KYOWA KIRIN

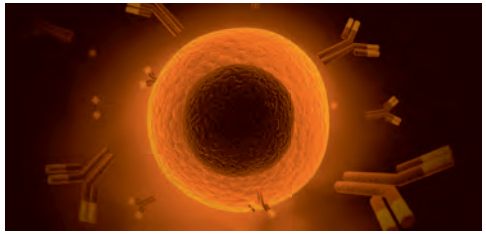
Annual Report 2018

For the year ended December 31, 2018

Leaping Forward

TOWARD SUSTAINABLE GROWTH

Contents



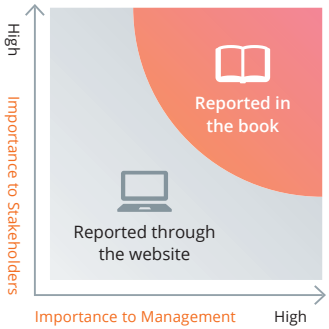
Editorial Policy

We have published this integrated report to help investors understand the Kyowa Hakko Kirin Group's values, management vision, strengths, 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. In this year's report, we focus on our strengths in biotechnology, the source of the Group's value creation.

In 2018, we launched our first two global strategic products overseas, marking an important milestone in our efforts to become a Global Specialty Pharmaceutical Company.

We look forward to your continued support as the Kyowa Hakko Kirin Group expands its presence worldwide.

Environment
Social
Governance
Guidance for Collaborative Value Creation



Annual Report (PDF version)
https://ir.kyowa-kirin.com/en/library/annualreport.html

Kyowa Hakko Kirin Website
https://www.kyowa-kirin.com/
Financial Information
https://ir.kyowa-kirin.com/en/finance.html
Sustainability
http://www.kyowa-kirin.com/sustainability/
ESG Data
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Concerning the Scope of This Report

The scope of this report is Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries in Japan and overseas, and certain non-consolidated subsidiaries and affiliates are mentioned in a part of the report. Environmental data is annotated for the convenience of readers. The reporting period includes calendar year 2018, and 2019 in part.

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 Hakko Kirin Co., Ltd. (Kyowa Hakko Kirin); KYOWA HAKKO BIO CO., LTD. (Kyowa Hakko Bio); FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. (Fujifilm Kyowa Kirin Biologics).

Numerical Data

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

MANAGEMENT PHILOSOPHY

The Kyowa Hakko 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

Commitment to Life

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

Innovation

Innovation

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

The Kyowa Hakko Kirin Group has world-class research and development capabilities in the field of biopharmaceuticals.

To strengthen those capabilities, we continue to actively invest in research and development in line with our firm commitment to innovation. Led by our research centers in Japan and San Diego in the US, we are driving forward research efforts on a global scale in search of new drug candidates.

Teamwork/Wa*

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

One of our strengths as a Group is to shrink distances between divisions and affiliates worldwide to achieve seamless cooperation. We will continue to take on new challenges by harnessing that strength to support a high level of teamwork.

We will also create new value by working closely with all stakeholders, including patients and their families and medical professionals.

* Harmony and loop among people

Integrity

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

Initiatives are being implemented worldwide to realize the Sustainable Development Goals (SDGs). As a company, we have a social responsibility to also address SDG-related issues as part of our business activities. Specifically, we are working to tackle social issues that have a direct connection to our business – developing innovative new drugs for conditions with unmet medical needs, contributing to the economics of healthcare by reducing medical costs, improving quality of life (QOL), and contributing to the field of pre-symptomatic treatment, such as preventative healthcare.

History of Creating Value

Origin

Identity

Integration

Kirin Kyowa Hakko Kyowa Hakko Kirin

1885

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

1907

Kirin Brewery Co., Ltd. established

1949

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

1951

First for Japan

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

1956

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

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

1988

Open Innovation

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

Technological Innovation

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

Technological Innovation

Developed POTELLIGENT, groundbreaking new antibody production technology that dramatically increases antibody activity

2007

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

2008

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

Kyowa Hakko Kirin Co., Ltd. starts operations

Kyowa Hakko

Kirin Pharma

Consolidation

Challenge

Making the leap to a Global Specialty Pharmaceutical Company (GSP)

Strengthening Biopharmaceuticals

2010

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

Move into Biosimilars Business

2012

Established FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd., a joint-venture with FUJIFILM Corporation, to develop, make and sell biosimilars

KYOWA KIRIN FUJIFILM

Joint venture with shared strengths

Fujifilm Kyowa Kirin Biologics

Establishing Western Operations

2014

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

Archimedes

2017

Kyowa Kirin Frontier Co., Ltd. established to secure domestic marketing approval for authorized version of flagship product Nesp

Strengthening Biopharmaceuticals

2016

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

2011

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

ProStrakan

Establishing Western Operations

Strengthening Biopharmaceuticals

2010

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

2012

Poteligeo Injection 20mg, therapeutic antibody for adult T-cell leukemia-lymphoma (ATL), launched in Japan; first drug based on POTELLIGENT technology

Drug based on POTELLIGENT technology

Strengthening Biopharmaceuticals

2013

Signed agreement with US firm Ultragenyx Pharmaceutical Inc. to develop and commercialize burosumab (KRN23), a fully human antibody against fibroblast growth factor 23 (FGF23)

2018

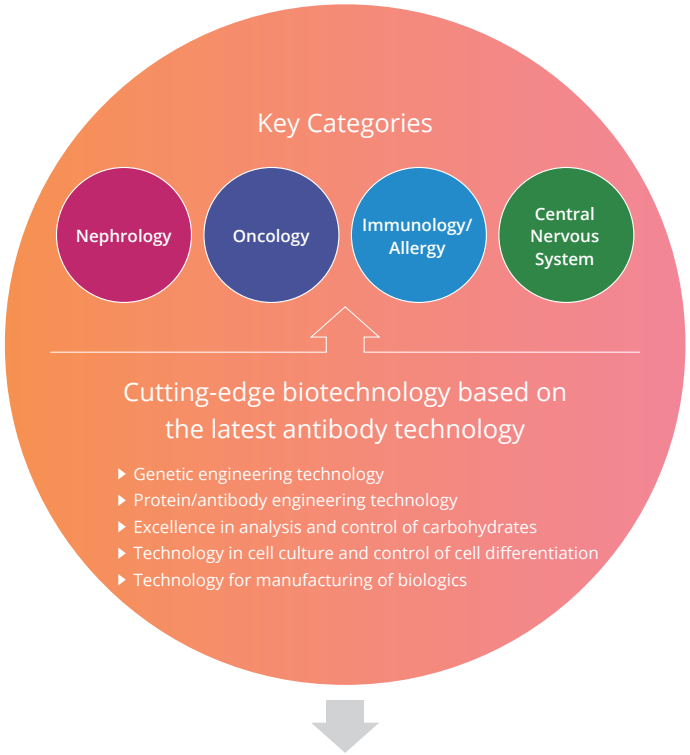
Laid the foundations for the leap to a GSP

- Crysvita (burosumab/KRN23) approved in the US and Europe, sales to start in April 2018; Crysvita is a treatment for patients with X-linked hypophosphatemia and is the result of joint research efforts with Ultragenyx Pharmaceutical Inc. since 2013
- Poteligeo (mogamulizumab/KW-0761) approved in the US and Europe as a treatment for mycosis fungoides (MF) and Sézary syndrome (SS); sales to start in the US from October 2019
- Newly provided the controlling function of business in the Asia/Oceania region to a sales subsidiary in Singapore
- Hulio (FKB327) approved and launched in Europe; Hulio is a biosimilar of fully human anti-TNFα monoclonal antibody adalimumab

Our Approach to Research and Development

Targeting resources on four key categories, backed by antibody technology

Leveraging cutting-edge biotechnology anchored by antibody technology, Kyowa Hakko Kirin is focusing research and development efforts on four key areas – nephrology, oncology, immunology and allergy, and the central nervous system – to create new medical value and speed up the drug discovery process.



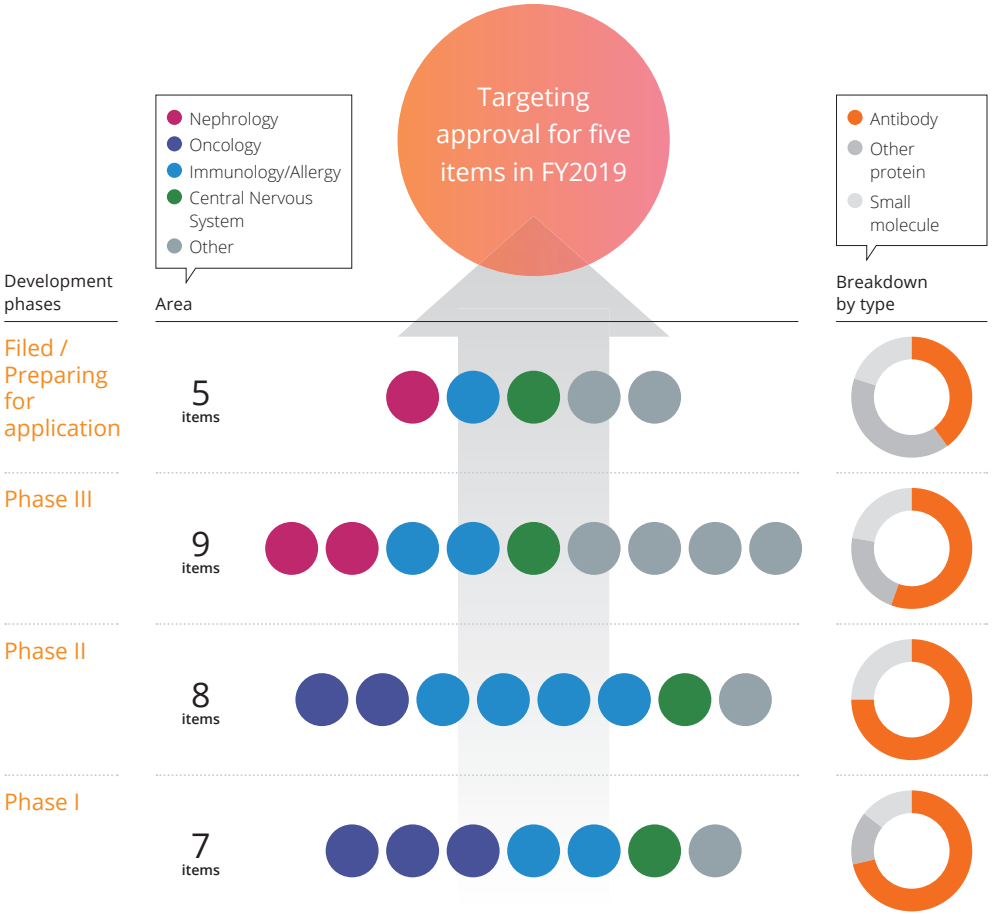
Objectives

- Become a Global Specialty Pharmaceutical Company
- Develop innovative new drugs such as therapeutic antibodies, small-molecule drugs and nucleic acid drugs

A strong pipeline from technology-driven drug discovery

Drawing on research and development capabilities and production technology from earlier work in biopharmaceuticals, coupled with maximum use of open innovation, we are deploying new drug discovery activities in four modalities – therapeutic antibodies, small molecule drugs, therapeutic nucleic acids and regenerative medicine. We call our unique approach Technology-Driven Drug Discovery.

Pipeline (As of December 31, 2018)



Message from Chairman

Nobuo Hanai, Ph.D.
Director of the Board,
Chairman

Aiming to become a Global Specialty Pharmaceutical Company (GSP) with a workforce based on shared core values

Our Core Values

The Kyowa Hakko Kirin Group's core values are anchored by a core concept – Commitment to Life – which guides us in our work every day. Our core values are imbued with a firm commitment to the lives of patients and all other stakeholders. We are witnessing dramatic changes in our operating environment. The impact of those changes is only likely to become even greater. In response, pharmaceutical companies will be forced to completely reconfigure their existing business models. But there are things that cannot and should not change. In Kyowa Hakko Kirin's case, it is our Commitment to Life. I would like to explain those core values in more detail first, because spreading them to all Group employees worldwide underpins our efforts to help Kyowa Hakko Kirin make the next leap forward.

Commitment to Life comprises three keywords. The first is Innovation. It can take more than 20 years to create a new drug from the initial discovery phase. Many development compounds never make it to market. Developing new drugs is not an easy process and requires immense patience. That's why, more than anything, we have to ensure our employees remain passionate about staying the course, even if they come up against what seem to be insurmountable challenges. We have to stimulate passion – the driving force behind innovation – not suppress it. That is one of the management team's most important jobs.

The second keyword is Teamwork / Wa. In Japanese, "wa" means harmony and loop among people. A genius working alone cannot create a revolutionary new drug. Success can only come by harnessing the capabilities and combining all the strengths of

Core Values

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

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

Teamwork/Wa*
One for all, all for one. Work in diverse teams and respect each other. Go beyond boundaries and collaborate with stakeholders.
* Harmony and loop among people

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

Pushing ahead with restructuring to create "One Kyowa Kirin"

everyone in a research and development team. In the same way, as new drug development becomes more complex, open innovation through partnerships with universities and other pharmaceutical companies is becoming increasingly important, rather than working alone. Everybody in those teams, from university professors to researchers at other firms, has the same motivation – to develop new drugs as quickly as possible for patients suffering from illness. That's why it is vital to establish liaison teams across different organizations to drive forward new drug development. Also, drug development only makes sense if patients can use the new products. Today's medical professionals need to see scientific evidence and other advanced, highly detailed information before they decide to prescribe drugs to their patients. To ensure we respond to those needs, we are actively training medical science liaisons (MSLs), as well as medical representatives (MRs), to create the conditions where medical professionals and patients have full confidence in our products.

The last keyword is Integrity. Pharmaceuticals are subject to numerous rules and regulations, which also vary from country to country. Complying with those rules is a given, off course, but the most important aspect of Integrity is to put high value on ethics by always asking ourselves if we are doing the right thing. We also have to keep in mind that our business ultimately helps to make society better. In FY2019, we decided to adopt "One Kyowa Kirin" as the end goal of our current management restructuring program. I will pull out all the stops to ensure our core values are firmly engrained in our workforce worldwide in order to further strengthen the combined capabilities of the Kyowa Hakko Kirin Group.

Realizing CSV Management

The Kirin Group is aiming to realize CSV management by tackling and solving social issues through its business activities. High-priority issues are designated as CSV commitments and are linked to relevant United Nations' Sustainable Development Goals (SDGs).

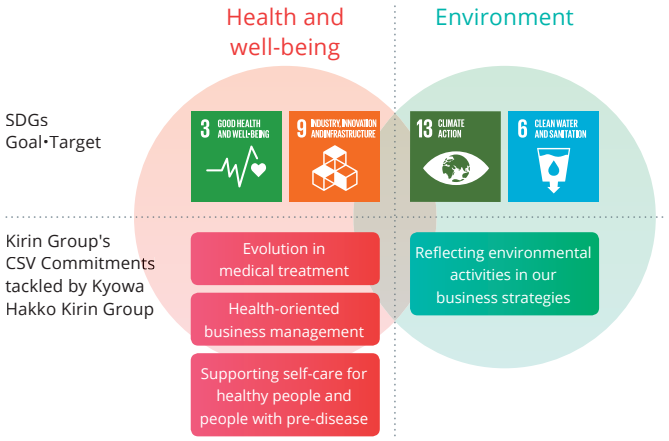
Kyowa Hakko Kirin has adopted four of the Kirin Group's CSV commitments in the health and environmental fields – drive advances in medical treatment, realize health and productivity management, support self-care for healthy people and pre-symptomatic patients, and reflect environmental activities in business strategies. None of those activities can deliver results overnight, but it is important that we make steady progress. For example, with the second commitment – realize health and productivity management – we believe the health of our employees is vital to support all types of value creation. To set an example to society, we are focusing on creating healthy working environments, such as actively implementing policies to reduce smoking rates and working closely with occupational physicians to support mental health.

For more details, please see page 16 of this report.

Dialogue with Stakeholders

Companies that are solely focused on the pursuit of profit are likely to fall out of favor with investors. In my meetings with

CSV Commitment



Committed to helping as many patients as possible

investors, I have noticed they are taking a tougher stance on environmental, social and governance activities. For some time, we have been operating our business based on the principles of CSV management, aiming to set the standard for other companies in environmental and social activities. In governance, we have also been stepping up efforts each year to address recommendations in Japan's revised Corporate Governance Code. Examples include making executive pay transparent and introducing a succession plan. As a pharmaceutical company that has a direct impact on peoples' lives by supplying drugs to treat illness, public expectations on us are great. I personally feel a real sense of responsibility in meeting those expectations. Going forward, we will continue to actively engage with stakeholders, using their input to run the business in a way that increases corporate value.

Our Long-term Vision

Given the state of Japan's national finances, there is no guarantee that our healthcare system will be able to continue in its current form for the next 10 or 20 years. We could even see a rapid increase in high-cost healthcare services accessible to only the very wealthiest in society. I firmly believe that advances in healthcare should benefit everybody equally. As a pharmaceutical company, we can help achieve that by reducing the cost of research, development and production to create highly cost-effective treatments. By harnessing the power of digital technologies such as AI and big data, I think we can reduce the cost of new drug discovery even further. Also, in some cases, teaming up with other companies and sharing business resources and strengths will play an important role in efficient drug discovery. I think we are now at the point where the whole industry should switch from a competitive mindset to collaboration.

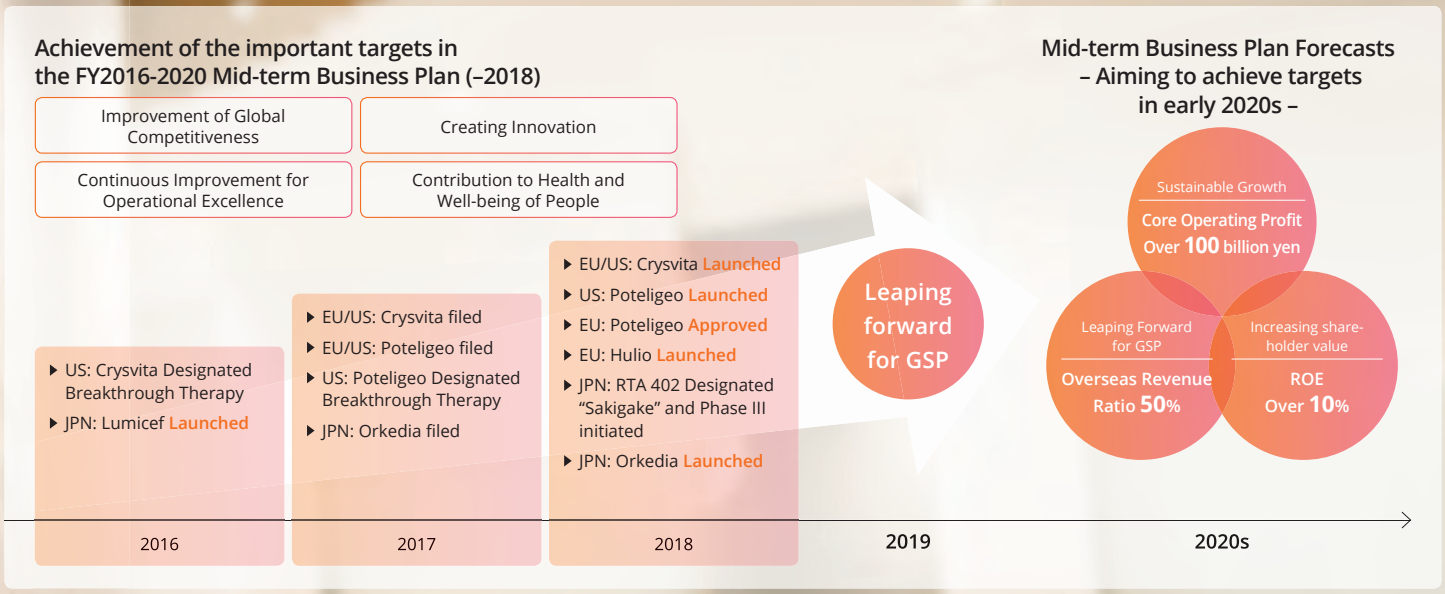
In 10 or 20 years from now, I want Kyowa Hakko Kirin to be a company that remains fully committed to helping as many patients as possible. To realize that vision, we need to build solid foundations today, which I see as my most important duty.

Nobuo Hanai, Ph.D.
Director of the Board,
Chairman

Message from President

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

New products launches have put us on the path to becoming a global player



Progress with Mid-term Business Plan

Kyowa Hakko Kirin is aiming to make the leap to a Global Specialty Pharmaceutical Company (GSP) based on four strategic pillars in the FY2016-2020 Mid-term Business Plan – Improvement of Global Competitiveness, Creating Innovation, Continuous Improvement for Operational Excellence, and Contribution to Health and Well-being of People. To make that leap, our main goal is to develop a steady stream of superior drugs and penetrate markets worldwide. In 2018, Crysvita (burosumab/KRN23) and Poteligeo (mogamulizumab/KW-0761) were approved by authorities in the US and EU. Crysvita was being sold in the US and some parts of Europe. Poteligeo was also launched in the US. Market uptake has been higher than expected and we are confident about the growth prospects of both products. We have also seen good progress in Japan with the launch of several new products over the last three years. In short, we are creating a steady stream of superior new drugs in line with the goals of our Mid-term Business Plan.

However, development of Crysvita and Poteligeo and efforts to make the biosimilar business profitable are slightly behind the schedule envisaged when we formulated the business plan. Expenses related to the marketing of new drugs in the US and Europe are also trending ahead of projections. Moreover, the transfer of Kyowa Medex and Kyowa Hakko Bio were not factored into initial projections, therefore our original Mid-term Business Plan targets for 2020 now look out of reach, despite our best efforts.

Nevertheless, our strategy itself remains on track and I am confident we can achieve our three main performance targets – core operating profit of ¥100 billion or more, ROE of at least 10%, and an overseas revenue ratio of 50% – in the early stages of the next Mid-term Business Plan, provided we continue to steadily implement our strategy and maximize the value of our global strategic products.

Building a "One Kyowa Kirin" Structure

Due to current conditions in the operating environment and our business, we decided that we need to implement management reforms to drive further growth at this timing. One key part of the reforms is building a "One Kyowa Kirin" structure.

Under our current operating structure, Kyowa Kirin International, headquartered in Europe, is responsible for sales in the North America region through its local subsidiary – in other words a sub-subsidiary of Kyowa Hakko Kirin. As part of our reforms, we have overhauled that structure, making Kyowa Kirin USA Holdings the company responsible for operations in North America under the direct management of head office in Japan. The new structure ensures closer control over marketing in North America. Under that structure, head office and Kyowa Kirin USA Holdings will work together to accelerate growth in the promising US market, while also ensuring effective governance.

In addition, we launched Kyowa Kirin Asia Pacific in Singapore in 2018 to oversee our operations in Asia and Oceania. Those changes have resulted in forming a regional-axis structure with four main regions, including Japan.

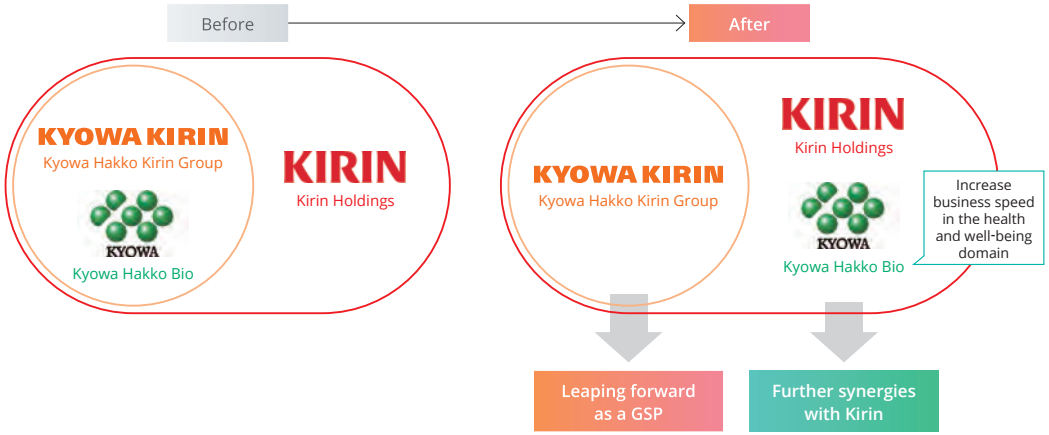
In addition, we are also building a function-axis structure such as R&D, pharmacovigilance and quality assurance (PV&QA) on a global scale. We have put in place this organizational structure driven by both regional and functional matrices, as an important first step in creating a "One Kyowa Kirin" structure.

Business Restructuring

As part of business restructuring, we have decided to sell our bio-chemicals business, Kyowa Hakko Bio, to parent company Kirin Holdings. The decision was the result of much discussion about how to accelerate growth in both the bio-chemicals and pharmaceutical business in light of future changes in the operating environment. Given Kirin Holdings' increased focus on the health sector in its business strategy, we believe Kyowa Hakko Bio will have more opportunities to maximize corporate value as a directly controlled subsidiary of Kirin Holdings. At the same time, the sale of Kyowa Hakko Bio will allow us to concentrate management resources on the pharmaceutical business as we aim to become a GSP. Those two factors were the main reasons behind the decision to sell Kyowa Hakko Bio.

To ensure the Kyowa Hakko Kirin Group generates growth, we have to transition to a global business model, while also reinforcing our operating base in Japan. To support that shift, we need to create a lean organization made up of outstanding employees with the will to drive change independently. As part of our organizational reforms, we announced a voluntary retirement program to provide full support for employees who want to leave the Group to pursue new career goals.

Maximizing Kyowa Hakko Bio's corporate value and concentrating Kyowa Hakko Kirin's resources on the pharmaceutical business



New Product Development

We are making steady progress with the development of KHK4083, KW-6356 and RTA 402 – three new drugs with the potential to support the Group's future profits.

In phase I clinical trials for the treatment of atopic dermatitis, KHK4083 was shown to have a continuing beneficial impact on patients after drug administration ended. KHK4083 has now progressed to phase II trials in multiple countries.

Also under development is KW-6356, a next-generation treatment for Parkinson's Disease and a follow on from our existing product KW-6002 (marketed as Nouriast in Japan). The drug has progressed to phase IIb clinical trials after phase IIa trials confirmed improvements in motor symptoms in patients with early-stage Parkinson's disease when KW-6356 was used as a monotherapy.

RTA 402 is a promising revolutionary new treatment for diabetic kidney disease that has potential to delay the initiation of hemodialysis. The drug is currently undergoing phase III clinical trials. Japan's Ministry of Health, Labour and Welfare has granted RTA 402 the "Sakigake (priority review)" designation, and we also have great hopes for the drug.

As shown by RTA 402, we continue to reinforce our already strong position in the nephrology category. In November 2018, we signed a strategic commercialization deal in Japan for daprodustat, a potential new treatment drug for renal anemia being developed by GlaxoSmithKline. The deal reinforces our pipeline and increases our presence in the nephrology category.

Conclusion

As a pharmaceutical company, we have a vital public role to play in saving lives and improving QoL of patients. That role is a key element of Kirin Group's commitment to CSV management. Crysvita, launched in 2018, is a drug for patients with X-linked hypophosphatemia (XLH), a hereditary disease. At the launch event for Crysvita in the US, I had the opportunity to meet people with XLH. One person expressed their thanks, saying that after anxiously waiting for the launch of Crysvita, the new drug would not only help them, but also their children and their grandchildren. I will never forget their tears and smile. More than ever, I understand that the final value Kyowa Hakko Kirin provides must be putting smiles on as many patients' faces as possible. Companies have to generate profits, but they also have a duty to make the world a better place. Developing a single drug takes immense time and effort. Before launching a new product, we have to overcome numerous obstacles and setbacks. Despite those challenges, everyone in the Kyowa Hakko Kirin Group will continue to do their best to contribute to the health and wellbeing of people worldwide. Given the long-term nature of our business, I hope we can count on your continued support and understanding as shareholders and investors for many years to come.

"Everyone at Kyowa Hakko Kirin is doing their best to support the health and wellbeing of people worldwide"

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

CSV Management

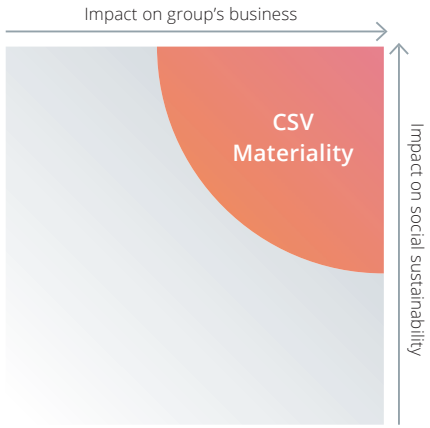
In our corporate philosophy, we at Kyowa Hakko Kirin Group are committed to creating new value by capitalizing on its strengths in life sciences and technologies with the aim of contributing to the health and well-being of people around the world. This "new value" is nothing but the value that can be 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.

CSV Materiality

In practicing its CSV management, we identified issues that need to be tackled with top priority as CSV material issues (materiality) in view of their impacts on social sustainability and our business, and in reference to ISO 26000 and other guidelines. CSV materiality is also consolidated into our FY2016-2020 Mid-term Business Plan.

The four health and environmental issues that are also important to the Kirin Group included in the identified 20 CSV material issues are shared as targets by the Kirin Group's CSV Commitment. In other words, the Kyowa Hakko Kirin Group is working together in response to the needs or demands of society as the Kirin Group.

Materiality Matrix



Recognizing Society’s Demands on Kyowa Hakko Kirin

We practice management from the perspective of the Sustainable Development Goals (SDGs)*, which are advocated as an international framework for social issues. "Contribute to the health and well-being of people around the world " in our corporate philosophy is consistent with Goal 3 in the SDGs: "Good health and well-being." Therefore, this Goal 3 is positioned as the core issue of our group. Our CSV Materiality set from both social and business perspectives is responsible for all 13 SDGs including Goal 3.

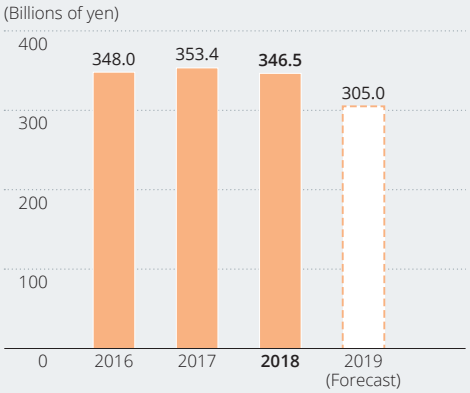
By analyzing and responding to social demands, we not only strengthen our group's risk management, but also aim to improve the management level and grow by considering the solution of social issues as a business opportunity and creating innovation and new value.

* SDGs: A collection of 17 goals that international society should address over 15 years between 2016 and 2030 in order to realize sustainable global development. The SDGs were adopted by the United Nations summit in September 2015.

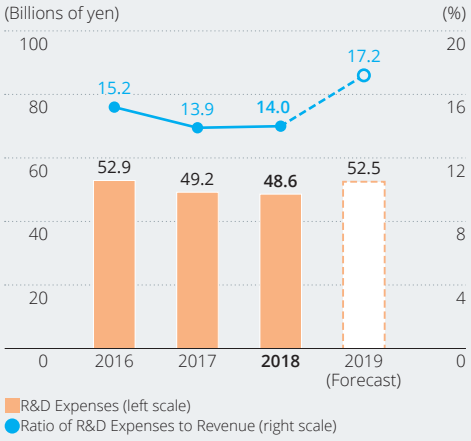
CSV Materiality		Kyowa Hakko Kirin Group’s target SDGs
・Foster corporate culture in line with the Core Values ・Promote compliance ・Strengthen risk management ・Strengthen organizational governance system	(Organizational Governance)	Derived from Kirin Group’s CSV commitments
・Respect human rights	(Human Rights)	Consistent with our corporate philosophy
・Ensure employee safety ・Promote employee health ・Promote diversity of employee and work style ・Develop employee competencies	(Labor Practices)	
・Prevent global warming ・Preserve water resources	(Environment)	
・Prevent bribery ・Ensure transparency in relationships with medical institutions ・Provide appropriate pharmaceutical information ・Ensure reliability in clinical research	(Fair Operating Practices)	
・Create new products and services centered on leading-edge technology ・Provide high-quality and safe products and services ・Ensure stable supply of products and services	(Consumer Issues)	
・Contribute to communities ・Contribute to advances in life sciences	(Community Involvement and Development)	

Financial Highlights

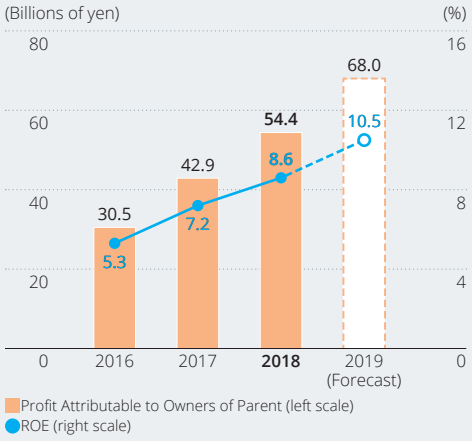
Revenue



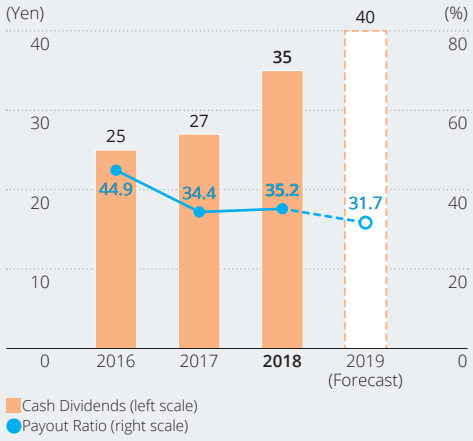
R&D Expenses / Ratio of R&D Expenses to Revenue



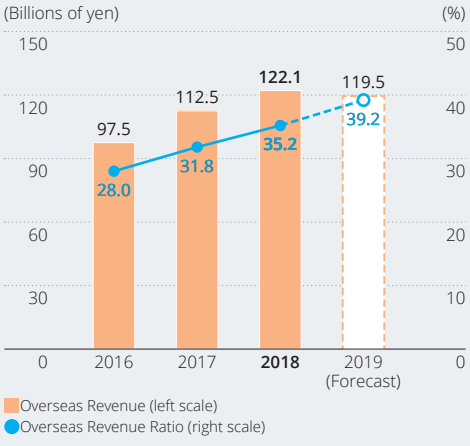
Profit Attributable to Owners of Parent / Return on Equity (ROE)



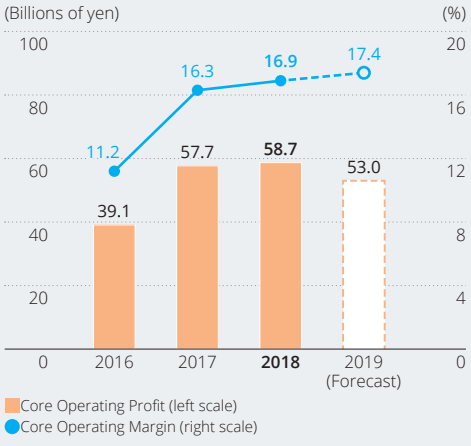
Cash Dividends / Payout Ratio



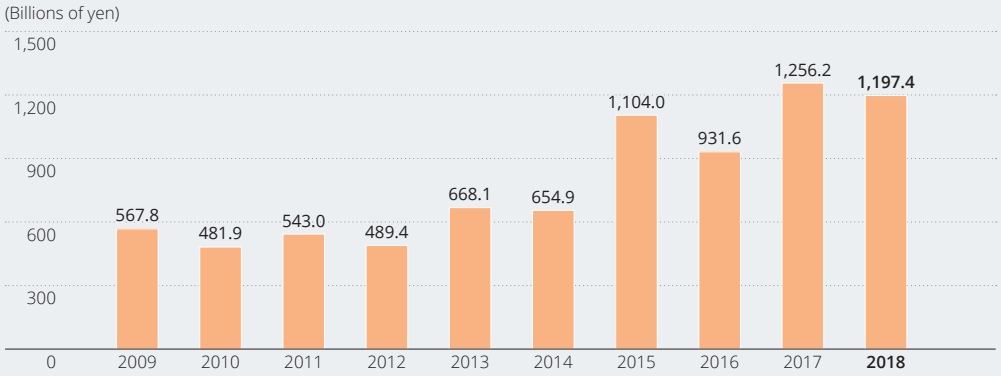
Overseas Revenue / Overseas Revenue Ratio



Core Operating Profit / Core Operating Margin



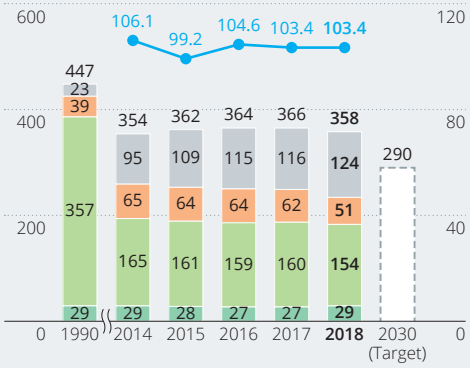
Market Capitalization



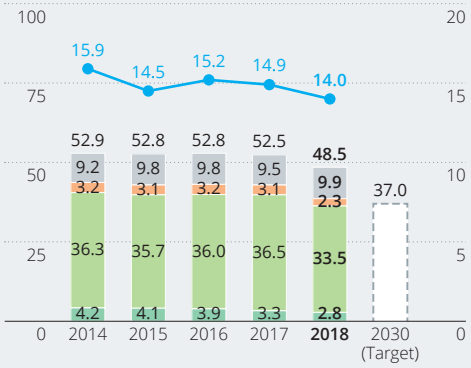
ESG Highlights

Please see ESG Data Collection for details.
https://kyowa-kirin.com/sustainability/esg_data/

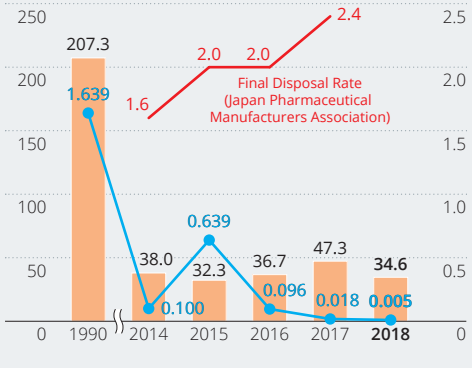
CO_2 Emissions *1,2



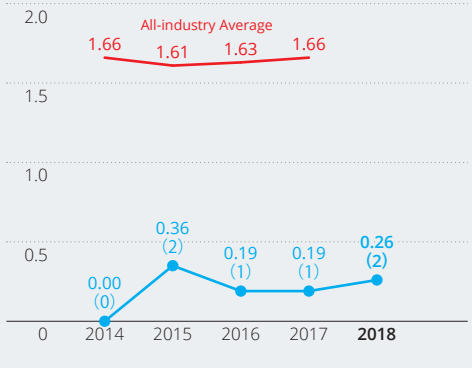
Water Use *1,2



Waste Generation *3,4

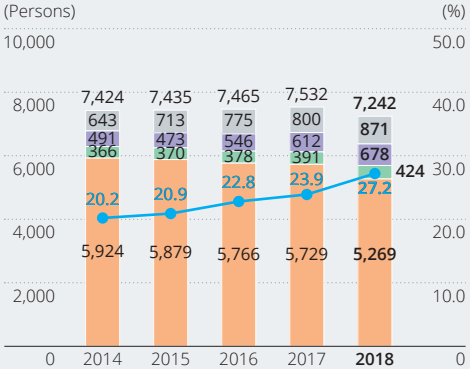


Accident Frequency Rate *3,5

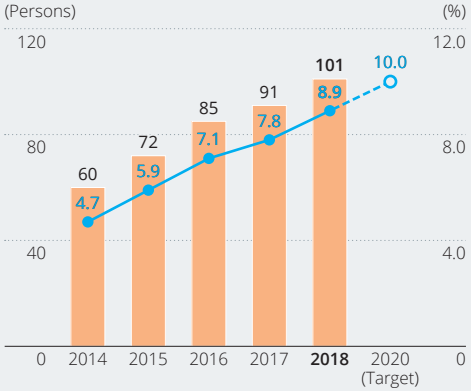


The numbers in parentheses are the number of accidents that required time off from work.

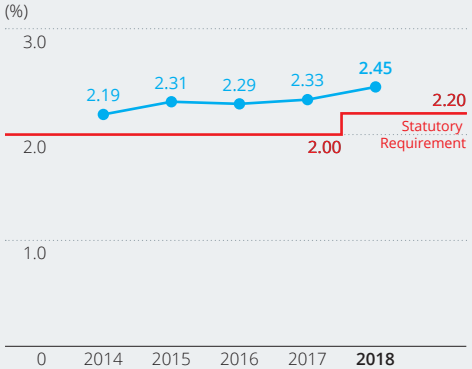
Number of Employees / Ratio of Overseas Employees



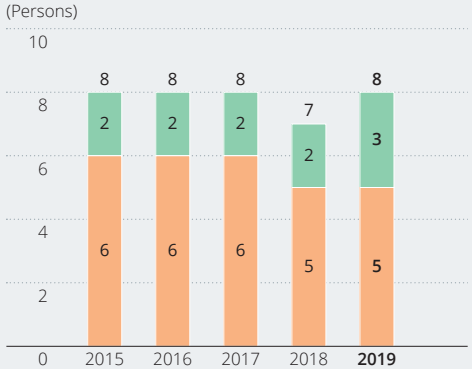
Number of Female Managers / Ratio of Female Managers *6



Ratio of Workers with Disabilities *7



Number of Directors



*1 In Japan, the plants and research laboratories of Kyowa Hakko Kirin, Kyowa Medex (excluded in 2018 due to deconsolidation), Kyowa Hakko Bio and Kyowa Pharma Chemical are covered. Overseas, the plants of Kyowa Hakko Kirin China Pharmaceutical, BioKyowa (U.S.A.), Shanghai Kyowa Amino Acid, and Thai Kyowa Biotechnologies are covered.
*2 Net Sales used for calculating per-unit data until 2015 are based on J-GAAP and after 2016 on IFRS.
*3 The plants and research laboratories in Japan of Kyowa Hakko Kirin, Kyowa Medex (excluded in 2018 due to deconsolidation), Kyowa Hakko Bio and Kyowa Pharma Chemical are covered.
*4 In 2015, the final disposal volume increased by about 170 tons because of the malfunction of the volume reduction facilities of the disposal contractor. We have reviewed the method of disposal and decreased final disposal volume from 2016.
*5 The rates indicate the number of casualties from fatal lost-time accidents per million working hours.
*6 Calculated based on the new criteria from 2015.
*7 As of June each year.

Financial Summary

Consolidated Earnings

Revenue declined ¥6.8 billion year on year, mainly reflecting the impact of drug price revisions and the sale of subsidiary Kyowa Medex. However, core operating profit increased ¥1.0 billion and profit attributable to owners of parent rose ¥11.5 billion. Revenue, core operating profit and profit attributable to owners of parent all exceeded our full-year forecasts announced on October 30, 2018. The upside to our forecasts mainly reflected a stronger-than-expected start to sales of Crysvita and Poteligeo.

	2017 Results	2018 Results	Changes	2018 Plan	Achieved Rate
Revenue	353.4 billion yen	346.5 billion yen	–6.8	335.0 billion yen	103%
Core Operating Profit	57.7 billion yen	58.7 billion yen	+1.0	54.0 billion yen	109%
Core Operating Margin	16.3%	16.9%		16.1%	
Profit Attributable to Owners of Parent	42.9 billion yen	54.4 billion yen	+11.5	52.0 billion yen	105%

Results by Segment

Pharmaceuticals Business

Revenue
271.5 billion yen (Down 1.5% year on year)

Core Operating Profit
50.3 billion yen (Down 0.4% year on year)

Revenue

Revenue in the pharmaceuticals business declined ¥4.3 billion year on year.

In Japan, sales of Rituximab BS, G-Lasta and other new drugs increased, but that was insufficient to offset the impact from drug price revisions and generic/competing drugs, leading to a drop in domestic revenue of ¥6.5 billion year on year.

Overseas, sales of new drugs Crysvita and Poteligeo, both launched in 2018, rose steadily. Sales also remained strong in Asia, supporting a sharp increase in overseas revenue of ¥13.2 billion year on year.

Technology licensing revenue rose ¥0.1 billion, with revenue from the sale of a priority review voucher for Crysvita cancelled out by a decline in revenue related to benralizumab.

The exclusion of Kyowa Medex from the scope of consolidation and other factors also reduced revenue in the pharmaceuticals business by ¥11.0 billion year on year.

Core Operating Profit

Gross profit increased year on year, with growth in overseas sales of pharmaceuticals offsetting weaker sales from domestic pharmaceuticals and a drop in profits from the sale of Kyowa Medex.

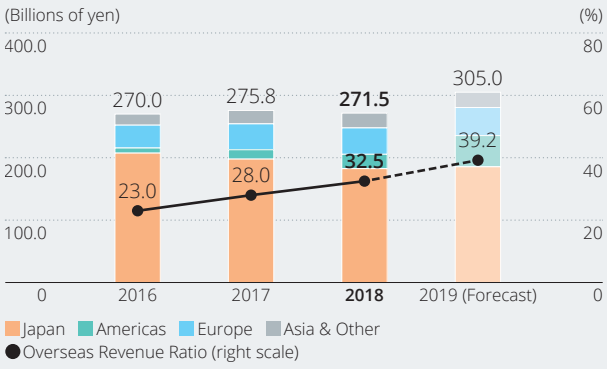
Selling, general and administrative expenses increased ¥6.6 billion year on year. Launch and marketing costs for Crysvita and Poteligeo were the main factors behind the rise in expenses.

Research and development expenses declined for KRN23 and KW-0761, but increased for RTA 402 and KHK4083. As a result, expenses were roughly the same level as in FY2017, down ¥0.5 billion year on year.

Share of loss of investments accounted for using equity method narrowed ¥4.4 billion year on year due to milestone revenue and one-time payments under a European marketing agreement for FKB327.

As a result, core operating profit declined ¥0.2 billion year on year to ¥50.3 billion.

Pharmaceuticals Business Revenue by Region



Bio-chemicals Business

Revenue
78.2 billion yen (Down 3.6% year on year)

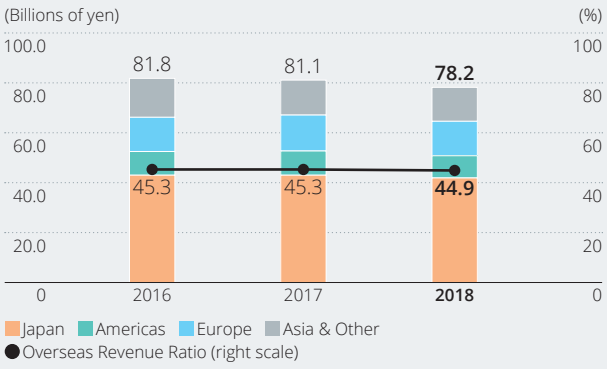
Core Operating Profit
8.1 billion yen (Up 13.1% year on year)

Revenue and Core Operating Profit

Revenue in the bio-chemicals business declined ¥2.9 billion year on year.

The business implemented initiatives to improve profitability, such as focusing on high-margin products, working to restore price competitiveness and targeting resources on core businesses. That led to the drop in revenue, but gross profit increased year on year. Core operating profit increased ¥0.9 billion year on year and the business achieved its core operating margin target of 10%.

Bio-chemicals Business Revenue by Region



Pipeline (As of December 31, 2018)

Area	Type	Code Name (Generic Name)	Indication	Country or region of development	Development phases
					Phase I / Phase II / Phase III / Filed
Nephrology	○	KRN321 (darbepoetin alfa)	Renal anemia (on dialysis)	China	Preparing for application
			Renal anemia	Indonesia	
		KHK7580 (evocalcet)	Hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism	Japan	
		RTA 402 (bardoxolone methyl)	Diabetic kidney disease	Japan	
Oncology		KHK2375 (entinostat)	Breast cancer	Japan	
	●	KW-0761 (mogamulizumab)	Adult T-cell leukemia/lymphoma	U.S.A. / Europe / Others	
			Solid tumor	U.S.A.	
		KHK2455	Solid tumor	U.S.A.	
	●	KHK2823	Cancer	U.K.	
Immunology / Allergy	●	KHK4827 (brodalumab)	Psoriasis	Singapore / Malaysia / Hong Kong / Korea	
			Axial spondyloarthritis	Japan / Korea / Taiwan	
			Autoimmune disease	Japan	
	●	KHK4563 (benralizumab)	Chronic obstructive pulmonary disease	Japan	
			Eosinophilic chronic rhinosinusitis	Japan	
	●	KHK4083	Ulcerative colitis	U.S.A. / Europe / Others	
				Japan	
			Atopic dermatitis	Japan / North America / Europe	
	●	ASKP1240 (bleselumab)	Recurrence of focal segmental glomerulosclerosis (FSGS) in de novo kidney transplant recipients	U.S.A.	

* ● : Antibody ○ : Other protein No mark : Small molecule

Area	Type	Code Name (Generic Name)	Indication	Country or region of development	Development phases
					Phase I / Phase II / Phase III / Filed
Central Nervous System		KW-6002 (istradefylline)	Parkinson's disease	U.S.A.	Preparing for application
	●	KW-0761 (mogamulizumab)	HTLV-1 associated myelopathy	Japan	
		KW-6356	Parkinson's disease	Japan	
	●	KHK6640	Alzheimer's disease	Europe / Japan	
Other	○	AMG531 (romiplostim)	Aplastic anemia	Japan	
			Aplastic anemia	Korea	
			Idiopathic (immune) thrombocytopenic purpura	China	
	●	KRN23 (burosumab)	X-linked hypophosphatemia	Israel / Swiss / UAE	
			X-linked hypophosphatemia in adult patients	North America / Europe / Japan / Korea	
			X-linked hypophosphatemia in pediatric patients	North America / Europe / Australia / Japan / Korea	
			Tumor-induced osteomalacia / Epidermal nevus syndrome	U.S.A. / Japan / Korea	
	○	KW-3357 (antithrombin gamma)	Disseminated intravascular coagulation, congenital antithrombin deficiency	Europe	

* ● : Antibody ○ : Other protein No mark : Small molecule

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.

The Source of Our Value Creation: Strengths in Biotechnology

Biopharmaceuticals – Opening up New Possibilities

Helping patients with hard-to-treat conditions

Kyowa Hakko Kirin is deploying new drug discovery activities with the focus of four modalities – therapeutic antibodies, small molecule drugs, nucleic acid drugs and regenerative medicine. Our novel drug discovery is firmly supported by the exquisite experience in research, development and manufacture of biologics, which all originally started to pursue cell culture technologies, and by open innovation. This unique style of drug discovery is what we call technology-driven drug discovery.

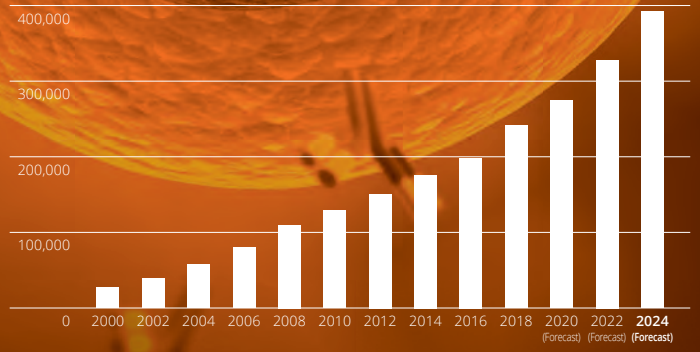
The distinguished fundamental technologies of Kyowa Hakko Kirin are characterized by POTELLIGENT and fully human-antibody producing technologies which we successfully established, and they contribute to efficient production of therapeutic antibodies.

Making the most of our knowledge and experience in protein and antibody engineering technology as well as in control of glycosylation, we are engaged in research and development of next generation therapeutic antibodies such as immune-activating antibodies and tissue-homing antibodies in collaboration with external research institutes.

Biopharmaceuticals have real potential

Global sales of biopharmaceuticals

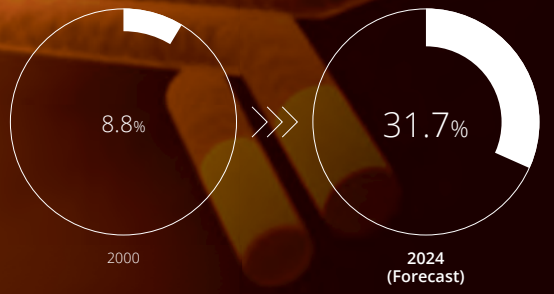
(Millions of US dollars)



Source: EvaluatePharma

Biopharmaceutical share of the global drug market

(%)



Developing innovative new drugs using the latest antibody technologies

Therapeutic antibodies are a class of biopharmaceutical based on antibodies, a type of protein used by the human immune system to fight infection.
Kyowa Hakko Kirin is creating new medicines using two unique proprietary antibody technologies – POTELLIGENT technology and fully human antibody generating technology.

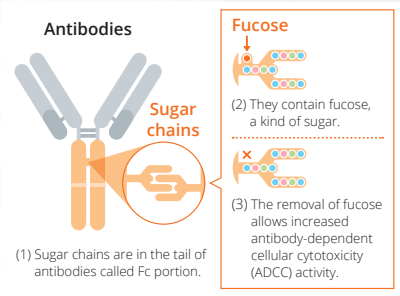
Technology to produce ADCC-enhanced therapeutic antibodies that effectively kill target cells

POTELLIGENT technology

POTELLIGENT technology is the removal of fucose from antibody sugar chains, which leads to a dramatic enhancement*1 in ADCC*2 activity and increased binding affinity to immune cells.

Our first drug to use the technology is anticancer treatment antibody Poteligeo, which directly targets specific cancer cells. Poteligeo was launched in Japan and the US in 2012 and 2018, respectively, and was granted approval in Europe.

*1 An increase in activity of 100 times compared with normal antibodies in an experimental stage.
*2 Antibody-Dependent Cellular Cytotoxity: A mechanism whereby an effector cell actively attacks a target cell to which specific antibodies bind.



World-class antibody production technology

Fully human antibody generating technology

Kyowa Hakko Kirin has applied a revolutionary technique called HAC*3 that enables transfer of human antibody genes to mice, leading to the creation of mice that generate fully human antibodies. With this revolutionary new technology, we have been able to rapidly produce a wide range of different antibodies, just as the human body does, while also reducing the antigenicity of antibodies. The technology has opened up enormous possibilities for the use of therapeutic antibodies in clinical settings.

*3 Human Artificial Chromosome

Cutting-edge biopharmaceutical production technology

Takasaki Plant / Bio Process Research and Development Laboratories

The Takasaki Plant and the Bio Process Research and Development Laboratories use their close proximity to each other to work closely on world-class biopharmaceutical research and production.

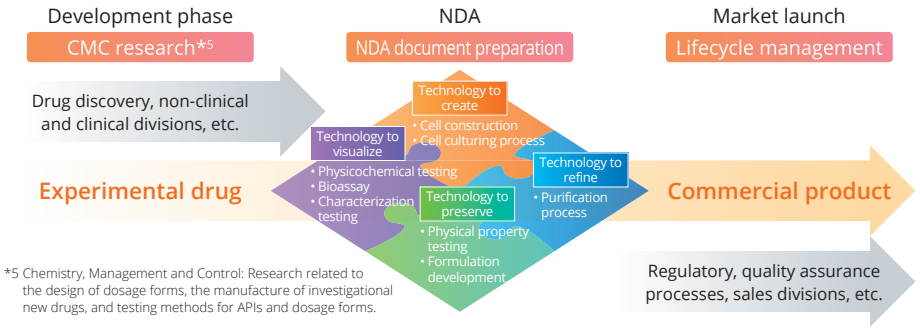
Drawing on Kyowa Hakko Kirin's unique technologies accumulated over more than 20 years, which started with the production of erythropoietin, the Takasaki Plant produces and supplies high-quality pharmaceuticals to patients worldwide using a system that complies with GMP standards*4 in Japan, the US and Europe.

The Bio Process Research and Development Laboratories builds manufacturing processes, develops analysis technologies and designs dosage forms to support the efficient production of high-quality products. The facility supports the Group's production of biopharmaceuticals by combining advanced technologies with technology for four key factors in biopharmaceutical production – technology to create, visualize, preserve and refine.


Takasaki Plant

*4 Good Manufacturing Practices: International manufacturing and quality management standards for pharmaceuticals

Factors in biopharmaceutical production technology



*5 Chemistry, Management and Control: Research related to the design of dosage forms, the manufacture of investigational new drugs, and testing methods for APIs and dosage forms.

Working closely with partners to develop new drugs

As part of its drug discovery and research processes, Kyowa Hakko Kirin is actively embracing open innovation, which draws on information and expertise from outside the Kyowa Hakko Kirin Group. We work closely with universities, medical institutions and venture companies from the earliest stages of the research and development. For example, three therapeutic antibody drugs launched in 2018 – benralizumab, burosumab and mogamulizumab – are the result of more than 20 years of research with partners in academia, who have been involved right from the start of the research process.

Benralizumab is the result of joint research on IL-5 receptors with Professor Kiyoshi Takatsu of the University of Tokyo (now at the Toyama Prefectural Institute for Pharmaceutical Research); burosumab was born out of joint research on hypophosphatemic osteomalacia with Professor Seiji Fukumoto at the University of Tokyo (now at Tokushima University); and mogamulizumab is the combined result of advanced research on chemokines by Professor Kouji Matsushima of the University of Tokyo (now at Tokyo University of Science), translational research using clinical samples by Professor Ryuzo Ueda of Nagoya City University (now at Aichi Medical University), and our own POTELLIGENT technology. In addition to using POTELLIGENT technology and other proprietary antibody technologies, we have formed strategic alliances to drive forward new drug development in our antibody business. Combining our R&D capabilities and manufacturing technologies with full use of open innovation is a key characteristic of our approach to R&D at Kyowa Hakko Kirin.

At our research center in San Diego, US, we are harnessing our long-term relationship with the La Jolla Institute for Immunology and teaming up with other external research institutes to expand our product pipeline. In Japan, we are actively forging links with partners in the public, private and academic sectors, such as a joint government-industry-academia drug discovery research project run by the Japan Agency for Medical Research and Development (AMED), as part of our efforts to identify new drug targets and create next-generation drug discovery technologies.

We will continue to organically combine internal and external expertise and know-how to support the development of our distinctive and innovative new medicines.

INSIGHTS from partners

Joint research with Kyowa Hakko Kirin has been enjoyable and challenging

Director, Toyama Prefectural Institute for Pharmaceutical Research
Kiyoshi Takatsu, Ph.D.

My research group started working with Kyowa Hakko around 40 years ago. Back then, we were in the early days of cytokine research and I was at Osaka University conducting research on thyrotropin-releasing factor (TRF), current IL-5. At Osaka University, I became proficient in cellular fusion techniques to establish cell lines for the production of TRF. At around the same time, a researcher from Kyowa Hakko, Hajime Yoshida was at the university on an internal study program. He expressed an interest in learning about monoclonal antibody technologies, which prompted us to start working together. I remember it all very clearly.

In 1991, I was offered the opportunity to lead the research laboratory at the Institute of Medical Science, University of Tokyo. In the laboratory, the first joint researcher I encountered was another employee from Kyowa Hakko, Masamichi Koike, and I worked as his academic advisor. After receiving his doctor's degree, Masamichi returned to Kyowa Hakko, where he launched a project to establish cell lines to produce the anti-human interleukin 5 receptor alpha (IL-5Rα) chain antibody. I helped with the project where I could. Thanks to the hard work of the project team, they succeeded in creating humanized anti-human IL-5Rα chain antibody (benralizumab), and I had the good fortune of working with them in the early days of that research.

After reaching the mandatory retirement age at the University of Tokyo, I joined the Toyama Prefectural Institute for Pharmaceutical Research as a part-time employee of Toyama Prefecture. With endowments from Kyowa Hakko Kirin and 13 other pharmaceutical firms in Toyama Prefecture, the Department of Immunology and Pharmacological Genetics was established in the Graduate School of Medicine and Pharmaceutical Science, University of Toyama. Even now after 12 years since then, our research is still carrying on with that support. Our team has achieved a large number of breakthroughs in many areas, from the identification of innate lymphoid cells (ILC2) as a source of IL-5, to the discovery of the link between IL-5-producing ILC2 and hypereosinophilic syndrome. Based on a joint research agreement with Kyowa Hakko Kirin, we published research theses in 2017 describing the development of a mouse model for pulmonary arterial hypertrophy (PAH) caused by IL-5–producing ILC2 and the discovery that the administration of anti-mouse IL-5Rα chain antibody with enhanced ADCC activity suppresses the symptoms of PAH.

Through joint research efforts with Kyowa Hakko Kirin, I have enjoyed seeing significant progress and breakthroughs via industry-academia collaboration in fields of mutual interest, while at the same time feeling responsibility for the direction of research and the need to deliver research outcomes in a timely manner. More than anything, I have been impressed by the Company's ability to drive forward research.

My research at University of Toyama has been supported by Kyowa Hakko Kirin over a decade. It has led to acquire research outcomes greater than expected, and provided valuable opportunities to grow the researchers of the next generation. I would like to thank everyone at Kyowa Hakko Kirin for all their support over the years and wish them every success for the future.

2nd Japan Bioindustry Award ceremony (Award for the development of biologics for asthma based on the discovery of the IL-5/IL-5 receptor; Professor Takatsu, second from right)
Photo provided by the Japan Bioindustry Association

Using AI-based drug discovery to accelerate R&D

As a result of the next-generation sequencers, that have dramatically reduced the cost and time of gene sequencing, huge projects in the early 2000s, such as the human genome and cDNA projects, can now be conducted at a laboratory level. In addition to the gene sequencing environment, microarrays, which generate gene expression profiling data became the technological fundamentals for rapid accumulation of the vast amount of data. At the same time, we are seeing improvements in the speed and cost of computing resources, driving advances in the multilayered analysis of big data.

For many years, Kyowa Hakko Kirin has introduced new technologies such as bioinformatics*1 and cheminformatics*2 into drug discovery processes. We have used these technologies to deliver a wide range of benefits to our research – not simply to identify specific genetic sequences or make other pinpoint discoveries – helping to deepen our drug discovery research capabilities. Today, machine learning, deep learning and other automated analytical methods have the potential to shorten and simplify complex analytical processes, and we are now actively looking at ways of applying the new technology.

We are exploring the possibilities of AI in three areas: (1) to accumulate and analyze in-house data in the research phase, (2) to consult and partner with academia and IT companies/ventures, and (3) to utilize anonymized data from clinical settings and other sources. In the first area, we aim to accelerate the optimization of research compounds and predict target molecules in research compounds, comprehensively analyze information from genome sequences and gene expressions at the individual cell level, and identify potential candidates for effective predictive markers. In the second area, we want to tap external resources to reinforce areas in-house where we lack experience and techniques, and explore new approaches to drug discovery using effective big data analysis, such as drug repurposing*3. In the third area, we want to use AI to conduct extensive analysis of the large amounts of multilayered medical data being accumulated every day – while ensuring ethical standards – to identify new target conditions and molecules, as well as effective predictive markers.

Analysis methods and approaches, as well as the type of data, differ in each area, so we need to have a clear understanding of the different data characteristics to ensure meaningful analysis. That's why we have established specialist teams for each area to explore the potential of AI.

We plan to accelerate and improve the efficiency of the Group's R&D activities while constantly looking at possible applications for digital technology in all our drug discovery R&D processes.

*1 Bioinformatics: A scientific field or type of technology that combines biology and information engineering. Bioinformatics is the use of information engineering to interpret biological data such as measurements from digital images of life forms or information from genetic sequences to solve a range of biological problems.
*2 Cheminformatics: A scientific field or type of technology that combines chemistry and information engineering. Cheminformatics is the use of information engineering to analyze the structure, substance and characteristics of digitally created compounds to solve a range of chemistry problems in the pharmaceuticals sector and other fields.
*3 Drug repurposing: A development method using compounds halted mid-development or drugs already on sale for new indications, which are approved and launched as new products. Also known as drug repositioning.

Three potential areas for AI in drug discovery research

1 Accumulate and analyze in-house data in the research phase

2 Consult and partner with academia and IT companies/ventures

3 Utilize anonymized data from clinical settings and other sources

Accelerate research and development

INSIGHTS from researchers

Initiatives in data science

Director, Biometrics Department, R&D Division
Toshinari Masui

We established a Clinical Data Science Research Group in the Biometrics Department in April 2018. The group is tasked with utilizing internal and external clinical trial data by harnessing data science approaches to increase the success rate of clinical trials and promote the use of clinical data in drug discovery research. In short, our mission is to apply real-world data*4 to research and development. Through a daily process of trial and error, we are laying the groundwork for the active adoption of AI and other new technologies to efficiently use large volumes of data. To create new drugs, we will need to combine AI and other new technologies with existing R&D approaches. Our job is to take on the challenges to rapidly deliver effective and attractive new drugs to patients.

*4 Real-world data: Data on drugs gleaned from real-world environments, rather than from experimental conditions such as clinical trials. Examples include data from digital medical files or statements of medical expenses.

Clinical Data Science Research Group, Biometrics Department
(Toshinari Masui, center of front row)

Provide “Only One” Values with Our Dreams – Committed to Develop Unique Drugs –

Our research efforts are aimed at creating a steady stream of innovative new medicines, with a special focus on oncology, nephrology, immunology and allergy, and the central nervous system, in line with two strategic pillars in our FY2016-2020 Mid-term Business Plan – improve global competitiveness and create innovation. In 2018, for the first time, the Kyowa Hakko Kirin Group delivered two proprietary medicines (burosumab and mogamulizumab) to patients worldwide. We are delighted to receive precious comments and voices from the patients, which motivate us even further to challenge and offer innovative medicines to the frontline of healthcare.

Vice President, Head, R&D Division

Mitsuo Satoh, Ph.D.

When an application for a development product is filed, Mitsuo Satoh, Ph.D., Vice President, Head of the R&D Division fills in one of the two blank eyes of a “daruma doll.” When the approval is obtained, he fills in the other eye to finish the “daruma doll.” Which means the number of "daruma dolls" increases in the office, as the development of late phase pipeline progress steadily. To share the joy of achievement, we send “daruma dolls” of globally developed products to overseas offices of joint-development companies as well. It has been our pleasure to receive positive and smiley responses from them, and we believe “daruma dolls” contribute to foster togetherness with partners as well.

Making the leap to a Global Specialty Pharmaceutical Company

Three leading drugs toward becoming a Global Specialty Pharmaceutical Company made great progress - burosumab (KRN23) and mogamulizumab (KW- 0761) received approval in the US and Europe, and istradefylline (KW-6002) has been submitted for approval in the US. The Group is now looking to its R&D team to deliver innovative new medicines to patients following the three products. We are developing a number of promising candidates for the Group’s next global pipeline: KHK4083, created using our strengths in biotechnology such as POTELLIGENT technology and fully human antibody generating technology, has shown excellent potential as a treatment for atopic dermatitis; KW-6356, a next-generation adenosine A_{2A} receptor antagonist, which follows on from istradefylline as a treatment for Parkinson’s disease; and KHK2455, a best-in-class IDO inhibitor for the treatment of solid tumors. Clinical development of these potential global drugs is being led by vGDO*, which integrates teams in Japan (Head Office), the US, Europe and Asia and is set to play a key role in efforts to make Kyowa Hakko Kirin leap to a Global Specialty Pharmaceutical Company. In parallel, our R&D activities for Japan area have also been forged, as shown by the successful initiation of clinical development programs including bardoxolone methyl (RTA 402), a promising revolutionary new treatment for diabetic nephropathy, and tenapanor (KHK7791), a first-in-class treatment for hyperphosphatemia. Our tireless efforts in R&D are directed to the patients not only in the US or EU, but also in Japan and Asian area; it is our commitment to deliver beneficial new drugs worldwide by making the most of our strengths in the focused therapeutic area.

* virtual Global Development Organization: A virtual organizational structure that brings together the separate development functions of Kyowa Hakko Kirin Head Office and its subsidiaries in the US, Europe and Asia in global development efforts. Global development involves cross-border discussions between different regional teams.

Creating innovation

Kyowa Hakko Kirin’s research section plays a crucial role in creating innovation. We focus on four modalities – next-generation antibody drugs, nucleic acid drugs, new types of small molecule drugs and regenerative medicine – as part of a technology-driven drug discovery process aimed at increasing our ability to create groundbreaking new drugs that are competitive in the global market. On top of such in-house drug discovery process, open innovation activities have been the impetus for the pipeline creation; with our extensive knowledge and experience acquired through development of mogamulizumab and burosumab, we have been working on combining our research platform of therapeutic antibody with external drug seeds/candidates. It is also noteworthy that the continuous challenges of our young researchers have been gradually but steadily evolving the technologies for antibodies as well as in nucleic acid delivery systems to grow as pinpoint-targeting antibody, and cell- /organ-specific targeting delivery systems.

Provide “Only One” Values with Our Dreams – Committed to Develop Unique Drugs –

“Let us always provide only-one values with our dreams!” has been the key message from Head of R&D to our R&D colleagues. No matter what roles you are assuming, all our R&D efforts are directed sorely to create unique and original values; the values that may be small individually, but the positive and dedicated dynamics will reach clear-cut differences and advantages in our innovative drugs for the patients and the society. This is how we picture our R&D activities and we keep moving forward as Global Specialty Pharmaceutical Company in pursuit of innovation for patients, providing only-one values with our dreams.

Value Creation Process

The Kyowa Hakko Kirin Group will continue to contribute strongly to the health and well-being of people around the world by constantly relying on innovation as our foundation and utilizing state-of-the-art biotechnology to respond to changes and rolling out products and services that meet true customer needs and have unique high value.

INPUTS

Injection of Management capital

Financial capital
Operating cash flow 56.2 billion yen

Intellectual capital
R&D expenses 48.6 billion yen
Ratio of R&D expenses to revenue 14.0%

Manufactured Capital
Capital expenditures 10.9 billion yen
Production facilities 10 facilities

Social and relationship capital
Overseas subsidiaries 43 companies
Marketing offices in Japan 105 offices

Natural capital
Energy usage 155,000kL of oil equivalent
Water Use 48.5 million m³

Human capital
Employees 7,242 people
Training hours 24,825 hours

Value

Utilizing Highly Unique Value

Deliver new value to people worldwide through innovation

Innovation

Responding to Changes through Innovation

Taking advantage of our wide variety of business bases and creating new value from new ideas in our core competence

Strategies

Promoting management strategies

- Creating Innovation
- Improvement of Global Competitiveness
- Continuous Improvement for Operational Excellence

Production
Marketing
PV & QA
R&D

Foundation

Business base
CSR / Governance

OUTPUTS

Growth of management capital

- Financial capital ▸ P.28
- Intellectual capital ▸ P.29
- Manufactured Capital ▸ P.30
- Social and relationship capital ▸ P.31
- Natural capital ▸ P.36
- Human capital ▸ P.37

OUTCOME

Contribution to Health and Well-being of People

- Providing products and services that meet customer needs
- Creating new value that is focused on health
- Tackle issues facing the world today (SDGs)

Environmental Changes Surrounding Medical Treatment

- Specialization of medical care
- Fragmentation of medical needs
- Reinforcing measures for medical cost containment
- Increasing consciousness of healthy life expectancy
- Promotion of open innovation

Creating and Strengthening Financial Capital

Financial Strategy

Targeting sustained growth in ROE by maximizing the value of global strategic products and actively investing in value creation

Increasing ROE

The Kyowa Hakko Kirin Group has selected return-on-equity (ROE) as a key performance indicator to increase corporate value over the medium to long term. We are targeting ROE of 10% or higher (our goal for increasing shareholder value) in the early 2020s, so that returns are consistently above the cost of shareholders' equity. To achieve that goal, we aim to increase the overseas revenue ratio to 50%, which will support our efforts to transform Kyowa Hakko Kirin into a Global Specialty Pharmaceutical Company (GSP), and generate core operating profit of ¥100 billion or more, which is our target for sustainable growth.

To achieve ROE of 10% or higher in the near term and increase ROE even further over the longer term, we will put priority on maximizing the value of global strategic products, which have been positioned as growth drivers to transform the Group into a GSP. Additionally, on a global basis, we will increase margins (return on revenue) by streamlining operations and optimizing our global tax structure and improve the total asset turnover ratio by reducing the cash conversion cycle (CCC).

Investing in Value Creation

As a research and development-focused pharmaceutical company, Kyowa Hakko Kirin's overriding mission (social value) is to consistently create revolutionary new medicines that address unmet medical needs.

Kyowa Hakko Kirin is one of the leading research and development companies worldwide in the field of biopharmaceuticals. To enhance our drug discovery capabilities and generate sustained growth, we will invest heavily in research and development. We have basically set the line for annual R&D expenses at roughly 20% of revenue, but with overseas revenue expected to rise, we expect to have scope to invest even more aggressively.

In addition to investment to expand our pipeline of next-generation drugs, such as the next phase of global products, we will continue to invest in strengthening drug discovery platforms and technologies to support innovation over the long term. Together with our active proprietary drug discovery efforts, we will expand the pipeline by collaborating with a wide range of different partners in industry, government and academia through open innovation drug discovery and by utilizing strategic alliances (in-licensing, tie-ups, etc.)

Another priority is to make upfront investments in upgrading and expanding the Group's global sales network to ensure we increase revenue and maximize value from our global strategic products.

As of the end of 2018, the Company had nearly ¥200 billion in cash on hand (cash and deposits plus loans receivable from parent company), giving us sufficient resources to consider strategic investments to drive future growth, such as M&A.

When evaluating the viability of potential investments or development projects, we use two qualitative standards: net present value (NPV) and expected present value (EPV). Both standards are based on the hurdle rate (by region) which reflect the rate we expect to have to pay investors to invest in our assets (WACC). In investment decisions, we focus on whether the investment will contribute to an increase in corporate value over the medium and long term by generating returns in excess of the cost of capital.

Increasing Shareholder Returns

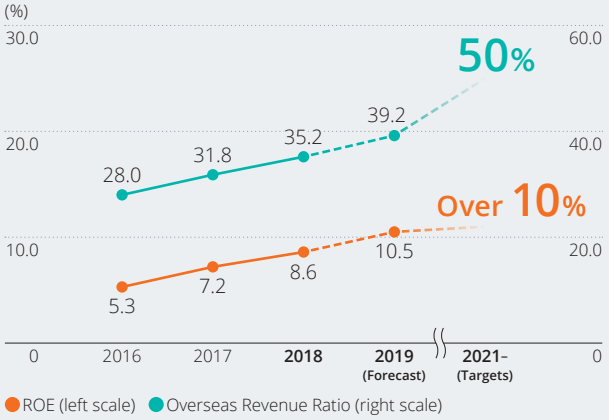
Our basic policy on profit distribution is to pay stable dividends while ensuring sufficient internal reserves for long-term investment, such as research and development, capital investment and pipeline expansion to support future growth in corporate value. We also flexibly repurchase own shares as needed.

Under the FY2016-2020 Mid-term Business Plan, we aim to pay stable and consistent dividends in line with profit growth, targeting a consolidated dividend payout ratio of 40%. Based on that policy, we paid a dividend of ¥35.00 per share for FY2018, a hike of ¥8.00 and the second consecutive year of increase. We plan to raise the dividend again in FY2019, by ¥5.00 per share to ¥40.00.

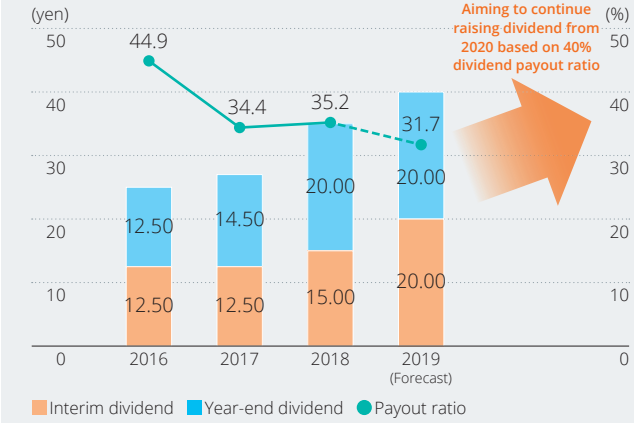
In addition, in February 2019, we repurchased 10,700,000 shares (worth ¥22.6 billion) and retired 36,483,555 shares (equivalent to 6.33% of total shares outstanding before the retirement) to improve capital efficiency and increase shareholder returns.

Going forward, we intend to continue increasing shareholder returns, supported by sustained growth in profits.

ROE / Overseas Revenue Ratio



Dividends per Share / Payout Ratio



Creating and Strengthening Intellectual Capital

Pharmaceuticals Business Research and Development

Driving forward R&D to continue creating global strategic products

Progress in FY2018

R&D in each category and efforts to build drug discovery platforms for each modality are gaining momentum

Many years of collaborative work with WDO* – our R&D organization in the US and Europe – finally yielded results in 2018, with in-house drugs burosumab (KRN23) and mogamulizumab (KW-0761) receiving approval in the US and Europe.

In Japan, we received approval for evocalcet (KHK7580) and applied for an additional indication for romiplostim (AMG531), and in South Korea, we progressed to the approval phase for brodalumab (KHK4827), laying the foundations for further growth in Asia and worldwide. We are making good progress in building a late-phase development pipeline in each treatment category as part of efforts to launch the next generation of global strategic products: in the nephrology category, we started a phase III clinical trial of bardoxolone methyl (RTA 402) in Japan; in the immunology and allergy category, we began a phase II clinical trial of KHK4083 in Japan, the US and Europe; and in the central nervous system category, results from a phase IIa clinical trial in Japan confirmed the efficacy of KW-6356. In the oncology category, we have teamed up with other companies to maximize the value of KHK2455 through joint development efforts.

In addition, we are working to expand our pipeline in the discovery and early development stages through collaborative projects with research bodies in Japan and overseas, including our own research laboratory in San Diego, an important biotechnology cluster. In 2018, we set up four laboratories aligned with our target modalities and stepped up efforts to establish innovative drug discovery technology platforms, which also harness open innovation. One recent example is the Progressive Research for Immunology and Antibody (Primab) project with Keio University. We plan to continue actively developing our R&D capabilities to attain the targets in the Mid-term Business Plan.

Notification of approval for mogamulizumab in the US and the traditional daruma doll to mark the approval

* Western Development Organization: Functional organization exclusively undertaking all the operations related to new drug development of Kyowa Hakko Kirin in Europe and the US.

Goals for FY2019

Create a steady stream of next-generation global strategic products by leveraging the competitive advantages of each internal organization

We will continue to build an independent and collaborative R&D organization along category and function lines – one of the goals set by the Group in 2016 to become a Global Specialty Pharmaceutical Company (GSP) – launch global strategic products, and identify promising new development candidates to support future growth. Leveraging the technologies and expertise accumulated in target treatment areas as part of that process, we aim to build a valuable pipeline of drugs for future treatment systems five to ten years from now and continue driving innovation.

In 2019, the second year of the "Leaping Forward Phase" of our Mid-term Business Plan, we will focus all our efforts on securing US approval for KW-6002 (istradefylline), which we have positioned as one of our global strategic products. In Japan, we aim to secure approval for burosumab and romiplostim.

Another key challenge we cope with urgently is to enhance the development structure/organization in Asia which is inevitable to strengthen our presence in fast growing markets in Asia including China. We consider our current experience to submit new drug approval applications for romiplostim and brodalumab to be a great opportunity to seek for enhancement and optimization of the development structure/organization. It is also to note that we are trying to use real-world data for our clinical trials which has rapidly advanced in recent years to boost the success rate in developing the next generation of global strategic products in Japan, the US, Europe and Asia.

To reinforce our pipeline in the discovery and early development phases, which supports the Group's growth over the medium and long term, we will continue to promote open innovation – a key characteristic of our approach to R&D – and deepen our category strategy through translational research. At the same time, we aim to establish innovative drug discovery technology platforms through our four modality laboratories established in 2018, and continue to create a series of development pipeline candidates.

FOCUS ON

A global R&D network straddling regions and companies

The R&D Division integrates the Group's global development efforts with a virtual Global Development Organization (vGDO), which connects development teams at head office and subsidiaries in the US, Europe and Asia along functional lines. As part of our efforts to realize our "One Kyowa Kirin" vision, we are sending R&D team members from Japan to overseas sites and inviting staff from our US research laboratory (San Diego) and development center (Princeton) to work in Japan.

An evening with expats from US research and development sites and their family staying in Tokyo

Team building exercise (cooking competition) as part of a vGDO meeting

Creating and Strengthening Manufactured Capital

Pharmaceuticals Business Production and SCM

Ensuring stable supplies of high-quality pharmaceutical products based on advanced technology

Progress in FY2018

Global supplies of biopharmaceuticals get underway

Our Takasaki Plant has manufacturing facilities of Drug Substance (DS) and Drug Product (DP) which are fitted with the latest biopharmaceutical manufacturing equipment for antibody drugs. Over the last few years, we have been preparing for the launch of global strategic products to ensure stable supplies of high-quality pharmaceuticals to patients worldwide, based on GMP* systems that conform to the strictest guidelines overseas. In 2017 and 2018, the Takasaki Plant passed Pre-Approval Inspections by US and European authorities, allowing us to begin supplying two global strategic products to the US and Europe after they were approved in 2018. We are now making preparations to supply the products to other markets worldwide.

* GMP (Good Manufacturing Practices): The practices required in order to conform to the guidelines of Manufacturing and Quality Control for pharmaceuticals and quasi-pharmaceuticals.

Goals for FY2019

Making the leap to the next level with world-class production technologies

Kyowa Hakko Kirin has advanced manufacturing and analysis technologies for biopharmaceutical production. We are using those technologies to achieve world-class standards in product quality and productivity. We will also continue to develop new manufacturing technology for antibody drug substance to improve productivity.

To meet the needs of patients and medical professionals, we will use our proprietary formulation technology to develop new dosage forms and injection methods.

And to help the Group make its leap to a Global Specialty Pharmaceutical Company, we will continue to train our personnel and build a powerful organization.

FOCUS ON

Supplying high-quality pharmaceuticals

Strengthening production and quality management

We are strengthening production and quality management at our plants, such as shifting to automated processes, introducing the latest analyzers and improving the reliability of production and quality data, so that patients can take high-quality pharmaceuticals with confidence.

Expanding production facilities

We aim to increase the Takasaki Plant's production capacity for antibody drugs to 2.5-times the current level by 2025. To reach that goal, we will continue to expand DS and DP manufacturing facilities from 2019. We will also start up a new manufacturing facility fitted with cutting-edge equipment. These expanding production facilities will give us the capacity to supply many different products to patients worldwide.

Advanced manufacturing equipment at the Takasaki Plant

Projected increase in production capacity

2025

Roughly 2.5-times current level

Building a global SCM* system

We established a SCM Department as part of global organizational changes to improve regional cooperation and appropriately manage the Group's supply chain. The new structure will allow us to supply pharmaceutical products to patients worldwide certainly.

* Supply Chain Management: Refers to the management of goods across all aspects of operations (supply chain), from the raw materials to production and the supply of finished products to customers.

Reinforcing BCP*

In preparation for disasters such as earthquakes and typhoons, we are reinforcing our BCP to maintain stable supplies of pharmaceuticals. Specifically, we are increasing supply sources for raw materials, earthquake-proofing production facilities, holding emergency training drills and overhauling our emergency procedures.

* BCP (Business Continuity Planning): Plans to ensure continued business operations or the rapid recovery of operations in case of natural disasters and other emergencies.

Creating and Strengthening Social and Relationship Capital

Pharmaceuticals Business Operations in Japan

Working to promote the usage of new drugs and contributing to community healthcare

Progress in FY2018

Contributing to healthcare by promoting market penetration of new drugs

In January 2018, we released Rituximab-BS Infusion [KHK], a biosimilar of rituximab, a monoclonal antibody against CD20, which could also address the social demand of containing healthcare costs. In May, we launched next-generation calcium-sensing receptor agonist Orkedia, which has much the same therapeutic effect as Regpara, a treatment for secondary hyperthyroidism, with lower incidence of upper gastrointestinal tract disorder. And in June, we got a new gel formulation of Dovobet, a topical combination drug for psoriasis vulgaris and the leading topical treatment for psoriasis in Japan. The gel formulation is easier to apply to the scalp, which is one of the most frequently affected areas of patients with psoriasis, and it is expected to improve adherence to treatment. In December, we also added a 0.5mg version of Fentos Tape, a transdermal, long-acting cancer pain relief patch. The new size allows accurate dose controls.

Goals for FY2019

Promoting and reinforcing our category strategy

In 2019, we will continue to focus on and strengthen new drugs into the four treatment categories where we already have a strong position – nephrology, oncology, immunology and allergy, and the central nervous system (CNS). In the nephrology category, we plan to launch Darbepoetin Alfa Injection Syringe [KKF], an authorized version*1 of our flagship product Nesp. Since its launch in July 2007, Nesp has been adopted by many medical institutions due to its superior clinical efficacy and safety for the treatment of renal anemia for all stages of the treatment process, from storage to hemodialysis. Like Rituximab-BS, we will promote its market penetration to contribute to the issue of rising medical costs and satisfy patients' needs. In the oncology category, we aim to gain approval for the additional indication of aplastic anemia for romiplostim, a thrombopoietin receptor agonist marketed as Romiplate for subcutaneous injection in Japan. The new indication will provide a safe and effective alternative treatment for patients who have had an insufficient response or are not suited to immunosuppressive therapies such as anti-human thymocyte immunoglobulin. In the CNS category, we entered an agreement for the sales rights in Japan of HP-3000, a potential new transdermal patch for Parkinson's disease that is being developed by Hisamitsu Pharmaceutical Co., Inc. We will offer a new treatment option for Parkinson's along with our core product Nouriast. Outside the four categories, we plan to launch burosumab (KRN23, product name in the US and Europe: Crysvita) in Japan, following its release in the US and Europe. We will deliver it to patients as soon as we receive approval and also promote awareness of the disease.

Going forward, we will continue to support healthcare provision by providing information relevant to the changing healthcare environment and medical practitioners' needs by promoting the penetration of new medicines. At the same time, medical representatives (MR) and regional liaison officers*2 will work together to actively support policies aimed at tackling healthcare issues in each community, such as measures to prevent the increasing severity of lifestyle-related diseases*3.

*1 The manufacture and sale of generic versions of original drugs under license from the pharmaceutical company that holds the patent, using the same ingredients and manufacturing methods.
*2 Staff with medical management consultant qualifications who meet with diverse stakeholders and support the implementation of solutions developed by MRs to address community healthcare issues.
*3 A wide-ranging Ministry of Health, Labour and Welfare project to tackle lifestyle-related diseases, aimed at prolonging healthy life expectancy and moderating national healthcare expenses.

FOCUS ON

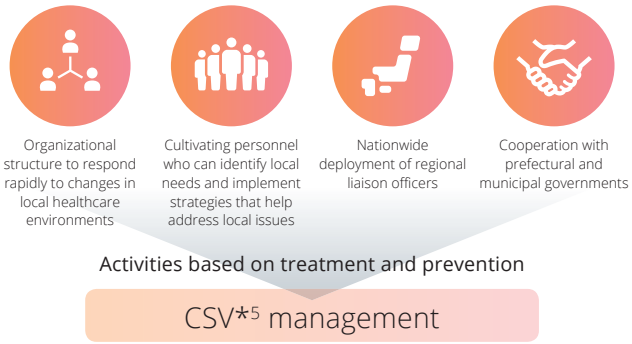
Supporting community healthcare solutions to prevent the increasing severity of lifestyle-related diseases

The elderly population in Japan is predicted to spur greater demand for healthcare and nursing care. In response, the government is overhauling healthcare provision to build an integrated community care system. At the same time, to realize its goal of extending healthy life expectancy, the government is promoting measures in each region to prevent major lifestyle-related diseases and stop them becoming more severe. However, the extent and impact of those measures has not necessarily been consistent in each region. Against that backdrop, we reformed our organizational structure in April 2017 to allow us to respond more rapidly to the changes in the healthcare environment in each region (sales offices were aligned with the secondary medical areas and sales teams at each office were reorganized into an area-based system). Also, in 2016, we started a continuous training program (practical workshops run by line managers and area team leaders*4) to cultivate staff who can implement strategies that help us respond to community needs more rapidly.

To make more effective contributions to community healthcare issues, we also started deploying regional liaison officers nationwide in 2018 to coordinate with local government officials and a broad range of other stakeholders in each community, as well as healthcare professionals. In many areas of Japan, the increase in lifestyle-related diseases is a serious problem and to address this issue, we are contributing to patients' health by promoting Onglyza, a treatment for type-2 diabetes, which is closely associated with the progression of chronic kidney disease, and renal anemia treatment Nesp. However, we are also putting considerable effort into preventative healthcare, such as raising awareness of medical conditions, encouraging people to have health checkups and creating opportunities for interdisciplinary workshops. When local governments need to be involved, we sign agreements with prefectural and municipal governments to implement joint private-public initiatives.

*4 Training designed to help personnel consistently and rapidly use the plan, do, check, act (PDCA) cycle based on clear goals in order to raise the organization's competence (frontline capabilities).

Initiatives in community healthcare



*5 Creating Shared Value: The idea that companies can increase corporate value by balancing the "creation of economic value" with the "creation of social value" through initiatives to address social issues.

Creating and Strengthening Social and Relationship Capital

Pharmaceuticals Business Overseas Operations

Targeting an overseas revenue ratio of 50%, we are expanding our business, building a highly productive sales structure and developing human resources to support those efforts.

Progress in FY2018

Record overseas revenue

In 2018, we launched proprietary drug Crysvita in Europe and the US and proprietary drug Poteligeo in the US. Poteligeo also received marketing authorization in Europe. Since launch in April 2018, Crysvita has registered sales of ¥7.7 billion in the US and Europe, while Poteligeo has recorded US sales of ¥2.1 billion since launch in October, beating our forecasts. Sales of existing products Abstral, Pecfent and Moventig also increased year on year in Europe, which together with the two new products, contributed to a solid performance in 2018.

In Asia, we increased sales of existing products, especially in the nephrology and oncology categories, two fields we have worked hard to develop. In the nephrology category, Kyowa Hakko Kirin products, particularly Nesp and Regpara, have built a strong reputation among medical professionals in Asia. In China, Regpara was added to the National Essential Drug List (NEDL) in October 2018, following on from its inclusion in the National Reimbursement Drug List (NRDL) in 2017. Those developments are likely to support further growth in demand.

In FY2018, overseas revenue in the pharmaceutical business (excluding technology licensing revenue) totaled ¥72.2 billion, a record-high for Kyowa Hakko Kirin.

* Sales data covers the period January to December 2018

Goals for FY2019

Establish our position as a Global Specialty Pharmaceutical Company

We expect overseas revenue to exceed ¥100 billion in FY2019 (excluding technology licensing revenue). We aim to use the overseas business to drive the Kyowa Hakko Kirin Group's growth and establish our position as a Global Specialty Pharmaceutical Company. In the key US and European markets, we will ensure stable supplies of new drugs Crysvita and Poteligeo to patients in need. We plan to launch these drugs in multiple countries in Europe in 2019. To ensure the new drugs reach a broad market as soon as possible, we will reinforce our business base, expand sales networks and provide relevant information about conditions and products to support further uptake.

In Asia, we aim to establish our presence as a leading company in the nephrology and oncology categories and take on challenges in new treatment fields. In 2019, we plan to launch Lumicef in the immunology and allergy category in Asia. Our development pipeline in Asia is already strong. Drawing on the expertise we have accumulated in the region through local subsidiaries, we will work to maximize the value of new and existing products.

To achieve our goal of becoming a Global Specialty Pharmaceutical Company with its roots in Japan, we will put in place a framework to deliver our products to patients worldwide to support a new phase of rapid growth.

FOCUS ON

Asia Pacific Headquarters

The pharmaceuticals market in the Asia Pacific region is projected to grow at a faster pace than in the US, Europe or Japan. Given that outlook, in April 2018 we transferred responsibility for managing all the Group's pharmaceutical business operations in Asia and Oceania (excluding Japan) to Kyowa Hakko Kirin (Singapore) Pte. Ltd., our Singapore sales subsidiary. The following August, we changed the name of the company to Kyowa Kirin Asia Pacific (KKAP). Going forward, KKAP will lead efforts to reinforce our business in Asia and Oceania to achieve our goal of becoming a Global Specialty Pharmaceutical Company. Using Singapore's extensive business infrastructure, we plan to further strengthen the functions of the Asia Pacific Headquarters to build a top-class business hub for the Asia Pacific region.

Concrete Initiatives

1. Develop and execute growth and product portfolio strategies tailored to the region, in line with local pharmaceutical needs in Asia and Oceania (excluding Japan).
2. Consolidate responsibility for product supply chain management (SCM), post-sales support, pharmacovigilance and quality assurance (PV & QA) and other operations in Asia and Oceania (excluding Japan), and comply with regulations in each country or territory.
3. Increase sales of the Company's products in new countries and territories in Asia and Oceania (excluding Japan), as well as in countries where we already have a local subsidiary.

Scenery around the KKAP's office

Creating and Strengthening Social and Relationship Capital

Pharmaceuticals Business

Pharmacovigilance and Quality Assurance

We work to ensure reliability in all stages of the pharmaceutical life cycle – from the development stage to the post-marketing stage – to provide stable supplies of effective, safe and high-quality pharmaceuticals to people worldwide.

Progress in FY2018

In FY2018, we secured marketing approval in the US and Europe for our two global pharmaceutical products.

In product safety, under our global safety committee, global product safety teams and issue-specific global taskforces worked closely with overseas subsidiaries on safety, rapidly collecting and evaluating safety information from various sources worldwide and creating systems to provide that information promptly to medical practitioners on the front-line. We also updated our global safety database and its operating rules to address new regulations related to the electronic transmission of individual case safety reports based on ICH E2B (R3) message standards.

In product quality, we created a new global quality assurance committee and established global policies and standards in conjunction with the launch of our global products in the US and Europe, ensuring we comply with international regulations by coordinating with our overseas subsidiaries. Going forward, we will use the global committee to share progress reports and support activities in each region to improve business efficiency and increase product quality.

Goals for FY2019

In FY2019, the second year of sales for our global products in the US and Europe, we will work to strengthen the global pharmacovigilance and quality assurance (PV & QA) system.

In product safety, under the supervision of our global safety committee, global safety teams will lead efforts to accurately evaluate safety information from sources worldwide, prepare various safety reports based on that information, submit timely reports to regulatory authorities in each region and provide appropriate information to frontline medical practitioners. We will also build systems to respond rapidly to regulatory changes in the US, Europe and other markets worldwide and continue implementing projects to standardize our global activities and improve efficiency. In addition, we will strengthen safety monitoring activities in the Asia / Oceania region to address our expanding sales areas and tighter regulations.

In product quality, we plan to make ongoing improvements to our global quality assurance system, under the guidance of our global quality assurance committee. Specifically, we will consult with all teams about any major quality issues reported by manufacturing sites or other locations, assess quality standards at newly selected manufacturing sites, conduct regular quality reviews of global products, regularly evaluate the activities of issue-specific global taskforces, and verify steps being taken to address any issues highlighted in quality audits.

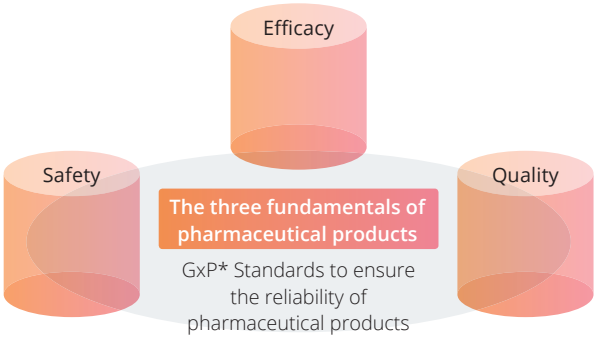
Four Principles for Safety, Quality and Regulatory Compliance in the Pharmaceutical Business(4C)

1) Sincere response
Cordiality

2) Activity with all members participating
Cooperation

3) Consistent reliability assurance system
Consistency

4) Compliance with laws and regulations and responding to social demands
Compliance



* GxP refers to "Good x Practice," ("Good" and end in "Practice"), that is, the standards established to ensure the reliability of efficacy, safety, and quality of a pharmaceutical product from the development stage to the post-marketing stage.
In Japan, there are standards, such as GCP, GLP, GVP, GPSP, GMP, and GQP; globally, each region has its own similar standards.

FOCUS ON

Strengthening the global PV & QA system

To manufacture and sell global products, we need to build a global PV & QA system that complies with GxP and meets other regulatory standards in each market. We will also need to continually strengthen the system as our lineup of global products increases and regulations become more rigorous.

Measures to strengthen the global PV & QA system

1. Structure
   - Prepare and improve global policy / SOP
   - Create a system to coordinate decision-making by global quality and safety committees, which comprise managers at head office and overseas subsidiaries, and the activities of global product safety teams and global taskforces set up to address specific PV & QA issues
   - Use a global safety database to integrate global case history assessments and report information provided to authorities
   - Audit overseas subsidiaries, contract organizations and medical institutions
2. Personnel training and exchanges
   - Use domestic study programs, academic conferences, industry programs, specialist courses in each field, and awareness training for general employees to train personnel
   - Develop a culture of teamwork through personnel exchanges between head office and overseas subsidiaries and through global safety and quality workshops to improve our ability to resolve global issues
3. Awareness
   - Create a Quality Culture to underpin all quality assurance activities

All pharmaceutical products have both benefits for patient treatment and risks in the form of potentially adverse reactions.

To provide safer pharmaceutical products that give patients even greater peace of mind, we will implement timely assessments and reviews of drug benefits and risks and continue to actively provide appropriate information to frontline practitioners, based on safety information collected from sources worldwide.

Creating and Strengthening Social and Relationship Capital

Pharmaceuticals Business

Biosimilars

Creating high-quality biosimilars in Japan to help control healthcare costs worldwide

Progress in FY2018

Since its establishment in 2012, Fujifilm Kyowa Kirin Biologics has been working to develop and supply biosimilars that are needed worldwide.

In 2018, the company's first proprietary product, a biosimilar of therapeutic antibody adalimumab (FKB327, marketed as Hulio), was granted marketing authorization by the European Medicines Agency (EMA) in September. Through an agreement with Mylan, a global pharmaceutical company, Fujifilm Kyowa Kirin Biologics has granted Mylan exclusive marketing rights for Hulio in the European market. Mylan started sales of Hulio in October 2018, giving patients in Europe the first opportunity worldwide to use our biosimilar product. We are also filing for approval and preparing to launch FKB327 in other countries outside Europe.

Meanwhile, we continue to make progress with a global phase III clinical trial of FKB238, a biosimilar of antibody drug bevacizumab. FKB238 is being developed by Centus Biotherapeutics, a joint venture between Fujifilm Kyowa Kirin Biologics and UK firm AstraZeneca. The global trial of patients with non-small cell lung cancer in 25 countries enrolled its final patient in January 2018 and has accumulated clinical data.

Goals for FY2019

In 2019, we plan to file new drug applications for FKB327 in countries outside Europe and respond to additional requests for inspections and data from authorities after filing. In regions outside Europe, we will accelerate negotiations on sales alliances and work with sales partners to build a global launch structure (pharmacovigilance and quality assurance, post-launch safety management systems, etc.) to ensure stable supplies of high-quality products.

With FKB238, we plan to file new drug applications in Japan, the US and Europe based on the results of the global phase III clinical trial. We will work with AstraZeneca to prepare FKB238 for launch.

FOCUS ON

Hulio launched in Europe

Hulio is the first Japan-made biosimilar to be granted marketing approval in Europe. More than 10 companies have been working on the development of an adalimumab biosimilar, but in 2018, a group including Fujifilm Kyowa Kirin Biologics and three other companies became the first to launch the biosimilar in Europe in 2018. Humira, the original drug sold by AbbVie, is the world's top selling drug, with sales of ¥2.4 trillion* in 2017 (including ¥430 billion* in Europe). Biosimilars like Hulio are therefore expected to help significantly reduce healthcare costs.

The drug is available in three forms: Self-injectable pen that can be used by patients themselves, Prefilled syringe designed with safety in mind, and Vial for pediatric use. To ensure safety for patients, the self-injectable pen and Prefilled syringe are made out of plastic instead of glass to prevent breakages. The delivery mechanisms do not use silicone oil and contain only small amounts of insoluble microparticles.

* Source: IQVIA

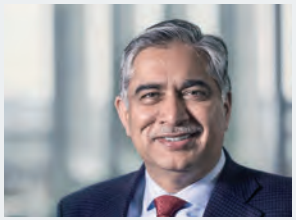
Self-injectable pen

Prefilled syringe

Feedback from sales partners

We are confident Hulio can make a valuable contribution

We're pleased with the continued progress of our strategic partnership with Fujifilm Kyowa Kirin Biologics and the strong collaboration of our science and technology teams to bring Hulio to market for patients. As the cost of healthcare continues to rise around the world, we know the important role that biosimilars play to ensure patients can access the medicines they need. The availability of Hulio positively impacts the lives of patients in Europe suffering from chronic diseases such as autoimmune disorders. We look forward to continuing this important collaboration.



Rajiv Malik, President of Mylan N.V.

Mylan is a global company with a presence in 165 countries and more than 35,000 employees worldwide (Sales of ¥1,333.6 billion in 2017)

Creating and Strengthening Social and Relationship Capital

Bio-Chemicals Business

In the pharmaceutical, healthcare practitioner, and functional foods and supplement fields, Kyowa Hakko Bio and its subsidiary Kyowa Pharma Chemical provide a wide range of products and services that support people's health and quality of life, worldwide.

Progress in FY2018

In the pharmaceutical field, the bio-chemicals business steadily increased sales of high-quality amino acids and high value-added products such as Citicoline. Efforts to improve profitability included maintaining prices at appropriate levels, targeting resources on high-margin products, and taking steps to normalize inventory levels, leading to steady improvement. In the mail-order business, sales of mainstay products such as Ornithine, Arginine EX and Citrulline increased, contributing to growth in the business.

The business also continues to realign its production sites, including transferring production of amino acids for infusion and medical purposes to plants in Thailand and China (Shanghai). Production capacity for nucleic acid and peptides are being increased at the Yamaguchi Production Center (Hofu). As planned, production at the Yamaguchi Production Center (Ube) halted in 2018 and has been consolidated to the Hofu site. Meanwhile, in research and development, we developed a new manufacturing process for human milk oligosaccharides (HMOs) and are now actively working towards commercialization.

Goals for FY2019

In FY2019, we will work to improve margins on existing products, reinforce the mail-order business, create new products and businesses as well as upgrade the quality assurance (QA) system.

To improve margins on existing products, we will continue to implement policies from FY2018, such as channeling resources into high-margin products and actively pursuing further cost savings by consolidating manufacturing and increasing productivity. We will also step up marketing of proprietary branded materials (Cognizin, Setria Performance Blend and Velox) in the sports nutrition field. In the mail-order business, we will develop and commercialize new products to meet a wide range of customer needs.

We are accelerating research and development activities to create new products and businesses that can support future growth in the bio-chemicals business. To support that process, we realigned our R&D organization in 2018 and established the Research & Innovation Center. Our goal is to step up efforts to ensure R&D successes feed through to our business. Lastly, we will continue to upgrade the QA system by making improvements from both a structural and personnel standpoint.

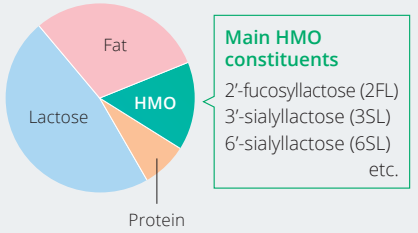
FOCUS ON

Developing New Materials

Human milk oligosaccharides (HMOs)

HMO is the generic term for oligosaccharides found in human breast milk. Oligosaccharides are the most abundant solid component of human milk after lactose. Oligosaccharides are almost absent in cow's milk and other types of milk, but they are found in high concentrations in early human breast milk. Recent research has found that oligosaccharides have a selectively positive impact on the formation of bifidus bacteria in the gut flora of infants. Using fermentation technology developed for amino acids, Kyowa Hakko Bio has created technology for the volume production of three types of HMO (2'-fucosyllactose, 3'-sialyllactose and 6'-sialyllactose). The company is now working on new business projects and further research to use the HMOs as additives for powdered milk and functional food products. In October 2018, we welcomed a large number of people to our booth at the Health Ingredients Japan Forum. Many visitors said they were hopeful that Kyowa Hakko Bio would launch Japan's first HMO product in the near future.

Solid nutrients in human breast milk



Marketing Activities

Velox Charge wins Gold Prize at Wellness Food Japan Awards 2018

Velox Charge received the Gold Prize in the Sports Food Category at the Wellness Food Japan Awards 2018. Velox Charge is a sports supplement specifically designed to be taken before physical exercise (pre-workout). We are marketing our amino acid formulation of Citrulline and Arginine, which has been patented in Japan and the US, under the brand name Velox. We plan to develop our range of Velox formulation products and grow the pre-workout supplement market to help runners and other athletes in Japan improve their performance.

Wellness Food Japan Awards 2018

Velox Charge

Contributing to Society through Sport

Japanese Fencing Federation sponsor

Kyowa Hakko Bio has sponsored the Japan Fencing Federation since 2016 with the aim of contributing to society through sport. Fencing requires concentration and endurance, which makes our pre-workout sports supplement Velox Charge (formulation of Citrulline, Arginine and BCAA) a good fit for the sport. On August 30, 2018, we invited the athletes in Japan's fencing team to our headquarters to hear them talk about their medal victories at the Asia Fencing Championship and their pursuit for success at the Tokyo Olympics in 2020.


Yuki Ota, President, Japan Fencing Federation


Supplements presented to Japan's fencers by Takeshi Minakata, President of Kyowa Hakko Bio

Creating and Strengthening Natural Capital

Environment

Kyowa Hakko Kirin makes dedicated efforts to protect the global environment while promoting activities that are geared toward realizing a sustainable society.

Environmental Management

The Kyowa Hakko Kirin Group makes dedicated efforts to protect the global environment for the next generation. In this regard, the Group takes into consideration the environmental impacts of its products throughout their entire life cycle extending from research and development through production, marketing, use and disposal, as well as across the supply chain based on the Kyowa Hakko Kirin Group Environmental Policy.

In an effort to further advance its activities, the Group has adopted and implemented the ISO 14001 environmental management system. The reason why our activities fitted the ISO 14001 has been expressed either through a self-declaration accredited under the ISO 14001:2015 standard or third-party confirmation.

Response to Material Issues and Other Countermeasures

Working to prevent global warming and to preserve water resources, the Kyowa Hakko Kirin Group has identified the reduction of CO_2 emissions and water consumption as a CSV material issues of the Group. From a long-term perspective and as a member of the Kirin Group, Kyowa Hakko Kirin has set a target for the reduction of CO_2 emissions in accordance with the Science Based Target (SBT) initiative. Together with its long-term target for reducing water consumption, the Company's long-term target for the reduction of CO_2 emissions has also been incorporated into the Kirin Group's CSV Commitment.

As far as the prevention of global warming is concerned, the Company is targeting a reduction in its global CO_2 emissions to 20% less than the level recorded in FY2015 by FY2030. At the same time, steps have been taken to establish single fiscal year per-unit energy consumption targets at plants and research laboratories, and to engage in efforts aimed at increasing production efficiency, etc. In similar fashion, the long-term goal has been set to reduce the worldwide consumption of water by 30% from the level reported in FY2015 by FY2030. Single fiscal year per-unit reduction targets have also been identified for business sites. Meanwhile, in FY2018, per-unit energy consumption contracted 0.1% compared with the previous year (global target: down 1% year on year; failed to achieve this target due to a per-unit deterioration caused by a change in manufacturing items and per-unit water consumption fell 12% compared with the previous year (global target: down 1% year on year).

In addition to its energy-saving endeavors, Kyowa Hakko Kirin is promoting the widespread use of clean energy. Among a host of initiatives, the Company installed photovoltaic (PV) power generation facilities at various locations including Tokyo Research Park and Fuji Research Park as well as its Ube and Takasaki plants. Steps have also been taken to construct PV power generation facilities on part of the land at Kyowa Hakko Bio Co., Ltd.'s Yamaguchi Production Center. These facilities boast a maximum output of 13.2 MW, which is enough to power roughly 4,000 households.

Taking full advantage of the Japanese Government's Joint Crediting Mechanism (JCM), the Kyowa Hakko Kirin Group also promoted efforts to reduce greenhouse gas emissions on a global scale when constructing a new plant at Thai Kyowa Biotechnologies Co., Ltd.

Task Force on Climate-Related Financial Disclosures (TCFD)

The Kirin Group, to which Kyowa Hakko Kirin is a member, has announced its support for the recommendations of the Task Force on Climate-Related Financial Disclosures (TCFD). Guided by these recommendations, the Kyowa Hakko Kirin Group is also committed to disclosing our climate-related information.

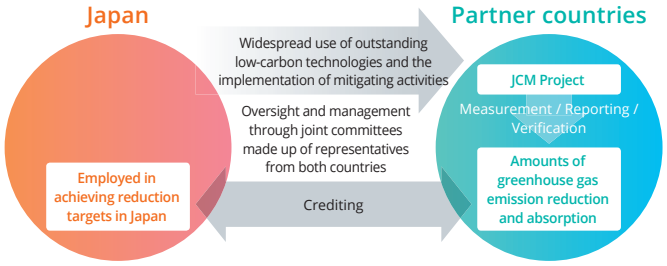
Biodiversity Preservation

As part of its activities to conserve the ecosystem and biodiversity, the Kyowa Hakko Kirin Group has been endeavoring to preserve water by engaging in the Kirin Group's water-source preservation project since FY2007. The Company's Takasaki and Ube plants together with the Kyowa Hakko Bio Yamaguchi Production Center, respectively mainstay plants for the production of pharmaceuticals and fermentation products, also carry out weeding, planting and tree thinning activities in an effort to preserve forests that provide water resources. The Kyowa Hakko Kirin Takasaki Plant has entered into a three-party agreement with Gunma Prefecture and Kurabuchi Furusato Public Corporation, under which it engages in Kyowa Hakko Kirin Takasaki Water Source Forest Conservation Activities. Working in collaboration with local communities, the Group engages in a variety of activities to preserve the ecosystem. By business site, specific examples include cleaning local rivers, releasing young amago trout into rivers (Shizuoka Prefecture) and preserving and cultivating grasslands in Akiyoshidai (Yamaguchi Prefecture). The Kyowa Hakko Kirin Fuji Plant continues to clean up a nearby river through Shizuoka Prefecture's River Friendship Program in collaboration with local administrative agencies. Meanwhile, other initiatives include the planting of mangroves in collaboration with the local government as well as coral at Thai Kyowa Biotechnologies.

Kyowa Hakko Kirin complies with the Kirin Group's Guidelines on Access to Genetic Resources in gaining access to raw materials and specimens. The benefits arising out of their use are then shared with 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), steps have been taken to put in place an internal committee to conduct proper management.

Joint Crediting Mechanism (JCM)



In 2018, Kyowa Hakko Kirin received the Gunma Prefecture Environmental Prize (Environmental Achievement Award). This award is a measure of the Company's efforts to preserve and nurture green forests in Gunma Prefecture through ongoing forest maintenance, tree thinning and weeding activities in the forest reserve of Kurabuchi-machi, Takasaki-shi for over 10 years.

Planting of coral

Creating and Strengthening Human Capital

Talent Management Policy

Considering its employees as the source of innovation, the Kyowa Hakko 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. In an effort to fulfill its management philosophy amid the increasingly drastic changes surrounding our business, we believe it to be critically important to recruit and foster people capable of exercising leadership and autonomously taking on the challenge of reform.
It is also imperative to help every one of our employees achieve healthy, fulfilling and high-quality lives and to harness the unique capabilities of employees with diverse backgrounds and offer them opportunities to co-create new value.

Diversity and Inclusion

The Kyowa Hakko Kirin Group believes work environments with mutual respect between all kinds of people and the capability that enables employees to maximize their potential help to further stimulate the vigorousness and innovation of the Group. Therefore, we are making dedicated efforts to create work environments where diversity is respected.

Diverse Human Resources

Kyowa Hakko Kirin has a diverse workforce, but empowering women is particularly important to increase the Group's competitiveness. As of December 31, 2018, the proportion of female managers was 8.9%. In order to increase the figure to 10% or more by 2020, various implementations have been put into actions.

For example, we offered training programs to prepare female employees for managerial positions as well as career education. Besides, seminars were held and articles introducing Ikuboss were posted on the intranet to raise the awareness of the importance of Ikuboss. Moreover, we provide employees with support for a smooth return to work after taking childcare leave by hosting the Back-to-Work Support Forum. To support employees with family members needing nursing care, we provide them with seminars regarding a balance between work and family and necessary information.

Kyowa Hakko Kirin is creating work environments that welcome people with diverse sexual orientations and gender identities.

To adjust the mindset of the top management, we hold LGBT awareness lectures for senior executives and run seminars and e-learning programs for all employee on a continuous basis to improve their knowledge and understanding about the LGBT community. We have also revised personnel system and policies where same-sex partnership is recognized as marriage. The KHK Working Regulations also specifically forbid harassment on the basis of sexual orientation or gender identity. Additionally, we have set up a hotline to provide advice about sexual orientation and gender identity to all employees in need.

Succession Management

In order to maintain talents for developing Kyowa Hakko Kirin Group into a Global Specialty Pharmaceutical Company (GSP), we are presently building a personnel system which helps to turn the employees into specialists in different fields.

We introduced a new talent management system in January 2018. The new system strengthens talent management by bringing together a whole host of information to help us identify promising individuals, such as performance evaluations, work experiences, training course track records, language skills, and work experiences regarding global business.

Together with improvements to job descriptions for division and organization heads, the talent management system allows us to manage pools of potential leaders and strategically cultivate career paths for potential employees by assigning them to relevant divisions and corresponding responsibilities at the early stage. To provide chances especially for young talents, we have revised the Human Resources development system by giving them suitable training and experience.

IkuBoss seminar

Kyowa Hakko Kirin received the highest level of accreditation (Eruboshi level 3) in 2016 from the Minister of Health, Labour and Welfare in accordance with the Act on the Promotion of Women's Participation and Advancement in the Workplace.

Employee awareness surveys

The Kyowa Hakko Kirin Group conducts a uniform Group-wide employee awareness survey at Kyowa Hakko Kirin and its subsidiaries within and outside Japan.

The result rate was as high as 95% in 2018. The results of the latest survey showed improvements in the understanding and support of employees in strategies of the Group and support provided work-life balances. However, the survey revealed that more work needs to be done in providing employees opportunities to develop their careers. By identifying our organization's strengths and areas that need improvement and implementing initiatives to solve issues clarified through the survey, we are striving to bring out the maximum potential in each and every employee, to encourage people to make transformations and continue creating new values, and to build organizations conducive to such a corporate culture.

Creating and Strengthening Human Capital

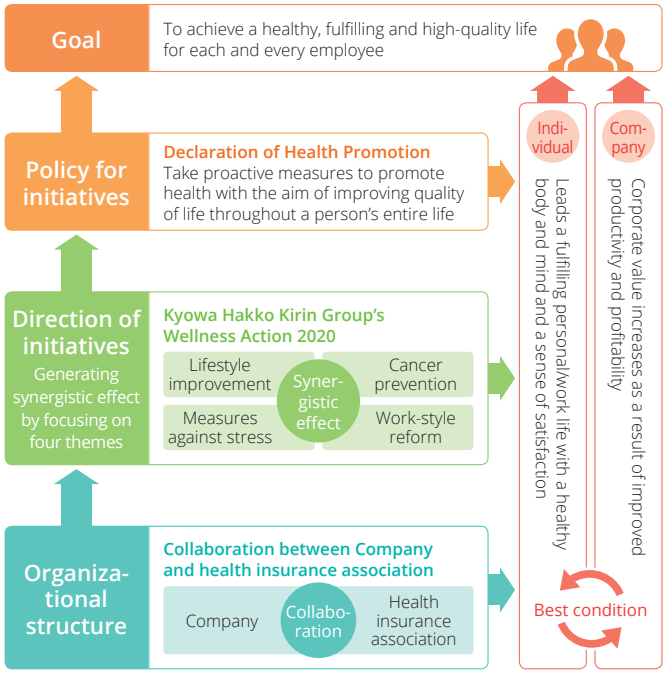
Health and Productivity Management

The Kyowa Hakko Kirin Group promotes health and productivity management, in its belief that the sound development of a company depends upon the sound bodies and minds of each and every employee.

Kyowa Hakko Kirin Group's Health and Productivity Management

In May 2015, our top management team announced the Declaration of Health Promotion and initiated the KHK Group Wellness Action 2020 in 2016 through collaboration between the Company and its health insurance association.

Upholding the goal of helping employees achieve healthy, fulfilling and high-quality lives, we have set a Group-wide direction, toward which we implement initiatives under four themes: lifestyle improvement, cancer prevention, measures against stress, and work-style reform.



Health and Productivity Management KPIs

In 2018, we formulated the KHK Group Wellness Action 2020 Goals as KPIs for health and productivity management.

To build the foundations for further growth under the next mid-term business plan, KPIs for FY2018 were designed to minimize health-related risks and promote positive and dynamic workplaces.

Concrete measures to improve health and productivity management

The Company and its health insurance association are collaborating on various initiatives to encourage employees to take the initiative in leading healthier lives.

Examples

- Strengthened our regular physical checkup program with additional test items, exceeding legal requirements (e.g., biochemical tests, cancer screenings)
- Program to protect high-risk individuals from aggravation
- Lectures on health-related topics
- Mental health counseling service by industrial physicians and contractors
- Walking events
- Discounts on sports club membership
- Financial support for employees receiving medical care to quit smoking
- Financial support for preventing diseases (e.g., comprehensive health checkup, seasonal flu shot, elimination of Helicobacter pylori infection)
- Support for employees undergoing cancer treatment while continuing to work (available only at Kyowa Hakko Kirin); and support for employees returning to work after a long period of sick leave

News from 2018

1) We established Post-checkup Response Guidelines to ensure high-risk employees receive the right follow-up support after health checkups.
2) Due to the rapid development in medical technology, we recognize there is a growing need for support in recovery for employees when they get back to work. Therefore, we established a program to support employees who need to receive treatment for cancer and other conditions after getting back to work.
3) To reduce the ratio of employees who smoke to 5%, we implemented measures including the online Quit-Smoking Program, lectures about quitting smoking and a survey regarding smoking habits of employees.
4) We implemented a range of other health and productivity initiatives (sports day, lectures, etc.) tailored to the characteristics of each business site.
5) Kyowa Hakko Kirin was recognized as an enterprise with excellent health and productivity under the Certified Health and Productivity Management Organization Recognition Program (White 500) run by the Ministry of Economy, Trade and Industry for two consecutive years (2017 and 2018).
6) In 2018, Kyowa Hakko Kirin was certified as a Sports Yell Company for the second year running by the Japan Sports Agency and as a company that supports the sporting activities of its employees for the fourth consecutive year by the Tokyo Metropolitan Government.

"Kenkokeiei," which means health and productivity management in Japanese, is a registered trademark of the Workshop for the Management of Health on Company and Employee, an NPO.

A Dialogue between the Company's Outside Officers

Maximize Outside Officers' Strengths in Order to Enhance Corporate Value

Kyowa Hakko Kirin's goal is to engage in sound and highly transparent management as part of efforts to ensure its sustainable growth and enhance corporate value over the medium to long term. Here, we report on a dialogue between two of the Company's outside officers on such topics as Kyowa Hakko Kirin's approach toward management and relations with its various stakeholders.

Yuji Inoue
Independent Officer
Outside Audit & Supervisory Board Member

Kentaro Uryu
Independent Officer
Outside Director of the Board

A Transparent Board of Directors That Incorporates External Perspectives

Inoue: Kyowa Hakko Kirin's Board of Directors is defined to a large degree by a well-developed platform that allows the Company to incorporate and make the best use of external skills in its ongoing management. In addition to providing detailed documentation, responsible staff from each department conduct lectures, including advance explanations of proposals to be submitted to the Board of Directors, as often as necessary to fully satisfy any concerns. Thanks to this, I am better positioned to fully leverage my experience as a business manager and offer advice when decisions are required on such matters as a new investment project. In this regard, I believe that the Board of Directors operates in a highly sophisticated manner and is distinguished by its ability to extract the most value from external skills.

Uryu: I totally agree. Kyowa Hakko Kirin's Board of Directors is comprised of individuals with diverse backgrounds, who have excelled across a wide range of fields. As a result, deliberations by the Board are conducted in a free and vigorous spirit while incorporating a broad array of knowledge. For my part, I offer my advice based on my knowledge as a legal professional and years of experience as an international lawyer. In addition, all supporting documentation is provided well before each meeting is held. This is extremely important in allowing me to carefully consider each matter and to gather my thoughts before entering into any discussions.

Inoue: That's correct. While each meeting of the Board of Directors is conducted in an ideal fashion, deliberations on future growth strategies and other factors including the length of discussions and exchange of opinions from both inside and outside the Company dictate that the minutes of each meeting are of a considerable volume. I would hope that the Board of Directors will remain highly effective in the future.

Kyowa Hakko Kirin's Strengths and Pending Issues from an outside view

Uryu: One of the Company's core strengths is its highly specialized expertise in biopharmaceuticals, a market that is expected to experience substantial growth in the future. This expertise encompasses a wide range of activities including global-scale research and development, production and sales as well as pharmacovigilance and quality assurance. It is this strength that provided the impetus for the commercial release of new drugs in 2018 and allows Kyowa Hakko Kirin to develop new products on a continuous basis.

Inoue: Another strength rests in the Company's decision to narrow the core focus of its business on specific areas including the kidney and cancer fields. Through the selective injection of its management resources, Kyowa Hakko Kirin is better positioned to maintain its outstanding ability to develop new drugs. In order to keep pace with overseas mega-pharmaceutical companies, and to achieve its goal of becoming a Global Specialty Pharmaceutical Company (GSP), it is vital that the Company lifts its standing and presence. Rather than just rely on a closed approach, I believe it will become increasingly important for Kyowa Hakko Kirin to pursue open innovation and alliances with companies and organizations in Japan and overseas.

Uryu: I also believe that Kyowa Hakko Kirin derives considerable strength from its decision to specialize in areas where it continues to excel. Having said this, it is important that the Company avoid sticking too rigidly to a limited number of specific fields. It should not be afraid to take up a challenge when the opportunity exists. As one example, Kyowa Hakko Kirin's biotechnologies can be applied to the regenerative therapeutics and nucleic acid drug fields. With this in mind, the Company should make every effort to build the necessary mechanisms that allow outstanding young talent to seek out new challenges in untapped fields with an appropriate degree of freedom. The majority of companies that are today enjoying ongoing growth are those that are cultivating new fields while focusing on core businesses. With this in mind, I would like to see the Company take on the challenge of pursuing new opportunities without the fear of failure.

Kyowa Hakko Kirin's Corporate Culture (Values)

Inoue: Kyowa Hakko Kirin's employees are for the most part earnest, open-minded, adventurous and bold. Appointed in March 2018, I have only served as an outside company auditor for just on one year. Over this short period, however, I have called on research facilities and plants, etc., a number of times. Irrespective of the location and frontline site, employees were extremely forthcoming with information despite my role as an outside officer. Given the lack of any barriers, my understanding of the Company's business has progressed in leaps and bounds extending well beyond anything I could learn if tied to a desk. This understanding is proving extremely useful when making comments during Board of Directors' meetings.

Uryu: First appointed an outside company auditor in 2015, I have served as an outside director since 2018. Over this period, I have been most impressed by Kyowa Hakko Kirin's sincere and honest corporate culture. This very corporate culture has contributed greatly to the Company's manufacturing prowess and the ability to create new drugs. In this regard, a sincere and honest attitude toward work remains critical to each and every employee's ability to confront each issue, clear each task and achieve established objectives. At the same time, a uniform corporate culture and values that have been instilled in the minds and hearts of employees over many years are extremely important in ensuring robust cooperation among disparate countries and departments. I believe that as the Group works in unison and maintains a collective sympathy toward these values, a surge of energy will emerge to power the Company forward toward further growth.

Diversity of Human Resources

Inoue: Issues still remain with respect to the empowerment of women. Women make up close to half of all managers at certain overseas mega pharmaceutical companies. Kyowa Hakko Kirin still has a significant way to go before it achieves this level. With this in mind, the Company should focus on building into its management those skills of its female workforce, remaining confident in its ability to succeed on the world stage and both putting in place and reinforcing its female staff evaluation and support systems.

Uryu: I couldn't agree more. Opportunities for women to excel remain insufficient. Recognizing that an error in the pharmaceutical field can have life-threatening repercussions, the tendency to protect and retain existing conservative systems is only natural. The fact that Kyowa Hakko Kirin has adopted a traditional structure that is centered on men is I believe a predictable outcome. However, in order to ramp up the pace of growth by triggering innovation, the Company must acknowledge diverse human resources with different genders and backgrounds as a powerful driving force. On this point, executive departments are vigorously promoting a series of reforms. As a result, I suspect we will see the first female executive officer emerge from the ranks of the Company's full-time staff in the not too distant future.

Inoue: One more issue relating to the diversity of human resources is the hiring and training of overseas personnel who can make their mark globally. Again, Kyowa Hakko Kirin has a long way to go before fully addressing this issue. In order to accelerate the pace of global growth, I would like to offer my wholehearted support behind efforts to bolster overseas human resources including overseas executives and senior officers.

Strengthening Relations with Shareholders and Investors

Uryu: I strongly believe that the overarching principle of management is to focus on the interests of shareholders. With this in mind, it is my role as an outside director to serve as a conduit between the Company's senior executive and its stakeholders, and to convey to management how it is being assessed. In addition, it is vital that I am fully apprised of the working of the IR Department and to cast a strict eye over the proper and timely disclosure of high-quality information. Moving forward, I will make every effort to ensure that the right information is shared with all interested parties both within and outside the Company and promote cooperation while steadily creating new value.

Inoue: I am committed to ensuring the open and timely disclosure of information to investors and shareholders. Taking into consideration the highly specialized nature of the pharmaceutical industry and its many differences with other sectors, I recognize the importance of providing information that is easy to understand to not only institutional investors as a matter of course, but also individual investors. On the understanding that IR activities are more than just an external communication tool, I recognize that I must also help convey the thoughts and policies of management to employees promote an internal common purpose. On this basis, steps must be taken to engage more vigorously in IR activities that strengthen relations with stakeholders going forward. As an outside officer, I will not spare any effort to fulfill these responsibilities.

Corporate Governance

Basic Policy on Corporate Governance

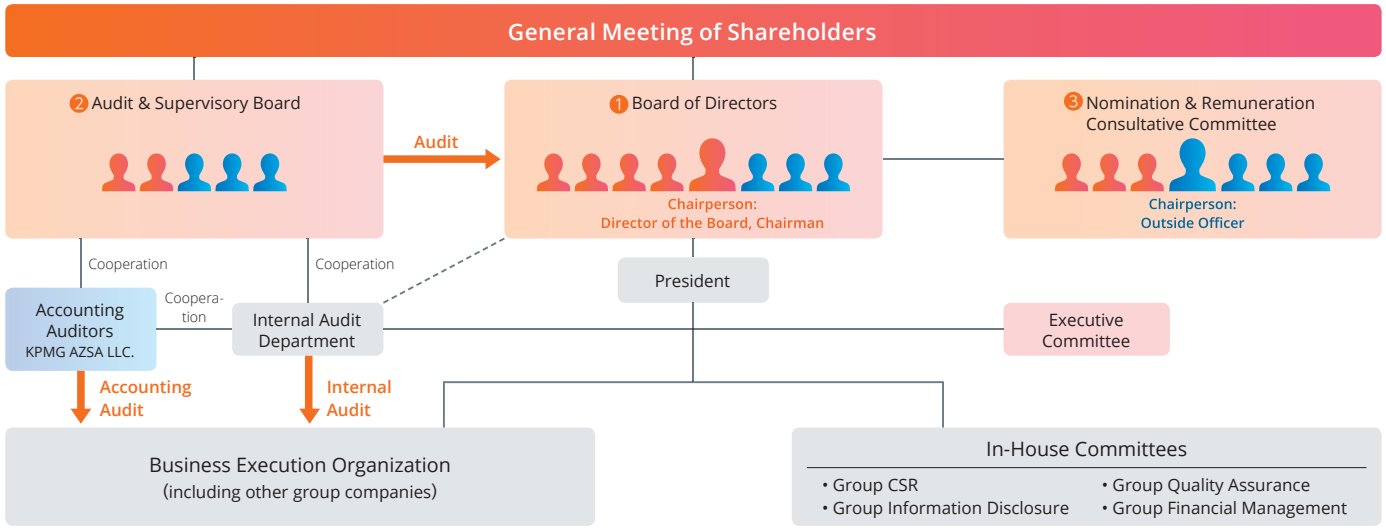
From a management perspective, Kyowa Hakko Kirin engages in business activities that include putting in place an appropriate organizational structure and systems while carrying out various measures in an effort to realize its corporate philosophy of "contributing to the health and well-being of people worldwide by creating new value with the pursuit of advances in life sciences and technology." Also, recognizing the importance of increasing management transparency and strengthening the monitoring and supervisory functions in order to continuously enhance its corporate value, the Company has formulated an overarching policy with the aim of further upgrading and expanding corporate governance. This Corporate Governance Policy takes into consideration the purpose and intent of the Corporate Governance Code that came into effect in Japan in 2015.

- Based on its corporate philosophy and the Mid-Term Business Plan, and as a company responsible for supporting the foundation of society, Kyowa Hakko Kirin will enhance its corporate governance to promote its sustainable growth and improve its corporate value over the medium to long term, by ensuring the transparency and fairness of its decision-making processes, establishing speedy and strong decision-making and operating systems and putting in place proper supervisory and monitoring systems.
- Recognizing that cooperation with stakeholders is indispensable for realizing the goals of its Mid-Term Business Plan and corporate philosophy, the Company values the viewpoints of its respective stakeholders.
- The Company fulfills its accountability with integrity by promptly disclosing information to shareholders and investors based on the principles of transparency, fairness and continuity, and proactively engaging in constructive dialogue with shareholders and investors.
- The Company maintains its independence while respecting the group management policy of Kirin Holdings Company, Limited.

Please refer to the "Corporate Governance Policy" section of the Company's website for details.
https://ir.kyowa-kirin.com/en/governance/governance.html

Corporate Governance Structure (As of March 20, 2019)

Directors Outside Directors



1 Board of Directors

The Board of Directors makes decisions on matters stipulated by law and the execution of the Group's important operations, which include long-term management visions, mid-term business plans and annual business plans of the Group and key Group companies. The Board is also responsible for monitoring the execution of directors' duties, and for developing appropriate internal control systems across the Group.

The number of directors forming the Board of Directors in the Company should not exceed 10 directors in accordance with its Articles of Incorporation. At least two independent outside board directors are appointed to ensure the knowledge, experience, skills and insights necessary for the Company to grow into a "Global Specialty Pharmaceutical Company," to maintain the diversity of Board members, to establish a generally balanced and highly transparent governance system and to ensure that management is monitored effectively and objectively.

Board of Directors Meetings in 2018	Number of meetings: 15 Director attendance: 98.2% Company auditor attendance: 97.3%

2 Audit & Supervisory Board

The Audit & Supervisory Board and its individual members (company auditors) audit directors regarding the execution of their duties, as an independent body that acts for the benefit and on behalf of shareholders, to monitor and verify the processes necessary to ensure the integrity of management, with an eye to the Group's sustainable growth and the improvement of its corporate value over the medium to long term.

Company auditors will actively express opinions at meetings of the Board of Directors, by making use of their independence and the ability of full-time members to gather information from within the Group, and work to establish a system that ensures effective auditing conducted by individual company auditors.

Board of Company Auditors Meetings in 2018	Number of meetings: 14 Company auditor attendance: 97.1%

3 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, 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 of individual group companies, remuneration systems, levels and amounts for directors, executive officers and company auditors of individual group companies, and presents the proposals to the Board of Directors.

Nomination Consultative Committee Meetings in 2018	Number of meetings: 13
Remuneration Consultative Committee Meetings in 2018	Number of meetings: 10

Evaluation of the Effectiveness of the Board of Directors

Based on improvements from the previous fiscal year, the Company regularly evaluates the effectiveness of the Board of Directors in order to identify any priority issues for the next fiscal year.

Evaluation Method in FY2018

The Company employed the services of an external advisor and conducted a survey in October 2018. While taking into consideration the progress made in implementing improvements from the previous fiscal year, the focus of this survey was directed toward specific issues associated with the Company's growth and matters of concern raised by third parties. Drawing on an analysis of the results of the survey, a review was conducted, and opinions exchanged mainly by directors and company auditors during a meeting in November 2018.

Survey Scope:
Directors, company auditors and executive officers participating in Board of Directors meetings as observers

Survey Items:
1. Growth strategies, 2. Group management, 3. Risk management, 4. Remuneration system, 5. Succession planning, 6. Dialogue with shareholders, 7. Discussion topics, 8. Information disclosure / Upgrading and expanding of deliberations

Evaluation Results

Survey scores, remarks, comments from external advisors and the results of opinions exchanged confirmed the effectiveness of the Board's activities.

Action for the Next Fiscal Year

Kyowa Hakko Kirin will once again acknowledge its growth strategy and the risks associated with the globalization of its business while deepening deliberations of its Board of Directors in order to make the leap forward to become a Global Specialty Pharmaceutical Company (GSP), an objective identified under its FY2016-2020 Mid-term Business Plan.

Internal Control System

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.

Basic policy on construction of the Internal Control System

1	Compliance framework
2	Information storage and management framework
3	Risk management framework
4	Efficient execution of duties framework
5	Reporting on the execution of duties, and other Group internal control framework
6–10	Company auditor-related framework

CEO Succession Planning

The Nomination & Remuneration Consultative Committee continuously deliberates on the selection and development of individuals with the capacity to assume the position of CEO while reporting to the Board of Directors. As a part of the selection process, the Committee considers and deliberates at length on specific key criteria. Bearing in mind the Company's corporate philosophy and Core Values of "commitment to life", "innovation", "teamwork/Wa" and "integrity", the Committee considers traits that the ideal CEO should have (for example, someone with a firm understanding of the values he or she would like to provide to society, or someone who can think beyond national boundaries and come up with a vision for the company), while also determining the necessary requirements in terms of knowledge, skills, and work experience. While selecting candidates in accordance with these attributes, the Committee also provides recommendations on the manner in which candidates can be developed.

Kyowa Hakko Kirin Group Compliance Policy Summary

Relationship with Society	We, as good members of society, will build friendly and ethical relationships with all our stakeholders.
Relationship with Employees	We will respect each member's individuality and endeavor to maintain a friendly workplace environment.
Compliance with Rules	We will behave with integrity and ethically, while complying with rules.
Respect for Human Rights	We will respect human rights and characteristics of all people.
Environmental Preservation	We will actively engage in the preservation of the global environment to safely hand it over to the next generation.
Information Management	We will properly manage information concerning our businesses.

Criteria regarding the Independence of Outside Officers

Kyowa Hakko 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 Hakko Kirin appoints three independent outside board directors who satisfy the separately established "Criteria for Independence of Outside 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

Remuneration for board directors, executive officers and company auditors has been designed to strengthen awareness toward the responsibility of executives to contribute to the Company's further sustainable growth and improvement of its corporate value, to acquire and retain officers who aspire to making the leap forward to become a Global Specialty Pharmaceutical Company and to motivate executives to contribute to the Company by executing their respective duties.

Remuneration for executive board directors and executive officers is comprised of a basic compensation component, an annual performance-based bonus and stock options as medium- and long-term incentives. For the annual performance-based bonus, fiscal year targets for revenue, profit (executive board directors) and core operating profit (executive officers) together with Mid-term Business Plan targets have been set as evaluation criteria. Remuneration for non-executive directors (outside directors) and company auditors is made up of a fixed compensation component only to ensure that they fully fulfill their functions to supervise the business management of the Company.

Looking ahead, the Nomination & Remuneration Consultative Committee will continue to review the remuneration for board directors, executive officers and company auditors to ensure that the systems in place work as an appropriate incentive to promote the healthy and sustainable growth of the Company and to improve its corporate value.

Professional Skills of Independent Outside Officers (As of March 20, 2019)

	 Kentaro Uryu Outside Director	 Akira Morita Outside Director	 Yuko Haga Outside Director	 Jun Arai Outside Company Auditor	 Yuji Inoue Outside Company Auditor
Corporate management			○	○	○
Global management	○		○	○	○
Finance and accounting				○	○
Legal affairs	○				
Public administration		○			
Healthcare		○	○		

Executive Remuneration

Position	Total Remuneration (Millions of yen)	Breakdown of Remuneration (Millions of yen)			Number of Directors and Outside Company Auditors
		Basic Remuneration	Annual Performance-Based Bonus*1	Stock Option*2	
Directors (Excluding Outside Directors)	373	203	95	75	6
Company Auditors (Excluding Outside Company Auditors)	26	26	—	—	2
Outside Directors	27	27	—	—	3
Outside Company Auditors	51	51	—	—	4

- Directors' Consolidated Remuneration (¥100 million or more)

Nobuo Hanai

Total amount 147 million yen

*1 The amount of annual performance-based bonus is the provision for directors' and officers' bonus applicable to the fiscal year.
*2 The amount of stock option remuneration is the expenses amount for the fiscal year.

Executive Training Systems

Taking into consideration the Company's fiduciary responsibilities and accountability to shareholders, Kyowa Hakko Kirin recognizes the importance of providing its executives with the knowledge and information required to realize its corporate philosophy by building an effective and efficient corporate governance structure and to achieve the sustainable growth of the Group while enhancing corporate value over the medium to long term. In providing its executive with this training and information, Kyowa Hakko Kirin is guided by the following policy.

Training policy

- The Company provides the training and information necessary for directors and company auditors to perform their roles and fulfill their responsibilities.
- Upon assuming office, directors and company auditors will receive lectures and training from specialists and relevant departments regarding the Japanese Companies Act, corporate governance, risk management and other relevant matters. Subsequently, training and workshops will continue to be provided as necessary regarding the amendment of relevant laws and regulations as well as business issues.
- Upon assuming office, outside directors and outside company auditors will receive explanations of the Group's businesses, and will participate in observation tours of key sites.

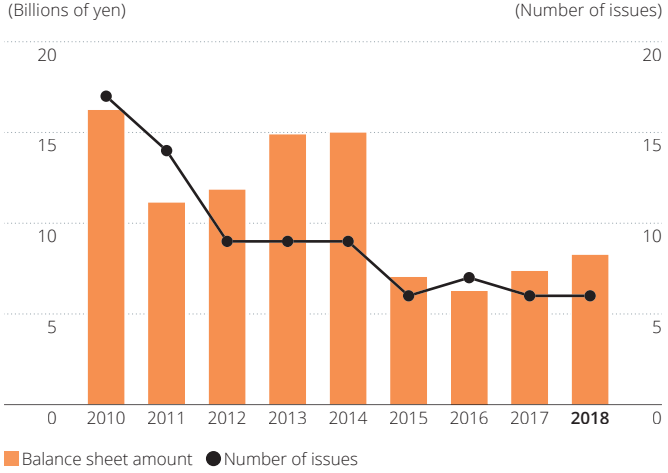
In addition to providing information relating to business operations, legal affairs, risk management and other relevant matters in connection with the aforementioned training, the Company held in-house lectures on a variety of topics including LGBT, SDGs and diversity issues in FY2018. In this manner, considerable effort was made to deepen the knowledge of executives allowing them to better carry out their duties.

Policy on Cross-Shareholding

To realize sustainable growth and enhance its corporate value over the medium to long term, the Company uses return on equity (ROE) as one of its key management indicators, and sets medium- and long-term ROE targets. The Company's basic policy for return to shareholders is to distribute dividends constantly at a consolidated payout ratio of around 40% (based on profit before goodwill amortization). The Company may buy back its shares flexibly as necessary, considering the business environment, capital efficiency and any other factors.

If the Company plans to implement a capital transaction that will result in the change of control or significant dilution of share value, the Board of Directors will thoroughly examine the proposed transaction from the viewpoint of protecting its corporate value for all stakeholders and make a reasonable decision.

Trends in Cross-Shareholding Amounts (only listed securities)



Dialogue with Shareholders / IR activities

Kyowa Hakko 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 strategy, finance and research and development 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.

Status of IR Activities (implemented in FY2018)

Financial results briefings / telephone conferences	**4 times**	R&D briefings	**1 time**
Visits to overseas investors by the president	**1 time** (16 companies in North America and the U.K.)	Visits to investors in Japan by the president	**1 time** (eight companies)
Conferences organized by securities companies	**2 times** (aggregate number of companies: 12)	Small meetings	**6 times** (aggregate number of companies: 55)
One-on-one meetings	**Aggregate number of companies: 242**		

Financial results briefings

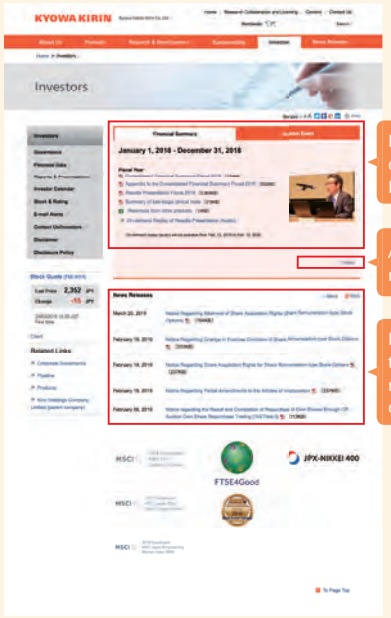

R&D briefings

Information Disclosure

Recognizing the need for transparency and fairness, Kyowa Hakko Kirin makes every effort to ensure the disclosure of high-quality information in accordance with its disclosure policy. In this manner, the Company works diligently to upgrade and expand dialogue with investors and shareholders. In addition to the Timely Disclosure Network (TDNet) system provided by the Tokyo Stock Exchange, Kyowa Hakko Kirin utilizes a shareholder and investor website, set up in both Japanese and English, as a tool to ensure the immediate and fair disclosure of information.

Company's Shareholder and Investor Website

https://ir.kyowa-kirin.com/en/index.html



General Meeting of Shareholders

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. Until the notices are sent by mail, the information is 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. During the General Meeting of Shareholders, a summary of the Company's performance is clearly explained on a screen or via a narration. Shareholders vote on measures after receiving ample explanation.

Many people attended the Company's 96th Ordinary General Meeting of Shareholders.

External Assessments

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

FTSE4Good

FTSE Blossom Japan !

Member of SNAM Sustainability Index 2018

MSCI 2018 Constituent MSCI ESG Leaders Indexes

MSCI 2018 Constituent MSCI Japan ESG Select Leaders Index !

MSCI 2018 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).

Matters Resolved by the 96th Ordinary General Meeting of Shareholders (held on March 20, 2019)

Proposal No. 1: Appropriation of surplus

- This proposal was approved and adopted as originally proposed. The year-end dividend was decided to be ¥20 per share.

Proposal No. 2: Partial amendments to the Articles of Incorporation

- This proposal was approved and adopted as originally proposed. The resulting changes are as follows:
  1. Change of trade name from KYOWA HAKKO KIRIN KABUSHIKI KAISHA (expressed in English as Kyowa Hakko Kirin Co., Ltd.) to KYOWA KIRIN KABUSHIKI KAISHA (expressed in English as Kyowa Kirin Co., Ltd.) (amendment to Article 1).
     (Effective date: July 1, 2019)
  2. Abolishment of senior managing directors and managing directors among directors of the Board with titles (amendment to Article 25), and abolishment of executive advisors (deletion of Article 27).
     (Effective date: March 20, 2019)
  3. Moving-up of the article numbers of subsequent articles in accordance with the above changes. (The clauses are unchanged.)

Proposal No. 3: Election of eight (8) Directors of the Board

- As originally proposed, six (6) candidates for reelection, Messrs. Nobuo Hanai, Masashi Miyamoto, Yutaka Osawa, Toshifumi Mikayama, Noriya Yokota and Kentaro Uryu, and two (2) new candidates, Mr. Akira Morita and Ms. Yuko Haga, were elected, and all of them assumed their offices on the day.

Proposal No. 4: Election of one (1) Audit & Supervisory Board Member

- As originally proposed, Mr. Keiji Kuwata was newly elected, and he assumed his office on the day.

Proposal No. 5: Authorization for the Board of Directors to determine the offering terms (*boshu jiko*) of share acquisition rights (*shinkabu yoyakuken*) as share remuneration-type stock options

- As originally proposed, authorization for the Board of Directors of the Company to determine the offering terms of share acquisition rights as share remuneration-type stock options for Directors of the Board (limited to executive Directors of the Board), Executive Officers of the Company and certain Directors of the Board of the Company's subsidiaries was approved and adopted.

Proposal No. 6: Change in exercise period for certain share acquisition rights (share remuneration-type stock options)

- This proposal was approved and adopted as originally proposed.

Management Members

Board Members

1 Director of the Board, Chairman
Nobuo Hanai, Ph.D.*1

2 Executive Director of the Board, President and Chief Executive Officer
Masashi Miyamoto, Ph.D.*1

3 Executive Director of the Board, Executive Vice President
Yutaka Osawa*1

4 Director of the Board, Senior Managing Executive Officer
Toshifumi Mikayama, Ph.D.

5 Director of the Board
Noriya Yokota

6 Outside Director of the Board
Yuko Haga*2

7 Outside Director of the Board
Kentaro Uryu*2

8 Outside Director of the Board
Akira Morita*2

Audit & Supervisory Board Members (Company Auditors)

9 Outside Company Auditor
Akira Shimizu

10 Company Auditor
Hiroshi Komatsu

11 Outside Company Auditor
Jun Arai*2

12 Outside Company Auditor
Yuji Inoue*2

13 Company Auditor
Keiji Kuwata

*1 Concurrently serves as executive officer
*2 Independent Board Directors and Company Auditors

Directors' Profiles

Director of the Board, Chairman

Nobuo Hanai, Ph.D.

Apr. 1976: Joined Kyowa Hakko Kogyo Co., Ltd.
Feb. 2003: President and Chief Executive Officer, BioWa, Inc.
Jun. 2006: Executive Officer, Kyowa Hakko Kogyo Co., Ltd.
President and Chief Executive Officer, BioWa, Inc.
Oct. 2008: Executive Officer, Head, Development Division, Kyowa Hakko Kirin Co., Ltd.
Apr. 2009: Managing Executive Officer, Head, Development Division, Kyowa Hakko Kirin Co., Ltd.
Jun. 2009: Director of the Board, Managing Executive Officer, Head, Development Division, Kyowa Hakko Kirin Co., Ltd.
Mar. 2010: Director of the Board, Senior Managing Executive Officer, Head, Development Division, Kyowa Hakko Kirin Co., Ltd.
Mar. 2012: Executive Director of the Board, President, Kyowa Hakko Kirin Co., Ltd.
Mar. 2018: Executive Director of the Board, Chairman, Kyowa Hakko Kirin Co., Ltd.
Mar. 2019: Director of the Board, Chairman, Kyowa Hakko Kirin Co., Ltd. (to present)

Reasons for Selection
The Company has judged that in view of his many years' experience as its Executive Director of the Board responsible for business management of the Company, Dr. Nobuo Hanai is the right person to educe effective functioning of the Board of Directors and to strengthen decision making on material matters of management as well as the supervising function over the execution of operations, using his extensive experience and high level of insight regarding overall business management.

Executive 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.
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: Executive Director of the Board, Managing Executive Officer, Director, Corporate Strategy & Planning Department, Kyowa Hakko Kirin Co., Ltd.
Mar. 2018: Executive 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 Executive 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.

Executive 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.
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: Executive 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, Senior Managing Executive Officer

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.
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, Director, Overseas Business Department, Kyowa Hakko Kirin Co., Ltd.
Mar. 2018: Director of the Board, Senior Managing Executive Officer, Director, Overseas Business Department, Kyowa Hakko Kirin Co., Ltd.
Apr. 2018: Director of the Board, Senior Managing Executive Officer, Kyowa Hakko 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
Mar. 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. (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 Director)

Kentaro Uryu

Apr. 1995: Admitted to Tokyo Bar Association
Apr. 1995: Joined Tsunematsu Yanase & Sekine Law Firm (presently Nagashima Ohno & Tsunematsu Law Firm)
Jan. 1996: Joined Matsuo & Kosugi Law Firm
Feb. 1999: Joined Salomon Smith Barney (presently Citigroup Global Markets Japan Inc.)
Apr. 2000: Long-term expert, Japan International Cooperation Agency
Aug. 2002: Attorney-at-Law, Managing Partner, Uryu & Itoga Law Firm (to present)
Aug. 2008: CEO, U&I Advisory Service Co., Ltd. (to present)
Jun. 2014: Outside Director, FRUTA FRUTA, Inc.
Sep. 2014: External Director, GMO TECH, Inc.
Mar. 2015: Outside Company Auditor, Kyowa Hakko Kirin Co., Ltd.
Jun. 2015: Outside Company Auditor, ITOCHU Corporation (to present)
May 2016: Representative Director, KUJ Co., Ltd.
Mar. 2018: Outside Director of the Board, Kyowa Hakko Kirin Co., Ltd. (to present)

Reasons for Selection
The Company has judged that Mr. Kentaro Uryu has continued to apply his experience and high level of insight as a legal professional in the management of the Company since his assumption of office as Outside Company Auditor in March 2015 and as outside Director of the Board in March 2018, and is the right person to fully perform the role of decision making on material matters of management and supervising the execution of operations.

Director of the Board (Outside Director)

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. (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 Director)

Yuko Haga

Apr. 1989: Senior Consultant, Tokyo Office, Price Waterhouse Consultants
Apr. 1991: Representative, Haga Management Consulting Office (to present)
Jun. 2000: Director, Linkworld Co., Ltd.
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 (to present)
Jun. 2017: Board Member, Non Profit Organization Japan Abilities Association (to present)
Mar. 2019: Outside Director of the Board, Kyowa Hakko Kirin Co., Ltd. (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.

Company Auditors' Profiles

Outside Company Auditor

Akira Shimizu

Apr. 1982: Joined Kirin Brewery Company, Limited
Jun. 2001: General Manager, Business Promotion Department of Agribio Division, Kirin Brewery Company, Limited
Mar. 2008: Director, General Manager, Seedling Business Division, Kirin Agribio Co., Ltd.
Apr. 2010: President & CEO, Japan Agribio Company, Limited
Apr. 2013: Deputy Director, Group internal audits, Kirin Holdings Company, Limited
Apr. 2014: Senior Advisor, Group Internal Audits, Kirin Holdings Company, Limited
Mar. 2016: Outside Company Auditor (Full-time), Kyowa Hakko Kirin Co., Ltd. (to present)

Reasons for Selection
The Company has judged that Mr. Akira Shimizu possesses abundant experience as a Group internal auditor of Kirin Holdings Company, Limited, which included working as an internal auditor as well as a company auditor of the Group's subsidiaries, and will utilize his broad-ranging knowledge based on experience in such fields as research and development, overseas business and corporate management in the auditing operations of the Company.

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.
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: Company Auditor (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 a Company Auditor and is the right person to appropriately perform the duties as the a Company Auditor of the Company by ensuring that the audit and supervisory functions are fully effective across a broad range of fields.

Outside Company Auditor

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. (to present)
Mar. 2017: Outside Audit & Supervisory Board Member, Kyowa Hakko Kirin Co., Ltd. (to present)

Reasons for Selection
The Company has judged that Mr. Jun Arai possesses considerable knowledge in finance and accounting accrued during his long-standing service in charge of the accounting and financial departments at Showa Shell Sekiyu K.K., and experience in corporate management as a Representative Director and President, and will apply this broad-ranging insight to guiding and auditing the Company's overall management.

Outside Company Auditor

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 Auditor (Full-time), Ricoh Company, Ltd.
Jun. 2014: Outside Corporate Auditor, Infoteria Corporation
Jun. 2015: Outside Director, ANRITSU CORPORATION (to present)
May 2016: Outside Corporate Auditor, Ryohin Keikaku Co., Ltd. (to present)
Mar. 2018: Outside Audit & Supervisory Board Member, Kyowa Hakko 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

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. (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.

Compliance

Over and above strict adherence to all statutory and regulatory requirements, the Kyowa Hakko Kirin Group recognizes that compliance entails quickly grasping societal demand while engaging in ethical manner.
With this in mind, the Group works diligently to build and maintain healthy and positive ties with all stakeholders.

Structure to Promote Compliance

In order to put our philosophy into practice, we at the Kyowa Hakko Kirin Group act in accordance with our Core Values and with high ethical standards and aim to be a corporate group trusted by society. Regarding compliance as the foundation of all our corporate activities, we have established an organizational structure to comply with all laws and ordinances, internal and external guidelines and rules and social conventions.

We have also put in place the Kyowa Hakko Kirin Group Code of Conduct, which provides guidelines for the overall behavior of executives and employees, and Group Policies that outline codes of conduct for individual areas of business. The Kyowa Hakko Kirin Group is committed to promoting compliance by disseminating the Code of Conduct and Group Policies.

The status of promoting compliance and the progress of countermeasures aimed at addressing material issues are deliberated by the Group CSR Committee, which is held on a quarterly basis, and reported to the Board of Directors. The countermeasure are improved continuously through the deliberation and reporting. The Code of Conduct has been translated into the languages of countries in which our sites are located. Every effort is being made to ensure that the Code is instilled in all Group employees around the world. Each executive and employee pledges to comply with the Code of Conduct, and the degree of understanding and adherence are monitored through employee awareness surveys. Moreover, the Group conducts various training programs such as a corporate ethics lecture for executives, on-site training, and e-learning to foster a corporate culture that enables executives and employees to adapt flexibly to changes in social norms.

Anti-Bribery Initiatives

International agencies, such as the United Nations and the Organisation for Economic Co-operation and Development (OECD), are calling for the strengthening of measures aimed at preventing bribery, which is recognized as an impediment to the sustainable development of society including healthy economic growth. For its part, the Kyowa Hakko Kirin Group continues to provide its executives and employees with annual training while endeavoring to educate individual departments at high risk to ensure a deeper understanding of the "Kyowa Hakko Kirin Group Policy for Anti-Bribery Measures" and "Regulation for Anti-Bribery" by Group companies.

Group companies work diligently to prevent bribery appointing anti-bribery managers and establishing help desks in line with this Policy and Regulation. In addition, we monitor and audit how each Group company complies with the regulations and standards on bribery prevention and revisions to anti-bribery laws in each country, and are reviewing continuously our anti-bribery structure.

Transparency

The Kyowa Hakko Kirin Group has enacted the "Transparency Policy for the Relationships between Corporate Activities, Healthcare Professionals, Healthcare Organizations and Patient Organizations" and regulations, to ensure the transparency of activities aimed at innovative drug discovery in collaboration with medical communities and patient organizations. We deeply respect the independence of medical communities and patient organizations and engage in corporate activities while considering conflicts of interest.

Rollout to the Supply Chain (CSR Procurement)

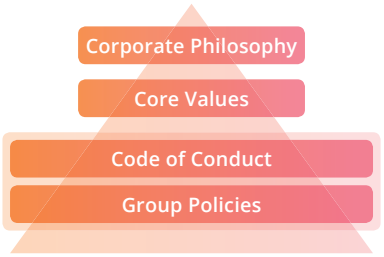
The Kyowa Hakko Kirin Group has stipulated the "Kyowa Hakko Kirin Group Procurement Policy" which is designed to ensure that we promote the CSR procurement in collaboration with our suppliers so that we will meet the expectations of various stakeholders and adapt to social changes. As a part of efforts to fulfill this policy, we have also published the "CSR Procurement Guidebook" including the "Supplier Code of Conduct" which establishes our fundamental expectations for suppliers. Through these and other means, we are promoting fair, equitable and transparent procurement activities with suppliers.

To ascertain the status of suppliers' CSR activities we conduct questionnaire surveys composed of questions on topics covered by the "Supplier Code of Conduct" such as relationship with society, relationship with employees, compliance with rules, respect for human rights, environmental conservation and information management. To encourage suppliers to make continuous improvements in their CSR activities, we feed back the results of questionnaire surveys and conduct site visits of suppliers to keep track of their activities. We periodically hold briefing sessions for suppliers focusing on the CSR procurement. These sessions are designed to introduce and deepen the understanding of the Group's approach toward the CSR procurement including the importance of ensuring compliance across the entire supply chain. Going forward, we will also work to promote the compliance focusing on the human rights of partners including suppliers, environmental conservation and bribery.

Internal Reporting

The Kyowa Hakko Kirin Group has in place a whistle-blowing contact in order to prevent, detect at an early stage and correct acts that contravene the Kyowa Hakko Kirin Group Code of Conduct, as well as acts that seriously damage the brand value of the Kyowa Hakko Kirin Group. We have introduced a mechanism under which a report about a board member is passed directly to a company auditor. The whistle-blowing systems are operated under internal rules that explicitly require informants and those cooperating with related investigations to be protected. In 2018, there were 20 whistle-blowing cases in Japan and overseas.

Outline of relations between the Corporate Philosophy and Group Policies



Group Policies

- Transparency Policy for the Relationships between Corporate Activities, Healthcare Professionals, Healthcare Organizations and Patient Organizations
- Environmental Policy
- Policy regarding Interaction with Patient Organizations
- Procurement Policy
- Community Involvement Activities Policy
- Talent Management Policy
- Policy for Anti-Bribery Measures
- Quality Assurance Policy
- Promotion Policy
- Clinical Research Policy
- Occupational Health and Safety Policy

Risk Management

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

Risk Management System

To secure the long-term trust of customers and society and continue our business to achieve our management goals, we have implemented risk management in all group company under the Kyowa Hakko Kirin Group Risk Management Policy established, referencing international standards such as ISO 31000 and the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In the Kyowa Hakko Kirin Group, risk management refers to a set of ongoing activities: identifying and analytically assessing risks that may affect business management, responding to risks, confirming the impact of responses, and making improvements to responses. The status of risk management activities is reported at quarterly meetings of the Group CSR Committee, which confirms the effectiveness of risk management measures and reports the results to the Board of Directors.

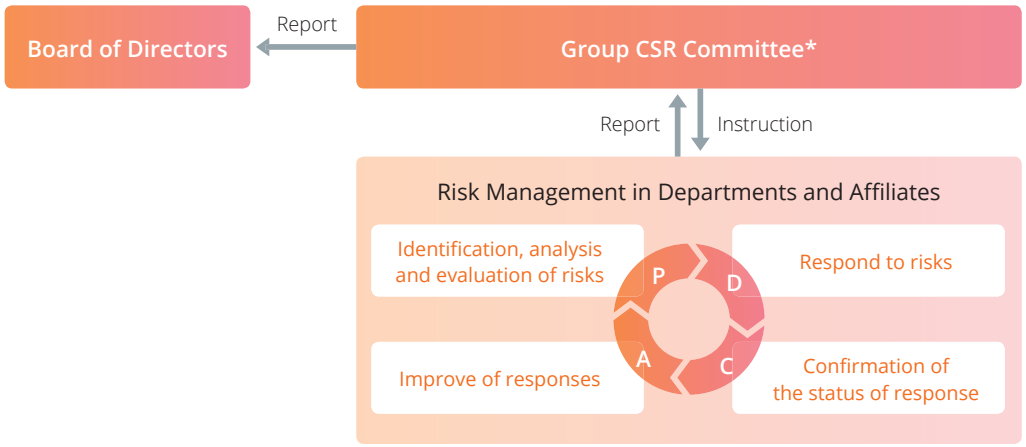
Crisis Management

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 the crisis and restore normal business operations as soon as possible. In particular, we believe it is crucial to quickly report any early signs of a crisis to senior managers or the relevant department (called "Bad News Fast") and to monitor certain implementation of reoccurrence preventive measures formulated after the completion of response to crisis.

Business Continuity Plan

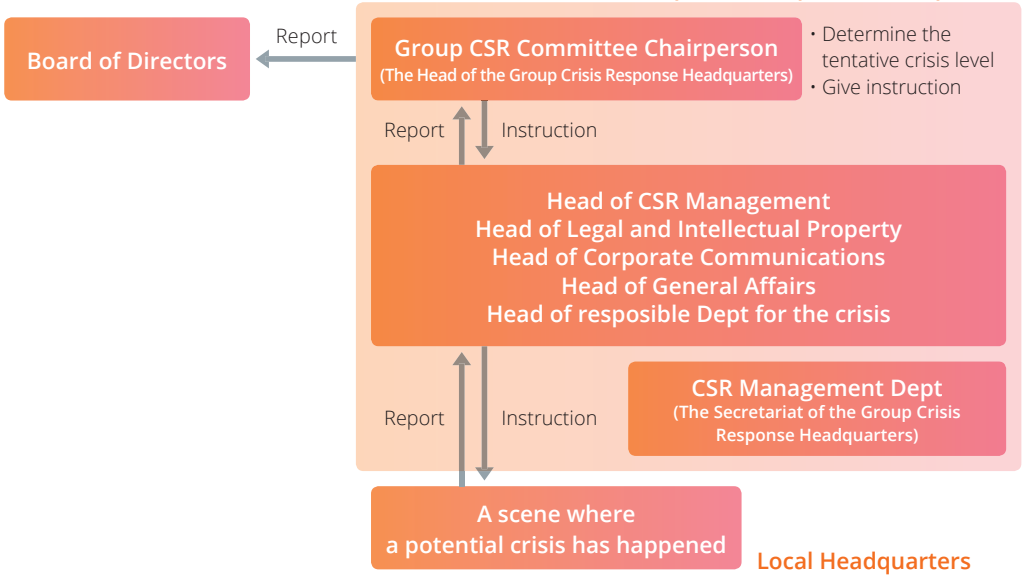
We have developed a Business Continuity Plan (BCP) to fulfill our corporate social responsibility by ensuring continued production and shipment of products even in the event of difficulty to continue normal business operations due to a disaster or accident. New ideas and know-how gained through trainings and workshops are reflected in Company-wide BCP guideline, BCP basic plans and BCP action plans to ensure constant improvements.

Risk Management System



* Group CSR Committee consists of directors in departments and presidents in affiliates

Crisis Management System



Financial Information

WEB link

Financial Ratios

Consolidated Statements of Cash Flows

Financial Summary

Adoption of International Financial Reporting Standards

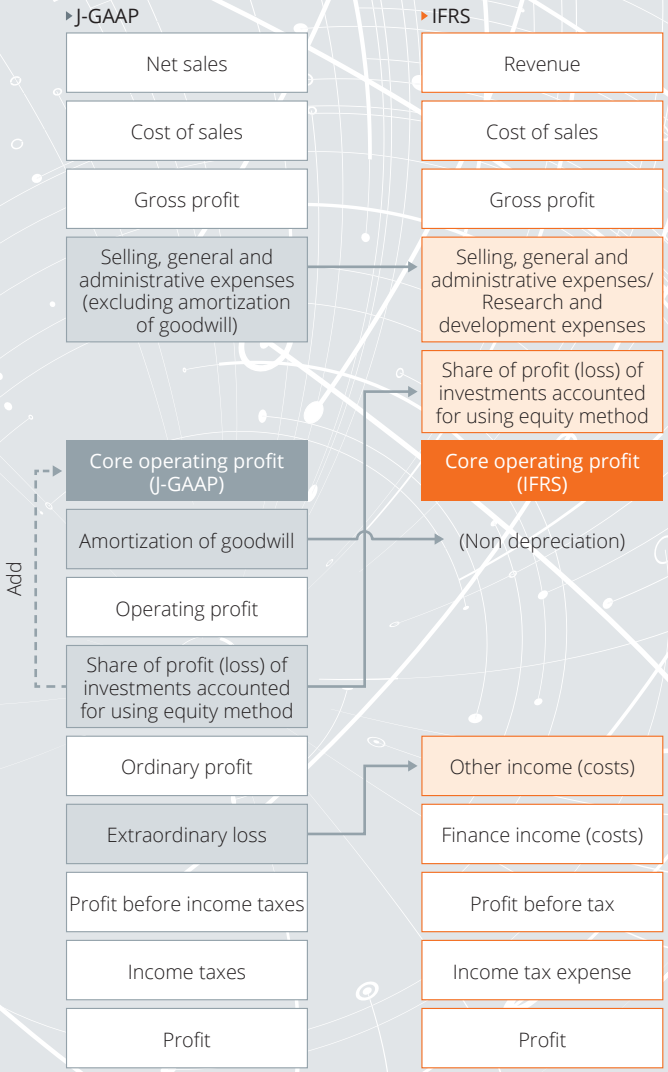
The Group has adopted the International Financial Reporting Standards ("IFRS") since FY2017 to enhance the international comparability of its financial reporting for the capital market, and unify the process of the Group's accounting. In addition, financial data for FY2016, the fiscal year prior to the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

About adoption of "core operating profit" (IFRS)

The Group uses "core operating profit" (Japanese GAAP)*1 as an indicator of sustainable growth in the five-year Mid-term Business Plan for FY2016 to 2020. After the adoption of IFRS, the Group adopts "core operating profit" (IFRS)*2 as an indicator showing recurring profitability from operating activities.

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

Major differences between IFRS and J-GAAP



Eleven-Year Selected Financial Data

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries
For the years ended December 31, 2010 to 2018, the nine months ended December 31, 2009 and year ended March 31, 2009

	IFRS			J-GAAP								IFRS
	(Millions of yen)			(Millions of yen)								(Thousands of U.S. dollars*1)
For the Year:	**2018/12**	2017/12	2016/12	2015/12	2014/12	2013/12	2012/12	2011/12	2010/12	2009/12	2009/3	**2018/12**
Revenue	**¥ 346,531**	¥ 353,380	¥ 347,956	¥ 364,316	¥ 333,446	¥ 340,611	¥ 333,158	¥ 343,722	¥ 413,738	¥ 309,111	¥ 460,183	**$3,124,435**
Gross profit	**227,189**	224,321	214,592	225,393	205,904	212,761	210,690	197,555	190,979	139,739	200,297	**2,048,411**
Selling, general and administrative expenses (including R&D expenses)	**168,398**	162,113	163,124	181,628	169,731	160,987	157,785	150,940	145,568	111,496	154,910	**1,518,326**
Core Operating Profit (J-GAAP:Operating profit)	**58,694**	57,731	39,116	43,765	36,173	51,773	52,905	46,614	45,410	28,243	45,387	**529,207**
Profit attributable to owners of parent	**54,414**	42,899	30,450	29,774	15,898	30,078	24,199	25,608	22,197	8,797	11,726	**490,610**
Capital expenditure and investments in intangible assets	**20,029**	20,714	33,270	20,039	29,487	35,183	27,808	19,697	29,374	25,135	18,523	**180,592**
Depreciation and amortization	**22,221**	22,032	23,784	23,126	23,885	21,592	20,904	22,833	22,188	17,003	18,779	**200,350**
R&D expenses	**48,647**	49,216	52,929	51,604	47,737	43,682	44,808	47,961	44,210	34,979	48,389	**438,614**
Cash Flows:												
Net cash provided by operating activities	**¥ 56,181**	¥ 64,902	¥ 66,881	¥ 66,526	¥ 19,377	¥ 56,884	¥ 59,134	¥ 40,634	¥ 64,189	¥ 24,203	¥ 41,069	**$ 506,548**
Net cash peovided by (used in) investing activities	**(39,929)**	(45,265)	(49,824)	(57,747)	16,805	(77,163)	(98,772)	18,460	(32,373)	(13,246)	(3,981)	**(360,013)**
Net cash peovided by (used in) financing activities	**(16,501)**	(18,287)	(13,871)	(14,060)	(37,184)	(12,579)	(19,189)	(30,740)	(14,446)	(16,906)	(20,978)	**(148,778)**
Cash and cash equivalents at the end of the period	**15,867**	14,685	13,076	12,784	17,013	19,242	50,334	107,555	79,882	63,745	69,286	**143,060**
At Year-End:												
Total current assets	**¥ 385,844**	¥ 348,150	¥ 314,999	¥ 324,433	¥ 283,192	¥ 329,320	¥ 303,988	¥ 284,217	¥ 288,852	¥ 276,587	¥ 279,475	**$3,478,891**
Total assets	**741,982**	708,295	683,801	720,764	719,135	719,257	679,342	658,873	695,862	695,268	699,041	**6,689,949**
Total current liabilities	**80,459**	78,409	88,072	84,823	85,182	85,076	85,774	78,465	102,483	110,080	108,522	**725,446**
Interest-bearing debt	**2,527**	2,814	7,000	4,840	4,868	6,207	5,699	6,042	7,515	13,228	13,540	**22,785**
Equity	**649,621**	616,028	577,036	614,858	605,368	595,415	555,898	540,023	544,992	540,343	543,070	**5,857,188**
Number of employees	**7,242**	7,532	7,465	7,435	7,424	7,152	7,243	7,229	7,484	7,436	7,256	
Per Share Data:	(Yen)			(Yen)								U.S. dollars*1
Profit attributable to owners of parent*2	**¥ 99.40**	¥ 78.38	¥ 55.65	¥ 54.40	¥ 29.05	¥ 54.95	¥ 44.12	¥ 45.16	¥ 38.96	¥ 15.40	¥ 20.42	**$ 0.896**
Equity attributable to owners of parent	**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	940.79	938.42	**10.699**
Cash dividends	**35**	27	25	25	25	25	20	20	20	15	20	**0.316**
Common Stock Price Range (Per share):												
High	**¥ 2,478**	¥ 2,227	¥ 2,098	¥ 2,321	¥ 1,510	¥ 1,256	¥ 970	¥ 953	¥ 1,040	¥ 1,178	¥ 1,235	**$ 22.34**
Low	**1,894**	1,515	1,412	1,094	1,006	833	757	628	773	793	586	**17.08**
Stock Information (Thousands of shares):												
Number of common stock issued	**¥ 576,484**	576,484	576,483	576,483	576,483	576,483	576,483	576,483	576,483	576,483	576,483	**—**
Weighted average number of common stock issued	**547,412**	547,290	547,224	547,285	547,348	547,391	548,449	567,029	569,711	570,935	574,083	**—**
Financial Ratios:	(%, except EBITDA)			(%, except EBITDA)								
Return on assets (ROA)	**7.5**	6.2	4.4	4.1	2.2	4.3	3.6	3.8	3.2	1.3	1.6	**—**
Core operating return on assets (J-GAAP:Operating profit)	**8.1**	8.3	5.6	6.1	5.0	7.4	7.9	6.9	6.5	4.1	6.3	**—**
Return on equity attributable to owners of parent (ROE)	**8.6**	7.2	5.3	4.9	2.7	5.2	4.4	4.7	4.1	1.6	2.2	**—**
Ratio of equity attributable to owners of parent to total assets	**87.6**	87.0	84.4	85.2	84.1	82.6	81.7	81.8	78.2	77.1	77.0	**—**
Debt/equity ratio	**0.4**	0.2	0.9	0.8	0.8	1.1	1.0	1.1	1.4	2.5	2.5	**—**
Core operating margin (J-GAAP:Operating profit)	**16.9**	16.3	11.2	12.0	10.8	15.2	15.9	13.6	11.0	9.1	9.9	**—**
EBITDA*3 (Millions of yen)	**95,984**	78,220	66,981	78,018	64,101	83,190	78,160	79,864	74,614	45,056	60,098	**—**
Payout ratio*4	**35.2**	34.4	44.9	35.1	54.4	34.8	32.8	32.5	36.2	54.3	53.8	**—**

*1 U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥110.91=U.S.$1, the approximate exchange rate at December 31, 2018.

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

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

*4 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 (MD&A)

Figures presented as J-GAAP in these materials have been rounded down to the nearest tenth and ones presented as IFRS have been rounded.

Subsidiaries Included in the Scope of Consolidation

The number of Kyowa Hakko Kirin's consolidated subsidiaries stood at 49 as of December 31, 2018. Kyowa Kirin Pharma FZ-LLC and Kyowa Kirin Canada, Inc. were newly established during the fiscal year under review. As a result, these companies have been included in the Company's scope of consolidation. On January 4, 2018, Kyowa Hakko Kirin transferred 66.6% of its shares in Kyowa Medex Co., Ltd. to Hitachi Chemical Co., Ltd. Having lost majority control, the status of Kyowa Medex Co., Ltd. has now changed from a consolidated subsidiary to an affiliated company accounted for by the equity method.

Income

(Billions of yen)

	Fiscal year ended December 31, 2018	Fiscal year ended December 31, 2017	Change
Revenue	**346.5**	353.4	–6.8
Core Operating Profit	**58.7**	57.7	1.0
Profit attributable to owners of parent	**54.4**	42.9	11.5

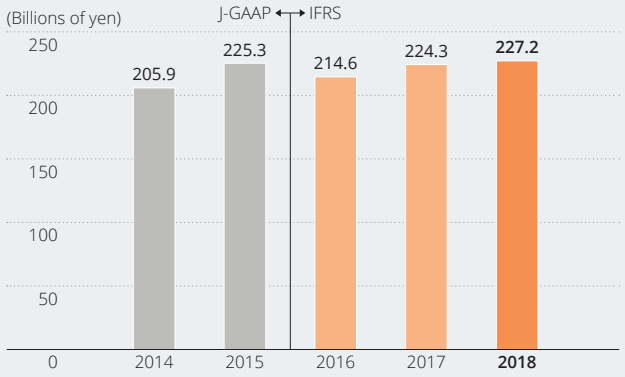
Revenue and Core operating profit

Consolidated revenue decreased and core operating profit increased for the current fiscal year mainly due to the launch or growth-in-sales of global strategic products in the European and U.S. markets, and improved share of profit (loss) of investments accounted for using equity method, in addition to the exclusion of Kyowa Medex Co., Ltd. from the scope of consolidation and the impact of reductions in drug price standards in Japan, etc.

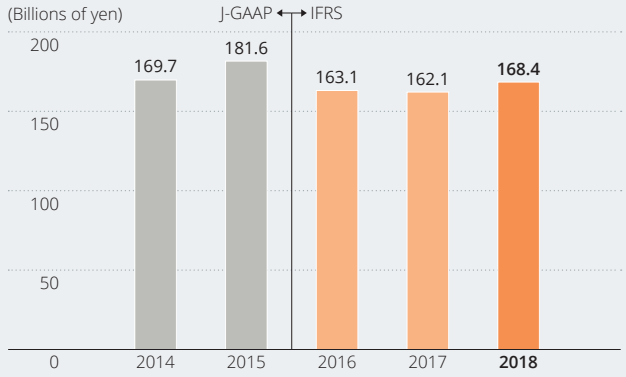
Profit attributable to owners of parent

Profit attributable to owners of parent respectively increased due mainly to the recording of a gain on sale of investments in subsidiaries in association with the partial transfer of shares of Kyowa Medex Co., Ltd. and a gain on sale of non-current assets.

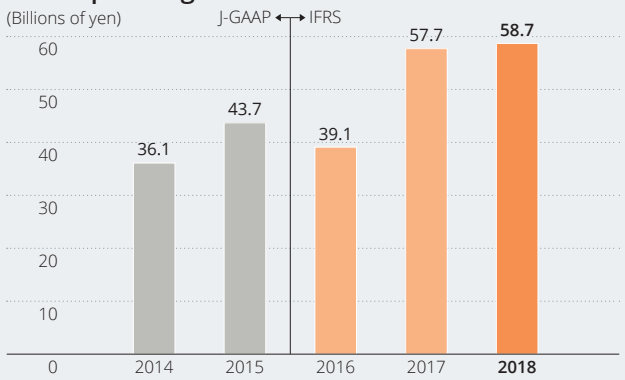
Gross Profit



Selling, General and Administrative Expenses (including R&D expenses)

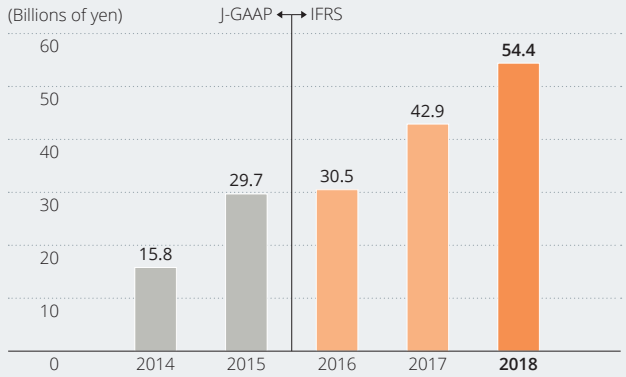


Core Operating Profit



* Figures for the fiscal year ended December 31, 2014 and 2015 are operating profit under J-GAAP.

Profit Attributable to Owners of Parent



Performance by Business Segment

Net sales by reportable segment and segment income (loss) are presented in the table below.

	IFRS (Millions of yen)			IFRS (Thousands of U.S. dollars*)
	2018/12	2017/12	2016/12	**2018/12**
Revenue:				
Pharmaceuticals				
Revenue from external customers	**¥270,438**	¥274,776	¥269,263	**$2,438,358**
Inter-segment revenue	**1,072**	990	785	**9,666**
Total	**271,510**	275,766	270,048	**2,448,024**
Bio-Chemicals				
Revenue from external customers	**¥ 76,093**	¥ 78,605	¥ 78,693	**$ 686,077**
Inter-segment revenue	**2,112**	2,531	3,114	**19,038**
Total	**78,204**	81,136	81,807	**705,115**
Adjustments	**(3,184)**	(3,521)	(3,899)	**(28,704)**
Consolidated total	**¥346,531**	¥353,380	¥347,956	**$3,124,435**
Segment Core operating profit:				
Pharmaceuticals	**¥ 50,306**	¥ 50,530	¥ 33,529	**$ 453,572**
Bio-Chemicals	**8,128**	7,189	5,556	**73,285**
Adjustments	**261**	11	31	**2,350**
Consolidated total	**¥ 58,694**	¥ 57,731	¥ 39,116	**$ 529,207**

* U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥110.91=U.S.$1, the approximate exchange rate at December 31, 2018.

Pharmaceuticals Business

(Billions of yen)

	Fiscal year ended December 31, 2018	Fiscal year ended December 31, 2017	Change
Revenue	**271.5**	275.8	–4.3
Core Operating Profit	**50.3**	50.5	–0.2

Revenue in Japan decreased from the previous fiscal year due to the impact of excluding Kyowa Medex from the scope of consolidation, the impact of the reductions in drug price standards implemented in April, and the impacts of generics and rival products. Revenue of core product Nesp, a renal anemia treatment drug, decreased compared to the previous fiscal year, due to the impact of reductions in drug price standards and other factors. Revenue from long term NHI products such as Allelock, an anti-allergy agent, Coniel, a hypertension and angina pectoris drug, Asacol, an ulcerative colitis treatment drug, and Depakene, an anti-epileptic drug, decreased due to the impacts of the market penetration of generics, etc. Revenue from Regpara, a treatment for secondary hyperparathyroidism, decreased due to the impact of rival products, while sales of new product Orkedia, also a treatment for secondary hyperparathyroidism, commenced in May. Firm growth in revenue was also realized for G-Lasta, an agent for decreasing the incidence of febrile neutropenia, Lumicef, a treatment for psoriasis, and Nouriast, an antiparkinsonian agent, among others. Concerning Dovobet, a topical combination drug for psoriasis vulgaris, sales of Dovobet Gel, a new form of the treatment, began in June. Rituximab BS [KHK], an anticancer agent, whose sales commenced in January, has achieved market penetration and sales growth as planned.

Revenue from international business increased compared to the previous fiscal year due to the launch of new global strategic products. In the Americas and Europe, the market penetration of Crysvita, a treatment for X-linked hypophosphatemia whose sales commenced in the U.S. and Germany in April, performed solidly, and the number of patients grew steadily. Furthermore, sales of Poteligeo, an anticancer agent, commenced in the U.S. in October and it has begun penetrating the market as planned. In addition, revenue from products such as Abstral, a treatment for cancer pain, also grew robustly. Revenue in Asia increased compared to the previous fiscal year with steady growth in revenue being achieved for Regpara, a treatment for secondary hyperparathyroidism, among others, particularly in China and South Korea.

With respect to licensing revenue, royalties revenue increased despite the decline in milestone revenue from AstraZeneca in relation to benralizumab.

Core operating profit was broadly unchanged from the previous fiscal year, mainly due to an increase in selling expenses accompanying the launch in the U.S. and European markets of global strategic products; despite an increase in gross profit due to strong sales of Crysvita, a treatment for X-linked hypophosphatemia, and Poteligeo, an anticancer agent; global strategic products launched in Europe and the U.S.; and improved share of profit (loss) of investments accounted for using equity method.

Bio-Chemicals Business

(Billions of yen)

	Fiscal year ended December 31, 2018	Fiscal year ended December 31, 2017	Change
Revenue	**78.2**	81.1	–2.9
Core Operating Profit	**8.1**	7.2	0.9

Revenue in Japan decreased compared to the previous fiscal year due mainly to the effect of the sale of the plant growth regulators business. Revenue from active pharmaceutical and health food ingredients business decreased compared to the previous fiscal year due to the effect of the adjustment to part of the merchandise lineup. In the mail-order business, revenue from Arginine EX, Citrulline and others boosted, and revenue increased compared to the previous fiscal year.

Revenue from international business decreased compared to the previous fiscal year. In the Americas and Europe, revenue decreased compared to the previous fiscal year due to the effect of intensified competition regarding some products. In Asia, revenue was broadly unchanged from the previous fiscal year.

Core operating profit increased compared to the previous fiscal year due partly to cost savings achieved by shifting production to overseas plants.

Cash Flow

Cash and cash equivalents as of December 31, 2018 were ¥15.9 billion, an increase of ¥1.2 billion compared to the balance of ¥14.7 billion as of December 31, 2017.

Net cash provided by operating activities was ¥56.2 billion, a 13.4% decrease compared to the previous fiscal year. The main factors included profit before tax of ¥73.4 billion, depreciation and amortization of ¥22.2 billion, despite income taxes paid of ¥14.2 billion, etc.

Net cash used in investing activities was ¥39.9 billion, an 11.8% decrease compared to the previous fiscal year. Major outflows included a net increase of ¥38.1 billion in loans receivable from parent, ¥10.5 billion for purchase of property, plant and equipment, and ¥9.6 billion for purchase of intangible assets. Major inflows included ¥9.1 billion in proceeds from sale of investments in subsidiaries resulting in change in scope of consolidation, ¥6.2 billion in proceeds from sales of property, plant and equipment, and ¥5.8 billion in collection of loans receivable.

Net cash used in financing activities was ¥16.5 billion, a 9.8% decrease compared to the previous fiscal year. The main outflows included dividends paid of ¥16.1 billion.

Financial Position

Assets

Assets as of December 31, 2018 were ¥742.0 billion, an increase of ¥33.7 billion compared to the end of the previous fiscal year. Non-current assets declined by ¥4.0 billion to ¥356.1 billion, due mainly to decreases in property, plant and equipment. Current assets increased by ¥37.7 billion to ¥385.8 billion, due mainly to an increase in loans receivable from parent as fund management.

Liabilities

Liabilities as of December 31, 2018 were ¥92.4 billion, the same level as at the end of the previous fiscal year.

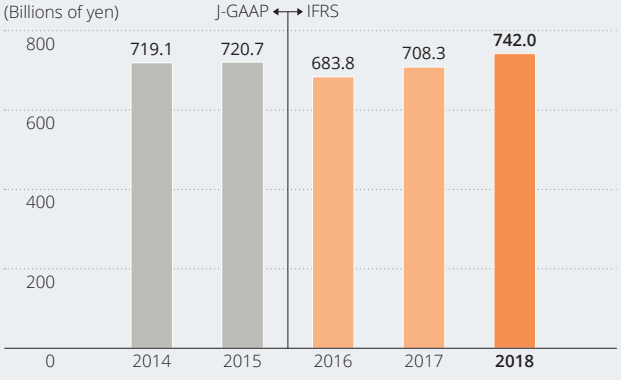
Equity

Equity as of December 31, 2018 was ¥649.6 billion, an increase of ¥33.6 billion compared to the end of the previous fiscal year, due to the booking of profit attributable to owners of parent and others, despite a decline because of payment of dividends. As a result, the ratio of equity attributable to owners of parent to total assets was 87.6%, an increase of 0.6 percentage points compared to the end of the previous fiscal year.

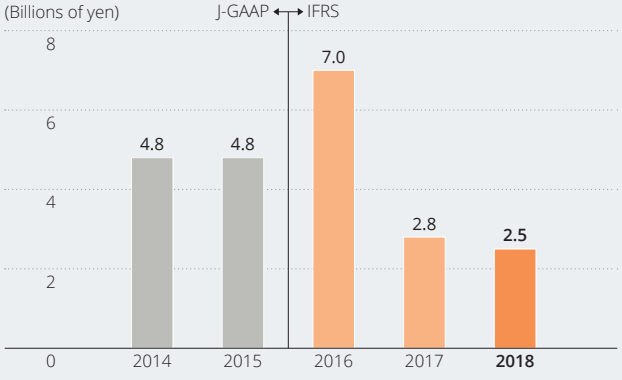
Performance Indicators

Return on equity (ROE) stood at 8.6%, an increase from 7.2% the previous fiscal year, and return on assets (ROA) at 7.5%, an increase from 6.2% the previous fiscal year. Core operating return on total assets came to 8.1%, an decrease from 8.3% the previous fiscal year. EBITDA stood at 96.0 billion yen, an increase of 22.7% compared to the previous fiscal year.

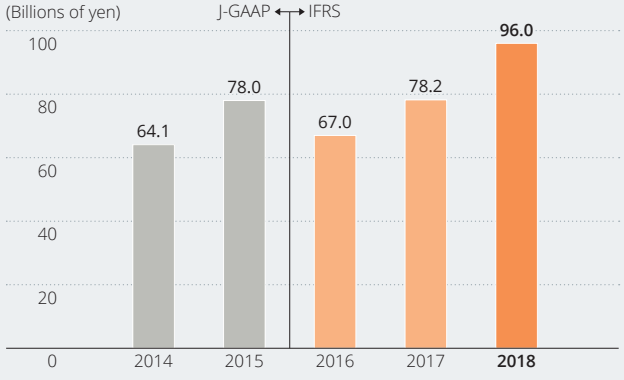
Total Assets



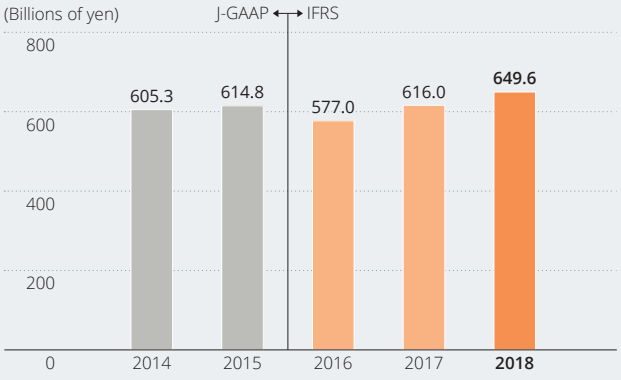
Interest-Bearing Debt



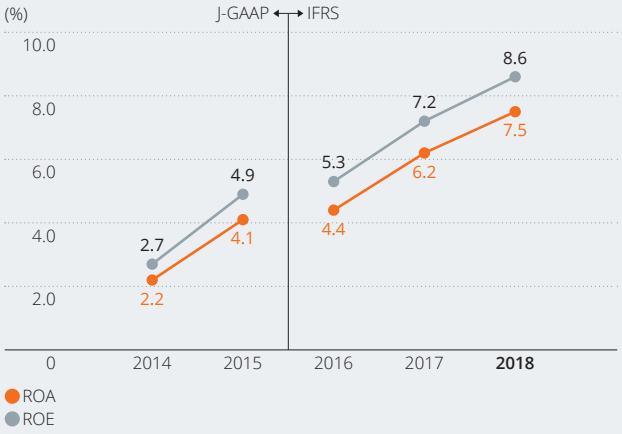
EBITDA



Equity



ROA • ROE



Capital Requirements and Financing

The Group mainly uses funds derived from operating activities to finance its investments.

The Kyowa Hakko Kirin Group's capital requirements mainly consist of purchases of raw materials for manufacturing products, purchases of goods and supplies, and operating expenses such as manufacturing expenses and selling, general and administrative expenses. Principal operating expenses consist of payroll costs such as wages and bonuses, research and development expenses and promotional expenses. The Kyowa Hakko Kirin Group continuously makes capital investments for purposes such as expanding and streamlining production facilities and strengthening research and development capabilities. In addition, strategic investments are made to maximize the development pipeline and product portfolio value inclusive of new candidate substances and product lineup.

When procuring funds to support business activities, Kyowa Hakko Kirin leads to secure stable, low-cost capital for the Kyowa Hakko Kirin Group. We have implemented a global cash management system (CMS), which we use to support the efficient use of funds and reduction of financing costs through approaches such as capital pooling.

Kyowa Hakko Kirin maintains a short-term credit rating sufficient to meet its funding requirements and is able to raise short-term funds through the flexible issuance of domestic commercial paper. The Company

has secured a commitment line of credit and put in place a limit for the issuance of domestic commercial paper. Utilizing these and other procurement methods, Kyowa Hakko Kirin is in a position to quickly undertake strategic investments that exceed the Group's cash in hand. We are also taking measures to improve our financial strength and increase our creditworthiness while considering the funding environment and other factors.

Capital Expenditure and Investments in Intangible Assets

As a basic policy, Kyowa Hakko 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, 2018 stood at ¥20.0 billion, a decrease of ¥0.7 billion (3.3%) compared to the previous fiscal year. Depreciation and amortization for the fiscal year amounted to ¥22.2 billion, an increase of ¥0.2 billion (0.9%) compared to the previous fiscal year.

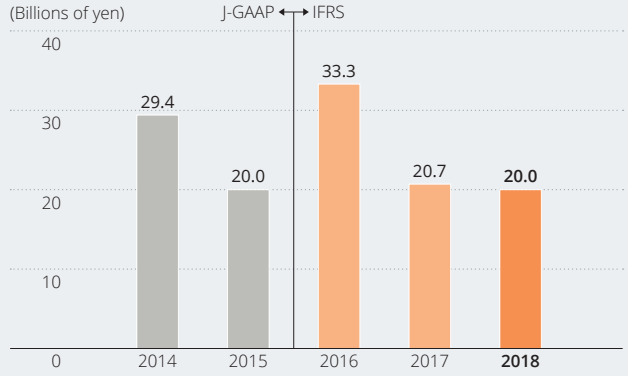
Capital Expenditure and Investments in Intangible Assets

	IFRS (Millions of yen)			J-GAAP (Millions of yen)	
	2018/12	2017/12	2016/12	2015/12	2014/12
Pharmaceuticals	**¥13,487**	¥12,932	¥25,331	¥11,537	¥17,012
Bio-Chemicals	**6,542**	7,782	8,001	8,501	12,476
Adjustments	**—**	(1)	(42)	—	(1)
Consolidated total	**¥20,029**	¥20,714	¥33,270	¥20,039	¥29,487

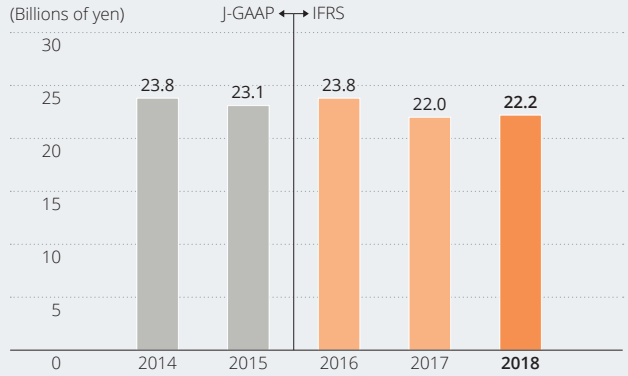
Depreciation and Amortization

	IFRS (Millions of yen)			J-GAAP (Millions of yen)	
	2018/12	2017/12	2016/12	2015/12	2014/12
Pharmaceuticals	**¥16,243**	¥15,287	¥16,838	¥16,569	¥17,075
Bio-Chemicals	**5,982**	6,749	6,947	6,558	6,811
Adjustments	**(4)**	(4)	(1)	(1)	(1)
Consolidated total	**¥22,221**	¥22,032	¥23,784	¥23,126	¥23,885

Capital Expenditure and Investments in Intangible Assets



Depreciation and Amortization



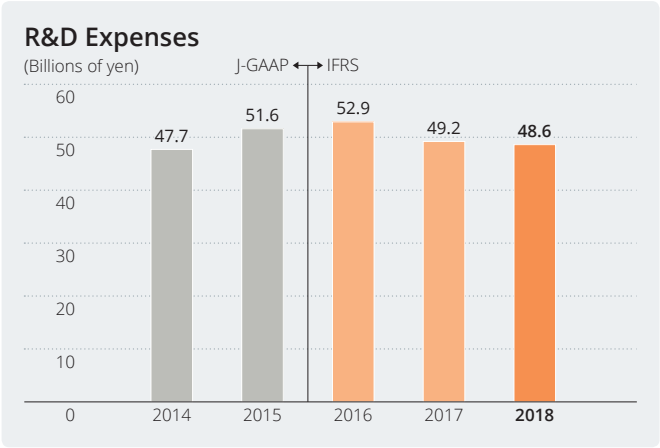
R&D Expenses

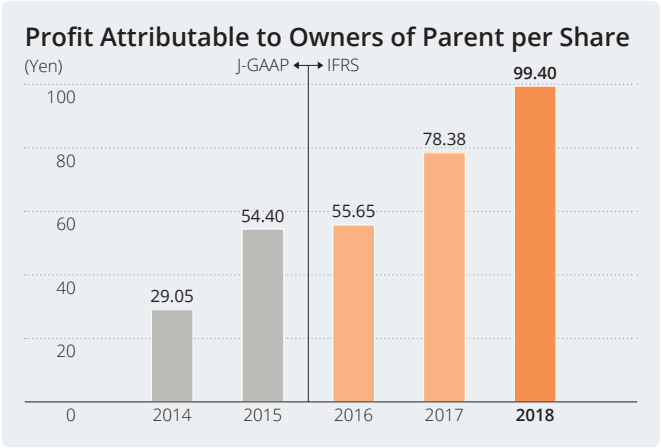
R&D expenses for the fiscal year ended December 31, 2018 stood at ¥48.6 billion, a decrease of 1.2% compared to the previous fiscal year. The ratio of R&D expenses to sales for the year came to 14.0%, an increase of 0.1 percentage points from 13.9% the previous fiscal year.

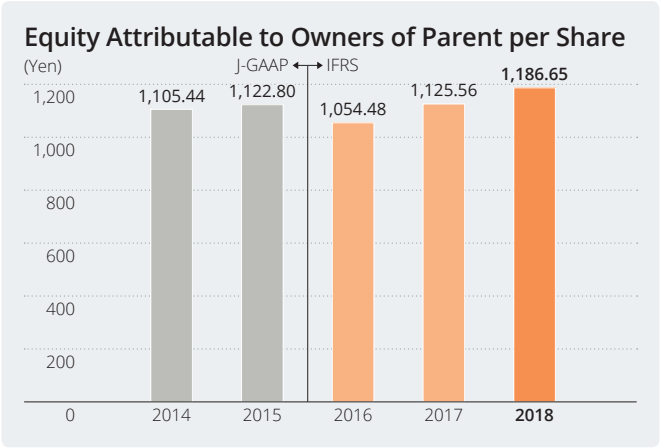
R&D expenses in the Pharmaceuticals segment totaled ¥45.7 billion and accounted for 94.0% of total R&D expenses. The ratio of R&D expenses to sales in the Pharmaceuticals business stood at 16.8%, an increase of 0.1 percentage points compared to the previous fiscal year. The R&D expenses in the Bio-Chemicals business amounted to ¥3.0 billion, the same level as the previous fiscal year.

Per Share Data

Profit attributable to owners of parent per share for the fiscal year ended December 31, 2018 stood at ¥99.40 compared to ¥78.38 the previous year. Equity attributable to owners of parent per share on December 31, 2018 totaled ¥1,186.65 compared to ¥1,125.56 on December 31, 2017.







Management Plan

A wide range of healthcare-related needs, including the reduction of medical costs and increased use of generic products, have become issues of universal concern in recent years. At the same time, nations throughout the world continue to await the development of innovative drugs that address unmet medical needs. Against this backdrop, research and development-oriented pharmaceutical companies are being forced to adapt swiftly to changes in their operating environment and to shift their businesses to the world stage.

For its part, the Kyowa Hakko Kirin Group is committed to contributing strongly to the health and well-being of people around the world and becoming a Japan-based world-leading R&D-focused life science company by engaging in "Creating Shared Value (CSV)" management that helps boost corporate value. To this end, the Group will continue to rely on innovation as its foundation, utilize state-of-the-art biotechnology to changes and roll out products and services that meet true customer needs and have high unique value. Using cutting-edge biotechnology centered on antibody technology, the Group has made nephrology, oncology, immunology/allergy and the central nervous system (CNS) the focus of its research and development. By investing resources efficiently, the Group is also working to further speed up the creation of new medical value and drug creation.

During the fiscal year under review, the Kyowa Hakko Kirin Group took steps to achieve the four strategic priorities set out in its five-year Mid-term Business Plan announced in January 2016. In specific terms, every effort was made to improve global competitiveness, create innovation, continuously improve operational excellence and contribute to the health and well-being of people. Based on these efforts, the Group has initiated steps to steadily take the leap forward to become a Global Specialty Pharmaceutical Company (GSP).

Under the first strategic priority of improving global competitiveness, the Group successfully launched burosumab (product name in the US and Europe: Crysvita), a long sought after global strategic product, in the European and US markets, as well as mogamulizumab (product name in the US and Europe: Poteligeo) in the US market. The Group also filed an application for approval for istradefylline (product name in Japan: Nouriast), a therapeutic drug for the treatment of Parkinson's disease, in the US. In order to maximize the value of these global strategic products, energies are being directed toward measures aimed at promoting market penetration and expanding business areas focusing on Europe and the US. Turning to the pharmaceuticals market in Asia, where growth is expected, Kyowa Hakko Kirin delegated the Asia/Pacific region's control function to its local subsidiary Kyowa Kirin Asia Pacific Pte. Ltd. in April 2018. Working through this subsidiary, the Group is reinforcing its business base in a bid to secure stable growth.

Under the second strategic priority of creating innovation, by combining the expertise gained through the study of diseases and patients' needs at research facilities established in each of the four categories of nephrology, oncology, immunology/allergy, and CNS, with the cutting-edge technology platforms for drug discovery cultivated in the fields of therapeutic antibodies, one area of strength, small molecule drugs, nucleic acid drugs, and regenerative therapeutics, as well as outside technologies from open innovation, the Kyowa Hakko Kirin Group is building an attractive pipeline as a pharmaceutical company that discovers new drugs. Currently, an international joint phase II clinical trial is under way for the anti-OX40 fully human antibody KHK4083, which was discovered using POTELLIGENT technology that facilitates the production of antibodies with enhanced antibody-dependent cellular cytotoxicity (ADCC) activity, and human antibody-producing technologies, targeting ulcerative colitis and atopic dermatitis. In addition, RTA 402 (generic name: bardoxolone methyl), a small-molecule compound licensed from Reata Pharmaceuticals, Inc., which is presently in the process of a phase III clinical trial in Japan, has been granted "SAKIGAKE (Priority Review) Designation" for the treatment of diabetic kidney disease by Japan's Ministry of Health, Labour and Welfare.

Under the third strategic priority of continuously improving operational excellence, the Kyowa Hakko Kirin Group is working to heighten its profitability by further strengthening cooperation in a consistent manner across every function from R&D to manufacturing and sales. At the same time, the Group is advancing the Core Values and Code of Conduct that all employees of the Group in the globe are required to adhere to while making efforts to build a global governance framework and ensure thorough compliance awareness. In 2019, the Group established a new global management structure. Organized under the four Japan, EMEA, North America (US/Canada) and Asia/Pacific regions and by the functions critical to a GSP, efforts are now geared toward further global expansion under the "One Kyowa Kirin" banner. Upholding its responsibility as a pharmaceutical company, Kyowa Hakko Kirin will continue to build an even more reliable production platform by further advancing its production technology in order to deliver a stable supply of pharmaceuticals that must be of high quality. In order to cultivate a greater sense of unity within the Group's operations and accelerate the integration and penetration of the Kyowa Kirin brand on a global basis, plans are in place to change the Company's trade name to Kyowa Kirin Co., Ltd. In Japan, steps will be taken to ramp up the pace of area strategy implementation with a view to meeting the needs of community health initiatives and providing high-quality healthcare data. Through these endeavors, the Group will adapt smoothly to the hastening trend toward globalization and maximize the value of its strategic products by addressing ancillary issues that occur on a timely basis. Complementing these measures, the Kyowa Hakko Kirin Group will promote "smart work" and health-centric business management. Every effort will be made to provide an environment in which diverse personnel can mutually respect one another while playing an active role.

Under the fourth strategic priority of contributing to the health and well-being of people, the Kyowa Hakko Kirin Group is working to engage in efforts that involve discovering innovative drugs that satisfy unmet medical needs, additional indications and dosage formulations of products, and also ensuring stable supplies of high-quality products while taking action in response to societal demands for lower medical costs as a part of its CSV management.

In its biosimilars business, which is a joint venture with FUJIFILM Corporation, Mylan N.V., with which Kyowa Hakko Kirin maintains a sales alliance relationship, began marketing an adalimumab biosimilar of the fully human anti-TNF-α monoclonal antibody as a treatment for chronic autoimmune disease in adults and immunological disorders in children after obtaining authorization from the European Commission (EC) in September 2018. Steady progress is also being made on an international joint clinical trial for a bevacizumab biosimilar, for which the Group is collaborating with AstraZeneca. Furthermore, Group company Kyowa Kirin Frontier Co., Ltd. received manufacturing and marketing approval (MMA) in Japan for Darbepoetin Alfa Injection Syringe (KKF) in August 2018. Darbepoetin Alfa Injection Syringe (KKF) is a long-acting

erythropoiesis-stimulating agent and an authorized generic version of Nesp, a Group flagship product. Going forward, Kyowa Kirin Frontier is taking preparatory steps to put in place a stable supply structure with a view to launching sales in 2019.

In the bio-chemicals business, the Kyowa Hakko Kirin Group worked diligently to address the key issues of strengthening the profit base, providing value with a focus on people's health and bolstering quality assurance capabilities as well as the ability to respond to regulatory requirements by taking advantage of its high share of the market in specialty areas encompassing the pharmaceuticals, medical and healthcare fields. As far as the strengthening of its profit base is concerned, the Kyowa Hakko Kirin Group is concentrating resources on highly profitable products and investing in overseas plants. Commercial production in Thailand is progressing in line with plans. Preparations are also being made in China through ongoing efforts to at new production facilities. In a bid to provide value with a focus on people's health, the Group is pursuing health value that is backed by science with respect to its proprietary brand material Cognizin. In the mail-order business, the Group is looking at its existing materials with a view to uncovering new functions. The goal is also to develop new products that satisfy customers' needs. Endeavoring to bolster quality assurance capabilities as well as the ability to respond to regulatory requirements energies are being directed toward putting in place a global standard quality control and assurance structure and systems while calling on external experts and promoting improvements.

The Kyowa Hakko Kirin Group has considered at length a variety of measures aimed at maximizing the sustainable growth and corporate value of Kyowa Hakko Bio Co., Ltd. Against this backdrop, Kirin Holdings Company, Limited decided to bring Kyowa Hakko Bio under its wing as a direct subsidiary after deliberating on and evaluating the potential of further collaboration in the healthcare business, an area of particular focus that is recognized as a driver of future growth. This decision to make Kyowa Hakko Bio a direct subsidiary reflects Kirin Holdings' confidence in its ability to more effectively employ mutual strengths and management resources, increase the pace of development in various areas beginning with the healthcare business and maximize Group synergies as well as the corporate value of Kyowa Hakko Bio. In specific terms, and with the decision to transfer 95% of Kyowa Hakko Bio's shares from Kyowa Hakko Kirin to Kirin Holdings, the Company is also better placed to accelerate the pace of its own growth by concentrating management resources on its Pharmaceuticals business centering mainly on the development of new drugs. This in turn is expected to help maximize the corporate value of the Kyowa Hakko Kirin Group.

Guided by its corporate philosophy which encapsulates the goal of "contributing to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies," the Kyowa Hakko Kirin Group is promoting the "leap forward to become a GSP company," the principal objective under its Mid-term Business Plan, as a research and development-oriented pharmaceutical company.

Outlook for 2019

As a result of the Company's decision to transfer the shares of Kyowa Hakko Bio., Ltd., the Company plans to categorize the Bio-Chemicals business as a discontinued operation from the first quarter of fiscal 2019 (January 1, 2019 to March 31, 2019). Accordingly, profit from discontinued operations is planned to be presented separately from the continuing operations. Revenue, core operating profit, and profit before tax in the Consolidated Earnings Forecasts for the Fiscal Year Ending December 31, 2019 (from January 1, 2019 to December 31, 2019) show figures for continuing operations, and which exclude discontinued operations. Also effective the first quarter of fiscal 2019, the "Pharmaceuticals business" is planned to be the sole reportable segment of the Group.

Consolidated financial earnings forecasts for fiscal 2019 are for revenue of ¥305.0 billion, core operating profit of ¥53.0 billion, profit before tax of ¥47.0 billion, and profit attributable to owners of parent of ¥68.0 billion. Revenue, core operating profit, and profit before tax from the continuing operations (Pharmaceuticals business) for fiscal 2018 were ¥271.5 billion, ¥50.3 billion, and ¥67.0 billion, respectively, and if compared the forecasts to these amounts from the continuing operations, the changes compared to the fiscal 2018 are forecasted to be up 12.3%, up 5.4%, and down 29.9%, respectively.

In the Pharmaceuticals business, although we expect impacts from a reduction in drug price standards in Japan, revenues are expected to increase compared to 2018 due to growth in the global strategic products Crysvita and Poteligeo. Moreover, although we expect increases in selling expenses for expanding revenues and maximizing the value of global strategic products and in research and development expenses, core operating profit is expected to increase due to growth in overseas revenue.

A year-on-year increase is forecasted for profit attributable to owners of parent because the gain on sale of investments in subsidiaries from the transfer of shares of Kyowa Hakko Bio (post-tax) will be recorded in profit from discontinued operations.

Profit Distribution

Kyowa Hakko Kirin regards the return of profits to its shareholders as one of its key management priorities.

Our basic policy on profit distribution is to deliver stable dividends, while maintaining fully adequate internal reserves for future business expansion and other developments, and considering factors such as our consolidated results for the respective fiscal years and the dividend payout ratio. We plan to improve our capital efficiency by acting rapidly with regards to purchase of treasury shares. Kyowa Hakko Kirin intends to use internal reserve funds for investments required to drive new growth, such as those in research and development, capital expenditures, and our development pipeline's expansion that are expected to contribute to the improvement of our future corporate value.

With respect to the dividend policy, we will aim to achieve a stable and continuous increase in the level of dividend payment according to growth in profits, guided by the consolidated dividend payout ratio of 40% stated in the FY2016-2020 Mid-term Business Plan.

In accordance with the above-mentioned policy, the Board of Directors has resolved to pay a year-end dividend for fiscal 2018 of ¥20 per share. As a result, we expect to increase dividends for the second year in a row. The annual dividend is expected to be ¥35, an increase of ¥8 compared to the previous fiscal year, including an interim dividend of ¥15.

For the fiscal year ending December 31, 2019, we expect to pay an annual dividend of ¥40 per share, an increase of ¥5 compared to the fiscal year under review, consisting of an interim dividend of ¥20 and a year-end dividend of ¥20.

Risk Factors

With respect to the Kyowa Hakko Kirin Group's business performance and financial position, the major risks that may significantly affect investors' assessments include, but are not limited to, those described below.
The Group recognizes that these risk events may occur, and takes steps to prevent the occurrence of those risk events that it can control through its risk management system. At the same time, the Group will do its utmost to respond in the event of the occurrence of these risk events.

* Items in this section dealing with future events reflect the assessment of the Group at the end of the current consolidated fiscal year (December 31, 2018).

(1) Risks Associated with R&D Investment

In ethical drug operations, the development of new drugs requires long periods of time and substantial R&D expenditures. In the long-term development of new drugs, there may be cases where the expected efficacy or safety is not confirmed. This may result in the abandonment of plans to continue with R&D.

In addition, in the bio-chemicals business, the Group invests R&D resources into the development of new products and new technologies to differentiate itself from its competitors. However, as with R&D for pharmaceuticals business, there is no guarantee that these investments will produce results.

Moreover, as with the above, in cases where the expected R&D results are not realized, the Group's future growth and profitability may decline and our business performance and financial position may also be adversely affected.

(2) Risks Related to Intellectual Property Assets

The Group strictly manages its intellectual property assets and closely monitors infringement by third parties. Nevertheless, in cases where the Group's intellectual property rights are infringed upon, sales revenue of the Group's products or licensing revenue could decline earlier than forecast and the Group's business performance and financial position could be adversely affected. Furthermore, while the Group pays particular attention not to violate the intellectual property rights of others, in cases where the Group is subject to litigation based on allegations of infringement of intellectual property rights, the Group may be required to cease such activities, and pay compensation and/or settlement, and our business activities, business performance and financial position may be adversely affected.

(3) Risks of Side Effects

Pharmaceutical products undergo strict safety assessments at the development stage and are approved following reviews by the relevant national regulatory authorities. However, following launch, there have been cases whereby previously unknown side effects based on the accumulated results of users become apparent. In such cases where unexpected side effects are discovered following launch, the Group's business performance and financial position, etc., could be adversely affected.

(4) Risks Related to Pharmaceutical Regulations

The pharmaceuticals business, the Group's core business, operates under the pharmaceutical regulatory authorities of the countries in which we operate. In Japan, the Group's business performance and financial position could be adversely affected by trends in the reform of Japan's healthcare system, such as the promotion of generic drugs usage, in addition to price reductions under the public pharmaceutical price system.

As for overseas pressure to suppress medical cost is becoming higher, and in cases where a price reduction cannot be compensated for by an increase in volumes, the Group's business performance and financial position could be adversely affected.

(5) Legal Regulation Risks

In the course of carrying out its operations in Japan and overseas, the Group must strictly comply with legal regulations.

The Group emphasizes compliance to try to ensure that it does not violate the laws to which it is subject, and the Group is working to bolster internal control functions through such means as administrative oversight. However, there is no guarantee that the Group will be able to completely eliminate the possibility of committing a violation of these legal regulations. If, because we are unable to observe these legal regulations, new product development is delayed or stopped, or manufacturing or sales activities are restricted, the Group's credibility could be damaged. In such cases, the Group's business performance and financial position could be negatively impacted.

Furthermore, in the future, if laws and regulations that must be observed in Japan and overseas change, the Group's business performance and financial position could be adversely affected.

(6) Risks of Fluctuations to Foreign Exchange Rate

The Group conducts transactions denominated in foreign currencies such as receiving income from overseas sales, licensing-out of technologies overseas, and acquiring raw materials overseas. Therefore, any sudden change in exchange rates could adversely affect the Group's financial position and business performance. Fluctuations to the exchange rate could also affect our ability to be price competitive on products sold in markets shared with overseas competitors.

In addition, the gains and losses, and assets and liabilities of overseas-consolidated subsidiaries converted in local currencies are translated into yen for the preparation of the consolidated financial report. The exchange rate at the time of conversion could have an effect on values following currency conversion.

(7) Disaster-related and Accident-related Risks

Earthquakes, fires, pandemics such as influenza, large-scale electrical blackouts, and other events potentially occurring in different locations could result in the suspension of business activities at the Group's headquarters, plants, research facilities or offices. The Group handles substances that are subject to various legal regulations and guidelines, and as a result of natural disasters, etc., these substances could enter the external environment and cause damage to the surrounding area.

Although the Group maintains a disaster prevention system and has prepared a business continuity plan, should a major event or accident occur it might result in significant damage and negatively impact the Group's position of trust in society. Additionally, the Group's business performance and financial position could be adversely affected.

(8) Litigation-related Risks

A lawsuit filed against the Group concerning our business activities (e.g., side effects of pharmaceutical products, product liability, labor-related problems, fair trade), could have a negative impact on the Group's operating results, financial condition, etc.

(9) Security and Information Management Risks

As the Group utilizes a variety of information systems, system malfunctions, computer viruses, etc., may impede our business. We handle large amounts of information including personal information, and in the case that these information are divulged outside the company, the Group's business performance and financial position could be adversely affected.

(10) Environmental Risks

The Group ensures thorough compliance with environment-related laws and regulations regarding air, water quality, noise, vibrations, offensive odors, soil contamination, ground subsidence, waste, etc. However, in the event that environmental-preservation problems such as pollution arise, or if a revision in the relevant laws occurs, leading to costs incurred in having to provide compensation to the surrounding areas, fix the environmental damages, or invest in new facilities the Group's business performance and financial position could be adversely affected.

(11) Risks Related to Alliances with Other Companies

The Group enters into an alliance with other companies in the form of joint development, joint marketing, technology partnership or joint venture establishment and/or outsources operations such as production, logistics and marketing to other companies. However, if problems arise and/or the Group fails to achieve results from such alliances or operations outsourcing for any reason, or experiences a contract alteration or alliance termination, the Group's business performance and financial position could be adversely affected.

(12) Risks Related to Securing and Training Personnel

The Group employs a diverse array of individuals who demonstrate their abilities and engage in business activities in Japan and overseas. However, if the Group is unable to secure personnel with highly specialized skills in each country or sufficiently train employees to perform specific jobs, the Group's business performance and financial position could be adversely affected.

(13) Risks Related to Stable Supply

The Group is expanding its businesses worldwide and is ensuring the creation of a secure supply system. However, if technical or legal issues arise in manufacturing or logistical facilities, or stoppages arise in the supply of raw material and fuel, leading to the supply of our products being stopped, delayed, or being insufficient to meet a greater-than-expected growth in demand the Group's business performance and financial position could be adversely affected.

(14) Risks Related to Competition and Patent Expiration

In the event that revenue declines as a result of competition between the Group's and other companies' products and/or the entry of generic products following the expiry of the Group's patents, the Group's business performance and financial position could be adversely affected.

(15) Risks Related to Overseas Business Expansion

The Group is expanding its businesses globally, but there are risks of political instability caused by terrorism or conflicts, uncertain economic conditions, and difficulties resulting from differences in culture and/or customs. If the Group is unable to avoid such risks, the Group's business performance and financial position could be adversely affected.

(16) Other Risks

In addition to the above, there are other risks that could adversely affect the Group's business performance and financial position, and they include poor market penetration of products, changes to share prices and interest rates, impairment of fixed assets, etc.

Investor Information (As of December 31, 2018)

Stock Listing
Tokyo

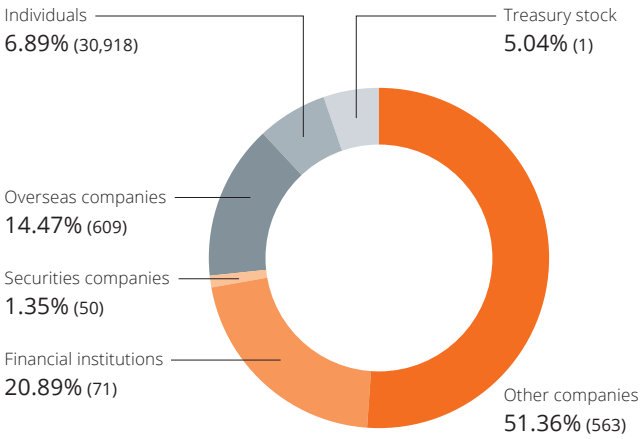
Securities Code
4151

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 : 576,483,555

Number of Shareholders
32,212

Shareholding by Type of Investor (Number)



Note: Kyowa Hakko Kirin repurchased 10,700,000 of its own shares on February 6, 2019. The Company then cancelled 36,483,555 shares of treasury shares on February 19, 2019.

Principal Shareholders

	Number of Shares Held (Thousands)	Percentage of Total Shares Issued (%)
Kirin Holdings Company, Limited	288,819	52.76
The Master Trust Bank of Japan, Ltd. (Trust Account)	39,843	7.28
Japan Trustee Services Bank, Ltd. (Trust Account)	20,016	3.66
The Norinchukin Bank	10,707	1.96
State Street Bank & Trust Company 505001(Standing Proxy: Mizuho, Ltd., Settlement & Clearing Services Division)	6,874	1.26
Mizuho Trust & Banking Co., Ltd. (Retirement Benefit Trust for Mizuho Bank, Ltd.)*	6,809	1.24
Japan Trustee Services Bank, Ltd. (Trust Account 5)	4,915	0.90
Goldman Sachs and Company (Regular account)	4,901	0.90
State Street Bank West Client-Treaty 505234 (Standing Proxy: Mizuho, Ltd., Settlement & Clearing Services Division)	4,489	0.82
Japan Trustee Services Bank, Ltd. (Trust Account 9)	4,282	0.78

* The 6,809 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.
Note: The 29,043 thousand shares (5.04%) held by the Company as treasury stock are excluded from the above because treasury stock has no voting rights.

Stock Price and Trading Volume

Network

(As of December 31, 2018)

Name of Company	Percentage Owned Directly or Indirectly by the Company	Share Capital (1,000)	Principal Business
PHARMACEUTICALS			
Japan			
Kyowa Medical Promotion Co., Ltd.	100.00%	¥50,000	Promotion and sales of pharmaceuticals
Kyowa Kirin plus Co., Ltd.	100.00%	¥112,500	Insurance, wholesale and retail
Kyowa Kirin Frontier Co., Ltd.	100.00%	¥100,000	Manufacturing and sales of pharmaceuticals
U.S.A.			
Kyowa Kirin USA Holdings, Inc.	100.00%	US $76,300	Supervision and management of specific subsidiaries (U.S.A.)
BioWa, Inc.	100.00%	US $10,000	Out-licensing of antibody technology (U.S.A.)
Kyowa Kirin Pharmaceutical Development, Inc.	100.00%	US $100	Development of pharmaceuticals (U.S.A.)
Kyowa Kirin Pharmaceutical Research, Inc.	100.00%	US $100	Generation of new drug candidate substances and promotion of research alliance (U.S.A.)
Kyowa Kirin, Inc.	100.00%	US $0.2	Sales of pharmaceuticals (U.S.A.)
Kyowa Kirin Canada, Inc.	100.00%	CA $0.1	Sales of pharmaceuticals (Canada)
Europe			
Kyowa Kirin International plc	100.00%	£13,849	Supervision and management of specific subsidiaries (U.K.)
Strakan International S.A.	100.00%	£9,720	Holding Company (U.K.)
Kyowa Kirin Pharmaceutical Development Limited	100.00%	£501	Development of pharmaceuticals (U.K.)
Kyowa Kirin Limited	100.00%	£6,952	Sales of pharmaceuticals (U.K.)
Kyowa Kirin Ireland Limited	100.00%	€0.1	Sales of pharmaceuticals (Ireland)
Kyowa Kirin Pharma SAS	100.00%	€1,241	Sales of pharmaceuticals (France)
Kyowa Kirin Farmacéutica, S.L.U.	100.00%	€216	Sales of pharmaceuticals (Spain)
Kyowa Kirin GmbH	100.00%	€51	Sales of pharmaceuticals (Germany)
Kyowa Kirin Holdings B.V.	100.00%	€111	Sales, licensing-in and licensing-out of pharmaceuticals (Netherlands)
Kyowa Kirin Pharma B.V.	100.00%	€18	Sales of pharmaceuticals (Netherlands)
Kyowa Kirin S.r.l.	100.00%	€10	Sales of pharmaceuticals (Italy)
Kyowa Kirin AB	100.00%	SEK 200	Sales of pharmaceuticals (Sweden)
Archimedes Pharma Limited	100.00%	£543	Supervision and management of specific subsidiaries (U.K.)
Kyowa Kirin Services Ltd	100.00%	£0.3	Sales and development of pharmaceuticals (U.K.)
Archimedes Pharma UK Limited	100.00%	£78	Sales of pharmaceuticals (U.K.)
Kyowa Kirin Sàrl	100.00%	CHF 20	Sales of pharmaceuticals (Switzerland)
Kyowa Kirin Austria GmbH	100.00%	€35	Sales of pharmaceuticals (Austria)
Kyowa Kirin Farmaceutica, Unipessoal Lda.	100.00%	€5	Sales of pharmaceuticals (Portugal)
Kyowa Kirin Pharma s.r.o.	100.00%	CZK 100	Sales of pharmaceuticals (Czech Republic)
Asia			
Kyowa Hakko Kirin China Pharmaceutical Co., Ltd.	100.00%	CNY 246,794	Manufacturing and sales of pharmaceuticals (China)
Kyowa Hakko Kirin Korea Co., Ltd.	100.00%	KRW 2,200,000	Sales of pharmaceuticals (Korea)
Kyowa Hakko Kirin (Taiwan) Co., Ltd.	100.00%	TW $262,450	Sales of pharmaceuticals (Taiwan)
Kyowa Hakko Kirin (Hong Kong) Co., Ltd.	100.00%	HK $6,000	Sales of pharmaceuticals (Hong Kong)
Kyowa Kirin Asia Pacific Pte. Ltd.	100.00%	SG $1,000	Sales of pharmaceuticals and control of business in the Asia and Oceania region excluding Japan (Singapore)
Kyowa Hakko Kirin (Malaysia) Sdn. Bhd.	100.00%	RM 1,000	Sales of pharmaceuticals (Malaysia)
Kyowa Kirin Pharma FZ-LLC.	100.00%	AED 50	Sales of pharmaceuticals (UAE)
Kyowa Hakko Kirin (Thailand) Co., Ltd.	100.00%	THB 100,000	Sales of pharmaceuticals (Thailand)
Japan (Equity-method affiliate)			
FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.	50.00%	¥100,000	Development, manufacturing and sales of biosimilar pharmaceuticals
Kyowa Medex Co., Ltd.	33.4%	¥450,000	Manufacturing and sales of diagnostic reagents
BIO-CHEMICALS			
Japan			
KYOWA HAKKO BIO CO., LTD.	100.00%	¥10,000,000	Manufacturing and sales of pharmaceutical and industrial raw materials, and health care products
KYOWA PHARMA CHEMICAL Co., Ltd.	100.00%	¥6,276,000	Manufacturing and sales of active pharmaceutical ingredients and pharmaceutical intermediates
Kyowa Engineering Co., Ltd.	100.00%	¥70,000	Design and installation of plant facilities and equipment
U.S.A.			
BioKyowa Inc.	100.00%	US $20,000	Manufacturing and sales of amino acids (U.S.A.)
Kyowa Hakko U.S.A., Inc.	100.00%	US $1,000	Sales of fine chemicals including amino acids (U.S.A.)
Kyowa Hakko Bio U.S. Holdings, Inc.	100.00%	US $1	Supervision and management of specific subsidiaries (U.S.A.)
Europe			
Kyowa Hakko Europe GmbH	100.00%	€1,030	Sales of fine chemicals including amino acids (Germany)
Kyowa Hakko Bio Italia S.r.l.	100.00%	€700	Sales of fine chemicals including amino acids (Italy)
Asia			
Shanghai Kyowa Amino Acid Co., Ltd.	100.00%	CNY 156,436	Manufacturing and sales of amino acids (China)
Thai Kyowa Biotechnologies Co., Ltd.	100.00%	THB 2,000,000	Manufacturing and sales of amino acids (Thailand)
Kyowa Hakko (H.K.) Co., Ltd.	100.00%	US $153	Sales of fine chemicals including amino acids (Hong Kong)
Kyowa Hakko (Guangdong) Pharmaceutical Co., Ltd.	100.00%	CNY 3,361	Sales of fine chemicals including amino acids (China)
Kyowa Hakko Bio Singapore Pte. Ltd.	100.00%	US $4,000	Sales of fine chemicals including amino acids (Singapore)

Note: All of the companies listed are consolidated subsidiaries, except FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. and Kyowa Medex Co., Ltd. which are affiliated companies accounted for using equity method.

Corporate Data

Corporate Data (As of December 31, 2018)

Kyowa Hakko 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.kyowa-kirin.com/

Number of Employees
3,918 (Consolidated: 7,242)

Date of Foundation
July 1, 1949

Paid-in Capital
¥26,745 million

Principal Plants

Japan
Pharmaceuticals
- Takasaki Plant
- Ube Plant

Bio-Chemicals
- Yamaguchi Production Center (Hofu, Ube)
- Healthcare Plant (Tsuchiura)
- Kyowa Pharma Chemical

Overseas
Pharmaceuticals
- Kyowa Hakko Kirin China Pharmaceutical Co., Ltd.

Bio-Chemicals
- BioKyowa Inc. (U.S.A.)
- Shanghai Kyowa Amino Acid Co., Ltd.
- Thai Kyowa Biotechnologies Co., Ltd.

R&D Network

Japan
Pharmaceuticals
- Tokyo Research Park
- Fuji Research Park
- Bio Process Research and Development Laboratories
- CMC R&D Center

Bio-Chemicals
- R&I Center
- Technical Research Laboratories

Overseas
Pharmaceuticals
- Kyowa Kirin Pharmaceutical Development, Inc. (U.S.A.)
- Kyowa Kirin Pharmaceutical Research, Inc. (U.S.A.)
- Kyowa Kirin Pharmaceutical Development Limited (U.K.)
- Kyowa Hakko Kirin China Pharmaceutical Co., Ltd.
- Kyowa Hakko Kirin Korea Co., Ltd.

Management Members (As of March 20, 2019)

Board Members

Director of the Board, Chairman
Nobuo Hanai, Ph.D.*1

Executive Director of the Board, President and Chief Executive Officer
Masashi Miyamoto, Ph.D.*1

Executive Director of the Board, Executive Vice President
Yutaka Osawa *1

Director of the Board, Senior Managing Executive Officer
Toshifumi Mikayama, Ph.D.

Director of the Board
Noriya Yokota

Outside Director of the Board
Kentaro Uryu*2

Outside Director of the Board
Akira Morita*2

Outside Director of the Board
Yuko Haga*2

Company Auditors

Outside Company Auditor
Akira Shimizu

Company Auditor
Hiroshi Komatsu

Outside Company Auditor
Jun Arai*2

Outside Company Auditor
Yuji Inoue*2

Company Auditor
Keiji Kuwata

*1 Concurrently serves as executive officer
*2 Independent Board Directors and Company Auditors

Executive Officers

Managing Executive Officers

Hiroshi Sugitani
Vice President,
Head, Sales & Marketing Division

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

Wataru Murata
Director,
Human Resources Department

Executive Officers

Takashi Oishi
Director,
Medical Affairs Department

Satoshi Nakanishi, Ph.D.
Director,
Corporate Social Responsibility Management Department

Niro Sakamoto
Director,
General Affairs Department

Hiroshi Sonekawa
Director,
Area Marketing Strategy Department
Sales & Marketing Division

Shinichiro Mohri
Vice President,
Head, Pharmacovigilance and Quality Assurance Division &
Director, Corporate Quality Management Department

Mitsuo Satoh, Ph.D.
Vice President,
Head, R&D Division

Nobuyuki Tsukahara
Director,
Nagoya Branch
Sales & Marketing Division

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

Chikakuni Kotani
Managing Director,
Kyowa Kirin Asia Pacific Pte. Ltd.

Motohiko Kawaguchi
Director,
Accounting Department

Yasuo Fujii
Director,
Business Development Department

Shin Inoue
Director,
Sales & Marketing Planning Department
Sales & Marketing Division

Fumihiko Kanai
Vice President,
Head, Production Division