim of raising awareness toward change and promoting revised behavior. By having each and every senior manager demonstrate transformative leadership in management, the Company is hoping to facilitate seamless communication in the organization and, as a consequence, realize systematic human resource development and organizational change throughout the Kyowa Kirin Group together with the achievement of sustainable growth as a Global Specialty Pharmaceutical Company (GSP).

Support for demonstrating middle management ability

Kyowa Kirin has created an environment where it can maximize the abilities of middle management, which is the "essential" that connects senior management and staff members, and is promoting support measures that allow them to play an active role in realizing the desired corporate culture. Through "dialogue," we will ensure the psychological safety of middle management and create an environment where constructive conflict can occur. Kyowa Kirin will provide multifaceted support so that middle management can play a part in realizing the corporate culture the Company envisions and also lead the organization.

Human Resources

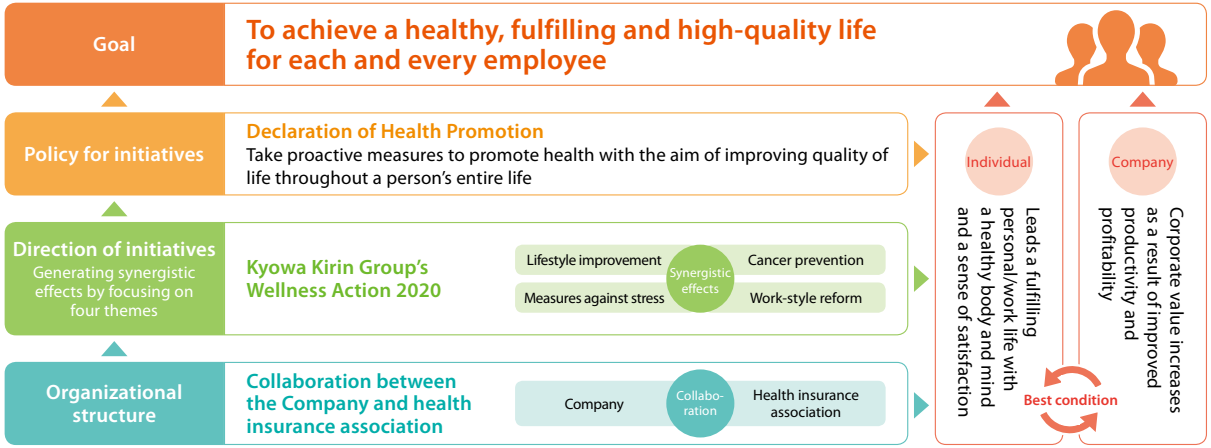
Health and Productivity Management

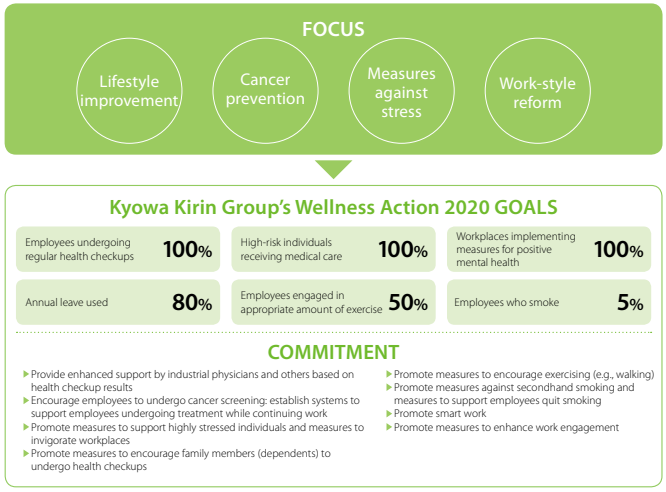
Create an organization in which an active and diverse group of people can work toward "innovation creation"

Based on the idea that healthy, prosperous as well as smiling faces of employees and their families will lead to the realization of its management philosophy, the Kyowa Kirin Group is actively working on health promotion based on the senior management's health declaration. To minimize health risks and create healthy and safe workplaces, we put in place "Wellness Action 2020 GOALS" as a KPI for Health and Productivity Management*, while confirming and evaluating each initiative both quantitatively and qualitatively, at forums such as Executive Committees. Consequently, we have been graded as an enterprise with excellent health and productivity under the Certified Health and Productivity Management Organization Recognition Program (White 500) for five consecutive years.

2021 健康経営優良法人 Health and productivity ホワイト500

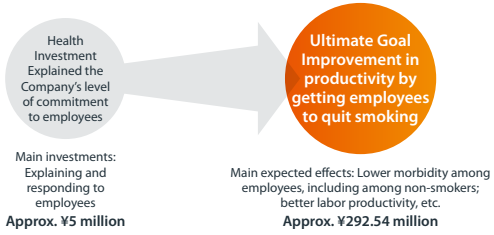
* Health and Productivity Management is a registered trademark of the NPO Kenkokeiei.





No-Smoking Initiative

Achieved 5% smoker ratio (as of November 2020)



Walking Campaign

TOPICS

Initiatives under COVID-19 pandemic

As a pharmaceutical company, we are also actively working to prevent the spread of COVID-19 infections. As a general rule in Japan, those who can work from home are asked to do so, the rule being that the Company maximum attendance rate remains at 30%. At all sites that require attendance including plants and research labs, we are proactively taking thorough measures to prevent infections.

Asia/Oceania

Whilst fulfilling our social responsibilities as a pharmaceutical company in the midst of the global pandemic caused by COVID-19, Kyowa Kirin Asia Pacific (KKAP) also took the health of our employees in the Asia/ Oceania region and their families seriously. Based on our cherished two core values of Teamwork/Wa and Integrity, we implemented a number of initiatives, such as the introduction of an Employee Assistance Program and regular virtual gatherings, to bring smiles to the faces of our employees.

In recognition of our efforts, Singapore Business Review presented KKAP with two awards in the Pharmaceutical Industry ~ Employee Engagement of the Year, and COVID-19 Management Initiative of the Year.

Japan

Smile Project

Through in-house social media, we are making efforts to bring smiles and small behavioral changes to employees through casual efforts that are not tied to workplaces or work time. In the "Smile Project," which was launched during the pandemic, volunteer project members uploaded postings freely contributed by employees, in addition to "10-minute lunchtime radio from human resources manager Mura-chan" and a quiz about health.

Human Resources

D&I, Corporate Culture Reforms

Diversity & Inclusion (D&I) Initiatives Empowering Difference

Promoting active roles for diverse human resources

Kyowa Kirin is focusing on D&I as part of efforts to build a working environment where its employees can demonstrate their abilities that they possess to the fullest extent, we therefore conduct the employee awareness survey every year and link the result from D&I-related questionnaires in it into improving action.

In Japan, as the active participation of women in particular is positioned as a material issue, Kyowa Kirin is implementing several initiatives, including: (1) Leadership training to develop women who will play active roles in future managerial positions; (2) Online video creation by junior female MRs aimed at human resource development and improvement of organizational abilities; (3) Unconscious bias training sessions for sales office managers; and (4) Back-to-Work Support Forums for employees taking childcare leave. Thanks to these and other initiatives, we have maintained Level 3 Eruboshi accreditation since August 2016. Also, as of December 31, 2020, 10.9% of managers at Kyowa Kirin were women, and we aim to increase that to more than 18% in 2025.

The employment rate of persons with disabilities stands at 2.45%, which exceeds the statutory employment rate for the entire domestic group, and we are endeavoring to create environments in which persons with disabilities will find it even easier to work.

Looking ahead, we are planning to implement a Diversity & Inclusion Declaration during FY2021 to promote diversity globally.

Supporting work-life balance

Providing information about nursing care support services to all of its employees in Japan via the corporate intranet, and running e-learning seminars for employees aged 40 and older to acquire basic knowledge about nursing care, the Company is creating the environment for them to continue their careers while balancing their personal lives with their work. In addition, for the child-rearing generation, we have decided to set up and introduce an admission support service for an in-house nursery school in the Takasaki/Mishima area (scheduled to open in 2022).

LGBTQ

Kyowa Kirin is working to create workplaces that welcome people with diverse sexual orientations and gender identities, including people from the LGBTQ community. Initiatives in this regard include: (1) Revisions to the Employee Code of Conduct; (2) the running of training sessions for senior executives and employees to improve their understanding and raise awareness; (3) revisions to personnel systems and policies so that same-sex partners can use personnel systems in regions where same-sex partnership is recognized as marriage; and (4) the setting up of a hotline that can provide advice about sexual orientation and gender identity to all employees.

Toward a corporate culture suited to a Global Specialty Pharmaceutical Company (GSP)

Under the One Kyowa Kirin structure, we have embarked on corporate culture reforms to accelerate globalization and promote management strategies for further growth. We are developing initiatives focusing on dialogue activities to verbalize the corporate culture we want to have as a Global Specialty Pharmaceutical Company (GSP) and to evolve the behavior that embodies the values of each employee.

Executive Discussions and Executive Joint Declaration

After having analyzed the results of various surveys of employees and conducting thorough discussions by all executives for a period of five months, we have established OKK (One Kyowa Kirin) Key Behavior "Overcome Barriers" as the corporate culture that we want to have. We also issued an Executive Joint Declaration so that Directors take the lead in efforts so that employees can overcome all the difficulties that separate themselves and others and the barriers of new challenges. We aim this avowed goal "Overcome Barriers" to become a habit as our new corporate culture.

Executive discussions and Executive Joint Declaration

Pulse surveys

We are conducting pulse surveys to ascertain the degree by which efforts to transform the corporate culture have become instilled and entrenched. In addition to the employee awareness surveys that we have been conducting, we regularly conduct surveys that specialize in corporate culture reform activities, thereby effectively promoting activities while building up a picture of current issues.

TOPICS

Dialogue in each department

We carry out dialogue activities at each workplace so that each employee can understand and empathize with the purpose of the corporate culture reforms. We are promoting activities through dialogue and group work on the "barriers" and corporate culture issues that individuals are sensing. In the years ahead, we plan to hold workshops in which global leaders participate and workshops that connect management philosophy, vision, and values with the "Overcome Barriers" Key Behavior.

Dialogue with the CEO/Meet Up

We have started Meet Up, a forum for direct dialogue between the president and employees. The first session was held for employees under the age of 30 to solicit applicants to think about the "the future in 10 years' time." Going forward, we will continue to hold Meet Up sessions on a regular basis and create opportunities for each employee to act autonomously as the new buds of reform through direct dialogue between the front lines and senior management.

Dialogue with the CEO/Meet Up

Corporate Governance

Highlights

Basic Policy on Corporate Governance

From a management perspective, Kyowa Kirin engages in business activities that include putting in place an appropriate organizational structure and systems while carrying out various measures in an effort to realize its corporate philosophy of "contributing to the health and well-being of people worldwide by creating new value with the pursuit of advances in life sciences and technology." Guided by its new Medium Term Business Plan, Kyowa Kirin is working diligently to strengthen corporate governance while looking ahead to the next five years by implementing a variety of measures in 2021. This includes making changes to the composition of the Company's Board of Directors as well as its remuneration system. At the same time, Kyowa Kirin is engaging in in-depth discussions regarding the effectiveness of its Board of Directors that are representative of a Global Specialty Pharmaceutical Company.

Click!
Corporate Governance Policy
Corporate Governance Report

A Transparent Governance Structure That Leverages the Strengths of Outside Officers

Please see P.40 for details.

- Outside Director appointed as Chairperson of the Board (from March 2020)
- Independent Directors account for 50% of the Board (from March 2021)
- Outside Director appointed as Chairperson of the Nomination & Remuneration Consultative Committee
- All independent outside officers participate in the Nomination & Remuneration Consultative Committee
- The opinions of Outside Directors reflected in the consideration process of the Medium Term Business Plan

Strengthening the Effectiveness of the Board of Directors

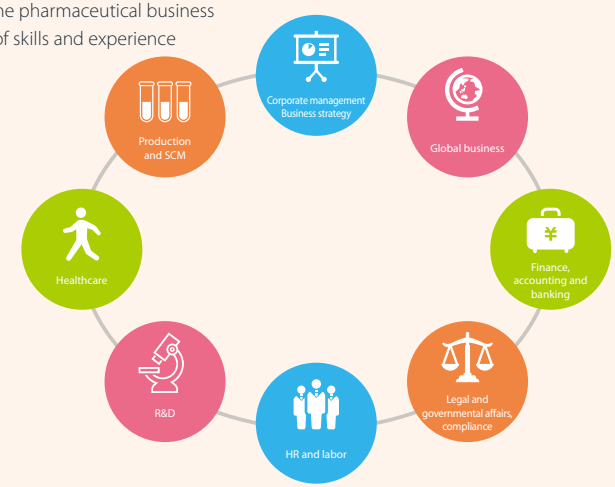
Please see P.41 for details.

- In addition to the conventional questionnaire format, identified a wide range of issues through interviews undertaken by external advisors and supplementary opinion exchange meetings with independent officers

Board Members with a Wide Array of Skills

Please see P.40 for details.

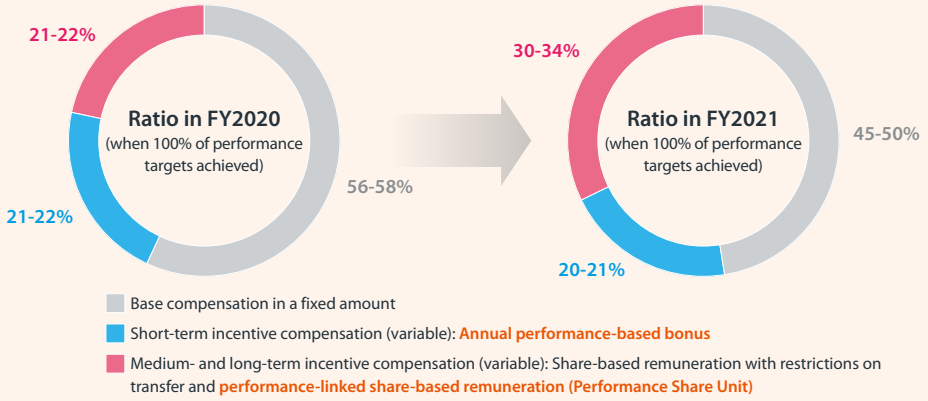
- Internal officers with expertise in the pharmaceutical business
- Outside officers with a wide array of skills and experience
- Two female independent officers



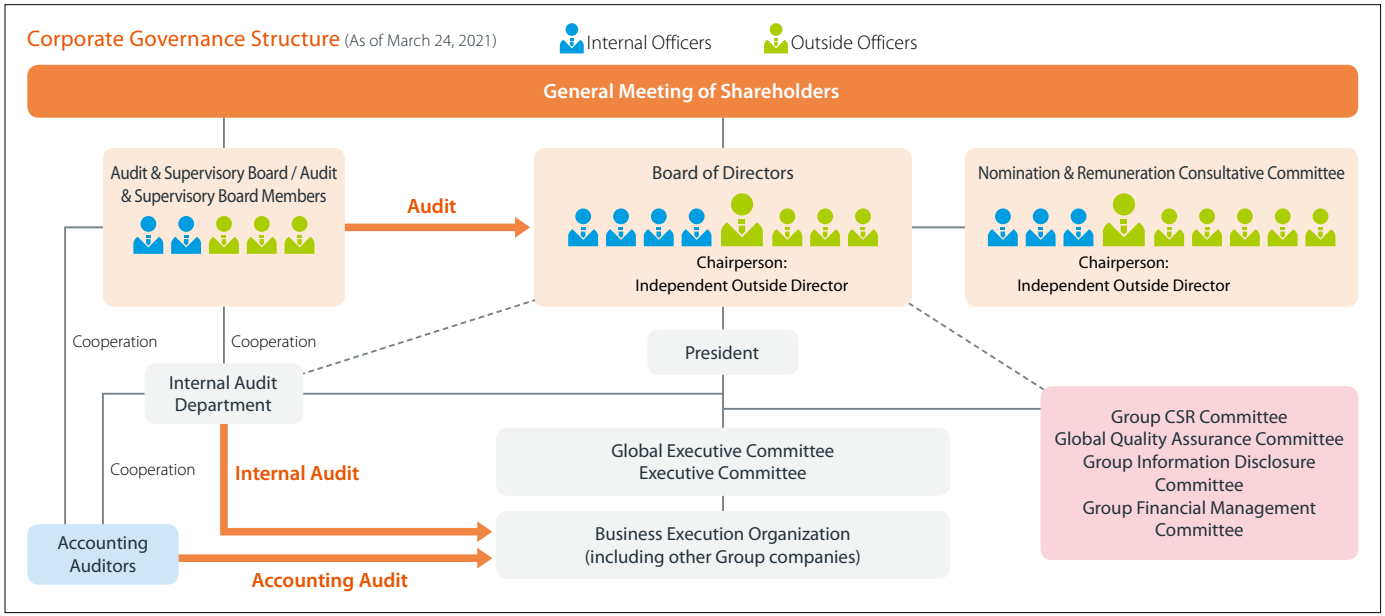
Strengthening the Link between Executive Remuneration and Performance

Please see P.42 for details.

- Medium Term Business Plan KPIs linked to executive remuneration
- Steps taken to introduce Performance Share Unit and increase the ratio of performance-based remuneration



A Transparent Governance Structure That Leverages the Strengths of Outside Officers



Board Members with a Wide Array of Skills

			Nomination & Remuneration Consultative Committee	Board of Directors and Audit & Supervisory Board attendance rate	Professional skills							
					Corporate management Business strategy	Global business	Finance, accounting and banking	Legal, governmental affairs and compliance	HR and labor	Healthcare	R&D	Production and SCM
Board of Directors	Masashi Miyamoto	Representative Director, President & CEO, Ph.D.	●	100%	●	●		●		●	●	
	Yutaka Osawa	Representative Director, Executive Vice President	●	100%	●			●		●	●	●
	Toshifumi Mikayama	Director, Executive Vice President, Ph.D.	●	100%	●	●				●	●	
	Noriya Yokota	Director		100%	●	●	●		●	●		●
	Akira Morita	Independent Outside Director [The Board chair]	●	100%				●		●		
	Yuko Haga	Independent Outside Director, Ph.D.	●	100%	●	●				●		
	Jun Arai	Independent Outside Director	Chairperson	—	●	●	●					
	Takashi Oyamada	Independent Outside Director	●	—	●	●	●					
Audit & Supervisory Board	Hiroshi Komatsu	Company Auditor (full-time)		100%	●	●	●			●		
	Masaki Ueno	Outside Company Auditor (full-time)		100%		●		●				
	Yuji Inoue	Independent Outside Company Auditor (part-time)	●	100%	●	●	●					
	Keiji Kuwata	Company Auditor (part-time)		100%	●							●
	Tomomi Yatsu	Independent Outside Company Auditor (part-time)	●	—			●	●				

Directors and Board of Directors

Taking into account its fiduciary duties and accountability to shareholders, the Board of Directors works diligently to realize the Company's corporate philosophy, and secure the Group's sustainable growth while increasing corporate value over the medium to long term, by establishing effective and efficient corporate governance. The Board of Directors makes decisions on significant matters pertaining to business execution by the Group. This includes the long-term management vision, medium-term and annual business plans of the entire Group and key Group companies, as well as statutory matters. The Board of Directors is also responsible for supervising the execution of Directors' duties, and establishing an adequate internal control system for the entire Group.

With respect to the Board's composition, the maximum number of Directors is 10, in accordance with the Articles of Incorporation. Upon considering the knowledge, experience, skills and insights necessary to become a Global Specialty Pharmaceutical Company and ensuring diversity, we established a transparent governance system, which is well-balanced as a whole. In order to ensure the effectiveness of objective management oversight, four independent Directors have been appointed to the Board from outside the Company, which is half the total number of current Directors, and the position of Board Chair is assumed by an independent Outside Director.

Audit & Supervisory Board Members and the Audit & Supervisory Board

The Audit & Supervisory Board has five members, including three outside Audit & Supervisory Board Members (two of whom meet the criteria for independent Audit & Supervisory Board Member). As an independent body mandated by shareholders, the Audit & Supervisory Board audits and verifies the status of establishing sound management for the Group's sustainable growth and enhancement of corporate value over the medium to long term.

Leveraging the ability of full-time Members to gather information within the Group as well as their independence, Audit & Supervisory Board Members actively express their opinions at Board of Directors' meetings. At the same time, Audit & Supervisory Board Members also strive to put in place and improve the framework used to ensure the effectiveness of auditing by each Member. Furthermore, in order to better provide information to Outside Directors, Audit & Supervisory Board Members exchange opinions with Outside Directors, and provide information which they have obtained through their auditing activities.

Nomination & Remuneration Consultative Committee

The Company has opted to establish the Nomination & Remuneration Consultative Committee in order to supplement the functions of the Board of Directors as its advisory body and create an even more transparent corporate governance system. The majority of Nomination & Remuneration Consultative Committee members are independent outside officers, and the committee chairperson is selected from independent Outside Directors, which is intended to facilitate objective and fair deliberations.

The Nomination & Remuneration Consultative Committee deliberates and decides on proposals for policies regarding the appointment and removal of directors, executive officers and company auditors and candidates for these officers, appointment and removal of senior directors, duties of individual directors, the policy for determining the successor of the current CEO of the Group, candidates for presidents and other officers of individual Group companies, remuneration systems, levels and amounts paid to individual officers, and presents proposals to the Board of Directors.

Reinforcement of the Effectiveness of the Board of Directors

To identify gaps between expected roles and responsibilities of the Board of Directors set forth in the "Kyowa Kirin Corporate Governance Policy" and the actual state of the Board of Directors in 2019-2020, we conducted an evaluation on the effectiveness of the Board of Directors. With respect to the evaluation of the Board's effectiveness, from the perspective of ensuring the effectiveness of governance, we identified wide-ranging issues, not limited to operational issues of the Board of Directors.

I. Changes in the evaluation method for Board effectiveness in 2020

Until 2019, our evaluation of the Board's effectiveness was solely based on a survey. As 2020 was the year that the next Medium Term Business Plan was formulated, we also conducted interviews with independent officers (Directors/Audit & Supervisory Board Members) and Representative Directors for the purpose of identifying issues from a medium- to long-term perspective. Furthermore, at the suggestion of the Board chair, who is an independent Outside Director, we organized a meeting where only independent officers exchange their opinions, and identified key issues to be addressed; and, then, all Directors and Audit & Supervisory Board Members exchanged their opinions on such issues. These are the changes in the evaluation method.

Evaluation Method in FY2020

i) Survey Scope: All directors and company auditors	Same survey method as the previous year
ii) Interviews by third-party advisors Scope: Representative Directors and independent officers	Processes added this year
iii) Opinion exchange meetings with independent officers	Processes added this year Held a meeting for independent officers to exchange opinions on issues identified from survey and interview results
iv) Opinion exchange meetings with all Directors and Audit & Supervisory Board Members	Taking into consideration evaluations up to the aforementioned opinion exchange meeting with independent officers, undertook an exchange of opinions

Main themes of the survey and interview questions

1) Growth Strategy/Medium Term Business Plan; 2) Global Governance System; 3) Governance System as a Listed Subsidiary; 4) Capital Strategy; 5) Risk Management (improvement of the system); 6) Risk Management (countermeasures against COVID-19); 7) Remuneration System; 8) Succession Planning; 9) Dialogue with Shareholders; 10) Topics of Deliberations; and 11) Training for Directors and Audit & Supervisory Board Members

II. FY2020 issues and initiatives to be taken in FY2021

Based on the evaluation results of the Board's effectiveness, we plan to implement the following measures for improvement in 2021:

1) Medium- to long-term global governance system

Considering that our business will be further globalized, we will share information on the pharmaceutical industry from a global viewpoint, and increase opportunities for discussion. With respect to the global governance system, we will create opportunities for discussion involving outside officers in a planned manner as our medium- to long-term challenge.

2) Training for Directors and Audit & Supervisory Board Members

In order to strengthen information sharing within the Company, we will increase opportunities for outside officers to participate in various committees and to visit the frontlines of such areas as production, research and sales. Furthermore, we will hold study sessions in line with our management issues by inviting external experts.

3) Strategic dialogue with shareholders

We will create opportunities for the Board of Directors to discuss the communication plan with respect to the Medium Term Business Plan; and also ensure more timely feedback on dialogue with shareholders to the Board of Directors, and reflect opinions of outside officers in our dialogue strategy.

III-1. Achievements in addressing issues identified in the 2019-2020 evaluation

Issue	What was implemented	Evaluation
1) Arrangement of opportunities for discussion other than Board meetings	As 2020 was the year that the next Medium Term Business Plan was developed, we arranged opportunities to discuss the ideal state of the Company, focusing on such themes as vision and materiality, from a medium- to long-term perspective, after Board meetings; and also held three extraordinary management meetings as a forum for freely exchanging opinions between executives and Board meeting participants.	Many respondents appreciated these discussion opportunities prior to making Board resolutions.
2) Report on dialogue with shareholders	With respect to the method of feedback on dialogue with shareholders to the Board of Directors, e-mail was used to be the main information sharing tool. Now the Group Information Disclosure Committee reports on market evaluations and dialogue with shareholders at Board meetings, and Board members have the opportunity to deliberate on each matter as required.	While the reporting at Board meetings and creative IR solution activities put forward against the backdrop of a business environment impacted by COVID-19 were evaluated positively, the evaluation results identified the need for further enhancement of information disclosure, as well as new challenges, including a strategy for disclosing our Medium Term Business Plan.
3) Enhancement of reporting on succession planning	While progress on succession planning was previously reported to the Board of Directors once a year, the frequency of reporting was revised to twice a year, enhancing the reporting on what was considered and the implementation status of the plan.	Respondents appreciated the fact that the CEO selection process and candidate development plan were appropriately reported, enabling the Board of Directors to fully deliberate on such matters.

III-2. Continued efforts as a listed subsidiary to strengthen governance

Issue	What was implemented	Evaluation
4) Strengthening the governance system as a listed subsidiary	In order to ensure the effectiveness of objective corporate management oversight, three (currently four) Outside Directors were appointed at the time of effectiveness evaluation, representing more than one-third (currently one-half) of the Board. In 2020, Mr. Morita, an independent Outside Director, was appointed as Board chair, and worked on further improving governance. Furthermore, we have changed the method for evaluating the Board's effectiveness to be more transparent and mainly led by outside officers, by using third parties to conduct interviews and organizing meetings to exchange opinions with independent outside officers.	Independent outside officers always pay attention to governance as a listed subsidiary. In case of any agenda that may give rise to possible conflict of interests with the parent company, officers from the parent company leave the board meeting. As appropriate measures have been taken, this year's evaluation remained as high as last year.

Basic policy on executive remuneration

Remuneration for executives is designed to increase commitment to the Company's further sustainable growth and improvement in corporate value, to attract and retain talent who aspire to help the Company make the leap forward to a Global Specialty Pharmaceutical Company, to motivate executives to contribute to the Company by fulfilling their respective duties and determined through a transparent and appropriate process by adopting an objective viewpoint. In order to realize this basic policy, investigations and deliberations on executives' remuneration are conducted by the Nomination & Remuneration Consultative Committee, which consists of a majority of independent officers, and is chaired by an independent Director.

Claw back provision

Kyowa Kirin has established a claw back provision that allows the Nomination & Remuneration Consultative Committee to request the return of Executive Director and Executive Officer remuneration in the case of such events as illegal acts or violations of laws and regulations.

Criteria regarding the Independence of Outside Officers

Kyowa Kirin has put in place and made public details of its own unique set of selection standards in connection with the criteria used to ensure the independence of outside officers. To do this, the Company took close reference from the provisions for independent outside officers stipulated in the "Enforcement Rules for Securities Listing Regulations" of the Tokyo Stock Exchange as well as the independent directors' nomination reference model of the Japan Association of Corporate Directors in order to secure the transparency and objectivity of its governance function while exerting proper management oversight.

Functions of Outside Board Directors and Outside Company Auditors

In order to improve the fairness and transparency of its corporate governance while ensuring the Group's sustainable growth and boosting corporate value over the medium to long term, Kyowa Kirin appoints four independent Outside Board Directors. Independent Outside Board Directors not only actively offer business advice on management issues, supervise the execution of business activities and monitor conflicts of interest, they also play a role in accurately conveying the opinions of stakeholders, including minority shareholders, at meetings of the Board of Directors. In addition, the Company appoints two independent Outside company auditors in order to ensure the objectivity and neutrality of audits as well as the soundness of management. In an effort to strengthen the abilities of independent outside officers to gather information, meetings are held between full-time company auditors and non-executive Board Directors, including independent Outside Board Directors.

Executive Remuneration

	Fixed compensation	Short-term incentive compensation (variable)		Medium- and long-term incentive compensation (variable)	
Type	Basic Remuneration	Annual Performance-Linked Bonus		Share-based remuneration	
				Share-based remuneration with restrictions on transfer	Introduction of performance-linked share-based remuneration (Performance Share Unit) from FY2021
Payment eligibility	Directors and Audit & Supervisory Board Members	Executive (Internal) Directors		Executive (Internal) Directors	
Purpose (Incentive for Officers)	Provide remuneration commensurate with the role and responsibilities of each officer, referencing peer company size and remuneration levels	Raise awareness toward the need to contribute to improving business performance each fiscal year		Have Directors of the Board of the Company share in the benefits and risks of share price fluctuations with the shareholders, and provide greater incentive to the Directors of the Board of the Company to elevate the share price and boost corporate value	Provide incentives for achieving the Medium Term Business Plan and the sustainable enhancement of corporate value by clarifying the link between remuneration, corporate performance and the Company's stock value, and promote further value sharing with shareholders
Payment method	Cash	Cash		Stock	Stock and cash (in roughly equal amounts)
Payment schedule	Monthly	A certain time each year (generally April)		A certain time each year (generally April)	
Evaluation indicator	—	Annual targets (revenue and net profit)	Medium Term Business Plan (core operating profit) * Evaluation based on performance-linked share-based remuneration from 2021.	—	ROE / Revenue CAGR / core operating profit ratio
Factor for determining the amount of remuneration	Role and responsibilities	Achievement of targets (Payment rate of 0% to 200%) * Non-financial target for the Director responsible for compliance only		Base amount determined based on basic remuneration and stock price	Base amount determined based on basic remuneration, stock price, and achievement of targets for three consecutive fiscal years (Variation rate of 0% to 150%)
Ratio in FY2020 (when 100% of performance targets achieved)	1	Around 0.35 to 0.4		Around 0.35 to 0.4	
Ratio from FY2021 (when 100% of performance targets achieved)	1	Around 0.4 to 0.45		Around 0.6 to 0.75	

Remuneration*1 by position (FY2020)

Position	Total Remuneration (Millions of yen)	Breakdown of Remuneration (Millions of yen)				Number of Eligible Officers
		Basic Remuneration	Annual Performance-Linked Bonus*2	Stock Option*2	Share-based remuneration with restrictions on transfer*2	
Directors (Excluding Outside Directors)	262	191	8	13	49	4
Company Auditors (Excluding Outside Company Auditors)	27	27	—	—	—	1
Outside Directors	46	46	—	—	—	3
Outside Company Auditors	56	56	—	—	—	4

*1 Above information includes one Director and one Outside Audit & Supervisory Board Member who retired as of the date of the 2020 Ordinary General Meeting of Shareholders.
*2 The amounts of performance-linked annual bonuses, remuneration in the form of stock options, and share-based remuneration with restriction on transfer were recorded as expenses for FY2020. For your information, allotment of stock options has been abolished since FY2020.
*3 In response to the administrative action imposed on Kyowa Hakko Bio Co., Ltd., the manufacturer of the active ingredient of Mitomycin, along with the voluntary recall of the product in 2019, Executive Directors offered to partially return their remuneration. The Company accepted their offers for the return of monthly remuneration as well as the declination of eligible bonuses.

CEO Succession Planning

The Nomination & Remuneration Consultative Committee conducts ongoing discussions about the selection and development of individuals with the capacity to assume the position of CEO and reports its findings to the Board of Directors. The discussion theme includes knowledge, skills and experience needed for the role of CEO, as well as the following ideal profile of CEO, for example:

- Deep understanding of and full commitment to the Company's philosophy and core values
- Strong sense of responsibility toward society (patients) and the Company (employees)
- Firm idea of the values he or she would like to provide to society
- Competence to create a future vision for the Company and penetrate it beyond national borders

The committee then recommends candidates to the Board of Directors based on these attributes and also advises on how candidates can be developed.

Policy on Cross-Shareholding

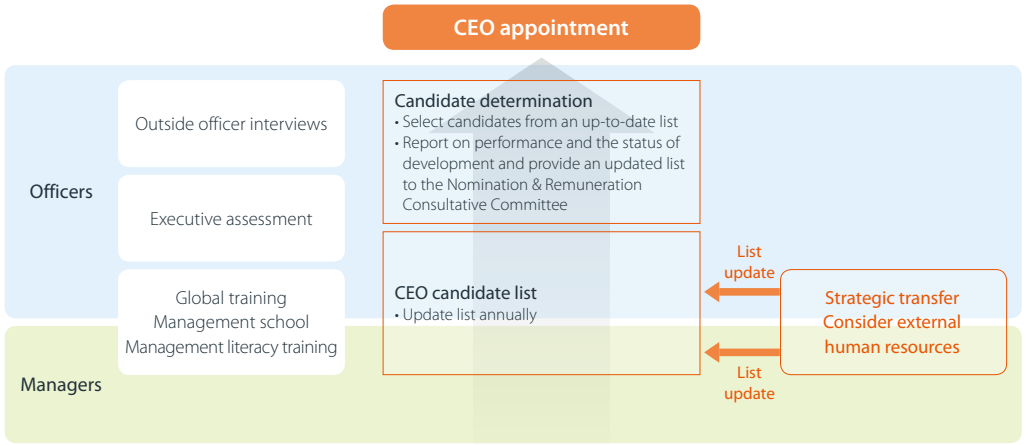
The Company does not engage in cross shareholdings with other companies unless it determines that such cross-shareholdings are useful for promoting the Group's sustainable growth and improving its corporate value over the medium to long term. The Board of Directors verifies the reasonableness of the individual cross-shareholdings on a yearly basis. If the Board determines that the reasonableness of any cross-shareholding has weakened, the Company will discuss and negotiate with the cross-shareholding partner about reducing or eliminating the cross-shareholding. Meanwhile, the number of stock issues held for policy purposes was seven, and the amount on the balance sheet was ¥7.7 billion as of the end of FY2020.

When the Company exercises the voting rights on shares of a company held for cross-shareholding purpose, it should decide whether to vote for or against each agenda item, taking into account whether each agenda item will help boost the corporate value of the company concerned and whether each agenda item will support the sustainable growth of the Group and enhance its value over the medium to long term.

Internal Control

Based on the basic policy of our parent company Kirin Holdings Company, Limited, we have established a "Basic Policy on Internal Control System" to ensure the appropriateness of operations. Under this basic policy, the establishment and operations of the system are confirmed by the Board of Directors, and the main details are made public. Moreover, in accordance with the Group's "Basic Policy on Compliance" and "Basic Policy on Risk Management," the Company promotes compliance in good faith and strives to ensure a system that responds appropriately to risks. With the enforcement of the revised Companies Act of 2015, we are making efforts to revise our basic policies and implement initiatives to strengthen the corporate governance of the Group. The internal audit unit, in charge of conducting audits on how the internal control system is developed and operated, was subjected to an external assessment by an outside specialized agency in 2017 and was rated as "Generally Conforming" to the International Standards for the Professional Practice of Internal Auditing.

Process to CEO Selection (Image)



FOCUS ON

Governance That Emphasizes the Protection of Minority Shareholders

Kyowa Kirin carries out research, development, manufacturing, marketing and import/export of ethical pharmaceuticals as a core company within the Pharmaceuticals Domain of Kirin Holdings Company, Limited.

In the Integration Agreement dated October 22, 2007, it is agreed that both companies recognize that, Kyowa Kirin will operate as an autonomous company with independence and flexibility, ensure management independence as a listed company, strive to maximize value for all shareholders and achieve consistent growth of its corporate value, while respecting Kirin Holdings' core group management policies, and Kirin Holdings will exert full and reasonable efforts to maintain Kyowa Kirin as a listed company.

Transactions with the Kirin Holdings, whether those be of goods and services provided by Kyowa Kirin or to Kyowa Kirin, are based on objective market information and other data, and as with ordinary transactions, rational terms are agreed, and the transaction is conducted appropriately.

In case of conducting a transaction with the controlling shareholder, as measures to secure the fairness and to avoid a possible conflict of interest, when making a decision at the Board of Directors, officers who also work for the controlling shareholder, Kirin Holdings do not participate in deliberation and resolution of such an agenda, and do not participate in our discussion and negotiations with Kirin Holdings.

Furthermore, in case of any material transaction, Kyowa Kirin establishes an independent third-party committee for the purposes of examining whether trade terms are not deemed disadvantageous to minority shareholders, and reporting the findings to the Board of Directors.

Stakeholder Engagement

Engagement 1

IR activities focused on dialogue with shareholders

Kyowa Kirin believes that constructive dialogue with investors and shareholders will lead to further improvements in corporate governance and, in turn, to increased corporate value over the medium to long term. Based on this understanding, the Company vigorously engages in IR activities spearheaded by the president, executives responsible for corporate planning, product strategy, finance, and R&D as well as the three full-time staff that make up the IR Department. By ensuring that the information gathered from these activities is properly conveyed to management, positive steps are being taken to practice productive two-way communication. Meanwhile, even during the COVID-19 pandemic, dialogues with investors and shareholders have continued on the same level as last year by taking full advantage of web/tele-conference.

IR Activities (implemented in FY2020)

Financial results briefings / telephone conferences	4 times
R&D briefings	1 time
IR meetings with the President	32 times (63 companies in total)
IR meetings with other senior management	5 times (8 companies in total)
IR meetings with IR staff	111 times (177 companies in total)

Engagement 2

Comprehensive Information Disclosure

Recognizing the need for transparency and fairness, Kyowa Kirin makes every effort to ensure the disclosure of high-quality information in accordance with its disclosure policy in order to improve dialogue with investors and shareholders. In addition to the Timely Disclosure Network (TDnet) system provided by the Tokyo Stock Exchange, Kyowa Kirin uses its own shareholder and investor website, in principle available in both Japanese and English with the exception of certain information, as a tool to ensure immediate and fair disclosure of information.

Company's Shareholder and Investor Website
https://ir.kyowakirin.com/en/index.html

Engagement 3

Shareholder meetings focused on dialogue

Convocation notifications concerning the General Meeting of Shareholders are, in accordance with the Corporate Governance Code, sent around three weeks prior to the meeting so that shareholders have sufficient time to consider the proposals to be voted on, and also are electronically posted on our website, etc. Furthermore, in consideration of foreign investors, English translations regarding the convocation notices and usage of the electronic voting platforms are made available. Securities Reports are also disclosed prior to meetings. During the General Meeting of Shareholders, a summary of the Company's performance is clearly explained on a screen and shareholders can vote on measures after receiving ample explanation.

Engagement 4

High marks from external bodies

In recognition of its strong environmental, social and governance (ESG) practices, Kyowa Kirin is included in multiple socially responsible investment (SRI) indexes in Japan and overseas.

FTSE4Good

FTSE Blossom Japan

2020 Sompo Sustainability Index

2020 CONSTITUENT MSCI JAPAN ESG SELECT LEADERS INDEX

2020 CONSTITUENT MSCI JAPAN EMPOWERING WOMEN INDEX (WIN)

! The FTSE Blossom Japan, MSCI Japan ESG Select Leaders and MSCI Japan Empowering Women (WIN) ESG indexes have all been adopted by the Government Pension Investment Fund (GPIF).

! The inclusion of Kyowa Kirin Co., Ltd. in any MSCI index, and the use of MSCI logos, trademarks, service marks or index names herein, do not constitute a sponsorship, endorsement or promotion of Kyowa Kirin Co., Ltd. by MSCI or any of its affiliates. The MSCI indexes are the exclusive property of MSCI. MSCI and the MSCI index names and logos are trademarks or service marks of MSCI or its affiliates.

Management

Aiming to be a company that brings a smile to the faces of patients by continuing to provide **life-changing** value.

Directors' Profiles

Representative Director of the Board, President and Chief Executive Officer

Masashi Miyamoto, Ph.D.

Apr. 1985 Joined Kirin Brewery Company, Limited
Apr. 2011 Director, Regulatory Affairs Department, Pharmacovigilance and Quality Assurance Division, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.)
Mar. 2012 Executive Officer, Director, Regulatory Affairs Department, Pharmacovigilance and Quality Assurance Division, Kyowa Hakko Kirin Co., Ltd.
Jul. 2014 Executive Officer, Director, Strategic Product Portfolio Department and Regulatory Affairs Department, Pharmacovigilance and Quality Assurance Division, Kyowa Hakko Kirin Co., Ltd.
Apr. 2015 Executive Officer, Director, Strategic Product Portfolio Department, Kyowa Hakko Kirin Co., Ltd.
Mar. 2017 Director of the Board, Managing Executive Officer, Strategic Product Portfolio Department, Kyowa Hakko Kirin Co., Ltd.
Apr. 2017 Director of the Board, Managing Executive Officer, Director, Corporate Strategy & Planning Department, Kyowa Hakko Kirin Co., Ltd.
Mar. 2018 Representative Director of the Board, President, Kyowa Hakko Kirin Co., Ltd. (to present)

Reasons for Selection
The Company has judged that Dr. Masashi Miyamoto is the right person to perform the role of decision making on material matters of management and supervising the execution of operations as Representative Director of the Board, using his extensive experience and high level of insight regarding overall business management, to push forward various measures for CSV management and for making a leap forward to become a global specialty pharmaceutical company with his strong leadership, and to promote sustainable growth as well as efforts aimed at enhancing the corporate value of the Group.

Representative Director of the Board, Executive Vice President

Yutaka Osawa

Apr. 1984 Joined Kyowa Hakko Kogyo Co., Ltd.
Apr. 2007 Director, Pharmaceutical Production Development Department, Kyowa Hakko Kogyo Co., Ltd.
Oct. 2008 Director, CMC Development Department, Development Division, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.)
Apr. 2009 Director, Production Planning Department, Production Division, Kyowa Hakko Kirin Co., Ltd.
Mar. 2013 Executive Officer, Director, Production Planning Department, Production Division, Kyowa Hakko Kirin Co., Ltd.
Apr. 2014 Executive Officer, Head, Production Division, Kyowa Hakko Kirin Co., Ltd.
Mar. 2017 Managing Executive Officer, Head, Production Division, Kyowa Hakko Kirin Co., Ltd.
Mar. 2018 Director of the Board, Managing Executive Officer, Head, Production Division, Kyowa Hakko Kirin Co., Ltd.
Mar. 2019 Representative Director of the Board, Executive Vice President, Kyowa Hakko Kirin Co., Ltd. (to present)

Reasons for Selection
The Company has judged that Mr. Yutaka Osawa has profound knowledge and a high level of insight gained through his extensive experience regarding research and development, overseas development and manufacturing, and is the right person to fully perform the role of decision making on material matters of management and supervising the execution of operations as Director of the Board, and to firmly deliver the important mission of ensuring stable supply of high quality products as a pharmaceutical company.

Director of the Board, Executive Vice President

Toshifumi Mikayama, Ph.D.

Apr. 1983 Joined Kirin Brewery Company, Limited
Mar. 2004 General Manager, Planning Division, Pharmaceutical Division, Kirin Brewery Company, Limited
Jul. 2007 Director of the Board, Executive Officer, Head, Research Division, Kirin Pharma Company, Limited
Oct. 2008 Executive Officer, Head, Research Division, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.)
Apr. 2010 Executive Officer, Director, Corporate Strategy & Planning Department, Kyowa Hakko Kirin Co., Ltd.
Mar. 2012 Managing Executive Officer, Director, Overseas Business Department, Kyowa Hakko Kirin Co., Ltd.
Mar. 2014 Director of the Board, Managing Executive Officer, Kyowa Hakko Kirin Co., Ltd.
Mar. 2018 Director of the Board, Senior Managing Executive Officer, Kyowa Hakko Kirin Co., Ltd.
Mar. 2021 Director of the Board, Executive Vice President, Kyowa Kirin Co., Ltd. (to present)

Reasons for Selection
The Company has judged that Dr. Toshifumi Mikayama is the right person to perform the role of decision making on material matters of management and supervising the execution of operations as Director of the Board, using his extensive experience and high level of insight regarding overall business management, and to promote overseas business continuously while driving the Company forward in its efforts to become a global specialty pharmaceutical company.

Director of the Board

Noriya Yokota

Apr. 1984 Joined Kirin Brewery Company, Limited
Mar. 2006 Managing Director, Kirin Australia Pty. Ltd.
Mar. 2011 General Manager, Sendai Plant, Production Division, Kirin Brewery Company, Limited
Mar. 2014 General Manager, Production Department, Production Division, Kirin Brewery Company, Limited
Apr. 2015 Director, Group Personnel & General Affairs, Kirin Holdings Company, Limited
Executive Officer, General Manager, Personnel & General Affairs Department, Kirin Company, Limited
Mar. 2017 Senior Executive Officer, Director, Corporate Strategy, Kirin Holdings Company, Limited
Director of the Board, Senior Executive Officer, Kirin Company, Limited
Director of the Board, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.) (to present)
Mar. 2018 Director of the Board, Senior Executive Officer & CFO, Kirin Holdings Company, Limited (to present)
Senior Executive Officer, Kirin Company, Limited

Reasons for Selection
The Company has judged that Mr. Noriya Yokota is the right person to perform the role of decision making on material matters of management and supervising the execution of operations as Director of the Board, using his extensive experience and high level of insight regarding overall business management, and to promote tight-knit cooperation with Kirin Group companies which have various business bases aimed at facilitating contributions to the health and well-being of people by providing solutions responding to various medical needs, through the use of our various business bases.

Director of the Board
Outside
Independent

Akira Morita

Oct. 1993 Professor, Faculty of Law and Economics, Chiba University
Apr. 1994 Professor, The University of Tokyo Graduate Schools for Law and Politics
Apr. 2004 Dean, Professor, Graduate School of Public Policy, The University of Tokyo
Jul. 2008 Director, Policy Alternatives Research Institute, The University of Tokyo
Apr. 2011 Chairman, Central Social Insurance Medical Council, Ministry of Health, Labour and Welfare
Apr. 2012 Professor, Department of Political Studies, Faculty of Law, Gakushuin University
Jun. 2012 Emeritus Professor, The University of Tokyo (to present)
Apr. 2014 Director-General, National Institute of Population and Social Security Research
Aug. 2014 Adjunct Professor, National Graduate Institute for Policy Studies (to present)
Apr. 2017 Professor, Department of Policy Studies, Tsuda University (to present)
Apr. 2017 Visiting Professor, Mie University Graduate School of Medicine (to present)
Apr. 2018 Director-General, Research Institute of Science and Technology for Society, Japan Science & Technology Agency (to present)
Mar. 2019 Outside Director of the Board, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.) (to present)

Reasons for Selection
The Company has judged that Mr. Akira Morita will utilize his academic experience and extensive knowledge as a researcher in the field of policy studies as well as his experience serving on deliberating committees for national and local government, and is the right person to contribute toward reinforcing the Company's governance function and in other ways by supervising the execution of operations from an independent standpoint and reflecting in the Company's management the perspective of protecting the rights of general shareholders.

Director of the Board
Outside
Independent

Yuko Haga, Ph.D.

Apr. 1989 Senior Consultant, Tokyo Office, Price Waterhouse Consultants
Apr. 1991 Representative, Haga Management Consulting Office (to present)
Apr. 2008 Executive Officer, Sompo Japan Healthcare Services Inc.
Feb. 2010 Director, Social Welfare Corporation Fujikenikukai (to present)
Apr. 2010 Visiting Professor, Department of Policy Management, Faculty of Policy Management, Shobi University
Apr. 2017 Associate Professor, Graduate School of Management, NUCB Business School
Jun. 2017 Board Member, Nonprofit Organization Japan Abilities Association (to present)
Mar. 2019 Outside Director of the Board, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.) (to present)
Apr. 2020 Professor, Graduate School of Management, NUCB Business School (to present)
Jun. 2020 Outside Director, MinebeaMitsumi Inc. (to present)

Reasons for Selection
The Company has judged that Ms. Yuko Haga will utilize her wealth of experience in the fields of medical treatment, nursing care, and healthcare, gained from her wide-ranging activities as a management consultant, as well as her insight as a researcher in corporate strategy, and is the right person to contribute toward reinforcing the Company's governance function and in other ways by supervising the execution of operations from an independent standpoint and reflecting in the Company's management the perspective of protecting the rights of general shareholders.

Director of the Board
Outside
Independent

Jun Arai

Apr. 1983 Joined Shell Sekiyu K.K.
Sep. 2002 General Manager, Management Information, Showa Shell Sekiyu K.K.
Apr. 2004 General Manager, Accounting, Showa Shell Sekiyu K.K.
Mar. 2005 Executive Officer, General Manager, Accounting, Showa Shell Sekiyu K.K.
Mar. 2006 Director, responsible for Accounting, Showa Shell Sekiyu K.K.
Mar. 2007 Managing Director, responsible for Corporate Planning, Finance, Financial Information Assurance, Corporate Governance, Showa Shell Sekiyu K.K.
Aug. 2008 Representative Director, Acting President, Showa Shell Sekiyu K.K.
Nov. 2008 Representative Director, President, Showa Shell Sekiyu K.K.
Mar. 2013 Representative Director, Group Chief Operating Officer, Showa Shell Sekiyu K.K.
Mar. 2014 Representative Director, President, Showa Yokkaichi Sekiyu Co., Ltd.
Apr. 2016 Outside Director, Daiwa SB Investments Ltd.
Mar. 2017 Outside Audit & Supervisory Board Member, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.)
Apr. 2019 Outside Director, Sumitomo Mitsui DS Asset Management Company, Limited (to present)
May 2020 Outside Corporate Auditor, Ryohin Keikaku Co., Ltd. (to present)
Mar. 2021 Outside Director of the Board, Kyowa Kirin Co., Ltd. (to present)

Reasons for Selection
Mr. Jun Arai was appointed outside Audit & Supervisory Board Member of the Company in March 2017. In his career, he has served for accounting and financial departments at Showa Shell Sekiyu K.K. for many years, and he has experienced in corporate management as a Representative Director and President, and he has utilized his considerable knowledge gained from that experience in his active performance as Audit & Supervisory Board Member. The company has judged that he is the right person to fulfill the role of decision making on material matters of management and supervising the execution of operations.

Director of the Board
Outside
Independent

Takashi Oyamada

Apr. 1979 Joined The Mitsubishi Bank, Limited (presently MUFG Bank, Ltd.)
Jun. 2005 Executive Officer, The Bank of Tokyo-Mitsubishi, Ltd. (presently MUFG Bank, Ltd.)
Executive Officer, Mitsubishi Tokyo Financial Group, Inc.
Jan. 2006 Executive Officer, The Bank of Tokyo-Mitsubishi UFJ, Ltd. (presently MUFG Bank, Ltd.)
Jan. 2009 Managing Executive Officer, The Bank of Tokyo-Mitsubishi UFJ, Ltd.
Jun. 2009 Managing Director, The Bank of Tokyo Mitsubishi UFJ, Ltd.
Member of the Board of Directors, Mitsubishi UFJ Financial Group, Inc.
May 2013 Senior Managing Executive Officer, The Bank of Tokyo-Mitsubishi UFJ, Ltd.
Jun. 2014 Representative Director, Deputy President, The Bank of Tokyo-Mitsubishi UFJ, Ltd.
Jun. 2015 Member of the Board of Directors, Representative Corporate Executive, Deputy President and COO, Mitsubishi UFJ Financial Group, Inc.
Apr. 2016 President & CEO, The Bank of Tokyo-Mitsubishi UFJ, Ltd.
Member of the Board of Directors, Mitsubishi UFJ Financial Group, Inc.
Jun. 2017 Senior Advisor, The Bank of Tokyo-Mitsubishi UFJ, Ltd. (to present)
Jun. 2018 Representative Director and Vice Chair, The Japan Institute of International Affairs (to present)
Dec. 2018 Outside Director, Mitsubishi Research Institute DCS Co., Ltd. (to present)
Jun. 2019 Outside Director, Mitsubishi Electric Corporation (to present)
Jun. 2019 Outside Director, Isetan Mitsukoshi Holdings Ltd. (to present)
Mar. 2021 Outside Director of the Board, Kyowa Kirin Co., Ltd. (to present)

Reasons for Selection
Mr. Takashi Oyamada possesses an extremely high-level of knowledge on management from his long experience as a banking executive, and he has knowledge and insight into a broad range of industries based on his abundant experience in the financial sector. The Company has judged that he is the right person to make decisions on material matters and supervise the execution of operations.

Company Auditors' Profiles / Executive Officers

Company Auditor
Hiroshi Komatsu

Apr. 1986 Joined Kyowa Hakko Kogyo Co., Ltd.
Feb. 2009 CFO, Hematech, Inc.
Apr. 2012 Manager, Corporate Planning Department, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.)
Apr. 2015 Deputy Director, General Affairs Department, Kyowa Hakko Kirin Co., Ltd.
Apr. 2016 Deputy Director, General Affairs Department, and Leader, Corporate Secretariat Group, General Affairs Department, Kyowa Hakko Kirin Co., Ltd.
Mar. 2018 Audit & Supervisory Board Member (Full-time), Kyowa Hakko Kirin Co., Ltd. (to present)

Reasons for Selection
The Company has judged that Mr. Hiroshi Komatsu has profound knowledge and insight gained through his broad range of experiences in accounting, finance, research and development, management of overseas subsidiaries, corporate planning and other areas as well as the ethical standards, fair and equal judgment required as an Audit & Supervisory Board Member and is the right person to appropriately perform the duties as an Audit & Supervisory Board Member of the Company by ensuring that the audit and supervisory functions are fully effective across a broad range of fields.

Company Auditor
Keiji Kuwata

Apr. 1985 Joined Kirin Brewery Company, Limited
Sep. 2010 Director of the Board, General Manager, Eastern-Japan Regional Division, Kirin Logistics Co., Ltd. (presently Kirin Group Logistics Company, Limited)
Apr. 2015 Executive Officer, General Manager, Corporate Planning Department, Kirin Company, Limited
Mar. 2016 Director, Corporate Strategy, Kirin Holdings Company, Limited
Mar. 2018 Senior Executive Officer, General Manager, Corporate Planning Department, Kirin Company, Limited
Mar. 2019 Audit & Supervisory Board Member, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.) (to present)
Company Auditor (Full-time), Kirin Holdings Company, Limited (to present)

Reasons for Selection
The Company has judged that Mr. Keiji Kuwata is the right person to appropriately perform the duties as a Company Auditor of the Company among the Group's broad fields, since he has long served in corporate planning, logistics and other fields in the Kirin Group, has a wealth of experience and profound insight into Group management in general, while also appropriately performing his role as a Director responsible for corporate strategy of the Kirin Holdings Company, Limited.

Company Auditor
Outside
Independent
Yuji Inoue

Apr. 1971 Joined Ricoh Company, Ltd.
Nov. 1985 Managing Director, Ricoh UK Ltd. (London)
Apr. 1993 General Manager, Finance Department, Finance and Accounting Division, Ricoh Company, Ltd.
Apr. 1998 General Manager, Finance and Accounting Division, Ricoh Company, Ltd.
Jun. 1999 Managing Director, General Manager, Sales Division, Ricoh Leasing Co., Ltd.
Apr. 2000 President, Ricoh Leasing Co., Ltd.
Jun. 2000 Group Executive Officer, Ricoh Company, Ltd.
Jun. 2004 Managing Director, Finance Solutions, Ricoh Company, Ltd.
Jun. 2005 President and Chief Executive Officer, Ricoh Leasing Co., Ltd.
Jun. 2009 Corporate Full-time Auditor, Ricoh Company, Ltd.
Jun. 2014 Outside Corporate Auditor, Infoteria Corporation (presently Asteria Corporation)
Jun. 2015 Outside Director, ANRITSU CORPORATION
May 2016 Outside Corporate Auditor, Ryohin Keikaku Co., Ltd.
Mar. 2018 Outside Audit & Supervisory Board Member, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.) (to present)

Reasons for Selection
The Company has judged that Mr. Yuji Inoue possesses a significant level of insight into finance and accounting through his experience in important posts in the accounting and finance division and as a Corporate Auditor in Ricoh Company, Ltd., as well as abundant experience from his service as President and Chief Executive Officer, and in other roles at Ricoh Leasing Co., Ltd., and will apply such insight and experience to the business management and audits of the Company.

Company Auditor
Outside
Masaki Ueno

Apr. 1998 Joined Kirin Brewery Company, Limited
Mar. 2012 General Manager, Legal Department, Kirin Holdings Company, Limited
Jan. 2013 General Manager, Legal Department, Kirin Company, Limited, Director of Group Legal, Kirin Holdings Company, Limited
Apr. 2015 Executive Officer, General Manager, Legal Department, Kirin Company, Limited, Executive Officer, Director of Group Legal, Kirin Holdings Company, Limited
Apr. 2019 Executive Officer, General Manager, Legal Department, Kirin Holdings Company, Limited
Mar. 2020 Outside Audit & Supervisory Board Member (Full-time), Kyowa Kirin Co., Ltd. (to present)

Reasons for Selection
The Company has judged that Mr. Masaki Ueno having long served in legal departments in the Kirin Group, he has a high level of insight and experience regarding corporate legal affairs including global M&A; and thus, together with his experience in the Corporate Strategy & Planning Department of Kirin Holdings Company, Limited, that he is a suitably qualified person with the ability of providing broad supervision of the Group and giving audit opinions based thereon.

Company Auditor
Outside
Independent
Tomomi Yatsu

Apr. 1983 Joined Tokyo Electron Ltd.
Oct. 1986: Joined Deloitte Touche Tohmatsu LLC
Sep. 1990 Registered as Certified Public Accountant
Oct. 2001 Joined New Tokyo International Law Office
Admitted to Tokyo Bar Association
Jun. 2009 Outside Auditor, Calbee, Inc.
Jun. 2010 Outside Audit & Supervisory Board Member, Taiko Pharmaceutical Co., Ltd.
Mar. 2012 Outside Audit & Supervisory Board Member, KOKUYO Co., Ltd.
Mar. 2015 Outside Audit & Supervisory Board Member, Yamaha Motor Co., Ltd.
Apr. 2015 Partner, TMI Associates (to present)
Jun. 2016 Outside Director, SMBC Nikko Securities Inc. (to present)
Jun. 2017 Outside Audit & Supervisory Board Member, IHI Corporation (to present)
Mar. 2019 Outside Corporate Auditor, Kuraray Co., Ltd. (to present)
Mar. 2021 Outside Audit & Supervisory Board Member, Kyowa Kirin Co., Ltd. (to present)

Reasons for Selection
Ms. Tomomi Yatsu is both a certified public accountant and an attorney at law. She also has an immense wealth of experience serving as outside audit & supervisory board member and outside director of corporations. The Company has deemed her to be an appropriate person capable of supervising the Company and expressing audit opinions from an independent perspective through her sophisticated knowledge and insight as an accounting and legal expert and in-depth knowledge and insight as an audit & supervisory board member of corporations.

Executive Officers

Senior Managing Executive Officer

Wataru Murata
Director
Human Resources Department

Managing Executive Officers

Kenya Shitara, Ph.D.
Director
Legal and Intellectual Property Department

Takeyoshi Yamashita, Ph.D.
Director
Corporate Strategy & Planning Department

Executive Officers

Hiroshi Sonekawa
Director
Vice President,
Head of Sales & Marketing Division

Mitsuo Satoh, Ph.D.
Director
Medical Affairs Department

Nobuyuki Tsukahara
Director
Nagoya Branch

Motohiko Kawaguchi
Director
Finance Department

Yasuo Fujii
Director
Business Development Department

Shin Inoue
Director
Sales & Marketing Planning Department

Fumihiko Kanai
Vice President, Head of R&D Division
and Head of Development Unit

Koichiro Ishimaru
Director
Corporate Social Responsibility
Management Department

Jean-David Rafizadeh-Kabe, MD, JD
Vice President,
Head of Pharmacovigilance Division

Yoshifumi Torii, Ph.D.
Vice President, Head of R&D Division
and Head of Development Unit

Hiroki Takamatsu
Vice President,
Head of Quality Assurance Division

Tomohiro Sudo
Director
Global Product Strategy Department

Kenji Shibata, Ph.D.
Director
Internal Audit Department

Shoko Itagaki
Director
Corporate Strategy & Planning Department

Toshiyuki Kurata
Vice President, Deputy Head of Production Division
and Director of Production Planning Department

Compliance

The Kyowa Kirin Group recognizes that compliance entails quickly grasping the needs of society while engaging in an ethical manner. With this in mind, the Group works diligently to build and maintain healthy and positive ties with all stakeholders.

Code of Conduct and Group Policies

In order to put the 2030 Vision into practice under our philosophy, the Kyowa Kirin Group acts in accordance with its Core Values and with high ethical standards while aiming to become a corporate group trusted by society. Considering compliance as the foundation of all our corporate activities, we have established an organizational structure to comply with all laws and regulations, internal and external guidelines and rules and social norms.

We have also put in place the Kyowa Kirin Group Code of Conduct, which provides principles and guidelines for the overall behavior of all the people who work in the Kyowa Kirin Group. As a standard that should be shared globally, the Code of Conduct has been translated into various languages and disseminated to the Group's employees all around the world. All employees of the Group pledge to comply with the Code of Conduct with the degree of understanding and adherence monitored through such means as employee awareness surveys.

In addition, we have put in place Group Policies that outline codes of conduct for individual areas of business and are working to promote compliance.

The Kyowa Kirin Group's Philosophy, Vision, Core Values Hierarchy
https://www.kyowakirin.com/sustainability/index.html

Compliance Framework

The Kyowa Kirin Group has established regional CSR committees in the four regions of Japan, North America, EMEA, and Asia/Oceania to discuss global and regional compliance-related activities and concerns on a quarterly basis.

In addition, a joint Group CSR Committee meeting encompassing the four regions is held once a year to deliberate on compliance strategies and action plans for the entire Group, and to report on the status of activities during the year. The Group CSR Committee is chaired by the Company's Representative Director and Executive Vice President, and comprised of the global function heads and overseas regional CSR heads.

Meanwhile, important matters discussed in these committees are reported to the Board of Directors.

Whistleblower System

The Kyowa Kirin Group has put in place the Compliance Line, an internal reporting process, in order to prevent, detect at an early stage and correct acts that are against the Kyowa Kirin Group Code of Conduct, as well as acts that seriously damage the brand value of the Kyowa Kirin Group. We have introduced a process under which reports concerning directors are passed directly to company auditors. On top of the strict adherence to confidentiality and a rule that those reporting an incident will not be subjected to any retaliation, steps have been taken to establish an internal and external point of contact for reporting that can be accessed by telephone, electronic and postal mail as well as online tools. In this manner, every effort is being made to create a simple and easy reporting environment. Moreover, messages from the CEO on such topics as the importance of the Compliance Line, confidentiality and non-retaliation are sent out on a continuous basis. The point here is to ensure that employees gain a better understanding of the system through e-learning and group training while maintaining a continuous awareness toward each point of contact for reporting. Details of the Compliance Line are readily available on the Company's website and posters displayed throughout the workplace. Overseas subsidiaries operate local internal reporting systems in each region. A global line that enables overseas subsidiaries to report directly to the Group's head office in Japan in their local language was also established in 2016. In 2020, there were a total of 29 cases reported through the Compliance Line in Japan and overseas.

Internal Audits

At the Kyowa Kirin Group, the internal audit unit conducts risk-based audits from an independent standpoint at approximately 100 locations, including subsidiaries in Japan and overseas. Internal audits verify and evaluate the status of compliance framework establishment and implementation at each site. In addition to pointing out issues and proposing recommendations for improvement, internal audits also help monitor conduct to ensure that appropriate corrective measures are taken. The results of internal audits are presented to the Representative Director and President, Executive Vice President and the Board of Directors. At the same time, efforts are directed toward strengthening collaboration and improving governance to enhance the effectiveness of audits within the Group by sharing details of the information discussed at regular meetings with company auditors as well as accounting auditors.

Compliance Training and Awareness Surveys

The Group conducts various training programs including a corporate ethics lecture for executives together with group training sessions and e-learning to foster a corporate culture that enables executives and employees to adapt flexibly to changes in social norms. In addition, the Company participates in the annual Awareness Survey of Human Rights and Compliance implemented by the Kirin Group. The results of the survey help to identify changes in employee awareness and issues that need to be addressed, and are utilized in formulating the Group's initiatives.

Major Compliance Training Results in FY2020*1

Category	Details	Scope				Number of Participants
		Kyowa Kirin (Non-consolidated)	Group Companies		Temporary and Contract Employees	
			Japan	Overseas		
Overall training	Human rights and compliance training	○	○		○	4,633
Training by employee group	Corporate ethics lecture meeting for executives	○				28
	Compliance training for newly appointed evaluators	○				83
	Compliance training for new employees	○				71
Training by specific field	The Kyowa Kirin Group Code of Conduct	○	○	○	○	4,638*2
	Anti-bribery and corruption prevention	○	○	○	○	6,154
	Whistleblower system	○	○		○	4,683
	Japan Pharmaceutical Manufacturers Association (JPMA) Code of Compliance "Promotion of Understanding the Code Month"	○	○		○	4,608
	Personal information protection	○	○		○	4,584
	Research ethics	○				424
	Sales data provision activities compliance training	○				6,413*3
	Interaction with various parties including healthcare professionals in Europe and the US	○				53

*1 Training has been conducted by the headquarters in Japan. Region-specific training has been conducted via respective region.
*2 Overseas Group companies' data has not been tabulated and is therefore excluded from the number of participants.
*3 Conducted four times each year for the Sales & Marketing Division.

Risk Management

In order to secure the trust of customers and society, the Kyowa Kirin Group identifies a variety of risks that arise during the course of its business activities and addresses them appropriately.

Group-wide Risk Management

The Kyowa Kirin Group recognizes that the realization of its vision, based on its corporate philosophy will lead to sustainable growth and the enhancement of corporate value over the medium to long term. In order to safeguard its corporate value from threats, the Group engages in enterprise risk management. Through various opportunities and the taking of appropriate risks, our risk management endeavors also help create new corporate value.

Risk Management System

Business execution lines at the Kyowa Kirin Group identify risks based on changes in the internal and external environment. Steps are also taken to analyze impact and likelihood of identified risks. After discussing and adjusting the results of this analytical assessment of internal and external environmental changes and risk trends while conversing with business execution lines, the CSR Committee secretariat organizes risks by category, assesses and identifies material risks. In addition to deliberating on the appropriateness of identifying material risks, the CSR Committee also monitors measures aimed at mitigating risks as well as progress while supporting the risk management of business execution lines. Moreover, the Group CSR Committee meets once a year to deliberate on the Group's overall risk management strategy and action plan, and to report on the status of activities during the year. Details of material risk mitigation measures and monitoring results discussed by the Committee are reported to the Board of Directors.

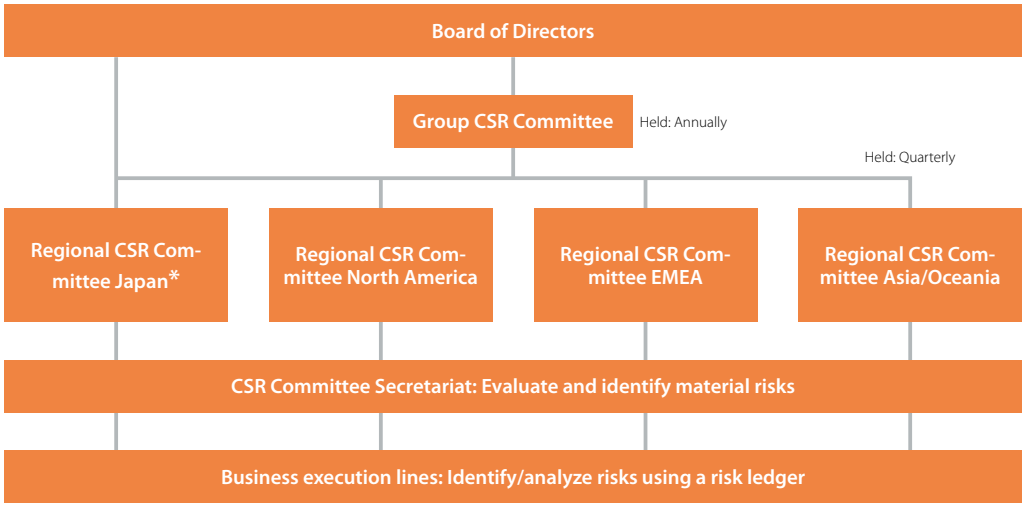
The global environment has undergone considerable change due to the COVID-19 pandemic. As a result, new risks are expected to arise in the conduct of global business activities. In order to engage in forward-looking risk management that proactively responds to these unprecedented risks, a risk management workshop was held for all executives and line management and their thoughts on risk management were shared. This initiative has helped foster a sound risk management culture while strengthening practical risk management skills.

Crisis Management

We define "crises" as situations that may have a profound impact on our business and require a rapid response among those that inhibit the achievement of our management goals. In addition, we define "crisis management" as activities that minimize the impact on our business when risks evolve into crises. We prioritize human life and health and act quickly and appropriately to minimize the impact of each crisis while restoring normal business operations as soon as possible. In particular, we believe it is crucial to promptly report any signs of a crisis to senior managers or the relevant department (called "Bad News Fast") at an early stage, establish cross-functional teams to develop an integrated response to the crisis while taking into account the impact on stakeholders, and monitor the implementation of measures to prevent any reoccurrence after the response to the crisis has been completed.

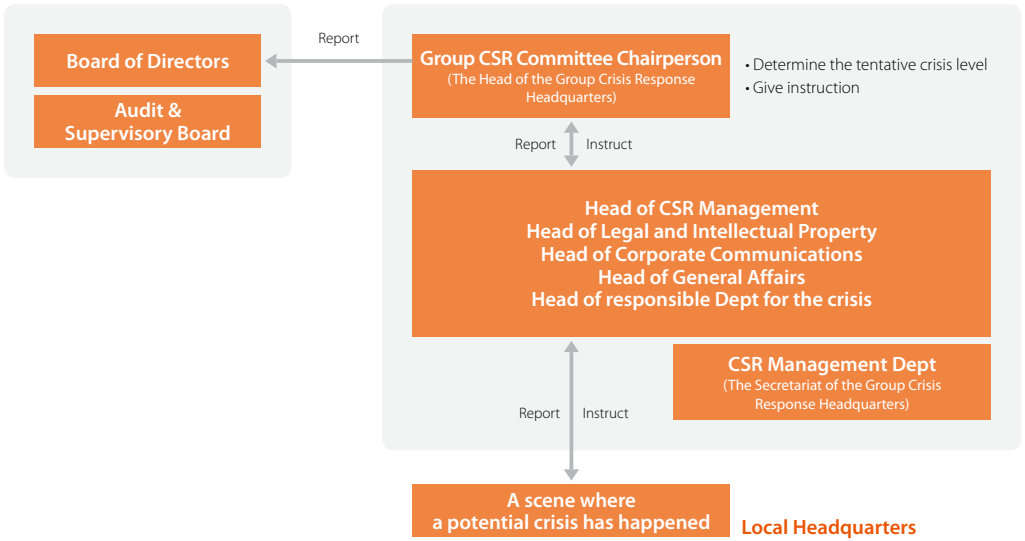
The Kyowa Kirin Group promoted establishment of a global crisis management system based on a matrix structure that is organized by function and region, and operated on an autonomous basis in 2020. When a global response is required, the Group coordinates between the Group's head office, region and function to promptly mitigate impact of crisis. Efforts are also being directed toward conducting crisis exercises that cover a wide range of items including pandemics, scandals, stable supply, cyber-attacks as well as wind and flood disasters that connect each region with the global head office, and to strengthen the Group's ability to respond to a crisis.

Risk Management System



* Other regions' reports collated and presented in Japan.

Crisis Management System



WHO WE ARE

Kyowa Kirin is a Japan-based Global Specialty Pharmaceutical Company (GSP).

Kyowa Kirin is rolling out a new matrix management structure that combines a regional organization based on four regions – Japan, North America, Europe/Middle East/Africa (EMEA), and Asia/Oceania – and a functional organization for functions with clear global standards for cross-regional collaboration such as R&D, regulatory affairs and quality assurance. Under this new structure, called One Kyowa Kirin, we aim to accelerate global expansion and further leap as a Japan-based Global Specialty Pharmaceutical Company.

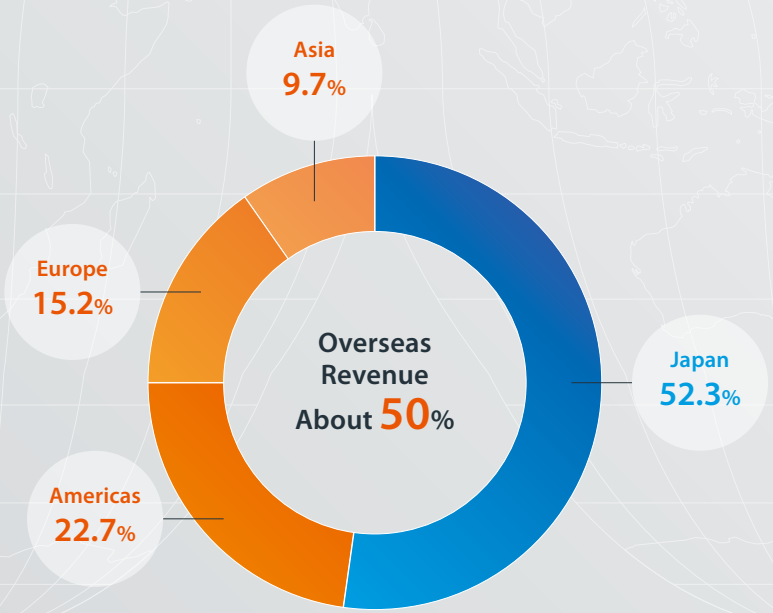
ONE KYOWA KIRIN

Matrix Management Structure (As of December 31, 2020)

	Japan	North America	EMEA	Asia and Oceania
Business sites*	4 companies	6 companies	20 companies	8 companies
Number of Employees	3,909	348	658	508
R&D				
Regulatory Affairs				
Quality Assurance				
Pharmacovigilance				
Production				
SCM				
Business Development				
…				

*Kyowa Kirin and its consolidated subsidiaries

Sales Breakdown by Customer Region (FY2020)



Our History

Formed in October 2008 through a merger between Kyowa Hakko Kogyo Co., Ltd. and Kirin Pharma Company, Limited, Kyowa Kirin is an R&D-based pharmaceutical company with state-of-the-art antibody technologies. Taking on new challenges as one of Japan's leading life-science companies, we are striving to contribute to the health and well-being of people around the world by creating new value.

Our Organization: Changes and Improvements

Technological advances and drug creation

Kirin 1885
Japan Brewery Company founded, forerunner company of Kirin Brewery Co., Ltd.

Kirin 1907
Kirin Brewery Co., Ltd. established

Kyowa Hakko 1949
Kyowa Hakko Kogyo Co., Ltd. established as a secondary company of Kyowa Sangyo Co., Ltd. as part of restructuring plans

Alliance
Kirin 1984
Established joint-venture Kirin-Amgen, Inc. with US company Amgen Inc. to conduct erythropoietin research and development

AMGEN

Open Innovation
Kirin 1988
Supported the establishment of the La Jolla Institute for Immunology in the US; Kyowa Kirin continues to collaborate with the institute, which helped discover KHK4083

Kirin 2007
Kirin Pharma Co., Ltd. established in conjunction with Kirin Brewery's move to a holding company structure

2008
Kyowa Hakko Kirin Co., Ltd. starts operations

Birth of a company with a unique business structure and strengths in biotechnology

Kyowa Hakko KYOWA — Kirin Pharma KIRIN Pharma

First for Japan
Kyowa Hakko 1951
First volume production of streptomycin in Japan using technology from US drug firm Merck & Co., helping to eliminate tuberculosis in Japan

Kyowa Hakko 1956
Successfully isolated mitomycin C and started commercial production as an anticancer drug

Kirin 1982
R&D Division established at head office, marking the Group's full-scale move into the pharmaceuticals business. Research Institute for Production Development starts active research efforts to commercialize erythropoietin

Small molecule drug
1975
DEPAKENE®
launched in Japan

Therapeutic protein
1990
ESPO®
launched in Japan

Therapeutic protein
1991
GRAN™
launched in Japan

Small molecule drug
1991
Coniel®
launched in Japan

Technological Innovation
Kyowa Hakko
Developed POTELLIGENT, groundbreaking new antibody production technology that dramatically increases antibody activity

Small molecule drug
2001
Rocaltrol®
launched in Japan

Small molecule drug
2001
Allelock®
launched in Japan

Small molecule drug
2006
Patanol®
launched in Japan

Therapeutic protein
2007
NESP®
launched in Japan

Small molecule drug
2008
REGPARA®
launched in Japan

Technological Innovation
Kirin
Technology established to produce a wide range of fully human antibodies, just as the human body does, using mice

Strengthening Biopharmaceuticals

Kyowa Kirin **2010**

Started realigning production sites to upgrade aging facilities, tackle location issues, raise GMP levels and improve cost competitiveness; completed 2017

Establishing Western Operations

Kyowa Kirin **2011**

Acquired UK company ProStrakan Group plc., making it a subsidiary (now Kyowa Kirin International plc.)

ProStrakan

Strengthening Biopharmaceuticals

Kyowa Kirin **2010**

One of Japan's leading facilities for producing investigational antibodies completed at the Bio Process Research and Development Laboratories

Kyowa Kirin **2012**

Established Fujifilm Kyowa Kirin Biologics Co., Ltd., a joint-venture with FUJIFILM Corporation, to develop, make and sell biosimilars

Establishing Western Operations

Kyowa Kirin **2014**

Acquired UK company Archimedes Pharma Ltd., making it a subsidiary

Archimedes

Strengthening Biopharmaceuticals

Kyowa Kirin **2016**

Completed construction of new biopharmaceutical API manufacturing facility at the Takasaki Plant, boosting production capacity

Kyowa Kirin **2019**

Adopted the global One Kyowa Kirin structure to improve the efficiency of Group management.
Sold Kyowa Hakko Bio Co., Ltd.

Targeting a new phase of growth by focusing on the pharmaceutical business

Our Organization: Changes and Improvements

Technological advances and drug creation

Harnessing unique technologies to create groundbreaking new drugs

Therapeutic protein
2011
Romiplate® Romiplostim
launched in Japan

Small molecule drug
2013
NOURIAST®
launched in Japan

Therapeutic protein
2014
G-Lasta®
launched in Japan

Therapeutic antibody
2018
Fasenra
launched in Japan and Europe

Small molecule drug
2018
ORKEDIA®
launched in Japan

Therapeutic antibody
2018
CRYSVITA®
launched in Europe

Therapeutic antibody
2019
CRYSVITA®
launched in Japan

Small molecule drug
2020
Duvroq
launched in Japan

Therapeutic antibody
2012
POTELIGEO® (mogamulizumab)
launched in Japan

Small molecule drug
2013
Onglyza®
launched in Japan

Therapeutic antibody
2016
LUMICEF®
launched in Japan

Therapeutic antibody
2018
Rituximab BS
launched in Japan

Therapeutic antibody
2018
POTELIGEO® (mogamulizumab)
launched in the US

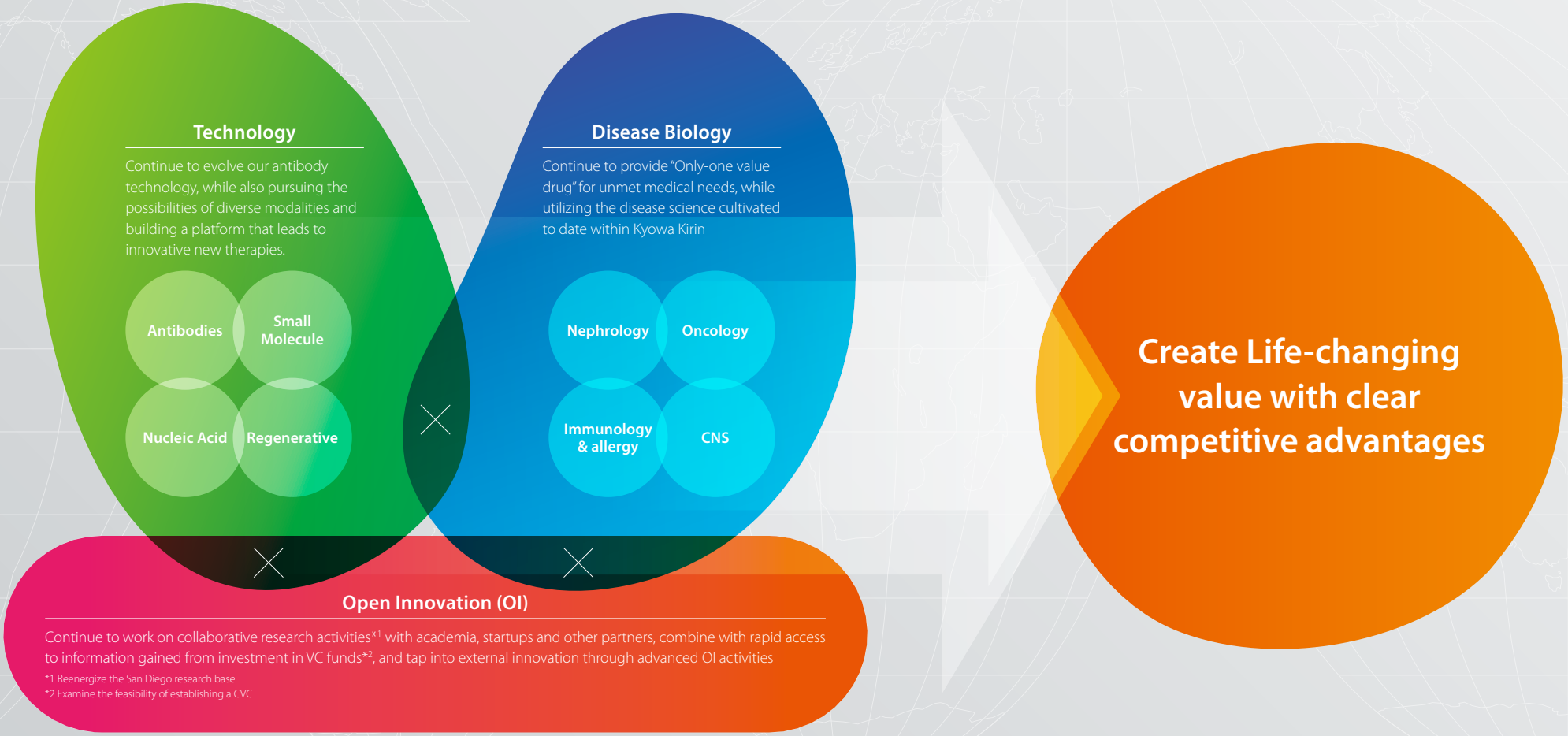
Small molecule drug
2019
NOURIANZ® (istradefylline) tablets
launched in the US

Therapeutic protein
2019
Darbepoetin Alfa Injection Syringe [KKF]
launched in Japan

Therapeutic antibody
2020
POTELIGEO® (mogamulizumab)
launched in Europe

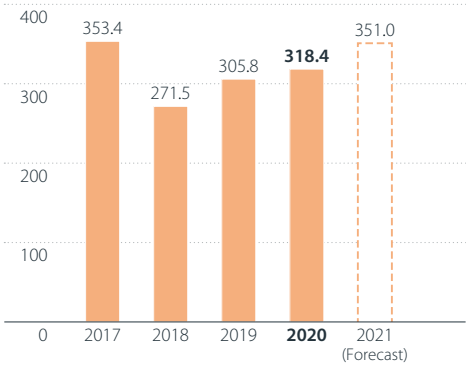
Research & Development Concept

The Kyowa Kirin Group is aiming to build a competitive technology platform by enhancing and combining its drug discovery technologies and its drug discovery modalities. By matching that technology platform with disease-oriented science and by harnessing open innovation with partners that have specific strengths, we aim to develop completely new technologies or select efficient drug discovery targets to create life-changing value.

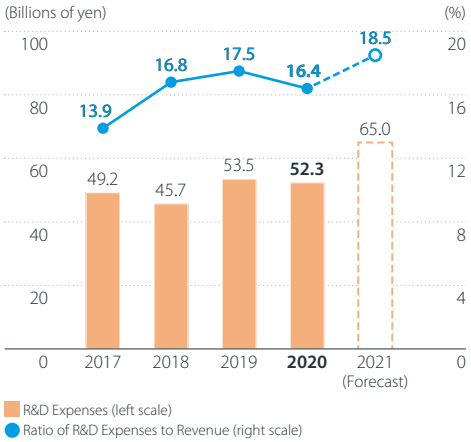


Financial Highlights

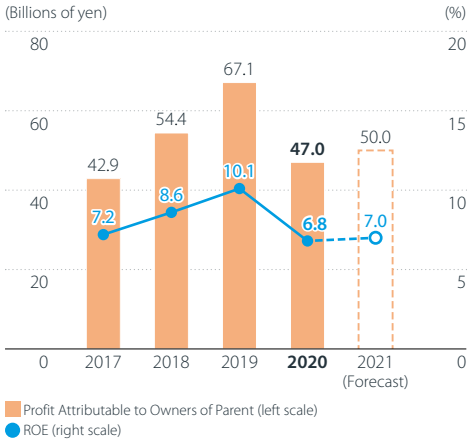
Revenue*1



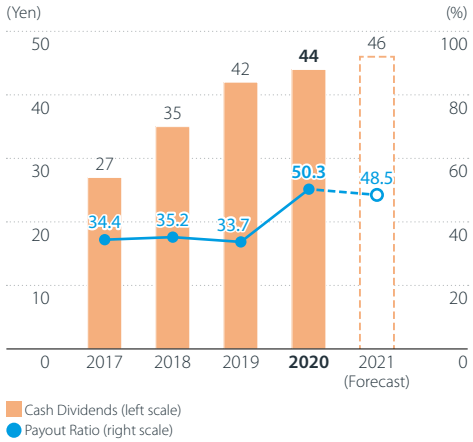
R&D Expenses*1 / Ratio of R&D Expenses to Revenue



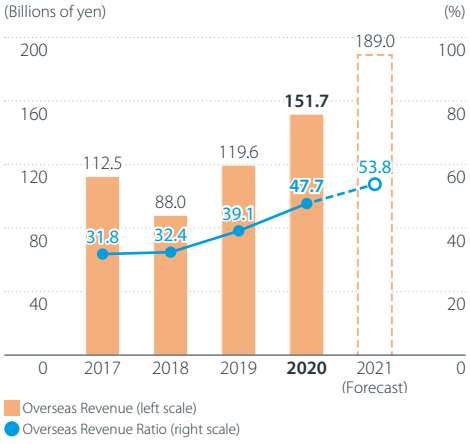
Profit Attributable to Owners of Parent / Return on Equity (ROE)



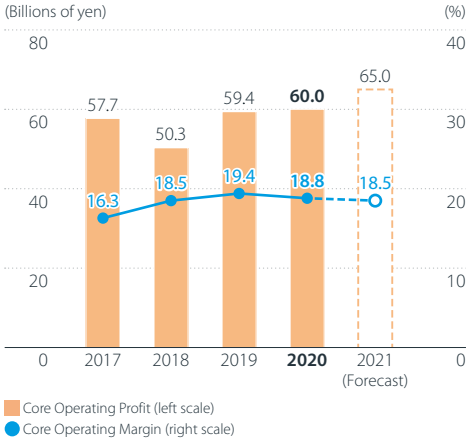
Cash Dividends / Payout Ratio *2



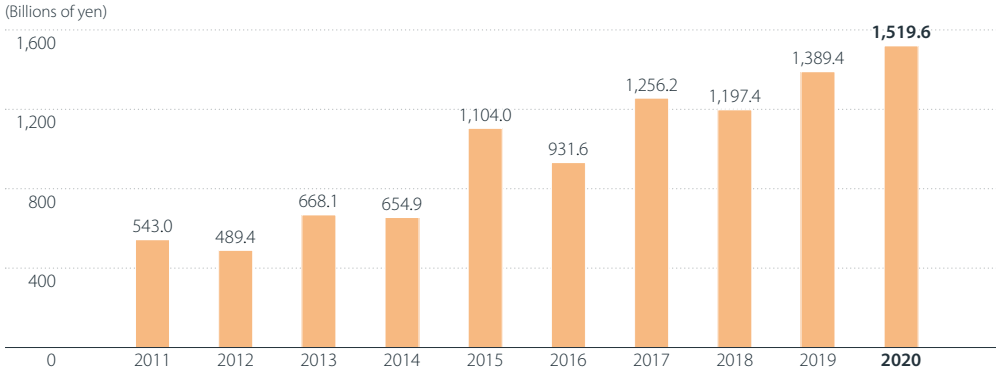
Overseas Revenue*1 / Overseas Revenue Ratio



Core Operating Profit*1 / Core Operating Margin



Market Capitalization

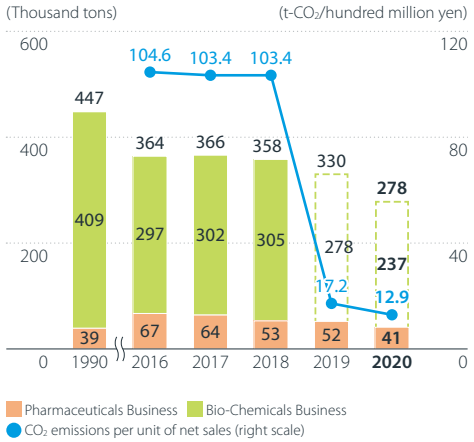


*1 Revenue, Overseas revenue, R&D expenses and Core Operating Profit on and after 2018 represent figures in the continued operation (Pharmaceuticals) excluding the discontinued operation (Bio-chemicals).
*2 Dividend payout ratio for 2021 is the ratio of dividends to core earnings (Profit attributable to owners of parent – Other income and expenses (excluding tax effects)).

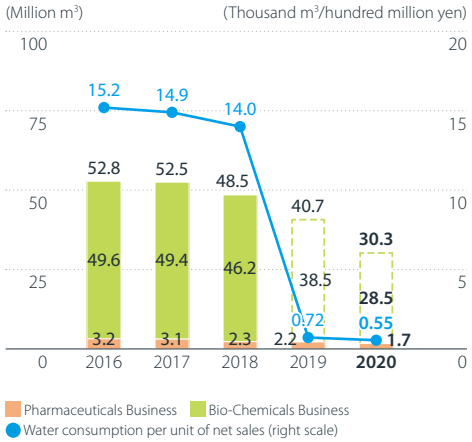
ESG Highlights

Please see ESG Data Collection for details.
https://www.kyowakirin.com/sustainability/esg_data/index.html

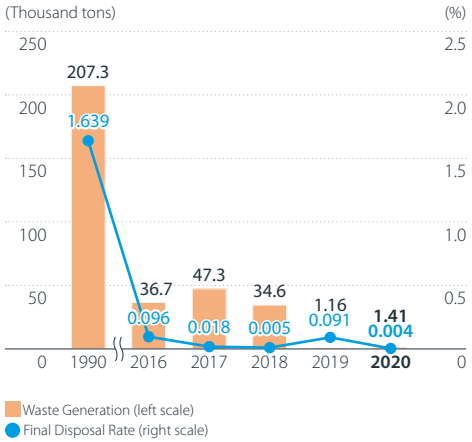
CO_2 Emissions *1,2



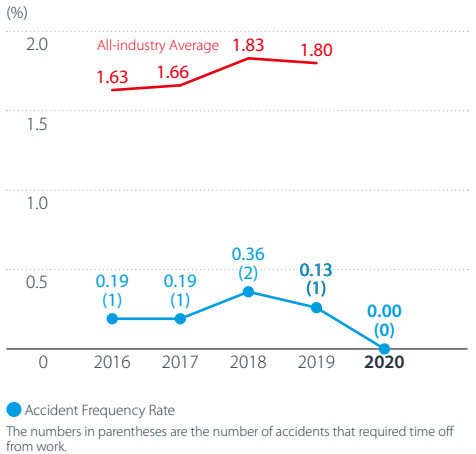
Water Use *1,2



Waste Generation *3

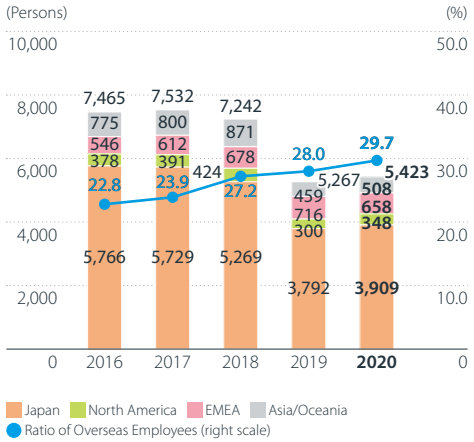


Accident Frequency Rate *4,5

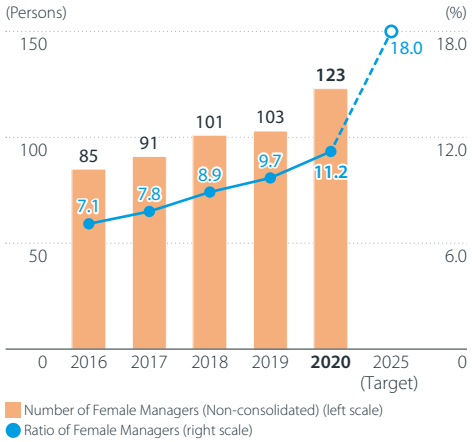


The numbers in parentheses are the number of accidents that required time off from work.

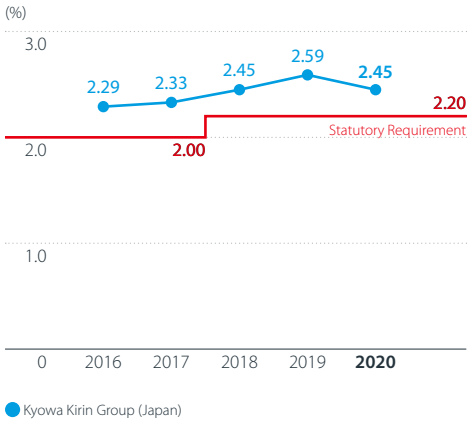
Number of Employees / Ratio of Overseas Employees



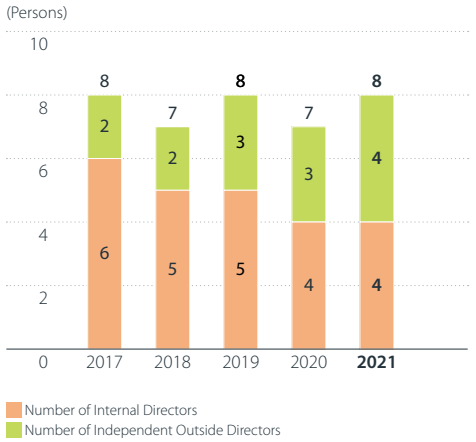
Number of Female Managers / Ratio of Female Managers



Ratio of Workers with Disabilities *6



Number of Directors



*1 Covers plants and research laboratories worldwide. Figures up to and including 2018 are for Pharmaceuticals and Bio-Chemicals; figures for 2019 and later are for Pharmaceuticals only. The dotted lines for 2019 and 2020 show the Bio-Chemicals business.
*2 Net Sales used for calculating per-unit data for 2015 are based on J-GAAP and after 2016 on IFRS.
*3 It covers plants and research laboratories in Japan. Figures for 2018 and prior are for Pharmaceuticals and Bio-Chemicals, and those for 2019 are for Pharmaceuticals only.
*4 The plants and research laboratories in Japan of Kyowa Kirin, Kyowa Medex (excluded in 2018 due to deconsolidation), Kyowa Hakko Bio and Kyowa Pharma Chemical are covered until 2018. In 2019, all locations are covered.
*5 The rates indicate the number of casualties from fatal lost-time accidents per million working hours.
*6 As of June each year.

Review of FY2016-2020 Medium Term Business Plan

Strive and Leap for GSP

During the FY2016-2020 Medium Term Business Plan, we launched all three global strategic products in overseas markets, progressed late-phase clinical studies for next-generation products in our development pipeline, and expanded the research pipeline.

We pushed back the timeframe for achieving two of the plan's quantitative targets – core operating profit of ¥100 billion and ROE of 10% or higher. However, the overseas revenue ratio – a key indicator of the Group's transformation into a Global Specialty Pharmaceutical Company – reached 48%, well above the 28% in the plan's first year.

During the new Medium Term Business Plan, we aim to achieve the postponed targets for core operating profit and ROE by steadily balancing investment in growth with cost control to maintain the Group's growth momentum as a Global Specialty Pharmaceutical Company.

Quantitative Summary

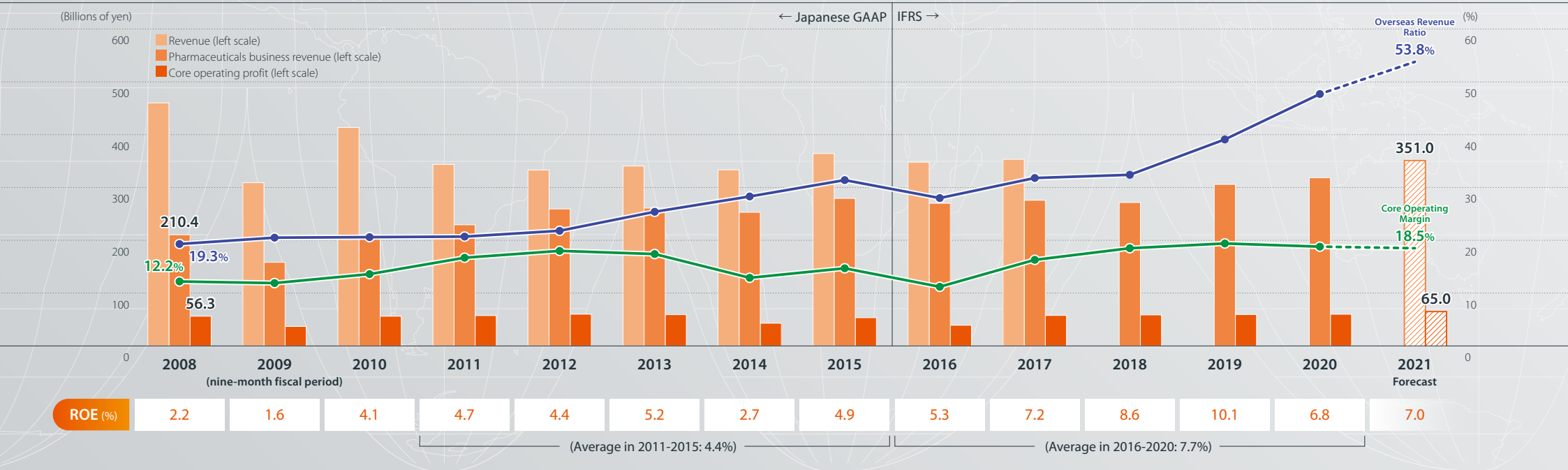
	Targets (when plan was formulated)	Actual
Sustainable Growth Target	Core operating profit **¥100 billion** or more	**¥60.0 billion**
Transformation into GSP Target	Overseas revenue ratio **50%**	**48%**
Increasing Shareholder Value Target	ROE **10%** or higher	**6.8%**

STEP 1 2008-2009 **Integrated our strengths**
- Kyowa Hakko Kirin formed
- Sold food products business

STEP 2 2010-2012 **Select & Concentrate**
- Sold chemicals business
- Acquired ProStrakan
- Launched Poteligeo in Japan

STEP 3 2013-2015 **Strive toward GSP**
- Launched Nouriast in Japan
- Acquired Archimedes

STEP 4 2016-2020 **Leaping forward for GSP**
- Launched Crysvita in the US and Europe
- Launched Poteligeo in the US and Europe
- Sold diagnostics business
- Sold biochemical business
- Launched Nourianz in the US
- Launched Crysvita in Japan



ROE (%)	2.2	1.6	4.1	4.7	4.4	5.2	2.7	4.9	5.3	7.2	8.6	10.1	6.8	7.0

(Average in 2011-2015: 4.4%) (Average in 2016-2020: 7.7%)

CSV Materiality Initiatives

Under its previous FY2016-2020 Medium Term Business Plan, the Kyowa Kirin Group identified issues that need to be tackled with top priority as CSV material issues in view of their impacts on social sustainability and the Group's business. The issues identified have been reflected in the annual business plans of Group companies and each department.
The status of initiative implementation is monitored by the designated committee and reported to the Board of Directors.

Category	CSV Materiality	Performance indicators	Key outcomes for FY2020
Organizational Governance	● Foster a corporate culture in line with the Core Values ● Promote compliance ● Strengthen risk management ● Strengthen the organizational governance system	Promoting our management philosophy, values and Code of Conduct (Employee awareness survey to gauge level of understanding) (1) "Good understanding of management philosophy" (2) "Good understanding of values" (3) "Understanding of Code of Conduct content"	(1) 83% (2) 83% (3) 89%
		Addressing material risks	P67
		Whistle-blower system (1) Number of reports (2) Awareness at overseas subsidiaries	(1) 29 (2) 95% P48
		Strengthening compliance and risk management systems	Established Group/Regional CSR Committees P48,49
		Establishing a system for collecting and sharing information	Governance-risk-compliance platform* in operation in Japan and being introduced overseas * An integrated risk management platform with centralized risk and incident information and workflow functions
		External ESG evaluation	P44
Human Rights	● Respect human rights	International issue checklist	• Conducted supplier surveys while also investigating several companies suspected of incurring human rights risks and confirmed that there were no problems (JP) • Checked human rights issues by referring to external assessment and other tools (JP) • Provided an overview of human rights policy and due diligence during human rights training
Labor Practices	● Promote employee health ● Promote diversity of employee and work style ● Develop employee competencies ● Ensure employee safety	Employees undergoing regular health checkups	Employees undergoing health checkups 99.9% High-risk individuals receiving medical care 95.7% P37
		Response implementation rate after regular health checkups	
		Ratio of female managers	11.2% P38,55
		Ratio of employees with disabilities	2.45% P55
		Employee awareness survey results compared with the previous year	Percentage of affirmative responses to the employee awareness survey question: "my direct supervisor supports my learning and growth" 70% (+3% YoY)
		Level of traffic safety measure achievement	• Leased vehicle autonomous emergency braking system installation rate 100% • Leased vehicle drive recorder installation rate 100% • Communication-type drive recorder installation rate for new employees and inexperienced drivers 100%
		Number of accidents (sum total that did and did not require time off from work)	1 accident: 0 accidents that required time off from work; 1 accident that did not require time off from work P55
Environment	● Prevent global warming ● Preserve water resources	Reducing CO_2 emissions (1) CO_2 emissions (2) Per-unit energy consumption	(1) 41,105 tons (2) Reduced by 2.9% from previous year P32,55
		Reducing water usage (1) Water usage (2) Per-unit water consumption	(1) 1,745,675 m^3 (2) Reduced by 21% from previous year P55
		Final disposal rate for industrial waste	0.004% P55
		Number of environmental accidents (Number of environmental accidents that had a nominal or greater impact on the Kyowa Kirin brand and a minimal or greater impact on Kirin Group companies.)	0
Fair Operating Practices	● Ensure supply chain compliance ● Prevent bribery ● Ensure transparency in relationships with medical institutions ● Provide appropriate pharmaceutical information ● Ensure reliability in clinical research	Supply chain due diligence implemented across the entire Kyowa Kirin Group	• Implemented supplier due diligence managed by the Japan region and additionally surveyed suppliers with issues
		Degree of initiative implementation based on the Kyowa Kirin Group Policy for Anti-Bribery Measures	• Monitored through risk management initiatives • Conducted Group-wide training through e-learning • Investigated the bribery risks of third-party vendors
		Degree of information disclosure regarding the nature of value provided to healthcare professionals, healthcare organizations and patient organizations by the date specified under relevant guidelines	• Completed establishment of a global collaboration system • Completed in 15 countries, including disclosure under new laws and regulations such as the Clinical Research Act
		Degree of initiative implementation based on the guidelines on activities to provide sales information on prescription drugs	• Conducted the committee meetings for supervision of activities to provide sales information on prescription drugs (two times during the year) • Conducted CSR trainings (quarterly) • Conducted new monthly case study-oriented trainings (monthly) • Monitored unapproved or off-label drugs • Established a system for reviewing lecture slide via outsourcing and undertook seminar monitoring
		Management of the Kyowa Kirin Group Clinical Research Policy and degree of policy initiative implementation	• Major revision of the Kyowa Kirin Group Clinical Research Policy • Review by the research ethical review committee (six times during the year) • Conducted research ethics training (once during the year) • Monitored deviation prevention initiative implementation (once during the year)
Consumer Issues	● Create a variety of products and services with social value ● Provide high-quality and safe products and services	Become a Global Specialty Pharmaceutical Company (GSP) by supplying new proprietary medicines to patients worldwide	1) Achieved more than three multi-regional launches of new proprietary medicines 2) Progress made in the launch of products identified in 1) above with sales extending to a cumulative total of more than 50 countries
		Establish a Group quality assurance system including management of contract manufacturers	P27,31
Community Involvement and Development	● Contribute to communities ● Contribute to advances in life sciences	Degree of initiative implementation based on the Kyowa Kirin Group Community Involvement Activities Policy	• Engaged in community involvement activities utilizing the unique characteristics of each site • Provided donations and in-kind support for COVID-19-related medical activities
			• Provided donations for research and academic activities • Engaged in disease awareness activities

Pipeline (As of December 31, 2020)

antibody protein small molecule ◎New Molecular Entity Progress with approvals in Jan-Dec 2020

Nephrology

As of December 31, 2020

Code Name (Generic name)/Formulation	Mechanism of Action	Indication	Area	Stage	In-House or Licensed
				Ph I / Ph II / Ph III / Filed / Approved	
KRN321 (Darbepoetin Alfa)/Injection	Long-Acting Erythropoiesis Stimulating Agent	Renal Anemia (on Hemodialysis)	CN	Approved	Kirin-Amgen
KHK7580 (Evocalcet)/Oral	Calcimimetic	Secondary Hyperparathyroidism	CN and Asia	Ph III	Mitsubishi Tanabe Pharma
◎RTA 402 (Bardoxolone Methyl)/Oral	Antioxidant Inflammation Modulator	Diabetic Kidney Disease	JP	Ph III	Reata
KW-3357 (Antithrombin Gamma)/Injection	Recombinant Human Antithrombin	Preeclampsia	JP	Ph II	In-House
KHK7791 (Tenapanor)/Oral	NHE3 inhibitor	Hyperphosphatemia Under Maintenance Dialysis	JP	Ph III	Ardelyx

Oncology

KW-0761 (Mogamulizumab)/Injection	Anti-CCR4 Humanized Antibody	Mycosis Fungoides and Sézary Syndrome	KR, CH, SA and AU	Approved	In-House
◎KHK2375 (Entinostat)/Oral	HDAC Inhibitor	Breast Cancer	JP	Ph III	Syndax
KRN125 (Pegfilgrastim)/Injection	Long-Acting Granulocyte Colony-Stimulating Factor	Mobilization of Hematopoietic stem cell into Peripheral blood	JP	Ph II	Kirin-Amgen
		Automated Injection Device for Decreasing the Incidence of Febrile Neutropenia in Patients Receiving Cancer Chemotherapy	JP	Ph I	
◎KHK2455/Oral	IDO 1 Inhibitor	Solid Tumor	NA	Ph I	In-House
		Urothelial carcinoma	NA	Ph I	In-House
◎ME-401 (Zandelisib)/Oral	PI3Kδ inhibitor	Indolent B-cell Non-Hodgkin's Lymphoma	JP	Ph III	MEI Pharma
		Follicular Lymphoma	NA, EU, Asia and Oceania	Ph III	
		B-cell malignancies	NA	Ph I	

Glossary

Phase I Clinical Trial	Studies in small numbers of healthy people (patients in some cases) to verify safety issues including side effects.
Phase II Clinical Trial	Studies in small numbers of patients to verify effective and safe dosage and regimen.
Phase III Clinical Trial	Studies in large numbers of patients to confirm efficacy and safety in comparison with standard drugs or placebo.

* All trials are conducted under supervision of clinical doctors and with the consent of participants.

Immunology/Allergy

As of December 31, 2020

Code Name (Generic name)/Formulation	Mechanism of Action	Indication	Area	Stage	In-House or Licensed
				Ph I / Ph II / Ph III / Filed / Approved	
KHK4827 (Brodalumab)/Injection	Anti-IL-17 Receptor A Fully Human Antibody	Psoriasis	MY, CN and MO	Approved	Kirin-Amgen
		Psoriatic arthritis	TW	Approved	
		Ankylosing spondylitis and non-radiographic axial spondyloarthritis	JP	Approved	
		Systemic Sclerosis	JP	Ph III	
		Palmoplantar Pustulosis	JP	Ph III	
◎KHK4083/Injection	Anti-OX40 Fully Human Antibody	Atopic Dermatitis	JP, NA and EU	Ph II	In-House
◎ASKP1240 (Bleselumab)/Injection	Anti-CD40 Fully Human Antibody	Recurrence of Focal Segmental Glomerulosclerosis (FSGS) in de novo kidney transplant recipients	NA	Ph II	In-House

Central Nervous System

KW-6002 (Istradefylline)/Oral	Adenosine A_{2A} Receptor Antagonist	Parkinson's Disease	EU	Filed	In-House
KW-0761 (Mogamulizumab)/Injection	Anti-CCR4 Humanized Antibody	HTLV-1 associated myelopathy (HAM)	JP	Ph III	In-House
◎KW-6356/Oral	Adenosine A_{2A} Receptor Antagonist	Parkinson's Disease	JP	Ph II	In-House
◎KHK6640/Injection	Anti-Amyloid Beta Peptide Antibody	Alzheimer's Disease	JP and EU	Ph I	Immunas Pharma

Other

KRN23 (Burosumab)/Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemia (XLH)	CH, KW, HK, TW, OM and QA	Approved	In-House
			BH, AU, CN, SA and SG	Filed	
		Adult X-linked Hypophosphatemia (XLH)	EU	Approved	
		FGF23-Related Hypophosphatemic Rickets and Osteomalacia	KR	Approved	
		Tumor Induced Osteomalacia (TIO)	US	Approved	
			EU and CN	Filed	
AMG531 (Romiplostim)/Injection	Thrombopoietin Receptor Agonist	Aplastic Anemia Who Have Had an Inadequate Response to Conventional Therapy	TW	Approved	Kirin-Amgen
			Asia	Ph III	
		Idiopathic (Immune) Thrombocytopenic Purpura	CN	Filed	
		Aplastic Anemia Who Were Previously Untreated with Immunosuppressive Therapy	JP and Asia	Ph III	
KW-3357 (Antithrombin Gamma)/Injection	Recombinant Human Antithrombin	Disseminated Intravascular Coagulation, Congenital Antithrombin Deficiency	EU	Ph I	In-House
KHK4951		Wet Age-Related Macular Degeneration	JP	Ph I	In-House

Financial Information

WEB link

Key Financial Data

Cash Flow Data

Financial Summary

Adoption of International Financial Reporting Standards

The Group has adopted the International Financial Reporting Standards ("IFRS") since FY2017 to enhance the international comparability of its financial reporting for the capital market, and unify the process of the Group's accounting. In addition, financial data for FY2016, the fiscal year prior to the adoption of IFRS, is reformulated and displayed in an IFRS format.

Adoption of "core operating profit" (IFRS)

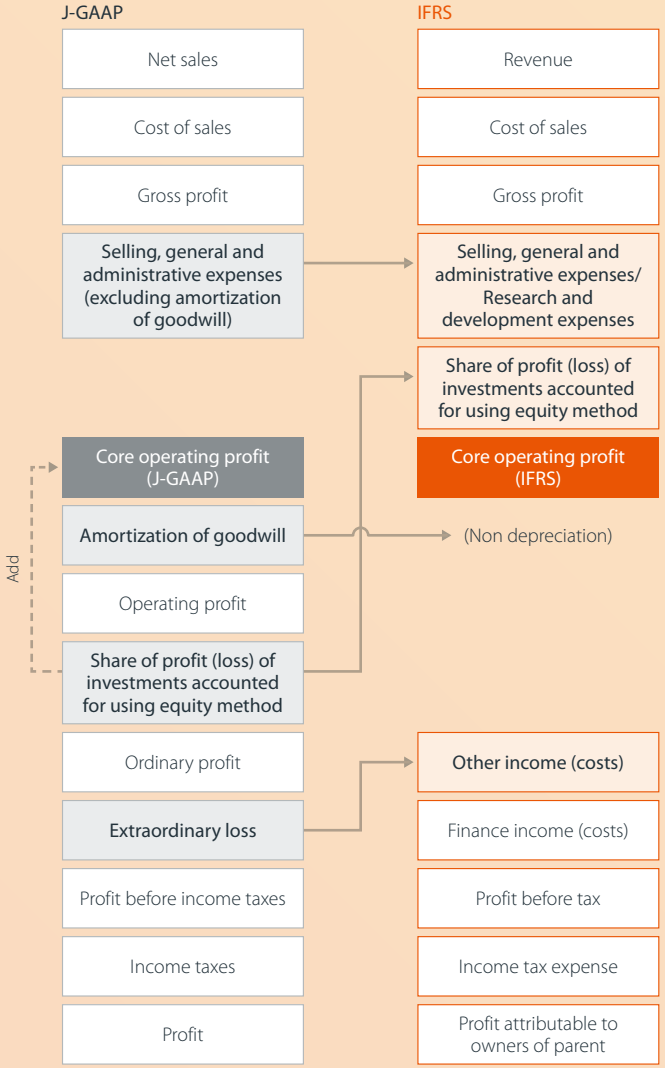
The Group has adopted "core operating profit" (IFRS) as an indicator showing recurring profitability from operating activities.

* Gross profit – Selling, general and administrative expenses – Research and development expenses + Share of profit (loss) of investments accounted for using equity method

Bio-Chemicals Business

Following the conclusion of an agreement on February 5, 2019 in which Kyowa Kirin Co., Ltd. (the "Company") agreed to transfer 95% of the shares of its consolidated subsidiary Kyowa Hakko Bio Co., Ltd. to Kirin Holdings Company, Limited, the Bio-Chemicals business is categorized as a discontinued operation from FY2019. Accordingly, the consolidated financial statements for FY2018 have been restated to reflect the change, and from FY2019, the Group has only one reportable segment: the "Pharmaceuticals business."

Major differences between IFRS and J-GAAP



Eleven-Year Selected Financial Data

	IFRS					J-GAAP						IFRS
	(Millions of yen)					(Millions of yen)						(Thousands of U.S. dollars*1)
For the Year:	**2020/12**	2019/12	2018/12	2017/12	2016/12	2015/12	2014/12	2013/12	2012/12	2011/12	2010/12	**2020/12**
Revenue*2	**¥ 318,352**	¥ 305,820	¥ 271,510	¥ 353,380	¥ 347,956	¥ 364,316	¥ 333,446	¥ 340,611	¥ 333,158	¥ 343,722	¥ 413,738	**$3,075,268**
Gross profit*2	**237,912**	226,200	198,149	224,321	214,592	225,393	205,904	212,761	210,690	197,555	190,979	**2,298,224**
Selling, general and administrative expenses (including R&D expenses)*2	**178,922**	170,827	147,745	162,113	163,124	181,628	169,731	160,987	157,785	150,940	145,568	**1,728,379**
Core Operating Profit (J-GAAP: Operating profit)*2	**59,955**	59,353	50,306	57,731	39,116	43,765	36,173	51,773	52,905	46,614	45,410	**579,159**
Profit attributable to owners of parent	**47,027**	67,084	54,414	42,899	30,450	29,774	15,898	30,078	24,199	25,608	22,197	**454,284**
Capital expenditure and investments in intangible assets*2	**34,782**	22,586	13,489	20,714	33,270	20,039	29,487	35,183	27,808	19,697	29,374	**335,997**
Depreciation and amortization*2	**20,466**	18,797	16,243	22,032	23,784	23,126	23,885	21,592	20,904	22,833	22,188	**197,700**
R&D expenses*2	**52,312**	53,511	45,659	49,216	52,929	51,604	47,737	43,682	44,808	47,961	44,210	**505,329**
Cash Flows:												
Net cash provided by operating activities	**¥ 39,502**	¥ 53,655	¥ 56,181	¥ 64,902	¥ 66,881	¥ 66,526	¥ 19,377	¥ 56,884	¥ 59,134	¥ 40,634	¥ 64,189	**$ 381,585**
Net cash provided by (used in) investing activities	**252,559**	(933)	(39,929)	(45,265)	(49,824)	(57,747)	16,805	(77,163)	(98,772)	18,460	(32,373)	**2,439,710**
Net cash provided by (used in) financing activities	**(26,003)**	(47,371)	(16,501)	(18,287)	(13,871)	(14,060)	(37,184)	(12,579)	(19,189)	(30,740)	(14,446)	**(251,188)**
Cash and cash equivalents at the end of the period	**287,019**	20,762	15,867	14,685	13,076	12,784	17,013	19,242	50,334	107,555	79,882	**2,772,596**
At Year-End:												
Total current assets	**¥ 442,482**	¥ 448,610	¥ 385,844	¥ 348,150	¥ 314,999	¥ 324,433	¥ 283,192	¥ 329,320	¥ 303,988	¥ 284,217	¥ 288,852	**$4,274,359**
Total assets	**801,290**	784,453	741,982	708,295	683,801	720,764	719,135	719,257	679,342	658,873	695,862	**7,740,437**
Total current liabilities	**80,749**	87,530	80,459	78,409	88,072	84,823	85,182	85,076	85,774	78,465	102,483	**780,031**
Interest-bearing debt	**17,842**	17,185	2,527	2,814	7,000	4,840	4,868	6,207	5,699	6,042	7,515	**172,351**
Equity	**698,396**	678,250	649,621	616,028	577,036	614,858	605,368	595,415	555,898	540,023	544,992	**6,746,481**
Number of employees	**5,423**	5,267	7,242	7,532	7,465	7,435	7,424	7,152	7,243	7,229	7,484	—
Per Share Data:	(Yen)					(Yen)						(U.S. dollars*1)
Profit attributable to owners of parent*3	**¥ 87.56**	¥ 124.57	¥ 99.40	¥ 78.38	¥ 55.65	¥ 54.40	¥ 29.05	¥ 54.95	¥ 44.12	¥ 45.16	¥ 38.96	**$ 0.846**
Equity attributable to owners of parent	**1,300.12**	1,263.16	1,186.65	1,125.56	1,054.48	1,122.80	1,105.44	1,085.17	1,013.61	970.16	954.58	**12.559**
Cash dividends	**44**	42	35	27	25	25	25	25	20	20	20	**0.995**
Common Stock Price Range (Per share):												
High	**¥ 3,060**	¥ 2,594	¥ 2,478	¥ 2,227	¥ 2,098	¥ 2,321	¥ 1,510	¥ 1,256	¥ 970	¥ 953	¥ 1,040	**$ 29.56**
Low	**1,849**	1,674	1,894	1,515	1,412	1,094	1,006	833	757	628	773	**17.86**
Stock Information (Thousands of shares):												
Number of common stock issued	**540,000**	540,000	576,484	576,484	576,483	576,483	576,483	576,483	576,483	576,483	576,483	—
Weighted average number of common stock issued	**537,109**	538,542	547,412	547,290	547,224	547,285	547,348	547,391	548,449	567,029	569,711	—
Financial Ratios:	(%, except EBITDA)					(%, except EBITDA)						
Return on assets (ROA)	**5.9**	8.8	7.5	6.2	4.4	4.1	2.2	4.3	3.6	3.8	3.2	—
Core operating return on assets (J-GAAP: Operating profit)*2	**7.6**	7.8	6.9	8.3	5.6	6.1	5.0	7.4	7.9	6.9	6.5	—
Return on equity attributable to owners of parent (ROE)	**6.8**	10.1	8.6	7.2	5.3	4.9	2.7	5.2	4.4	4.7	4.1	—
Ratio of equity attributable to owners of parent to total assets	**87.2**	86.5	87.6	87.0	84.4	85.2	84.1	82.6	81.7	81.8	78.2	—
Core operating margin (J-GAAP: Operating profit)*2	**18.8**	19.4	18.5	16.3	11.2	12.0	10.8	15.2	15.9	13.6	11.0	—
EBITDA*2, *4 (Millions of yen)	**72,974**	63,750	83,421	78,220	66,981	78,018	64,101	83,190	78,160	79,864	74,614	—
Payout ratio*5	**50.3**	33.7	35.2	34.4	44.9	35.1	54.4	34.8	32.8	32.5	36.2	—

*1 U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥103.52=U.S.$1, the approximate exchange rate at December 31, 2020.

*2 Figures on and after 2018 represent figures in the continued operation (Pharmaceuticals) excluding the discontinued operation (Bio-chemicals).

*3 Profit attributable to owners of parent per share is based upon the weighted average number of shares of common stock outstanding during each year.

*4 EBITDA = Profit before tax + Interest expenses + Depreciation and amortization (+ Amortization of goodwill)

*5 Under J-GAAP, consolidated payout ratios are calculated using net income before the deduction of amortization of the goodwill that resulted from the reverse acquisition in April 2008 (Kirin Pharma share transfer).

Management's Discussion & Analysis

Figures presented in these materials have been rounded off.

Subsidiaries Included in the Scope of Consolidation

The number of consolidated subsidiaries in the Kyowa Kirin Group stood at 37 as of December 31, 2020. Strakan International S.A. has been excluded from the scope of consolidation due to an absorption-type merger with Kyowa Kirin International plc.

Income

(Billions of yen)

	Fiscal year ended December 31, 2020	Fiscal year ended December 31, 2019	Change
Revenue	**318.4**	305.8	12.5
Core Operating Profit	**60.0**	59.4	0.6
Profit attributable to owners of parent	**47.0**	67.1	–20.1

Revenue and Core Operating Profit

Revenue increased year on year, mainly reflecting steady growth for global strategic products in North America and EMEA and strong sales in Asia, primarily in China, despite the impact of lower revenue in Japan due to reductions to NHI drug prices and the switch to Darbepoetin Alfa Injection Syringe [KKF], an authorized generic version of renal anemia treatment Nesp. Foreign exchange factors had a negative impact on revenue of ¥2.9 billion.

Core operating profit increased year on year, reflecting a rise in gross profit due to an increase in overseas revenue, despite higher selling, general and administrative expenses and a decline in share of profit (loss) of investments accounted for using equity method. Foreign exchange factors had a negative impact on core operating profit of ¥1.3 billion.

Profit Attributable to Owners of Parent

Profit attributable to owners of parent decreased, mainly due to the absence of profit from discontinued operations recorded in the previous fiscal year, which outweighed a decline in business restructuring expenses and impairment losses, in addition to growth in core operating profit.

Revenue by Regional Controlling Company

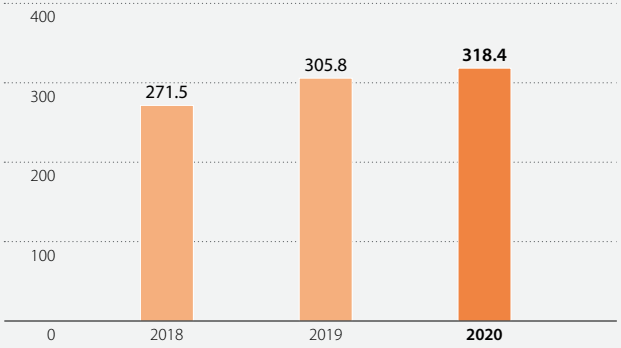
Revenue by regional controlling company is presented in the table below.

	(Billions of yen)		(Millions of U.S. dollars*)
	2020/12	2019/12	**2020/12**
Japan	**¥159.9**	¥174.7	**$1,545**
North America	**59.9**	39.0	**579**
EMEA	**48.4**	42.9	**467**
Asia/Oceania	**25.9**	23.1	**250**
Others	**24.2**	26.0	**234**
Total consolidated revenue	**¥318.4**	¥305.8	**$3,075**

* * U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥103.52= U.S.$1, the approximate exchange rate at December 31, 2020.

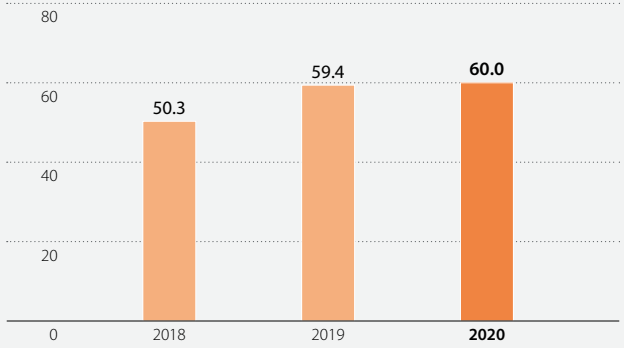
Revenue

(Billions of yen)



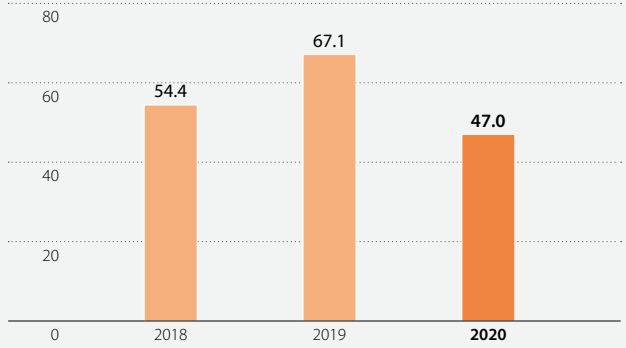
Core Operating Profit

(Billions of yen)



Profit Attributable to Owners of Parent

(Billions of yen)



Japan

Despite higher sales for new product groups, revenue decreased year on year due to a significant impact from the switch to Darbepoetin Alfa Injection Syringe [KKF], an authorized generic version of renal anemia treatment Nesp which went out of patent, and reductions to NHI drug prices in October 2019 and April 2020.

- Darbepoetin Alfa Injection Syringe [KKF] rapidly replaced Nesp for the treatment of renal anemia.
- Duvroq, an oral treatment for renal anemia, has steadily gained ground in the market since launch in August 2020.
- Revenue from Patanol, anti-allergy eye drops, and Allelock, an anti-allergy agent, decreased due to lower pollen counts and restrictions on clinician visits during the COVID-19 pandemic.
- Revenue from Orkedia, a treatment for secondary hyperparathyroidism, increased. Meanwhile, revenue from Regpara, another treatment for secondary hyperparathyroidism, declined due to the switch to Orkedia and the impact of rival products.
- Revenue from Romiplate, a treatment for chronic idiopathic thrombocytopenic purpura, increased after the drug received approval in June 2019 for the treatment of patients with aplastic anemia who do not respond adequately to conventional therapies.
- G-Lasta, an agent for decreasing the incidence of febrile neutropenia, and Rituximab BS [KHK], an anticancer agent, both registered firm growth in revenue.
- Crysvita, a treatment for FGF23-related diseases, and Haruropi, a Parkinson's disease treatment patch, have steadily gained ground in the market since launch in December 2019.

North America

Revenue increased year on year due to firm growth for global strategic products.

- Revenue from Crysvita, a treatment for X-linked hypophosphatemia, has been growing steadily since its launch in 2018. The drug received approval for the additional indication of tumor induced osteomalacia in June 2020.
- Revenue from Poteligeo, an anticancer agent, was flat year on year, reflecting the impact of the COVID-19 pandemic.
- Nourianz (product name in Japan: Nouriast), an antiparkinsonian agent launched in October 2019, has been penetrating the market favorably.

EMEA

Revenue increased year on year due to firm growth for global strategic products.

- Revenue from Crysvita, a treatment for X-linked hypophosphatemia, has been growing steadily, in line with an increase in the number of countries where it has been launched since its first launch in 2018. Sales approval for the extended indication for older adolescents and adults was received in September 2020.
- Anticancer agent Poteligeo has been gaining ground in the market, in line with steady growth in the number of countries where it has been launched, including Germany in June 2020.

Asia/Oceania

Revenue increased year on year, led by strong sales in China.

- Revenue from Regpara, a treatment for secondary hyperparathyroidism, increased year on year due to market expansion in China.

Others

Revenue decreased year on year.

- The decline reflected a contraction in other income from other business activities including contracted manufacturing, outweighing an increase in technology out-licensing revenue, including royalty income from AstraZeneca for benralizumab.

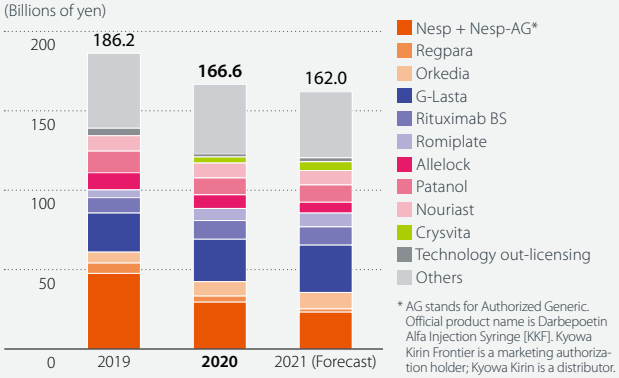
Cash Flow

Cash and cash equivalents as of December 31, 2020 totaled ¥287.0 billion, an increase of ¥266.3 billion from ¥20.8 billion as of December 31, 2019, mainly reflecting the transfer of all loans receivable from parent to loans with durations of three months or less, which are included in the scope of cash and cash equivalents.

The main contributing factors affecting cash flow during the current fiscal year were as follows:

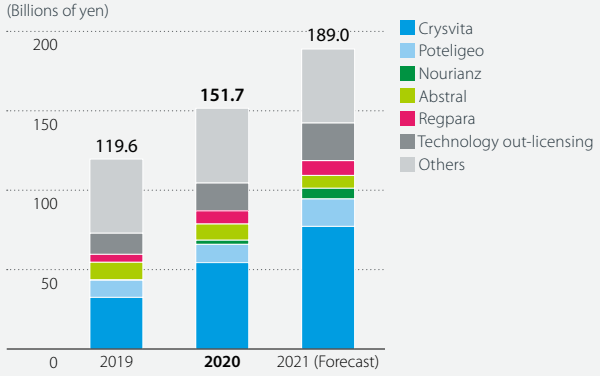
- Net cash provided by operating activities was ¥39.5 billion, a 26.4% decrease compared with the previous fiscal year. Major inflows included profit before tax from continuing operations of ¥52.3 billion and depreciation and amortization of ¥20.5 billion. Major outflows included income taxes paid of ¥28.7 billion.
- Net cash provided by investing activities was ¥252.6 billion, compared with net cash used of ¥0.9 billion in the previous fiscal year. Major inflows included a net decrease of ¥285.6 billion in loans receivable from parent. Major outflows included ¥25.1 billion for purchase of intangible assets and ¥10.1 billion for purchase of property, plant and equipment.
- Net cash used in financing activities was ¥26.0 billion, a 45.1% decrease compared with the previous fiscal year. Major outflows included dividends paid of ¥23.6 billion.

Revenue of Major Items (Japan)

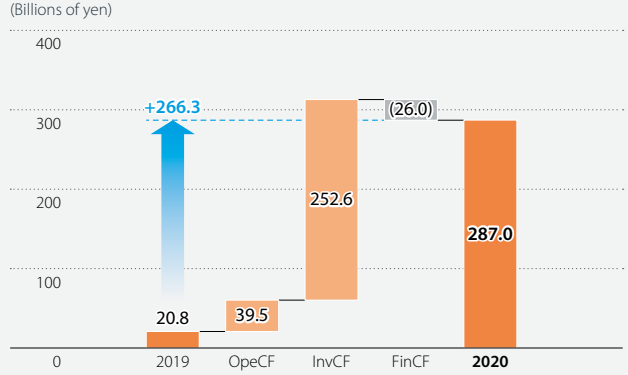


* AG stands for Authorized Generic. Official product name is Darbepoetin Alfa Injection Syringe [KKF]. Kyowa Kirin Frontier is a marketing authorization holder; Kyowa Kirin is a distributor.

Revenue of Major Items (Overseas)



Cash Flow



Financial Position

Assets

Assets as of December 31, 2020 totaled ¥801.3 billion, an increase of ¥16.8 billion compared with the end of the previous fiscal year.

- Non-current assets increased ¥23.0 billion to ¥358.8 billion, due mainly to increases for the purchase of intangible assets associated with in-licensing of development products and for deferred tax assets.
- Current assets fell ¥6.1 billion to ¥442.5 billion, due mainly to a decline in cash reserves (total of cash and cash equivalents and loans receivable from parent), partly reflecting the purchase of intangible assets, which outweighed large increases in cash and cash equivalents due to the transfer of the entire amount of loans receivable from parent to loans with durations of three months or less, which are included in the scope of cash and cash equivalents.

Liabilities

Liabilities as of December 31, 2020 totaled ¥102.9 billion, a decrease of ¥3.3 billion compared with the end of the previous fiscal year, due mainly to a decline in income taxes payable.

Equity

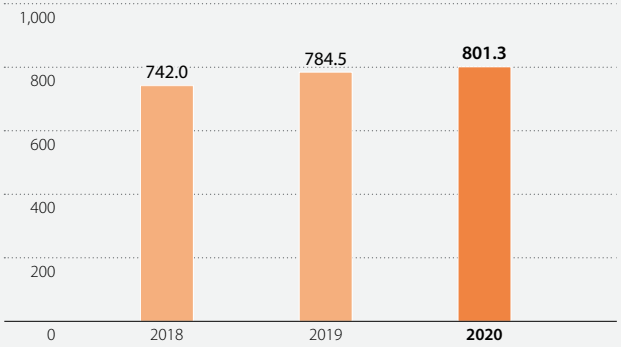
Equity as of December 31, 2020 totaled ¥698.4 billion, an increase of ¥20.1 billion compared with the end of the previous fiscal year, mainly reflecting profit attributable to owners of parent, which outweighed declines due to the payment of dividends and a decrease in exchange differences on translation of foreign operations resulting from the impact of exchange rates, etc. As a result, the ratio of equity attributable to owners of parent to total assets was 87.2%, an increase of 0.7 percentage points compared with the end of the previous fiscal year.

FY2016-2020 Medium Term Business Plan Targets

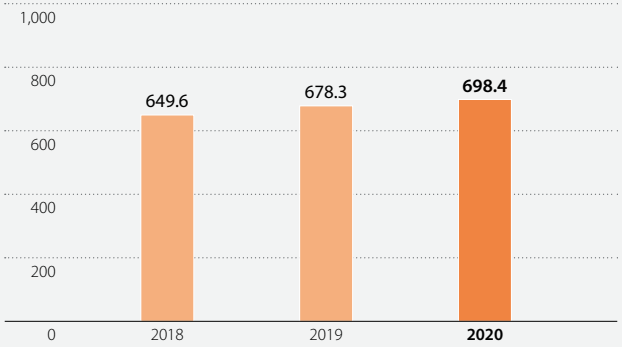
Aiming to make the leap to a Global Specialty Pharmaceutical Company (GSP) during the FY2016-2020 Medium Term Business Plan, Kyowa Kirin focused on achieving four strategic goals – improve global competitiveness, create innovation, continuously improve operational excellence and contribute to the health and well-being of people. In the US and Europe, we rolled out three global strategic products, Crysvita, Poteligeo and Nourianz, and also worked to maximize their value and put the necessary business platform in place for our GSP ambitions.

Of the three financial targets in the plan, we largely achieved our target for overseas revenue ratio, driven by the growth of the global strategic products. However, we missed our targets for core operating profit and ROE, due to advance use of selling, general and administrative expenses related to the buildout of our global sales network and business base, and the sale of shares in Kyowa Medex Co., Ltd. and Kyowa Hakko Bio Co., Ltd., which were not factored into our original plan. Under our new Medium Term Business Plan, which started in 2021, we aim to continue enhancing the Group's growth potential, capability to innovate and profitability in order to attain the remaining financial targets.

Total Assets



Equity



Targets and Actual of FY2016-2020 MTBP

		2020 Targets (J-GAAP)	2020 Actual (IFRS)
Sustainable Growth Target	Core operating profit	¥100 billion or more	¥60.0 billion
Transformation into GSP Target	Overseas revenue ratio	50%	48%
Increasing Shareholder Value Target	ROE	10% or higher	7%

R&D Expenses

R&D expenses for the fiscal year ended December 31, 2020 stood at ¥52.3 billion, a decrease of 2.2% compared to the previous fiscal year. The ratio of R&D expenses to sales for the year came to 16.4%, a decrease of 1.1 percentage points from 17.5% the previous fiscal year.

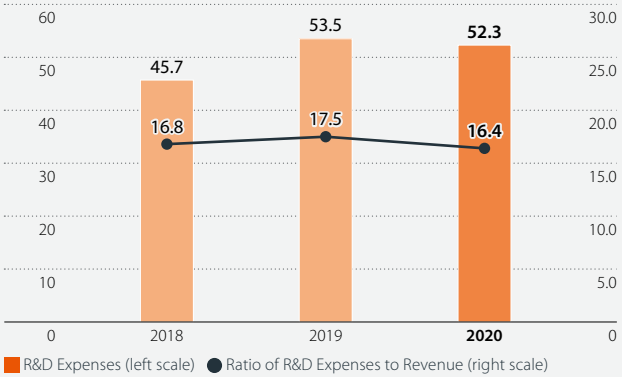
Capital Expenditure and Investments in Intangible Assets

As a basic policy, Kyowa Kirin implements capital expenditure strategically in consideration of achieving a desirable balance between it and depreciation. Capital expenditure and investments in intangible assets for the fiscal year ended December 31, 2020 stood at ¥34.8 billion, an increase of ¥12.2 billion (54.0%) compared to the previous fiscal year. Depreciation and amortization for the fiscal year amounted to ¥20.5 billion, an increase of ¥1.7 billion (8.9%) compared to the previous fiscal year.

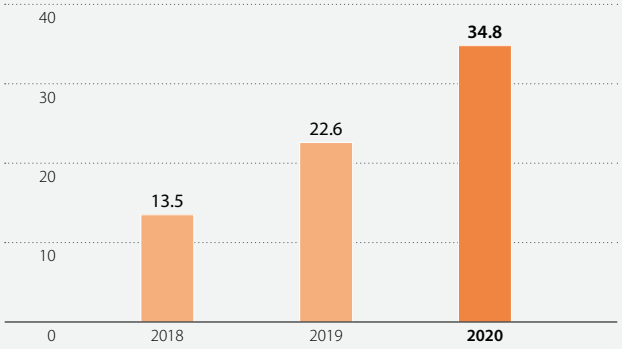
Per Share Data

Profit attributable to owners of parent per share for the fiscal year ended December 31, 2020 stood at ¥87.56 compared to ¥124.57 the previous year. Equity attributable to owners of parent per share on December 31, 2020 totaled ¥1,300.12 compared to ¥1,263.16 on December 31, 2019.

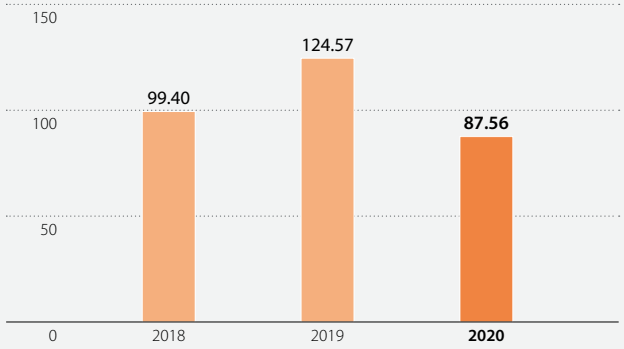
R&D Expenses



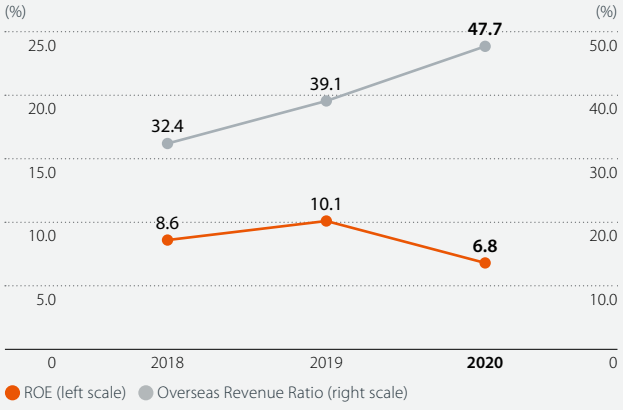
Capital Expenditure and Investments in Intangible Assets



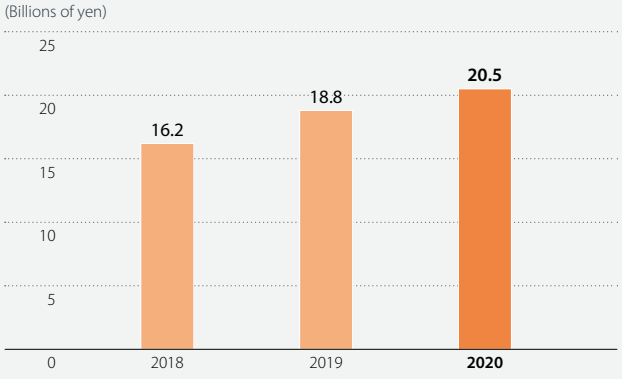
Profit Attributable to Owners of Parent per Share



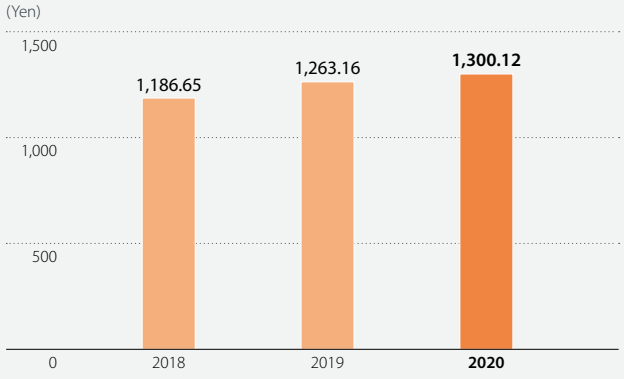
ROE/Overseas Revenue Ratio



Depreciation and Amortization



Equity Attributable to Owners of Parent per Share



Outlook for FY2021

For FY2021, we forecast consolidated revenue of ¥351.0 billion (up 10.3% compared with the current fiscal year), core operating profit of ¥65.0 billion (up 8.4%), profit before tax of ¥64.0 billion (up 22.5%) and profit attributable to owners of parent of ¥50.0 billion (up 6.3%).

- Although we expect impacts in Japan such as a reduction in NHI drug prices scheduled for April 2021, we see revenues increasing year on year driven by significant overseas growth for global strategic products Crysvita, Poteligeo and Nourianz. Moreover, although we anticipate an increase in selling, general and administrative expenses to maximize the value of global strategic products and to rapidly establish a competitive global business base, as well as a significant increase in R&D expenses related to progress in late-stage development projects (R&D expenses ratio will increase from 16% to 19%), we forecast an increase in core operating profit, supported by growth in overseas revenue.
- We forecast a year-on-year increase for profit before tax due to a decline in other expenses, as well as growth in core operating profit.
- We forecast year-on-year growth for profit attributable to owners of parent despite an expected increase in income tax expenses.
- We forecast net cash provided by operating activities will increase year on year, reflecting growth in profit before tax and a decline in income taxes paid.
- We forecast a year-on-year decline in net cash used by investing activities, reflecting a drop in cash used in the purchase of intangible assets. Regarding strategic partnering, M&A and other strategic investments for acquiring drug discovery technologies and pipelines, the Company will evaluate and conduct investment using a flexible approach.
- We forecast net cash used by financing activities will be largely unchanged year on year. Regarding the purchase of treasury shares and the sourcing of funds, we will remain flexible and take appropriate steps in response to the economic and funding environment.

Based on the above, we forecast cash and cash equivalents as of the end of FY2021 will increase year on year.

Profit Distribution

The Company regards the return of profits to shareholders as one of its key management priorities.

The basis of the Company's policy regarding the distribution of profits is to consistently pay dividends while taking into account a comprehensive range of factors, including consolidated results and the dividend payout ratio for each fiscal year, while also increasing retained earnings for future business development and other purposes. We plan to improve capital efficiency by flexibly considering with regards to the purchase of treasury shares. The Company intends to use internal reserves for investments that drive new growth, such as investment in research and development, capital expenditure and expanding the development pipeline, which are expected to enhance the Group's corporate value.

Regarding dividend policy, in the FY2016-2020 Medium Term Business Plan, the Company targeted a consolidated dividend payout ratio of 40% and set a policy of ensuring a stable and continuous increase in dividend payments in line with profit growth.

In accordance with the above-mentioned policy, the Board of Directors has approved a resolution to pay a year-end dividend of ¥22 per share for FY2020.

As a result, we have increased the dividend for four consecutive years. The annual dividend was determined to be ¥44 per share, an increase of ¥2 compared with the previous fiscal year, including an interim dividend of ¥22.

Outlook for FY2021

(Billions of yen)

	2020/12	2021/12 (Outlook)	Year-on-year change
Revenue	318.4	**351.0**	32.6
Core Operating Profit	60.0	**65.0**	5.0
Profit before tax	52.3	**64.0**	11.7
Profit Attributable to Owners of Parent	47.0	**50.0**	3.0

* Note: These forecasts assume average exchange rates of ¥105/US$, ¥140/British pound and ¥15.4/Chinese Yuan

	2020/12	2021/12 (Outlook)	Calculation method
ROE	7%	**7%**	Profit / Average beginning and ending equity
Revenue growth ratio	4%	**10%**	Revenue / Revenue for the previous fiscal year
R&D expense ratio	16%	**19%**	Research and development expenses / Revenue
Core operating profit ratio	19%	**19%**	Core operating profit / Revenue

(yen)

	2020/12	2021/12 (Outlook)
Dividend per share (Second quarter-end)	22	**23**
Dividend per share (Fiscal year-end)	22	**23**
Dividend per share (Annual)	44	**46**
Dividend payout ratio*	50.3%	**48.5%**

* The outlook for fiscal 2021 indicates the dividend payout ratio based on core EPS (calculated as an indicator showing recurring profitability by dividing core profit (determined by subtracting "other income," "other expenses" and the related "income tax expense" from "profit") by the average number of shares during the period).

Risk Factors

This section describes material risks identified by the Kyowa Kirin Group as of December 31, 2020. However, the Group may face other unforeseen risks caused by changes in internal and external conditions. Risks not described here may have a negative impact on the Group's business performance and financial position.
The Group defines risks as factors that could have an uncertain impact on business targets, including both threats and opportunities.

Risks Related to Maximizing the Value of Global Strategic Products

Details of risks and expected main impacts

The Kyowa Kirin Group is working to maximize the value of three drugs that have been positioned as global strategic products – Crysvita, a treatment for X-linked hypophosphatemia, Poteligeo, an anticancer agent, and Nourianz (product name in Japan: Nouriast), an antiparkinsonian agent. However, delays to sales area expansion caused by setbacks in market launch preparations, slow progress with market penetration due to difficulties identifying potential patients, sharply lower-than-expected sales due to a shortfall in projected product prices in new markets, and impediments to stable supplies caused by quality issues, manufacturing problems and other issues, may prevent the Group from attaining its business targets.

Key mitigation measures

To maximize the value of global strategic products, the Group is implementing initiatives to spur market uptake and expanding its business reach, centered on the US and Europe. In addition, the Group is aiming to reinforce its global management structure to facilitate seamless cooperation between business divisions and affiliates on a global level. Establishing a robust production system and enhancing quality assurance systems will be key to creating a platform that ensures those objectives are fully realized. Consequently, the Group is tackling Risks Related to Product Quality and Risks Related to Stable Production and Supply as material risks, as described in key mitigation measures below.

Risks Related to R&D

Details of risks and expected main impacts

In R&D, the Group is aiming to create new medical value and accelerate drug discovery by combining its existing portfolio of technologies with the latest advances in disease science. The Group's technology strategy is to build a drug discovery platform that uses next-generation antibody technology and other various modalities, while its disease area strategy is to combine insights into disease biology with its technologies to develop a steady stream of new drugs that address unmet medical needs. However, in the process of developing new drugs over long periods of time, there may be cases where R&D has to be abandoned, for example if expected efficacy is not confirmed or for safety and other reasons, which may prevent the Group from expanding its drug pipeline and undermining growth potential and profitability.

Key mitigation measures

The Group is actively stepping up investment in R&D (aiming for an R&D expenses ratio of 18-20%) to identify the next global drug candidates and take other steps to reinforce its pipeline of new drugs to support future growth. In addition, to complement proprietary research, the Group is actively working on strategic partnering activities (in-licensing, tie-ups, etc.) to drive open innovation drug discovery with industry, government agencies and academia, and to acquire platform technologies and pipeline assets. In 2020, the Group launched a collaboration with Axcelead Drug Discovery Partners Inc., a drug discovery solutions provider formed by the spinout of Takeda Pharmaceutical Company Limited's drug discovery platform business. The aim of the tie-up is to combine Axcelead's long-established, extensive technologies and expertise in small-molecule drug discovery with the Group's own innovative drug discovery technologies to broaden the R&D pipeline with groundbreaking new compounds. The Group is also extending its R&D alliance with InveniAI LLC, a US company providing AI and machine learning applications, aiming to identify novel drug discovery targets for the Group's proprietary next-generation antibody technologies and explore new disease applications.

Risks Related to Healthcare Cost-Control Policies

Details of risks and expected main impacts

Japan and other countries are tightening control of healthcare costs. In addition to reducing prices of original drugs, governments are encouraging wider use of generic drugs as part of efforts to reform healthcare systems. These trends may have a negative impact on the Group's business performance and financial position. In addition, while innovative new drugs are still likely to be valued in this environment, delays to the development of practical, groundbreaking new drugs may undermine the Group's growth potential and profitability.

Key mitigation measures

The Kyowa Kirin Group monitors healthcare policy trends in each country while also forecasting post-launch pricing for development compounds and their anticipated impact on revenue. The Group also works to prepare strategic drug approval packages that highlight the practicality and novelty of the drug.

Risks Related to Parent and Group Company Management

Details of risks and expected main impacts

In January 2020, the Company received a report from its Group Investigation Committee, which was led by a third party, into the voluntary recall of an antiemetic agent (Mitomycin-C) in 2019. Based on the report's recommendations, the Company formulated measures to prevent any recurrence of issues that prompted the recall. The Company also formulated a specific improvement plan with three key objectives – create a strong production and quality assurance system, improve risk management, and reform corporate culture, as management's top priority – while also strengthening the Group's governance to prevent any recurrence. In the event that these measures are not fully effective, trust in the Company as a pharmaceutical manufacturer may be eroded if production, sales and other business activities are restricted or halted due to emerging risks.

Key mitigation measures

To enhance risk management, the Group is working to improve its ability to respond to new and materializing risks through a number of initiatives, such as running workshops for all executives and management-level employees to strengthen enterprise risk management capabilities, and identifying material issues (materiality) that the Group needs to address over the medium and long term. The Group also aims to improve crisis management capabilities by conducting crisis training drills in Japan and overseas. Please refer to Risks Related to Product Quality for details about how Kyowa Kirin is building a robust quality assurance system and Risks Related to Compliance for details about corporate culture reforms.

Risks Related to Product Quality

Details of risks and expected main impacts

Pharmaceutical manufacturing requires facilities (hard assets) and procedures and people (soft assets) that are compatible with good manufacturing practice (GMP). Should a GMP inspection or an internal audit by a national authority find a serious GMP issue, the regulatory authority may issue instructions for production to be suspended. In addition, if for any reason there are any concerns about the safety or quality of the product with regard to raw materials or manufacturing processes used to make the product, these may give rise to a product recall.

Key mitigation measures
The Group's quality assurance functions are centered on the Global QA Head, who reports directly to the President and guides quality assurance activities in each region. Specifically, the Global Quality Assurance Committee, regular and ad hoc Global Product Council and other quality assurance bodies discuss critical quality-related issues reported by key regional subsidiaries, evaluate quality performance at newly selected manufacturing sites, regularly assess product quality, review the activities of global taskforces established to address specific issues, and monitor issues identified in audits and progress with related response measures. The Group has also established a Global GxP Audit & Regulatory Compliance Department as an independent, specialist audit unit to reinforce product quality audits within the Group and at contractors. In addition, the Group is introducing an electronic Quality Management System (eQMS) to appropriately manage and utilize large volumes of quality assurance information on a global level and to drive continuous improvements in processes and reliability. With eQMS, key quality management processes (education and training, document management, anomalies, complaints, corrective and preventative actions, modifications, audits, etc.) are all managed electronically.

Risks Related to Stable Production and Supply

Details of risks and expected main impacts
In FY2020, the Group's overseas revenue ratio reached 48%, spurred by strong growth in sales of global strategic products. With the overseas revenue ratio expected to rise further, stable supplies of the Group's products could be affected by a failure to more accurately predict demand in each region or an inability to increase supply capacity further at proprietary plants or through cooperation with contract manufacturers and other suppliers, which may erode trust in Kyowa Kirin as a pharmaceutical company, depress revenues or lead to delays in new drug applications.

Key mitigation measures
The Group is introducing sales and operations planning (S&OP) to optimize the entire supply chain. S&OP is being used to increase the accuracy of demand forecasting by rapidly identifying changes in product sales and needs, and to enable quick adjustments to supply-demand from the perspective of profitability, in line with business plans. In addition, to respond to spikes in demand and tight supply-demand conditions, the Group is expanding its network of contractors, investing in Group plants, rolling out digital technology to enhance manufacturing operational efficiency, and increasing headcount and upgrading training systems in the Production Division.

Risks Related to the Management of Suppliers and Contractors

Details of risks and expected main impacts
The Group enters into alliances with other companies, in the form of joint development projects, joint marketing and technology partnerships or joint ventures, and outsources operations related to the supply of raw materials for pharmaceutical products, production, logistics and marketing to other domestic and overseas suppliers. However, if the alliances and outsourcing contracts fail to deliver the expected results or are dissolved due to issues related to human rights, legal compliance, the environment, information security, or if there are quality issues with contracted deliverables, the Group could face difficulty securing stable supplies of its products or issues in logistics and sales, which may erode trust in Kyowa Kirin as a pharmaceutical company, depress revenues or lead to delays in new drug applications.

Key mitigation measures
The Group requires suppliers to ensure thorough compliance in accordance with compliance clauses in business contracts. Furthermore, the attitudes and actions required of the suppliers that make up the Group's supply chains are stipulated in the Supplier Code of Conduct and are understood by suppliers. In addition to conducting questionnaire surveys on the items described in the Supplier Code of Conduct and feeding the results back to suppliers, the Group is working on activities designed to ascertain the actual status of compliance activities and improve the status of those activities. Based on responses from the questionnaire surveys and remedial activities by suppliers, the Group objectively evaluates supplier risk in conjunction with risk information from external supplier databases.

Risks Related to Information Security

Details of risks and expected main impacts
As the Group utilizes a variety of information systems, confidential information may be leaked outside the Company or systems may be rendered inoperable in the event of unauthorized system access or following a cyberattack. In addition, cyberattacks on servers at suppliers could have a negative impact on the Group, such as unauthorized access to the Group's confidential information or personal data, interruption to the Group's business activities, or brand damage. As explained in key mitigation measures for Risks Related to Pandemics, the move to home working is improving productivity, but the number of employees using home communication environments or working alone is rising, which increases the risk of surveillance, cyberattacks and email errors that may lead to information leaks.

Key mitigation measures
The Group is taking steps to upgrade information security, such as introducing technology countermeasures in response to cybersecurity threats that are becoming more diverse and sophisticated each year, and developing playbooks that include information such as the recommended initial response flow in the event of an incident and procedural manuals. The Group is also working to mitigate risks at suppliers, including verifying security measures. In 2020, the Group conducted an emergency response drill simulating the leak of personal information governed by the General Data Protection Regulation (GDPR), an EU data protection law, and another drill simulating a global cybersecurity incident. The aim of the training is to improve the Group's ability to rapidly respond to and minimize damage from information security incidents.

To enhance information security in home working environments, the Group sends notifications to remind employees about security and shares information about actual information security incidents as part of workplace housekeeping. It also uses remote networking tools to have multiple people check work processes in each team.

Risks Related to Compliance

Details of risks and expected main impacts
The Group is required to comply with a range of laws and regulations governing pharmaceutical R&D, manufacturing, sales, imports and exports. In addition, pharmaceutical companies must strictly adhere to regulations in each country and voluntary industrywide standards regarding pharmaceutical promotion. Failure to comply with these laws, regulations and voluntary standards could result in sanctions that delay or halt the development of new drugs, or restrict or halt production, sales and other business activities, which may erode trust in Kyowa Kirin as a pharmaceutical company.

Key mitigation measures
In the Kyowa Kirin Group, compliance is not restricted to legal compliance. The Kyowa Kirin Group Code of Conduct stipulates general actions that every executive and employee must take to quickly identify the needs of society and to act ethically. In addition, the Group is establishing systems and conducting continuous training to ensure compliance with laws and regulations and voluntary standards. To strengthen compliance, each Regional CSR Committee, which convene on a quarterly basis, and the Group CSR Committee, which meets annually, promote continuous improvement by discussing progress made with measures to address important issues and reporting to the Board of Directors the status of compliance. The Group has also put in place a whistle-blowing hotline to prevent or detect and correct at an early stage any acts that would be in violation of the Group Code of Conduct or that could significantly impair the Group's brand value.

To ensure every employee upholds the highest ethical standards in line with the Group's values and Code of Conduct, the Group collected data from an employee questionnaire survey and from director resolutions in 2020 to ascertain which areas of the Group's corporate culture needed to change, and implemented measures to modify behavior.

Risks Related to Human Resources

Details of risks and expected main impacts

The Group is working to embed its global management system to encourage individuals from diverse backgrounds to demonstrate their abilities and engage in business activities in Japan and overseas. However, if the Group is unable to develop and hire the personnel who will be responsible for its global management system, this may adversely affect the continuation of its business activities.

Key mitigation measures

The Group believes people are the source of innovation. In line with that thinking, the Group develops and implements human resources training plans designed to maximize the potential of its diverse workforce to cultivate personnel who are motivated to drive change and create new value. Kyowa Kirin has established a Talent Review Council to ascertain the Group's current supply-demand gap in personnel and discuss what each division needs to do to provide more opportunities to maximize the capabilities of each employee, based on the future vision for the Group's organization. In addition, Kyowa Kirin runs a training program to cultivate the next generation of business leaders from a pool of potential personnel. The Group assesses and screens the employees, identifies preferred candidates early on and assigns them to challenging assignments, including overseas roles.

Risks Related to the Environment

Details of risks and expected main impacts

The Group recognizes that climate change is an issue that affects its business activities. Climate change-related abnormal weather patterns that cause spikes in materials prices and frequent flood damage may impact stable supplies of the Group's products. In addition, in the future, Kyowa Kirin may face additional costs from the introduction of a carbon tax or to respond to tighter environmental regulations, or fail to attain its greenhouse gas reduction targets, which may undermine the Group's brand value.

Key mitigation measures

The Group is currently formulating a roadmap to reduce its greenhouse gas emissions over the medium and long term. In the medium term, the Group aims to cut emissions of greenhouse gases by focusing on energy-saving measures and expanding the use of renewable energy. In 2020, the Group selected Aqua Premium* to provide 75% of power at its Takasaki Plant. Aqua Premium is a 100% hydropower electricity supply service that generates zero CO_2 emissions. Going forward, the Group will explore the use of renewable energy at other business sites, targeting 100% renewable energy usage by 2040. Looking further ahead to 2050, the Group will seek to convert plant facilities from fossil fuel use to hydrogen and other new energy sources and work to reduce greenhouse gas emissions in its supply chain, aiming to achieve net-zero greenhouse gas emissions across its entire value chain. In addition, the Group has declared its support for the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD). The Group is expanding information disclosure in line with the recommendations, focusing on climate change-related risks and opportunities and the expected impacts on business activities.

* Electricity payment plan provided by Tokyo Electric Power Company Energy Partner Inc.

Risks Related to Natural Disasters

Details of risks and expected main impacts

Natural disasters such as earthquakes and typhoons in regions worldwide could lead to the closure of the Group's head office, plants, research centers and other business sites or halt business activities, potentially impacting drug discovery or clinical development, stable supplies of products, collection of product safety data, and the provision of product information, which may have a negative impact on the Group's business performance and financial position.

Key mitigation measures

The Group has developed a coordinated disaster prevention plan with its business sites to ensure the safety of employees and their families in the event of a disaster. Based on the plan, the Group regularly conducts employee safety confirmation drills and safety equipment upgrades/checks. The Group has also developed a Business Continuity Plan (BCP) to continue supplies of pharmaceutical products, safety monitoring activities and the provision of product information when normal business activities are disrupted. In 2020, the Group conducted a BCP drill simulating a very large typhoon traversing Japan. Lessons learned during the drill are being used to continually enhance the BCP.

Risks Related to Pandemics

Details of risks and expected main impacts

Novel coronavirus (COVID-19) infection disease has spread worldwide since early 2020, leading to a global pandemic. Depending on the scale of the current and future pandemics, the Group's head office, plants, research centers and other business sites could be forced to close or cease business activities due to onsite infection clusters, or raw material suppliers could halt supplies and logistics may be affected. Disruption at medical facilities and other issues could prevent the Group from ensuring stable supplies of products or collecting product safety data, or delay the provision of product information to medical professionals and progress with clinical studies. In addition, any impact on government authorities in each country could slow down new drug approvals and price negotiations, delaying the launch of new products. Under those conditions, the Group's business performance and financial position may be adversely affected.

Key mitigation measures

In January 2020, the Group activated its Crisis Response Teams to ensure business continuity in response to the COVID-19 outbreak. Focusing on reducing the risk of infection, the Group implemented remote working as the main mode of work, including working from home, and actively introduced web meeting tools for internal and external communication to enable employees to continue their duties. At the same time, every effort is being taken to ensure the safety of employees that need to attend work, including those in the Production Division, such as temperature checks, face masks, social distancing, divided indoor spaces and air purification. The Group has also made careful preparations to prevent the spread of infection in the event that an employee becomes infected and for other scenarios. Home working is also the main mode of work at the Group's overseas businesses, but online training is being conducted to prepare for the restart of normal business activities and promotional activities are being moved to digital channels. The Group is positioning home working as one of its work practice reforms and is switching to digital tools and systems, which is helping to lift productivity.

In addition to the above, the domestic and overseas pharmaceutical industry faces a number of other risks to its business activities. These include, but are not limited to, risks related to intellectual property rights, risks related to product side-effects, risks related to legal disputes, risks related to competition and patent expiry, risks related to fluctuations in fuel costs, risks related to fluctuations in exchange rates and financial markets, and country risk, which could all have a negative impact on the Group's business performance and financial position.

Corporate Data

Corporate Data (As of December 31, 2020)

Kyowa Kirin Co., Ltd.

Head Office
1-9-2, Otemachi, Chiyoda-ku, Tokyo 100-0004, Japan
Tel: 81-3-5205-7200
Fax: 81-3-5205-7182
URL: https://www.kyowakirin.com/

Number of Employees
Consolidated: 5,423

Date of Foundation
July 1, 1949

Paid-in Capital
¥26,745 million

Principal Plants

Japan
Takasaki Plant (Takasaki City, Gunma)
Ube Plant (Ube City, Yamaguchi)

Overseas
Kyowa Kirin China Pharmaceutical Co., Ltd.

R&D Network

Japan
Tokyo Research Park (Machida City, Tokyo)
Fuji Research Park (Sunto-gun, Shizuoka)
CMC R&D Center (Sunto-gun, Shizuoka)
Bio Process Research and Development Laboratories (Takasaki City, Gunma)

Overseas
Kyowa Kirin Pharmaceutical Development, Inc.
Kyowa Kirin Pharmaceutical Research, Inc.
Kyowa Kirin Pharmaceutical Development Limited
Kyowa Kirin China Pharmaceutical Co., Ltd.
Kyowa Kirin Korea Co., Ltd.

Network (As of December 31, 2020)

Name of Company	Proportion of Voting Rights Held	Share Capital (1,000)	Principal Business
Japan			
Kyowa Medical Promotion Co., Ltd.	100%	¥50,000	Promotion and sales of pharmaceuticals
Kyowa Kirin plus Co., Ltd.	100%	¥112,500	Insurance, wholesale and retail
Kyowa Kirin Frontier Co., Ltd.	100%	¥100,000	Manufacturing and sales of pharmaceuticals
Asia/Oceania			
Kyowa Kirin China Pharmaceutical Co., Ltd.	100%	US$ 29,800	Manufacturing and sales of pharmaceuticals (China)
Kyowa Kirin Korea Co., Ltd.	100%	KRW 2,200,000	Sales of pharmaceuticals (Korea)
Kyowa Kirin (Taiwan) Co., Ltd.	100%	TW $262,450	Sales of pharmaceuticals (Taiwan)
Kyowa Kirin (Hong Kong) Co., Ltd.	100%	HK $6,000	Sales of pharmaceuticals (Hong Kong)
Kyowa Kirin Asia Pacific Pte. Ltd.	100%	SG $30,837	Sales of pharmaceuticals and control of business in the Asia and Oceania region excluding Japan (Singapore)
Kyowa Kirin (Malaysia) Sdn. Bhd.	100%	RM 1,000	Sales of pharmaceuticals (Malaysia)
Kyowa Kirin Australia Pty Ltd	100%	AU $ 5,000	Sales of pharmaceuticals (Australia)
Kyowa Kirin (Thailand) Co., Ltd.	100%	THB 100,000	Sales of pharmaceuticals (Thailand)
U.S.A. / Europe			
Kyowa Kirin USA Holdings, Inc.	100%	US $76,300	Supervision and management of specific subsidiaries (U.S.A.)
BioWa, Inc.	100%	US $10,000	Out-licensing of antibody technology (U.S.A.)
Kyowa Kirin Pharmaceutical Development, Inc.	100%	US $100	Development of pharmaceuticals (U.S.A.)
Kyowa Kirin Pharmaceutical Research, Inc.	100%	US $100	Generation of new drug candidate substances and promotion of research alliance (U.S.A.)
Kyowa Kirin, Inc.	100%	US $0.2	Sales of pharmaceuticals (U.S.A.)
Kyowa Kirin Canada, Inc.	100%	CA $0.1	Sales of pharmaceuticals (Canada)
Kyowa Kirin International plc	100%	£13,849	Supervision and management of specific subsidiaries (U.K.)
Kyowa Kirin Pharmaceutical Development Limited	100%	£501	Development of pharmaceuticals (U.K.)
Kyowa Kirin Limited	100%	£6,952	Sales of pharmaceuticals (U.K.)
Kyowa Kirin Ireland Limited	100%	€0.1	Sales of pharmaceuticals (Ireland)
Kyowa Kirin Pharma SAS	100%	€1,241	Sales of pharmaceuticals (France)
Kyowa Kirin Farmacéutica, S.L.U.	100%	€216	Sales of pharmaceuticals (Spain)
Kyowa Kirin GmbH	100%	€51	Sales of pharmaceuticals (Germany)
Kyowa Kirin Holdings B.V.	100%	€111	Sales, licensing-in and licensing-out of pharmaceuticals (Netherlands)
Kyowa Kirin Pharma B.V.	100%	€18	Sales of pharmaceuticals (Netherlands)
Kyowa Kirin S.r.l.	100%	€10	Sales of pharmaceuticals (Italy)
Kyowa Kirin AB	100%	SEK 200	Sales of pharmaceuticals (Sweden)
Archimedes Pharma Limited	100%	£543	Supervision and management of specific subsidiaries (U.K.)
Kyowa Kirin Services Ltd	100%	£0.3	Sales and development of pharmaceuticals (U.K.)
Archimedes Pharma UK Limited	100%	£78	Sales of pharmaceuticals (U.K.)
Kyowa Kirin Sàrl	100%	CHF 20	Sales of pharmaceuticals (Switzerland)
Kyowa Kirin Austria GmbH	100%	€35	Sales of pharmaceuticals (Austria)
Kyowa Kirin Farmaceutica, Unipessoal Lda.	100%	€5	Sales of pharmaceuticals (Portugal)
Kyowa Kirin Pharma s.r.o.	100%	CZK 100	Sales of pharmaceuticals (Czech Republic)
Kyowa Kirin Pharma S.R.L.	100%	RON 10	Sales of pharmaceuticals (Romania)
Kyowa Kirin Pharma FZ-LLC.	100%	AED 50	Sales of pharmaceuticals (UAE)
Japan (Equity-method affiliate)			
FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.	50.0%	¥100,000	Development, manufacturing and sales of biosimilar pharmaceuticals

Note: All of the companies are consolidated subsidiaries, except FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.

Investor Information (As of December 31, 2020)

Stock Listing
Tokyo

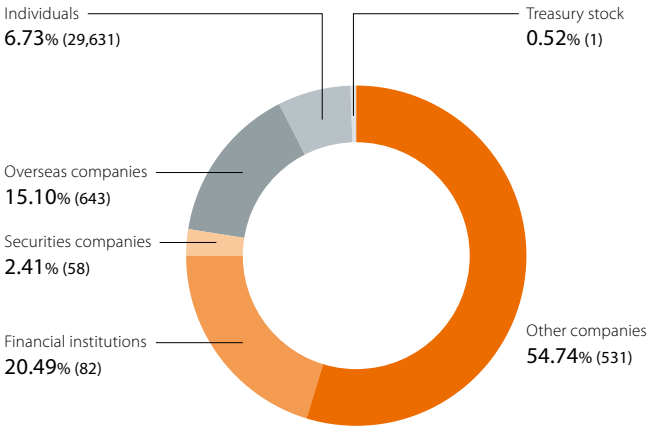
Securities Code
4151

Transfer Agent of Common Stock
Sumitomo Mitsui Trust Bank, Limited
1-4-1, Marunouchi, Chiyoda-ku, Tokyo
100-8233, Japan
http://www.smtb.jp/personal/agency/index.html

Number of Shares of Common Stock
Authorized: 987,900,000
Issued: 540,000,000

Number of Shareholders
30,946

Shareholding by Type of Investor (Number)

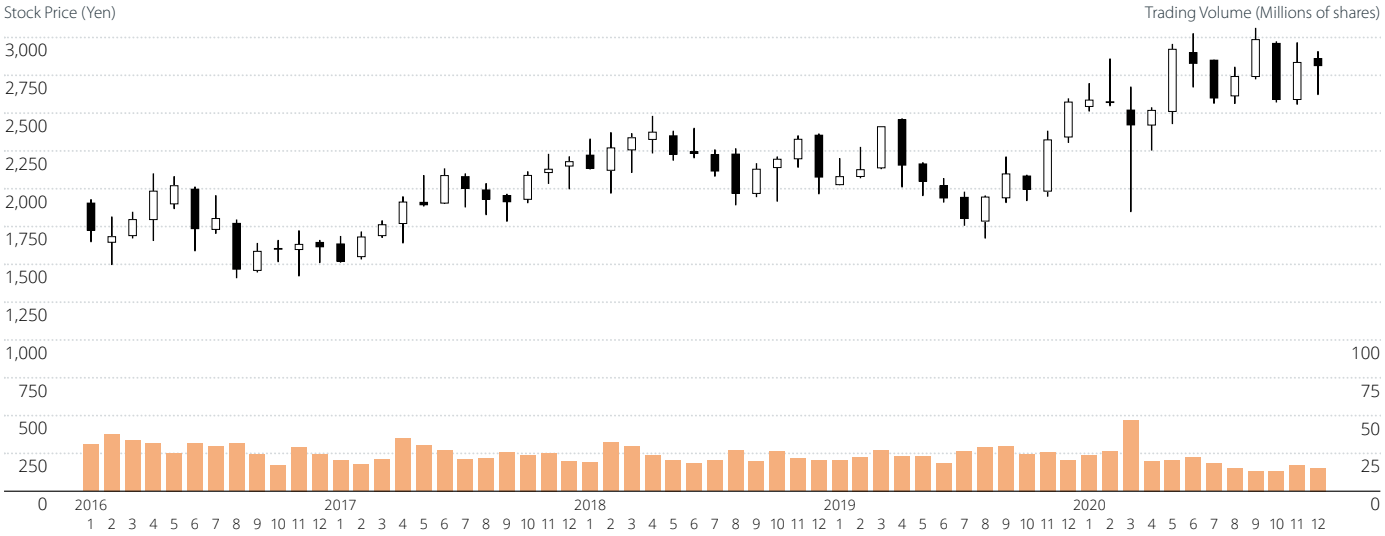


Principal Shareholders

	Number of Shares Held (Thousands)	Percentage of Total Shares Issued (%)
Kirin Holdings Company, Limited	288,819	53.77
The Master Trust Bank of Japan, Ltd. (Trust account)	43,422	8.08
Custody Bank of Japan, Ltd. (Trust account)	23,827	4.44
State Street Bank & Trust Company 505223	7,839	1.46
Custody Bank of Japan, Ltd. (Trust account 7)	5,527	1.03
Mizuho Trust & Banking Co., Ltd. (Retirement Benefit Trust for Mizuho Bank, Ltd.)	4,539	0.85
State Street Bank West Client-Treaty 505234	4,337	0.81
SMBC Nikko Securities Inc.	3,812	0.71
JPMorgan Chase Bank 385781	3,651	0.68
State Street Bank & Trust Company 505103	3,416	0.64

*1 The 4,539 thousand shares held by Mizuho Trust & Banking Co., Ltd. (Retirement Benefit Trust for Mizuho Bank, Ltd.) are the trust assets entrusted by Mizuho Bank for its retirement benefit trust, and voting rights for the shares are retained by Mizuho Bank.
*2 The 2,823 thousand shares held by the Company as treasury stock are excluded from the above because treasury stock has no voting rights.

Stock Price and Trading Volume



Total Shareholder Return (TSR)

	Past 4 years	Past 3 years	Past 2 years	Past 1 year	Current year
Kyowa Kirin Co., Ltd.	**85.7%**	**116.5%**	**113.0%**	**141.1%**	**156.0%**
TOPIX Total Return Index	100.3%	122.6%	103.0%	121.7%	130.7%