KYOWA KIRIN

Annual Report 2017

For the year ended December 31, 2017

Leaping Forward

Countdown to Takeoff

Contents

Editorial Policy

To help investors understand the Kyowa Hakko Kirin Group's business model, management strategy, operating conditions, and future picture, we have prepared this integrated report, while drawing on the International Integrated Reporting Council's (IIRC's) International Integrated Reporting Framework as well as the Guidance for Collaborative Value Creation released by the Ministry of Economy, Trade and Industry. Our overseas drug development made significant headway in 2017, and we are finally moving closer to making the leap forward to become a Global Specialty Pharmaceutical Company (GSP), which is our goal. For this reason, the Special Feature section highlights our overseas business strategy, which is designed to attain our goal, as well as work style reform, a component of our human resource strategy that supports the business strategy.

We would appreciate if you could give your help and support to the Kyowa Hakko Kirin Group, an organization pursuing global endeavors.

Niro Sakamoto,
Executive Officer, in charge of Corporate Communications Department

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

Kyowa Hakko Kirin Website
http://www.kyowa-kirin.com/

Financial Information
http://ir.kyowa-kirin.com/en/finance.html

Sustainability
http://www.kyowa-kirin.com/sustainability/

ESG Data Collection
http://www.kyowa-kirin.com/sustainability/esg_data/

Concerning the Scope of This Report

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 2017, and 2018 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

Sum of the breakdown may not equal to the total due to rounding.

Management
Philosophy

The Kyowa Hakko Kirin Group companies strive to contribute 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.

Core Values

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

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

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

"Core Values" are a way of thinking and attitude that supports the activity of each officer and employee belonging to the Kyowa Hakko Kirin Group. It consists of core concept "Commitment to Life" and three key words.

Group Structure

A Pharmaceutical Company with a Globally Unique Business Structure

The drug discovery business for pharmaceuticals is at the core of the Kyowa Hakko Kirin Group. Our unique business structure, which incorporates biosimilars, diagnostics, and bio-chemicals, provides us with many business opportunities, and enables us to offset the high-risk drug discovery business. Few companies are like Kyowa Hakko Kirin, and the possibilities from synergies among our businesses are great advantages of the Group.

Kyowa Hakko Kirin Group

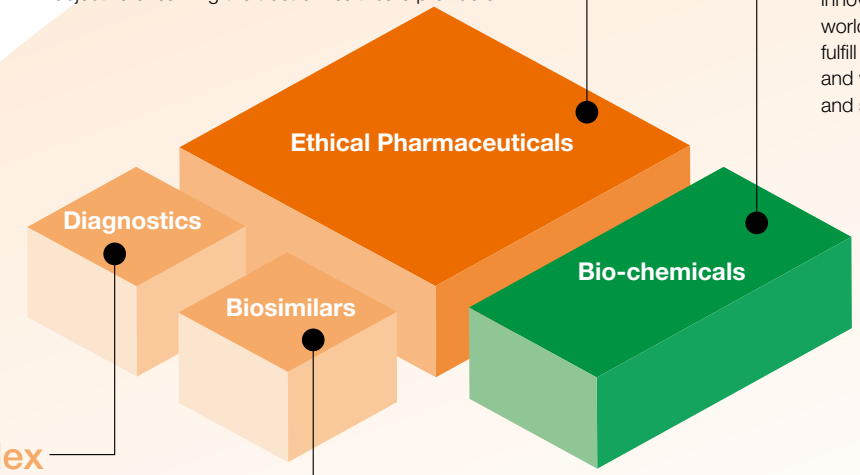
The Kyowa Hakko Kirin Group has advanced unique research with its sophisticated technology in the business fields of “pharmaceuticals” and “bio-chemicals” while developing and providing various high-quality products. The field of biotechnology offers immense possibilities. As a representative life science company of Japan, we strive to realize new possibilities and continue to contribute to the health and lives of people around the world.

Kyowa Hakko Kirin

Focusing on the four categories of nephrology, oncology, immunology/allergy, and the central nervous system, we are enhancing cooperation from research and development to production, sales and marketing to rapidly evolve into a global specialty pharmaceutical company. We will steadily launch products from our well-stocked pipeline of development candidates while creating an effective, highly specialized sales and marketing organization with the objective of earning the trust of healthcare providers.

Kyowa Hakko Bio

Kyowa Hakko Bio supplies a range of products in Japan and overseas, including amino acids, nucleotides, vitamins, peptides, and synthetic compounds. We will be a biochemical innovator which provide people in the world with products and services to fulfill their healthcare needs, using deep and wide knowledge of fermentation and synthesis.



Kyowa Medex

In cooperation with Kyowa Hakko Kirin’s R&D operations, Kyowa Medex seeks to generate synergies with the pharmaceuticals business and enhance added value through the development and launch of diagnostic reagents, analyzers, and companion diagnostics that contribute to personalized care.

* As of January 4, 2018, we sold 66.6% of shares in Kyowa Medex to Hitachi Chemical Company, Ltd., making it an equity-method affiliate from a consolidated subsidiary of the Kyowa Hakko Kirin Group.

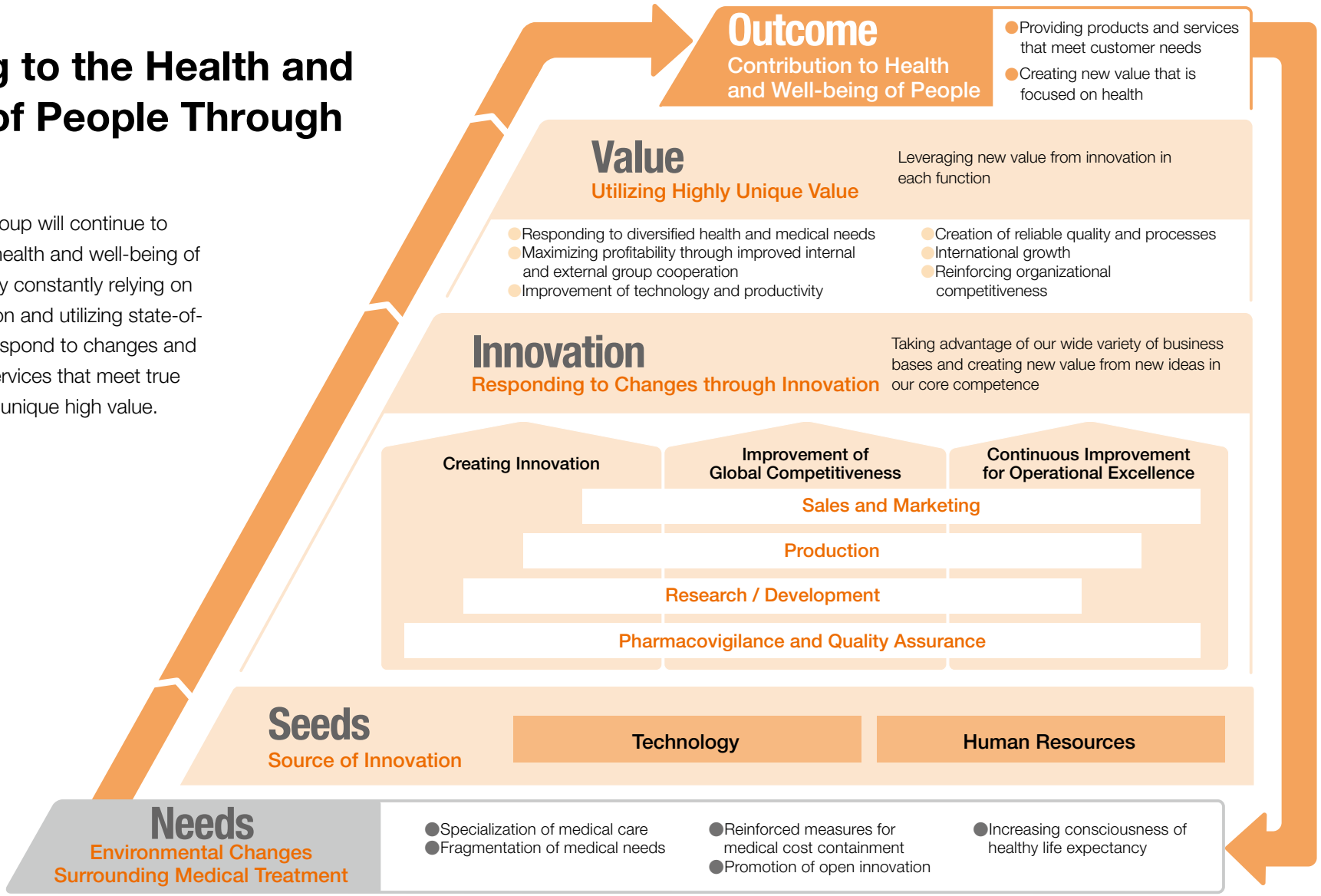
Fujifilm Kyowa Kirin Biologics

The mission of Fujifilm Kyowa Kirin Biologics is to deliver reliable, high-quality and cost-competitive biosimilars by using new technologies that merge Kyowa Hakko Kirin’s strength in biopharmaceutical manufacturing technologies with engineering technologies for manufacturing, quality control, and analysis developed by FUJIFILM Corporation through its various businesses.

Business Model

Contributing to the Health and Well-being of People Through Innovation

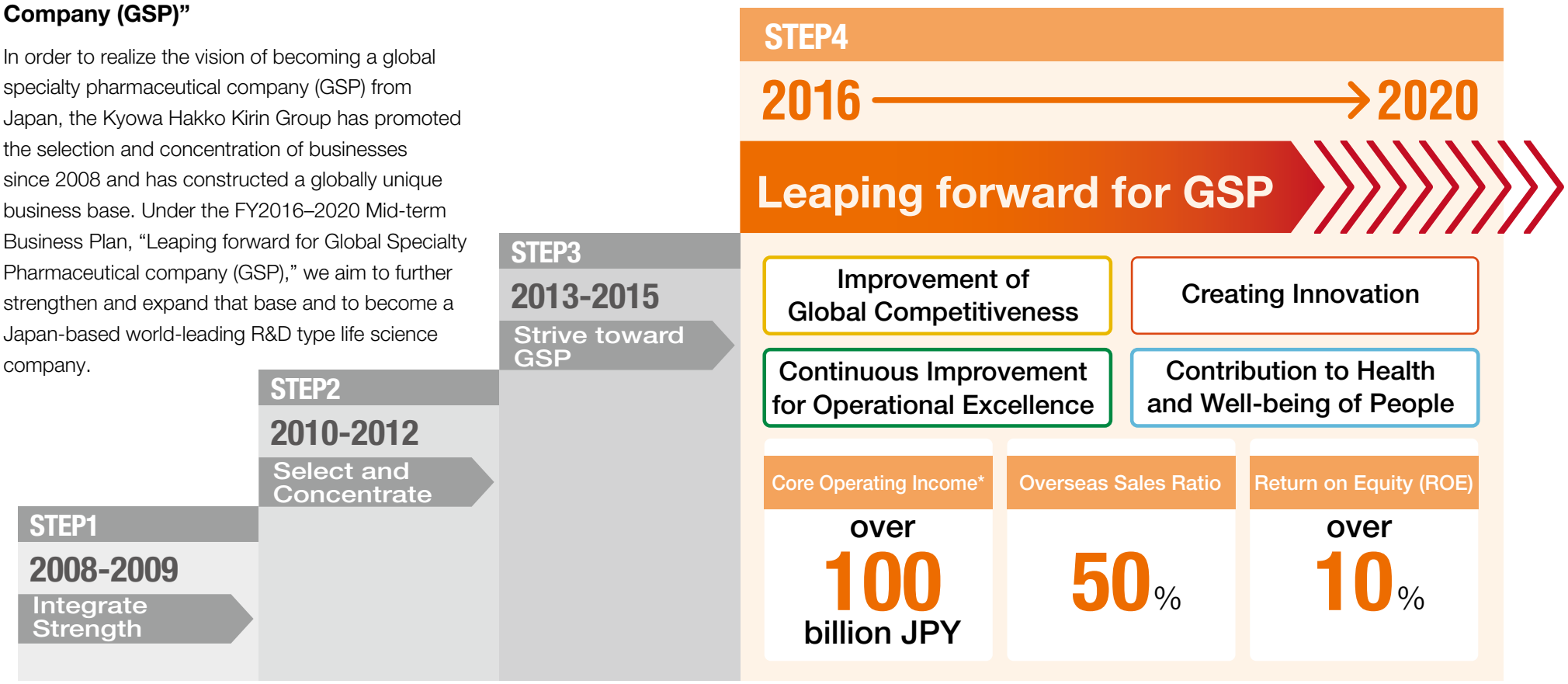
The Kyowa Hakko Kirin Group will continue to contribute strongly to the health and well-being of people around the world by constantly relying on innovation as our foundation and utilizing state-of-the-art biotechnology to respond to changes and rolling out products and services that meet true customer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



Road Map to Our Vision

FY2016-2020 Mid-term Business Plan
"Leaping forward for Global Specialty Pharmaceutical Company (GSP)"

In order to realize the vision of becoming a global specialty pharmaceutical company (GSP) from Japan, the Kyowa Hakko Kirin Group has promoted the selection and concentration of businesses since 2008 and has constructed a globally unique business base. Under the FY2016–2020 Mid-term Business Plan, "Leaping forward for Global Specialty Pharmaceutical company (GSP)," we aim to further strengthen and expand that base and to become a Japan-based world-leading R&D type life science company.



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

We are about to take off for our leap forward to become a GSP

In FY2017, the second year of our FY2016-2020 Mid-term Business Plan, on the back of robust business performance, we were able to make significant progress toward new growth.
In the coming FY2018, drugs bearing our brand are expected to be launched in the global market and we are about to take off for our leap forward to become a Global Specialty Pharmaceutical Company (GSP).

Nobuo Hanai

Representative Director
Chairman and CEO

Looking Back on Our Performance in FY2017

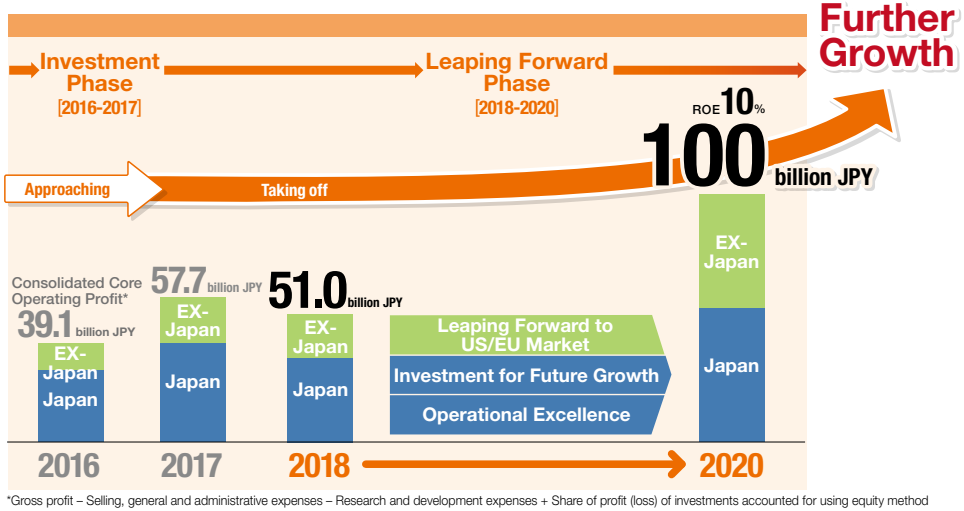
We were able to achieve performance that surpassed expectations in the 2nd year of the Mid-term Business Plan

FY2017 was a year for roaring in preparation for our leap forward to become a Global Specialty Pharmaceutical Company (GSP), in which we felt a strong response. In terms of financial performance, we achieved a better results than FY2016.

As the hottest topic, we can cite the progress of our global strategic products. Namely, burosumab (KRN23), an investigational recombinant fully human monoclonal IgG1 antibody against the phosphaturic hormone fibroblast growth factor 23 (FGF23) under development to treat X-linked hypophosphatemia (XLH), and mogamulizumab (KW-0761), a humanized monoclonal antibody targeting CC chemokine receptor 4 (CCR4), which is already available on the Japanese market. As for these drugs, we have successfully filed an application with European and U.S. regulatory authorities, respectively. In addition, anti-IL-5 receptor humanized antibody benralizumab (KHK4563) that is carrying our POTELLIGENT® technology and that we out-licensed to AstraZeneca, has been developed smoothly. As a result, benralizumab obtained approval from the U.S. Food and Drug Administration (FDA) and have reached a stage where we can expect to win approval soon in Japan and Europe as well*. Moreover, we were able to make steady progress on adenosine A_{2A} receptor antagonist istradefylline (KW-6002), under development, for a therapeutic drug for Parkinson's disease with a view to filing a reapplication with the FDA as well. The Mid-term Business Plan has been moving forward step by step with an eye toward the phase for our leap forward.

In 2017, we also made two major decisions, i.e., transfer of Kyowa Hakko Bio's plant growth regulator business and transfer of Kyowa Medex, a diagnostics business subsidiary. These are constructive moves after considering concentrating our resources and further growth of both businesses.

* Benralizumab obtained approval in Japan and Europe in January 2018.



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

Progress of the FY2016-2020 Mid-term Business Plan

With four strategic pillars, the plan has been moving forward steadily

- **Improvement of Global Competitiveness** (Leaping Forward to US/EU Market)
- **Creating Innovation** (Proactive Investment for R&D)
- **Continuous Improvement for Operational Excellence** (Group Management)
- **Contribution to Health and Well-being of People** (Creating Shared Value)

Improvement of Global Competitiveness

The percentage of overseas sales is expected to grow steadily down the road

Since its integration in 2008, our group has consistently aimed at becoming a GSP that covers the entire range of business activities from drug discovery to development, manufacture and sales on its own. In FY2018, we expect to launch our global strategic products burosumab and mogamulizumab in Europe and the U.S. and I believe that it should be a key year for us to take another new step as a GSP*.

With the launch of those products in the western markets, we expect the percentage of our overseas sales to grow steadily down the road. Under the Mid-term Business Plan, we set forth the target of boosting the overseas sales ratio to 50% in FY2020 and we certainly have its achievement in sight now.

We also initiated an effort at stably supplying low-cost high-quality products. In the pharmaceuticals business, we completed the restructuring of our domestic manufacturing bases, which started in 2010, as scheduled. In the bio-chemicals business, we made steady progress on an effort to better organize our domestic manufacturing bases by transferring operations to Thailand and Shanghai. These activities have proven key moves for us to step up our global competitiveness.

* Burosumab obtained approval in Europe in February 2018.

Creating Innovation

We focus on securing and developing human resources, i.e., the source of innovation

We are proud of the fact that our group has a globally top-level research and development capacity in the biopharmaceutical area. In order to

enhance the capacity further, creating innovation is one of the critically important business challenges and we will continue investing in R&D aggressively.

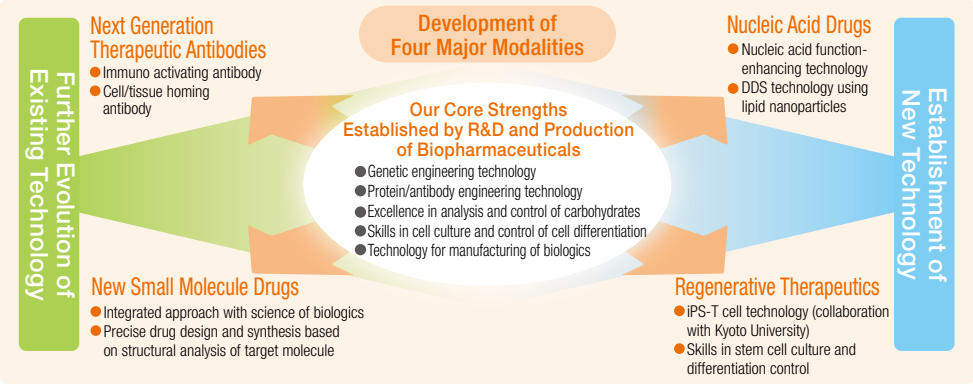
In quest of seeds of new drugs, we engage in the research activities globally centered on our R&D laboratories in Japan and San Diego. Both labs promote open innovation in collaboration with academic institutes and organizations and have produced favorable results so far. We hope to stimulate innovation in R&D further through collaborations in the leading-edge scientific field.

In terms of open partnerships, it is very important to form an alliance in the information technology (IT) field as well. In recent years, artificial intelligence (AI) has made remarkable progress and its application in pharmaceutical development and personalized care has gained prominent attention. In the IT field, where new innovations are expected, such as increased speed and efficiency of drug discovery by using big data in the real world, including healthcare information, we will vigorously team up with leading-edge players.

Also in 2017, in order to achieve our group management philosophy, we revisited our policy of securing and developing human resources that gives shape to “Core Values” and “Code of Conduct,” thereby formulating the Kyowa Hakko Kirin Group Talent Management Policy. This policy redefines our philosophy common to the whole group with a view to building people and organization that keep challenging to reform and create new values. I believe that the source of innovation lies in “people” and securing and developing outstanding human resources is our most important mission of all.

The environment surrounding pharmaceuticals has become increasingly diversified. In order to respond to these changes flexibly, we need to leverage the abilities that each individual with diverse backgrounds has. We will work on fostering a free and vigorous climate where a wide variety of human resources get together and they can display their abilities and individualities to the maximum extent possible.

Utilization of open innovation and development of four major modalities



Continuous Improvement for Operational Excellence

By leveraging the Kirin Group’s synergy, we will move ahead on building a new business process

In FY2017, we focused mainly on two initiatives in terms of business process improvement.

The first one is to improve production technology. In the biopharmaceutical world that has been making remarkable progress, we take pride in being in the leading pack but we must keep enhancing our leading-edge technology. In addition, in terms of suppressing medical cost that has come under scrutiny in recent years, cost reduction will play a pivotal role in sharpening the competitive edge. In our group the Bio Process Research and Development Laboratories take the lead to work closely with manufacturing sites in addressing technology improvement continuously.

We move ahead with business improvement and cost reduction like these thoroughly not only in the production division but also in any other divisions company-wide. As a result, return on assets (ROA) has been increasing and favorable results have been yielded step by step.

The other is an initiative by the Kirin Group as a whole. The Kirin Group works on a cross-sectoral project in a bid to improve business processes overall. At present, several projects, such as joint procurement of materials and shared administration system in the accounting and human resources departments, are under way, in which we take part. In this way, by leveraging synergy as the Kirin Group we will go about building outstanding business processes.

Contribution to Health and Well-being of People

We believe that CSV is the compass for our management strategy

The Kirin Group promotes efforts with CSV* as the nucleus of business management. In our group, it is one of the very important subjects when we think about how to solve social challenges and things that none other than we can do. I believe that CSV will serve as the compass for the Kyowa Hakko Kirin Group down the road.

There are still a large number of overlooked rare diseases for which no therapy is available as yet in the world, where there are high unmet needs. There are adults and children who are anxiously waiting for new therapies all over the world. I believe that although new drug development is very difficult, challenging ourselves to develop one by taking advantage of our strength to save as many patients as possible is our mission as a pharmaceutical company. Consequently our corporate value is boosted, which is exactly the type of CSV management that we aim for. The practice of CSV will have much to do with sustainable growth from this point onward. I believe that it is important not

only to take up a challenge but to produce results by taking advantage of our strength to realize it as well.

Meanwhile, with an eye toward creating a healthy and affluent society, we are addressing the issue of suppressing medical cost. In the biosimilar business, by leveraging our group's unique sophisticated production technology, we are moving forward with the aim of supplying low-cost and high-quality biosimilars stably.

Biochemical products handled by the bio-chemicals business, such as amino acids and nucleic acids, also play a key role in preventing diseases through tackling the presymptomatic condition. We will continue to expand the business so that it may play a role as part of the Kirin Group, which sets forth food and well-being as its philosophy, along with the pharmaceuticals business.

* CSV stands for "Creating Shared Value" and refers to realizing improved corporate value through both the creation of social value and the creation of economic value by addressing social issues.

Building of the Global Governance System

We will build a global governance system with the aim of sound business operation

In order to succeed in leaping forward for a GSP, it is essential to build a global governance system. Both Kyowa Hakko Kirin and Kyowa Kirin International, which develops business in Europe and the U.S., appoint personnel who have broad international experience as outside directors, thereby enhancing fairness and transparency of our global management. In addition, we are stepping up efforts at compliance by bolstering the global auditing system and an internal whistle-blower system as well.

Furthermore, quality control of products is also critically important. We are required to control quality not only of products but of the global supply chain as a whole, including raw materials and suppliers, as well. For this reason, we shored up the function of the quality audit department directly under the president. Given that quality control and assurance can be referred to as the linchpin of function for a pharmaceutical company, we will continue proactively investing in it, including human resources that are assigned to it.

Assuming the Office of Chairman

With an eye toward a new stage to take a step forward as GSP, we are ready with an even more robust management setup

As of the General Shareholders' Meeting day in March 2018, I resigned from my office as president and assumed the post of representative director and chairman and chief executive officer (CEO). This is because the Nomination Consultative Committee reached the conclusion that it should be the right moment to hand management over to the next generation given that 2018 marks a major milestone in which we expand our European and the U.S. business through products that we created on our own, such as burosumab and mogamulizumab, thereby taking off as GSP. I would like Dr. Masashi Miyamoto, who was appointed as the next representative director and president and chief operating officer (COO) to lead from the front as president and exercise his skills in managing the pharmaceuticals business to his heart's content, thereby gaining his experience with a view to assuming the office of CEO in the future. I will remain at the helm of the Kyowa Hakko Kirin Group as a whole with the aim of building the corporate governance system and the mechanism to generate synergy, a challenge that presently faces a crucial phase.

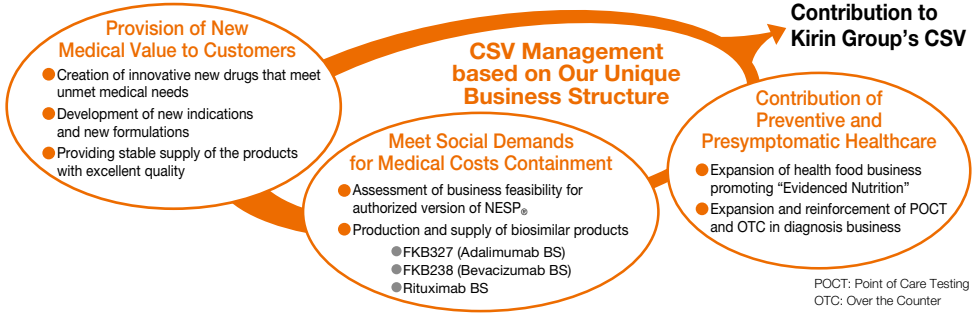
Message to Stakeholders

After roaring in preparation for takeoff, we will continue to move forward

We are pleased to announce that we were able to achieve performance that surpassed original plans in FY2017. In the coming FY2018 new drugs bearing the KYOWA KIRIN brand will be launched for the first time in the global market. After roaring in preparation for takeoff, our leaping forward for GSP as well has finally come into view.

While the Mid-term Business Plan has made smooth progress, we will continue to focus on propelling the four management strategies with a view to climbing upward after taking off. Furthermore, we are already contemplating the next phase after making a leap. Our new drug pipeline responsible for the next generation has also yielded favorable results step by step. We will continue to mobilize the power of the Kyowa Hakko Kirin Group to face challenges and achieve sustainable growth. With that, let me encourage you to count on us.

CSV to which Kyowa Hakko Kirin Group aspires



POCT: Point of Care Testing
OTC: Over the Counter

Message from President & COO

Building a global business platform with a view to sustainable growth

I assumed the post of representative board director and president and chief operating officer (COO) on March 23, 2018. To put burosumab and mogamulizumab on the market, we will build a global platform as early as possible. At the same time, we will put our utmost efforts into achieving the FY2016-2020 Mid-term Business Plan and strive to create a business foundation with the aim of sustainable growth going forward.

Masashi Miyamoto
Representative Director
President and COO

Thoughts on Our Management Philosophy

Creating new value is our important mission

We have in place a philosophy that says “the Kyowa Hakko Kirin Group companies strive to contribute 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.”

In order for the Group to grow sustainably from now on, “creating new value” is important. New value that the Group must create is to contribute to the health and well-being of patients and their families, as well as medical professionals, by providing new drugs.

After studying pharmacology as a student, I joined the Group and was involved in research and development in mainly this field for more than 10 years. Then, I moved on to experience a variety of duties, such as the execution of strategies on research and operations and corporate planning, which included a two-year posting in the U.S.

Throughout my career path, I have always cherished my resolve to “create new value.” This is not unique to me; probably, this resolve is shared by all the employees of the Group.

COO Message

Role and Mission as President and Chief Operating Officer

Building a global platform as early as possible

Burosumab (KRN23), anti-FGF23 fully human monoclonal antibody, under development to treat X-linked hypophosphatemia (XLH), and mogamulizumab (KW-0761), anti-CCR4 humanized monoclonal antibody, are the new drugs that will be extremely important for the Group to create new value befitting it; they are likely to be put on the market in FY2018. In my opinion, our important near-term mission is to establish a platform to deliver these two new drugs to patients and medical professionals around the world, including Japan. From now on, Kyowa Kirin International will prepare for the sale of the new drugs in Europe and the U.S. We will develop a globally unified sales strategy, supply chain, and quality assurance system and thereby build a platform for the Group to aim to become a Global Specialty Pharmaceutical Company.

In order to realize a global business platform, it is essential for the Group to enhance the functions of its headquarters. Although, to date, management has been communicating closely with the top managements of overseas group companies and maintaining an open and compact system, we will further develop our governance structure, with the headquarters in Japan serving as the hub.

Operational streamlining is a big challenge that we must tackle from now on. Having been involved in R&D for many years, I understand that new drug development requires enormous efforts and much time. Bearing this fact in mind, we will actively introduce advanced IT techniques, such as AI, to streamline operations.

Streamlining efforts will target not only R&D but also all business tasks. From a broad perspective, you will find that many challenges must be faced. Ensuring that operational streamlining is accompanied by work style reform is indispensable. My work style is being mindful of smart work and working in a well-modulated manner. Whenever an opportunity arises, I mention this style to my employees. Spending time on rejuvenating yourself while off work will help you to come up with new ideas and discoveries, which will be mirrored in your work.

Reinforcing R&D Capabilities

Implementing aggressive initiatives with an eye on new, next-generation drugs

Burosumab and mogamulizumab have received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA). Globally, it is rare that a pharmaceutical company having the business size of Kyowa Hakko Kirin successively wins this type of designation. In my opinion, such wins are the results of putting the Group's capabilities into practice.

More than two decades have passed since we initiated the research on these new drugs. From the start, we have engaged in R&D in collaboration with the academias. Open innovation-based R&D, an inherited approach of Kyowa Hakko Kirin, is a major characteristic of these efforts. We will continue to link internal and external knowledge and expertise organically, thereby developing valuable and innovative drugs unique to the Group.

In addition, collaboration with Kirin Group companies is also a theme we should work on in the coming years. Combining the operations pursued by Kirin Group companies and the insights that we have accumulated independently would bring about a possibility of creating further new value.

Message to Stakeholders

Putting utmost efforts into pursuing the Mid-term Business Plan

Certainly, FY2018, which marks the third year of the FY2016-2020 Mid-term Business Plan, will be an extremely important year for leaping forward for Global Specialty Pharmaceutical Company. As President and COO, I will put my utmost efforts into achieving the Mid-term Business Plan. I believe that another important mission for me is to create a business foundation with a view to ensuring the company's sustainable growth, going forward.

The year 2018 marks the 10th anniversary of the founding of Kyowa Hakko Kirin. I was involved in the start-up of the organization, as well. Although the following decade was not an easy period, I now feel certain that the Group is currently in the process of growing into a company with unique value, which is rare in this world. By putting together the capabilities of all employees, we will continue steadily in our path to make the Group a Japan-based Global Specialty Pharmaceutical Company.

Taking a major step in making the leap forward to become a GSP with the launch of KRN23 and KW-0761 in Europe and the U.S.

Burosumab (KRN23) and mogamulizumab (KW-0761), new drugs bearing our brand to be launched in European and U.S. markets in 2018, represent a major strategic move toward becoming a Global Specialty Pharmaceutical Company (GSP). Through these products, we will deliver appropriate treatment to those who are suffering from rare diseases all over the world. Moreover, our overseas strategy with subsequent further growth, including expanding the sales structure of our existing pharmaceutical products, is making progress step by step.

Director of the Board
Senior Managing Exective Officer
Director, Overseas Business Department
Toshifumi Mikayama, Ph.D.

Set to launch two KYOWA KIRIN brand products in European and U.S. markets at last

Our Mid-term Business Plan, which was formulated with a view to enhancing our competitive edge globally in a bid to make the leap forward to become a GSP, has been advancing extremely smoothly thus far.

We have filed an application for the approval of burosumab, an anti-FGF23 fully human monoclonal antibody, with European and U.S. regulatory authorities so far. Conditional approval is expected in Europe in February 2018 and we will launch the product in Germany in spring as the first step. In general, we are required to conduct a phase III clinical trial for a new drug application. The reason we were able to obtain conditional approval in Europe based on the results of Phase II clinical trial was that the certainty of its clinical benefits was acknowledged.

Burosumab targets a rare disease caused by a genetic abnormality, which can hamper bone growth considerably in children. Considering that no appropriate therapy is available and many patients have yet to obtain medical care, burosumab should offer big hopes to patients.

In distributing burosumab in Europe and the U.S., we will proactively provide patients with various types of information. However, our future significantly hinges on how the insurance system and the insurers in each country evaluate the price of this drug. For this reason, we have formed a special team internally in a bid to ensure an appropriate drug price.

We expect over 100 billion yen of burosumab's annual sales ultimately and the profit from it will generate the fund to develop new drugs in the future.

Meanwhile, mogamulizumab, anti-CCR4 humanized monoclonal antibody, was designated as a Breakthrough Therapy by the U.S. Food and Drug Administration (FDA) in 2017. Moreover, we applied for new drug approval in Europe and the U.S. in the same year. It is expected to be approved by the middle of 2018. We will launch mogamulizumab first in the U.S. and then in Europe. Our U.S. sales account for approximately three billion yen of our sales in Europe and the U.S., which total approximately 40 billion yen. Under these circumstances, it is highly significant for us to release the first product of our own in the U.S., the world's biggest pharmaceutical market, and huge expectations have been placed on this challenge.

Build a new sales structure aimed at business development in various countries

We have already put a stable sales structure in place in major European Union (EU) member nations and will go on to establish a sales company in Eastern Europe and the Middle and Near East as well to bolster the sales structure for the two drugs. In 2016, we in-licensed a drug with an eye toward marketing them in Eastern Europe and have moved ahead with efforts to build a sales network for these drugs along with other products of our own.

In Europe and the U.S., ways of marketing drugs have been increasingly changing. For this reason, changing or strengthening the sales structure accordingly holds the key. Existing drugs can be handled by medical representatives (MRs) but in the case of drugs for rare diseases, such as burosumab and mogamulizumab, the role to

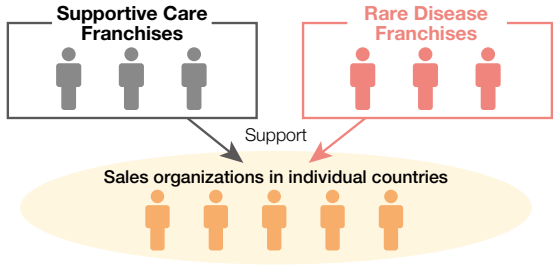
be performed by MSL* is essential. With the aim of placing these two drugs on the market smoothly and launching them at full throttle, we have established a new professional structure called “Rare Disease Franchises” while hiring top-caliber and experienced MSLs serially on a country-by-country basis. In addition to MSLs, those well versed in rare diseases who perform other roles have joined our company one after another. This is proof that public interest in our new drugs is growing and we are very proud of it.

Efforts are still required to enhance the value of pharmaceuticals further after they are launched. Thus, the Medical Affairs Department has taken the leadership in accumulating clinical researches in collaboration with a wide array of divisions and properly delivering the results to major healthcare facilities and professionals in cooperation with MSLs of respective countries, thereby spreading the value of the KYOWA KIRIN brand throughout the world.

Meanwhile, in Asia, given that these two drugs are therapeutic antibodies and expensive, we are studying how to expand them down the road. There are a large number of patients who need these drugs in the region as well. How should we deliver these drugs to them? I believe that there are tons of things that we can do, including approaching governments, cooperating with charity funds, and educating doctors.

* MSL stands for Medical Science Liaison. They perform the role of promoting the proper use of drug products and helping optimize their value from medical and scientific perspectives both internally and externally. They have a high level of expertise on, and academic knowledge of, disease areas.

Schematic view of the new sales structure



Expect to grow the business of existing products in Europe, the U.S., and Asia as well

In terms of our existing products, in European and U.S. markets, our business has been developing steadily with focus on supportive care items to relieve pain and nausea caused by cancer treatment.

However, sales of Moventig™, which was in-licensed in 2016 for the treatment of opioid-induced constipation (OIC), fell short of expectations right after its release and how to boost sales was a challenge. This drug improves symptoms of constipation caused by cancer treatment and high therapeutic efficacy is expected when it is taken for a period of three months. However, once symptoms are somewhat improved, patients tend to stop taking it. To combat this issue, we have launched a drive to inform patients of its proper use. As a result, sales have been picking up smoothly. Its further penetration into the market can be expected.

In Asia, the mainstay of our products is drugs for dialysis patients. We made a foray into the field more than 20 years ago and business has been increasing constantly. Currently, we have sales bases in seven countries and it’s about time to make the next leap forward.

There is no doubt that Asian nations will continue growing substantially in the next decade or two. Even today, in such countries as China, the number of dialysis patients is rising sharply as their economic power increases. The key to responding to these environmental changes lies in human resources. In Asia in particular, culture and ways of thinking vary from country to country and in some nations, management is difficult by simply sending staff from the head office. We believe it is effective to have experienced local people capable of management join us with a view to expanding our business further in the region.

Against this background, in FY2018, we will set up a base in Singapore to supervise our operations in the Asian region in a bid to shore up our portfolio management and sales strategy for the region as a whole. On top of these, in addition to the seven countries, we are considering expanding our sales bases into Vietnam, Indonesia, the Oceania, and others as well.

Step up risk management to ensure achievement of GSP initiative further

Delivering pharmaceutical products that we created on our own to the global market is the business vision that we have shared since Kyowa Hakko Kirin was born in 2008. It’s about time that unflagging efforts we have made take shape. As a manufacturer of new drugs bearing the KYOWA KIRIN brand, the Group’s entire workforce, which encompasses all the plants that manufacture our products and the subsidiaries that are responsible for sales throughout the world, not to mention the Overseas Business Department, shares a sense of excitement about making a leap forward right now.

We will try our best to take swift action in countries where we are allowed to sell and expand our business areas into Eastern Europe, Asia, and Latin America in order to deliver our products to patients who have had no access to effective therapies as soon as possible. However, we must not forget the fact that regulations, laws, and ways of thinking about risks vary from country to country. No grave incident has occurred in terms of compliance but in promoting our global operations further, we will carry out risk management even more vigorously than before.

Social contribution activities, such as charity marathons or gateball events that our overseas subsidiaries organize under the name of KYOWA KIRIN to support patients, will likely increase in significance in the future. We will continue to contribute to society as much as we can.

Let me close this note by encouraging you to place high expectations on Kyowa Hakko Kirin, which is set to make the leap forward to become a GSP from Japan.

Pursue work style reform designed to improve productivity

**In the FY2016–2020 Mid-term Business Plan, we focus "Continuous Improvement for Operational Excellence" as one of four strategic pillars, and set our goals of complying regulatory compliance and promoting employees' health.
As part of such endeavors, the Group has put in place the Smart Work Promotion Plan, working to rectify the practice of working long hours and streamline operations.**

Smart Work Promotion Plan

The climate for the work style and working hours is undergoing perplexing changes, requiring companies to be compliant with laws and regulations on working hours.

The Smart Work Promotion Plan put in place by the Kyowa Hakko Kirin Group represents an initiative to shift to an organizational culture that attaches importance to hourly productivity-focused work style, namely, smart work, and to build a highly-creative workplace environment with the aim of keeping employees healthy and ensuring thorough compliance. During FY2017, proactive initiatives befitting each department continued in the form of arrangements for rectification of the practice of working long hours, taking of annual leave, and transmission of the division head's message.

Under the Kyowa Hakko Kirin Group Talent Management Policy, we deploy various action plans for the management challenges such as diversity and inclusion (D&I) efforts, including female empowerment and disability employment expansion, as well as health-centric business management. Through these action plans, we seek to ensure each employee exercises his or her competence to the maximum, contributing to the organization's capabilities.

WEB Kyowa Hakko Kirin Group Talent Management Policy
http://www.kyowa-kirin.com/sustainability/human_rights_labor_practices/development/pdf/khk_group_talent_management_policy.pdf

Initiative for smart work and achievements

Rectifying the practice of working long hours and raising the rate of annual leave taking

We strive to rectify the practice of working long hours and raise the rate of annual leave taking by making sure each department's performance goals include numerical targets on working hours and annual leave taking. At the same time, we review the outcome at management meetings. Although the Group's average overtime work hours and annual leave days are not at the level requiring rectification, the fact that the operations of departments and employees were skewed was seen as a challenge. For FY2017, we set the targets for reducing the longest overtime work hours at each department* and of having all employees take at least five annual leave days, instead of just rectifying the average overtime work hours and annual leave days, encouraging departments and employees to make team operations less skewed. As a result, 67.8 percent of departments achieved the goal of reducing longest overtime work hours, and the annual leave days taken averaged 13.3 days, and 99.4 percent of employees took at least five annual leave days.

Since work style varies much from one job category to another and from one department to another, it is important to revise operations in a manner befitting each workplace. Therefore, we stipulated a qualitative goal of "arranging for each department head to transmit a top message." Moreover, we implemented an initiative to identify challenges and devise action plans on a workplace basis under the leadership of the department head.

* The numerical target is set as the number of working hours being 10 percent lower than the longest overtime work hours at each department of Kyowa Hakko Kirin for FY2016, and we monitored the ratio of departments that achieved the target.

Initiative for operational streamlining

A pressing challenge for the Research Core Function Labs. of the Research Functions Unit, R&D Division, was to perform operations efficiently due to a large number of service requests from other departments. In this respect, the personnel implemented an initiative to put smart work into practice with the involvement of all staff members of the labs. Specifically, the personnel helped employees gain a better understanding about diversity and work style reform in seminars offered by external lecturers. Moreover, through group work sessions, they identified challenges for themselves and their departments, and shared information going beyond their workplace boundaries. Each department then moved on to work on an initiative to streamline its operations. A questionnaire survey was conducted, following which the staff shared the progress of initiatives and newly found challenges with each other in the research labs. They organized seminars and group work sessions on the subject of these challenges, and continued to put smart work into practice while running a Plan-Do-Check-Act (PDCA) cycle.

Group work session underway for operational streamlining

Assisting diverse work style

Joined IkuBoss-alliance

On February 24, 2017, Kyowa Hakko Kirin joined IkuBoss-alliance run by the non-profit organization Fathering Japan. Using this occasion as a catalyst, we will further accelerate efforts to promote diversity and build a proper workplace environment through employees' mutual understanding. Moreover, we aim to improve all employees' work-life balance and enable the Company to grow in a sustained manner.

At the signing ceremony for IkuBoss-alliance

Held seminars on diversity, work reinstatement, and nursing care

The Company holds various seminars to foster an organizational culture empowering diverse employees to work actively and enthusiastically.

In June 2017, for organization heads including officers, we organized the Diversity Management Seminar as an event intended to allow them to understand IkuBoss-based organization management. Moreover, in September 2017, we held the Diversity and Inclusion (D&I) Seminar designed for leaders in a position to manage staff members to gain the knowhow to embrace each member's diversity and empower him or her to work actively.

Each autumn, to assist employees who have taken leave of absence for childcare to return to work smoothly and work actively, the Company organizes a reinstatement aid seminar to consider the post-reinstatement work style and life. As regards nursing care challenges that will become more widespread in the future, we provide information, via a nursing care aid seminar, about preparations that can be made before nursing care needs to be given to parents.

D&I Seminar in progress

VOICE

All staff members care about the work style to cherish teamwork

Setsuhiro Azuma, Sales Office Manager of Saitama Sales Office 1, Chiba-Saitama Branch, Sales & Marketing Division

I believe that, to promote smart work, it is important for all sales office staff members to care about their work style, so I always talk about it in meetings. I instruct employees with time constraints to get the job done within regular working hours, but I assign a role to them only to a non-burdensome extent and have them care about organizational contribution, thus raising their motivation. I tell employees properly that their results will be evaluated fairly and offer them career advancement. They are well understood by colleagues, resulting in a relationship of trust being built.

Currently, we work to raise productivity by re-allocating customer facilities of each sales staff, allowing them to save journey time and spend enough time at the customer office for sales activities. From now on, we will promote team activities, which will take the form of further bolstering the cooperation framework within each area team to deliver results early and permeating products in collaboration with distributors.

Achieving growth while balancing work and childcare with the use of various schemes

Hiroko Yokomatsu, Saitama Sales Office 1, Chiba-Saitama Branch, Sales & Marketing Division

I used the pre- and post-birth maternity leave and childcare leave schemes. When I was reinstated, management held a reinstatement aid seminar, in which I heard about senior colleagues balancing work and childcare and was briefed on schemes available for me. At present, I work while being exempted from overtime work. Faced with time constraints, I make inventive efforts to deliver higher productivity by preparing reports promptly, so I can spend the time to discover customer needs.

The promotion of smart work has made it possible for me to handle e-mails using pockets of time and simplify the document-making process. First and foremost, the restriction imposed on leaving work and sending e-mails late in the evening has allowed me to work without feeling the gap with other employees on a relative basis.

My goal for the future is to serve as an MR (Medical Representative) responsible for other areas and segments and to have another child. I wish to grow while balancing work and childcare and accumulating experience.

Striving to streamline operations while giving care to my high productivity hours

Takahiro Arai, Clinical Development Group 3, Clinical Development Center, R&D Division

I am currently involved in running international collaborative clinical trials in Asia. As I frequently go on overseas business trips, I regularly make inventive efforts to discharge duties efficiently when I work in the office.

I routinely use the flexi-time scheme in earnest. When I want to leave the office early for family reasons, I come to work earlier than normal to minimize the effect on duties. Using the work-from-home scheme allows me to save commuting time and utilize morning hours in which I can concentrate on work. After working at home, I can spend much time with my family, balancing my work and life better. One step to raise productivity is to work in a well-modulated manner while giving care to the hours in which I experience high concentration. On days when I work in the office, I give priority to tasks intended to be done while communicating with colleagues.

This is my fourth year in Clinical Development. I feel my work is still less than satisfactory in many respects. The question is how much I can grow by accumulating experience within the limited time. I want to streamline operations constructively with a sense of purpose.

Major Topics of FY2017

●Recognized under the White 500 program

We were recognized under the Certified Health and Productivity Management Organization Recognition Program (White 500) run jointly by the Ministry of Economy, Trade and Industry and the Nippon Kenko Kaigi as an initiative to honor large enterprises practicing excellent health and productivity management in collaboration with insurers.

2017
健康経営優良法人
Health and productivity
ホワイト500

●Entered into an agreement on sale of shares in Chiyoda Unyu

Kyowa Kirin Plus, a consolidated subsidiary of Kyowa Hakko Kirin, resolved to sell its subsidiary Chiyoda Unyu to HAMAKYOREX CO., LTD. and entered into a share sale agreement.

●Kyowa Hakko Bio agreed to sell plant growth regulator business to Sumitomo Chemical

Kyowa Hakko Bio agreed with Sumitomo Chemical Company, Limited on the sale of the former's plant growth regulator business, which deploys "Gibberellin Kyowa" and "Fulmet."

●Kyowa Hakko Bio received highest assessment in the ERUBOSHI (ERUBOSHI means "L Star." "L" stands for Lady, Labour and Laudable)

Following in the steps of Kyowa Hakko Kirin, Kyowa Hakko Bio received the highest accreditation 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 in recognition of its initiatives to promote the participation of women in the workplace.

女性が活躍しています！

●Established Kyowa Kirin Frontier

We established Kyowa Kirin Frontier as part of "CSV management based on our unique business structure" that we idealize in our Mid-term Business Plan. The company will work on efforts to acquire the approval for manufacturing and marketing authorization for an "Authorized version" of NESP®, a flagship product of Kyowa Hakko Kirin.

●Joined IkuBoss-alliance

Kyowa Hakko Kirin joined IkuBoss- alliance, a network of companies seeking to foster the ideal boss of the new age, which is an initiative run by the non-profit organization Fathering Japan.

●Entered into an agreement to sell shares in Kyowa Medex

Kyowa Hakko Kirin resolved to sell a portion of shares in its consolidated subsidiary Kyowa Medex, and entered into a share sale agreement with Hitachi Chemical Company, Ltd.

●Certified as Sports Yell Company

Kyowa Hakko Kirin was certified as Sports Yell Company for being a company that pursued efforts to assist and encourage sporting activities of its employees, by Japan Sports Agency.

SPORTS YELL COMPANY

Jan | Feb | Mar | Apr | May | June | July | Aug | Sep | Oct | Nov | Dec

●Application for approval of evocalcet (KHK7580), a new calcium receptor agonist, filed in Japan

Kyowa Hakko Kirin submitted an application for manufacturing and marketing authorization of evocalcet to the Ministry of Health, Labour and Welfare in Japan. Evocalcet is a new calcium receptor agonist, for secondary hyperparathyroidism in patients receiving hemodialysis.

●U.S. FDA granted Breakthrough Therapy Designation for mogamulizumab, an anti-CCR4 humanized antibody.

Mogamulizumab (KW-0761), has received Breakthrough Therapy Designation from the U.S. FDA for the treatment of mycosis fungoides and Sézary syndrome* in adult patients who have a history of systemic therapy.

* Major subtypes of cutaneous T-cell lymphoma (CTCL)

●Release of "Kyowa Hakko Bio iMUSE"

Kyowa Hakko Bio released "Kyowa Hakko Bio iMUSE," a Lactococcus Plasma-contained supplement, as one of the product series of "iMUSE," a new brand developed in collaboration with the Kirin Group.

●Release of Kyowa Hakko Bio's "VELOX Charge"

Kyowa Hakko Bio released "VELOX Charge," a supplement for sports-related activities containing VELOX™ (citrulline and arginine), which is an amino acid formulation patented in Japan and the U.S.

●Burosumab, an anti-FGF23 fully human monoclonal antibody (KRN23)

EMA accepted the application for marketing authorization in January.

U.S. FDA accepted the biologics license application in October.

The European Medicines Agency (EMA) accepted the application for marketing authorization of burosumab for X-linked hypophosphatemia (XLH), in January, and the U.S. Food and Drug Administration (FDA) accepted the biologics license application and granted burosumab Priority Review designation status in October.

●Mogamulizumab, an anti-CCR4 humanized antibody (KW-0761)

EMA accepted the application for marketing authorization in October.

U.S. FDA accepted the biologics license application in November.

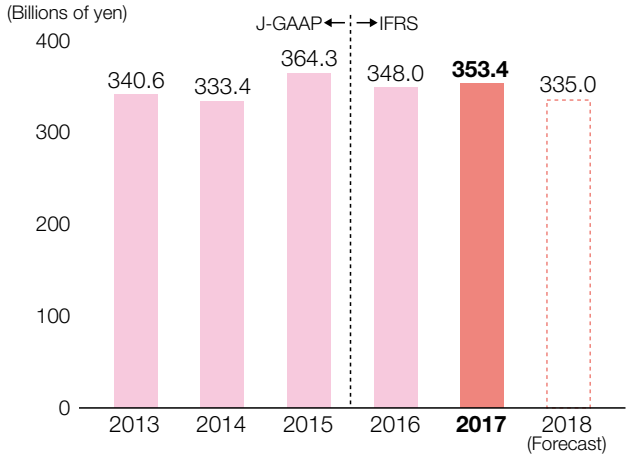
EMA accepted the application for marketing authorization of mogamulizumab in October for CTCL in adult patients who have a history of systemic therapy. The U.S. FDA accepted the biologics license application and granted mogamulizumab Priority Review designation status in November.

Financial & ESG Highlights

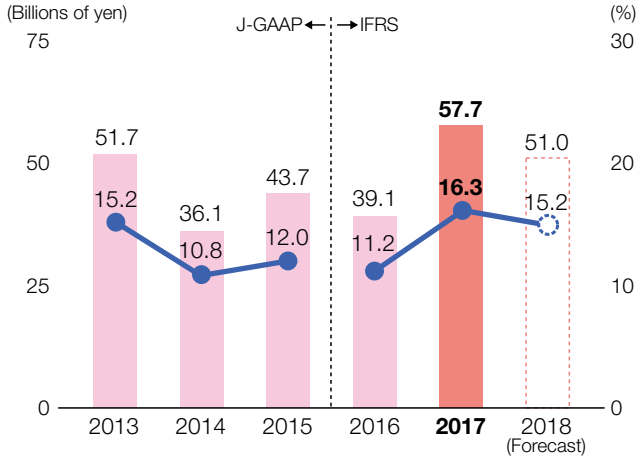
Financial Highlights (For the year ended December 31, 2017)

* The Group has adopted International Accounting Standards (IFRS) since the fiscal year ended December 31, 2017.

Revenue

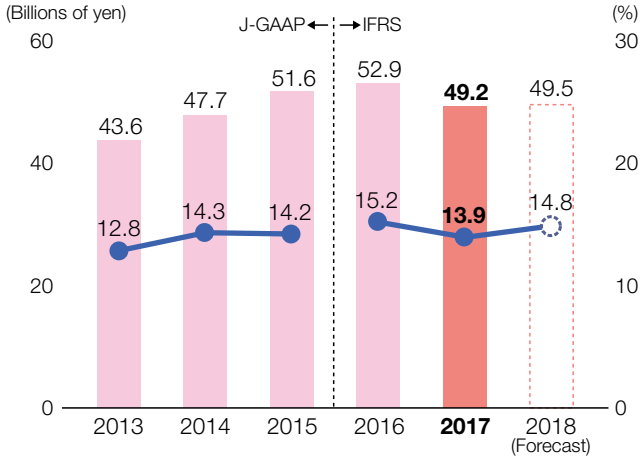


Core Operating Profit/Core Operating Margin

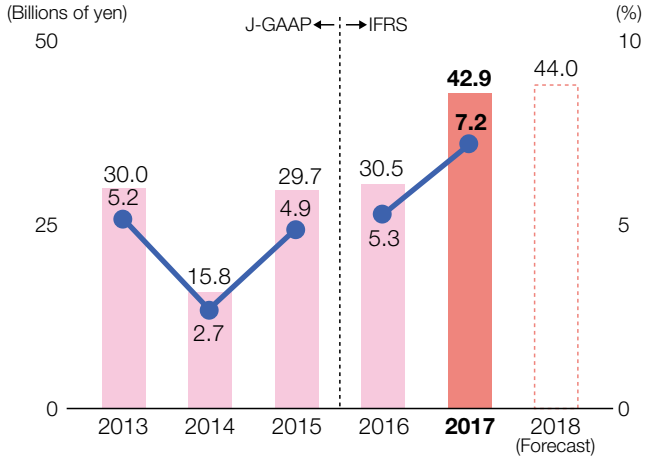


* Figures and ratios for the periods from the fiscal year ended December 31, 2013 to the fiscal year ended December 31, 2016 are operating profit and operating margin under J-GAAP.

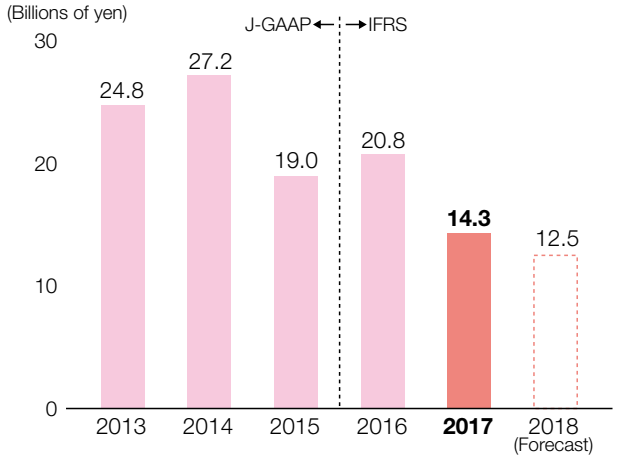
R&D Expenses/Ratio of R&D Expenses to Sales



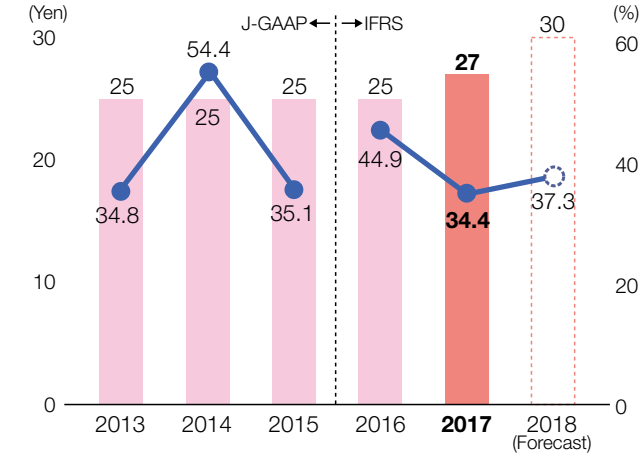
Profit Attributable to Owners of Parent/ROE



Capital Expenditures (Only tangible assets)



Cash Dividends/Payout Ratio



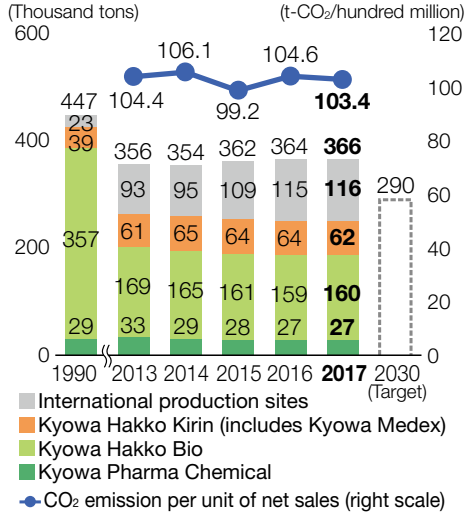
* The consolidated payout ratios for the period from the fiscal year ended December 31, 2013 to the fiscal year ended December 31, 2015 are calculated using net income before the deduction of amortization of the goodwill that resulted from the reverse acquisition in April 2008 (Kirin Pharma share transfer).

Financial & ESG Highlights

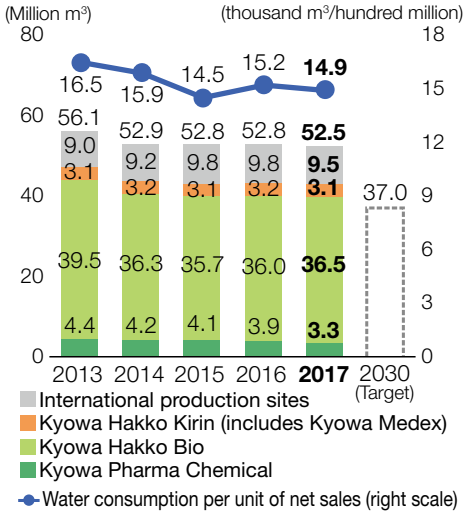
ESG Highlights

1. The domestic plants and research laboratories of Kyowa Hakko Kirin, Kyowa Medex, Kyowa Hakko Bio and Kyowa Pharma Chemical are covered. The overseas plants of Kyowa Hakko Kirin China Pharmaceutical Co., Ltd., BioKyowa Inc. (U.S.A.), Shanghai Kyowa Amino Acid Co., Ltd., and Thai Kyowa Biotechnologies Co., Ltd. are also covered.
2. Data is for the financial years from April to March until 2012, and from January to December from 2013.
3. Net Sales used for calculating per-unit data until 2015 are based on J-GAAP and after 2016 on IFRS.
4. The domestic plants and research laboratories of Kyowa Hakko Kirin, Kyowa Medex, Kyowa Hakko Bio and Kyowa Pharma Chemical are covered.
5. 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 the following year.
6. The number of fatal and lost time accidents per million working hours.
7. Calculated based on the new criteria from 2015.
8. As of June each year. The figures until 2013 are for Kyowa Hakko Kirin (non-consolidated).The figures for 2014 and later are for the Kyowa Hakko Kirin Group (domestic).

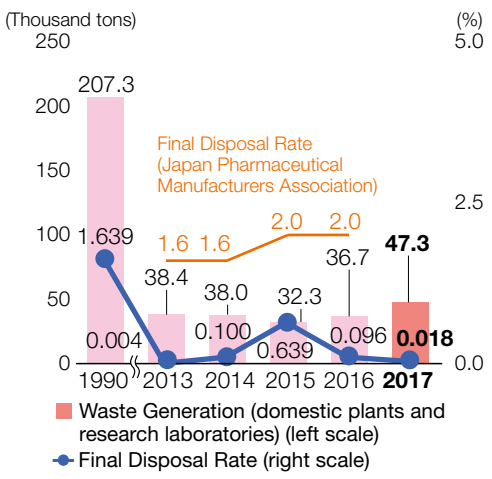
CO_2 Emissions 1,2,3



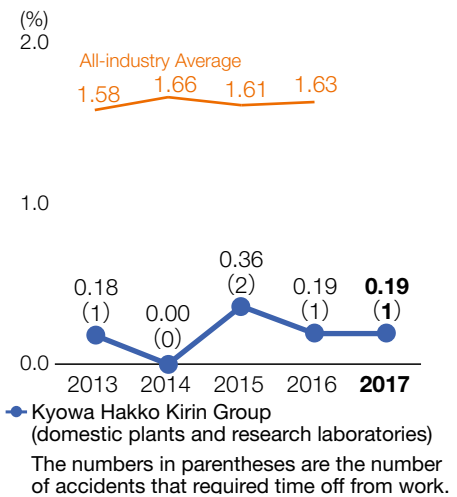
Water Use 1,3



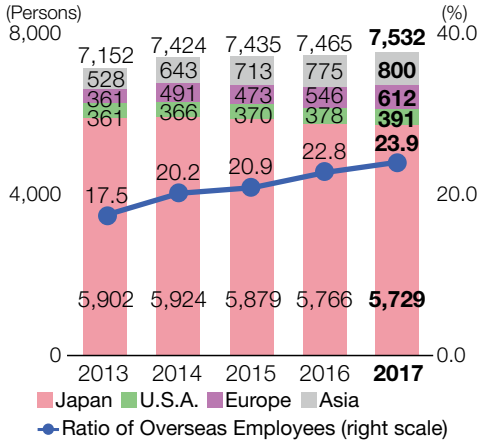
Waste Generation 2,4,5



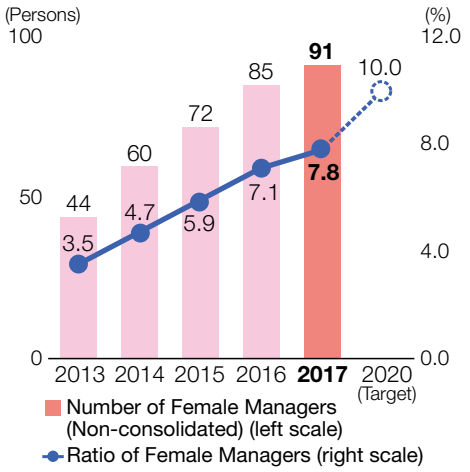
Accident Frequency Rate 4,6



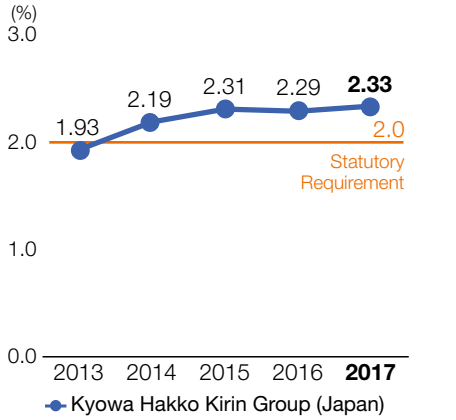
Number of Employees/ Ratio of Overseas Employees



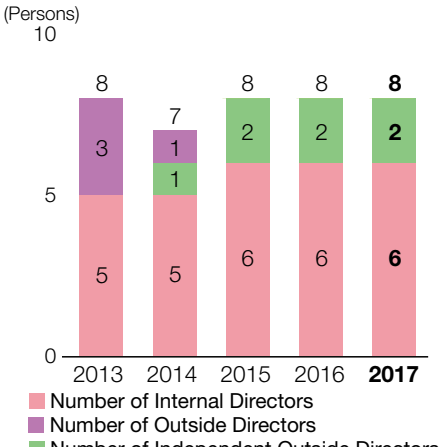
Number of Female Managers/ Ratio of Female Managers 7



Ratio of Workers with Disabilities 8



Number of Directors



Please see ESG Data Collection for details.
WEB

Goals and Results of CSR Materiality

The Kyowa Hakko Kirin Group aims to contribute to the realization of a sustainable society and simultaneously grow the Company by specifying our CSR materiality that must be addressed in a prioritized manner from both social and business perspectives.

We identify and implement our CSR materiality through the following process, and set goals for them before continuing to put in efforts to resolve the issues.

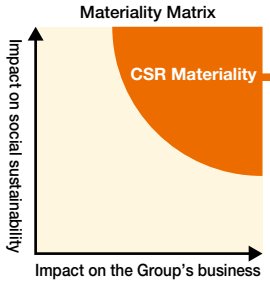
Step1 Listing of issues
List issues to be deliberated as CSR initiatives according to international guidelines, such as ISO26000.

Step2 Assessment of impact on social sustainability and business
Prioritize the listed issues from the perspective of impact on social sustainability and our business, and formulate a materiality matrix.

Step3 Identification of materiality (material issues)
In the materiality matrix, identify issues that need to be addressed with priority under the Mid-term Business Plan as our CSR materiality.

Step4 Confirmation of validity and finalization
Finalize the materiality by obtaining the approval of the Group CSR Committee after hearing from executives and discussions with relevant divisions.

Step5 Implementation and assessment
Incorporate the materiality into the business management plan for the relevant fiscal year. Arrange for the Group CSR Committee to monitor updates on progress and changes in social requirements and review the plan for necessary adjustments.



ISO26000	CSR Materiality	Main Goals of 2017	Main Results of 2017
Organizational Governance	○Foster corporate culture in line with the Core Values ○Promote compliance ○Strengthen risk management system	●Permeate the Kyowa Hakko Kirin Group Core Values and Code of Conduct ●Improve compliance awareness ●Prevent crisis from occurring ●Develop an internal reporting system	●Organized training on the Kyowa Hakko Kirin Group Core Values and Code of Conduct ●Organized training on compliance ●Operated the risk management system ●Built the global internal reporting system Pages 41-43
Human Rights	○Respect human rights	●Improve awareness about human rights	●Participated in the establishment of the Kirin Group Human Rights Policy ●Established the Kyowa Hakko Kirin Group Human Rights Promotion Committee ●Organized training on human rights awareness
Labor Practices	○Promote employees' health ○Promote diversity of employees and their workstyle	●Shorten overtime work hours ●Reduce industrial accidents ●Improve ratio of female managers ●Pursue the employment of workers with disabilities	●Formulated the Talent Management Policy ●Pursued efforts to improve productivity (Smart Work) ●Accident frequency rate: 0.19% ●Ratio of female managers : 7.8% ●Ratio of workers with disabilities: 2.33% (as of June 2017) Pages 15-16
Environment	○Prevent global warming ○Protect water resources	●CO_2 emissions and water consumption volume: Implement measures aimed to achieve the targets of 2030 ●Per-unit energy consumption: Lower by at least 1% annually	●Established the CO_2 emission reduction target for 2030 in line with the SBT initiative* and implemented a relevant initiative ●Established the water consumption reduction target for 2030 and implemented a relevant initiative Pages 25 and 43 ●Per-unit energy consumption: Energy consumption rate 0.19% increase a year
Fair Operating Practices	○Prevent bribery ○Ensure transparency in relationships with medical institutions ○Provide appropriate pharmaceutical information ○Ensure reliability in clinical research	●Implement measures relating to laws and regulation on bribery prevention ●Develop the structure to secure transparency in relationship with medical professionals, medical institutions, and patient organizations in Europe and the U.S. ●Implement measures for providing appropriate pharmaceutical information ●Develop a framework to secure reliability in clinical research	●Continued to provide education on bribery prevention ●Established the Kyowa Hakko Kirin Group Transparency Policy for the Relationships between Corporate Activities, Healthcare Professionals, Healthcare Organizations and Patient Organizations ●Provided code of practice (COP) education ●Performed deliberations toward developing a framework to respond to the Act on Clinical Research Page 42
Consumer Issues	○Ensure stable supply of high-quality and safe products and services ○Provide diverse products and services centered on leading-edge technology	●Develop a global supply chain management system ●Provide innovative new drugs for diseases for which there are currently no satisfactory treatments ●Provide inexpensive and high-quality biopharmaceuticals, thus contributing to suppressing medical expenses	●Completed the reorganization of production facilities and built a global supply structure ●Strengthened the global pharmacovigilance and quality assurance system ●Engaged in activities to foster a quality culture ●Acquired the designation of "innovative new drug" by the U.S. Food and Drug Administration (FDA) for the products developed ●Promote biosimilar business Pages 21-34
Community Involvement and Development	○Contribute to communities	●Contribute to the next generation and grow together with local communities in domains for which biotechnology and health are key words	●Implemented the Bio Adventure activities (science classes for young students) ●Interacting through sports events (such as Kyowa Hakko Kirin Table Tennis Friendly Match)

* Science Based Targets (SBT) initiative: Established by CDP, the United Nations Global Compact, etc. in 2015, the SBT initiative has been encouraging companies to set greenhouse gas emission reduction targets based on scientific grounds (SBTs).

Review of Operations

Achievements and progress in FY2017

Research and Development

Steady progress in R&D for the next leap forward

Under a global R&D system, we made considerable progress toward marketing products under development, including on **applications for approval of KHK7580** in the nephrology category **in Japan**, **KW-0761** in the oncology category **in Europe and the U.S.**, and **KRN23** in the other category **in the U.S.**

In addition to the development of our pipeline in collaboration with our overseas research sites and through **open innovation activities**, we have been making steady progress by engaging ourselves in R&D of leading-edge technology for **four major modalities: antibodies and biologics, new small molecule, nucleic acid, and regenerative medicines.**

Production

Completed the reorganization of production facilities and established the global supply system

The **reorganization of production facilities** that started in 2010 **was completed as per schedule** by the transfer of all products manufactured at Fuji Plant to Ube Plant, Takasaki Plant, CMC R&D Center, and contract manufacturing organizations by FY2017.

Takasaki Plant produced global strategic products and received inspections from European and U.S. regulatory authorities. In collaboration with Kyowa Kirin International, the plant prepared for stable supply by **establishing a global SCM* system** to release products upon approvals in Europe and the U.S.

* Abbreviation of Supply Chain Management, a method of managing operations from production to distribution and sales.

Biosimilars

Application for approval of FKB327 filed in Europe, and phase III trial of FKB238 underway

The application for approval of FKB327, our first biosimilar product, was submitted **to a European regulatory authority** in April, and then accepted in May.

To obtain this approval, we have been responding to inquiries from this regulatory authority. At the same time, a phase III extension clinical trial is ongoing to collect the long-term efficacy and safety information of FKB327. We presented results of this extension trial at the EULAR Congress in June and at the ACR Annual Meeting in November.

As well, **global phase III trials on FKB238**, developed by Centus Biotherapeutics, a joint venture company with AstraZeneca in the U.K., **is ongoing in non-small cell lung cancer patients in 25 countries.**

Domestic Sales

Completed transition to the area-based system of sales offices and teams

Reorganization from the previous specialty-based system, mainly comprising sales offices specialized in hospitals, practitioners, and dialysis facilities, **to the area-based system, which organizes sales offices based on a secondary medical care zone,** was completed. In parallel, we have proceeded to **transform into an area-based strategic organization** through the transition of sales teams to the area-based system. In addition, we have implemented training for approximately 250 area team leaders nationwide to ensure that they can swiftly grasp regional needs and propose prompt solutions. Furthermore, to address issues in regional medical care organizations and satisfy the diversified needs of stakeholders, we **placed regional liaisons,** who support MRs, **across the country.**

Overseas Sales

Increasing capabilities toward the launch of burosumab, and developing business partnerships in Asia

Prior to receiving marketing approval for burosumab in Europe, we **reformed our sales system** by initiating the early access program (EAP), organizing Rare Disease Franchises specialized in rare diseases, and establishing sales subsidiaries in the Eastern European, Middle East, and Near East markets.

We proceeded with business expansion by **out-licensing of CONIEL®** to Zhejiang in China, and **in-licensing of Nephoxil®, a drug for the treatment of hyperphosphatemia**, in Korea.

Pharmacovigilance and Quality Assurance

Strengthen the global PV and QA* system and stay committed to human resource development

Global committees on safety and quality, comprising personnel in charge of PV and QA at the headquarters and overseas subsidiaries, were held and relevant issues were discussed in accordance with global policies on safety and quality. **The global PV and QA system was strengthened** through activities carried out by the global safety teams and global quality teams formed by product and by issue, respectively, as well as through audits carried out on overseas subsidiaries.

We continue **developing professionals** who will be responsible for maintaining and improving our global PV and QA system. To this end, we hold workshops on PV and QA; dispatch and station staff at overseas subsidiaries; and send staff to academic institutions in Japan to study these matters further.

* Pharmacovigilance and Quality Assurance

Vision | Pharmaceuticals Business

Kyowa Hakko Kirin will be a Japan-based Global Specialty Pharmaceutical Company contributing to human health and well-being worldwide through innovative drug discovery and global commercialization, driven by state-of-the art antibody technologies mainly in the core therapeutic areas of oncology, nephrology and immunology.

Pharmaceuticals Business

Steady progress on R&D and system improvement toward becoming a Global Specialty Pharmaceutical Company (GSP)

In Japan, the sales of new products such as G-Lasta®, LUMICEF®, NOURIAST®, and Onglyza® grew favorably even in a competitive business environment due to the penetration of generic drugs and the entry of competitor drug against REGPARA®. In Europe and the U.S., sales of major products such as Abstral®, a drug for the treatment of cancer pain, grew firmly. Moventig™, a drug for the treatment of opioid-induced constipation, has also been steadily progressed. Furthermore, development of benralizumab (KHK4563), an anti-IL-5 receptor humanized antibody, and to which our proprietary POTELLIGENT® technology is being applied, has been progressing smoothly under our licensee, AstraZeneca. In the U.S., approval for benralizumab was obtained in November 2017, and in Japan and Europe, the approval is likely to be obtained soon*1. In addition to favorable results in all regions including Asia, technology licensing revenue from KHK4563 has markedly increased, and thus, the overall pharmaceuticals business has achieved an increase in both sales and profits as compared to FY2016.

Major products [pharmaceutical products]

In terms of R&D activities, we have made great progress toward obtaining regulatory approval of burosumab (KRN23), an anti-FGF 23 fully human antibody, which we are jointly developing with Ultragenyx, in early 2018*2. The Committee for Medicinal Products for Human Use (CHMP) has recommended a conditional approval, and the U.S. FDA has granted burosumab with Priority Review Designation status.

In addition, we have filed an application for the approval of mogamulizumab (KW-0761), an anti-CCR4 humanized monoclonal antibody, in Europe and the U.S. based on satisfactory results from the phase III trial in patients with Cutaneous T-cell lymphoma (CTCL), and have also received Breakthrough Therapy Designation in the U.S. as the second product that follows on burosumab. This demonstrates our outstanding ability in drug development.

In other aspects, our important R&D pipeline across the Group has steadily progressed with applications submitted in Japan for the approval of evocalcet (KHK7580), a calcium-sensing receptor agonist and the second-generation product of REGPARA®, as well as in Europe for the approval of a biosimilar FKB327.

As for the reorganization of manufacturing facilities in Japan that started in 2010, transfer and integration have been completed as scheduled. The reorganization of sales offices in Japan was also completed. We will continue strengthening our area strategies to meet the needs of community health initiatives. Furthermore, new systems are being established for the launch of burosumab and mogamulizumab in Europe and the U.S.

*1 Benralizumab obtained approval in Japan and Europe in January 2018.
*2 Burosumab obtained approval in Europe in February 2018.

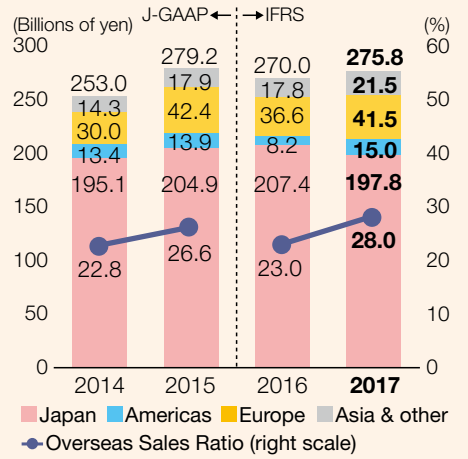
Marketing of two items overseas and improvement of productivity in Japan as our main pillars

2018 will be a year in which we take-off toward becoming a GSP, especially with the launch of burosumab and mogamulizumab. To nurture burosumab hereafter as a main pillar of profit in the Group, we will start marketing operations in Europe and the U.S. swiftly and expand our sales territories.

In Japan, policies that are harsh towards pharmaceutical companies are expected to be introduced owing to the necessity of conntainment of social security and medical costs. In response, we will improve productivity across the Group by strengthening our area strategies, improving the efficiency of our manufacturing activities, and promoting “Smart Work.” In addition, we will carve a more solid path for our medium- and long-term growth by accelerating the development of bardoxolone methyl (RTA 402) for patients with diabetic nephropathy, and discovering the next global strategic product candidates in our four disease categories.

Composition of Sales in 2017

Pharmaceuticals Business Revenue by Region



Research and Development (R&D)

Toward the Leaping Forward Phase, we will strategically proceed with the late phase development including additional indications, as well as R&D of the pipeline in the early phase.

Initiatives in FY2017

Making steady progress in R&D in each category and innovative technology development

As a result of propelling R&D in Japan and internationally, and in cooperation with the WDO*1, we made positive progress of marketing products that were under development in 2017, including applications for the approval of KHK7580 (evocalcet) in the nephrology category in Japan, KW-0761 in the oncology category in Europe and the U.S., and KRN23 (burosumab), in the other category, in the U.S.

In addition, late phase development, including new indications is ongoing for KHK7580 and RTA 402 (baldoxolone mthyl) in the nephrology category, KW-0761 in the oncology category, KHK4827 (brodalumab) and KHK4563 (benralizumab) in the immunology and allergy category respectively, KW-0761 in the central nervous system category, and KRN23 in the other category. Strategic joint development with other companies was also implemented to ensure that these development activities are speedy and global.

Our research programs as well as the pipeline in the exploratory and early development stages that follow the above mentioned products are also proceeding in collaboration with our overseas research sites, and through proactive open innovation activities with the industry, government, and academia.

We concluded a comprehensive research partnership agreement with the National Cancer Center Japan in January 2017. By applying advanced cancer research technologies and a wealth of experience in clinical trials of the Center to our research programs, we expect to continuously discover innovative new drugs.

Furthermore, we have continuously engaged in R&D of leading-edge technology for four major modalities*2, antibodies and biologics, new small molecule, nucleic acid, and regenerative medicines. One of the achievements in 2017 was "Variabody*3," a multi-functional antibody created in collaboration with RIKEN.

In addition to innovative technology development, R&D in each category are progressing steadily in the second year of the Mid-term Business Plan or the year of approach toward Leaping Forward in 2020.

*1 Western Development Organization (functional organization exclusively undertaking all the operations related to new drug development of Kyowa Hakko Kirin in Europe and the U.S.).
*2 Classes of drug discovery technologies (methods and means) that facilitate the realization of the envisioned therapeutic concept.
*3 A multi-functional antibody was successfully created by connecting multiple sites useful for chemical modification on therapeutic antibodies, which were identified using artificial amino acids. This connection technology created antibodies that were collectively named as "Variabody."

Status of Major Development Pipeline

Nephrology

- Application for the approval of KHK7580 (generic name "evocalcet"), a new calcium receptor agonist, with an indication for secondary hyperparathyroidism in patients on maintenance hemodialysis was filed in Japan in April. In addition, a phase III clinical trial was initiated in patients with hypercalcemia, who had parathyroid carcinoma or primary hyperparathyroidism and who were unable to undergo parathyroidectomy or relapse after parathyroidectomy in October.
- A phase II clinical trial of RTA 402 (generic name "bardoxolone methyl") is ongoing in patients with chronic kidney disease with type II diabetes in Japan.
- Preparing for the re-application of the approval of KRN321 (brand name in Japan "NESP®"), a long-acting erythropoiesis stimulating agent with an indication for renal anemia in patients on dialysis in China.

Oncology

- Decided to discontinue the development of ARQ 197, a c-Met inhibitor (generic name "tivantinib") in Japan.
- Application for the approval of KW-0761, an anti-CCR4 humanized antibody (brand name in Japan "POTELIGEO®") with an indication for hematologic cancer accepted in Europe in October and in the U.S. in November.

Immunology / Allergy

- Application for the approval of KHK4563, an anti-IL-5 receptor humanized antibody (generic name "benralizumab") with an indication for bronchial asthma filed by AstraZeneca to whom the development rights were licensed-out in Japan in February. In addition, a phase III clinical trial in patients with bronchial asthma in Japan and Korea, and a phase III clinical trial in patients with chronic obstructive pulmonary disease in Japan is ongoing as part of multi-regional clinical studies conducted by AstraZeneca.
- A phase III clinical trial of KHK4827, a fully human anti-IL-17 receptor antibody (brand name in Japan "LUMICEF®") initiated in patients with axial spondyloarthritis in Japan and Korea in April. In addition, a phase III clinical trial is ongoing in patients with psoriasis in Korea. Furthermore, the indication for home self-injection was approved in Japan in September.
- Additions to the dosage and administration of "Asacol®," a drug for the treatment of ulcerative colitis, jointly developed with ZERIA Pharmaceutical Co. Ltd. was approved in Japan in May.

Central Nervous System

- Preparing for re-application for the approval of KW-6002, an adenosine A_{2A} receptor antagonist (brand name in Japan "NOURIAST®") for the treatment of Parkinson's disease is ongoing in the U.S.
- A phase III clinical trial of KW-0761, an anti-CCR4 humanized antibody (brand name in Japan "POTELIGEO®") initiated in patients with HTLV-1-associated myelopathy in Japan in June.

Others

- Application process for the approval of KRN23, an anti-fibroblast growth factor 23 fully human antibody (nonproprietary name "burosumab") with an indication for pediatric X-linked hypophosphatemia is ongoing in Europe (accepted in December 2016). Application for the approval with the indication for pediatric X-linked hypophosphatemia in the U.S. was filed in August (accepted in October). Furthermore, an international joint phase III clinical trial in adult patients with X-linked hypophosphatemia is ongoing in North America, Europe, Japan, and Korea; and an international joint phase III clinical trial in pediatric patients with X-linked hypophosphatemia is ongoing in North America, Europe, Australia, Japan, and Korea. In addition, a phase II clinical trial in patients with tumor-induced osteomalacia or epidermal nevus syndrome is ongoing in the U.S., Japan, and Korea.
- A phase III clinical trial of AMG531, a thrombopoietin receptor agonist (brand name in Japan "ROMIPLATE®") in patients with chronic idiopathic (immune) thrombocytopenic purpura is ongoing in China. In addition, a phase II/III clinical trial in patients with aplastic anemia is ongoing in Japan and Korea.
- Marketing approval of "ACOALAN® Injection 1800," additional formation of the recombinant antithrombin agent (brand name in Japan "ACOALAN®") acquired in Japan in September.

Research and Development (R&D)

Future Prospects

Further reinforcing the strength of individual organizations toward the establishment of a global drug-discovery system

We further promote self-initiative and mutual collaboration among category-based and function-based organization, which is the characteristic structure in the R&D division. We will also aim for the market launch of three global strategic products, and continue to develop products with high value. By leveraging technology and experiences in focused disease areas through the above process, we continue to expand our valuable pipelines in the midst of new treatment systems five to ten years in the future, thus we will continually strive toward the next innovation. The above is our ideal of "embodying a particular image in becoming a Global Specialty Pharmaceutical Company (GSP)," which was issued in 2016.

We got off to a solid start in 2016 and continued through 2017. Now, we are at the midway point of the Mid-term Business Plan in 2018, the year of the "Leaping Forward Phase."

Our first priority in 2018 is placed on being fully engaged in the release of KRN23 (burosumab) and KW-0761 (mogamulizumab) in Europe and the U.S., and as planned. In Japan, we will make every effort to acquire the approval of KHK7580 (evocalcet), thereby reinforcing the strength of the nephrology category. Furthermore, by making steady progress toward developing a distinctive late phase development pipeline for each disease category, we will form and establish a global drug-discovery system. In addition, to improve the success rate of clinical trials, we will appropriately and actively apply the existing clinical data to the clinical development plan and study design.

We will also continue to flexibly engage in early exploratory research and technology development research in view of our mid- and long-term prospects.

We will make every effort to discover pipelines that meet the needs of personalized care, and excel in drug effect and safety through selection and concentration in each field by meticulous approaches to the category-based strategies as well as translational research. In the four major modalities, we will further accelerate Technology-Driven Drug Discovery*4, and thereby engage in the discovery of a series of products with competitive advantages.

We will actively promote our open innovation drug discovery involving industry, government, and academia to conduct innovative and efficient research and development.

Through the above commitment, we will strengthen our capability of research and development to realize continuous growth.

*4 A basic idea intended to establish unique drug discovery style by maximizing our proprietary capability of research and development, and technical expertise for manufacturing and nurturing through the development of biopharmaceuticals and open innovation.

When an application for a development product is filed, Dr. Mitsuo Sato, 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." As development of late phase pipeline is progressing steadily, "daruma dolls" are increasing in our company. "Daruma dolls" of globally developed products are presented to overseas joint-development companies, giving warm pleasure to people overseas. "Daruma dolls" contribute to the infusing of togetherness with partners. We will clear any hurdle toward leaping forward for GSP with the strong will of "getting repeatedly knocked down but bouncing back up each time" as with "daruma dolls."

Takasaki Daruma Doll: Special product of Takasaki City where our production site is located. Fortuitous cranes and turtles are arranged at the positions of the eyebrows and mustache, making the Takasaki Daruma Doll a representative lucky daruma doll.

Activities as a member of society

Drug discovery activities under high ethical standards

- Cellular, microbial, and chemical substances used in research are handled complying with relevant laws and regulations for example through a reagent management system. We implement appropriate environmentally conscious waste disposal as well.
- With respect to animal studies, we will maintain the level as accredited by a third party, Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) and proper management of animal breeding facilities and study conducted with consideration made for the welfare of animals.
- The rules for handling recombinant and biological materials in accordance with the law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms and related ordinances are in place, and the committee that reviews experiment plans for conformity is established.
- Basic research utilizing human-derived samples, etc. and medical research on humans are conducted in compliance with relevant guidelines, etc. and reviewed from scientific and ethical viewpoints by the research ethical review committee that includes external members.
- Our clinical trials and post-marketing surveillance are conducted in accordance with the spirit of the Helsinki Declaration, with responsibility to respect human rights and protect personal information, and in compliance with the Pharmaceutical and Medical Device Act (former Pharmaceutical Affairs Act), Good Clinical Practice (GCP: standard for conducting clinical trials on drugs), and Good Post-marketing Study Practice (GPSP: standard for conducting post-marketing surveillance and tests on drugs).

Initiatives to improve access to drugs

- In 2016, we joined the Global Health Innovative Technology Fund ("GHIT Fund"), which is a Japan-based public-private partnership organization established to enhance drug discovery that contributes to the control of infections in developing countries. Through this partnership, we support product development to control infections prevalent in developing countries.

Production

We stably supply high-quality and highly effective pharmaceutical products based on advanced technology.

Initiatives in FY2017

Completion of the reorganization of production facilities and establishment of the global supply system

To accommodate the changing business environment in Japan and globalization toward business expansion, we have proceeded with the reorganization of our production facilities, actions to comply with overseas regulations from both hardware and software standpoints, improvement of competitiveness, and establishment of the global product supply system.

The reorganization of the production facilities started in 2010 completed as scheduled by transferring all the products manufactured at Fuji Plant to Ube Plant, Takasaki Plant, CMC R&D Center, and contract manufacturing organizations in FY2017.

Takasaki Plant implemented the production of global strategic products in the manufacturing building for antibody bulk drug substances and injections, and received inspections of European and the U.S. regulatory authorities. We have made solid progress toward leaping as a Global Specialty Pharmaceutical Company (GSP) in 2018. In collaboration with Kyowa Kirin International, the plant prepared for stable supply by establishing the global SCM* system to release products upon approvals from Europe and the U.S. expected in FY2018.

At Ube Plant, the manufacturing building for formulations completed in 2012 entered a stable operation phase, efficiently producing products transferred from Fuji Plant. In addition, the plant is smoothly proceeding with the preparation for production of new products.

* SCM stands for Supply Chain Management and is a method of managing operations from production to distribution and sales.

Future Prospects

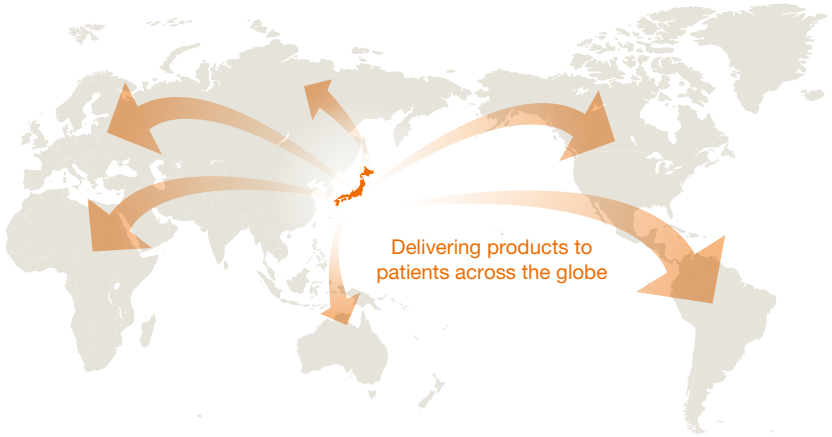
Making further leaps with the world's top-class production technology

Our biopharmaceutical drug production utilizes superior production technology and analysis technology with which we will realize top product quality and productivity in the world. Aiming for further cost reduction, we will continuously pursue the development of new production technology for antibody bulk drug substances.

To meet the needs of patients and medical professionals, we will also pursue the development of new dosage forms by utilizing our proprietary formulation techniques. With respect to the four major modalities, we already have some achievements in the forms of therapeutic antibodies and new small molecule drugs. In addition to these modalities, we aim to further advance the production technology for nucleic acid drugs and regenerative therapeutics in line with the development status.

To make further leaps forward on our path toward becoming a GSP, we will continue to develop essential human resources and create a company with high organizational ability.

Construction of Global Production and Distribution System



Activities as a member of society

Activities for CO_2 emissions reduction and environmental preservation

- Considering the reduction of the impact of our production activities on the environment, we have begun activities to achieve our global group targets for 2030 CO_2 emissions reduction (20% reduction compared to 2015), and for 2030 water use reduction (30% reduction compared to 2015) to preserve water resources. As for the Group's overall performance in 2017, CO_2 emissions were 366 thousand tons (101.1% compared to 2015) and water use was 52.5 million m^3 (99.5% compared to 2015).
- As part of environmental preservation activities, Fuji Plant cleaned the nearby Kise River, and Ube and Takasaki Plants implemented the "Water source forestation project."

Communication with local communities and contribution to fostering the next generation

- We attach importance to communication with local communities, and thus actively participate in events held by the local communities in which our plant is located.
- We hold science experiment sessions for children, contributing to fostering the next generation. Through these activities, we hope that people in the local communities around the plant or laboratory understand our business and strength, and thereby recognize us as a trustworthy and familiar neighbor.

Domestic Sales

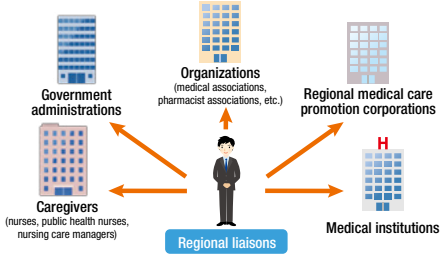
We pursue sustainable growth by building an organizational system that can accommodate environmental changes surrounding medical treatment and being committed to market penetration of new drugs.

Initiatives in FY2017

Transition to the area-based system of sales offices and teams to meet the regional needs

To build an organizational system that can swiftly grasp regional needs and propose prompt solutions, a transition took place from the previous channel-based system mainly organizing three types of sales office based on hospitals, practitioners, and dialysis facilities to the area-based system organizing them based on a secondary medical care zone*1. In parallel, sales teams are also being re-organized into the area-based system. We have also implemented training for approximately 250 area team leaders nationwide (area team leader practicums*2) in addition to specialized seminars by sales channel, and furthermore placed regional liaisons*3 who support the area strategy in each area in Japan.

Activities of regional liaisons



*1 A regional medical care zone consisting of plural municipalities that is determined by considering how many hospital beds are required for each zone. A community health initiative aspires to create independent medical care zones by assigning roles to hospitals and promoting collaboration between hospitals within a secondary medical care zone, and by streamlining the process from hospital admittance, recovery, to discharge.

*2 Training which ensures that plans with clear goals are continuously and swiftly drawn up, implemented, verified, and improved in order to raise the organization's competence (genbaryoku).

*3 Staffs who access diversified stakeholders and provide solutions that MRs propose and implement to meet the regional medical needs.

Future Prospects

Promotion of category-based strategy and further enhancement of new drugs

We will focus more on and enhance our new drugs in the four disease categories of nephrology, oncology, immunology and allergy, and central nervous system which are our strong points.

In the nephrology category, we are going to launch evocalcet (KHK7580), a next-generation calcium receptor agonist, which has much the same therapeutic effect with REGPARA® but has shown a lower incidence of the upper gastrointestinal tract disorder, contributing to improvement of QOL in patients on hemodialysis.

In the oncology category, we are going to launch rituximab biosimilar "KHK" for infusion, a drug product of a chimeric monoclonal antibody against CD20 and our first biosimilar product. We will respond to the diversified needs of patients and medical professionals from a viewpoint of CSV management*4.

In the immunology and allergy category, we are going to launch a new gel formulation of Dovobet®, a topical combination drug for psoriasis vulgaris. The gel formulation facilitates application to hairy parts of the body, such as head, which is one of the parts that is frequently affected by psoriasis. The new formulation is therefore expected to improve handiness for patients. Considering LUMICEF®, a psoriasis treatment drug, a home self-injection became available in September 2017. This can reduce the frequency of clinic visits of patients, contributing to improvement of QOL.

*4 CSV stands for Creating Shared Value, and its idea is that a company should realize the enhancement of corporate value of the company with both the "creation of social value" and "creation of economic value" by tackling social issues.

Drugs for the treatment of complications associated with bone metabolism arising from dialysis therapy, evocalcet (ORKEDIA®), REGPARA®, Rocaltrol®, and PHOSBLOCK®

Drugs for the treatment of psoriasis, LUMICEF®, Dovobet® ointment, and Dovobet® gel

Swift responses to environmental changes in the area with new organizational system

In response to the initiatives toward the national goal of "Building an integrated community care system*5," the sales organization was reorganized into an area-based system based on a secondary medical care zone. Simultaneously, we will respond to the medical needs for prevention against increasing severity*6, which is planned and promoted in each area. For instance, in the area of nephrology, we will contribute to solving issues in each area related to chronic kidney disease through our activities to promote Onglyza®, a treatment drug for diabetes that is highly associated with the progression of chronic kidney disease, as well as NESP® a renal anemia treatment drug.

*5 For the purpose of respecting the dignity of the elderly and supporting their independent life, this system is supposed to provide comprehensive regional support and service so that the elderly can live out the last phase of their life in a region in which they are accustomed to residing and continue a lifestyle that suits them.

*6 Project for comprehensive measures against lifestyle diseases promoted by the Ministry of Health, Labour and Welfare for the purpose of realizing prolonged healthy life expectancy, proper medical expenses, etc.

Activities as a member of society

Environmental and safety considerations for business vehicles

- We started the replacement with hybrid vehicles to reduce the use of gasoline and CO_2 emissions several years ago. Currently, all our vehicles are hybrid.
- Following the introduction of hybrid vehicles, we are now introducing business vehicles equipped with an autonomous emergency braking system to prevent traffic accidents. We aim to have all the vehicles equipped with this system in 2 years. In addition, we started using a drive recorder mainly on new employees' vehicles to ensure smooth traffic safety guidance.

Overseas Sales

To achieve an overseas sales ratio of 50%, we are engaging in expanding our overseas business, increasing a highly productive Medical & Sales capability, and developing human resources.

Initiatives in FY2017

Committed to the preparation for marketing of KRN23 in Europe

In 2017, we set up the self-sales system for burosumab (KRN23), an anti-fibroblast growth factor 23 fully human antibody, our proprietary pipeline product in Europe. To deliver this product to patients as soon as possible, we started the Early Access Program ahead of its approval in Europe. To prepare for non interventional post-approval safety study, disease registration of XLH patients (XLH patient registry programme) was started in the U.K. Furthermore, Kyowa Kirin International plc (KKI), which is in charge of sales in Europe, established Rare Disease Franchises to build the Medical & Sales capability specified in rare diseases. As part of the above project, we initiated enlightening activities for XLH disease by opening the "XLH link," a website in July 2017 for developing disease awareness of XLH and supporting patients.

WEB "XLH Link," is the information website for patients with XLH
www.xlhlink.com

Strengthen the sales operation in European and U.S. markets

In view of marketing of KRN23, we established sales subsidiaries in the Czech Republic and the United Arab Emirates (UAE), and thereby started operations in the Central and Eastern Europe as well as six countries in the Middle and Near East (GCC)*1. We already concluded a contract with Amgen Inc. for sales operations of Neupogen® and Neulasta®, drugs for treatment of neutropenia, starting in January 2019. In the future, KKI will start promotion activities in the GCC market.

In addition, we started the sales of Moventig™, one of the major products in Europe, in France, the Netherlands, and Greece, and have been gaining recognition of this drug among medical professionals for its superior effect through the promotion of its appropriate use.

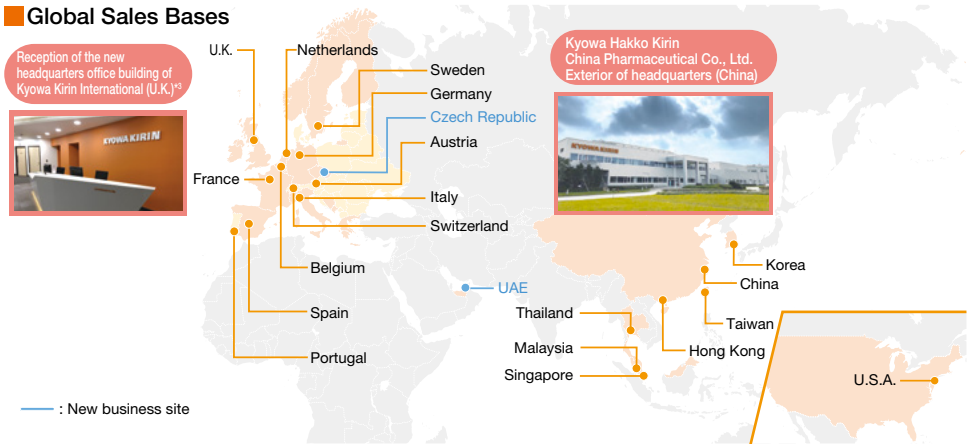
The sales of Abstral®/PecFent® steadily grew despite tough competition with other drugs for the management of episodes of breakthrough pain, by taking advantage of characteristics of the dosage forms that reflect the diversified needs of patients.

In the U.S., we are making steady progress in establishing the Medical & Sales capability toward marketing of mogamulizumab (KW-0761), an anti-CCR4 humanized monoclonal antibody, in 2018. As part of the above, we set up "Patient Hub Services*2," which is designed to connect patients with medical institutions, pharmacies, and insurance companies.

In association with such business expansion, we refurbished KKI headquarters with a new office*3 established in December.

*1 Six countries of Saudi Arabia, Qatar, the United Arab Emirates, Oman, Kuwait, and Bahrain.
*2 Comprehensive services, such as delivery of drugs and inquiries for medical expenses offered to patients in place of medical institutions and insurance companies. The contents differ depending on the product and disease specificity.

Global Sales Bases



Developing business partnerships in Asia

In Asia, we proceeded with business expansion by developing partnerships, while expanding and maintaining sales of the existing products.

In China, REGPARA® was listed in the National Drug Reimbursement List in February. This listing enhanced market penetration, leading to drastic sales growth. In May, we gave the sales right of CONIEL®, a drug for the treatment of hypertension, to Zhejiang Medical Technology Development.

In Korea, we in-licensed Nephoxil®, a drug for the treatment of hyperphosphatemia in patients with end-stage renal disease, from Panion & BF Biotech in February and submitted the application for drug approval to Ministry of Food and Drug Safety in July.

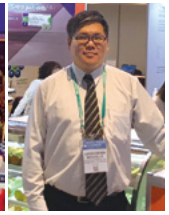
In Malaysia, we established Kyowa Hakko Kirin (Malaysia) Sdn. Bhd. as 100%-owned subsidiary of Kyowa Hakko Kirin (Singapore) Pte. Ltd. in April. Furthermore, NESP® was listed in the Blue Book issued by the Government of Malaysia in August. With this listing, we expect to promote the penetration of the "KYOWA KIRIN" brand in Malaysia as well as strengthen the sales.

Overseas Sales

Promoting personnel exchange with subsidiaries in Asia

To develop human resources necessary for global business expansion, we have actively promoted personnel exchange of Kyowa Hakko Kirin Headquarters with subsidiaries in Asia from 2014. In 2017, one person each from China and Taiwan received training for marketing in the nephrology or oncology categories at the Kyowa Hakko Kirin Headquarters for several months. During the training period, they were provided opportunities to expand their horizons and elevate their standpoint by being engaged in actual operations for planning international seminars and holding Asia marketing meetings.


Zhang Yuecong


Andy Chen

Furthermore, we have been granting "Excellent Performer Award" and "KHK Uniqueness Asia MR Award" as annual awards since 2016. With these awards, we commend personnel at local subsidiaries in Asia for their embodiment of "Integrity, Innovation, Teamwork/Wa," our core values, and superior MRs for their provision of highly valuable service to customers.


Award winners

Future Prospects

Strengthen sales activities centered on burosumab mainly in Europe and the U.S.

We have started to build sales channels in view of the market launch of KRN23, our first in-house brand product for the global market, in Europe and the U.S. in 2018 so that high quality products can be supplied without delay. In addition, we will build sales channels for KW-0761 to prepare for approval in Europe and the U.S.

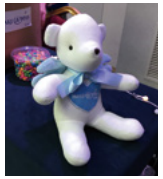
We recognize the withdrawal of the U.K. from the European Union (EU) (Brexit) as an external environment change that might affect our business. To prepare for the environmental changes associated with this Brexit, the U.K.-based KKI headquarters has listed necessary operations and developed their action plans. We continue to keep a close watch on the trend as well as collect information from the local subsidiaries expeditiously, and thereby take appropriate measures against potential risks.

On the other hand, in Asia, we aim for further growth by continuing highly productive sales activities of products in the nephrology and oncology categories based on business policies that are in line with the business environment of each country as well as launching our pipeline products without delay, although the market environment in Asia is highly competitive and tough due to the glut of generic products and continual mark-down of drug reimbursement prices. We will promote personnel exchange with local subsidiaries in Asia with the expectation that the personnel returned from the exchange training will lead the local business operations with their global view and deep knowledge.

Activities as a member of society

Contribute to patient support activities

- In Korea, we have continued the "Make-A-Wish*4 project," which is intended to make pediatric patients suffering from diseases feel happy through various activities and this project has been continued for more than 10 years since 2006. As part of the project, personnel of Kyowa Hakko Kirin Korea (KKKR) and their families participate in an annual charity marathon to support pediatric cancer patients. In addition, all the KKKR personnel participate in the production of "Wish-bear." Approximately 130 teddy bears were delivered to pediatric patients suffering from incurable diseases.


Wish-bear hand-made by personnel

*4 A non-profit volunteer organization established to make the dreams of children with critical illness aged 3 to <18 years come true so that they are encouraged to live and fight against their illnesses. The organization is based in the U.S. and has branch offices in 39 countries.

- In Hong Kong, the Hong Kong Nephrology Group comprising of physicians and medical professionals holds an annual gate ball (Japanese croquet) game for patients with renal failure. Through sponsorship of the game and participation, Kyowa Hakko Kirin (Hong Kong) Co., Ltd. wants to support patients with renal failure and their families who are confronting the treatment.


Participants practicing gate ball

Support of enlightening activities for lymphoma

- In the U.S., Kyowa Kirin, Inc. (KKUS) based in NJ implemented enlightening activities for lymphoma by setting-up "Month for getting to know lymphoma." As part of this, KKUS personnel participated in a charity walk event with the purpose of raising money for The Leukemia & Lymphoma Society. The participation in this event is a good opportunity to deepen disease knowledge and understanding of the patients.

Through these activities, personnel at local subsidiaries recognize our functions as a GSP.

Pharmacovigilance and Quality Assurance (PV & QA)

We will continue to supply products of excellent quality with high-value-added information to customers, thereby contributing to the realization of health and well-being.

Initiatives in FY2017

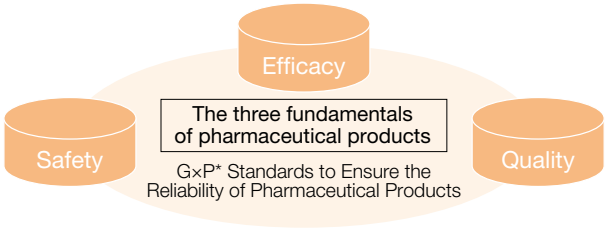
Strengthen the global PV & QA system and develop human resources

To manufacture and sell our in-house brand of new drugs in the three markets of Japan, Europe and the U.S., it is urgently necessary to build a PV & QA system that fulfills Good Practice (G×P) standards in each of these three regions. To this end, we discuss issues with global committees for safety and quality that comprise of managers at the headquarters and overseas subsidiaries in light of the global policies for safety and quality matters. In addition, we strengthened the global PV & QA system through the activities of the global safety teams and the global quality teams formed by product and by issue respectively, as well as through audits on overseas subsidiaries.

Furthermore, we hold annual workshops on PV & QA for personnel in charge at overseas subsidiaries; dispatch and station staff at overseas subsidiaries; send staff to academic institutions in Japan for study; and enable staff participation in various society activities. We have encouraged the improvement of teamwork as critical for global problem solving and continue developing professionals who will be responsible for maintaining and improving our global PV & QA system.

In keeping with our Policy, we will adhere to these four Principles (4Cs)

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



* G×P refers to "Good×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.

Future Prospects

Aiming at greater safety and peace of mind, we will thoroughly provide appropriate information to the front line of healthcare

All pharmaceutical products have both benefits for patient treatment and risks in the form of adverse reactions. The balance of benefits and risks of a drug are changed based on the accumulated data from drug development phase through post-marketing. Among our company's PV & QA activities, ongoing activities to maximize a drug's benefits and minimize its risks is positioned as one of the basics of "drug development."

To afford greater safety and peace of mind to patients using our pharmaceutical products, we will implement timely assessments and reviews of drug benefits and risks, and continue to be thorough in providing appropriate information to the front line of healthcare (pharmacovigilance activities according to the drug risk management plan and implementation of safety assurance measures).

Holding firm to this basic stance in a global environment, we will be committed to ensuring reliability in all the stages from development to post-marketing phase to supply highly reliable drugs continuously and stably to people in the world.

Activities as a member of society

Collection of safety information about our drugs and training

- To ensure that the relevant safety information is collected, we provided training to all the personnel engaged in pharmaceuticals business. In this training, applicable examples were explained more specifically so that they understand what safety information should be collected and how they should report this to the safety management section.

Maintaining high ethical standards as a drug manufacturer

- We educate all the personnel engaged in medical business about drug induced suffering (a history of drug induced health hazard).
- We try to ensure that all the personnel understand the functions and responsibilities of the three major supervisors (marketing supervisor-general, safety management supervisor, and quality assurance supervisor) in drug marketing business, and can thereby work with them smoothly.

Development Pipeline

As of December 31, 2017

Area	Identification*1	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) [preparing for application]		China	
			Renal anemia		Indonesia	
		KRN1493 (cinacalcet hydrochloride)	Secondary hyperparathyroidism		Brunei	
		KHK7580 (evocalcet)	Secondary hyperparathyroidism		Japan	
			Hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism		Japan	
		RTA 402 (bardoxolone methyl)	Chronic kidney disease complicated by type II diabetes		Japan	
Oncology		(granisetron)	Chemotherapy induced nausea and vomiting (patch)		Malaysia	
	●	KW-0761 (mogamulizumab)	Cutaneous T-cell lymphoma		U.S.A./Europe/Japan	
			Adult T-cell leukemia/lymphoma		U.S.A./Europe/others	
			Solid tumor	(In combination with Nivolumab)	U.S.A.	
				(In combination with Durvalumab/Tremelimumab)	U.S.A.	
				(In combination with Docetaxel)	U.S.A.	
				(In combination with PF-05082566)	U.S.A.	
				(In combination with Nivolumab)	Japan	
		KHK2375 (entinostat)	Breast cancer		Japan	
		KHK2455	Solid tumor		U.S.A.	
	●	KHK2823	Cancer		U.K.	
Immunology/ Allergy	●	KHK4563 (benralizumab)	Asthma		Japan	
			Asthma		Korea	
			Chronic obstructive pulmonary disease (COPD)		Japan	
			Eosinophilic chronic rhinosinusitis (ECRS)		Japan	
	●	KHK4827 (brodalumab)	Psoriasis		Taiwan/Thailand/Singapore/ Malaysia	
			Psoriasis		Korea	
			Axial spondyloarthritis		Japan/Korea/Taiwan	
			Autoimmune disease		Japan	

*1 ● : Antibody ○ : Protein No mark : Small molecule

Development Pipeline

As of December 31, 2017

Area	Identification*1	Code Name (Generic Name)	Indication	Country or region of development	Development phases
					Phase I / Phase II / Phase III / Filed
Immunology/ Allergy	●	KHK4083	Ulcerative colitis	U.S.A./Europe/others	
			Ulcerative colitis	Japan	
			Atopic dermatitis	Japan	
	●	ASKP1240 (bleselumab)	Relapsing focal segmental glomerulosclerosis (FSGS) in renal transplant recipients	U.S.A.	
Central Nervous System	●	KW-0761 (mogamulizumab)	HTLV-I-associated myelopathy	Japan	
		KW-6002 (istradefylline)	Parkinson's disease [preparing for application]	U.S.A.	
		KW-6356	Parkinson's disease	Japan	
	●	KHK6640	Alzheimer type dementia	Europe	
			Alzheimer type dementia	Japan	
Other	●	KRN23 (burosumab)	X-linked hypophosphatemia	Europe/U.S.A.	
			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.	
			Tumor-induced osteomalacia/Epidermal nevus syndrome	Japan/Korea	
	○	AMG 531 (romiplostim)	Aplastic anemia	Japan/Korea	
			Idiopathic (immune) thrombocytopenic purpura	China	
	○	KW-3357 (antithrombin gamma)	Disseminated intravascular coagulation, congenital antithrombin deficiency	Europe	

*1 ● : Antibody ○ : Protein No mark : Small molecule

Glossary

Phase I Clinical Trial Studies in small numbers of healthy people*2 to verify safety issues including side effects.
*2 Some studies include patients

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.

Biosimilars

Fujifilm Kyowa Kirin Biologics will create Japan-based high quality biosimilars and contribute to medical cost containment on a global scale.

Initiatives in FY2017

Application for the approval of FKB327 accepted by the European regulatory authority and a phase III clinical trial of FKB238 underway

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

In 2017, the application for the approval of our first developed product, FKB327 (biosimilar of adalimumab, a therapeutic antibody) was submitted to the European regulatory authority in April and accepted in May. To obtain approval, we have been responding to inquiries from the regulatory authority. Simultaneously, a phase III extension clinical trial is ongoing to collect information about long-term efficacy and safety. We presented the results of phase III trial at the EULAR Congress in June and the ACR Annual Meeting in November.

As well, global phase III trials on FKB238 (biosimilar of bevacizumab, therapeutic antibody) developed by Centus Biotherapeutics, a joint venture company with AstraZeneca in the U.K., is ongoing in patients with non-small cell lung cancer in 25 countries.

Together with clinical trials, the latest technology was used to perform various quality tests on several manufactured lots of our company's developed product and the original reference product. These test results confirmed a high degree of equivalency and homogeneity of FKB327 and FKB238 with respect to the original reference products.

We have built a structure for the global development of biosimilars by pursuing development in collaboration with several partner companies in Japan and overseas. By engaging in numerous interviews and discussions with the FDA, EMA, and Japan's Pharmaceuticals and Medical Devices Agency (PMDA), we received advice. Through the above, we have deepened our understanding of the thinking of these authorities regarding biosimilars and have made progress toward obtaining regulatory approval.

Future Prospects

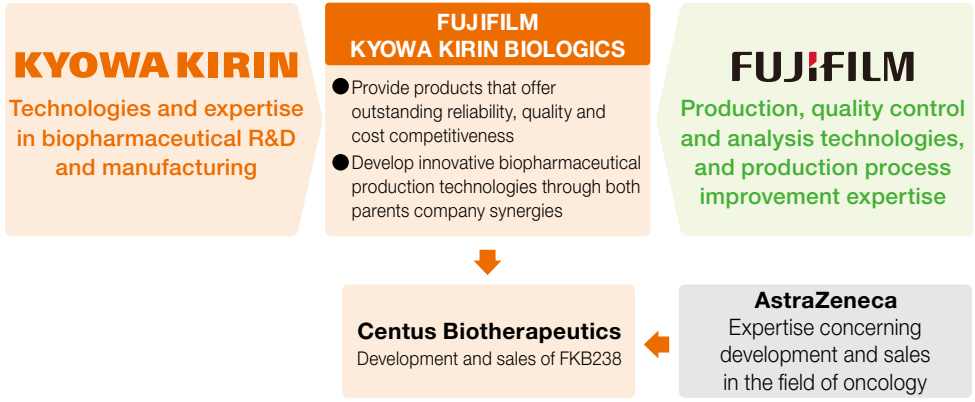
Initiatives toward the approval and marketing of FKB327, and preparation for the application of FKB238

In 2018, we plan to file an application for the approval of FKB327 in regions other than Europe. At the same time, we will develop a global sales structure focusing on each region, and build a condition to sustain the company growth. In addition, as the last patient registration in phase III clinical trial of FKB238 is planned, we will start preparation for the application to the regulatory anthorities.

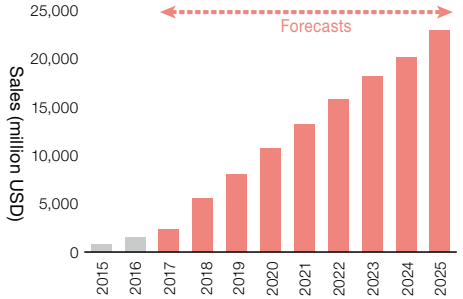
The important keys for sustainability and growth of the biosimilar business will be efficient development and reduction of manufacturing costs. For efficient development, we will prepare and implement development plans utilizing the know-how we have accumulated until now, and will challenge ourselves to introduce new ideas by engaging in many discussions with the regulatory authorities of each market. To reduce manufacturing costs, we will conduct investigations and introduce new technology and measures in collaboration with the R&D divisions of both parent companies.

We will aspire to be a company that is needed by the society by continuing to deliver high quality, low cost biosimilars to the front lines of healthcare on a global scale.

Biosimilar development structure



Biosimilars global market forecasts



Source: Data from Decision Resources, LLC

Vision | Bio-Chemicals Business

Kyowa Hakko Bio will be a biochemical innovator which provide people in the world with products and services to fulfill their healthcare needs, using deep and wide knowledge of fermentation and synthesis.

Bio-chemicals Business

Steady rise in the sales of high added value products and growth of the mail-order business

Kyowa Hakko Bio has been providing the pharmaceuticals, medical and healthcare fields with products and services to fulfill healthcare needs of people in the world.

In the pharmaceutical and medical treatment fields, the sales of high added value products such as Citicolline rose steadily, although in some cases including amino acids for infusions we could not supply for the high demand owing to the tight production capability.

In the healthcare field, the sales of the Japanese business, including those through the mail-order operation, increased. The growth in the mail-order sales of Ornithine, our mainstay product, slowed owing to a steep rise in advertisement expenses and an environment of intensified competition, but the growth of the other mainstay profitable products, such as Arginine EX, continues.

Kyowa Hakko Bio is pursuing the development of production facilities in Japan and overseas to build our constitution so that we are not easily affected by exchange rate fluctuations. Amino acids for infusion and medical purposes will largely be transferred to the Thai and Shanghai plants, and high added value products, such as nucleic acid and peptides, will continue to be manufactured at the Yamaguchi Production Center. In 2017, such reorganization and streamlining of production facilities progressed steadily.

Furthermore, we transferred the plant growth regulator business, one of our non-core businesses, to Sumitomo Chemical Co., Ltd. Through such actions, we made progress toward a concentration on our core competencies. To solve these management issues in the rapidly changing and increasingly competitive business environment, we introduced the executive officer system in 2017. With placement of executive officers dedicated to business execution, the functions of management supervision and business execution are now separate. In this way, we will continue the pursuit of making speedier and appropriate decisions and actions related to business execution.

Kyowa Hakko Bio health foods

Major products

Initiatives to create new products and businesses while improving profitability of the existing products

In 2018, we will pursue the strengthening of the production and supply systems, increasing the added value of existing products, and creating new products and businesses.

For the production and supply system, we will not only strengthen the quality control and quality assurance system, but also take profitability boosting actions, such as concentration of resources on highly profitable products, in parallel with the consolidation of unprofitable products and streamlining of the marketing inventory control operations.
To increase the added value of existing products, we will proceed with an embodiment of the healthcare marketing strategy.

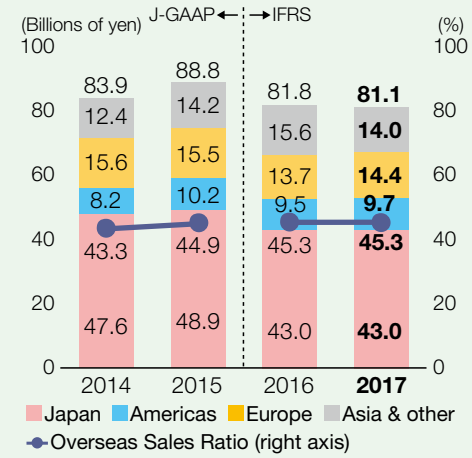
To create new products and businesses in the future, we will proceed with development of cell culture medium for regenerative medical practices by leveraging our proprietary, high-quality amino acids and the know-how about fermentation technology.

We will also develop new products combining the fermentation technology of Kyowa Hakko Bio and the synthesis technology of Kyowa Pharma Chemical, a subsidiary company.

Through these activities, we will expand the product portfolio in Japan and overseas. By creating new values, we will strive to contribute to the health and well-being of people around the world.

Composition of Sales in 2017

Bio-chemicals Business Revenue by Region



Marketing

In 2017, we established the Marketing Division to pursue not only the improvement of product values and branding, but also the development and commercialization of products that satisfy customers' needs.

Initiatives in FY2017

Strategic improvement of added value material through strengthening of the marketing function

In January 2017, the Marketing Division was inaugurated. Marketing Division has engaged in the embodiment of the global marketing strategy of the entire healthcare business, including BtoB and BtoC, and a cooperative arrangement among business sites based on the consistent sales policy. In addition, we will pursue increasing material value added through an active intellectual property strategy based on a marketing standpoint.

"Velox Charge," a product for athletes launched in September, is one of achievements of our marketing activities. Velox™ is the brand name of a product series based on an amino acid formulation patented by Kyowa Hakko Bio. The product was developed in cooperation with athletes by examining details in terms of not only the amount and timing of intake, but also taste and swallowability. Furthermore, we are proceeding with an expansion of new Velox™-containing products in collaboration with the other companies.

A sales promotion tool for "Velox Charge"

In addition, to increase the brand value of the mail-order business, we improved our presence in guide magazines and on shopping websites. Furthermore, we issued "AminoScope", a newsletter for overseas markets, to increase the recognition of the value of in-house products, such as amino acids.

AminoScope

Future Prospects

Creation of new values through collaboration with Kirin group companies and academia

We are proceeding with our collaboration with Kirin group companies and academia. We are conducting trials to develop products that satisfy a wide range of customers' needs, taking advantage of the individual strengths of group companies. In 2017, as a part of the above activities, Kyowa Hakko Bio released "Kyowa Hakko Bio iMUSE," a new product containing lactococcus plasma which is developed by Kirin. In addition, we are conducting research on health-enhancing substances in collaboration with universities around the world and introducing the value of them at academic meetings and exhibitions.

"Kyowa Hakko Bio iMUSE" and the other iMUSE products by Kirin group companies


Our exhibition booth

By boldly taking on new fields of health, we aspire to become a biochemical innovator needed by society.

Kyowa Quality
Setria Glutathione
SUSTAMINE
Cognizin
Pantesin

Branded materials deployed worldwide

Activities as a member of society

Support of mega-solar power business

- Aiming at an effective use of our in-house assets and promotion of the popularization of renewable energy, Kyowa Hakko Bio allowed DENKEN Co., Ltd., a solar-power business firm, to use a part of premise of Yamaguchi Production Center (Hofu). In this way, we aspire to improve environment in regions where our plants operate.

"ERUBOSHI" accreditation

- In 2017, we received the highest accreditation possible in the "ERUBOSHI," which assesses initiatives to promote the participation of women in the workplace. This accreditation is granted by the Minister of Health, Labour and Welfare based on assessment results based on data on recruitment, continued employment, working style, ratio of female managers, and improvement of career path.

We will promote the two wheels of governance, i.e., “offense” and “defense”

Kyowa Hakko Kirin has stepped up governance with an eye toward leaping forward for a Global Specialty Pharmaceutical Company (GSP). Mr. Jun Arai, who was appointed as an outside company auditor a year ago and is one of those who play the role of an engine for the initiative, had been engaged in financial affairs and corporate governance at Showa Shell Sekiyu K. K. for many years. In the light of his experience, we asked his impressions and expectations of our company in an interview.

Jun Arai, Outside Company Auditor
Joined Shell Sekiyu K.K. (presently Showa Shell Sekiyu K. K.) in 1983. After assuming the posts of director for accounting, managing director, and representative director and president, held the posts of group COO and representative director and president of Showa Yokkaichi Sekiyu Co., Ltd. Became outside director of Daiwa SB Investments Ltd. in 2016 and was appointed as outside company auditor of Kyowa Hakko Kirin Co., Ltd. in March 2017.

Impressions of Our Company after One Year in Office

I look forward to the future of the company that will leap forward with a social mission

Needs for healthcare and better health are growing not only in Japan but in other parts of the world as well. Whatever the company, unless it meets society’s needs for goods and services, it will lose its raison d’etre. Our initiative for leaping forward for GSP precisely represents our mission and strategy to grasp and meet the needs by making the best use of our management resources. That I look forward to our future very much is my impressions of the company after one year has passed since I assumed the office.

I engaged in a different field from pharmaceuticals or health products, that is, energy-related business, for more than 30 years. What is common to both industries is that we deal with things that are essential for people to live. Ensuring quality and stable supply is also a social mission that the two sectors have to fulfill. Taking up a challenge of conducting R&D over a long period of time boldly, facing a risk of success or failure is also common to the two.

In either industry, when you develop or challenge to do something new, issues will certainly manifest themselves that have yet to be identified. I believe that it is critically important to find them out and address them quickly. This is the point that I always try to check at the board of directors meeting of this company and my previous companies.

Evaluation of the Governance System and Your Own Role

Credit should be given to highly transparent and active discussions

What is important in corporate governance is that individual units incorporated in the system display their function to the full while maintaining a healthy relationship of tension. None other than prompt provision of accurate information, releasing of unreserved opinions and discussions based on them help keep the management system healthy.

At our Board of Directors meeting, board directors and company auditors, regardless of whether they are inside or outside the company, actively exchange views and opinions. Well-balanced and highly transparent discussions are conducted not only for new challenges with a view to leaping forward but for the existing business as well. Many make remarks that go beyond each individual’s scope of responsibility but it is also worthy of praise.

In terms of evaluation of the effectiveness of the Board of Directors initiated in 2016, evaluation or views and opinions not only of board directors but also of company auditors and executive officers are incorporated. This helps the Plan-Do-Check-Act (PDCA) cycle go smoothly and we can expect to increase effectiveness further.

Generally, when it comes to corporate governance, it tends to be regarded as “defensive” governance, in which you mainly look at whether health of management is maintained. However,

"offensive governance" is also very important in order for a company to implement strategy and grow sustainably, thereby enhancing corporate value. These are called the two wheels of governance. It is not adequate for outside company auditors to look at legal compliance in management of business and execution of operation alone. I believe that my role is to present opinions and extend support as much as I can with the aim of helping decision-making needed for sustainable growth while keeping the management system healthy. To do this, I strive to gather information on my own to fully identify thoughts of the management and employees. At the same time, I try my best to stay objective so that I can evaluate management from an independent point of view.

How about the Support System for Auditing?

Information gathering and reporting is satisfactory as issues at job sites are put on the agenda

As outside company auditors are not always in office, they need to review information in a short period of time. At this company, materials are provided in advance and explanatory meetings are held before an important meeting, which is very helpful. Materials submitted to the Board of Directors meeting contain precise information comprehensively. In expanding the scope of our business globally down the road, points to be supervised will keep increasing. In a bid to enhance the system for information gathering and reporting further, the Board of Directors has been moving ahead with measures step by step.

Meanwhile, I try to go and visit job sites actively. The company has a flexible system for visiting audit so I make the best use of the opportunities and visit different sites. In FY2017 I visited the Fuji Plant and the Ube Plant twice each and the Takasaki Plant once. By visiting job sites, as I can see employees who engage in operations seriously with my own eyes and identify issues there firsthand, it has proven very helpful to me.

What Do You Think of Our ESG?

It is important to take ESG into consideration in resolving social issues

In 2006 the United Nations advocated the Principles for Responsible Investment (PRI) and the concept of environmental, social and governance (ESG) factors came into the investment arena. Due in part to the fact that Government Pension Investment Fund, Japan (GPIF) signed the PRI in 2015, interest in ESG investment has grown further in recent years. I feel that as a requirement for a company that grows in the long term, greater importance is attached to whether it meets social demands or not than before.

We set forth "contributing to the health and well-being of people around the world" as its management philosophy. Health, and healthcare and pharmaceuticals that contribute to it are what people desire universally around the globe. I believe that we can contribute to society by living up to their expectations and supplying products that please them.

In our initiatives for resolving social issues, it is important to set the goals in consideration of ESG and make them a common perception that all the employees share. In addition, it is also important to engage with stakeholders proactively and accept various voices, including criticism. Through these activities, the quality of management will be enhanced and our corporate value will increase further. In synchronization with the process of growth, I look forward to seeing the Company's recognition will go on increasing from the ESG viewpoint.

Furthermore, in terms of the Corporate Governance Code and the Fair Disclosure Rule, my understanding is that companies should meet investors' requests proactively. Based on reports of research into the current situation, the Board of Directors will address these matters.

Challenges That the Company Should Address and Expectations on Us with a View to Increasing Corporate Value

The groundwork for leaping forward for global operations has been laid

Management resources are said to be people, goods and capital. And how to inject these into the global market determines success or failure of business. Without seeking quick results blindly, we need to settle down and face each individual challenge. All the members of the Board of Directors understand the importance of using and fostering human resources, not to mention R&D on new drugs, and are ready to make a move on this.

We should be careful about potential risks when global operations are gaining momentum and operations are expanding. In order to identify these risks quickly, are we keeping a watchful eye widely and is the system to discuss them and overcome them catching up? The Kyowa Hakko Kirin Group is a business that addresses this.

With an eye toward leaping forward for GSP, which is about to take off, I will try my best as an outside company auditor. Please keep an eye on our future.

Board of Directors
(As of March 23, 2018)

①Director of the Board
Managing Executive Officer

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, Vice President Head, Production Division, Kyowa Hakko Kirin Co., Ltd.
Mar.2017: Managing Executive Officer, Vice President 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.

②Representative Director of the Board
President and Chief Operational Officer

Masashi Miyamoto, Ph.D.

Apr. 1985: Joined Kirin Brewery Company, Limited
Apr. 2011: Director, Regulatory Affairs Department of Pharmacovigilance and Quality Assurance Division, Kyowa Hakko Kirin Co., Ltd.
Mar.2012: Executive Officer, Director, Regulatory Affairs Department of Pharmacovigilance and Quality Assurance Division, Kyowa Hakko Kirin Co., Ltd.
Jul. 2014: Executive Officer, Director, Strategic Product Portfolio Department and Regulatory Affairs Department of 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: Representative Director of the Board, Executive Managing Officer, Dorector, Corporate Strategy & Planning Department, Kyowa Hakko Kirin Co., Ltd.
Mar.2018: Representative Director of the Board, President and Chief Operational Officer, Kyowa Hakko Kirin Co., Ltd.

③Director of the Board
Senior Managing Executive Officer

Toshifumi Mikayama, Ph.D.

Apr. 1983: Joined Kirin Brewery Company, Limited
Mar.2004: General Manager, Planning Division of Pharmaceutical Division, Kirin Brewery Company, Limited
Jul. 2007: Director, 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, Kyowa Hakko Kirin Co., Ltd.
Mar.2018: Director of the Board, Senior Managing Executive Officer, Director, Overseas Business Department, Kyowa Hakko Kirin Co., Ltd.

④Representative Director of the Board
Chairman and Chief Executive Officer

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.
Oct. 2008: Executive Officer, 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, Kyowa Hakko Kirin Co., Ltd.
Mar.2010: Director of the Board, Senior Managing Executive Officer, Kyowa Hakko Kirin Co., Ltd.
Mar.2012: Executive Director of the Board, President and Chief Executive Officer, Kyowa Hakko Kirin Co., Ltd.
Mar.2018: Representative Director of the Board, Chairman and Chief Executive Officer, Kyowa Hakko Kirin Co., Ltd.

⑤Director 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, Cast Law Firm (presently Uryu & Itoga Law Firm) (to present)
Aug. 2008: CEO, SUI Advisory Service Co., Ltd. (presently U&I Advisory Service Co., Ltd.) (to present)
Jun. 2014: Outside Director, FRUTA FRUTA, Inc.
Sep. 2014: External Director, GMO TECH, Inc. (to present)
Mar. 2015: Outside Audit & Supervisory Board Member, Kyowa Hakko Kirin Co., Ltd.
Jun. 2015: Outside Audit & Supervisory Board Member, ITOCHU Corporation (to present)
Mar. 2018: Director of the Board, Kyowa Hakko Kirin Co., Ltd.

⑥Director of the Board
(Outside Director)

Yoshiko Leibowitz

Apr. 1968: RN, St. Luke's International Hospital, Tokyo
Sep. 1977: Instructor, Intercollegiate College of Nursing, Washington State University
May 1981: Nursing Supervisor, Thomas Jefferson University Hospital Ford Road Campus (FRC)
Jul. 1984: Assistant Director, Nursing Service Department, Thomas Jefferson University Hospital, FRC
Apr. 1995: Founder and Director, Continuous Home Care Inc. (Philadelphia, Pennsylvania)
Apr. 1998: Adult Nursing Chief Professor, Oita Medical University
Apr. 2002: Professor, Department of Nursing, Aomori University of Health and Welfare (AUHW)
Apr. 2003: Professor & Chair, Intercultural Communication, AUHW
Apr. 2007: President, AUHW
Apr. 2008: Chair of the Board of Trustees and President, Public University Corporation, AUHW
Jun. 2014: Professor Emeritus, AUHW (to present)
Mar. 2015: Director of the Board, Kyowa Hakko Kirin Co., Ltd. (to present)

⑦Director 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 of Production Division, Kirin Brewery Company, Limited
Mar. 2015: Director, Group Personnel & General Affairs, Kirin Holdings Company, Limited and Executive Officer, General Manager. Personnel & General Affairs Department, Kirin Company, Limited
Mar. 2017: Senior Executive Officer, Director, Corporate Strategy, Kirin Holdings Company, Limited (to present)
Director of the Board, Senior Executive Officer, Kirin Company, Limited (to present)
Director of the Board, Kyowa Hakko Kirin Co., Ltd. (to present)

Corporate Governance

In order to continue to enhance our corporate value and achieve our aim of becoming a Global Specialty Pharmaceutical Company (GSP), the Kyowa Hakko Kirin Group recognizes the importance for improving transparency in management and strengthening management oversight, and making all efforts to enrich our corporate governance.

Corporate Governance System

Kyowa Hakko Kirin has opted to have a board of company auditors, which supervises the execution of business by the Board of Directors, which is the final decision-making body of the Company, thereby enhancing the transparency and objectivity of the management of the Company.

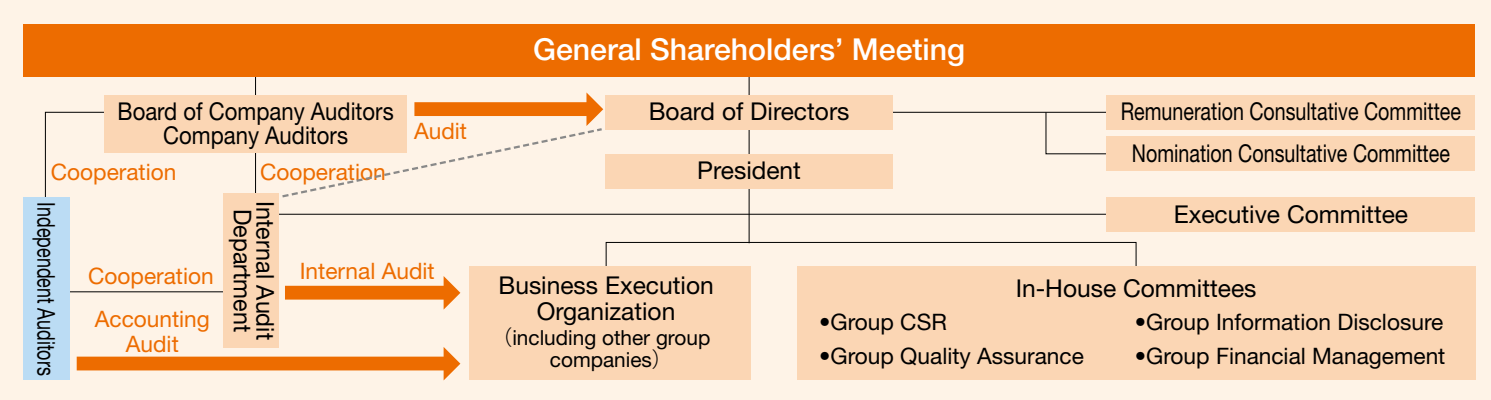
In addition, we have further enhanced the transparency of our management by voluntarily installing a "Nomination Consultative Committee" and "Remuneration Consultative Committee." We have also adopted a hybrid governance system that allows for a balance between executive and supervisory functions to be maintained.

Board of Directors

The Board of Directors of Kyowa Hakko Kirin oversees important business decisions and the execution of business, and the system is a highly transparent one that strikes a balance between the knowledge, experience, ability, and insight of the directors.

In addition, by leveraging on the objective and professional viewpoints of outside board directors, the Board aims to engage in appropriate decision-making and fulfill its management supervisory function.

Corporate Governance Structure



Corporate Governance Summary

Organizational Structure	Company with a board of company auditors
Chairman of the Board of Directors	Nobuo Hanai
Number of Board Directors*	8 (including 2 outside board directors)
Number of Company Auditors*	5 (including 3 outside company auditors)
Number of Independent Board Directors and Company Auditors*	2 outside board directors, 2 outside company auditors
Board of Directors Meetings in 2017	Number of meetings: 16 Director attendance: 100% Company auditor attendance: 98%

Board of Company Auditors Meetings in 2017	Number of meetings: 14 Company auditor attendance: 99%
Director Remuneration	Total remuneration for 2017, consisting of base compensation, performance-linked annual bonus, and stock options as medium- and long-term incentives (6 board directors excluding outside board directors): ¥391 million (base compensation: ¥240 million, annual bonus: ¥71 million, stock options: ¥80 million)
Company Auditor Remuneration	Total remuneration for 2017 (1 company auditor excluding outside company auditors): ¥26 million (base compensation: ¥26 million)
Accounting Auditor	Ernst & Young ShinNihon LLC

*As of December 31, 2017

Executive Remuneration

Remuneration for the board directors, executive officers, and company auditors has been deemed necessary to raise their awareness of the need to contribute to sustainable growth and the enhancement of corporate value, to secure talented employees who aspire to contribute to the leap forward to become a GSP, and to act as a base to motivate each of them to contribute to the company through the regular performance of their duties.

Remuneration for executive board directors and executive officers consists of base compensation, performance-linked annual bonus, and stock options as medium- and long-term incentives. As for non-executive board directors (outside board directors) and company auditors, remuneration is fixed in order to ensure that they can carry out their function to supervise the business in an optimal manner.

Remuneration for the board directors, executive officers, and company auditors will continue to be deliberated on by the Remuneration Consultative Committee in the future, in order to ensure that the compensation serves as an appropriate incentive that leads to the sound and sustained growth of the Group and the enhancement of its corporate value.

Board of Auditors

The company auditors and the Board of Company Auditors, as an independent entity with the mandate from shareholders, conduct audits on the execution of the duties by the board directors, so as to monitor and verify the soundness of management to ensure that it leads to the Group's sustainable growth and improved corporate value over the medium- and long-term.

The company auditors, by capitalizing on the full-time company auditors' abilities to gather information within the Group and their independence, actively deliver their opinions to the Board of Directors as well as strive to develop the system that ensures the effectiveness of audits by each company auditor.

Concerning the Response to the Corporate Governance Code

We have developed the Kyowa Hakko Kirin Corporate Governance Policy, and are undertaking the initiatives on the right with respect to the Corporate Governance Code.

Functions of Outside Board Directors and Outside Company Auditors

In order to increase the fairness and transparency of corporate governance, as well as achieve sustainable growth and raise the medium- and long-term corporate value of the Group, we appoint two or more independent outside board directors who meet the separately established "Criteria for Independence of Outside Directors." Independent outside board directors not only actively provide advice on management issues, oversee executive actions and monitor for actions that may present conflicts of interests; they also play a role in appropriately reflecting the position of stakeholders, including minority shareholders, in the Board of Directors.

In addition, in order to ensure objectivity and neutrality of audits as well as the soundness of management, we appoint multiple independent Outside company auditors. In order to strengthen the abilities

Basic Principles	Specific Examples and Initiatives
1. Ensuring the Rights and Equality of Shareholders	• Kyowa Hakko Kirin recognizes thoroughly of the importance of shareholders' rights; The company has taken substantial steps to ensure that shareholders, including minority shareholders, have the right to vote in the General Shareholders' Meeting and has also established an environment in which the shareholders can properly exercise their rights. We respect the will of minority shareholders in cases where they wish to exercise their special rights concerning the Company and its officers. • When a proposal to the General Shareholders' Meeting is made to delegate a new part of the resolutions from the General Shareholders' Meeting to the Board of Directors, the corporate governance structure of the company ensures that the Board of Directors can perform their roles and responsibilities appropriately.
2. Appropriate Cooperation with Stakeholders Other than Shareholders	• Kyowa Hakko Kirin has established a basic policy on cooperation with the stakeholders of the Group, and as a good member of society, aims to maintain lawful and healthy relationships with customers, shareholders, investors, employees, business partners, the community, the government, and all other stakeholders related to our businesses, in addition to respecting the regional economies, societies, cultural conventions, etc. of each country in which we do business, respecting the human rights of each of our workers, and creating a comfortable working environment. • Based on the above basic policy, we aim to co-create a unique brand value with customers, preserve the global environment, enjoy mutual prosperity while coexisting with our business partners, and develop communities through the business. Moreover, we view the employees of the Group as the source through which we ensure sustained growth and improvement of the medium-and long-term corporate value of the Company. Thus, we foster a corporate culture that strives toward innovation while ensuring the health and progression of all employees.
3. Ensuring Appropriate Information Disclosure and Transparency	• The company recognizes that the substantiality of information disclosure is a prerequisite for our constructive dialogue with shareholders*, and therefore discloses information in line with the "Disclosure Policy" which is separately established.
4. Responsibilities of the Board of Directors	• Based on the fiduciary responsibility and accountability to shareholders, the Board of Directors aims to fulfil the management philosophy of the Group through the establishment of effective and efficient corporate governance while aiming for sustainable growth and enhanced medium-and long-term corporate value of the Group. • The Board of Directors makes decisions regarding the important business operations and legal issues related to the long-term management vision, Mid-term Business Plan, annual management plan, etc. of the entire Group as well as major companies of the Group. It is also responsible for overseeing the execution of duties by board directors and establishing an appropriate internal control system for the entire Group. • The matters to be resolved by the Board of Directors are stipulated in the relevant laws and regulations, articles of incorporation, and "Regulations of the Board of Directors" established by the company. The authority for the execution of other duties is delegated to the executive officer responsible for each aspect of the business.
5. Communication with Shareholders	• Kyowa Hakko Kirin has separately established a basic policy on dialogue with shareholders, and actively creates opportunities for constructive dialogues, based on the recognition that such dialogues further enhance the Company's corporate governance and contribute to the improvement of the Company's medium- and long-term corporate value.

* The shareholders referred to in this case also include potential shareholders (investors).

of independent outside board directors to collect information, meetings are held between the full-time company auditors and non-executive board directors, including independent outside board directors.

Criteria regarding the Independence of Outside Officers

Regarding the requirements to ensure the independence of outside officers, our own nomination criteria has been established, with reference to the provisions for independent directors stipulated in the "Enforcement Rules for Securities Listing Regulations" of the Tokyo Stock Exchange and the reference model for the nomination of independent directors by the Japan Association of Corporate Directors.

Internal Control

Based on the basic policy of our parent company "Kirin Holdings Company, Limited," we have established a "Basic Policy on Internal Control System" to ensure the appropriateness of operations. Based on this basic policy, the establishment and operations of the system are confirmed by the Board of Directors, and its outline is 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 Conform (ing)" to the International Standards for the Professional Practice of Internal Auditing.

Basic policy on construction of the Internal Control System

(Items)

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

Important Matters Affecting Corporate Governance

Our company is a consolidated subsidiary of the pure holding company Kirin Holdings Company, Limited, which owns 50.1% of our issued shares. While respecting the basic policies regarding group management of Kirin, we have the independence and flexibility to autonomously conduct business activities, with our managerial independence ensured.

Nomination Consultative Committee and Remuneration Consultative Committee

The Nomination Consultative Committee and Remuneration Consultative Committee comprise of two internal board directors and three outside officers, and are each chaired by an outside officer.

The Nomination Consultative Committee deliberates and decides on the nomination policy of board directors, executive officers, and company auditors and the potential candidates for these positions, their selection and dismissal, the responsibilities of each board director, the selection policy for the CEO's successor, and the potential candidates for Presidents of main companies of the Group, following which the Committee submits proposals to the Board of Directors.

The Remuneration Consultative Committee deliberates and decides on the remuneration system, levels, and amounts for directors, executive officers, and company auditors of Kyowa Hakko Kirin as well as the main companies of the Group from an objective and fair perspective, following which the Committee submits proposals to the Board of Directors.

IR Activities and General Shareholders' Meeting

It is the view of the Company that constructive two-way communication with institutional investors and shareholders, through financial results briefings and one-on-one meetings, will lead to an enhanced corporate governance and improved medium-and long-term corporate value. For this reason, in order to further enhance the content of the dialogues with shareholders while paying special consideration to the equality of investors, the IR Team, under the supervision of the IR Director, works closely with all departments of the Company to actively conduct IR-related activities.

Convocation notifications concerning the General Shareholders' Meeting are, in accordance with the Corporate Governance Code, sent up to three weeks prior to the meeting so that shareholders have sufficient time to consider the proposals to be voted on during the meeting. Until the notices are sent by mail, the information is electronically posted on our website, etc. Furthermore, in consideration of foreign investors, English translations of the convocation notices and electronic voting platforms are made available. During the General Shareholders' Meeting, the summary of Company's performance is clearly explained on the screen or via the narration. Shareholders vote on measures after receiving ample explanation.

Cooperation with Stakeholders (CSV Management)

Based on the Kirin Group's unique idealogy regarding CSV*, which aims to make compatible the ideals of solving of societal issues and providing value to customers,we will advance our efforts in the Group towards the aim of achieving the creation of both economic value and social value, by regarding the contribution to the health and well-being of people – one of the Strategic Pillars in our FY2016-2020 Midterm Business Plan – as a part of our CSV management.

* CSV stands for Creating Shared Value, and its idea is that a company should achieve the enhancement of corporate value via the "creation of both social and economic value" when tackling social issues.

Compliance

The Kyowa Hakko Kirin Group considers compliance not only as adherence to laws and regulations, but also as an act to behave ethically in conformity to social needs and strives to build and maintain healthy and favorable relationships with various stakeholders.

Compliance Basic Policy and Code of Conduct

In order to realize the management philosophy, the Kyowa Hakko Kirin Group acts based on Core Values of the Group and with high ethical standards, and aims to be a corporate group that is trusted by society.

We regards compliance as the base of all of its corporate activities, and therefore has established appropriate rules and created an organizational structure to comply with all laws and ordinances, internal and external guidelines and rules, and social conventions.

In January 2016, we established the "Kyowa Hakko Kirin Group Compliance Policy," stipulating that we shall fulfill legal and ethical responsibility considering our relationship with society and employees, compliance with rules and regulations, respect for human rights, environmental preservation, and information management.

In October 2016, under the Policy, we established the "Kyowa Hakko Kirin Group Code of Conduct," defining concrete actions to be taken by each officer and employee. We translated the Policy and Code of Conduct into local languages, such as English and Chinese, publicizing them to the Group's employees globally. In 2017, We provided training on the Code of Conduct to all the employees of the Group and obtained employees' consent to complying with it.

Compliance Training

The Group is committed to cultivating workers and fostering an organizational culture that allows making responses to changes in social demands. As part of our efforts, we conduct a variety of educational programs, such as group training and e-learning courses. In 2017, we conducted such programs focusing on "Core Values and code of conduct," "human rights," "information security," and "dealing with a crisis."

For the Group's executives, in the meeting all the executive officers attended, we hold a lecture on subjects, such as due care of a prudent manager. Moreover, we organize a corporate ethics lecture meeting on subjects, such as compliance and organizational misconduct as well as the Group's Core Values and Code of Conduct by inviting external lecturers.

We check the state of compliance at each group company by means of various incident reports, employee awareness surveys, whistle blowing system, the state of participation in a variety of educational programs, comprehension-checking tests, etc., and utilize the findings to improve our compliance system, rules, and training. In addition, on an annual basis, we participate in the "Awareness Survey of Human Rights and Compliance" implemented by the Kirin Group to conduct a survey of all of our domestic employees in the Group and utilize the results of the survey for further improvements.

"Kyowa Hakko Kirin Group Compliance Policy" (excerpts)

●Relationship with Society

We, as good members of society, will build friendly and ethical relationships with all our stakeholders.

●Compliance with Rules

We will behave with integrity and ethically, while complying with rules.

●Environmental Preservation

We will actively engage in the preservation of the global environment to safely hand it over to the next generation.

●Relationship with Employees

We will respect each member's individuality and endeavor to maintain a friendly workplace environment.

●Respect for Human Rights

We will respect human rights and characteristics of all people.

●Information Management

We will properly manage information concerning our businesses.

Major training conducted, etc.

(targets: Kyowa Hakko Kirin domestic group companies)

- Kyowa Hakko Kirin Group Core Values and Code of Conduct*1
- Whistle blowing system*1
- Prevention of corruption*1
- Training on response to laws on transparency in Europe and the U.S.*2
- Japan Pharmaceutical Manufacturers Association (JPMA) Code of Practice
- Training on safety management for drugs
- Handling of obtained information concerning safety management for drugs*3
- Training on human rights and compliance (LGBT and anti-discrimination (DOWA))
- Training on handling targeted attack e-mail
- Environmental activities and significance for company

*1 Conducted in the entire group, including overseas sites and subsidiaries
*2 Conducted in Kyowa Hakko Kirin
*3 Conducted in Kyowa Hakko Kirin and Kyowa Medical Promotion

Anti-bribery Initiatives

In the recent years, international agencies, such as the United Nations and the Organaization for Economic Co-operation and Development (OECD) as well as national governments require global companies to implement an initiative to prevent bribery.

To reinforce the initiative, the Kyowa Hakko Kirin Group has established the "Guideline for Anti-Bribery Measures" and regulation for anti-bribery, and has rolled them out to group companies with the president's commitment, while providing annual continual training to executives and employees. Our group companies pursue efforts on the prevention of bribery by installing an anti-bribery manager and help desk according to the guideline and regulation. We monitor and audit how each group company complies with the operational rules on bribery prevention and revision to anti-bribery law in each country, thus developing a framework for preventing bribery on a group-wide basis.

Management of Transparency

The Kyowa Hakko Kirin Group collaborates with medical professionals, medical institutions, and patient organizations both nationally and internationally, in order to create innovative new drugs and inform medical professionals of the efficacy and side effects of new drugs after their release. In the process of such collaborations, the Group's involvement could potentially cause a serious conflict of interest with medical professionals, medical institutions and patient organizations. Therefore, the Group must respect their independence and give consideration in an effort to prevent such conflicts. The Group is committed to disclose information on the transfer of values to medical professionals, medical institutions and patient organizations pursuant to laws, and industry guidelines and codes in each country.

In consideration of this background, the Group, as a company that is trusted by society and contributed to the health and well-being of people, established the "Kyowa Hakko Kirin Group Transparency Policy for the Relationships between Corporate Activities, Healthcare Professionals, Healthcare Organizations and Patient Organizations" and Group transparency regulation, and has made efforts to further develop our global structure, thereby ensuring transparency for relationship with medical professional, medical institutions and patient organizations.

"Guideline for Anti-Bribery Measures"

1. The Kyowa Hakko Kirin Group ("KHK Group") strives to be fully aware of and to strictly observe all anti-bribery laws and to comply with the spirit of anti-bribery guidelines in every country and region where we do business.
2. KHK Group prohibits any form of bribery with anyone, including unjustly providing or receiving money, goods, entertainment or other benefits in excess of the scope recognized to be appropriate under the laws and guidelines of the countries and regions where we do business.
3. KHK Group will refuse further dealings with any trading partner or agent if it learns of any incident of bribery by them in connection with our business.
4. KHK Group requires that all officers and employees report any violation known to them.

Promotion of Compliance with Suppliers

Suppliers are important partners in order for the Group to deliver safe and high-quality products and services, and in our view, suppliers are entities that grow with us. To promote compliance with our suppliers, the Group has prescribed the Supplier Code of Conduct, based on the Kyowa Hakko Kirin Group Code of Conduct. Thus, we seek to upgrade the entire supply chain by conducting onsite inspections and interaction meetings. On our corporate website, we installed a "Supplier Hotline" as a help desk independent from the procurement department. Through the help desk, we receive information on an act performed by the Group's employee that breaches, or may potentially breach, laws or regulations in a supplier transaction with the Group.

Whistle Blowing System

The Kyowa Hakko Kirin Group has established an whistle blowing contact in order to prevent, detect early, and correct acts against the "Kyowa Hakko Kirin Group Code of Conduct" and acts that seriously detract the brand value of the KHK Group. In order to improve the usability of the whistle blowing system, we established an external contact and a counter of which a female staff member is in charge. In addition, we have introduced a mechanism by which a report about a board of director is to be directly notified to a company auditors. In 2017, we completed installing the global internal reporting contact and established a system that allows direct reporting from any overseas subsidiary to the head office in Japan.

The whistle blowing system is operated in accordance with the internal rules in which the protection of informants and those cooperating with the investigation are clearly prescribed.

In 2017, there were 29 cases of internal reporting in Japan.

Risk Management

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

Risk Management

In order to win long-term trust from customers and society and continue our business to achieve management goals, we have established the "Kyowa Hakko Kirin Group Risk Management Policy," and have implemented risk management in all group companies.

"Risk management" in the Kyowa Hakko Kirin Group refers to a series of ongoing activities to identify and analytically assess risks that may affect management, respond to the risks, confirm the responses made, and make improvements to the responses.

The state of implementation of our risk management is reported at the Group CSR Committee meeting held quarterly, and the effectiveness of the risk management, are verified in the meeting.

In addition, of the situations that inhibit the achievement of our management goals, we have defined as "crises" those that may have a profound impact and require a rapid response, where we prioritize human life and health, and act quickly and accurately with the aim of minimizing the impact of the crisis and promptly returning to normal business operations.

Improvement in BCP

We have formulated a Business Continuity Plan (BCP) as a means of fulfilling our CSR, such as for merchandise production and shipment even in the event of normal business activities becoming highly difficult to continue due to a disaster or accident. We arrange for company-wide BCP guideline, BCP basic plans, and BCP action plans to reflect any awareness and knowhow of countermeasures recognized through training and workshop, and continue to make improvements.

Environmental Safety

Under the "Kyowa Hakko Kirin Group Environmental Policy," we have prescribed voluntary management targets that are stricter than laws and regulations pursuant to management systems, such as ISO14001 with the aim of realizing a sustainable global environment. We have been promoting environmental activities by setting targets for global warming prevention, water resource protection, resource recycling (zero emission*), chemical substance emission reduction, and biodiversity preservation and by invigorating the Plan-Do-Check-Act (PDCA) cycle. Moreover, in collaboration with the parent company Kirin Holdings Company, Limited, we formulated a global target for 2030 on the reduction of CO_2 emissions and water consumption volumes.

The greenhouse gas (GHG) emissions by medium-term reduction target of the Kirin Group was approved by the Science Based Targets (SBT) initiative, a global initiative. This was a first example of such recognition in Japan's food industry. The Kyowa Hakko Kirin Group's targets were formulated according to SBT.

To prevent industrial accidents, we enhance occupational safety training in each management line, and we implement measures for traffic safety of business vehicles from both hardware and software standpoints. We improve environmental and safety activities and performance of all productions sites by audit.

As for chemical substances, we use "Reagent Management System" at our major domestic production sites and research laboratories, and thorughly manage them so as not handle regulated substances by mistake.

Environmental and safety audit of China (Shanghai) site (Shanghai Kyowa Amino Acid Co., Ltd.)

* The final landfill site disposal amount of waste is less than 0.1% of the total waste amount.

Information Security

To manage the information assets appropriately, the Kyowa Hakko Kirin Group has established the "Group Information Security Policy," under which it has established the "Group Information Security Management Regulations" and "Regulations for Confidential Information Management."

Pursuant to such policies and regulations, a person is appointed as the manager in charge of the information security of the Kyowa Hakko Kirin Group, and each department designates a person in charge as well, so we pursue efforts to ensure information security. We have also implemented education and training to raise awareness of information security among employees and make all efforts to ensure the appropriate management of information.

Quick Search

WEB link

Financial Ratios WEB

Consolidated Statements of Cash Flows WEB

Financial Summary WEB

Adoption of International Financial Reporting Standards

The Group has adopted the International Financial Reporting Standards ("IFRS") from the current fiscal year to enhance the international comparability of its financial reporting for the capital market, and unify the process of the Group's accounting.

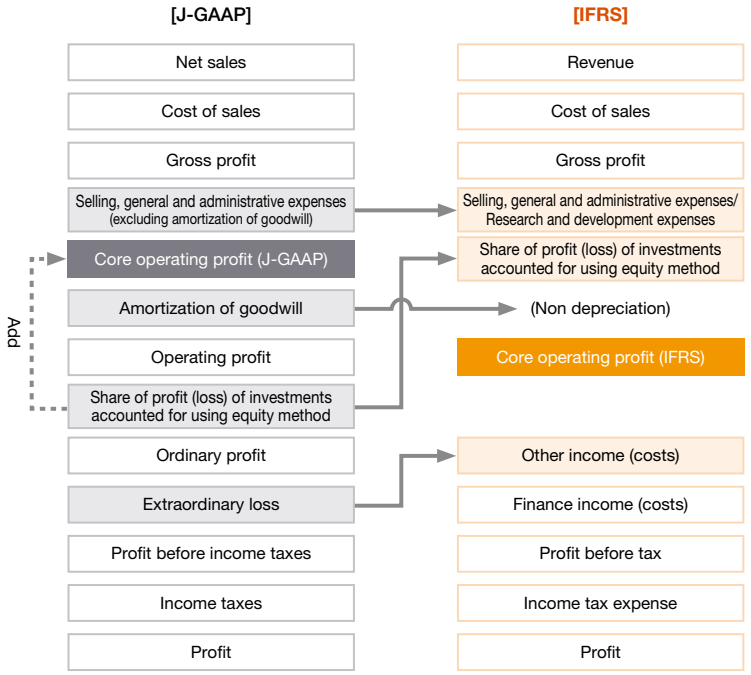
About adoption of "core operating profit" (IFRS)

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 2017, the nine months ended December 31, 2009 and years ended March 31, 2008 to 2009

	IFRS	J-GAAP										IFRS
	Millions of yen	Millions of yen										Thousands of U.S. dollars*1
	2017/12	2017/12	2016/12	2015/12	2014/12	2013/12	2012/12	2011/12	2010/12	2009/12	2009/3	2008/3	2017/12
For the Year:													
Revenue	¥ 353,380	¥ 350,728	¥ 343,019	¥ 364,316	¥ 333,446	¥ 340,611	¥ 333,158	¥ 343,722	¥ 413,738	¥ 309,111	¥ 460,183	¥ 392,119	$ 3,125,877
Gross profit	224,321	220,129	208,493	225,393	205,904	212,761	210,690	197,555	190,979	139,739	200,297	144,917	1,984,265
Selling, general and administrative expenses (including R&D expenses)	162,113	179,492	176,854	181,628	169,731	160,987	157,785	150,940	145,568	111,496	154,910	105,527	1,434,257
Core Operating Profit (J-GAAP:Operating profit)	57,731	40,637	31,638	43,765	36,173	51,773	52,905	46,614	45,410	28,243	45,387	39,390	510,668
Profit attributable to owners of parent	42,899	26,355	18,669	29,774	15,898	30,078	24,199	25,608	22,197	8,797	11,726	23,477	379,469
Capital expenditure (including intangible assets)	20,714	14,796	32,036	20,039	29,487	35,183	27,808	19,697	29,374	25,135	18,523	14,795	183,227
Depreciation and amortization	22,032	21,972	23,029	23,126	23,885	21,592	20,904	22,833	22,188	17,003	18,779	14,346	194,884
R&D expenses	49,216	53,663	53,822	51,604	47,737	43,682	44,808	47,961	44,210	34,979	48,389	34,109	435,350
Cash Flows:													
Net cash provided by operating activities	¥ 64,902	¥ 59,812	¥ 65,752	¥ 66,526	¥ 19,377	¥ 56,884	¥ 59,134	¥ 40,634	¥ 64,189	¥ 24,203	¥ 41,069	¥ 30,713	$ 574,101
Net cash peovided by (used in) investing activities	(45,265)	(40,226)	(48,968)	(57,747)	16,805	(77,163)	(98,772)	18,460	(32,373)	(13,246)	(3,981)	(9,492)	(400,402)
Net cash peovided by (used in) financing activities	(18,287)	(18,112)	(13,598)	(14,060)	(37,184)	(12,579)	(19,189)	(30,740)	(14,446)	(16,906)	(20,978)	(13,499)	(161,762)
Cash and cash equivalents at the end of the period	14,685	15,759	13,075	12,784	17,013	19,242	50,334	107,555	79,882	63,745	69,286	44,118	129,896
At Year-End:													
Total current assets	¥ 333,895	¥ 350,742	¥ 326,469	¥ 324,433	¥ 283,192	¥ 329,320	¥ 303,988	¥ 284,217	¥ 288,852	¥ 276,587	¥ 279,475	¥ 232,661	$ 2,953,516
Total assets	708,295	705,586	697,167	720,764	719,135	719,257	679,342	658,873	695,862	695,268	699,041	394,081	6,265,328
Total current liabilities	74,298	69,636	79,416	84,823	85,182	85,076	85,774	78,465	102,483	110,080	108,522	111,743	657,214
Interest-bearing debt	2,814	1,220	5,360	4,840	4,868	6,207	5,699	6,042	7,515	13,228	13,540	12,790	10,796
Equity	616,028	621,297	600,745	614,858	605,368	595,415	555,898	540,023	544,992	540,343	543,070	256,758	5,449,168
Number of employees	7,532	7,532	7,465	7,435	7,424	7,152	7,243	7,229	7,484	7,436	7,256	6,073	
Per Share Data:	Yen	Yen											U.S. dollars*1
Profit attributable to owners of parent*2	¥ 78.38	¥ 48.16	¥ 34.12	¥ 54.40	¥ 29.05	¥ 54.95	¥ 44.12	¥ 45.16	¥ 38.96	¥ 15.40	¥ 20.42	¥ 58.99	$ 0.693
Equity attributable to owners of parent	1,125.56	1,133.91	1,096.78	1,122.80	1,105.44	1,085.17	1,013.61	970.16	954.58	940.79	938.42	639.69	9.956
Cash dividends	27	27	25	25	25	25	20	20	20	15	20	10	0.239
Common Stock Price Range (Per share):													
High	¥ 2,227	¥ 2,227	¥ 2,098	¥ 2,321	¥ 1,510	¥ 1,256	¥ 970	¥ 953	¥ 1,040	¥ 1,178	¥ 1,235	¥ 1,430	$ 19.26
Low	1,515	1,515	1,412	1,094	1,006	833	757	628	773	793	586	933	9.08
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	399,243	
Weighted average number of common stock issued	547,290	547,290	547,224	547,285	547,348	547,391	548,449	567,029	569,711	570,935	574,083	397,716	
Financial Ratios:	%, except EBITDA	%, except EBITDA											
Return on assets (ROA)	6.2	3.8	2.6	4.1	2.2	4.3	3.6	3.8	3.2	1.3	1.6	6.1	
Core operating return on assets (J-GAAP:Operating profit)	8.3	5.8	4.5	6.1	5.0	7.4	7.9	6.9	6.5	4.1	6.3	10.2	
Return on equity attributable to owners of parent (ROE)	7.2	4.3	3.1	4.9	2.7	5.2	4.4	4.7	4.1	1.6	2.2	9.5	
Ratio of equity attributable to owners of parent to total assets	87.0	88.0	86.1	85.2	84.1	82.6	81.7	81.8	78.2	77.1	77.0	64.5	
Debt/equity ratio	0.2	0.2	0.9	0.8	0.8	1.1	1.0	1.1	1.4	2.5	2.5	5.0	
Core operating margin (J-GAAP:Operating profit)	16.3	11.6	9.2	12.0	10.9	15.2	15.9	13.6	11.0	9.1	9.9	10.1	
EBITDA*3 (Millions of yen)	78,220	71,522	66,003	78,018	64,101	83,190	78,160	79,864	74,614	45,056	60,098	53,162	
Payout ratio*4	34.4	38.0	43.7	35.1	54.4	34.8	32.8	32.5	36.2	54.3	53.8	16.9	

*1. U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥113.05=U.S.$1, the approximate exchange rate at December 31, 2017.
*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, the consolidated payout ratios for the period from the fiscal year ended March 31, 2009 to the fiscal year ended December 31, 2015 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), and the consolidated payout ratios for the fiscal years ended December 31, 2016 and 2017 are calculated using net income before amortization of the entire goodwill.

Message from Executive Officer in Charge of Finances

We will address the challenge to the best of our ability with an eye toward achieving dramatic growth

I have assumed the office of Executive Officer in charge of finances on March 23, 2018. With the launch of our global strategic products in the European and U.S. markets just around the corner, I feel tangibly that the FY2016-2020 Mid-term Business Plan has been moving forward steadily. We will continue to maintain sound financial strength for flexible strategic investment in the future.

Motohiko Kawaguchi
Executive Officer, Director of Accounting Department

Performance in FY2017

In the second year of the investment phase, we were able to produce solid results

In FY2017 we filed an application for approval for two items positioned as our global strategic products, namely, burosumab (KRN23), an investigational recombinant fully human monoclonal IgG1 antibody against the phosphaturic hormone fibroblast growth factor 23 (FGF23) and mogamulizumab (KW-0761), a humanized monoclonal antibody targeting CC chemokine receptor 4 (CCR4) in Europe and the U.S. Moreover, the development of anti-IL-5 receptor humanized antibody benralizumab (KHK4563) that we out-licensed to AstraZeneca made progress. Given these, it was a year where we made great strides with an eye toward leaping forward for a Global Specialty Pharmaceutical Company (GSP), the goal spelled out in the Mid-term Business Plan.

Meanwhile, in the domestic market, although sales of new products grew smoothly, sales of some drugs including our mainstay product NESP® and long-listed product ALLELOCK® were affected due in part to drug price revision or market penetration of competing products, including generics, making us face an uphill battle in a tough business environment.

Under these circumstances, we shored up sales promotion and made dedicated efforts, including operational improvement and cost reduction. As a result, we were able to post higher core operating profit than FY2016 in both pharmaceuticals and bio-chemicals businesses in FY2017.

Progress of FY2016-2020 Mid-term Business Plan

We will boost the percentage of overseas sales, thereby increasing core operating profit and improving ROE

In FY2017 we posted core operating profit of 57.7 billion yen. We set forth the business goal of achieving core operating income of at least 100 billion yen in FY2020, the final year of the Mid-term Business Plan. Although this is a challenging goal, I believe that we will be able to meet it if sales of our global strategic products, including burosumab, grow smoothly after they are launched.

The percentage of our overseas sales stood at 31.8% in FY2017. I expect this percentage to keep rising steadily down the road as we launch our global strategic products.

In the domestic market, pressure for reducing drug prices will likely remain strong and it should be difficult to boost profitability. Meanwhile, in the global market that we are about to tackle, given that drug prices are generally high and the corporate tax rate is low, while the selling expenses are not so high in case of rare diseases with small number of patients, we can expect to achieve higher profitability than in the domestic market. I thus believe that boosting the percentage of overseas sales can contribute significantly to improving core operating profit and ROE down the road.

As regards ROE, the third indicator spelled out as part of the FY2020 management goals, it stood at 7.2% in FY2017. The Kyowa Hakko Kirin Group is promoting strategy that increases ROA, thereby improving ROE. We will grow net profit, that is the numerator of ROA, by expanding overseas business. In addition, in Europe and the U.S., we can reduce stock and the cycle of recovering trade account receivables tends to be short compared with the domestic levels. For this reason, we can relatively curb current assets, such as inventories and operating receivables. In this way, while controlling an increase in total assets, which are the denominator, we will improve ROA. By racking up 100 billion yen of core operating profit through expanding our overseas business, I believe that we will be able to meet the target ROE of 10% or higher of itself.

Measures in FY2017

With reorganizing of domestic plants completed, we promoted efforts at optimizing assets further

In the pharmaceuticals business, we began reorganizing our domestic plants in 2010. Following the Yokkaichi and Sakai Plants, the Fuji Plant ended its operations in 2017 as scheduled; we thereby completed the restructuring of manufacturing bases. In the bio-chemicals business, in order to make our constitution less susceptible to the effects of exchange rate fluctuations, we set up a new plant in Thailand, which is operating smoothly. Furthermore, we also reorganized plants in Japan as well. As a result of these, I believe that our investment in plants for the Group as a whole peaked out.

Meanwhile, we continuously invest in R&D to enhance the value of our company's pipeline. In the pharmaceuticals business, we aim to invest about 20% of revenues in R&D. In line with this policy, we will promote strategic investment with the focus on flexibility.

Outlook after FY2018

We will promote financial strategy to realize flexible management

In addition to converting the business portfolio into the pharmaceuticals-intensive one, we have moved ahead with improvement step by step on the financial front as well. We have disposed of inefficient facilities and land, thereby reducing tangible assets. As a result, in recent years, the percentage of intangible assets, such as intellectual property rights, has been rising. Moreover, cash reserves, such as cash and deposits and loans to the parent company, have grown and we have been able to maintain sound financial strength. In 2017 our free cash flow was positive, with cash reserves totaling 157.9 billion yen as of the end of FY2017.

Against this background, we will put an environment in place that allows us to invest in the next growth phase flexibly. We will also proactively consider the possibility of investment to outside of the Group, such as acquiring intellectual property rights and M&A, not to mention R&D within the Group with the aim of expanding the pipeline. Our effort at recovering investments in the U.K.-based ProStrakan and Archimedes (currently, Kyowa Kirin International) that we acquired has been moving forward extremely smoothly. In order for us to make strategic investments timely like these with the future in view, we will keep sound financial strength that can generate cash intact.

For your information, we adopted International Financial Reporting Standards (IFRS) in our financial statements for FY2017 at our own discretion, instead of J-GAAP that we had adopted so far. There are mainly two reasons for this: one is to improve the comparability of financial information in the global capital market. In these years, among globally operating pharmaceutical companies, it is becoming a standard to disclose information based on IFRS. With this in mind, in order for those outside, including market players, to compare Kyowa Hakko Kirin's financial information with that of others properly, we reached the conclusion that it would be desirable to introduce IFRS. The other reason is that as our parent company, Kirin Holdings Company, Limited has also applied IFRS since FY2017, we unified accounting processing within the Group.

Message to Shareholders and Investors

We will aim for a dividend payout ratio of 40% and boost profits to grow further

In terms of our dividend, as spelled out in the Mid-term Business Plan, we will pay out dividends stably with the aim of achieving a payout ratio of 40% until 2018. In 2017, as our income grew year-over-year, we decided to raise a dividend by two yen per share. For the next term, we plan to raise a dividend further by three yen per share. To live up to shareholders and investors' expectations, we believe that it is essential to improve corporate value through continuous growth of income, not to mention such stable dividend payouts. For this reason, we had been aggressively investing in global strategic products in the investment phase, which has been bearing fruit step by step, and we feel a certain response.

With an eye toward leaping forward for a GSP, i.e., the major goal of the Group, we are trying our best through concerted efforts. As a person in charge of finances of the Group, I will devote myself to meeting the goal from the financial strategy aspect.

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 our consolidated subsidiaries for the current fiscal year ended December 31, 2017 stood at 47.

Income

(Billions of yen)

	Fiscal year ended December 31, 2017	Fiscal year ended December 31, 2016	Change
Revenue	**353.4**	348.0	5.4
Core Operating Profit	**57.7**	39.1	18.6
Profit attributable to owners of parent	**42.9**	30.5	12.4

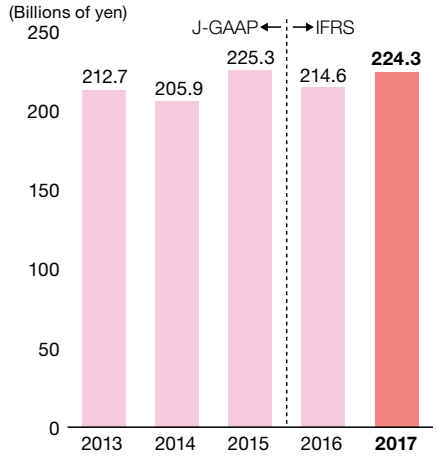
Revenue and Core operating profit

Consolidated revenue and core operating profit for the current fiscal year increased due mainly to an increase in licensing revenue, a decrease in research and development expenses, and improvement in share of profit (loss) of investments accounted for using equity method, despite the impact of reductions in drug price standards and other factors.

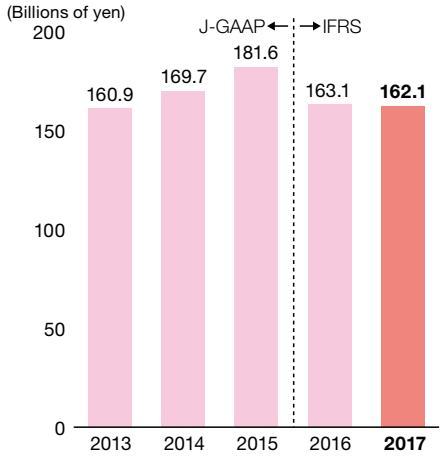
Profit attributable to owners of parent

Profit attributable to owners of parent respectively increased due mainly to the increase in core operating profit.

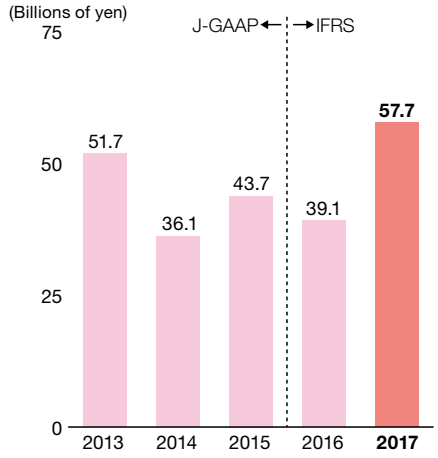
Gross Profit



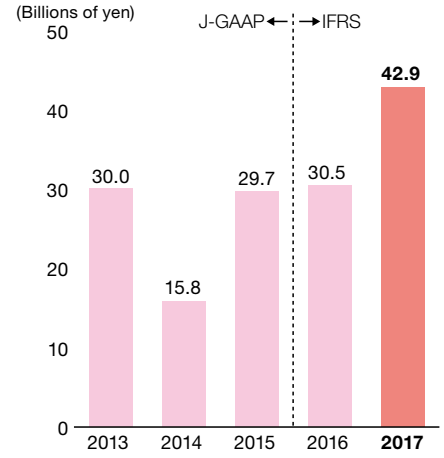
Selling, General and Administrative Expenses (including R&D expenses)



Core Operating Profit



Profit Attributable to Owners of Parent



* Figures and ratios for the periods from the fiscal year ended December 31, 2013 to the fiscal year ended December 31, 2016 are operating profit and operating margin under J-GAAP.

Performance by Business Segment

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

	IFRS		J-GAAP	IFRS
	Millions of yen		Millions of yen	Thousands of U.S. dollars*
	2017/12	2016/12	2015/12	**2017/12**
Revenue:				
Pharmaceuticals				
Revenue from external customers	**¥ 274,776**	¥ 269,263	¥ 278,402	**$ 2,430,566**
Inter-segment revenue	**990**	785	894	**8,759**
Total	**275,766**	270,048	279,296	**2,439,326**
Bio-Chemicals				
Revenue from external customers	**¥ 78,605**	¥ 78,693	¥ 85,913	**$ 695,311**
Inter-segment revenue	**2,531**	3,114	2,981	**22,388**
Total	**81,136**	81,807	88,895	**717,699**
Adjustments	**(3,521)**	(3,899)	(3,876)	**(31,147)**
Consolidated total	**¥ 353,380**	¥ 347,956	¥ 364,316	**$ 3,125,877**
Segment Profit (Core operating profit):				
Pharmaceuticals	**¥ 50,530**	¥ 33,529	¥ 36,202	**$ 446,973**
Bio-Chemicals	**7,189**	5,556	8,127	**63,595**
Adjustments	**11**	31	(565)	**99**
Consolidated total	**¥ 57,731**	¥ 39,116	¥ 43,765	**$ 510,668**

* U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥113.05=U.S.$1, the approximate exchange rate at December 31, 2017.

Pharmaceuticals Business

(Billions of yen)

	Fiscal year ended December 31, 2017	Fiscal year ended December 31, 2016	Change
Revenue	**275.8**	270.0	5.7
Core Operating Profit	**50.5**	33.5	17.0

Revenue in Japan decreased compared to the previous fiscal year due mainly to the impacts of the market penetration of generics in conjunction with measures to reduce medical costs and reductions in drug price standards implemented in April of last year.

Revenue from core products NESP®, a renal anemia treatment drug, were the same level as the previous fiscal year, despite being affected by the impact of the reductions in drug price standards.

Revenue from products such as G-Lasta®, an agent for decreasing the incidence of febrile neutropenia, NOURIAST®, an antiparkinsonian agent, and Onglyza®, a treatment for type 2 diabetes showed solid growth, and LUMICEF®, a treatment for psoriasis launched in September last year, is also steadily penetrating the market.

Revenue from long term NHI products such as ALLELOCK®, an anti-allergy agent, CONIEL®, a hypertension and angina pectoris drug, Depakene®, an anti-epileptic drug, and GRAN®, a neutropenia treatment drug, decreased due to the impacts of the market penetration of generics, etc.

International revenue increased compared to the previous fiscal year due mainly to the increase in licensing revenue. In Europe and the Americas, revenues increased compared to the previous fiscal year due to increased sales of products such as Abstral®, which is treatment for cancer pain, and Moventig™, an opioid-induced constipation (OIC) treatment, and other sources of revenues including upfront payment agreement and milestone revenue related to Benralizumab from AstraZeneca. Revenue in Asia increased compared to the previous fiscal year, reflecting steady sales particularly in Taiwan and China.

Bio-Chemicals Business

(Billions of yen)

	Fiscal year ended December 31, 2017	Fiscal year ended December 31, 2016	Change
Revenue	**81.1**	81.8	–0.7
Core Operating Profit	**7.2**	5.6	1.6

Revenue in Japan stayed at the same level as in the previous fiscal year. Revenue from active pharmaceutical and health food ingredients business were solid, increasing compared to the previous fiscal year. In the mail-order business, revenue increased compared to the previous fiscal year, boosted by revenue growth of products, notably Arginine EX.

Revenue from Kyowa Engineering decreased compared to the previous fiscal year.

Revenue from international business stayed at the same level as in the previous fiscal year. In the Americas and Europe, revenue increased compared to the previous fiscal year due to solid revenue of the active pharmaceutical and health food ingredients business. In Asia, revenue decreased compared to the previous fiscal year due to the effect of intensified competition regarding some products.

Cash Flow

Cash and cash equivalents as of December 31, 2017 were ¥14.7 billion, an increase of ¥1.6 billion compared to the balance of ¥13.1 billion as of December 31, 2016.

Net cash provided by operating activities was ¥64.9 billion, a 3.0% decrease compared to the previous fiscal year. The main factors included profit before tax of ¥55.8 billion, depreciation and amortization of ¥22.0 billion, despite income taxes paid of ¥16.9 billion, etc.

Net cash used in investing activities was ¥45.3 billion, a 9.2% decrease compared to the previous fiscal year. Major outflows included a net increase of ¥28.7 billion in loans receivable from parent, ¥14.8 billion for purchase of property, plant and equipment, and ¥7.6 billion for purchase of intangible assets such as the upfront payment under the license agreement for tenapanor, which was in-licensed from U.S. company Ardelyx, Inc. Major inflows included ¥6.1 billion in proceeds from the sale of the plant growth regulator business and ¥2.2 billion in proceeds from sales of property, plant and equipment.

Net cash used in financing activities was ¥18.3 billion, a 31.8% increase compared to the previous fiscal year. The main outflows included dividends paid of ¥13.7 billion and a net decrease of ¥4.2 billion in short-term borrowings.

Financial Position

Assets

Assets as of December 31, 2017 were ¥708.3 billion, an increase of ¥24.5 billion compared to the end of the previous fiscal year. In the current fiscal year, we decided to transfer part of our shareholdings in our consolidated subsidiary Kyowa Medex. Since we will consequently lose our control over the subsidiary, all assets of the subsidiary of ¥14.3 billion have been classified as assets held for sale. Non-current assets declined by ¥8.7 billion to ¥360.1 billion, due mainly to decreases in property, plant and equipment and intangible assets. Current assets increased by ¥33.2 billion to ¥348.2 billion, due mainly to an increase in loans receivable from parent as fund management.

Equity

Equity as of December 31, 2017 was ¥616.0 billion, an increase of ¥39.0 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 87.0%, an increase of 2.6 percentage points compared to the end of the previous fiscal year.

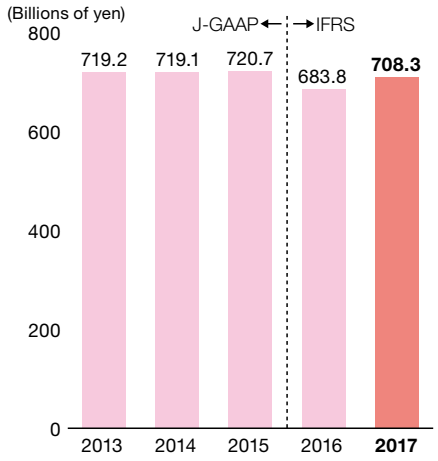
Liabilities

Liabilities as of December 31, 2017 were ¥92.3 billion, a decrease of ¥14.5 billion compared to the end of the previous fiscal year, due mainly to a decrease in trade and other payables. In addition, liabilities of Kyowa Medex of ¥4.1 billion have been classified as liabilities directly associated with assets held for sale.

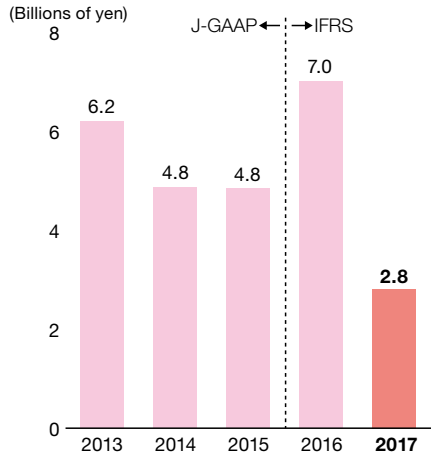
Performance Indicators

Return on equity (ROE) stood at 7.2%, an increase from 5.3% the previous fiscal year, and return on assets (ROA) at 6.2%, an increase from 4.4% the previous fiscal year. Core operating return on total assets came to 8.3%, an increase from 5.6% the previous fiscal year. EBITDA stood at 78.2 billion yen, an increase of 16.8% compared to the previous fiscal year.

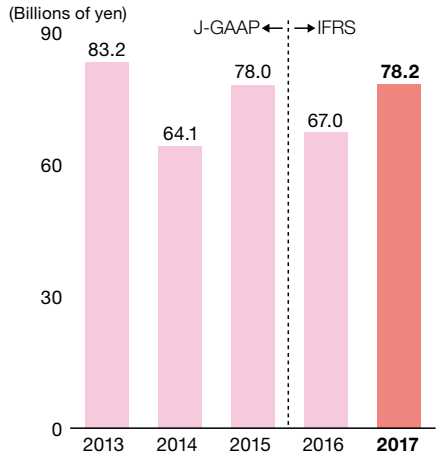
Total Assets



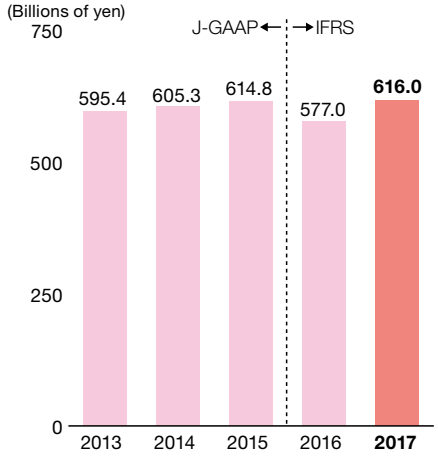
Interest-Bearing Debt



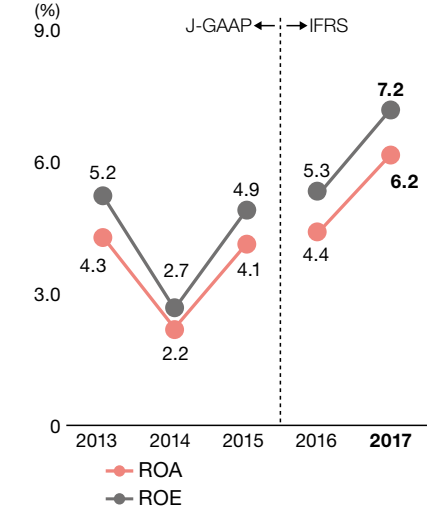
EBITDA



Equity



Returns (ROA, ROE)



Capital Requirements and Financing

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. We are also taking measures to improve our financial strength and increase our creditworthiness while considering the funding environment and other factors.

Capital Expenditure (Including Intangible Assets)

As a basic policy, Kyowa Hakko Kirin implements capital expenditure strategically in consideration of achieving a desirable balance between it and depreciation and amortization.

Capital expenditure for the fiscal year ended December 31, 2017 stood at ¥20.7 billion, an increase of ¥12.6 billion (37.7%) compared to the previous fiscal year. Depreciation and amortization for the fiscal year amounted to ¥22.0 billion, a decrease of ¥1.8 billion (7.4%) compared to the previous fiscal year.

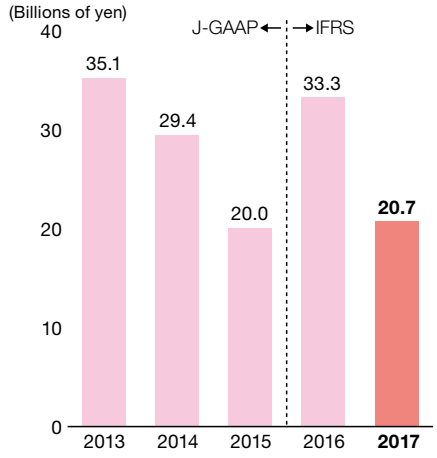
Capital Expenditure

	IFRS (Millions of yen)		J-GAAP (Millions of yen)			
	2017/12	2016/12	2016/12	2015/12	2014/12	2013/12
Pharmaceuticals	**¥ 12,932**	¥ 25,331	¥ 24,112	¥ 11,537	¥ 17,012	¥ 22,921
Bio-Chemicals	**7,782**	8,001	8,000	8,501	12,476	12,261
Adjustments	**(1)**	(42)	(75)	—	(1)	—
Consolidated total	**¥ 20,714**	¥ 33,270	¥ 32,036	¥ 20,039	¥ 29,487	¥ 35,183

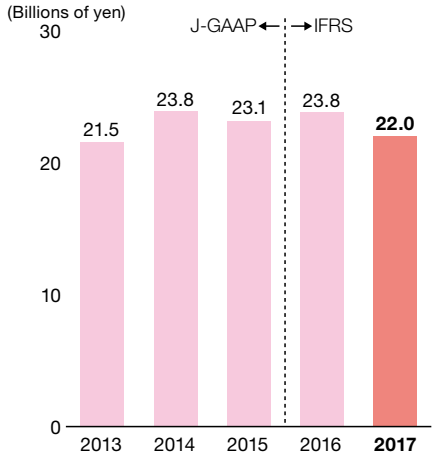
Depreciation and Amortization

	IFRS (Millions of yen)		J-GAAP (Millions of yen)			
	2017/12	2016/12	2016/12	2015/12	2014/12	2013/12
Pharmaceuticals	**¥ 15,287**	¥ 16,838	¥ 16,184	¥ 16,569	¥ 17,075	¥ 14,966
Bio-Chemicals	**6,749**	6,947	6,846	6,558	6,811	6,627
Adjustments	**(4)**	(1)	(1)	(1)	(1)	(1)
Consolidated total	**¥ 22,032**	¥ 23,784	¥ 23,029	¥ 23,126	¥ 23,885	¥ 21,592

Capital Expenditure



Depreciation and Amortization

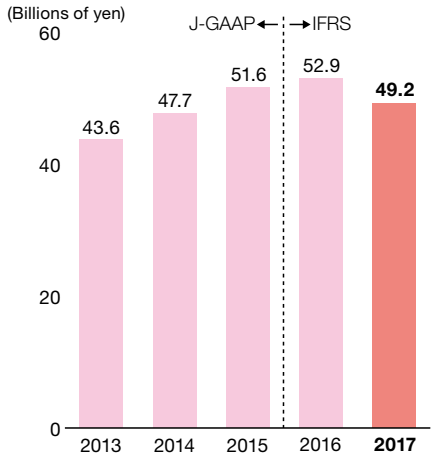


R&D Expenses

R&D expenses for the fiscal year ended December 31, 2017 stood at ¥49.2 billion, an decrease of 7.0% compared to the previous fiscal year. The ratio of R&D expenses to sales for the year came to 13.9%, an decrease of 1.3 percentage points from 15.2% the previous fiscal year.

R&D expenses in the Pharmaceuticals segment totaled ¥46.1 billion and accounted for 93.7% of total R&D expenses. The ratio of R&D expenses to sales in the Pharmaceuticals business stood at 16.7%, an decrease of 1.7 percentage points compared to the previous fiscal year. The R&D expenses in the Bio-Chemicals business amounted to ¥3.1 billion, the same level as the previous fiscal year.

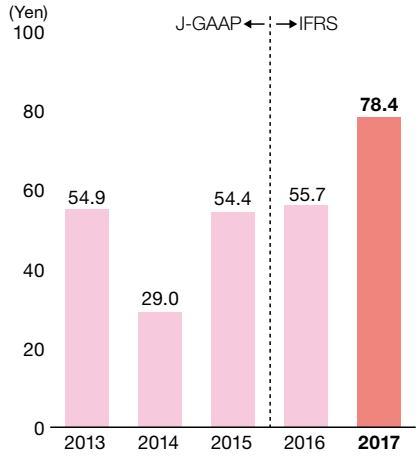
R&D Expenses



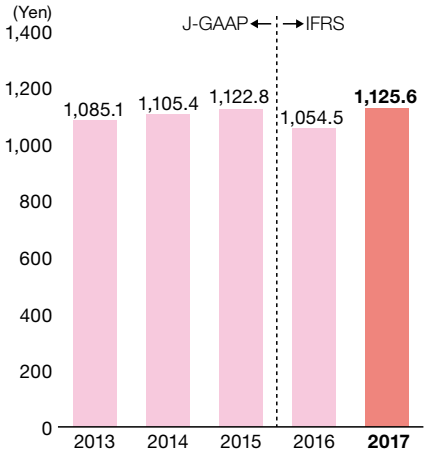
Per Share Data

Profit attributable to owners of parent per share for the fiscal year ended December 31, 2017 stood at ¥78.38 compared to ¥55.65 the previous year. Equity attributable to owners of parent per share on December 31, 2017 totaled ¥1,125.56 compared to ¥1,054.48 on December 31, 2016.

Basic Earnings Per Share



Equity Attributable to Owners of Parent Per Share



Management Plan

The Kyowa Hakko Kirin Group's management philosophy is to contribute 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. In accordance with this philosophy, with new drug business at its core, the Group is pursuing a unique pharmaceutical business model that combines its biosimilars and bio-chemicals businesses as it progresses toward a leap forward to become a Global Specialty Pharmaceutical Company, as set out in the new Mid-term Business Plan.

Under the Kyowa Hakko Kirin Group's five-year 2016 to 2020 Mid-term Business Plan with FY2016 being the first year of the plan, the management targets for FY2020, the final year of the plan, are to achieve a core operating income of at least ¥100 billion, an overseas sales ratio of 50% and ROE of 10% or higher.

In recent years, and in Japan in particular, growth in the pharmaceuticals market has leveled off due to the market penetration of generics and significant revisions to the drug price system in conjunction with progress in measures to reduce medical cost. Research and development-oriented pharmaceutical companies will have to accelerate their efforts to shift their sources of revenue from long-term listed drugs and the domestic market to new drugs and the global market.

In this environment, the Group is taking steps to achieve our four strategic priorities of Improvement of Global Competitiveness, Creating Innovation, Continuous Improvement for Operational Excellence, and Contribution to Health and Well-being of People, all premised on the notion of "Leaping Forward for a Global Specialty Pharmaceutical Company," as set forth in our five-year Mid-term Business Plan released in January 2016.

Under the first strategic priority of Improvement of Global Competitiveness, we are working toward contributing to the health and well-being of people around the world by successfully launching burosumab (KRN23), anti-FGF23 fully human monoclonal antibody and mogamulizumab (KW-0761), anti-CCR4 humanized monoclonal antibody our global strategic products, in the European and U.S. markets.

The Committee for Medicinal Products for Human Use (CHMP), the European Medicines Agency's (EMA) scientific committee, has adopted a positive opinion recommending the conditional marketing authorization of burosumab, which has been granted Priority Review status from the U.S. Food and Drug Administration (FDA). Thus, expectations are rising for the drug to obtain approval in early 2018. In Europe and the U.S., we filed a biologics license application for mogamulizumab for the treatment of patients with cutaneous T-cell lymphoma (CTCL), and the drug was also granted Priority Review status by the FDA like burosumab. To maximize the value of these global strategic products, the Group continues to take measures for its market penetration and expand the business area.

In Asia, where economic growth continues, we are strengthening the business base targeting stable future growth in China, and local subsidiaries in Korea, Taiwan, Singapore, Thailand, and other countries are implementing business strategies in accordance with local conditions and changes in the business environment in each country.

Under the second strategic priority of Creating Innovation, by combining the expertise we have gained by studying diseases and patients' needs at the research facilities we have 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 of our areas of strength , small molecule drugs, nucleic acid drugs, and regenerative therapeutics, as well as outside technologies from open innovation, we will aim to build an attractive pipeline as a pharmaceutical company that discovers new drugs. As for the pipeline of new drugs in late-stage development, based on the good results of phase 3 clinical studies we filed in Japan an application for approval of evocalcet, a next-generation calcium receptor agonist under development for the treatment of secondary hyperparathyroidism patients receiving hemodialysis. For the CNS category, we are now earnestly preparing to file an application for approval of istradefylline, an adenosine A_{2A} receptor antagonist being developed as a therapeutic drug for Parkinson's disease (product name in Japan: NOURIAST®) in the U.S.

Under the third strategic priority of Continuous Improvement for Operational Excellence, we are working to heighten our profitability by further strengthening cooperation in a consistent manner across every function from R&D to manufacturing and sales. At the same time, we strive to instill the Core Values and the code of conduct that all employees of the Group in the globe are required to adhere to. Moreover, we make efforts to build a global governance framework and ensure thorough compliance awareness. In particular in Japan, we are accelerating our area strategy to meet the needs of community health initiatives, and are providing high-quality healthcare data. In 2017, with production termination at the Fuji Plant, we completed the reorganization of our production sites in Japan as planned, which we had been working on since 2010. Upholding our responsibility as a pharmaceutical company, we will continue to build an even more reliable production platform by further advancing our production technology in order to deliver a stable supply of pharmaceuticals that must be of high quality. Furthermore, we will further enhance our initiatives including the promotion of "smart work" and provide an environment in which our diverse personnel can mutually respect one another while playing an active role.

Under the fourth strategic priority of Contribution to Health and Well-being of People, we are 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. These efforts are part of our "CSV Management" philosophy to create shared value with society, and

we will contribute to helping people with a diverse range of medical needs. In addition, as a member of the Kirin Group, we will continue efforts aimed at contributing to the health and well-being of people in collaboration with Kirin Holdings Company, Limited.

In our biosimilars business, which is a joint venture with FUJIFILM Corporation, we are making steady progress in developing top-quality, highly cost-competitive pharmaceutical products, with the aim of introducing them in markets around the world. In Europe, we filed an application for approval of an adalimumab biosimilar while engaging in our approval acquisition and a business partnership encompassing sales strategy. In addition, steady progress is being made on an international joint clinical trial for a bevacizumab biosimilar, for which we are collaborating with AstraZeneca.

The Group began to consider marketing authorized version drugs, and established Kyowa Kirin Frontier Co., Ltd. We will continue efforts to obtain approval for manufacturing and marketing in Japan of an authorized version of NESP®, a flagship product of the Group.

In the bio-chemicals business, we are addressing the key issues of strengthening the profit base and providing value with a focus on people's health, by taking advantage of our high share of the market in our specialty area encompassing the pharmaceuticals, medical and healthcare fields. For strengthening the profit base, we have been working to reorganize our production facilities and create high-profitability businesses. Steady progress has been made by the construction and preparations for full-scale production of plants for which investment has been made outside Japan, such as Thailand and China. As for efforts to create high-profitability businesses in the future, in a move to further advance the partnership with Kirin Group companies, we are now jointly developing new products such as under the "iMUSE" brand, launched together within the Kirin Group, by tapping into group companies' strengths in development, production and marketing. Moreover, we will continue endeavors to develop products for cell culture media designed for the field of regenerative therapeutics, an initiative leveraging our technologies in high-quality amino acids and culture techniques. As for providing value with a focus on people's health, we will propose new value by combining materials unique to the bio-chemicals business as done for VELOX™ and Setria® Performance Blend, products launched in 2017.

Outlook for 2018

Consolidated financial earnings forecasts for 2018 (January 1, 2018 to December 31, 2018) are for revenue of ¥335.0 billion, a decrease of 5.2% compared to 2017, core operating profit of ¥51.0 billion, down 11.7%, and profit attributable to owners of parent of ¥44.0 billion, an increase of 2.6%.

In the Pharmaceuticals business, although we are planning new product launches in Europe, the U.S. and Japan and an increase in licensing revenues, the revenue to be lower compared to 2017 because of a significant impact from reductions in drug price standards scheduled in April 2018 as well as the impact of excluding Kyowa Medex Co., Ltd. from the scope of consolidation. Also, in addition to the expected decrease in revenue, we are also expecting a decrease in core operating profit mainly on account of anticipated increases in selling expenses accompanying the launch in the U.S. and European markets of global strategic products.

In the Bio-Chemicals business, although we are expecting revenue 2018 to be lower than 2017 due to the impact of a decreased sales volume in China and the sale of the plant growth regulator business, core operating profit is expected to increase due to cost savings achieved by shifting production to overseas plants.

Profit attributable to owners of parent to be higher in 2018 than in 2017, on account of the recording of the gain from transfer of the shares of Kyowa Medex implemented on January 4, 2018.

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 investments, and considering factors such as our consolidated results and the dividend payout ratio for the respective fiscal years. 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.

In our 2016-2020 Mid-term Business Plan, until FY2018 we aim for a stable dividend payment, targeting a consolidated dividend payout ratio of 40%.

In accordance with the above-mentioned policy, the Board of Directors has resolved to pay a year-end dividend for 2017 of ¥14.50 per share. As a result, the annual dividend has been ¥27, an increase of ¥2 compared to 2016, including an interim dividend of ¥12.50.

For 2018, we expect to pay an annual dividend of ¥30 per share, an increase of ¥3 compared to 2017, consisting of an interim dividend of ¥15 and a year-end dividend of ¥15.

Risk Factors

* 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, 2017).

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 the Group uses a risk management system to prevent the occurrence of those risk events that can be controlled by the Group. At the same time, the Group will do its utmost to respond in the event of the occurrence of a risk event.

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 longterm development of new drugs, there may be cases where the expected efficacy or stability is not confirmed. This may result in the abandonment of the continuous R&D.

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

Moreover, as above, in cases where 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) Risk of Side Effects

Pharmaceutical products undergo strict safety audits at the development stage and following checks by the relevant national regulatory authorities are approved, however following launch, on occasion previously unknown side effects based on the accumulated results of users may become apparent. In such cases where an unexpected side effect is 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 factors including future trends in the reform of Japan's system of medical treatment aimed at promoting the use of generic drugs, in addition to price reductions under the domestic public pharmaceutical price system.

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 Risk

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) Risk of Fluctuations to Foreign Exchange Rate

The Group conducts foreign currency denominated transactions 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 denominated in local currencies are translated into yen for the preparation of the consolidated financial report. The exchange rate at the time of translation could have an effect on values following currency translation.

7) Disaster-related and Accident-related Risks

Earthquakes, fires, pandemics such as influenza, terrorism, conflict, 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 an event or accident as described above 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 Risk

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) IT security and Information Management Risk

As the Group utilizes a variety of information systems, system malfunctions, computer viruses, etc. may impede our business. We hold many pieces of information including personal information, and in the case of divulgence thereof 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, oscillations, offensive odors, soil contamination, ground subsidence, waste, etc. Due to environmental preservation issues such as environmental pollution arising or revisions etc. of pertinent laws and regulations, however, if the costs required for responsibility for compensation to surrounding areas, and improvement of the environment are entailed, or the necessity for new capital investments etc. arises, the Group's business performance and financial position could be adversely affected.

11) Risks related to alliance 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 the Group fails to achieve results from such alliance or operations outsourcing due to the changing business environment or experiences a contract alteration or alliance termination, the Group's business performance and financial position could be adversely affected.

12) 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 changes to the price of raw materials and fuel prices, changes to share prices and interest rates, impairment of fixed assets, and suspension of supply of products and raw materials.

Investor Information

Stock Listing
Tokyo

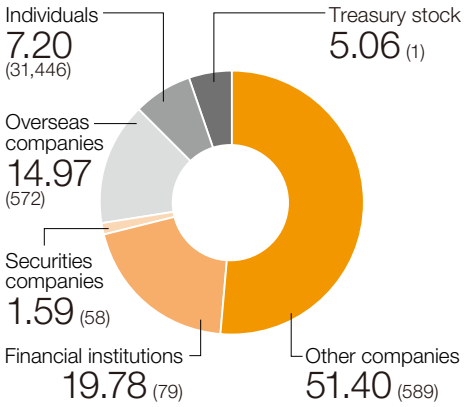
Securities Code
4151

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
32,745

Shareholding by Type of Investor (Number)



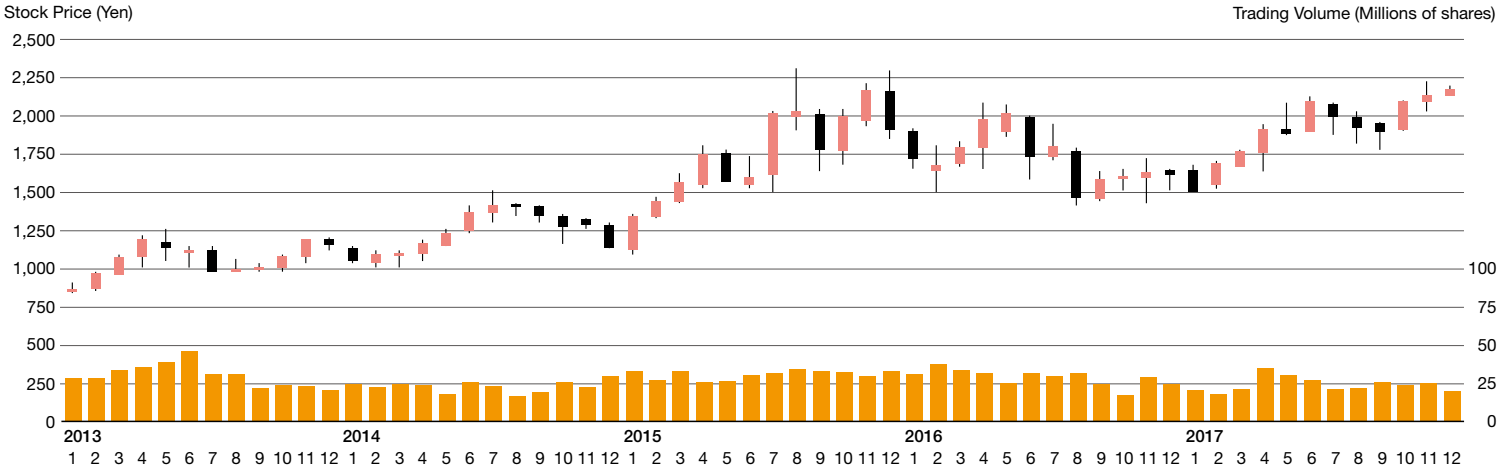
Principal Shareholders

(As of December 31, 2017)

	Number of Shares Held (Thousands)	Percentage of Total Shares Issued (%)
Kirin Holdings Company, Limited	288,819	50.10
The Master Trust Bank of Japan, Ltd. (Trust Account)	34,451	5.98
Japan Trustee Services Bank, Ltd. (Trust Account)	18,397	3.19
The Norinchukin Bank	10,706	1.86
Mizuho Trust & Banking Co., Ltd. (Retirement Benefit Trust for Mizuho Bank, Ltd.)*	6,809	1.18
JPMorgan Chase Bank 385147 (Standing Proxy: Mizuho, Ltd., Settlement & Clearing Services Division)	6,291	1.09
Japan Trustee Services Bank, Ltd. (Trust Account 5)	4,777	0.83
State Street Bank West Client-Treaty 505234 (Standing Proxy: Mizuho, Ltd., Settlement & Clearing Services Division)	4,551	0.79
Japan Trustee Services Bank, Ltd. (Trust Account 7)	4,169	0.72
Nomura Trust and Banking Co., Ltd. (investment account)	3,566	0.62

※The 29,176,451 shares (5.06%) held by the Company as treasury stock are excluded from the above because treasury stock has no voting rights.
* 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.

Stock Price and Trading Volume



Network*

(As of December 31, 2017)

Name of Company	Percentage Owned Directly or Indirectly by the Company	Share Capital (1,000)	Principal Business
PHARMACEUTICALS			
Japan			
Kyowa Medex Co., Ltd.*	100.00%	¥450,000	Manufacturing and sales of diagnostic reagents
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	Generating 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.)
Europe			
Kyowa Kirin International plc	100.00%	£13,848	Supervision and management of specific subsidiaries (U.K.)
Strakan International S.A.	100.00%	£9,720	Sales, licensing-in and licensing-out of pharmaceuticals (U.K.)
Kyowa Kirin Pharmaceutical Development Limited	100.00%	£501	Development of pharmaceuticals (U.K.)
Kyowa Kirin Limited	100.00%	£6,951	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%	€110	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%	£542	Supervision and management of specific subsidiaries (U.K.)
Kyowa Kirin Services Ltd	100.00%	£0.1	Sales and development of pharmaceuticals (U.K.)
Archimedes Pharma UK Limited	100.00%	£77	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 Hakko Kirin (Singapore) Pte. Ltd.	100.00%	SG $1,000	Sales and research of pharmaceuticals (Singapore)
Kyowa Hakko Kirin (Malaysia) Sdn. Bhd.	100.00%	RM 1,000	Sales of pharmaceuticals (Malaysia)
Japan (Equity-method affiliate)			
FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.	50.00%	¥100,000	Development, manufacturing and sales of biosimilar pharmaceuticals
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 2,000	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)

※All of the companies listed are consolidated subsidiaries, except FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. which is an affiliate accounted for using equity method.
* On January 4, 2018, the Company transferred 66.6% shares of consolidated subsidiary Kyowa Medex Co., Ltd. to Hitachi Chemical Company, Ltd.

Corporate Data (As of December 31, 2017)

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: http://www.kyowa-kirin.com/

Number of Employees
4,025 (Consolidated: 7,532)

Date of Foundation
July 1, 1949

Paid-in Capital
¥26,745 million

Principal Plants

Domestic

Pharmaceuticals
Takasaki Plant
Ube Plant
Kyowa Medex Fuji 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

Domestic

Pharmaceuticals
Tokyo Research Park
Fuji Research Park
Bio Process Research and Development Laboratories
CMC R&D Center
Kyowa Medex Research Laboratories

Bio-Chemicals
Healthcare Product Development Center
Bioprocess Development 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.
Kyowa Hakko Kirin (Singapore) Pte. Ltd.

Management Members (As of March 23, 2018)

Board Members

Representative Director,
Chairman and Chief Executive Officer
Nobuo Hanai, Ph.D.*1

Representative Director,
President and Chief Operating Officer
Masashi Miyamoto, Ph.D.*1

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

Director of the Board,
Managing Executive Officer
Yutaka Osawa
Vice President, Head,
Production Division

Directors of the Board
Noriya Yokota
Yoshiko Leibowitz*2
Kentaro Uryu*2

*1 Concurrently serves as executive officer
*2 Outside director

Company Auditors

Full-time Company Auditors
Akira Shimizu*3
Hiroshi Komatsu

Company Auditors
Motoyasu Ishihara
Jun Arai*3
Yuji Inoue*3

*3 Outside company auditor

Executive Officers

Managing Executive Officers

Yutaka Ouchi
Director,
Human Resources Department

Hiroshi Sugitani
Vice President, Head,
Sales & Marketing Division

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

Executive Officers

Kazuyoshi Adachi
Vice president, Head,
Pharmacovigilance and
Quality Assurance Division

Takashi Oishi
Director,
Medical Affairs Department

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

Niro Sakamoto
Director,
General Affairs Department
and Corporate
Communications Department

Tamao Watanabe
Director,
Business Development
Department

Wataru Murata
Director,
Corporate Strategy &
Planning Department

Yukihiro Noda
Director,
Nagoya Branch
Sales & Marketing Division

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

Shinichiro Mohri
Director,
Corporate Quality
Management Department

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

Nobuyuki Tsukahara
Director,
Tokyo Branch
Sales & Marketting Division

Takeyoshi Yamashita, Ph.D.
Director,
Regulatory Affairs Department

Chikakuni Kotani
Director,
Overseas Business
Department

Motohiko Kawaguchi
Director,
Accounting Department

Yasuo Fujii
Director,
Business Development
Department

Ryutaro Shimazaki
Vice President, Head,
R&D Division & Director,
Nephrology R&D Unit &
Deputy Director, Nepurology
R&D Unit Management Office