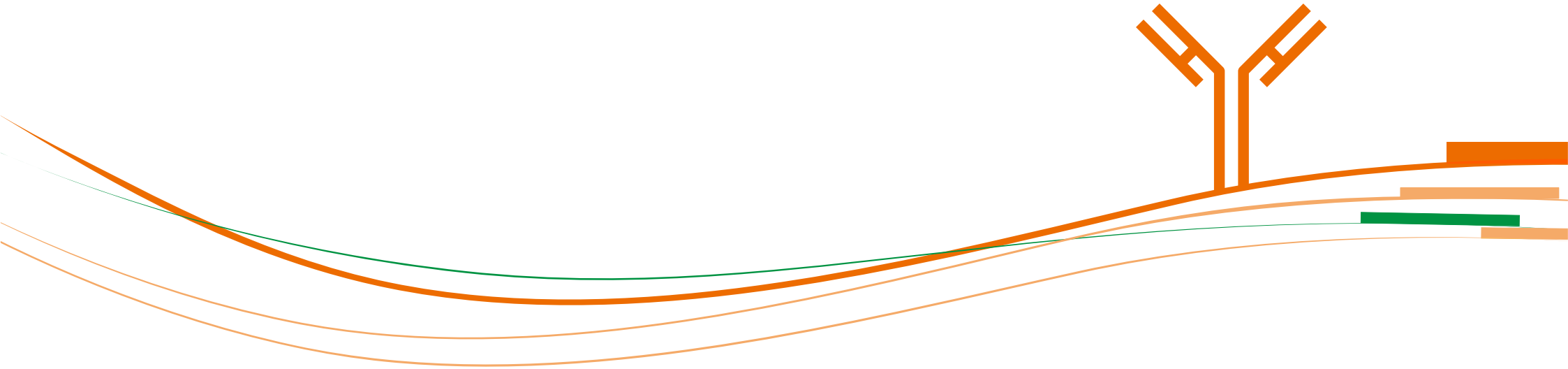
KYOWA KIRIN

Annual Report 2016

For the year ended December 31, 2016



Leaping Forward

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Editorial Policy

This is our Annual Report for 2016. The environment surrounding the pharmaceuticals industry is rapidly changing, and there is a movement to dramatically revise the framework that has underpinned the industry thus far. Despite this environment, “human resources” and “technology” will continue to be the baseline for innovation at Kyowa Hakko Kirin Group, which aspires to realize health and well-being. In the special features, we describe our human resource development that is promoting our globalization and our production technology for biopharmaceuticals. Please deepen your understanding of our group, which is taking initiatives to make the leap forward to become a Global Specialty Pharmaceutical Company (GSP).

Niro Sakamoto,
Executive Officer, Director 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

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

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

Concerning the Scope of This Report

This report covers Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries in Japan and overseas, as well as certain non-consolidated subsidiaries and affiliates. Environmental data is annotated for the convenience of readers. The reporting period includes calendar year 2016 and part of 2017.

Performance Forecasts

Forecasts contained in Annual Report 2016 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); Kyowa Medex Co., Ltd. (Kyowa Medex); Kyowa Pharma Chemical Co., Ltd. (Kyowa Pharma Chemical).

Numerical Data

Amounts in this report are rounded down. As a result, the sum and breakdown of data may not equal the totals.

Our Philosophy

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 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 Kyowa Hakko Kirin Group.

Kyowa Hakko Kirin Group

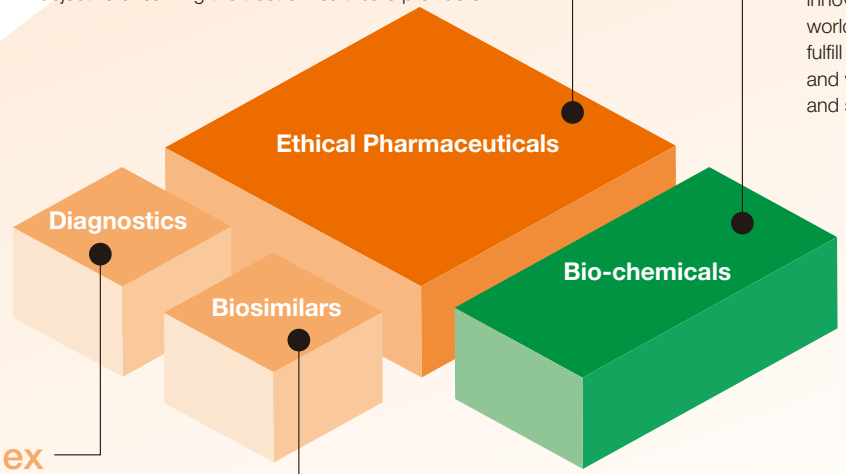
The Kyowa Hakko Kirin Group has advanced unique research with its sophisticated technology in the business fields of “pharmaceuticals” and “bio-chemicals” while developing and providing various high-quality products. The field of biotechnology offers immense possibilities. As a representative life science 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 cares.

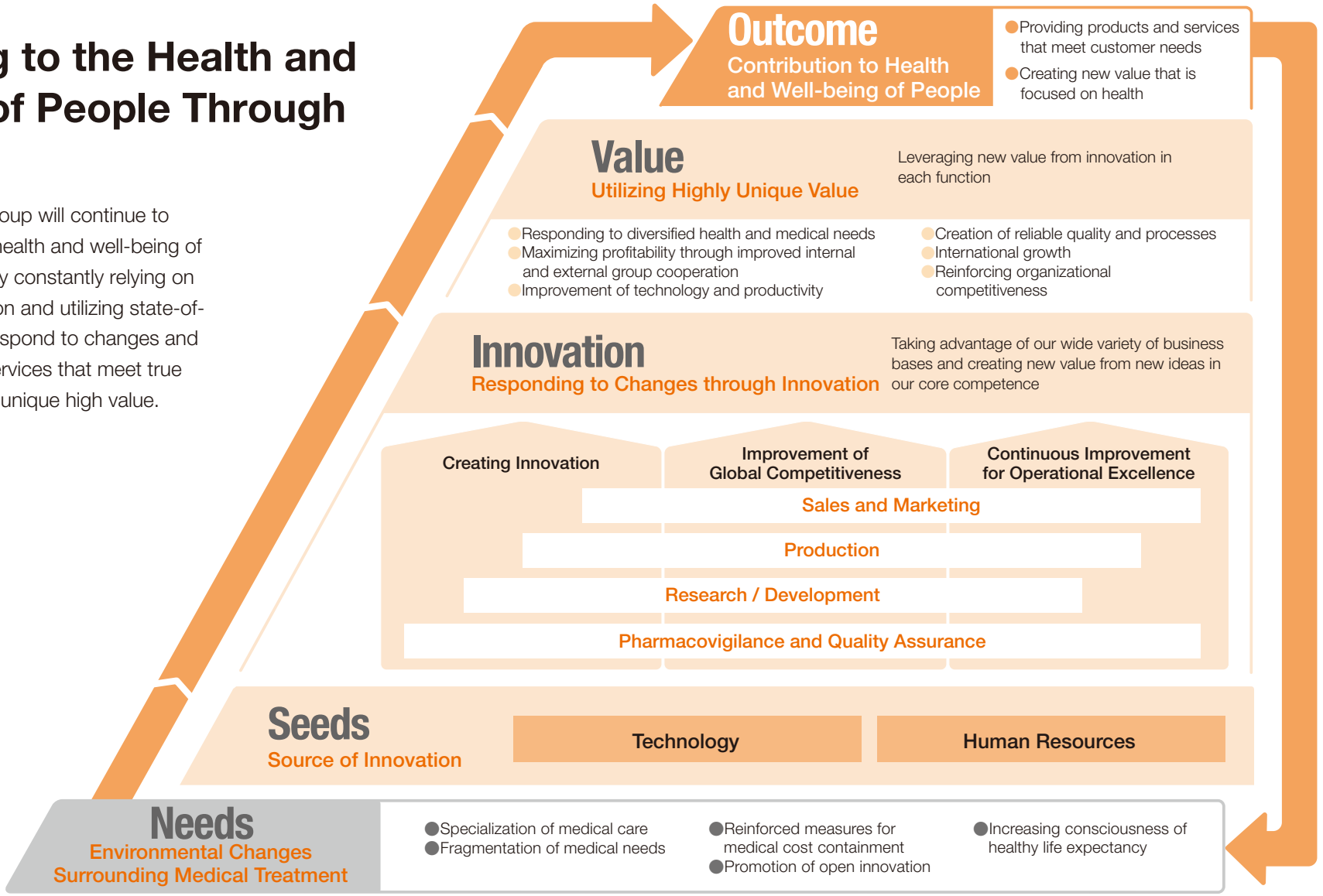
Fujifilm Kyowa Kirin Biologics

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

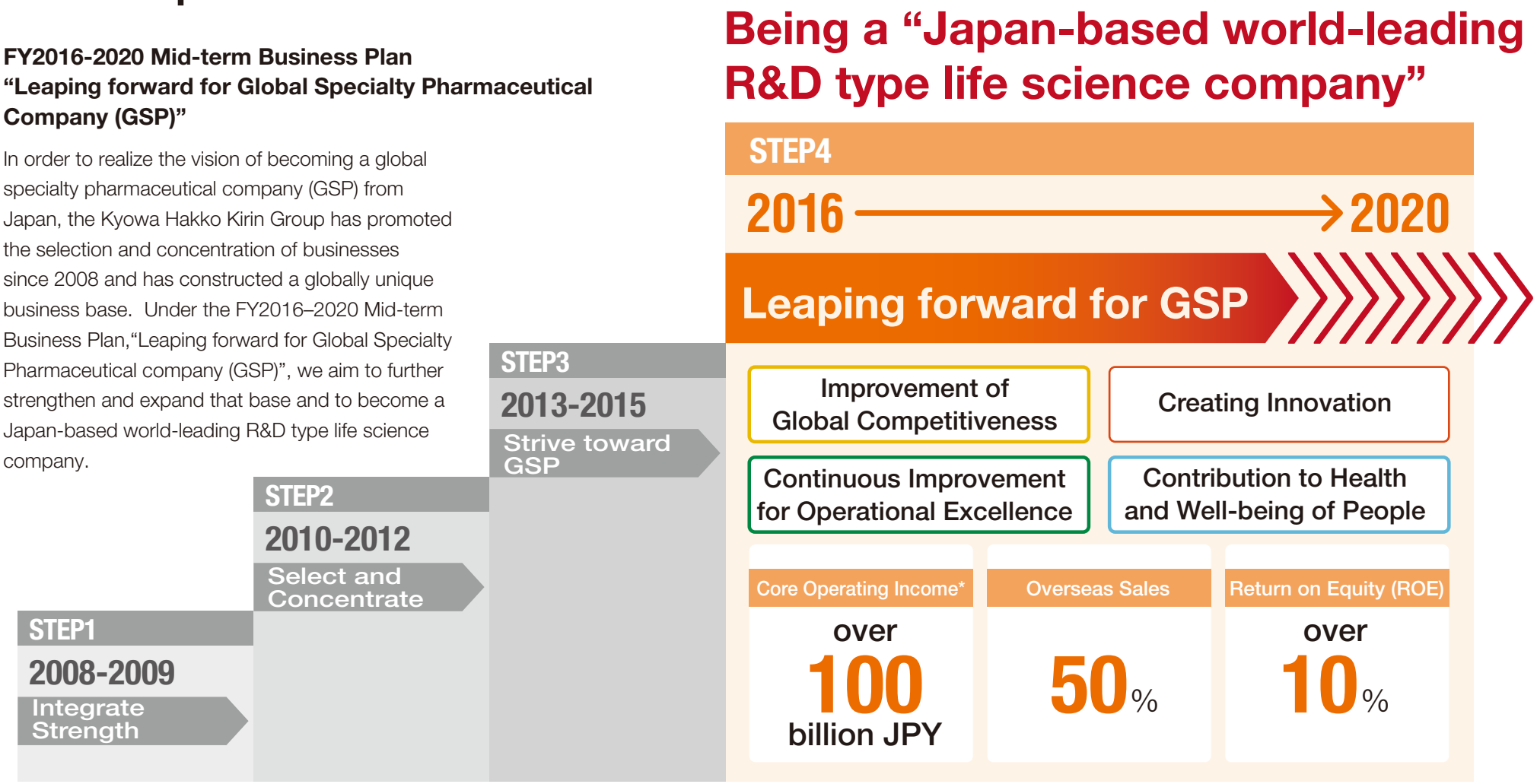
The Kyowa Hakko Kirin Group will continue to contribute strongly to the health and well-being of people around the world by constantly relying on innovation as our foundation and utilizing state-of-the-art biotechnology to respond to changes and rolling out products and services that meet true customer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



* Operating Income + Amortization of goodwill + Share of profit/loss of entities accounted for using equity method

Top Message

We have gotten off to a good start in leaping forward for GSP

2016 was the first year of our FY 2016–2020 Mid-term Business Plan. With our technological innovation capability, we are increasing our presence in European and the U.S. market through proactive investment in new drug development. With a single mind, we at Kyowa Hakko Kirin Group will take steady steps to achieve our leap forward to becoming a Global Specialty Pharmaceutical Company (GSP).

Nobuo Hanai

President and CEO

External Environment Until 2020

Aspiring to achieve our goals by discerning unstable social conditions and risk factors

Many unexpected events occurred around the world in 2016, such as the U.K. leaving the EU and the outcome of the presidential election in the U.S. As a company pursuing globalization, it is necessary that we reliably assess these environment changes.

In Japan, due to the aging population, decreasing birthrate and the increase in latter-stage elderly, the social security cost has become an issue. The movement to suppress medical cost is accelerating. Although Japan's drug price system was relatively stable until now, we may see dramatic reforms being made.

As a company that invests a great deal of time and money in new drug development, we are being called on not only to create value from our products but to create social value as a pharmaceutical company.

Until now, we have continued to meet the needs of each patient through our innovative new drugs. We also aspire to understand the diverse needs of society and continue to pursue innovation.

Looking Back on Our Performance in 2016

As the 1st year of the Mid-term Business Plan, we have made a good start

In Japan, we have continued to launch new drugs for the past several years. We proactively developed sales with a focus on new drugs in 2016, and achieved the performance that we originally expected.

As for overseas, we developed our business in Europe as Kyowa Kirin International plc, and began sales of our new drug Moventig® for the treatment of opioid-induced constipation from 2016. Our business in Europe is steadily growing.

In the U.S., to leap forward to become a Global Specialty Pharmaceutical Company, we plan to expand our business by launching global strategic products.

In Asia, we are ahead of budget overall and are making steady progress.

Overview of FY 2016–2020 Mid-term Business Plan

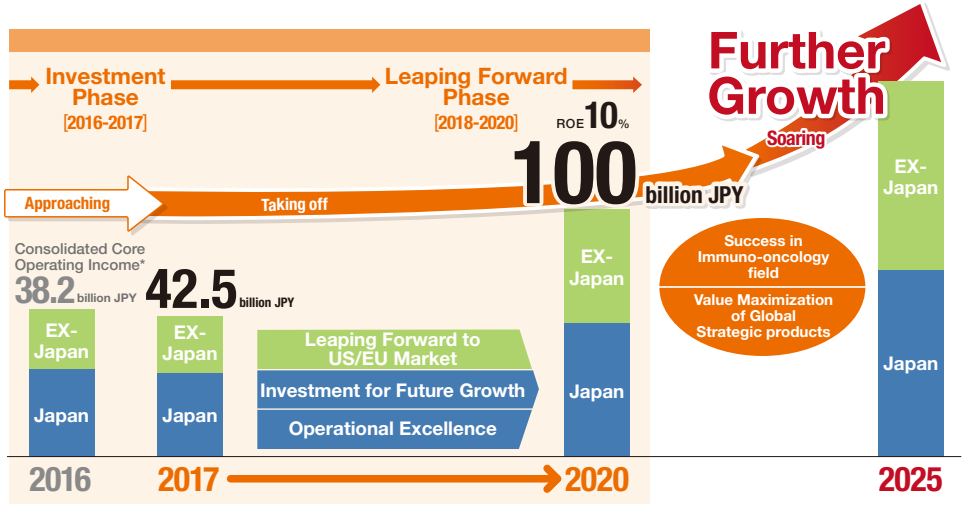
Achieving dramatic growth based on four strategic pillars

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)



* Operating Income + Amortization of goodwill + Share of profit/loss of entities accounted for using equity method

Improvement of Global Competitiveness

We will pursue global development with the Kyowa Kirin brand

As a R&D-oriented company, we achieved a major milestone with our original pipeline in 2016. Important development products for our future revenue stream include two antibody drugs, KRN23 for the treatment of X-linked hereditary hypophosphatemia (XLH)*1, and Benralizumab (KHK4563) for the treatment of asthma and chronic obstructive pulmonary disease.

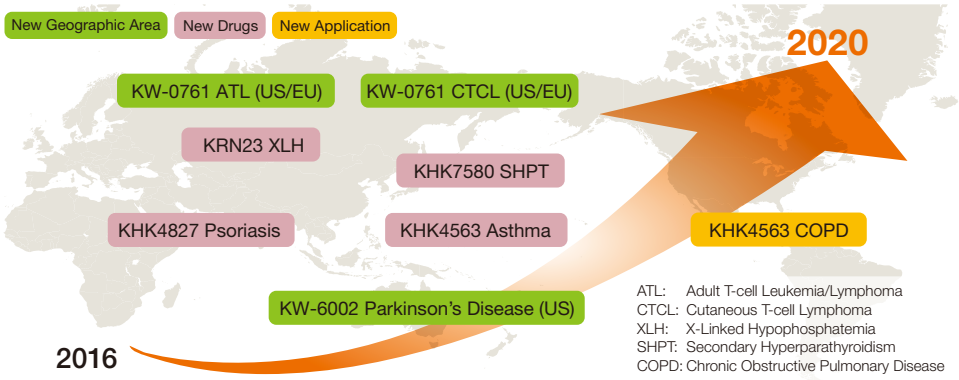
Although KRN23 is a product under joint development with Ultragenyx Pharmaceutical Inc. (Ultragenyx), we are capable of making sales and profits as our original brand drug. We have already entered into an agreement with AstraZeneca for the commercialization of Benralizumab (KHK4563), from which we expect large technology licensing revenues in the future. Good results have been achieved in late-stage clinical trials for these two development products. They are planned to be marketed on schedule, and we expect to achieve a 50% overseas sales ratio by 2020.

In 2016, to promote awareness of the brand around the world, we unified the corporate names of our pharmaceutical subsidiaries in Europe and the U.S. to “Kyowa Kirin.” As a company producing new drugs, we are preparing a global system for development, manufacturing, and sales by ourselves.

In 2017, we will proceed with development of a global supply system and enhance our pharmacovigilance system. In the U.S., we also plan to enhance our sales network in accordance with the new product launch strategy.

*1 XLH is a rare disease caused by excessive levels and activity of phosphatidic hormone FGF23 due to an abnormal PHEX gene on the X-chromosome. Hypophosphatemia results from phosphate wasting in the urine leading to bone growth and maintenance disorders and decline in QOL.

Major Pipeline Drugs Targeted for Approval



Creating Innovation

Meeting society's demands through in-depth development of our core therapeutic categories and pursuing advanced technologies

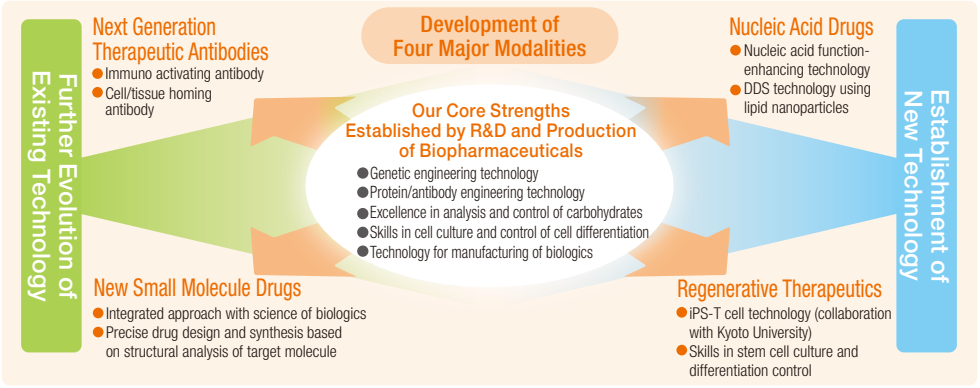
In this Mid-term Business Plan, we are deeply focusing on our four core therapeutic categories: nephrology, oncology, immunology & allergy, and central nervous system. We will pursue product strategies with therapeutic antibodies drugs and biopharmaceuticals, which are our core competence.

Our company possesses an R&D division dedicated to drug discovery technology and the Bio Process Research and Development Laboratories specialized for the process development of biopharmaceuticals. We are assembling excellent human resources and making efforts to enhance our R&D and production technology.

As the drug development process normally takes 15 years or more, it is inappropriate to slavishly pursue the latest trends. Researchers who can focus on future needs, and a corporate culture that can produce innovation are essential. We are cultivating a culture that can apply the ideas and sensibilities of our young scientists; this is the driving force behind our research and development.

On the other hand, discovering innovative drug candidates also requires support from outside the company. From the research stage, we will pursue new drug research and development together with universities, hospitals, and venture companies. We feel that promoting such joint research and open innovation is important. We have also begun developing new technologies such as nucleic acid drugs*2 and regenerative therapeutics. We are now at a stage of producing results from our research and development in nucleic acid drugs. In the field of regenerative therapeutics, we are conducting research into cancer immunotherapy*3 jointly with Kyoto University's Center for iPS Cell Research Application. We aspire to develop these areas into one pillar of our future resarch and development.

Utilization of open innovation and development of four major modalities



*2 Nucleic acids such as DNA and RNA are bound to macromolecules within the body to treat and prevent associated diseases.
*3 Therapies that attempt to destroy cancer cells by controlling the body's autoimmune system.

Continuous Improvement for Operational Excellence

Developing a business system to meet the requirements of a community health initiative and medical cost containment

Our group continues to improve its business processes to realize efficient asset management and to make proactive strategic investments. One of these activities is the reinforcement of organizations and functions according to the business environment changes in Japan.

In 2015, the Japanese government drew up a community health initiative to prepare for a future super-aging society. This plan sets out our aspiration to build a medical care provision system to meet actual regional conditions based on estimated healthcare requirements.

To respond to these changes in the business environment, effort for sales activities to meet the requirements of a medical care provision system that divides the country into regions called Secondary Medical Area will be necessary. By the end of 2016, our pharmaceutical business reorganized the 154 sales offices that we possessed in 2015 into 114 sales offices based on Secondary Medical Area. In 2017, we will switch over from hospital-based sales strategies to area strategies, and further accelerate our activities to contribute to regional healthcare. At the same time, we will pursue initiatives to raise the quality of MR activities to deliver accurate information to doctors.

In the bio-chemicals business, amino acids business for infusion feeding is doing well in Europe and the U.S., but this business tends to be greatly affected by exchange rate fluctuations. To lessen the impact of such exchange rate fluctuations, we are pursuing overseas production by possessing plants in Missouri, U.S., Shanghai, China, and Thailand. We plan to strengthen our production system such as through the expansion project of the Thai Plant, and will continue to expand our global business.

Contribution to Health and Well-being of People

Providing value to society through CSV management based on our distinctive business foundation

The business of Kyowa Hakko Kirin Group is to address social issues in the fields of pharmaceuticals, medical treatment, and healthcare. In contributing to CSV*4, to which Kirin Group aspires, we will strive to realize health and well-being of people in our business areas.

The business environment surrounding us is changing dramatically. Society will not fully respect us as a pharmaceutical company if we simply produce drugs to treat illnesses. It is important that we reliably discern from the perspective of CSV what kinds of social issues we should be solving, and what society is requesting us to do.

To this end, we must never cease evolving. CSV management will play a key role as a compass pointing the way in our evolution. It is clear that the mission for a

pharmaceutical company is to create and provide drugs for the patients' health. However, it will not truly be CSV unless we think in more depth about how to raise the patients' Quality of Life (QOL), in addition to focusing on the patients' recovery from illness. We will pursue CSV management thinking not only about each patient, but about what kind of value we can provide to society.

For example, in addition to responding to society's demands to suppress medical cost, we hope to expand the market of biosimilar business in which our company's high-level antibody production technology will play a key role. Our Adalimumab biosimilar, which shows high efficacy in the treatment of rheumatoid arthritis, has produced good results in phase III clinical trials, and we are aiming for new drug application in Europe and the U.S. in 2017.

*4 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.

CSV to which Kyowa Hakko Kirin Group aspires

CSV: Creating Shared Value
POCT: Point of Care Testing
OTC: Over the Counter

Improving Corporate Value

Pursuing activities to share our Core Values among employees and human resource development

Kyowa Hakko Kirin Group's corporate value is expressed by our management philosophy, 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." We have conceived our current Mid-term Business Plan and CSV management to realize this management philosophy.

In order to instill this philosophy within the whole group as our shared understanding, we need to push ahead with our work on the basis of "Core Values." So, in October 2016, we designated "Commitment to Life" as our group-wide "Core Values" and determined three keywords to put our "Commitment to Life" into practice: Integrity, Innovation, and Teamwork/Wa. "Commitment to Life" is a phrase that expresses our mindset to perform work that is of value to human life, and daily living. For this purpose, we will create "Innovation" through group-wide "Teamwork/Wa." It is particularly important to have "Integrity." We will accord the highest priority to addressing rule compliance and quality assurance. In 2017, I engage in activities that will allow us to share these "Core Values" as a group.

The source of these activities is "people." We must secure excellent human resources to continue providing new drugs through innovation. As we pursue globalization, the number of employees of diverse nationalities is also increasing in Japan and 11 of such employees are working with us.

Creating a corporate culture in which employees can energetically perform their work is also important. For this purpose, We endeavor to build a workplace environment in which each person will find it easy to work. We changed the office into a free address system (employees are free to change their seat) at the same time of our Head Office relocation in July 2016. By getting rid of the partitions that we had at our former office building, associations and communication among employees have increased, leading to information sharing and enhanced "Teamwork/Wa."

Taking this opportunity to introduce working style reforms and by promoting smart work*5, I hope to raise our efficiency so that we are more productive. Beginning at the Head Office, we will proceed to fully instill these practices at each facility, sales office, and laboratory.

*5 Smart work refers to having increased awareness to work efficiently and manage time appropriately, and for each workplace and employee to take small steps toward their goals even within a busy work schedule.

Message to Stakeholders

Pressing ahead with take-off preparations

In 2016, we took our first step in our leaping forward for Global Specialty Pharmaceutical Company. I am going to exercise strong leadership with a long-term perspective and through bold navigation so that we will prepare for take-off.

I ask our stakeholders to have great long-term expectations for Kyowa Hakko Kirin Group's leaping forward to become a Global Specialty Pharmaceutical Company.

Special Feature1

Developing human resources who can exercise leadership and take on the challenge of reforms

In making the leap forward to become a Global Specialty Pharmaceutical Company (GSP), we must cultivate a highly productive organizational climate that stimulates innovation. To develop human resources who will be the source of this productivity and innovation, we will prepare detailed training programs according to rank and purpose and build a framework for strategic human resource assignment and development that cuts across countries and regions.

Managing Executive Officer
Director of Human Resources Department
Yutaka Ouchi

Four points of focus in human resource development

As globalization rapidly proceeds and environmental changes become more acute, human resources who can exercise leadership and enable innovation will be indispensable. Leaders are required who have a broad range of interests and areas of concern, apart from their own area of specialism, and who can provide insight on current affairs, make decisions and follow through on them with a sense of momentum. We hope to foster leaders of Kyowa Hakko Kirin Group for the next generation.

Upgrade the training system to spur growth

We are currently endeavoring to enhance our training program. We are undertaking multilateral initiatives such as training according to rank, training to develop female managerial staff and executives, and global training to develop human resources who can participate actively in Japan and overseas.

For example, global training involves selecting staff members from around the world including Japan, and all aspects are conducted in English, including the presentation of results. Through such training, we are developing global human resources who can create strategies on their own, implement them, and exert leadership to promote change.

We are also engaged in initiatives to develop female management staff with a managerial perspective, and in future management training we plan to incorporate the perspective of “workstyle reforms” such as conducting “smart work,” which making how work more efficient and productive.

Aim for strategic human resource development

To seamlessly develop next-generation managerial staff from the time they are around 30 years of age, we have begun considering a strategic human resource plan. We will introduce a talent management system to systematically train and transfer (OJT) staff utilizing information on employee ability and amount of experience.

In recent years, we have been proactively hiring foreign employees with a focus on China and Asia. Our plan is to discover core human resources not only in Japan but in Europe, the U.S. and Asia, and to cultivate human resources who will be involved in management across borders.

We plan to focus on cultivating English ability, which is indispensable for employees who will play a global role in a company aspiring to become a GSP. KHK Headquarters has started a unique initiative called the GSP Step Up Project*. Through such ongoing activities, we will promote system-building to enable more diverse human resources to play active roles within the company.

* A program that involves voluntary participation by employees who need to use English in their everyday work duties or who wish to raise their English abilities. The purpose of this program is to raise communication skills by providing staff with diverse opportunities to apply their English abilities.

Human resource development program

	Training by rank	Developing female staff	KHK School Program through appointment/ public advertising	Self-development
Management level	Management training	Management training	Global training	Self-development support
General staff level	Training by rank / Training by position	Kirin Group training / Leadership training	Strategic training / Overseas dispatch program	Kirin challenge

Special Feature1

Involvement in human resource development by all companies

Kyowa Hakko Kirin Group aspires to develop human resources strategically in order to foster next-generation leaders. Business divisions and group companies are proactively promoting initiatives in line with their respective requirements, training systems, and human resource plans.

Research and Development

Provide opportunities to participate actively for young employees

Discussion by young employees and ODDO* members.

To support globalization of R&D including international collaboration research and global clinical trials, opportunities for the young employees are offered; for example, to attend overseas academic conference, to study at college/university outside Japan, to work in US, EU or Asia. We also design and conduct English training courses in Japan.

In the English training courses, attendees are granted with a chance to communicate and discuss R&D-related topics with the experts of overseas subsidiary companies.

* One Drug Development Organization (ODDO): A functional organization which unifies KHK's new drug development operations in Western countries.

Production

School Opened for Takasaki Plant and Bio Process Research and Development Laboratories

We have opened a school taught by experienced employees to transmit the theory behind manufacturing biopharmaceuticals, knowledge on reliability assurance, and high-level skills and know-how. We are developing human resources endowed with both knowledge and skills so that this will lead to the manufacture of high quality products.

Staff attending lectures

Pharmacovigilance (PV), Quality Assurance (QA) and Regulatory Affairs (RA)

Develop professionals responsible for the global system for safety, quality and regulatory affairs

We are intent on developing professionals who will be responsible for maintaining and improving our global PV and QA system. To this end, we hold annual PV, QA and RA workshops with attendance by personnel in charge at overseas subsidiaries, dispatch and station staff at overseas subsidiaries, and enable staff participation in various society activities.

PV, QA and RA Workshop 2016

Overseas Business

Develop human resources who can play active roles on the global stage by promoting personnel exchange with subsidiaries

We are promoting personnel exchange with overseas subsidiaries to develop human resources required for the global development of our business. As an example, Esther (shown in photo) transferred to Headquarters from Hong Kong in 2014, and has been involved in formulating Asian product marketing and implementing some measures as Product Manager.

Kyowa Medex

Developing human resources to meet the demands of globalization

Kyowa Medex carries out training to enable its human resources to respond to the needs of globalization. Since 2016, we have started Global Mindset Training to raise awareness and skills to promote our global business.

Subsidiary in Shanghai

Domestic Sales

Emphasis on communication skills and problem-solving abilities

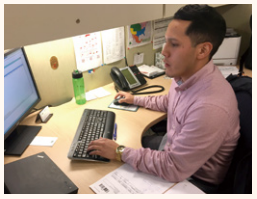
Sales Headquarters is focusing on developing human resources to raise communication skills and problem-solving abilities. Domestic sales staff who have been active in frontline sales are applying their skills over a broad range such as at other divisions and at overseas subsidiaries.

Area Team Leader Practicum Training

Kyowa Hakko Bio

Fostering borderless next-generation leaders

Kyowa Hakko Bio is engaged in cultivating next-generation leaders with a global outlook who are not limited by the divide between Head Office and overseas subsidiaries. Presently, several candidate leaders from overseas subsidiaries have been invited to Head Office where they are learning about management with a global perspective through participation in work relating to group strategy.



New York employee reading documents on Japan before being transferred there

Stable supply of high quality biopharmaceuticals through world-class production technology

As Bio Process Research and Development Laboratories and Takasaki Plant are situated next to each other, they are using this to their mutual advantage by conducting the world's best biologics research and production. We are working together to provide superior products to the people of the world.

Revolutionary antibody production technology to raise the action of antibodies

Biopharmaceuticals make use of biological molecules such as proteins possessing complex structures from which minimal adverse reactions and high efficacy can be expected. In an antibody drug, the main drug component is the antibody, which is the main player in an organism's immune system. Antibody drugs make use of the specificity of an antibody to recognize one target (antigen).

Antibody manufacturing technology possessed by Kyowa Hakko Kirin includes human antibody manufacturing technology utilizing mice, as well as POTELLIGENT® and COMPLEGENT® technology, which raise the action of antibodies.

Compared to ordinary antibody drugs, antibodies manufactured with POTELLIGENT® technology have been confirmed through animal tests, etc. to kill target cells such as cancer cells efficiently and demonstrate high antitumor efficacy. POTELIGEO® is the world's first antibody drug created using this technology and Takasaki Plant has succeeded in mass producing it.

The strengths of close cooperation between Takasaki Plant and Bio Process Research and Development Laboratories

Basic drug discovery research for biopharmaceuticals is conducted at the laboratories of R&D Division. As research proceeds and the development stage draws near, Bio Process Research and Development Laboratories are also participating in the R&D project to investigate the ways to manufacture high quality products efficiently. In the later development stage, manufacturing processes and analysis methods for commercial production are established in coordination with Takasaki Plant.

Four main factors are required in the production technology for biopharmaceuticals: 1) technology to build and culture cells that will efficiently produce the target protein; 2) technology to purify this protein; 3) technology to formulate it for use as a drug; and 4) analysis technology to verify its quality.

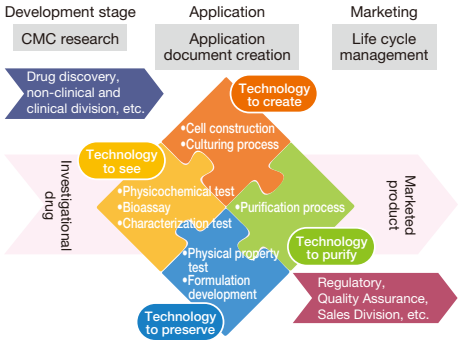
Bio Process Research and Development Laboratories combine state-of-the-art technology together with its proprietary technology and know-how that it has cultivated thus far to form the backbone of Kyowa Hakko Kirin's biologics production technology.

The results of this research and technology have been transferred to the Manufacturing section and Quality Control section of Takasaki Plant where they are being applied in the manufacture and quality control of investigational drugs and marketed products.

As Bio Process Research and Development Laboratories is located adjacent to Takasaki Plant, a great synergistic effect is achieved as the lab is able to receive prompt feedback from the manufacturing and quality control site.

Takasaki Plant

Factors in Biopharmaceuticals Production Technology



Special Feature2

Special Feature 2: Production Technology

Well-organized manufacturing control system and quality control system

Many of Kyowa Hakko Kirin's biopharmaceutical products are produced at Takasaki Plant such as NESP® and ESPO® for the treatment of renal anemia, and GRAN® for the treatment of neutropenia. This is where Kyowa Hakko Kirin's unique production technology has been developed over a 20-year span and continues to be transmitted and improved upon.

Takasaki Plant is equipped with well-organized manufacturing control system and quality control system. It is a state-of-the-art biopharmaceutical production plant in compliance with the international standard, Good Manufacturing Practice (GMP). It possesses a manufacturing line for investigational drugs and a manufacturing line for marketed products, and carries out production according to a quality policy that is consistent from development stage through marketed stage. From quality inspection of raw materials to the manufacturing process, quality test, and the final approval, the Manufacturing section, Quality section, and Quality Assurance section coordinate closely to realize stable supply of high quality pharmaceutical products.

Completed construction of a drug substance manufacturing building for biopharmaceutical products in August 2016

Takasaki Plant possesses many facilities for manufacturing drug substance and drug product. For drug substance, there are production facilities that utilize microorganisms and those that utilize animal cells.

In addition to the existing four buildings for animal cells, we further enhanced our manufacturing system by completing construction of a new drug substance manufacturing building for biopharmaceutical products (building HB6) in August 2016 for the purpose of expanding production capacity to meet increased future demand for therapeutic antibodies and the increased number of products. The HB6 building houses a genetically engineered animal cell culturing facility (12,000L culture tank), which is the largest class tank in Japan.

The HA5 building is a drug product manufacturing facility, which is capable of efficiently producing multiple drug products with a focus on biopharmaceutical injection products. Additionally, this sterile preparation manufacturing facility is a quake-absorbing structure, which is capable of production even during an earthquake.

These manufacturing facilities comply with GMP standards for Japan, the U.S., and Europe and are capable of supplying products globally. They represent the essence of our accumulated engineering know-how in biopharmaceutical manufacturing.

Our intention is to contribute to the health of people around the world through the stable production and supply of high quality biopharmaceutical products. Each person working at Takasaki Plant and Bio Process Research and Development Laboratories feels pride and fulfillment in undertaking this task.

Hereafter, we will proceed with initiatives to enhance our production and supply systems, which reflect our concern toward the environment and safety and will continue to be an entity that will meet the expectations of society.

Messages from the people in charge

Promptly delivering to patients the preparation design results that I had a hand in creating

Formulation Development, Bio Process Research and Development Laboratories, Production Division
Takahiko Ito

I am responsible for formulation development of biopharmaceuticals. To make a drug product, it is necessary to choose a suitable dosage form according to use, and design the formulation after sufficiently considering the properties of drug substance. Our work is to pursue R&D to provide a high quality and highly user-friendly drug product. Although solving issues is extremely difficult as the target product image and properties will differ for each drug, I can contribute to treatment by delivering to patients a product that is the results of the formulation development. This provides me with a sense of fulfillment for which there is no substitute.

Commitment to ensure quality and a spirit of inquiry toward stable production

Manufacturing, Drug Substance, Takasaki Plant, Production Division
Jun Hamamura

I am responsible for the drug substance manufacturing of antibody drugs. The quality of antibodies cannot be picked up and be confirmed by eye. However, it is precisely because quality cannot be visually confirmed that I have developed an appreciation for the depth of my work, which involves technology, knowledge, and much experience. Today, I feel pride in what I do as a person involved in monozukuri (making things). In the manufacture of pharmaceuticals, there are no absolute answers like, "it will be sufficient as long as we do this much." Commitment to ensure quality and a spirit of inquiry toward stable production are the real appeal for those responsible for manufacturing.

The last bastion to ensure drug quality before delivery to patients

Quality Assurance, Takasaki Plant, Production Division
Teruko Arai

I am responsible for the approval of marketed drug products and investigational drugs. In drug quality assurance, each process from the raw materials to the manufacturing process must be assessed and assured from numerous perspectives. From the development stages, a great many staff members are engaged day and night to bring a single drug to market. My job involves final judgment on the quality of drugs that have been developed with passion, manufactured and analyzed at Takasaki Plant before delivery to awaiting patients. It involves much responsibility and is worthwhile.

Topics

Important Topics of FY 2016

January

Release of KHB Arginine EX

Kyowa Hakko Bio released the new Arginine combination supplement “KHB Arginine EX” on January 15, 2016.

March

Operation of new product manufacturing facility in China

The construction of a new facility has been completed on the premises of Kyowa Hakko Kirin China Pharmaceutical Co., Ltd. as a part of restructuring our business operations for sustainable growth in China.

Selected as a Tokyo Leading Sports Promotion Company

Tokyo City selected us as a “Tokyo Leading Sports Promotion Company” in recognition of our interaction with the disabled and reconstruction support after the Great East Japan Earthquake through ping pong, and health promotion activities for employees, among others.

April

Unification of the “Kyowa Kirin” company name brand

We have unified our company name of all European pharmaceutical subsidiaries under one name, “Kyowa Kirin,” to become better recognized around the world as we proceed to develop our overseas business with the aim of leaping forward as a Global Specialty Pharmaceutical Company from Japan.

Received Commendation for Science and Technology by the Minister of Education, Culture, Sports, Science and Technology

We received this award in the Development Division for having greatly contributed to cancer therapy through development of novel antibody-based drug that applies our technology to increase antibody activity (POTELLIGENT®). We were co-recipients together with Professor Ryuzo Ueda of Aichi Medical University and Professor Kouji Matsushima of The University of Tokyo who have greatly contributed to the research and development of this drug.

We also received this award in the Understanding Promotion Division in recognition for our science education initiative for local young adults lead mainly by the Tokyo Research Park.

May

Awarded the FY 2015 Okochi Memorial Technology Prize

We were awarded this prize in recognition of discovering how a sugar called “fucose” in the sugar chain greatly affects antibody activity, developing a technology to artificially reduce fucose, and for applying this technology in several drug products.

June

Concluded agreement with Medgenics for the clinical development of anti-LIGHT monoclonal antibody

We have concluded the agreement with U.S. company Medgenics, Inc. for the clinical development of our first-in-class anti-LIGHT monoclonal antibody for Severe Pediatric Onset Inflammatory Bowel Disease (IBD).

U.S. Food and Drug Administration granted Breakthrough Therapy Designation for KRN23 for pediatric X-linked hypophosphatemia

Based on the interim analysis results of phase II trials targeting X-linked hypophosphatemia (XLH)*1 currently underway in the U.S. and Europe, KRN23, an investigational recombinant fully human monoclonal IgG1 antibody against the phosphaturic hormone fibroblast growth factor 23 (FGF23)*2, has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for the treatment XLH in pediatric patients one year of age and older.

*1 XLH is a rare disease caused by excessive levels and activity of phosphatidic hormone FGF23 due to an abnormal PHEX gene on the X-chromosome. Hypophosphatemia results from phosphate wasting in the urine leading to bone growth and maintenance disorders and decline in QOL.

*2 FGF23 is a polypeptide composed of 251-amino acids produced mainly from bone tissue, which acts on the kidneys, and by inhibiting reabsorption of phosphorus in the renal uriniferous tubules, its involvement is suggested in diseases such as X-linked hypophosphatemia, tumor-induced osteomalacia, and renal failure.

August

Completed of construction for the biopharmaceutical API manufacturing facility in the Takasaki Plant

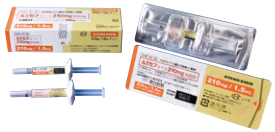
In order to meet the needs of production capacity with the increasing demand of antibody drugs and items in the future, Kyowa Hakko Kirin has completed the construction of the HB6 Plant in the Takasaki Plant.

September

Received highest assessment in the ERUBOSHI (ERUBOSHI means “L Star”. “L” stands for Lady, Labour and Laudable)

In recognition of our initiatives to promote the participation of women in the workplace, we 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.

Launch of LUMICEF® for psoriasis treatment, in Japan



LUMICEF® Subcutaneous Injection 210mg Syringe [generic name: Brodalumab (Genetical Recombination)] for approved indications including psoriasis vulgaris, psoriasis arthropica, pustular psoriasis, and psoriatic erythroderma was launched in Japan ahead of all other countries.

November

New release of KHB AminoStyle

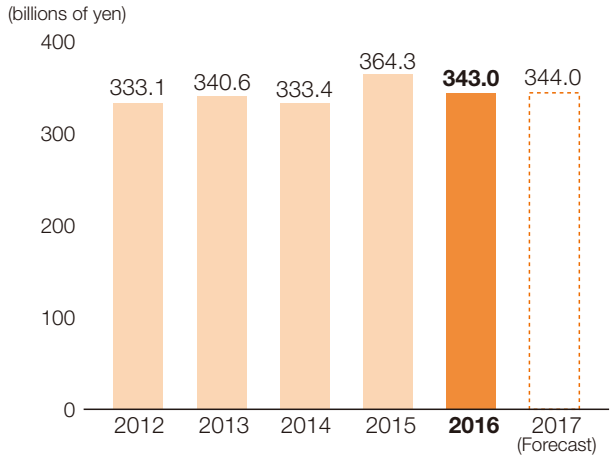
Kyowa Hakko Bio released the new AminoStyle, which contains 800mg of the health supporting amino-acid citrulline, following after its products containing amino-acid leucine 1,600mg, which is the basis for forming muscle, and the amino-acid valine 300mg and the amino-acid isoleucine 300mg, which support the activity of leucine.

January February March April May June July August September October November December

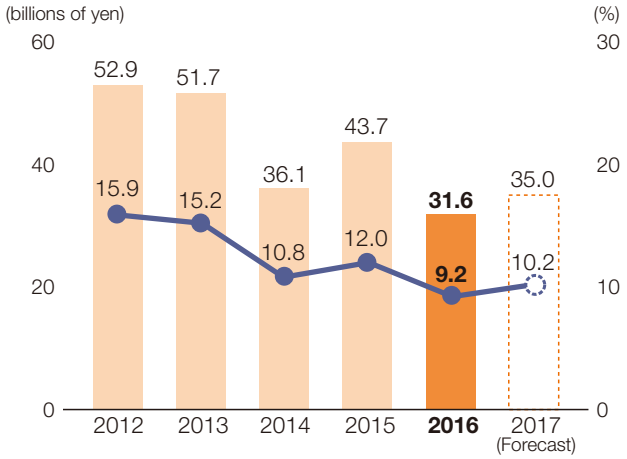
Financial & ESG Highlights

Financial Highlights (For the year ended December 31, 2016)

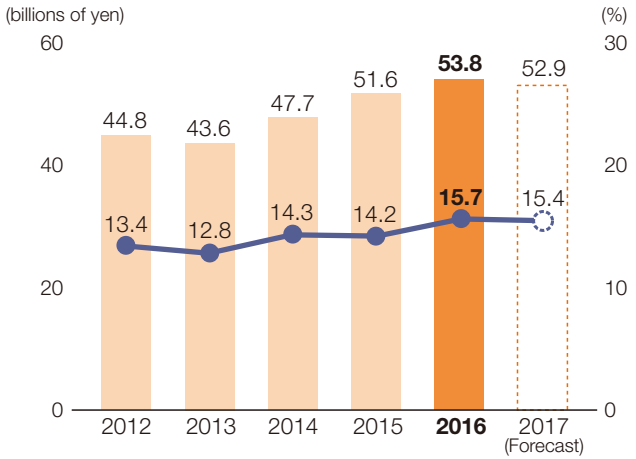
Net Sales



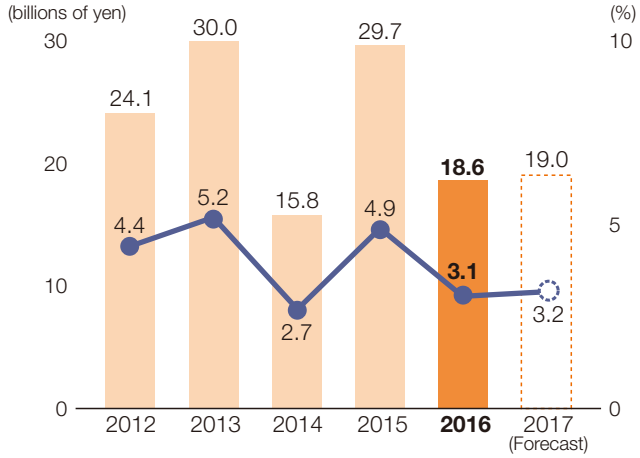
Operating Income/Operating Margin Ratio



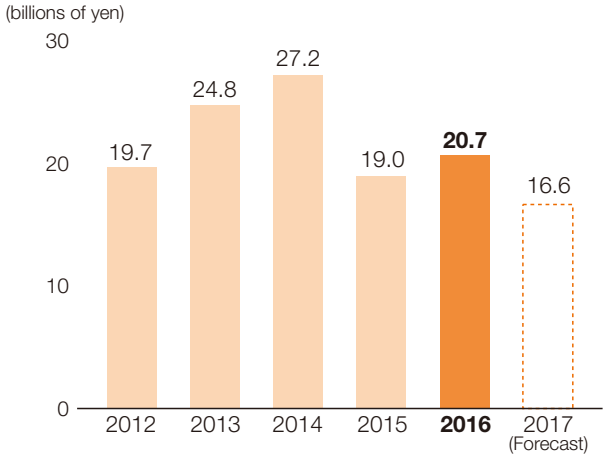
R&D Expenses/Ratio of R&D Expenses to Sales



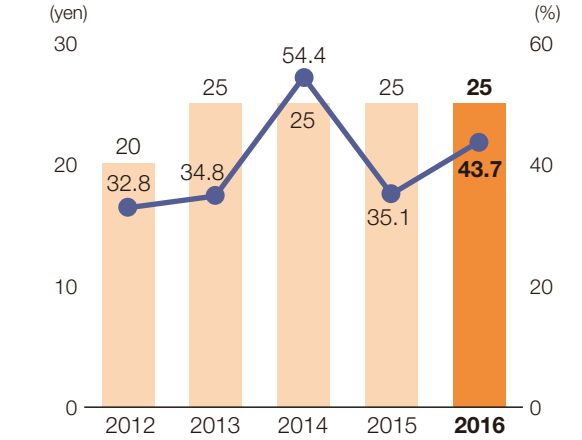
Net Income/ROE



Capital Expenditures (Only tangible assets)



Cash Dividends/Payout Ratio (before goodwill amortization)

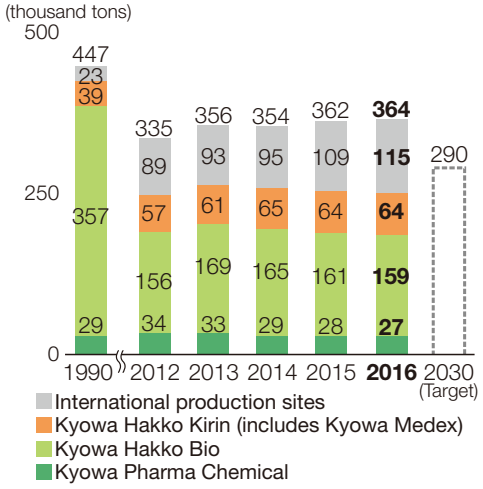


* The consolidated payout ratios for the period from the fiscal year ended December 31, 2012 to the fiscal year ended December 31, 2015 are calculated using net income before the deduction of amortization of the goodwill that resulted from the reverse acquisition in April 2008 (Kirin Pharma share transfer). The consolidated payout ratio for the fiscal year ended December 31, 2016 is calculated using net income before amortization of the entire goodwill.

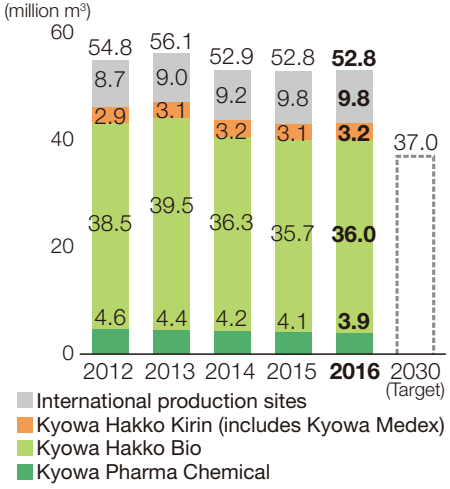
ESG Highlights

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. The domestic plants and research laboratories of Kyowa Hakko Kirin, Kyowa Medex, Kyowa Hakko Bio and Kyowa Pharma Chemical are covered.
4. In 2015, the final disposal volume increased by about 170 tons because of the malfunction of the volume reduction facilities of the disposal contractor. We have reviewed the method of disposal and decreased final disposal volume from the following year.
5. The number of fatal and lost time accidents per million working hours.
6. Data has been revised as worker's accident compensation applied in 2015 was confirmed.
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). Correction has been made due to an error in the data of 2015.

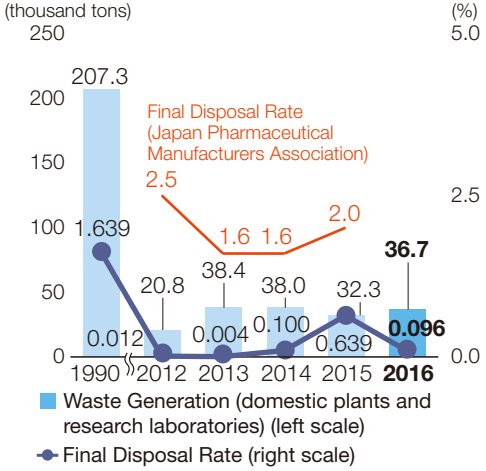
CO_2 Emissions [1,2]



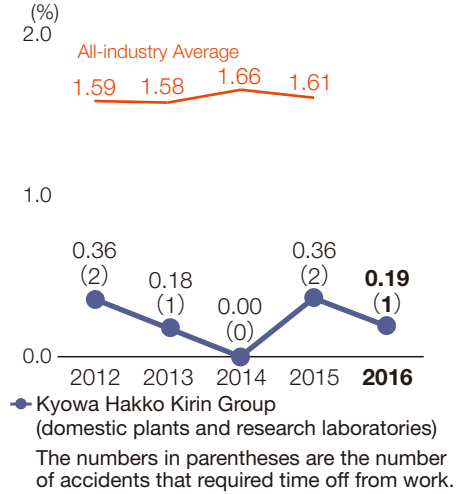
Water Use [1,2]



Waste Generation [2,3,4]

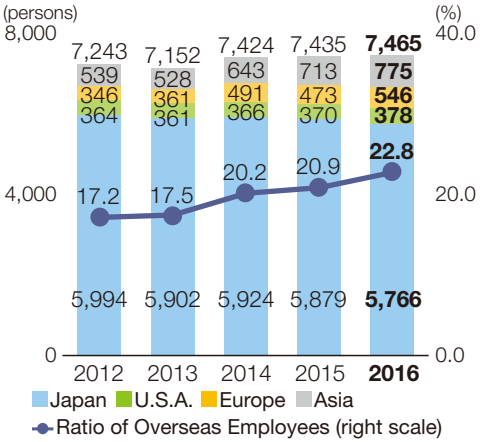


Accident Frequency Rate [2,3,5,6]

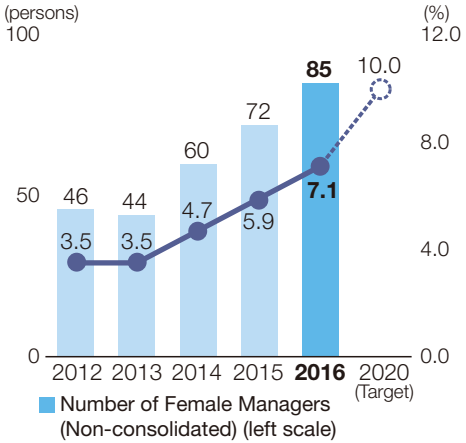


The numbers in parentheses are the number of accidents that required time off from work.

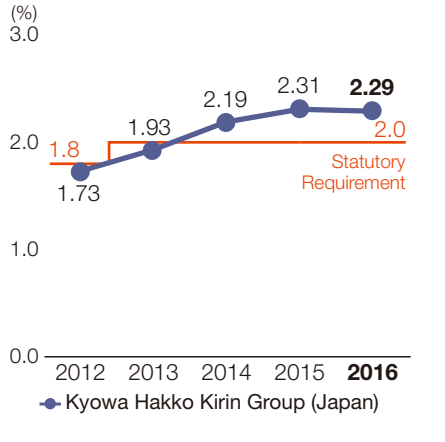
Number of Employees/ Ratio of Overseas Employees



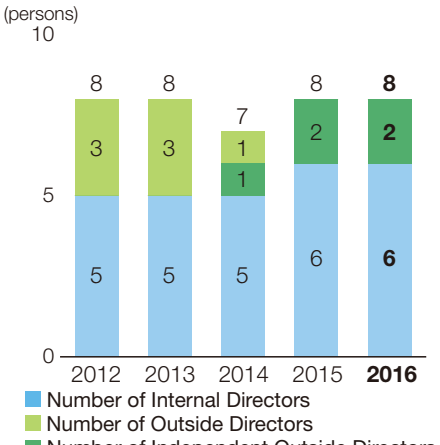
Number of Female Managers/ Ratio of Female Managers [7]



Ratio of Workers with Disabilities [8]



Number of Directors



Please see ESG Data Collection for details.
WEB

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

In making the leaping forward for a Global Specialty Pharmaceutical Company (GSP), we are steadily enhancing our business foundation such as by marketing new products and applying for approval in Japan and abroad.

◆Initiatives in FY 2016

Making a steady step toward becoming a GSP

While our domestic business was affected by the penetration of generic drugs and revisions of drug price, which accompanied policy measures to suppress medical costs, through focused allocation of our business resources on our major products and new drugs, sales of our mainstay product NESP® and new drug groups performed well. In September, we released our new product LUMICEF® in Japan ahead of all other countries, which enable us to provide a new option in psoriasis treatment.

In our overseas business, we took steps to penetrate the Kyowa Kirin brand into the market by unifying the company names of affiliates in Europe and the U.S., expanded our business area on the basis of the new release of Moventig® in the European market, and are enhancing our business foundation in preparation for the future marketing of our in-house products.

In the area of research and development, we are making progress in developing global strategic products (KRN23, KW-0761, KW-6002) positioned as key drivers for growth. Of these, KRN23, which we are jointly developing with Ultragenyx, was designated as a Breakthrough Therapy by the FDA in June, and we applied for approval with the European Medicines Agency (EMA) in November. We have also achieved important milestones with several products under development in Japan, as well as with the biosimilar drug FKB327 being developed in Europe and the U.S., and are raising expectations for our future growth.

In addition, we are preparing to leap forward to become a GSP such as by complying with the Corporate Governance Code and establishing governance to promote our global business.

Major products (pharmaceutical products)

◆Future Prospects

Aspiring to market and apply for approval our new in-house drugs in Europe and the U.S.

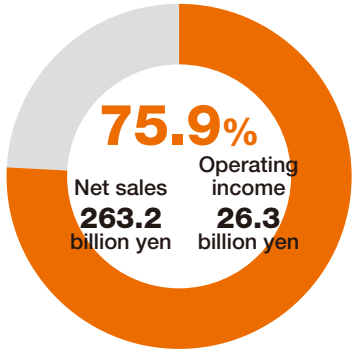
2017 will be a year in which we will make major strides to becoming a GSP Company, which include completing marketing preparations for KRN23 in Europe and applying for approval in the U.S., and plans to apply for approval for KW-0761 in Europe and the U.S.. While engaging in activities to maximize the value of each product, we will steadily promote the development of our pipeline in the field of immuno-oncology.

While aspiring for global growth, we will continue to focus on our domestic business that underpins our growth. We will promote our information provision activities to meet the needs of community health initiatives, and reinforce our presence in our core therapeutic areas.

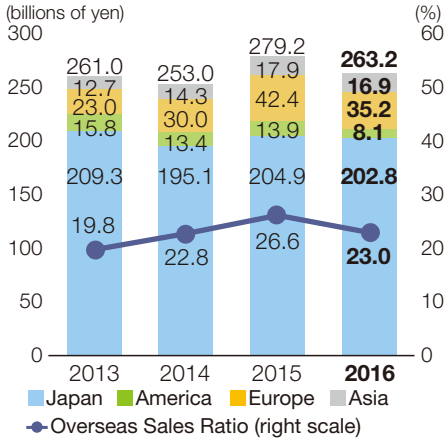
The restructuring of our production activities, which have been ongoing since 2010, will be completed within 2017, and we expect further improvement in productivity of the production technology which is our company's strengths.

Responding to the increase of social demand for medical cost containment, our biosimilar business, including FKB327, for which we plan to apply for approval in Europe and the U.S. in FY 2017, has been positioned as an important pillar of our company's CSV management, as well as providing the new value through the innovative new drugs. We are providing solutions to meet diversifying medical needs in this area.

Composition of sales in 2016



Pharmaceuticals Business Net Sales by Region



Pharmaceuticals Business | Research and Development

To bring the global strategic products on the market, and deploy drug discovery of value continuously, we keep on challenging in pursuit of the next innovation.

◆Initiatives in FY 2016

Achieving results in each category and engaging in leading-edge technology development research

In 2016, we pursued the development of KW-0761 in the oncology category, and the late phase development of KW-6002 in the central nervous system category in close cooperation with ODDO, the unified development organization of Europe and the U.S.. In collaboration with large international pharmaceutical companies and specialty pharmaceutical companies outside Japan, we proceeded the joint development of the pipeline, which are making steady process, including RTA402 in the nephrology category, KHK4827 and KHK4563 in the immunology and allergy category, and KRN23 which does not belong the four key categories.

Our research programs, as well as the pipeline in the early stages to follow on the above mentioned products, have also been growing; in collaboration with in-house research laboratories outside Japan, and through proactive open innovation activities with industry, government, and academia. Moreover, we have continued to engage in leading-edge technology development research in line with Technology-Driven Drug Discovery that we espouse. As one example of this, since 2016 we have been involved in the AMED research and development theme, “medical technology development to treat cancer, mental illness, and kidney diseases through multilayer-omics analysis.”

We consider our achievements in 2016 to compose a firm and steady step for the first fiscal year of the Mid-term Business Plan.

R&D Division Organization

Status of Main Development for New Drugs

Nephrology

<KHK7580> Calcium receptor agonist
- Phase III clinical trials in secondary hyperparathyroidism patients receiving hemodialysis in Japan have been conducted.

<RTA402> Antioxidant Inflammation Modulator
- Currently conducting a phase II clinical trial in patients with chronic kidney disease and type 2 diabetes in Japan.

<KRN321> Long-acting erythropoiesis stimulating agent (brand name in Japan, NESP®)
- In February, withdrew its application for new drug approval for the treatment of renal anemia in patients undergoing dialysis in China. The timeline for the re-filing is under discussion.

Oncology

<ARQ197> c-Met inhibitor
- Currently conducting a phase III clinical trial in patients with inoperative hepatocellular carcinoma with high expression of c-Met who have been treated with sorafenib treatment in Japan.

<KW-0761> Anti-CCR4 humanized antibody POTELIGEO®
- Currently conducting a phase III clinical trial including the U.S., Europe, and Japan, etc. in patients with cutaneous T-cell lymphoma, and a phase II clinical trial in the U.S. and Europe, etc. in patients with adult T-cell leukemia lymphoma.

Immunology / Allergy

<KHK4827> Fully human anti-IL-17 receptor antibody LUMICEF®
- In July, acquired approval in Japan for the treatment of psoriasis vulgaris, psoriasis arthritis, pustular psoriasis, and psoriatic erythroderma that respond inadequately to for which existing therapies. Launched in September.
- In January 2017, began a phase III clinical trial in patients with psoriasis in Korea.

<KHK4563> Anti-IL-5 receptor humanized antibody
- Currently conducting a phase III clinical trial in Japan and Korea in patients with bronchial asthma, and a phase III clinical trial in Japan in patients with chronic obstructive pulmonary disease as part of multi-regional clinical studies conducted by AstraZeneca to whom the development rights in Europe and the U.S., etc are licensed-out.

<Z-206> pH dependent controlled release tablet Asacol®
- In July, applied for supplemental new drug approval in Japan for additions to the dosage and administration of this ulcerative colitis treatment drug jointly developed with ZERIA Pharmaceutical Co. Ltd.

Central Nervous System

<KW-6002> Adenosine A2A receptor antagonist NOURIAST®
- Currently conducting a phase III clinical trial in patients with Parkinson’s disease in North America and Europe, etc.

Other than the Key 4 Categories

<KRN23> Anti-fibroblast growth factor 23 fully human antibody
- Currently conducting international joint phase III clinical trials in North America, Europe, Japan, and Korea in adult patients with X-linked hypophosphatemia. In October, began a phase III clinical trial in North America, Europe, Australia, Japan, and Korea in pediatric X-linked hypophosphatemia. Also, a phase II clinical trial in the U.S. is being conducted in tumor-induced osteomalacia or epidermal nevus syndrome, and in June, began a phase II clinical trial in Japan and Korea.
- In December, the application for approval of KRN23 for X-linked hereditary hypophosphatemia was submitted to the European Medicines Agency.

<AMG531> Thrombopoietin receptor agonist ROMIPLATE®
- Currently conducting phase III clinical trials in chronic idiopathic (immune) thrombocytopenic purpura patients in China. In June, we began phase II and III clinical trials in Japan and Korea in aplastic anemia patients.

<KW-3357> Recombinant antithrombin agent ACOALAN®
- In September, applied for approval of a 1800IU preparation in Japan.

Pharmaceuticals Business | Research and Development

◆Future Prospects

Further promoting the self-initiative and mutual collaboration among category-based and function-based organization

In 2016, we issued our ideal of "embodying a particular image" in becoming a Global Specialty Pharmaceutical Company (GSP) with presence in the dramatically changing business environment. This is the gist of this ideal:

"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 while developing products with high value to follow on their heels. By leveraging the technology and the experiences in focused disease area through the process above, we continue to expand our valuable pipelines in the midst of new treatment systems five or ten years in the future, thus we will continually strive toward the next innovation."

We got off to a solid start in 2016, the first year of investment phase in our Mid-term Business Plan. We keep the strategies as planned, meaning that 2017 is the second year of investment phase.

Our first priority is placed on being fully engaged in the regulatory submission and approval of our global strategic products. By making steady progress toward developing a distinctive late phase development pipeline for each disease category, we will form and strengthen the R&D organization.

Some signals are being detected in the course of clinical trials based on the anti-tumor immune response of KW-0761 in solid tumor program in combination with other immuno-oncology drugs which is one of the topics in our Mid-term Business Plan. A combination trial with our in-house developed product KHK2455 has begun and the expectations for growth in this field are rising.

We will also continue to flexibly engage in initial exploratory research and technology development research in view of our medium-and long-term prospects. Our research activities will be firmly supported by maximizing our strengths through selection and concentration in each field by meticulous approaches to the category-based strategies, which are to improve the success rate through translational research and challenging on technology development based on the four major modalities.

Our open innovation drug discovery is gradually producing results and we will continue to engage in this area involving industry, government, and academia. We will also continue to deepen our ties with the San Diego and Singapore research laboratories.

Through these initiatives, we endeavor to drive the "Leaping Forward Phase" from 2018 to 2020, and move us forward for further growth thereafter.

Ethical Concerns in Research and Development

Kyowa Hakko Kirin has established an internal system for compliance with relevant laws and regulations throughout the entire drug discovery process, and endeavors to implement R&D appropriately from an ethical standpoint while incorporating various educational trainings and third party assessments.

R&D Organizations Around the World

*Two sites in Japan: Tokyo Research Park and Fuji Research Park

Main Initiatives

- Cellular, microbial, and chemical substances used in research are handled complying with relevant laws and regulations for example through a reagent control 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.
- 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).

Pharmaceuticals Business | Production

We aim for the stable supply of high-quality and highly effective pharmaceutical products based on advanced technology.

◆Initiatives in FY 2016

Establishing a global supply system, improving competitiveness, and promoting the reorganization of production facilities

The environment surrounding Japan's pharmaceutical industry has changed greatly in the past few years due in part to the replacement of long-term listed drugs in the with generics as a policy for medical cost containment, and the drug price revision.

In dealing with these changes in the business environment, Production Division has been building production and distribution system to supply our products globally, and promoting the reorganization of production facilities. We have been constructing new facilities to increase production capacity and introducing the latest equipment to better meet global regulatory requirement. To ensure the ongoing marketing of new drugs, we have developed manufacturing processes and have supplied investigational drugs used in domestic and overseas clinical development.

Meanwhile, we are building a production and supply system for developed products destined for the Western market. While endeavoring to maintain and improve our GMP*1 level to acquire approval in Europe and the U.S., we have been preparing a system for stable supply after acquiring approval by conducting a joint review with Kyowa Kirin International (KKI) toward developing a global SCM*2.

The reorganization of production facilities has proceeded on schedule, and operation of Sakai Plant was terminated at the end of October 2015. The drug substance manufactured at this plant until now will continue to be manufactured by Kyowa Pharma Chemical. The operation of solid dosage manufacturing facility at Fuji Plant was terminated at the end of FY 2015, and its functions were transferred to Ube Plant and contract manufacturing organizations. In FY 2016, products transferred from Fuji Plant started to be shipped from Ube Plant.

At Takasaki Plant, construction of the new production building HB6 was completed in August 2016 to meet GMP requirements in Japan, the U.S., and Europe, enhancing the system toward the further stable supply of biopharmaceutical drug substances.

As for new products, we marketed LUMICEF®, a fully human anti-interleukin-17 receptor A antibody for the treatment of psoriasis. As for investigational drugs, we have supplied them on schedule and contributed to promoting new drug development.

We are also proactively engaged in conserving the global environment by reducing the impact of our production activities on the environment. We have begun activities to achieve global group targets for 2030 CO_2 emissions reduction (20% reduction compared to 2015) to prevent global warming, and for 2030 water use reduction (30% reduction compared to 2015) to preserve water resources. As for the group's overall performance in 2016, CO_2 emissions were 364 thousand tons (100.6% compared to 2015) and water use was 52.8 million m^3 (100% compared to 2015). We are also continuing to engage in various local environmental conservation activities to reduce waste and protect biodiversity.

*1 Good Manufacturing Practice (criteria for the manufacturing and quality control management of pharmaceutical products, etc.)
*2 Supply Chain Management (method of managing operations from production to distribution and sales)

◆Future Prospects

To realize top product quality and productivity in the world

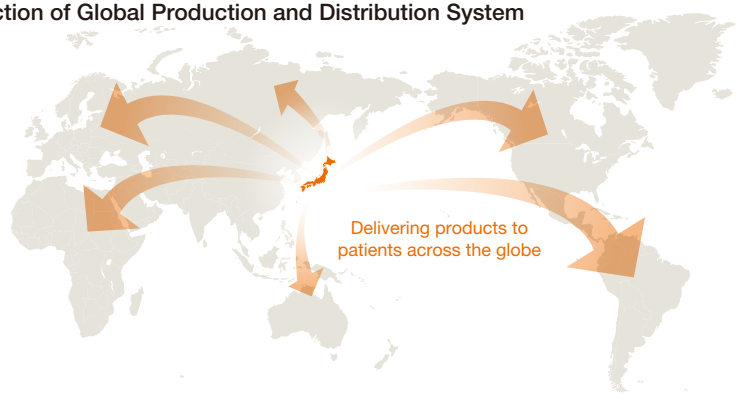
In delivering new products, including global strategic products currently being developed, as swiftly as possible to patients around the world, we are building and enhancing a global production and supply system in line with our development plan.

We will continue to pursue stable supply to patients by enhancing our product supply system in preparation for emergency situations, including risk mitigation measures during the supply of global products.

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 pursue new production technology for antibody bulk drug substances. We will establish new production technology for nucleic acid drugs and regenerative therapeutics, etc. which we are focusing on as new pharmaceutical products, and will use them to move further ahead. By utilizing our proprietary formulation techniques, we will proceed with product development in line with the needs of patients.

In fulfilling these policies and aspiring 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



Pharmaceuticals Business | Sales

We will respond to changes in the medical care provision system, build an organizational system, which includes restructuring sales offices, develop human resources, and enhance information provision activities with a focus on new drugs.

◆Initiatives in FY 2016

Transition to a sales system that can swiftly respond to environmental changes and grow sales in new drugs

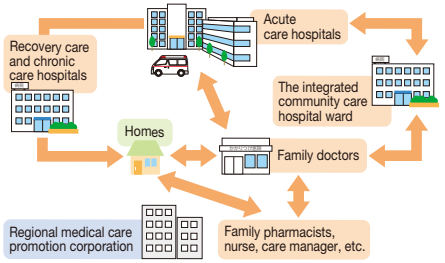
After revisions were made to the medical service fee in April 2016, a review of the medical care provision system has begun with the goal of building an integrated community care systems*1. To undertake activities in line with changing regional circumstances, we started to transition to a sales office system based on a secondary medical care zone from October 2015. Our intent is to build an organizational system that can swiftly respond to changes in the business environment. In addition, we have implemented training for branch managers and sales office managers (such as area strategy practicums*2) and are making the transition to an area strategy-type organization that can swiftly grasp area needs at the branch office and sales office levels and propose prompt solutions.

In the first year of our Mid-term Business Plan, we saw great growth in the sale of new drugs. G-Lasta® has become a top-selling granulocyte-colony stimulating factor (G-CSF) agent and is now one of the growing pillars of sales of the company. (Copyright © 2017 QuintilesIMS. Calculated based on JPN Dec. 2016 MAT. Reprinted with permission). In September 2016, we released the psoriasis treatment drug LUMICEF® ahead of all other countries in the world. This was our second antibody drug following on our ATL treatment drug POTELIGEO®. Through information provision and collection activities that are of value to medical personnel, we will continue to expand the sales of these drugs, together with our psoriasis treatment drug Dovobet®, antiparkinsonian agent NOURIAST®, and type 2 diabetes treatment drug ONGLYZA®.

*1 A support system for the elderly that includes five comprehensive services, "medical care, nursing care, care prevention, livelihood support, and lodging" that the nation is promoting as necessary services for the elderly so they can live out the last phase of their life in a region in which they are accustomed to residing and to continue a lifestyle that suits them.

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

Secondary Medical Area*3 that a sales office/area team is in charge of Acute care hospitals



*3 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.

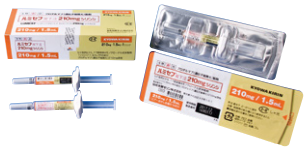
◆Future Prospects

Development of human resources who can solve problems and further enhancement of new drugs

The business environment in 2018 is expected to undergo major changes due to simultaneous revisions to medical service fees and long-term care fees, so 2017 will be an important year for us to respond to change. While the nation's goal of "building a medical care provision system" is now in sight, the speed of these changes and how they are carried out in each area is inconsistent. For this reason, we will build an organizational system that can respond swiftly to change by reorganizing sales offices and transitioning from a sales office team system to an area team system based on secondary medical care zones. Furthermore, we will carry out training for area team leaders to foster human resources who can identify the needs of medical personnel in each area, and swiftly propose and apply solutions.

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 area of nephrology, we will contribute to solving regional healthcare issues 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. In the area of the central nervous system and oncology, we will install new oncology-dedicated staff members in addition to our Parkinson's disease-dedicated staff members to further raise the presence of NOURIAST® and G-Lasta® and propose high quality drug treatment appropriate for the symptoms of each patient. In the area of immunology and allergy, we will contribute as a leading company in psoriasis treatment by penetrating our psoriasis drugs into the market over a wide range. They include Dovobet®, a basic treatment for psoriasis, and LUMICEF®, which is effective in moderate to severe psoriasis cases.

By responding to major changes in the business environment and through information provision activities meeting the needs of medical personnel, we will spur further growth in new drug sales. We will carry out management to make a leap as a global specialty pharmaceutical company through further growth in new drug sales by responding to major changes in the business environment and continuing information provision activities that meet the needs of medical personnel.



LUMICEF® has a new mechanism of action to selectively bind with the IL-17 receptor, thereby inhibiting the activity of IL-17, which is excessively produced in psoriasis patients.

Pharmaceuticals Business | Overseas Business

We are aiming to expand our overseas business and enhance our sales capability to achieve an overseas sales ratio of 50%.

◆Initiatives in FY 2016

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

"Improvement of global competitiveness," is positioned as a main pillar of our strategy in the Mid-term Business Plan. By boosting sales of global strategic products in Europe and the U.S., we are aming to achieve a 50% overseas sales ratio for Kyowa Hakko Kirin Group by 2020.

To realize this goal, we are enhancing the quality of our sales operation, developing our pipeline and sales infrastructure.

In Europe, we acquired product rights from AstraZeneca in March for the commercialisation and development of Moventig®*1, an opioid-induced constipation treatment drug. With the introduction of Moventig®, our product portfolio of Oncology field including supportive care is expected to strengthen in conjunction with other oncology products such as PecFent® and Abstral®, which are major products of KKI in Europe. Together with in-licensing Moventig®, we established sales subsidiaries in Austria, Switzerland, and Portugal, and strengthened our sales operation in Europe. In addition, we finished the reorganization of the sales bases of Archimedes Pharma (in Germany, France, Spain, etc.), which KKI had acquired in 2014, and have continued to optimize our sales operation.

In the U.S., we made a co-promotion agreement with R-PHARM for Ixempra®, a breast cancer treatment drug, and began to co-promote it in January 2017. We expect this deal will enable us to boost our sales operation in U.S., focusing on the oncology and supportive care, in addition to our existing products, Fareston® for breast cancer treatment and Suncuso® for the nausea and vomiting prevention.

Focus on major products in Asia

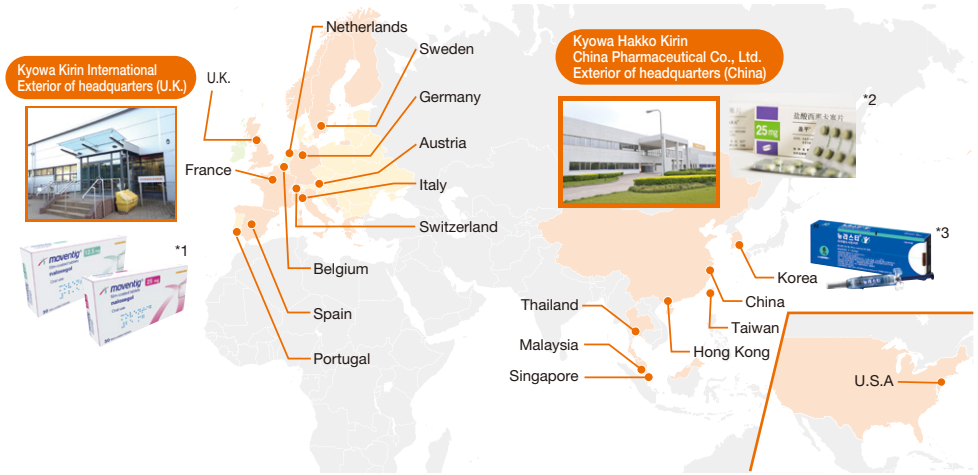
With the backdrop of a competitive market environment in Asia due to the glut of generic products and continual mark-down of drug reimbursement prices, we have focused our efforts on fields of nephrology and oncology, based on business policies that are in line with the business environment of each country.

In China, as a result of active promotion of REGPARA®*2, which was released in 2015, we succeeded in deep penetration of the product into the market at an early stage and sales have grown steadily. Hereafter, we will aim to develop the product pipeline and be prepared for growth.

In Korea, the long-acting G-CSF Neulasta®*3, for neutropenia treatment, together with the short-acting G-CSF Grasin®, captured the largest share of the G-CSF market in Korea. An approval of the expansion of health insurance coverage of the product in September is expected to boost its sales. In Malaysia, REGPARA®, which launched in 2012, was listed in Malaysia's MOH Drug Formulary (Blue Book) in September. As it is applicable for medical expense reimbursement, further market penetration can be expected.

Our business foundation in Asian regions including Taiwan, Hong Kong, Singapore, and Thailand has been strengthened by increased sales in NESP® and REGPARA® in the nephrology category. Henceforth, we will promote advance marketing of products under development for the future growth.

Global Sales Bases



◆Future Prospects

Building a sales team according to product proposition

In Europe and the U.S., we aim to build a sales operation tailored for the product characteristics of our global strategic products.

We have started to build a marketing team for a rare disease treatment in preparation for the launch of our X-linked hypophosphatemia (XLH) treatment KRN23 in Europe in 2018. In the U.S., promotional preparations by our partner Ultragenyx are steadily making progress.

For our other global strategic products, we are rushing to build sales channels to prepare for the approval of them in Europe and the U.S..

Pharmaceuticals Business | Pharmacovigilance and Quality Assurance

We will supply products of excellent quality with reliable information to customers.
(extracted from Policy for Safety, Quality and Regulatory Affairs in Pharmaceutical Business)

◆Initiatives in FY 2016

Consolidate management of safety information in Japan, the U.S., and Europe

To manufacture and sell our in-house brand of new drugs in the three markets of Japan, the U.S., and Europe, it is necessary to build a pharmacovigilance and quality assurance system that fulfills Good Practice (G×P) standards in each of these three regions.

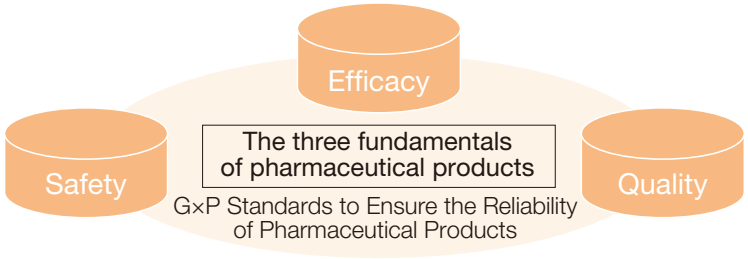
In particular, carrying out pharmacovigilance activities is one of the most important responsibilities of a pharmaceutical company, and we have begun full operation of a Global Safety Database to consolidate the management of safety information in these three markets.

We are making steady progress with our manufacturing control and quality control system for global products. We are developing a global pharmacovigilance and quality assurance system fulfilling requirements for "PIC/S* an international standard for GMP surveillance" and "Good Distribution Practice (GDP) a standard for the appropriate distribution of drugs."

* Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme

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, safety, and efficacy of a pharmaceutical product from the development stage to market launch. In Japan, there are standards such as GLP, GCP, GMP, GQP, GVP, and GPSP; globally, each region has its own similar standards.

GLP	: Good Laboratory Practice	Standards for the conduct of nonclinical laboratory studies concerning safety of pharmaceutical products
GCP	: Good Clinical Practice	Standards for the conduct of clinical trials for pharmaceutical products
GMP	: Good Manufacturing Practice	Standards for the manufacturing control and quality control of pharmaceutical products,etc.
GQP	: Good Quality Practice	Standards for the quality control of pharmaceutical products, etc
GVP	: Good Vigilance Practice	Standards for the post-marketing safety management of pharmaceutical products
GPSP	: Good Post-marketing Study Practice	Standards for the post-marketing study of pharmaceutical products

◆Future Prospects

"Drug development" to maximize a drug's benefits and minimize its risks

All pharmaceutical products have both benefits for patient treatment and risks in the form of adverse events. The balance of benefits and risks of a drug will be changed based on the accumulated data from drug development phase through post-marketing. Among our company's pharmacovigilance and quality assurance 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.

Holding firm to this basic stance in a global environment, we will contribute to the health and well-being of people around the world through the stable supply of highly reliable drugs.

Pharmaceuticals Business | Development Pipeline

As of January 24, 2017

Area	Identification*1	Code name/ Generic name	Indication		Country or region of development	Development phases
						Phase I / Phase II / Phase III / Filed
Nephrology		KRN1493	Secondary hyperparathyroidism		Brunei	
	○	KRN321	Renal anemia (on dialysis) [preparing for application]		China	
			Renal anemia		Indonesia	
			Myelodysplastic syndromes		Hong Kong/Singapore/Malaysia	
		KHK7580	Secondary hyperparathyroidism		Japan	
		RTA 402	Chronic kidney disease complicated by type II diabetes		Japan	
Oncology		Granisetron	Chemotherapy induced nausea and vomiting (patch)		Malaysia	
		ARQ 197	Hepatocellular cancer		Japan	
	●	KW-0761	Cutaneous T-cell lymphoma		U.S.A./Europe/Japan/others	
			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	Breast cancer		Japan	
		KHK2455	Solid tumor		U.S.A.	
	●	KHK2823	Cancer		U.K.	
Immunology/ Allergy		Z-206	Ulcerative colitis (Additions to Dosage & Administration)		Japan	
	●	KHK4827	Psoriasis		Korea	
	●	KHK4563	Asthma		Japan/Korea	
			Chronic obstructive pulmonary disease		Japan	
			Eosinophilic chronic rhinosinusitis		Japan	

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

Pharmaceuticals Business | Development Pipeline

As of January 24, 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	●	ASKP1240	Organ transplant rejection	U.S.A.	
				Japan	
	●	KHK4083	Ulcerative colitis	U.S.A./Europe/others	
				Japan	
Central Nervous System		KW-6002	Parkinson's disease	North America/Europe/others	
		KW-6356	Parkinson's disease	Japan	
	●	KHK6640	Alzheimer type dementia	Europe	
				Japan	
Other	●	KRN23	X-linked hypophosphatemia	Europe	
			X-linked hypophosphatemia in adult patients	North America/Europe/Japan/Korea	
			X-linked hypophosphatemia in pediatric patients	North America/Europe/Australia/Japan/Korea	
			Tumor-induced osteomalacia/Epidermal nevus syndrome	U.S.A.	
				Japan/Korea	
	○	AMG531	Idiopathic (immune) thrombocytopenic purpura	Thailand	
				China	
			Aplastic anemia	Japan/Korea	
	○	KW-3357	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.

Pharmaceuticals Business | Diagnostic Drugs

**We have unified product strategic functions and optimized our business and products in line with our strategy.
We will continue to take on this challenge, placing focus on developing overseas markets and creating business opportunities.**

◆Initiatives in FY 2016

Overseas business expansion and activities to transition to a high revenue constitution

In our Mid-term Business Plan, our highest priority theme will be to develop overseas markets with a focus on the U.S. and China, and create business opportunities encompassing all aspects of healthcare from personalized cares to self-medication.

In our overseas business, we have begun to develop a new fecal occult blood test business in the U.S. and expanded our business in China through collaboration between relevant divisions.

To “raise competitiveness through cost innovations” aimed at improving our profit structure, we have reduced our quantity of inventory with a focus on analysis equipment and parts, and reduced our stock of inventory assets. Our profit structure has been improved by revising our rebate criteria and negotiating the shortening of payment maturities to reduce accounts receivable.

We established the Corporate Strategy & Planning Department in April 2016 to “enhance organizational functionality” to optimize governance and risk management. By unifying product strategic functions, we have realized business activities in line with strategies and optimized product portfolio management.

We have made progress toward our goals for “global human resource development” by preparing and implementing Global Mindset Training for the first time.

We did not achieve our original sales budget. Factors that had a major impact on downward performance included changes in accounting recognition implemented in 2016 toward the inventory of distributors, reduced assessment of equipment and parts, and partial elimination of excessive products and raw materials. In FY 2016, the budget was revised to reflect these downward factors, and from FY 2017 we will implement measures to improve performance.

◆Future Prospects

Identifying opportunities for business expansion and accelerating overseas market development

In the in vitro diagnostic business, development time, cost, risks, and patent restrictions are all low, unlike for the pharmaceutical products. Ideas, focus points, and innovations generated during product planning and design can be easily reflected in product development, which greatly affects market competitiveness and the range of market segments into which the product can enter.

From January 2017, we will carry out the second stage of organizational and functional reforms that follow on 2015 to achieve the targets in our Mid-term Business Plan and to optimize our business operations.

Our objectives include the following: 1) early establishment of a QSR system* with a view to expanding our overseas business; 2) efficient operation of R&D resources; 3) raise customer satisfaction and improve business efficiency by unifying our response to customers; 4) build a SCM system by consolidating logistics functions; 5) enhance the asset management system.

Through such organizational reforms, we will further enhance our product strategy and sales strategy. We will focus on marketing new products in the U.S. and further expanding the Chinese business.

* Abbreviation for Quality System Regulation. This is a U.S. FDA Medical Device GMP standard that prescribes quality system regulations with which manufacturers must comply when exporting medical devices to the U.S.

Cholesterol measuring reagent contributing to the examination of lifestyle-related diseases

A1c iGear K, a device for measuring glycohemoglobin A1c, a blood test marker for diabetes

Kyowa Medex Co.,Ltd Fuji Plant / Research Laboratories

Test reagents utilizing antibody immune response

Pharmaceuticals Business | Biosimilars

As a Japan-based global biosimilars company, we will create high quality biosimilars on a global scale and contribute to medical cost containment.

◆Initiatives in FY 2016

FKB327 moving to the last development stage, and FKB238 starting phase III trials

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

In 2016, our first product developed FKB327 (biosimilars of therapeutic antibodies, Adalimumab) achieved the primary endpoint in phase III trials being conducted globally. These trials, which began in December 2014 mostly in the U.S. and Europe, compared the efficacy and safety of FKB327 in moderate to severe rheumatoid arthritis patients through double-blind comparison with the original reference product, Humira®. The equivalency of FKB327 with respect to Humira® was confirmed in ACR20 response rate* after 24 weeks of administration, which is the primary endpoint in this study. No major differences in adverse events were found between FKB327 and Humira®.

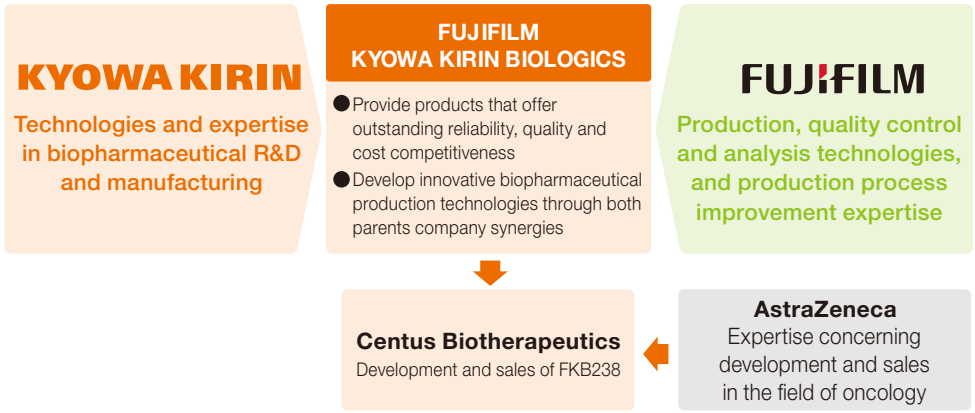
As well, global phase III trials on FKB238 (biosimilars of therapeutic antibodies, Bevacizumab) developed by Centus Biotherapeutics, a joint venture company with AstraZeneca in the U.K., have begun in non-small cell lung cancer patients primarily in the West.

Together with implementation of clinical trials, the latest technology was used to conduct various quality analysis 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) and by receiving advice from them, we have deepened our understanding of the thinking of these authorities regarding biosimilars and have made progress toward obtaining regulatory approval.

* An indicator based on American College of Rheumatology standards. It indicates the ratio of subjects in which improvement was seen in over 20% of swelling and tender joints counts, and over 20% improvement was seen in three out of the five assessment items including patient assessed 1) pain assessment, 2) disease activity overall assessment, and 3) motor function assessment; and 4) physician assessed disease activity overall assessment, and 5) acute-phase reactant (CRP value).

A joint venture established in 2015 for development and sales of biosimilars FKB238



◆Future Prospects

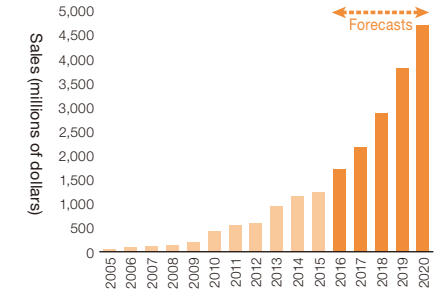
Initiatives toward application and marketing and pursuit of efficient development and lower costs of manufacturing

In 2017, we plan to apply to the regulatory authorities in each region for the pharmaceutical application of FKB327. At the same time, we will develop a global sales structure focusing on these three regions, and build a condition to sustain the company growth. We will proactively pursue phase III clinical trials for FKB238 and set a target for their completion.

Important keys to the sustainability and growth of our 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 society by continuing to deliver high quality, low cost biosimilars to the front lines of healthcare on a global scale.

Biosimilars global market forecasts



Source: compiled with reference to EvaluatePharma
Source: OPIR News Volume No.49 (November 2016), Office of Pharmaceutical Industry Research

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

With the rising concern for health-conscious living and quality, we have been pursuing improvements in the added value of our existing products. We are differentiating our products from competitors and will respond to the growing demand in each region.

◆Initiatives in FY 2016

Aiming to raise the added value of products as steadily developing production system.

Kyowa Hakko Bio has been developing its production system for the past few years to respond to expanding demand for high added value amino acids. At the Thai plant, which was completed in 2015, trial manufacturing to acquire data has finished and shipping has begun. Crude crystal amino acids manufactured in Thailand are processed into purer amino acids at the Shanghai Plant and are shipped to Asia and Europe where demand is growing.

Meanwhile, in the midst of rising concern for healthy living and quality, we have been pursuing initiatives to increase the added value of existing products. We are differentiating our products from the competition by clarifying the health maintenance and strength enhancing functions of our company's ingredients.

In the U.S., which is one of the largest health food markets in the world, we are raising brand value by citing effectiveness data for trademark registered products. The functionality of one of our brands, Cognizin (Citicoline), has been highly appraised. It has been adopted by the major health food chain National Brand with nationwide distribution in the U.S. and its sales have significantly expanded.

In our mail-order business, we have seen steady growth of our mainstay product Ornithine, as well as Arginine EX, which was newly released in 2016, through product development and a sales strategy that accurately grasps consumer needs.

Major products

Kyowa Hakko Bio health foods

◆Future Prospects

Enhancing the sales system and meeting demand in growth markets

In the field of fine chemicals, we will continue to develop new functions for ingredients, differentiate our products from competitors and promote sales of regional items, such as, by marketing halal food items. Kyowa Pharma Chemical aspires to become a pharmaceutical bulk drug business with a reliable system of cost, quality, and stable supply, etc. so that it will become a first supplier for pharmaceutical formulation makers.

In the healthcare field, we will focus on expanding sales and building recognition of our company's various health foods through effective marketing in our mail-order business, which is experiencing significant growth, and through a functional labeling system for food. We aspire to achieve a management system with which all stakeholders can be satisfied by implementing thoroughgoing compliance and by strengthening governance.

KQ™ Kyowa Quality

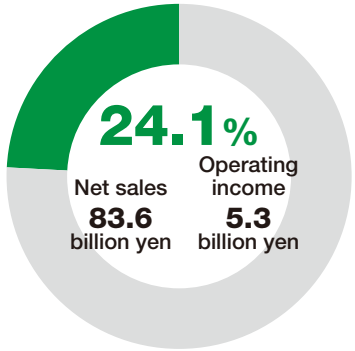
Setria® Glutathione

SUSTAMINE® Rehydrate. Replenish. Recover.

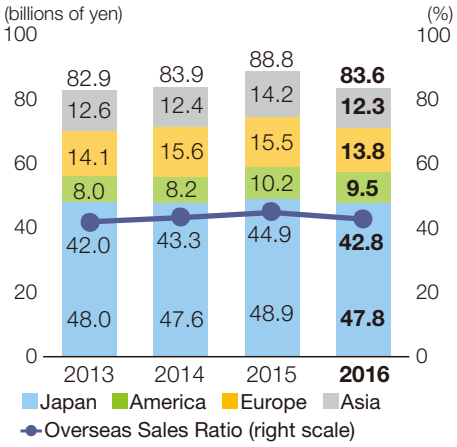
Cognizin® For the evolution of your mind®

Branded materials deployed worldwide

Composition of sales in 2016



Bio-chemicals Business Net Sales by Region



Bio-chemicals Business | Production

We will pursue development of production facilities in Japan and overseas, and enhance production efficiency and the product supply system. We will contribute to people's health and well-being by taking on new fields in health.

◆Initiatives in FY 2016

Reorganize plants to achieve further productivity improvements and stable supply

In the bio-chemicals business, we are 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. We are also streamlining production and strengthening our product supply system. The main projects to be completed in the next few years are as follows:

- Consolidation of Yamaguchi Production Center (Ube) into YPC (Hofu).
- Enhancement of Fermentation Plant in Thailand (crude crystal manufacturing plant)
- Expansion of Shanghai Refinement Plant (final refinement process)

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 Hofu Plant.

Hofu Plant, in preparing to consolidate functions with Ube Plant, is in the process of renewing facilities and introducing new technology. The neighboring Technical Research Laboratory is pursuing research into new high productivity manufacturing methods, introducing the latest expertise on site and providing technology support. Technology and technical support from Japan are also being implemented to facilitate smooth manufacturing at the Thai and Shanghai plants.

◆Future Prospects

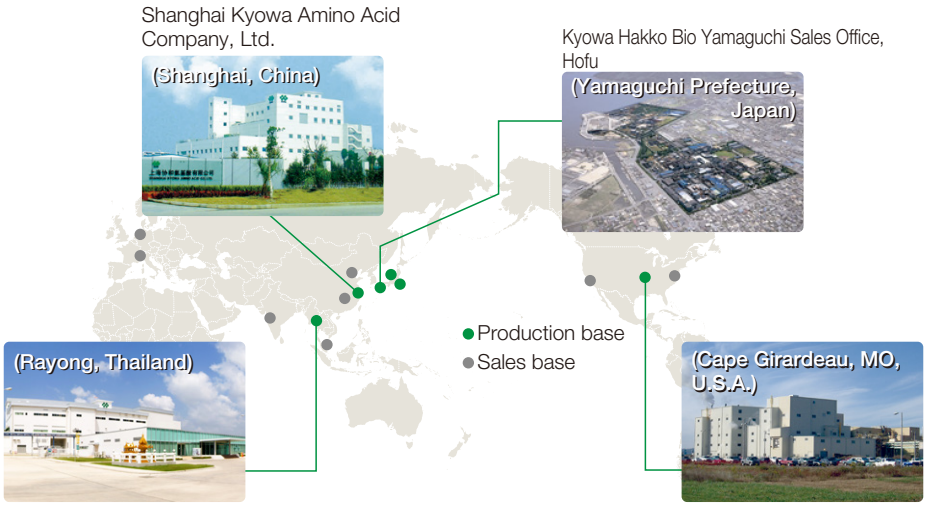
Taking on new fields and creating new value for health

Our goal is to borderlessly deliver new value to customers through our products and services and to create a society in which we can live symbiotically with customers. To do so, we will apply our in-house know-how on fermentation technology, microorganism breeding and cultivation. We will ascertain society's needs in preventive medicine and regenerative therapeutics and will pursue research in existing products, as well as in new business areas.

In addition, we will collaborate with academia and the pharmaceutical business to pursue R&D on culture media for regenerative therapeutics and new materials for pharmaceuticals. We will develop new health foods that are effective in disease prevention and pre-symptomatic disease states. We will contribute to the health and well-being of people by providing a scientific basis for efficacy, verifying safety and providing products of reliable quality to many customers.

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

Global Production Centers



Amino Acid Materials and Products Handled

Amino acids and peptides used in amino acids, nucleic acid and related substances comprise a variety of materials that are widely used in medical infusions, bulk pharmaceuticals, beverages, cosmetics, and health food.

Board of Directors (As of March 23, 2017)

⑤Director of the Board
Managing Executive Officer
Strategic Product Portfolio Department

Masashi Miyamoto

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. (to present)

④Director of the Board
Managing Executive Officer
Director, Overseas Business Department

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, Kirin Pharma Company, Limited
Oct. 2008: Executive Officer, Head, Research Division, Kyowa Hakko Kirin Co., Ltd.
Apr. 2010: Executive Officer, General Manager, Corporate Strategy & Planning Department, Kyowa Hakko Kirin Co., Ltd.
Mar. 2012: Managing Executive Officer, General Manager, Overseas Business Department, Kyowa Hakko Kirin Co., Ltd.
Mar. 2014: Director of the Board, Managing Executive Officer, Kyowa Hakko Kirin Co., Ltd. (to present)

③Director of the Board
Managing Executive Officer

Kazuyoshi Tachibana

Apr. 1978: Joined Kyowa Hakko Kogyo Co., Ltd.
Apr. 2005: General Manager, Pharmaceutical Strategic Planning Division and Pharmaceutical Manufacturing Strategy Department, Kyowa Hakko Kogyo Co., Ltd.
Jun. 2005: Executive Officer, Kyowa Hakko Kogyo Co., Ltd.
Oct. 2008: Executive Officer, Kyowa Hakko Kirin Co., Ltd.
Apr. 2009: Managing Executive Officer, Kyowa Hakko Kirin Co., Ltd.
Jun. 2009: Director of the Board, Managing Executive Officer, Kyowa Hakko Kirin Co., Ltd. (to present)

②Executive Director of the Board
Executive Vice President

Hiroyuki Kawai, Ph.D.

Apr. 1979: Joined Kirin Brewery Company, Limited
Mar. 2004: General Manager, Development Division of Pharmaceutical Division, Kirin Brewery Company, Limited
Jul. 2007: Director, Executive Officer, Kirin Pharma Company, Limited
Mar. 2008: Representative Director, Executive Vice President, Executive Officer, Kirin Pharma Company, Limited
Oct. 2008: Managing Executive Officer, Kyowa Hakko Kirin Co., Ltd.
Mar. 2010: Director of the Board, Managing Executive Officer, Kyowa Hakko Kirin Co., Ltd.
Mar. 2013: Director of the Board, Senior Managing Executive Officer, Kyowa Hakko Kirin Co., Ltd.
Mar. 2014: Executive Director of the Board, Executive Vice President, Kyowa Hakko Kirin Co., Ltd. (to present)

①Executive Director of the Board
President 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, 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. (to present)

⑧Director 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
(Outside Director)

Koichiro Nishikawa

Apr. 1970: Joined Hitachi, Ltd.
Aug. 1995: Vice President, Hitachi America, Ltd.
Apr. 1999: General Manager, Business Development Office, Hitachi, Ltd.
Apr. 2001: General Manager, Global Business Development Division, Hitachi, Ltd.
Jun. 2003: Executive Officer, Hitachi, Ltd.
Jan. 2006: Vice President and Executive Officer, Hitachi, Ltd.
Apr. 2007: Senior Vice President and Executive Officer, Hitachi, Ltd.
Apr. 2010: Senior Vice President and Executive Officer, Hitachi Cable, Ltd.
Apr. 2012: Senior Advisor, Hitachi Research Institute
Jun. 2013: International Affairs Committee member, Japan Association of Athletics Federations
Oct. 2013: President, Japan Industrial Track & Field Association
Mar. 2014: Director of the Board, Kyowa Hakko Kirin Co., Ltd. (to present)
May 2015: Audit & Supervisory Board Member, J. FRONT RETAILING Co., Ltd. (to present)

⑥Director 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
Apr. 2015: Executive Officer, General Manager, Personnel & General Affairs Department, Kirin Company, Limited and Director of Group Personnel & General Affairs, Kirin Holdings Company, Limited (to present)
Mar. 2017 Director of the Board, Senior Executive Officer, Kirin Company, Limited, and Senior Executive Officer, Director, Group Corporate Strategy, Kirin Holdings Company, Limited (scheduled)

Corporate Governance

In order to continue to improve our corporate value and achieve our aim of becoming a GSP, the Kyowa Hakko Kirin Group recognizes the need for improved transparency in management and strengthened management oversight, and has made all efforts to enrich the Corporate Governance System.

Corporate Governance System

Kyowa Hakko Kirin has selected to have a board of company auditors, in which the board of auditors 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 through monitoring and verification of the process and the content of the decisions made.

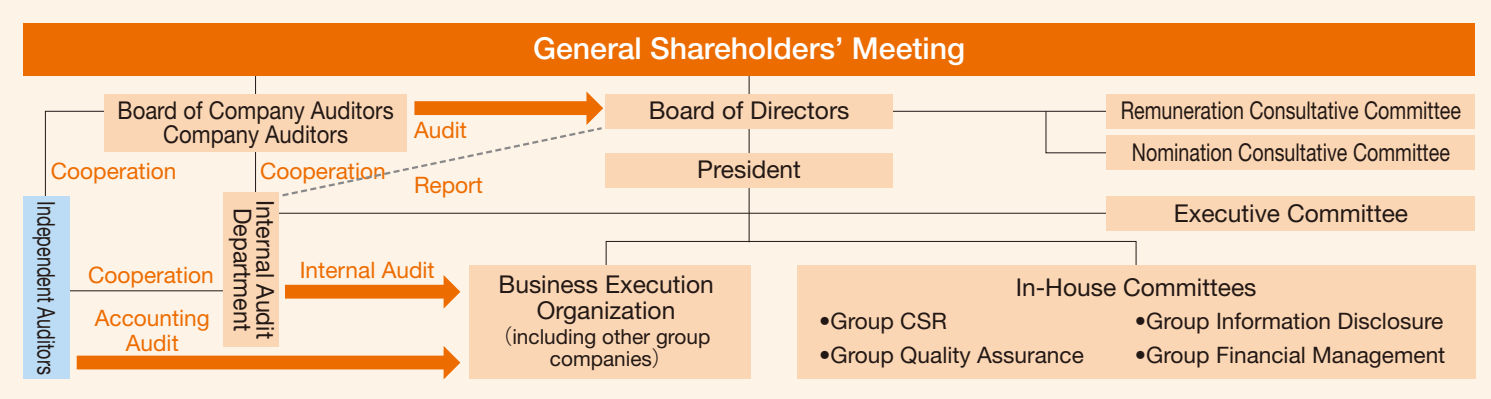
In addition, we have further enhanced the transparency of our management by voluntarily installing a "Nomination Consultative Committee" and "Remuneration Consultative Committee," as well as adopting a hybrid governance system that allows a balance between further enhancing the transparency of management and maintaining necessary executive and supervisory functions.

Directors/Board of Directors

The Board of Directors of the Kyowa Hakko Kirin oversees decisions made on important management issues and the administration of business management; the balance between the knowledge, experience, ability, and insight of directors has led to the realization of a system that is transparent.

In addition, by leveraging the objective and professional viewpoints of outside directors, the board aims to make appropriate decisions and fulfill its supervisory function. The selection process and procedures for candidates to the Board of Directors are deliberated on in the Nomination Consultative Committee and determined by the Board of Directors.

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 directors*	8 (including 2 outside directors)
Number of company auditors*	5 (including 3 outside company auditors)
Number of independent directors and company auditors*	2 outside directors, 2 outside company auditors
Board of Directors meetings in 2016	Number of meetings: 16 Director attendance: 100% Company auditor attendance: 100%

Board of Company Auditors meetings in 2016	Number of meetings: 14 Company auditor attendance: 100%
Director remuneration	Total compensation for 2016 consisting of performance-linked base compensation and stock options as medium-and long-term stock-based compensation (5 directors excluding outside directors): ¥323 million (base compensation: ¥278 million, stock options: ¥45 million)
Company auditor remuneration	Total compensation for 2016 (1 company auditor excluding outside company auditors): ¥25 million (base compensation: ¥25 million)
Accounting auditor	Ernst & Young ShinNihon LLC

*As of December 31, 2016

Executive Compensation

Remuneration for the Board of Directors, executive officers, and company auditors has been determined necessary to secure human resources appropriate for the management of the company, and act as a base to motivate officers to contribute to the company through the regular performance of duties. Remuneration specifically consists of performance-linked base compensation as a short-term incentive and stock options as medium-and long-term incentive. This remuneration is deliberated on by the Remuneration Consultative Committee and decided on by the Board of Directors.

Company Auditors/Board of Auditors

The Company Auditors and the Board of Auditors, as an independent body that receives a mandate from shareholders, monitor and verify the situation that the soundness of the management toward the group's sustainable growth and the improvement of corporate value over the medium to long term are consolidated by conducting audits of the execution of the duties of the Board of Directors.

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

Concerning the Response to the Corporate Governance Code

The Management Philosophy of the Kyowa Hakko Kirin Group 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." As a company responsible for the foundation of society, in order to achieve the sustainable growth and improve medium-and long-term corporate value of the company, it is essential to build and maintain good relationships with all stakeholders.

Based on this basic idea, we have developed a Corporate Governance Policy, and are undertaking the initiatives outlined below with respect to the Corporate Governance Code.

Basic Principles	Specific Cases and Initiatives
1. Ensuring the rights and equality of shareholders	• Kyowa Hakko Kirin has a deep awareness 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 general shareholders' meetings and has established an environment in which the shareholders can properly exercise their rights. We respect the will of minority shareholders 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 of the Shareholders' Meeting to the Board of Directors, the corporate governance structure of the company ensures that the Board of Directors can perform appropriate roles and responsibilities.
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 legal and healthy relationships with customers, shareholders, investors, employees, business partners, the community, the government, and all others 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 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 of 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 improving the health of all employees.
3. Ensuring appropriate information disclosure and transparency	• The company recognizes that the enhancement of information disclosure is a prerequisite of constructive dialogue with shareholders,* and therefore discloses information in line with the "Disclosure Policy," which has been separately created.
4. Responsibilities of the Board of Directors	• Based on the fiduciary responsibility and accountability to shareholders, the Board of Directors desires to realize the management philosophy of the group through the establishment of effective and efficient corporate governance while aiming for sustainable growth and the improved medium-and long-term corporate value of the group. • The Board of Directors determines the important business operations and legal matters related to the long-term management vision, Mid-term Business Plan, and annual management plan, etc. of the entire group and of major companies of the group. It is also responsible for overseeing the business actions taken by board members and constructing 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 other business functions has been delegated to the executive officer responsible for each business.
5. Communication with Shareholders	• Kyowa Hakko Kirin has separately established a basic policy on dialogue with shareholders, and based on the recognition of the contribution of the company's corporate governance system to the further enhancement and improvement of the medium-and long-term corporate value of the company, actively creates forums for constructive dialogue.

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

Corporate Governance

Function of Outside Directors and Outside Company Auditors

In order to increase the fairness and transparency of corporate governance, achieve sustainable growth and raise the medium-and long-term corporate value of the group, we appoint two or more independent outside directors who meet the separately established "criteria for independence of outside directors." Independent outside directors not only actively provide advice on management issues, oversight of executive actions and monitor acts that may present conflicts of interests, but 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 the objective and neutral viewpoint of audits and soundness of management, we appoint multiple independent outside company auditors. In order to strengthen the ability of independent outside directors to collect information, meetings are held between the full-time company auditors and non-executive directors, including independent outside directors.

Criteria regarding the Independence of Outside Officers

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

Internal Control

Based on the basic policy of the parent company "Kirin Holdings Company, Limited", we have established a "Basic Policy on the Internal Control System" to ensure the appropriateness of operations; the maintenance and operation of the system based on this basic policy is confirmed by the Board of Directors and externally reported.

Moreover, in accordance with the "Basic Policy on Compliance" and "Basic Policy on Risk Management" of the group, the Company promotes compliance in good faith and secures a system to make appropriate responses 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.

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 Items Affecting Corporate Governance

Our company is a consolidated subsidiary of the pure holding company Kirin Holdings Company, Limited, which owns 50.1% of the issued shares. While respecting the basic policies of the Kirin Holdings' group management, we have made a confirmation to respect our right to independently and flexibly conduct autonomous corporate activities, thereby ensuring the constant independence of management.

General Shareholders' Meeting

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 all 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, the English translation of the convocation notices and electronic voting platforms is available.

During the General Shareholders' Meeting, a summary of the performance of the company is clearly explained on the screen or with the narration.

Shareholders vote on measures after receiving sufficient explanation.

IR Activities

It is the view of Kyowa Hakko Kirin that constructive two-way communication with shareholders, including institutional investors, through briefings concerning financial results and individual projects, general shareholders' meetings and management plan announcements, will lead to the enrichment of corporate governance and improved medium-and long-term corporate value. For this reason, we have actively established opportunities for such dialogue. Moreover, in order to further enhance the content of dialogue 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 conduct IR-related activities.

Cooperation with Stakeholders (CSV management)

Based on "Kirin Group's unique CSV*" idea that both of solving social issues and providing value to customors would be satisfied, in the group, we will advance our efforts with the aim of realizing both the creation of economic value and creation of social value by regarding contribute to the health and well-being of people which is one of the Strategic Pillars of the FY2016-2020 Mid-term Business Plan, as our CSV management.

* 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.

Compliance

Compliance

Not only does the Kyowa Hakko Kirin Group comply with laws, ordinances, and internal and external regulations, but also recognizes the importance of ethical behavior in good faith in response to social demands and is working to build and maintain healthy and favorable relationships with stakeholders it reaches through its business.

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.

Compliance in our group is defined as "each officer and employee aiming to act ethically and meet the needs of society in good faith as they conduct their business activities." We regard compliance as the base of all of our corporate activities, and therefore have established appropriate rules and created an organizational structure to comply with all laws and ordinances, internal and external guidelines and rules, and social conventions. Furthermore, to contribute to further improvements, we confirm whether or not such system and rules properly function through surveys of compliance awareness for employees, the internal reporting system, the state of participation in a variety of educational programs, comprehension-checking tests, etc.

In January of 2016, we established the "Kyowa Hakko Kirin Group Compliance Policy" to define our legal and ethical responsibility concerning our relationship with society and employees, compliance with rules and regulations, respect for human rights, environmental preservation, and information management.

In October of 2016, we established the "Kyowa Hakko Kirin Group Code of Conduct" which defines concrete actions of the "Kyowa Hakko Kirin Group Compliance Policy". This code of conduct and the "Kyowa Hakko Kirin Group Compliance Policy", have been translated into English, Chinese, and other languages of the countries in which our sites are located. We roll out this code among all group members as rules each officer and employee must comply while conducting business activity.

Compliance Training

The group is committed to cultivating workers and fostering an organizational culture that allows making responses to changes in social norms. As part of our efforts, we conduct a variety of educational programs such as group training and e-learning courses.

In 2016, we conducted such programs focusing on "human rights," "prevention of corruption," "information security," "personal information protection," "environment," "dealing with a crisis."

Furthermore, for the group executives, we adopted the group's Management Philosophy, Core Values and the code of conduct for discussion at an executive officer study meeting, and held a corporate ethics lecture meeting on the topic of a dilemma between management and ethics.

In addition, we yearly participate in the "Awareness Survey of Human Rights and Compliance" implemented by the Kirin Group to conduct a survey for all of our domestic employees in the group, and utilize the results of the survey to improve the compliance system, rules and training.

"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)

- Internal reporting system*1
- Prevention of corruption*1
- Personal information protection
- Promotion of smart work*2
- In relation to human rights (LGBT, laws pertinent to persons with disabilities, etc.)
- Environmental activities (revision of the ISO 14001 standard)
- Japan Pharmaceutical Manufacturers Association (JPMA) Code of Practice
- Training on drug safety
- Handling of obtained information concerning drug safety*3
- Training on human rights and compliance
- Survey on compliance and human rights awareness in the Kirin Group

*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

Compliance

Anti-bribery Initiatives

To be trusted and recognized as high reputation from society, a company must operate the business holding a high compliance mind. In recent years, international organizations and governments, including the United Nations and the Organization for Economic Co-operation and Development (OECD) insist that global companies strengthen compliance with the anti-bribery measures.

The Kyowa Hakko Kirin Group has established "Guideline for Anti-Bribery Measures" and "Regulation for Anti-Bribery" and has roll out them to group companies with president's commitment. The guideline is disclosed on the Kyowa Hakko Kirin website.

Each group company complies with Japan's Unfair Competition Prevention Law, the U.S. Foreign Corrupt Practices Act (FCPA), the U.K. Bribery Act and other extraterritorial laws. We are also taking appropriate steps to comply with each nation's anticorruption laws and prevention of corruption involving public servants and other officials in foreign countries.

We have assigned an anti-bribery manager and established a help desk at each group company, established rules of implementation for each company, trained continuously for executives and employees, and currently conduct monitoring and auditing of each company.

"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.

Our Commitment to Transparency Disclosure

The Kyowa Hakko Kirin Group has established "Transparency Guideline for the Relation between Corporate Activities and Medical Institutions" and "Transparency Guideline for the Relation between Corporate Activities and Patient Organizations" in order to commit transparency disclosure in Japan. We have been making fair payments to medical institutions and/or patient organizations complying with these guidelines, and we have disclosed the information on the Kyowa Hakko Kirin website.

And also, we think that it is important for us to enhance compliance and transparency in our global business activities. In 2016, prior to launch our global strategic products on European and the U.S. markets, we aligned the company names of pharmaceutical business affiliates with "Kyowa Kirin". As a corporation providing pharmaceutical products in Europe and U.S., we strive to disclose the information regarding the transparency between medical personnel or medical institutions.

Internal Reporting System

The Kyowa Hakko Kirin Group has established an internal reporting contact in order to prevent, early detect, and correct acts against the "Kyowa Hakko Kirin Group Compliance Policy" and acts that seriously detract the brand value of KHK group. In order to improve the usability of the internal reporting system, we established an external contact and diversified reporting means (establishment of a counter of which a female staff member is in charge) in 2016.

In addition, we have introduced a mechanism by which a report about a board of director is to be directly notified to a company auditor and established a contact that allows direct reporting from an overseas subsidiary to the head office in Japan.

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

In 2016, there were 30 cases of internal reporting in Japan.

Compliance

Risk Management

As the Kyowa Hakko Kirin Group aiming for sound management, we strive to strength corporate governance along with working to establish thorough risk management policies by the construction and operation of a risk management system.

Risk Management

In order to win long-term trust from customers and society and achieve management goals to continue our business, Kyowa Hakko Kirin Group has implemented a risk management system in group companies.

"Risk management" in 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. Specifically, we root out risks by using a risk ledger, have created and currently operate a risk management program, confirm the progress of the risk management program each quarter, and monitor changes in risk and the manifestation of risks in each department. The results of the monitoring are reported to the group CSR committee.

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.

We established the "Kyowa Hakko Kirin Group Risk Management Policy" in 2016 to specify the purpose of risk management, definition of risk/crisis, and responsibility for the operation of line management.

Improvements in BCP

We are continuously making improvements to our Business Continuity Plan (BCP). Along with the formulation of company-wide BCP guidelines, BCP basic plan, and BCP action plan, we reflect the points we notice during the disaster prevention training and BCP training to the respective BCP documents as part of the Plan-Do-Check-Act (PDCA) cycle.

In December 2016, we conducted a large-scale earthquake simulation drill targeted for heads of departments including directors and executive officers.

Environmental Safety

We are promoting activities under an ISO14001-accredited environmental management system whose accreditation scope has been extended overseas, and by setting stricter values than laws and regulations to invigorate the PDCA cycle. Moreover, we endeavored to build up a framework by developing a new environmental policy aimed at Kyowa Hakko Kirin Group as well as establishing a group goal for 2030 (global) concerning global warming and water resources conservation. With regard to the prevention of global warming, in particular, we have set a CO_2-emissions-reduction target in accordance with the Science Based Targets (SBT) initiative to which Kirin Group makes a commitment.

In terms of safety, we enhance occupational safety training at every stage of lines, and with respect to the traffic safety of business vehicles, we are implementing measures from both hardware and software standpoints. We perform audits of all production sites including overseas ones in order to directly grasp the conditions at each site from both environmental and safety perspectives.

In our major domestic production sites and research center, we control to our compounds according to the relevant laws (controlled substances,etc), by reagents management/regulated compounds compliance check support systems. With regard to our supply chain, we conduct field surveys and hold networking events with the aim of improving the entire supply chain.

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

* THAI KYOWA BIOTECHNOLOGIES CO., LTD. gained an overseas site's first ISO-14001 accreditation.

Information Security

Kyowa Hakko Kirin recognizes that in order to secure customer confidence and improve our competitiveness, security of information assets is an important issue for management. To protect information assets, we have established the "Information Security Basic Policy," and under the policy, have established "Regulations for Confidential Information Management" with regard to the protection and handling of confidential information.

As part of such efforts, a person is appointed as the manager in charge of the information security of Kyowa Hakko Kirin Group, and each department designates a person in charge as well. Important items related to information security are to be discussed and reported in the group CSR Committee. We have also implemented education and training to raise awareness of information security among employees and make all efforts to ensure the protection of information.

In addition, in response to the establishment of the Individual Number System ("My Number System") for social security and tax, we appropriately manage specific personal information.

Strengthening the Governance System and Proceeding to the Next “Leap Forward”

To enhance our governance toward realizing our goals in the FY 2016–2020 Mid-term Business Plan, we began new measures from 2016 such as evaluation of the effectiveness of the Board of Directors. Outside Director Koichiro Nishikawa, Outside Director Yoshiko Leibowitz, and Vice President Hiroyuki Kawai met to discuss the current achievements, issues, and making progress toward the next “leap forward.”

Director of the Board
(Outside Director)
Koichiro Nishikawa

Served as a person in charge for business development in Hitachi, Ltd. for many years, he has detailed knowledge of business partnerships, M&A, etc. He became an outside director of Kyowa Hakko Kirin Co., Ltd. in March 2014.

Director of the Board
(Outside Director)
Yoshiko Leibowitz

Involved in nursing, education, and management for 30 years in the U.S.. After returning to Japan, she participated in the reformation and management of Aomori University of Health and Welfare as its first Chairperson of the Board of Trustees and President after privatization of the university. In March 2015, she became an outside director of Kyowa Hakko Kirin Co., Ltd.

Executive Director of the Board
Executive Vice President
Hiroyuki Kawai

Joined Kirin Brewery Company, Ltd in 1979. Assumed posts as General Manager of Development Division at Kirin Brewery, Director of Manufacturing Division at Kirin Pharma Co., Ltd, and Director of Production Division at Kyowa Hakko Kirin Co., Ltd. Assumed his current post in 2014.

◆Appointment Criteria and Role of Outside Directors

Placing importance on a global perspective and diversity

Kawai For the Kyowa Hakko Kirin Group to make the global leap, we have two main criteria for the appointment of outside directors. First, a candidate must have experience in managing a global company and overseas M&A. Second, a candidate must possess the perspective of medical personnel and manage from the viewpoint of diversity. It is for these reasons that we asked Mr. Nishikawa and Ms. Leibowitz to assume the post of outside director.

Nishikawa At my previous post, I was responsible for the practical operations of global management and M&A. I accepted this post as outside director with a desire to apply my experience in management. What I am conscious of doing is contributing to the streamlining of management as a representative of general minority shareholders. I participate in discussions at the Board of Directors meeting from the standpoint of how to improve the ROE expected by investors, and realize sustained growth for the company.

Leibowitz I have been involved in healthcare reforms and management in the U.S. for 30 years. In Japan, I have been involved in educational reforms. While I have never been conscious of my gender in the work that I do, I try to provide opinions at the Board of Directors meeting based on my experience, keeping my appointed role and diversity in mind.

◆To Enhance Global Governance

Need to appoint personnel working abroad as board members in the future

Nishikawa With a view to the global marketing of our global strategic products, I believe it is important in enhancing our global governance system to call upon those with overseas management experience to assume board member posts. What are your thoughts on governance at the Kyowa Hakko Kirin Group?

Kawai I think there is an urgent need to improve a standard of compliance worthy and corporate culture as an international company, which is highly sensitive to compliance risk. We are now establishing appropriate requirements

for global governance so that we can take steady steps to prepare the groundwork.

Leibowitz It is a great idea to appoint personnel who can play an active role as board members who possess diverse perspectives such as from overseas management experience, irrespective of gender or nationality. But as the saying goes, “Rome wasn’t built in a day,” global governance also cannot be realized suddenly in a short period of time. After assuming my post as outside director, I visited the Kyowa Hakko Kirin Group’s numerous offices and subsidiaries in Europe, the U.S., and Asia, and witnessed young Japanese employees working actively at their overseas postings. These employees experience working overseas while they are still sensitive to many things, and play an active role when they return to Japan. It would be nice to see global governance instilled in our group, making use of such human resources.

Kawai In the future, as overseas sales expand and our overseas sales ratio increases, it will be necessary to reinforce our global governance system. As you both have remarked, we will need to further consider incorporating an overseas perspective on governance when this happens.

◆Important Matters Discussed in 2016

It is important to thoroughly discuss weighty management issues

Kawai In Japan, the Corporate Governance Code was established in 2015, and a single guideline was provided. We held numerous discussions on governance at the Board of Directors meeting based on this code, and with feedback from our two outside directors, established our Corporate Governance Policy in 2016.

Leibowitz Codes and policies at most reflect the minimum amount of rules. It is necessary to discuss the structure, process, and results and raise visibility. In doing so, it will be possible to comply with global governance.

Nishikawa Compared to other industries, investments in the pharmaceutical industry are extremely high-risk and high-return and the invested amounts are also larger. In addition, it is not easy to change course once an investment begins. I have always stated how it is important to incorporate phase-gate management*1 into large-risk development investments, and to establish checkpoints in the development process. At our company also, we discussed large-scale and difficult investment projects from the viewpoint of phase-gate management.

Kawai I feel that it is important managing approach to discuss thoroughly with receiving such opinions from our two outside directors. As well, in 2016, it was also meaningful that we drew up Core Values of the group and Code of Conduct in writing in both Japanese and English.

Leibowitz It is very important to clarify and draw up such Core Values and Code of Conduct in writing. These are important in raising the awareness of each employee as to why we are doing the work that we do.

*1 Phase-gate refers to “checkpoints” that are established for each process. Unless certain conditions prescribed in advance are fulfilled, the project cannot move to the next stage. Project management by phase-gate enables problematic points and risks to be discerned early on and countermeasures to be taken.

◆Evaluation of the effectiveness of the Board of Directors

Organizing what should be discussed by the Board of Directors and the executive body

Kawai In conducting evaluation of the effectiveness of the Board of Directors, how to monitor group companies and follow the PDCA cycle were raised as issues for future discussion. The opinion was also mentioned that matters for discussion at the Board of Directors meeting should be reorganized. We are currently reorganizing the role and responsibility for Board of Directors and Executive Committee*2 so that long-term strategies and company operations are discussed at the Board of Directors meeting, while specific tactics are discussed primarily by executive officers. What are your impressions of Kyowa Hakko Kirin’s evaluation

of the effectiveness of the Board of Directors?

Nishikawa In terms of PDCA, Plan and Check are duties performed by the Board of Directors, and Do and Act are duties performed by the executive body. Of course, while they cannot be clearly divided, there is still room for improvement when viewed from that perspective.

As well, how much time was spent discussing a subject based on a briefing received before the Board of Directors meeting will also be an indicator in effectiveness evaluations. In comparison to other companies, this company spends a fair amount of time on information provision to its outside directors. I feel that the quality and quantity of information is of a good standard, even among Japanese companies.

Leibowitz In addition to separating discussions held at the Board of Directors meeting and the executive body, I also proposed following-up on issues raised at Board of Directors meetings.

Nishikawa As a result, subjects discussed do not simply end there, but measures taken with respect to previous issues are reported at the start of the next Board of Directors meetings.

Leibowitz Yes, that's true. In this sense, the Board of Directors' PDCA cycle is following, and it has become very easy to know how issues discussed at board meetings are being solved.

*2 Please refer to the figure "Corporate Governance Structure" on page 32 for details.

◆Diversity

It is also necessary to create a workplace that is easy to work at, and diversity at the Board of Directors meeting

Kawai How do you evaluate the group's initiatives to promote diversity?

Leibowitz Diversity refers not only to gender, but to diversity of workstyle and hiring the disabled. What is important is to create a workplace that is easy to work at for everyone. I hope to build environments where employees can work in good health and where those who are capable and motivated can develop as human resources.

Nishikawa When we speak of diversity at the Board of Directors meeting, candidates must be literate in a range of areas such as finance, law, science, and marketing. Today's business environment is rapidly changing, and business fields are also expanding worldwide. In this context, making accurate and swift management decisions requires comprehensive knowledge including finance, law, the latest technologies, and market analysis. I am mindful to provide objective advice based on my own experiences, such as by explaining how trends in the world are changing or how the overall axis of our business is shifting. I feel that this will lead to diversity in management decisions from the perspective of literacy.

Kawai As there are people with various standpoints, having respect for each of these views is a basic premise. For the company as a whole, we must promote diversity first. The Board of Directors that leads diversity management must sufficiently understand diversity and have more meaningful discussions on this subject.

◆Future Goals

The Board of Directors will do its utmost in aspiring to become a true Global Specialty Pharmaceutical Company (GSP)

Nishikawa As a pharmaceutical company with biopharmaceuticals as its main business, I believe that we are one of the best companies in Japan and an important asset for this country. It is important for us to enhance corporate value by developing this asset and contributing to the health and well-being of people. I will continue to make efforts for that as a board member.

Leibowitz The top reason for my joining the company is that I was impressed with our "Commitment to Life."*3 I have heard that much time was spent in creating this mission statement with the involvement of both employees and management. I believe that our good will toward the world's people and willingness of "taking the walk of life, one life at a time" is being put into practice, and that we are a great company. We have to make sure not to lose sight of our origins as we actualize our group-wide mission to become a GSP.

Kawai Thank you for your strong comments. We must achieve our Mid-term Business Plan by 2020 and develop as a GSP. Becoming a true GSP will require that we enhance our global corporate governance. While adequately incorporating the opinions of our two outside directors who possess valuable experience and knowledge, I as a member of the board intend to do my utmost hereafter for the development of Kyowa Hakko Kirin Group.

*3 Please refer to page 58 for details.

Financial Information

Quick Search

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43 CFO Message
An explanation of the financial strategy of the FY2016-2020 Mid-term Business Plan are provided.

45 Management's Discussion & Analysis (MD&A)
We report on the financial condition and management measures of the company during the fiscal year. We also perform an assessment and analysis of corporate performance and refer to forecasts for the next fiscal year.

53 Risk
Major risks concerning the performance, financial condition, etc. of the company, which may significantly affect the decisions of investors, are reported.

WEB link

WEB

- Financial Ratios
- Consolidated Statements of Cash Flows
- Financial Summary

Eleven-Year Selected Financial Data

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries
For the years ended December 31, 2010 to 2016, the nine months ended December 31, 2009 and years ended March 31, 2007 to 2009

	Millions of yen											Thousands of U.S. dollars[1]
	2016/12	2015/12	2014/12	2013/12	2012/12	2011/12	2010/12	2009/12	2009/3	2008/3	2007/3	**2016/12**
For the Year:												
Net sales	¥ **343,019**	¥ 364,316	¥ 333,446	¥ 340,611	¥ 333,158	¥ 343,722	¥ 413,738	¥ 309,111	¥ 460,183	¥ 392,119	¥ 354,274	$ **2,943,614**
Gross profit	**208,493**	225,393	205,904	212,761	210,690	197,555	190,979	139,739	200,297	144,917	131,424	**1,789,180**
Selling, general and administrative expenses	**176,854**	181,628	169,731	160,987	157,785	150,940	145,568	111,496	154,910	105,527	100,725	**1,517,676**
Operating income	**31,638**	43,765	36,173	51,773	52,905	46,614	45,410	28,243	45,387	39,390	30,698	**271,504**
Net income	**18,669**	29,774	15,898	30,078	24,199	25,608	22,197	8,797	11,726	23,477	12,694	**160,211**
Capital expenditure (including intangible assets)	**32,036**	20,039	29,487	35,183	27,808	19,697	29,374	25,135	18,523	14,795	14,497	**274,923**
Depreciation and amortization	**23,029**	23,126	23,885	21,592	20,904	22,833	22,188	17,003	18,779	14,346	10,006	**197,628**
R&D expenses	**53,822**	51,604	47,737	43,682	44,808	47,961	44,210	34,979	48,389	34,109	33,342	**461,873**
Cash Flows:												
Net cash provided by operating activities	¥ **65,752**	¥ 66,526	¥ 19,377	¥ 56,884	¥ 59,134	¥ 40,634	¥ 64,189	¥ 24,203	¥ 41,069	¥ 30,713	¥ 23,380	$ **564,255**
Net cash peovided by (used in) investing activities	**(48,968)**	(57,747)	16,805	(77,163)	(98,772)	18,460	(32,373)	(13,246)	(3,981)	(9,492)	(8,493)	**(420,219)**
Net cash peovided by (used in) financing activities	**(13,598)**	(14,060)	(37,184)	(12,579)	(19,189)	(30,740)	(14,446)	(16,906)	(20,978)	(13,499)	(24,417)	**(116,694)**
Cash and cash equivalents at the end of the period	**13,075**	12,784	17,013	19,242	50,334	107,555	79,882	63,745	69,286	44,118	36,613	**112,209**
At Year-End:												
Total current assets	¥ **326,469**	¥ 324,433	¥ 283,192	¥ 329,320	¥ 303,988	¥ 284,217	¥ 288,852	¥ 276,587	¥ 279,475	¥ 232,661	¥ 214,352	$ **2,801,594**
Total assets	**697,167**	720,764	719,135	719,257	679,342	658,873	695,862	695,268	699,041	394,081	378,870	**5,982,733**
Total current liabilities	**79,416**	84,823	85,182	85,076	85,774	78,465	102,483	110,080	108,522	111,743	106,565	**681,510**
Interest-bearing debt	**5,360**	4,840	4,868	6,207	5,699	6,042	7,515	13,228	13,540	12,790	13,136	**46,001**
Total net assets	**600,745**	614,858	605,368	595,415	555,898	540,023	544,992	540,343	543,070	256,758	244,082	**5,155,284**
Total shareholders' equity[2]	**599,970**	594,989	580,499	578,329	560,663	554,856	553,172	539,304	547,203	239,328	220,428	**5,148,631**
Number of employees	**7,465**	7,435	7,424	7,152	7,243	7,229	7,484	7,436	7,256	6,073	5,756	
Per Share Data:	Yen											U.S. dollars[1]
Net income–basic[3]	¥ **34.12**	¥ 54.40	¥ 29.05	¥ 54.95	¥ 44.12	¥ 45.16	¥ 38.96	¥ 15.40	¥ 20.42	¥ 58.99	¥ 31.31	$ **0.293**
Net assets	**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	607.49	**9.412**
Cash dividends	**25**	25	25	25	20	20	20	15	20	10	10	**0.215**
Common Stock Price Range (Per share):												
High	¥ **2,098**	¥ 2,321	¥ 1,510	¥ 1,256	¥ 970	¥ 953	¥ 1,040	¥ 1,178	¥ 1,235	¥ 1,430	¥ 1,154	$ **19.26**
Low	**1,412**	1,094	1,006	833	757	628	773	793	586	933	722	**9.08**
Stock Information (Thousands of shares):												
Number of common stock issued	**576,483**	576,483	576,483	576,483	576,483	576,483	576,483	576,483	576,483	399,243	399,243	
Weighted average number of common stock issued	**547,224**	547,285	547,348	547,391	548,449	567,029	569,711	570,935	574,083	397,716	405,270	
Financial Ratios:	%, except EBITDA											
Return on assets (ROA)	**2.63**	4.13	2.21	4.30	3.62	3.78	3.19	1.26	1.62	6.07	3.33	
Operating return on assets	**4.46**	6.07	5.03	7.40	7.91	6.88	6.53	4.05	6.26	10.19	8.04	
Return on equity (ROE)	**3.07**	4.90	2.65	5.24	4.43	4.73	4.11	1.64	2.17	9.47	5.1	
Equity ratio	**86.09**	85.20	84.13	82.58	81.68	81.79	78.16	77.07	77.04	64.53	63.8	
Debt/equity ratio	**0.89**	0.78	0.80	1.05	1.03	1.12	1.38	2.47	2.51	5.03	5.43	
Operating income margin	**9.22**	12.01	10.85	15.20	15.88	13.56	10.98	9.14	9.86	10.05	8.67	
EBITDA[4] (Millions of yen)	**66,003**	78,018	64,101	83,190	78,160	79,864	74,614	45,056	60,098	53,162	33,771	
Payout ratio[5]	**43.7**	35.1	54.4	34.8	32.8	32.5	36.2	54.3	53.8	16.9	31.9	

1. U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥116.53=U.S.$1, the approximate exchange rate at December 31, 2016.
2. Due to a change in accounting standards, figures for total shareholders' equity in the years ended March 31, 2007 have been restated.
3. Net income per share–basic is based upon the weighted average number of shares of common stock outstanding during each year.
4. EBITDA = Income before income taxes and minority interests + Interest expenses + Depreciation and amortization + Amortization of goodwill
5. 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). The consolidated payout ratio for the fiscal year ended December 31, 2016 is calculated using net income before amortization of the entire goodwill.

CFO Message

Aspire to sustainable growth through strategic overseas investment

We aim to expand overseas sales by moving ahead with applying for new drugs approval and launch in European and the U.S. market. We are proactively implementing our financial strategy to achieve our FY 2020 management goals which include a core operating profit of 100 billion yen or more, 50% overseas sales ratio, and ROE of 10% or higher.

Kazuyoshi Tachibana
Director of the Board, Managing Executive Officer

◆**Performance in FY 2016**

For the most part, we have achieved our goals

In FY 2016, our income and profits decreased compared to the previous year. This was in accord with our outlook at the beginning of the period, for which there are three main reasons. First, domestic drug price revision put pressure on earnings for the pharmaceuticals business. Second, our global strategic products have entered the late phase of development and R&D expenses have increased. Third, exchange rate factors such as the continuing yen appreciation have especially affected the performance of the bio-chemicals business.

On the other hand, we achieved our targets for sales volume increases with a focus on new drugs in Japan.

FY 2016 was the first year of our Mid-term Business Plan and is positioned as the investment phase for marketing new drugs overseas. Of these, clinical trials for the global strategic products are proceeding steadily and we were able to achieve our first-year targets for the most part.

◆**Progress of FY 2016–2020 Mid-term Business Plan**

With the expansion of the overseas business, we will increase core operating income and ROE

Core operating income for FY 2016 was 38.2 billion yen. As our global strategic products with having KRN23 as a primary focus are marketed and sales steadily rise in the future, I am confident that we will achieve our FY 2020 management goals.

In the biosimilar business, we announced positive results in phase III clinical trial for the Adalimumab biosimilar drug FKB327 in FY 2016. We are now preparing to apply for new drug approval in Europe and the U.S. in FY 2017, and the drug is expected to contribute to our future performance.

Our overseas sales ratio for the pharmaceuticals business in FY 2016 was 23% and is expected to continue to stably increase. In the future, the overseas sales share of group-wide sales will rise for certain as the global strategic products are marketed. While exchange rate trend has been unclear in recent years, if we discount these effects, we should be able to achieve a 50% overseas sales ratio by FY 2020 as initially envisioned in our Mid-term Business Plan.

ROE of 10% or higher, that we have set as one of our FY 2020 management goals, is a profitability indicator which reflects the International Financial Reporting Standards (IFRS) that we plan to transition over to at the end of the 2017 period. Aiming to achieve the ROE target, the group is developing a strategy for the improvement of ROA. After-tax net income (the numerator of ROA) will be increased mainly with overseas business expansion. With regard to total assets (the denominator of ROA), we will improve overall ROA by suppressing the increase in liquid assets such as inventories and account receivables, etc. As

we have finished making large capital investments both domestically and overseas, we should be able to achieve ROE of 10% or higher if we can achieve 100 billion yen in core operating income.

◆Measures in FY 2016

We are implementing asset optimization together with strategic investment

We have continued to invest in research and development to raise the value of our company's pipeline. We continued to conduct late phase clinical trials on our self-developed products, aiming to apply for new drug approval of our global strategic products. Also, we acquired the European sales rights for Moventig® a drug for the treatment of opioid-induced constipation from AstraZeneca through our Western subsidiary Kyowa Kirin International plc. This move reflects our future expectations for the European market. In Japan, we obtained approval for the psoriasis treatment drug LUMICEF® in July and began sales from September. We will continue such strategic investment hereafter.

With regard to capital investments, in the bio-chemicals business, a new plant in Thailand, which has established to improve our constitution so that we are not easily affected by exchange rate fluctuations, began operations. In the pharmaceuticals business, the reorganization of our domestic plants that we have been carrying out since 2010 is scheduled to end with the closure of the Fuji Plant in 2017. At this point, we feel that our group-wide investments into plants have peaked-out. Although we had increased inventories due to risks relating to stable supply in the process of the plant reorganization, we feel that inventories will reach appropriate levels assuming the reorganization continues to proceed smoothly hereafter.

◆Outlook after FY 2017

We will increase cash flow for agile future investment

The business environment surrounding our domestic pharmaceuticals business is becoming increasingly stringent every year. Drug prices have been revised once every two years and it is a negative factor for domestic business even now, but discussions are currently underway to make annual revisions in the new drug price system starting from FY 2018. Furthermore, the use of generic drugs is making greater headway than expected due to the government policy to promote them. In light of these situation, we will need to hasten the new product launches and penetration in overseas market.

As someone who is responsible for finances, my priority is to generate cash inflow. It is important to consider creating cash by reducing assets, as well as global tax management. One method for asset reduction is to suppress operating capital such as inventories as much as possible and to dispose of tangible assets like facilities and lands that are inefficient. As a result of firmly taking such financial measures, we were able to generate surplus free cash flow in 2016 as well.

At the end of FY 2016, we had 127.5 billion yen in cash reserves. The question is how to flexibly use it and make investments for our growth. Return on the past investment to acquire ProStrakan and Archimedes Pharma in the U.K. (currently Kyowa Kirin International) is proceeding extremely well. We will ensure our ability to generate cash reliably so we can make a strategic investment at an appropriate timing for the future.

◆A Message to Shareholders and Investors

Shareholder returns aiming for 40% dividend payout ratio

Presently we have an equity ratio in excess of 85% and some say that it is large. Common methods to reduce net worth are buying back of the company stocks and dividend increase. With regard to the buy-back, we comprehensively consider the management environment, economic environment, and market environment to make flexible decisions, and we have not conducted that since 2011. As the period from 2016 to 2017 in our Mid-term Business Plan is positioned as an investment phase to expand our overseas business and also our current share price is rising steadily, we are not thinking of the buy-back of the company stocks simply for the purpose of increasing ROE. Until 2015 we paid out dividends aiming for a 40% payout ratio with respect to net income prior to the deduction of amortization of goodwill accompanying reverse acquisition in 2008. The Board of Directors, however, decided

on a policy for stable dividend payments for the first three years in our Mid-term Business Plan starting from 2016 aiming for a 40% payout ratio with respect to net income prior to amortization of the entire goodwill.

In running our business activities, we are apt to turn our attention toward investment risks and short-term profits. However, we will be sensitive to the risks without being overly cautious and reliably discern whether we can expect to see returns over the long-term.

We are now entering an important stage in Kyowa Hakko Kirin's path toward becoming a Global Specialty Pharmaceutical Company that has been our major goal since our founding in 2008, and are making a group-wide effort to achieve this goal. As a person in charge of finances, I intend to make decisions with a wide perspective, while considering capital measures and investment strategy.

Management's Discussion and Analysis

All amounts are rounded down.

Subsidiaries in the Scope of Consolidation

The number of our consolidated subsidiaries for the current fiscal year ended December 31, 2016 stood at 46.

Income

(Billions of yen)

	Fiscal year ended December 31, 2016	Fiscal year ended December 31, 2015	Change
Net sales	**343.0**	364.3	– 21.2
Operating income	**31.6**	43.7	– 12.1
Ordinary income	**26.3**	39.2	– 12.8
Net income	**18.6**	29.7	– 11.1

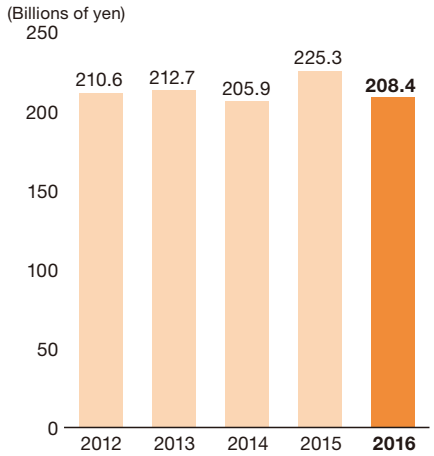
Operating Income

Consolidated net sales and operating income for the current fiscal year decreased due mainly to the effects of reductions in drug price standards and yen appreciation, the decline in licensing revenue and an increase in R&D expenses, despite growth in sales of new products.

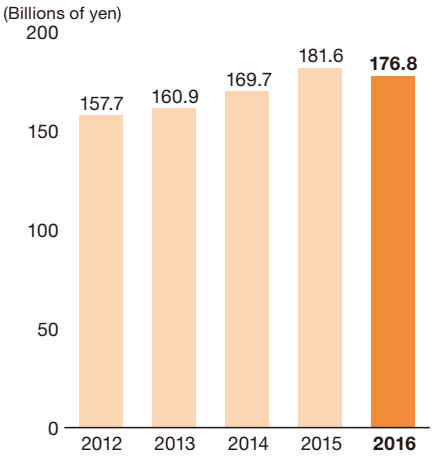
Ordinary Income and Net Income

Ordinary income and net income respectively decreased due to the decrease in operating income.

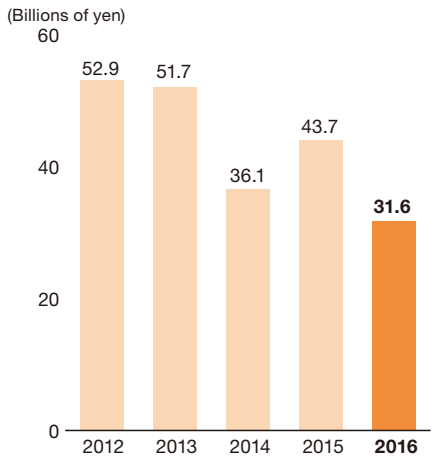
Gross Profit



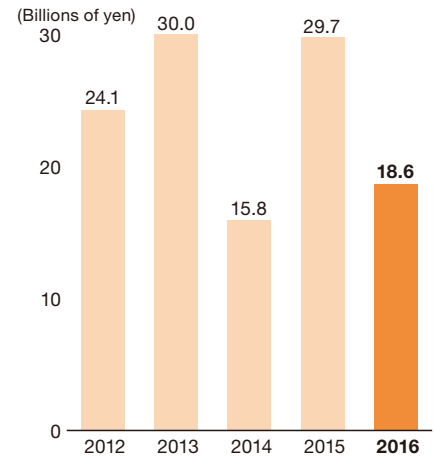
Selling, General and Administrative Expenses



Operating Income



Net Income



Performance by Business Segment

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

	Millions of yen			Thousands of U.S. dollars*
	2016/12	2015/12	2014/12	**2016/12**
Net sales:				
Pharmaceuticals				
Sales to external customers	**¥ 262,507**	¥ 278,402	¥ 251,882	**$ 2,252,699**
Inter-segment sales and transfers	**785**	894	1,129	**6,737**
Total	**263,292**	279,296	253,011	**2,259,437**
Bio-Chemicals				
Sales to external customers	**¥ 80,512**	¥ 85,913	¥ 81,564	**$ 690,914**
Inter-segment sales and transfers	**3,114**	2,981	2,405	**26,723**
Total	**83,626**	88,895	83,970	**717,638**
Adjustments	**(3,899)**	(3,876)	(3,535)	**(33,461)**
Consolidated total	**¥ 343,019**	¥ 364,316	¥ 333,446	**$ 2,943,614**
Segment income (loss):				
Pharmaceuticals	**¥ 26,325**	¥ 36,202	¥ 29,061	**$ 225,912**
Bio-Chemicals	**5,311**	8,127	7,277	**45,579**
Adjustments	**1**	(565)	(165)	**12**
Consolidated total	**¥ 31,638**	¥ 43,765	¥ 36,173	**$ 271,504**

* U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥116.53=U.S.$1, the approximate exchange rate at December 31, 2016.

Pharmaceuticals Business

(Billions of yen)

	Fiscal year ended December 31, 2016	Fiscal year ended December 31, 2015	Change
Net sales	**263.2**	279.2	– 16.0
Operating income	**26.3**	36.2	– 9.8

Sales in Japan decreased compared to the previous fiscal year due mainly to the impact of reductions in drug price standards implemented in April 2016, despite the growth in sales of new products.

Sales of core products NESP®, a long-acting erythropoiesis stimulating agent, and REGPARA®, a treatment for secondary hyperparathyroidism, were solid.

There was steady growth in sales of new products such as G-Lasta®, a sustained-duration Granulocyte Colony-Stimulating Factor (G-CSF) product, NOURIAST®, an antiparkinsonian agent, Onglyza®, a treatment for type 2 diabetes, and Dovobet®, a topical combination drug for psoriasis vulgaris.

Sales of long term NHI products such as ALLELOCK®, an anti-allergy agent, CONIEL®, a hypertension and angina pectoris drug, and GRAN®, a G-CSF product, decreased due to the impacts of the market penetration of generics, etc.

International sales decreased compared to the previous fiscal year due to the impact of yen appreciation and the decline in licensing revenue. In Europe and the U.S., while sales of major products such as Abstral® and PecFent®, which are treatments for cancer pain, increased, sales decreased compared to the previous fiscal year due to the impact of yen appreciation and the decline in licensing revenue. We acquired the European sales rights to Moventig®, an opioid-induced constipation (OIC) treatment, from AstraZeneca, and launched sales in April 2016. In Asia, despite steady sales particularly in China and Korea, sales decreased compared to the previous fiscal year, reflecting the impact of yen appreciation.

Bio-Chemicals Business

(Billions of yen)

	Fiscal year ended December 31, 2016	Fiscal year ended December 31, 2015	Change
Net sales	**83.6**	88.8	– 5.2
Operating income	**5.3**	8.1	– 2.8

Sales in Japan decreased compared to the previous fiscal year. In the pharmaceutical and medical treatment fields, sales declined year on year due mainly to the effect of a drop in the price of some products. In the healthcare field, sales increased year on year due to firm growth in mail-order sales of Ornithine, the new product Arginine EX and other products.

International sales decreased compared to the previous fiscal year, partly reflecting further yen appreciation in foreign exchange. In the Americas, sales decreased compared to the previous fiscal year due to yen appreciation, despite an increase in sales volume for Cognizin® (Citicoline), etc., which was adopted in a U.S. nationwide health food chain's supplement series. In Europe, sales decreased compared to the previous fiscal year, due to yen appreciation, despite strong sales of amino acids for infusion and industrial uses. In Asia, sales decreased compared to the previous fiscal year due to the effect of a drop in the price of some products resulting from intensified competition.

Cash Flow

Cash and cash equivalents as of December 31, 2016 were ¥13.0 billion, an increase of ¥0.2 billion compared to the balance of ¥12.7 billion as of December 31, 2015.

Net cash provided by operating activities was ¥65.7 billion, a 1.2% decrease compared to the previous fiscal year. The main factors included profit before income taxes of ¥30.2 billion, depreciation of ¥23.0 billion and amortization of goodwill of ¥12.6 billion, despite income taxes paid of ¥18.4 billion, etc.

Net cash used in investing activities was ¥48.9 billion, a 15.2% decrease compared to the previous fiscal year. Major outflows included purchase of property, plant and equipment, and intangible assets of ¥29.2 billion, a net increase of ¥18.7 billion in short-term loans receivable. Major inflows included proceeds from sales of property, plant and equipment of ¥4.7 billion.

Net cash used in financing activities was ¥13.5 billion, a 3.3% decrease compared to the previous fiscal year. The main outflows included cash dividends paid of ¥13.6 billion.

Financial Position

Assets

Total assets as of December 31, 2016 were ¥697.1 billion, a decrease of ¥23.5 billion compared to the end of the previous fiscal year. Current assets increased by ¥2.0 billion year on year to ¥326.4 billion as despite decreases in inventories and notes and accounts receivable - trade, there was an increase in short-term loans to the parent company as fund management. Non-current assets decreased by ¥25.6 billion to ¥370.6 billion, affected by the impact of yen appreciation, decreases in goodwill and sales right due to amortization, and others.

Liabilities

Liabilities as of December 31, 2016 were ¥96.4 billion, a decrease of ¥9.4 billion compared to the end of the previous fiscal year, due to decreases in income taxes payable, deferred tax liabilities and other items.

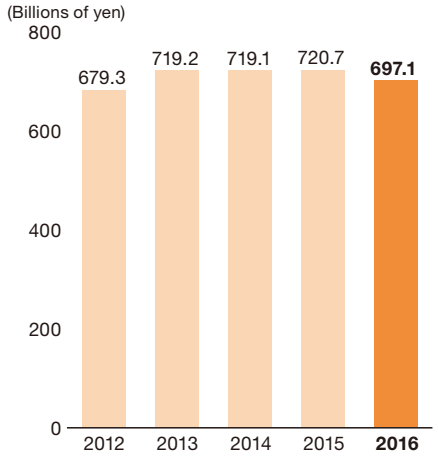
Net Assets

Net assets as of December 31, 2016 were ¥600.7 billion, a decrease of ¥14.1 billion compared to the end of the previous fiscal year, mainly due to payment of dividends and a decrease in foreign currency translation adjustment, which offset factors including the booking of net income. As a result, the equity ratio as of the end of the current fiscal year was 86.1%, an increase of 0.9 percentage points compared to the end of the previous fiscal year. The debt/equity ratio stood at 0.9%, an increase of 0.1 percentage points compared to the end of the previous fiscal year, and remains to show a high level of the Kyowa Hakko Kirin Group's financial soundness.

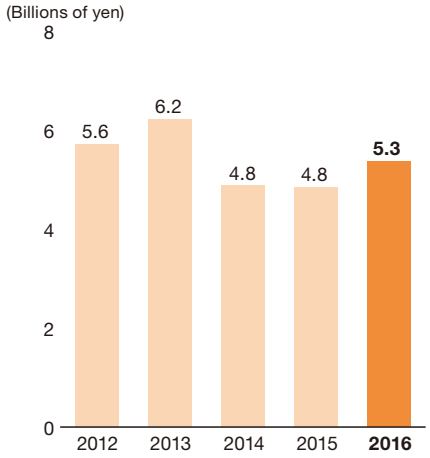
Performance Indicators

ROE stood at 3.07%, a decrease from 4.90% the previous fiscal year, and ROA at 2.63%, a decrease from 4.13% the previous fiscal year. Operating return on total assets came to 4.46%, a decrease from 6.07% the previous fiscal year. EBITDA stood at 66.0 billion yen, a decrease of 15.4% compared to the previous fiscal year.

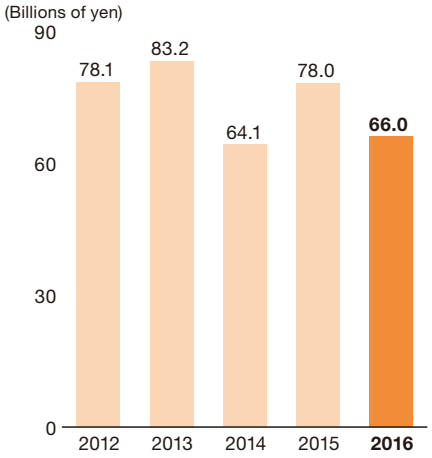
Total Assets



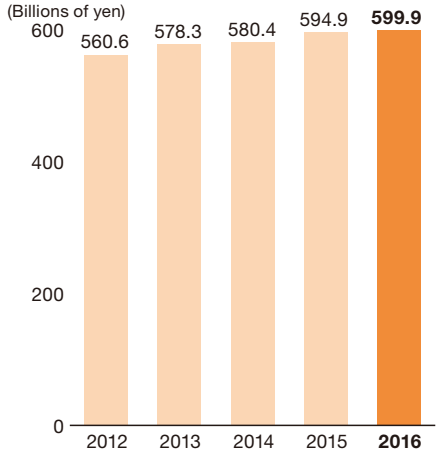
Interest-Bearing Debt



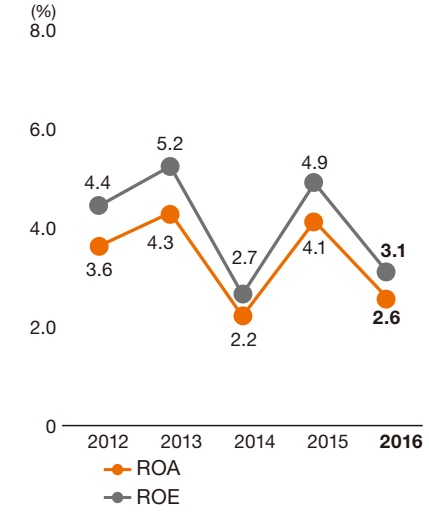
EBITDA



Shareholders' 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, 2016 stood at ¥32.0 billion, an increase of ¥11.9 billion (59.9%) compared to the previous fiscal year. Depreciation and amortization for the fiscal year amounted to ¥23.0 billion, a decrease of ¥0 billion (0.4%) compared to the previous fiscal year.

The table below shows a breakdown of capital expenditure and depreciation and amortization.

Capital Expenditure

(Millions of yen)

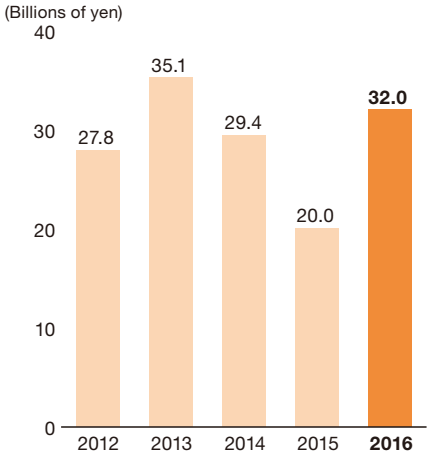
	2016/12	2015/12	2014/12	2013/12	2012/12
Pharmaceuticals	**¥ 24,112**	¥ 11,537	¥ 17,012	¥ 22,921	¥ 18,357
Bio-Chemicals	**8,000**	8,501	12,476	12,261	9,454
Adjustments	**(75)**	—	(1)	—	(3)
Consolidated total	**¥ 32,036**	¥ 20,039	¥ 29,487	¥ 35,183	¥ 27,808

Depreciation and Amortization

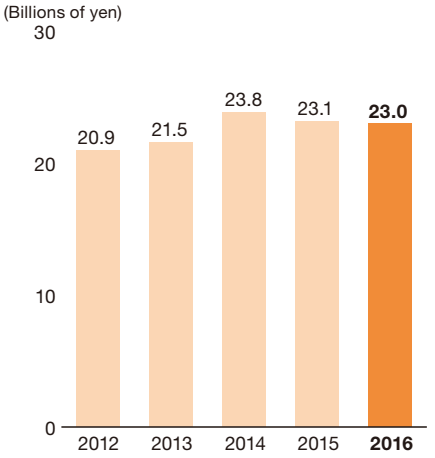
(Millions of yen)

	2016/12	2015/12	2014/12	2013/12	2012/12
Pharmaceuticals	**¥ 16,184**	¥ 16,569	¥ 17,075	¥ 14,966	¥ 14,625
Bio-Chemicals	**6,846**	6,558	6,811	6,627	6,280
Adjustments	**(1)**	(1)	(1)	(1)	(1)
Consolidated total	**¥ 23,029**	¥ 23,126	¥ 23,885	¥ 21,592	¥ 20,904

Capital Expenditure



Depreciation and Amortization

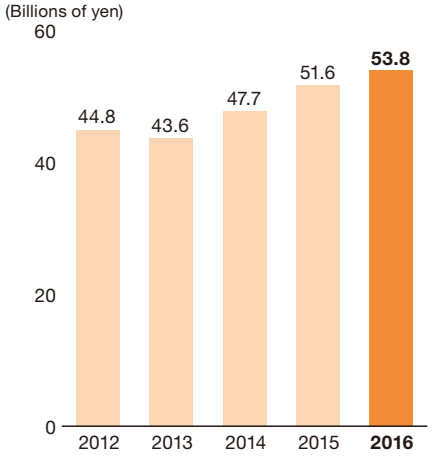


R&D Expenses

R&D expenses for the fiscal year ended December 31, 2016 stood at ¥53.8 billion, an increase of 4.3% compared to the previous fiscal year. The ratio of R&D expenses to sales for the year came to 15.7%, an increase of 1.5 percentage points from 14.2% the previous fiscal year.

The R&D expenses in the Pharmaceuticals segment totaled ¥50.5 billion and accounted for 94.0% of total R&D expenses. The ratio of R&D expenses to sales in the Pharmaceuticals business stood at 19.2%, an increase of 1.9 percentage points compared to the previous fiscal year. The R&D expenses in the Bio-Chemicals business amounted to ¥3.2 billion which is about the same level as in the previous fiscal year.

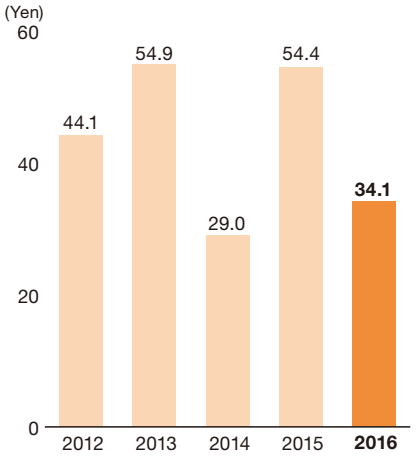
R&D Expenses



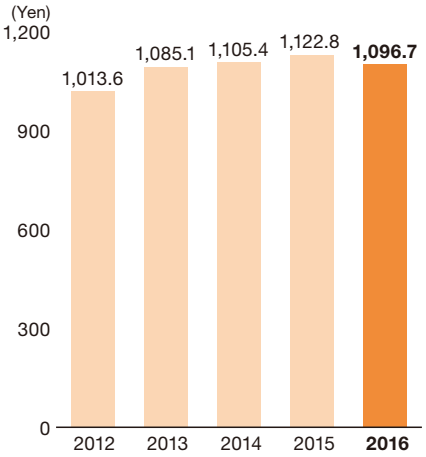
Per Share Data

Net income per share (before dilution) for the fiscal year ended December 31, 2016 stood at ¥34.12 compared to ¥54.40 the previous year. Net income per share before goodwill amortization amounted to ¥57.22. Net assets per share on December 31, 2016 totaled ¥1,096.78 compared to ¥1,122.80 on December 31, 2015.

Net Income per Share



Net Assets 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 our biosimilars, diagnostics and bio-chemical businesses as it progresses toward a leap forward to become a Global Specialty Pharmaceutical Company (GSP), 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 fiscal 2016 being the first year of the plan, the management targets for fiscal 2020, the final year of the plan, are to achieve core operating income of at least ¥100.0 billion, an overseas sales ratio of 50% and ROE of 10% or higher.

Note

*1 Core Operating Income: Operating Profit + Amortization of Goodwill + Equity Method Gain/Loss

*2 ROE: Net income before amortization of goodwill ÷ Shareholder's equity

In recent years, and in Japan in particular, growth in the pharmaceuticals market has leveled off due to the market penetration of generics in conjunction with progress in measures to reduce medical cost and significant revisions to the drug price system. Research and development-oriented pharmaceutical companies will have to accelerate their efforts to shift their sources of revenue from long term NHI products and the domestic market to new pharmaceuticals and the global market. In this environment, the Kyowa Hakko Kirin 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 GSP," 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 KRN23, one of our global strategic products, in the U.S. and European markets. We now have higher expectations for KRN23 to receive approval in the U.S. and Europe, as in June KRN23 received breakthrough therapy designation in the U.S. from the FDA, while in Europe at the end of the year the EMA accepted our application for approval for this drug. Going forward, we will continue to pursue early, successful market launches and aim to maximize KRN23's value. In addition, Benralizumab (KHK4563), currently under development for treatment of asthma and chronic obstructive pulmonary disease (COPD), is being licensed out to AstraZeneca and is expected to contribute to overseas sales in the form of licensing revenue going forward. 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, an area of our strengths, 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. In addition, in the pipeline of new drugs in late-stage development, a number of drugs, including KHK7580, being developed for the treatment of secondary hyperparathyroidism patients receiving hemodialysis, ARQ197, being developed for the treatment of inoperable hepatocellular carcinoma, and RTA402, under development for the treatment of chronic kidney disease (CKD) with Type 2 Diabetes, have achieved plan goals without problem, and we are accelerating our activities aimed at early filing for approval and market launches. Moreover, in the field of immuno-oncology, which has received a lot of attention in recent years, we will continue to pursue combination trials with other drugs, centered on KW-0761 (product name in Japan: POTELIGEO®).

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 aim to grow as a trusted company, which includes building a global governance framework and ensuring thorough compliance awareness. In particular in Japan, we are accelerating our area strategy to contribute to community healthcare, and are providing high-quality healthcare data. In addition, upholding our responsibility as a pharmaceuticals 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 which must be of high quality. Furthermore, we will further enhance our initiatives including 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, expanding the scope of application of products and adding dosage forms, 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 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. Concerning FKB327, an adalimumab biosimilar

candidate, we are engaged in a business partnership encompassing our sales strategy, and going forward we will continue to file applications in the U.S. and Europe. In addition, steady progress is being made on an international joint clinical trial for bevacizumab biosimilar candidate FKB238, with which we are collaborating with AstraZeneca.

We believe that diagnostics business will increasingly grow in importance going forward in line with further development with respect to personalized cares and preventative medicine, thereby bringing about more new business opportunities for our diagnostics business in the healthcare field. Kyowa Medex received approval in Japan for a new diagnostic reagent for primary aldosteronism, and also received approval for insurance application and launched sales of a diagnostic reagent for rickets and osteomalacia, which stem from Vitamin D deficiency. Overseas, Kyowa Medex is preparing to launch businesses of the FGF23 diagnostic reagent and fecal occult blood diagnosis in the U.S., and will continue to provide both advanced diagnostic reagents and diagnostic medical devices needed for the treatment of various diseases.

In the bio-chemicals business, we are addressing the key issues of strengthening the revenue 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. Concerning the reorganization of our production centers, during 2016 we completed trial manufacturing at Hofu using new facilities for products for which production is being transferred from the Yamaguchi Production Center (Ube) to the Yamaguchi Production Center (Hofu). In terms of providing value with a focus on people's health, as a part of our marketing strategy developed in the U.S. and rolled out worldwide, we delivered AminoScope®, a magazine published by our U.S. subsidiary, to our customers around the world. We will continue to reorganize our production centers to boost factory productivity, further enhance the value of branded products, and strengthen relationships with customers in the mail-order business. Moreover, we will continue to supply all of our customers with products that contain value exceeding their ingredients and substances for our customers' health by providing functionality data and leveraging our intellectual property rights.

Our 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 development at its core, the group is pursuing a unique pharmaceutical business model that combines its biosimilars, diagnostics and bio-chemicals businesses as it progresses toward a leap forward to become a GSP, as set out in the new Mid-term Business Plan.

Outlook for 2017

Consolidated financial earnings forecasts for fiscal 2017 (January 1, 2017 to December 31, 2017) are for net sales of ¥344.0 billion, an increase of 0.3% compared to the current fiscal year, operating income of ¥35.0 billion, up 10.6%, ordinary income of ¥30.0 billion, up 13.6%, and net income of ¥19.0 billion, an increase of 1.8%.

In the Pharmaceuticals business, sales are expected to be at the same level as the current fiscal year due mainly to anticipated growth of new products such as G-Lasta®, a sustained-duration G-CSF product and NOURIAST®, an antiparkinsonian agent, and the increase in licensing revenue, despite the market penetration of generics, impacts of exchange rate, etc. We also forecast an increase in operating income mainly due to an increase in licensing revenue and a decrease in R&D expenses despite the likelihood of higher expenses incurred in preparing for U.S. and European product launches.

In the Bio-Chemicals business, sales are expected to be at the same level as the current fiscal year. However, we forecast an increase in operating income due to an increase in mail-order sales of products that include core amino acids, nucleic acids, Ornithine and Arginine EX.

Ordinary income and profit attributable to owners of parent are also forecast to increase compared to the current fiscal year, due to the increase of operating income and the decrease of share of loss of entities accounted for using equity method.

Profit Distribution

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

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

In accordance with this basic policy, we plan to pay a year-end dividend for fiscal 2016 of ¥12.50 per share. As a result, the annual dividend is expected to be ¥25 per share, consisting of an interim dividend of ¥12.50 per share and a year-end dividend of ¥12.50 per share.

In our 2016 to 2020 Mid-term Business Plan, until 2018 we aim for a stable dividend payment, targeting a consolidated dividend payout ratio of 40% on a basis of profit before amortization of goodwill. For the fiscal year ending December 2017, we expect to pay an annual dividend of ¥25 per share, consisting of an interim dividend of ¥12.50 and a year-end dividend of ¥12.50.

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, 2016).

With respect to 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 non-pharmaceutical operations, 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 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 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 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, largescale electrical blackouts, and others events could result in suspension of business activities at our group head quarters, 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), 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) 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

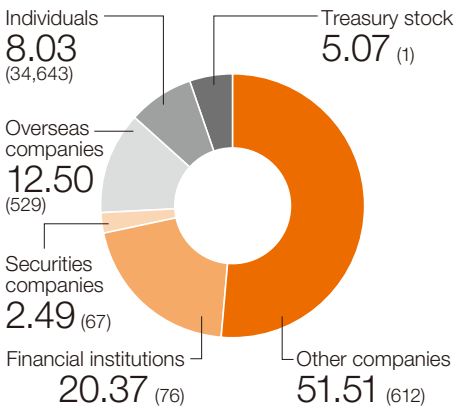
Securities Code
4151

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

Number of Shares of Common Stock
Authorized: 987,900,000
Issued: 576,483,555

Number of Shareholders
35,928

Shareholding by Type of Investor (Number)



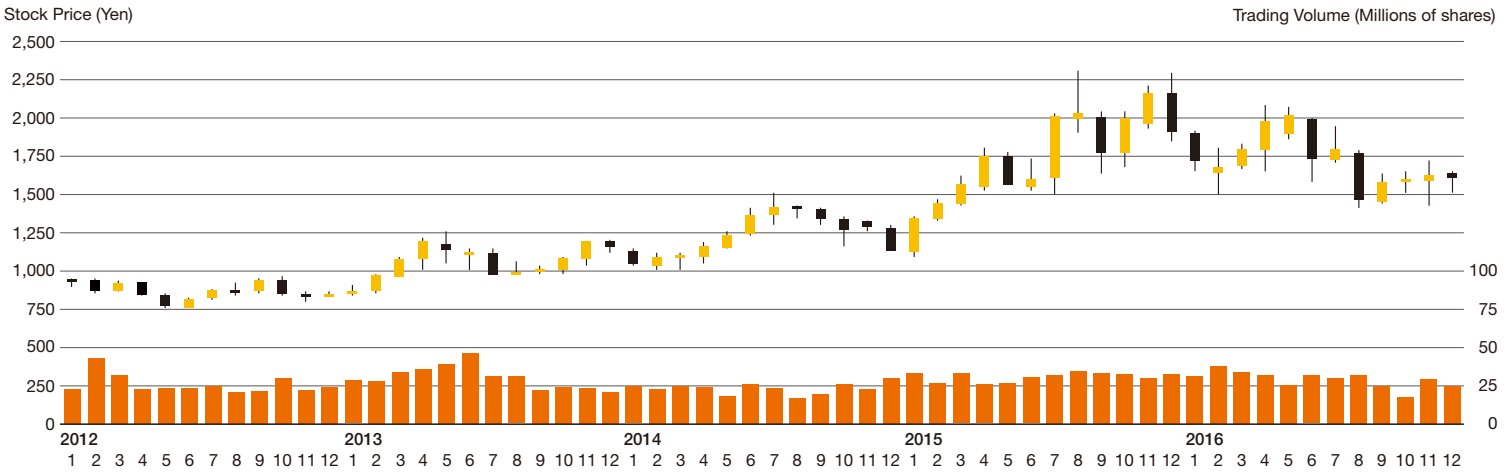
Principal Shareholders

(As of December 31, 2016)

	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)	32,457	5.63
Japan Trustee Services Bank, Ltd. (Trust Account)	19,321	3.35
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
Nomura Trust and Banking Co., Ltd. (investment account)	5,762	1.00
Japan Trustee Services Bank, Ltd. (Trust Account 9)	4,087	0.71
State Street Bank West Client-Treaty 505234 (Standing Proxy: Mizuho, Ltd., Settlement & Clearing Services Division)	3,983	0.69
Trust & Custody Services Bank, Ltd. (Securities Investment Trust Account)	3,809	0.66

The 29,261,490 shares (5.08%) 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

Network*

(As of December 31, 2016)

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
America			
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
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	Supervision and management of specific subsidiaries (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.)
Archimedes Development Limted	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)

Name of Company	Percentage Owned Directly or Indirectly by the Company	Share Capital (1,000)	Principal Business
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 of pharmaceuticals and research (Singapore)
Japan (Equity-method affiliate)			
FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.	50.00%	¥100,000	Development, manufacturing and sales of biosimilar pharmaceuticals
Europe (Equity-method affiliate)			
Centus Biotherapeutics Limited	25.00%	US $110,000	Development and sales of biosimilar pharmaceuticals (U.K.)
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
America			
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. and Centus Biotherapeutics Limited which are equity-method affiliates.

Corporate Data

Corporate Data (As of December 31, 2016)

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
4,088 (Consolidated: 7,465)

Date of Foundation
July 1, 1949

Paid-in Capital
¥26,745 million

Principal Plants

Domestic

Pharmaceuticals
Takasaki Plant
Fuji 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.
Kyowa Kirin Pharmaceutical Development, Inc. (U.S.A.)
Kyowa Kirin Pharmaceutical Research, Inc. (U.S.A.)
Kyowa Kirin International Plc (U.K.)

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 Hakko Kirin China Pharmaceutical Co., Ltd.
Kyowa Hakko Kirin Korea Co., Ltd.
Kyowa Hakko Kirin (Singapore) Pte. Ltd.

Management Members (As of March 23, 2017)

Board Members

Executive Director of the Board
President and Chief Executive Officer
Nobuo Hanai, Ph.D.*1

Executive Director of the Board
Executive Vice President
Hiroyuki Kawai, Ph.D.

Directors of the Board
Managing Executive Officers
Kazuyoshi Tachibana

Toshifumi Mikayama, Ph.D.
Director
Overseas Business Department

Masashi Miyamoto, Ph.D.
Director
Strategic Product Portfolio Department

Directors of the Board
Noriya Yokota
Koichiro Nishikawa*2
Yoshiko Leibowitz*2

*1 Concurrently serves as executive officer
*2 Outside director

Company Auditors

Full-time Company Auditors
Nobuhisa Yamazaki
Akira Shimizu*3

Company Auditors
Motoyasu Ishihara
Kentaro Uryu*3
Jun Arai*3

*3 Outside company auditor

Executive Officers

Managing Executive Officer

Yutaka Ouchi
Director
Human Resources Department

Hiroshi Sugitani
Vice President Head
Sales & Marketing Division and
Director
Nagoya Branch

Yutaka Osawa
Vice President Head
Production Division

Executive Officers

Hiroshi Okazaki, Ph.D.
Vice President Head
R&D Division
Director
Translational Research Unit

Kazuyoshi Adachi
Vice President Head
Pharmacovigilance and
Quality Assurance Division

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

Takashi Oishi
Director
Medical Affairs Department

Satoshi Nakanishi, Ph.D.
Director
CSR 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
Osaka Branch
Sales & Marketing Division

Hiroshi Sonekawa
Director
Area Marketing Strategy Department
Sales & Marketing Division

Shinichiro Mouri
Director
Quality Management Department

Mitsuo Sato
Vice President Head
R&D Division and Director
Immunology & Allergy R&D Unit

Nobuyuki Tsukahara
Director
Tokyo Branch

Takemi Yamashita
Director
Pharmaceutical Department
Pharmacovigilance and
Quality Assurance Division

Commitment to Life

Countless precious lives surround us.
Brought into this world, blessed, raised with loving care – full of dreams, happiness as the goal of life.
Deeply instill in us, and know that what we work for – the most precious presence of all on this planet.
Infinite possibilities for us, a pharmaceutical company.

Believe in ourselves, believe in our power, believe in what we have built together.
Not a large company, but with qualities like none other.
History so unique we can be proud of, technology unmatched,
And superior human beings that cannot be found elsewhere.

Be brave; do not shy away from challenges. Have passion; break away from the norm.
Innovation is not just about growth – but instead a leap towards the future, a grand growth with wings.
Wings never to be given to those who settle for the status-quo.

Don't just make medicine. Make people smile, bring light to their lives.
How strongly one longs to live. How deeply one is loved by their loved ones.
How sincerely one desires to help the one life they dedicate themselves to in the field of medicine.
Stay receptive, sharpen your sensitivities.
Let us become the top company in the world who cares the most for life.
Strength is not what saves the world. A caring heart is what the world calls for.

Strive to become a superb team.
One human being, excellent or not, is ever so powerless, as a power of one, mistakes, even a possibility.
Show the world the excellence of coming together. Amazing results, when we become one.
Be driven. Think of those fighting for their lives every day.
Their strong devotion to life speaks to our hearts.
Hurry – do not scurry, but we must not stand still. Stay sincere, always – may that be our vow.
We make medicine. This is, our walk of life.

Work, can bring happiness. Remember this, always.
Born on this planet in various parts of the globe, passing through life in different ways,
And like a miracle we found one another – our jobs, our team, our company.
Know this, and be fulfilled, always.
Be thankful of what you have, pour your heart and soul into the mission you were given,
Be proud of your work, the work to save precious lives.

We are, each and everyone of us, Kyowa Hakko Kirin.

Taking the walk of life, one life at a time.

The “Commitment to Life” was created when the company was established in October 2008 after discussions held between employees and management of Kyowa Hakko Kirin. As workers in a pharmaceutical company, we strive to bring smiles to all people who long for wellbeing through a sincere commitment to life that emphasizes cooperation with healthcare providers and continuously moving forward with life.

Please see the “Commitment to Life” page for details.
http://www.kyowa-kirin.com/about_us/commitment_to_life/