# KYOWA KIRIN

Annual Report 2015

For the year ended December 31, 2015

# Leaping Forward

# Contents



## Editorial Policy

Shigeru Morotomi,
Executive Officer, Director of Corporate Communications Department

Annual Report 2015 describes the unique business model and management strategy of our group while incorporating the concept of International Integrated Reporting Council (IIRC) International Integrated Reporting Framework so that readers can understand the image of the entire group. From this year, we have stopped the printed version of the annual report, and have created only a PDF version. Optimizing information and taking advantage of the advanced mobility through the cooperation with our website, we have edited the report into a compact and readable format. It is our sincere hope that this report will be of use to all stakeholders, including institutional investors. Our five-year mid-term business plan has commenced in 2016. We ask for your continued support as the Kyowa Hakko Kirin Group makes the leap forward to become a global specialty pharmaceutical company.


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 2015 and part of 2016.

### Performance Forecasts

Forecasts contained in Annual Report 2015 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/Vision/Commitment to Life

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.**

## 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.**

# Our Philosophy

## 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.

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

# Who we are

Group Structure/Business Model

## 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

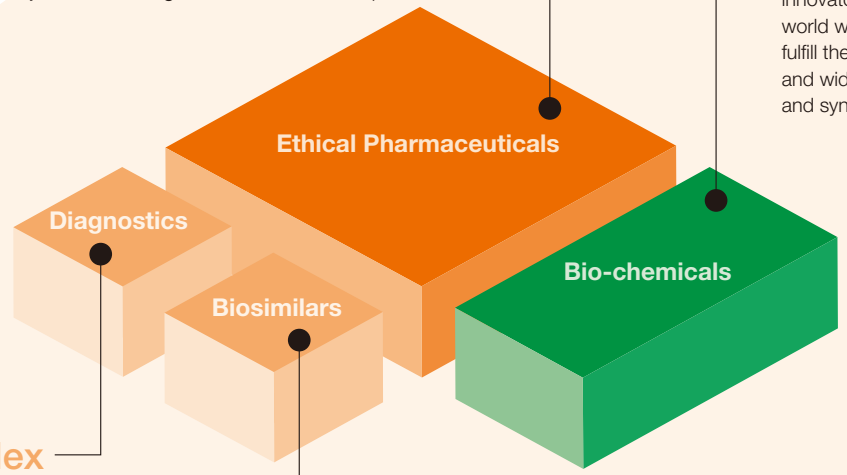
The Kyowa Hakko Kirin Group has advanced unique research with its sophisticated technology in the business fields of “pharmaceuticals” and “bio-chemicals” while developing and providing various high-quality products. The field of biotechnology offers immense possibilities. As a representative life science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

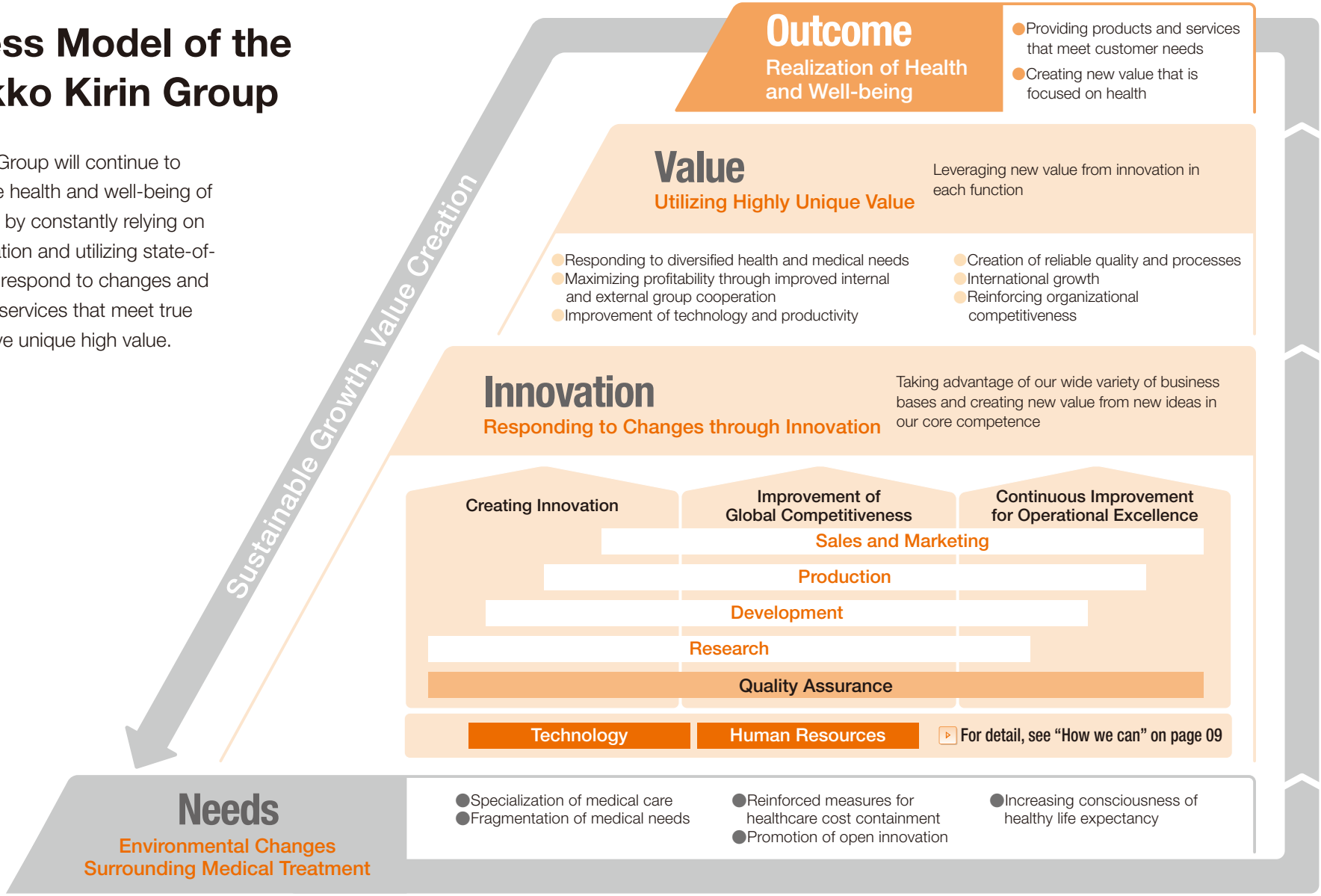
In cooperation with Kyowa Hakko Kirin’s R&D operations, Kyowa Medex seeks to generate synergies with the pharmaceuticals business and enhance added value through the development and launch of diagnostic reagents, analyzers, and companion diagnostics that contribute to personalized medicine.

### 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 and quality control developed by FUJIFILM Corporation through its various businesses.

# The Business Model of the Kyowa Hakko Kirin Group

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.



# What we do

FY2016-2020 Mid-Term Business Plan

## 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.

**Being a "Japan-based world-leading R&D type life science company"**

**STEP1**
2008-2009
Integrate Strength

**STEP2**
2010-2012
Select and Concentrate

**STEP3**
2013-2015
Strive toward GSP

**STEP4**
2016 → 2020

**Leaping forward for GSP**

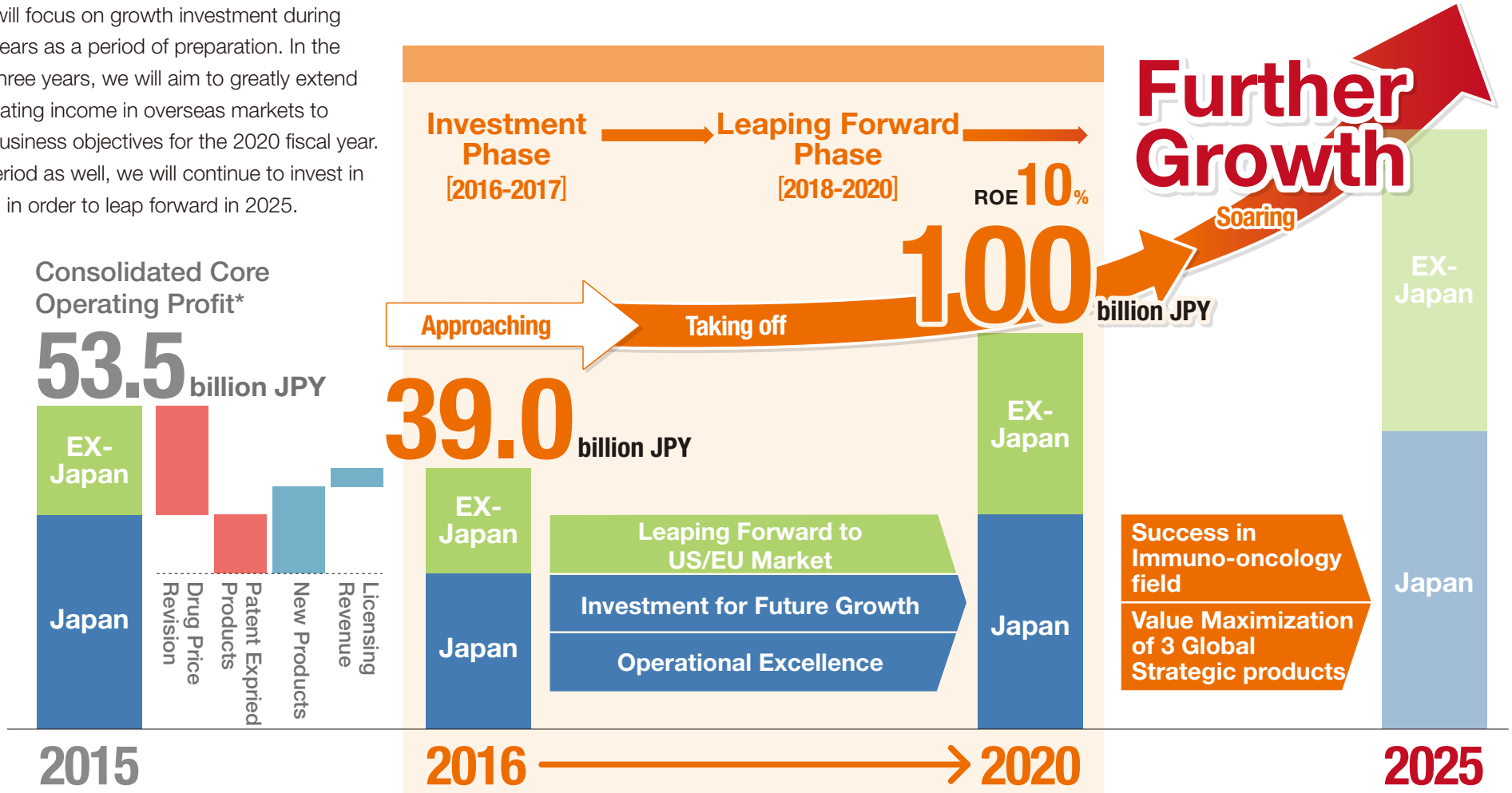
- Improvement of Global Competitiveness
- Creating Innovation
- Continuous Improvement for Operational Excellence
- Contribution to Health and Well-being of People

| Core Operating Profit* | Overseas Sales | ROE |
|---|---|---|
| over 100 billion JPY | 50% | over 10% |

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

## The Process to Become a GSP

Of the five-year mid-term business plan from FY 2016 to 2020, we will focus on growth investment during the first two years as a period of preparation. In the subsequent three years, we will aim to greatly extend our core operating income in overseas markets to achieve our business objectives for the 2020 fiscal year. During this period as well, we will continue to invest in development, in order to leap forward in 2025.




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

# How we can

Technical Capabilities/Human Resources

Technical Capabilities

## Technical Capabilities and Human Resources That Support Our Leap Forward

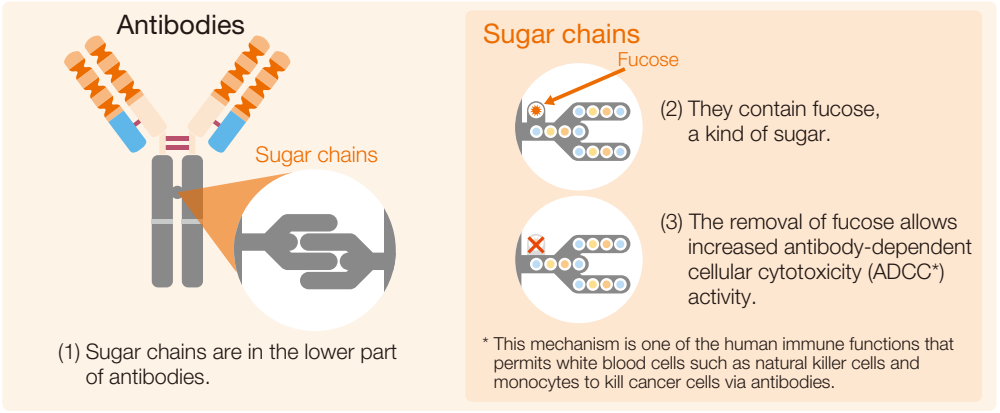
**Our original technological capabilities and variety of human resources provide us great ability of drug development. By fully maximizing these two forces, we will creat new value and continue to contribute to the health and well-being of people around the world.**

### Our Unique Therapeutic Antibody Technology

Therapeutic antibody technology is one of the representative technologies of Kyowa Hakko Kirin. As a result of many years of biopharmaceutical research, we have established POTELLIGENT® and COMPLEGENT® technologies, which dramatically enhance the performance of therapeutic antibodies, and we also established (or discovered) the technology that (or which?) enables us to generate fully human antibodies with the same diversity as naturally produced human antibodies. A consistent research platform and variety of technologies from creation to improvement of therapeutic antibodies have greatly contributed to our therapeutic antibody development.

The therapeutic antibody KW-0761 developed by Kyowa Hakko Kirin, has already been released as anti-CCR4 humanized antibody POTELIGEO® in Japan, and development is underway in Europe and the United State with the aim of early release in these markets. Furthermore, based on research in recent years, this drug has been found to have the potential as a therapeutic agent in immuno-oncology area to attack solid tumors by increasing the immunity of a patient.

**POTELLIGENT® Technology Overview**




### The Production Technology of Our Pharmaceuticals Business

The Bio Process Research and Development Laboratories is responsible for activities such as the development of the manufacturing process of biopharmaceuticals including therapeutic antibodies, analytical techniques, and formulation design. By combining the unique techniques and know-how developed to date with advanced technology, we have established a production process that has world-class quality and productivity.

The CMC R&D Center is primarily responsible for the drug formulation of small molecules manufacturing of clinical trial materials development of analytical methods for active pharmaceutical ingredients and drug products, in addition to tasks related to filing applications as well as research in product lifecycle management. By offering the great products that incorporate various developed technologies, we continue to provide new values to people around the world.

Moreover, we are currently leading the way in treatment of X-linked hypophosphatemia (XLH) through the current joint development of the therapeutic antibody KRN23 with our partner company,Ultragenyx. This drug has received Fast Track*1 designation from the FDA*2, and has attracted much attention from healthcare practitioners for its great potential as a pharmaceutical product.

*1 A program designed to promote the development of drugs to treat severe diseases and diseases with few treatment options.
*2 U.S. Food and Drug Administration (FDA) manages the approval of prescription drugs in the United States.

### The Production Technology of Our Bio-chemicals Business

The development of production technology of our bio-chemicals business is as follows: the Bioprocess Development Center is responsible for the development of novel manufacturing processes of various compounds, including amino acids using microorganisms and enzymes; the Technical Research Laboratories conducts research into industrialization to introduce the process development to the production sites; and the Healthcare Products Development Center conducts the research and development of functions in order to find the usefulness of the compounds as well as the research and development of the processing technology required for the development of granules, tablets or liquids of products.

In the future, we aim to create new value based on the fusion of state-of-the-art biotechnology and our accumulated know-how.

# How we can

Human Resources

## Global Cooperation with Emphasis on Diversity

In line with our mid-term business plan that started in 2016, we have placed importance on cultivating an innovative organizational culture to leap forward to become a global specialty pharmaceutical company. We believe that we can achieve sustainable growth by each of us respecting diversity so that our cross-cultural organization is full of vitality. Therefore, we are particularly focused on developing global human resources, promoting the activity of women and the employment of persons with disabilities. We believe that through such efforts, by knowing and understanding each other, we can achieve a level of communication that crosses companies, countries, regions, and languages, leading to expanded global cooperation and improved performance as well as corporate value.

### Overcoming Regional Barriers Making Diversity a Strength

I am working on global development of pharmaceutical products at the Princeton office, where I have many colleagues with different nationalities, different work experiences, and different reasons for joining the company. The fact that we, despite all those differences, met right here and are working hard together toward a common goal feels like a miracle or fate perhaps. I have to admit, however, that there are still various barriers that exist between Japan and other countries.

I believe a key to success in international business is to remove those geographic barriers. While of course it is necessary to promote the global integration of the organizational processes, systems and even architecture, it seems to me equally important that we eliminate the barriers lurking in each member's mindset and way of thinking. Feeling that there are many things that those working overseas can do for it, in 2015, ODDO expatriate employees created the "Ten Fundamentals for Expatriate" to act as daily guidelines on mindset and behavior. We aim to become a global company with high diversity as its strength by overcoming the geographic barriers.

Kyowa Hakko Kirin Pharma, Inc. /One Drug Development Organization (ODDO),Planning Department

**Takeshi Matsushita**

### Introduction of a New Manufacturing Process based on Cooperation between Sites

Since I joined the company, I have continued to be responsible for conducting research and development on the amino acid production process at the Technical Research Laboratories. Amino acids, one of the company's main products, are manufactured not only in Japan, but also globally. In 2015, we started operations of the new factory in Thailand, and those of us who are responsible for research were involved in the startup of the plant through the development of the processes to be introduced there. When we introduced the new processes that had been developed in the laboratory, we had to collaborate with many employees from inexperienced to veterans, including members based in global locations; cooperation with the overseas sites proved to be more difficult than performing research only in Japan. Since I have only been with the company for five years, I am still learning from experience and often rely on trial and error. However, this company has a relaxed environment in which all members can freely share opinions regardless of their age or experience, so I feel supported through discussions and the advice that I receive from my laboratory supervisor and colleagues as well as those working in other departments such as the factories. In my future work, I plan to utilize the perspective and way of thinking that I obtained though these various experiences in my future work.

Kyowa Hakko Bio, Technical Research Laboratories

**Naoko Anzai**

### Coming into Contact with Japanese Colleagues and Japanese Culture While Sharing Common Goals

ProStrakan is proud of our culture where our working environment seamlessly brings together people from a diverse set of backgrounds, beliefs, perspectives and lifestyles. This way of operating has allowed us to build a strong business and a wonderful atmosphere of employee development, respectful debate and an appreciation of all opinions. We truly believe employees learn and make better decisions in situations filled with others who are unlike themselves. Having operations across the EU and the US and supporting work visas for those originating from outside these regions contributes to this culture; as does working with global partners, considering always, patients whomever and wherever they might be.

We welcome colleagues from our Japanese Parent to live, work and visit ProStrakan as a way to help build a Global Specialty Pharmaceutical business whose employees have broad cultural exposure and understanding. ProStrakan employees participate fully in global initiatives that help to bridge not only cultural variation but additionally provide an education and appreciation of regional regulatory environmental differences.

ProStrakan is preparing to launch our first products conceived in KHK labs. Moving towards launch we are fortunate to have greater opportunity to work closely with our Japanese colleagues and as is our culture, we will welcome the diversity of backgrounds, beliefs perspectives and lifestyles knowing that such openness will lead to a great future and ultimately contribute to the health and wellbeing of people around the world.

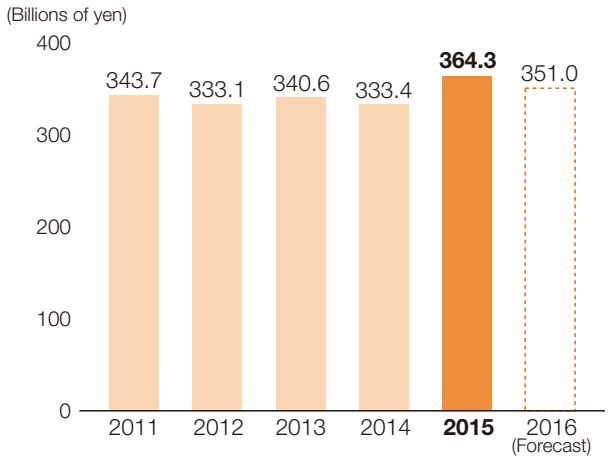
ProStrakan Group plc EXECUTIVE VICE PRESIDENT, HR

**Beth Tope**

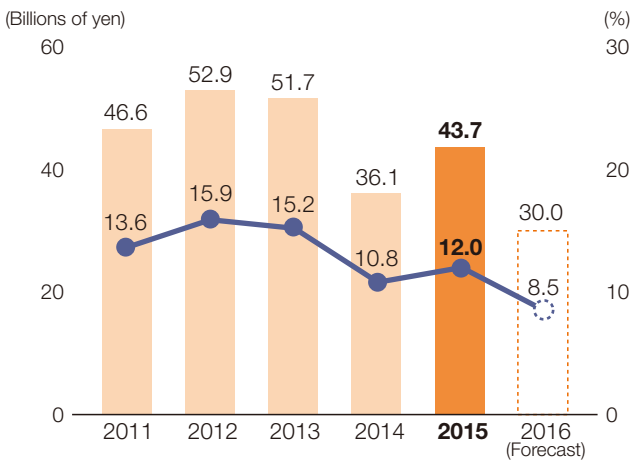
# Financial & ESG Highlights

## Financial Highlights (For the year ended December 31, 2015)

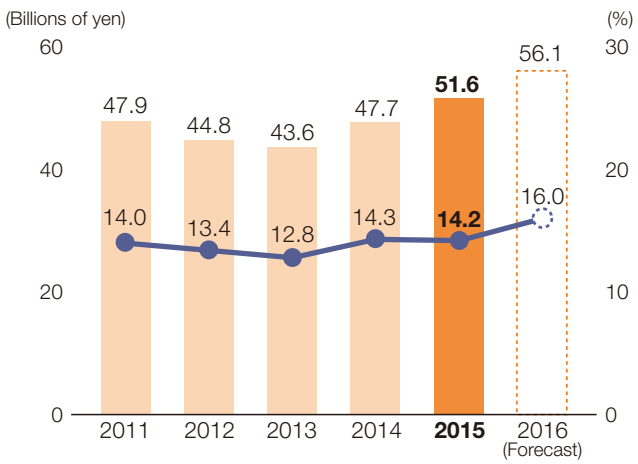
### Net Sales



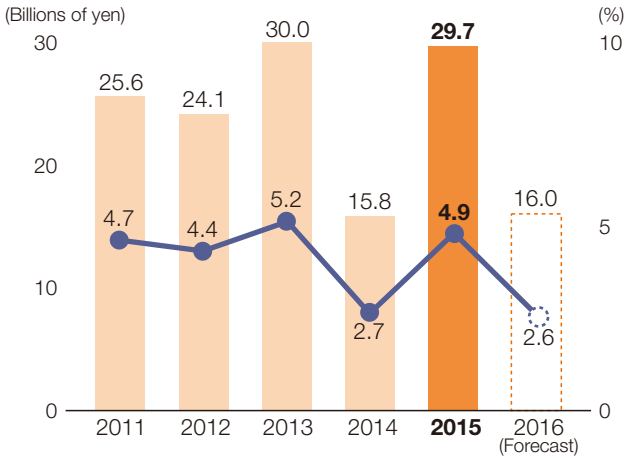

### Operating Income/Operating Margin



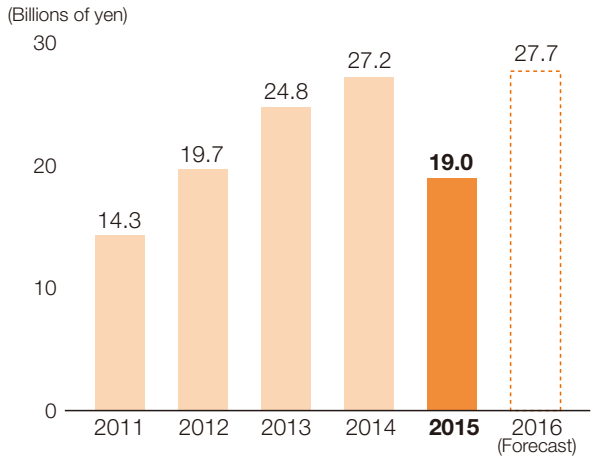

### R&D Expenses/Ratio of R&D Expenses to Sales



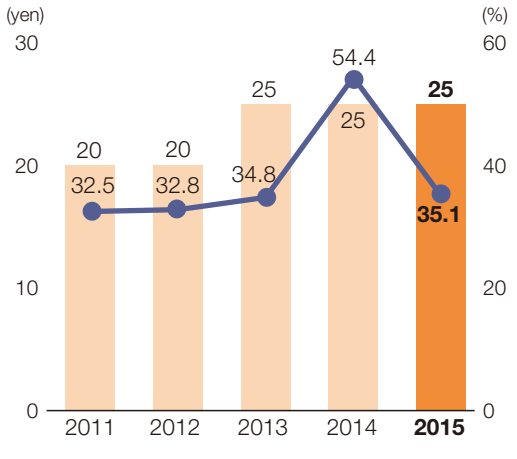

### Net Income/ROE




### Capital Expenditures (Tangible fixed assets)




### Payout Ratio (before amortization of goodwill)

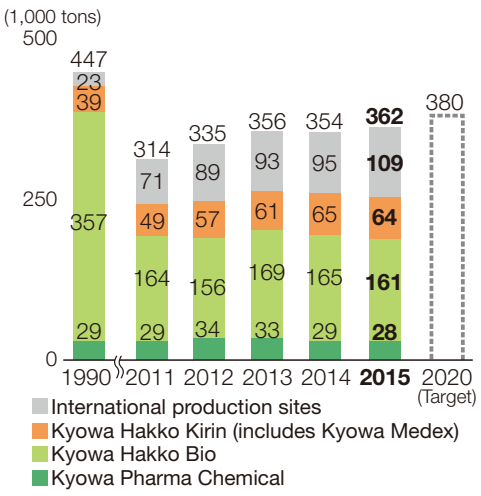


# Financial & ESG Highlights

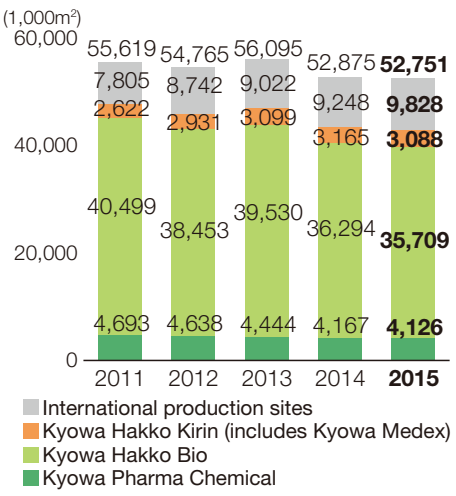
## ESG Highlights

1. The domestic plants and research laboratories of Kyowa Hakko Kirin, Kyowa Medex, Kyowa Hakko Bio and Kyowa Pharma Chemical are covered. The overseas plants of Kyowa Hakko Kirin China Pharmaceutical Co., Ltd., BioKyowa Inc. (U.S.A.), Shanghai Kyowa Amino Acid Co., Ltd., and Thai Kyowa Biotechnologies Co., Ltd. are also covered.
2. Data is for the financial years from April to March until 2012, and from January to December from 2013.
3. Increased due to the start of operations at the new amino acid production factory of Thai Kyowa Biotechnologies Co., Ltd. and increased production at overseas plants, but we are continuing efforts to make reductions.
4. Formulation of reduction targets for water usage is scheduled for 2016.
5. The domestic plants and research laboratories of Kyowa Hakko Kirin, Kyowa Medex, Kyowa Hakko Bio and Kyowa Pharma Chemical are covered.
6. Data have been corrected due to an error in the 2014 final disposal rate.
7. In 2015, the target of zero emissions (the final disposal volume of up to 0.1 percent of waste emission volume) was not achieved, as the final disposal volume increased by about 170 tons because of the malfunction of the volume reduction facilities of the disposal contractor. We will review the method of disposal for a smaller final disposal volume.
8. The number of fatal and lost time accidents per million working hours.
9. Calculated based on the new criteria from 2015.
10. As of June each year. The figures until 2013 are for Kyowa Hakko Kirin (non-consolidated). The figures for 2014 and later are for the Kyowa Hakko Kirin Group (domestic).

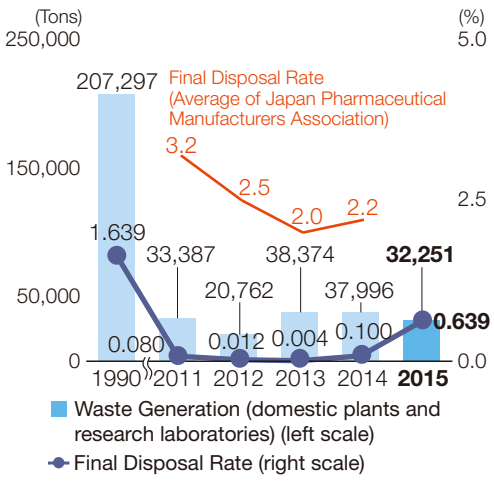
### $CO_2$ Emissions [1,2,3]



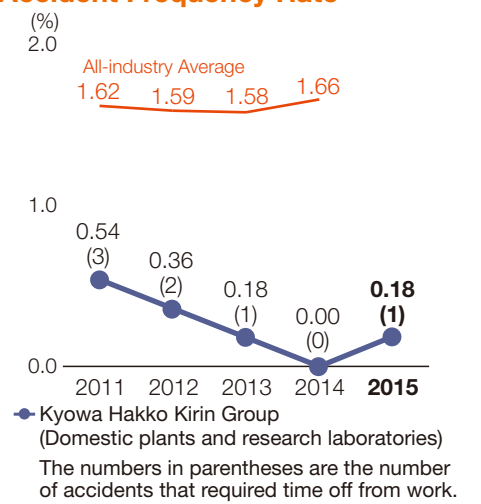

### Water Use [1,2,4]




### Waste Generation [2,5,6,7]

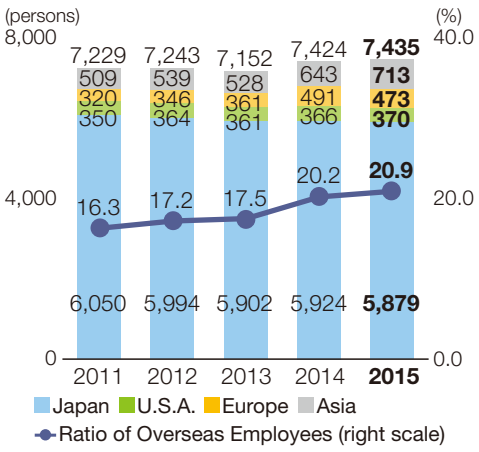



### Accident Frequency Rate [2,5,8]

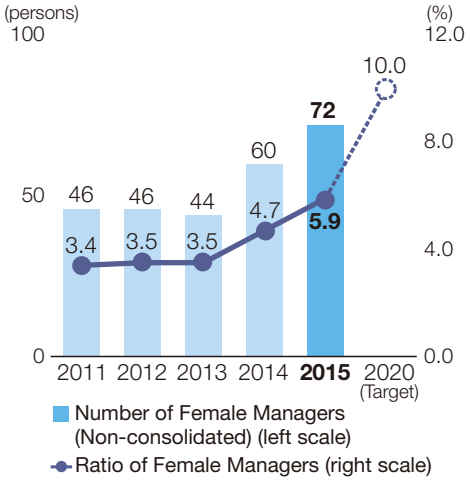



The numbers in parentheses are the number of accidents that required time off from work.

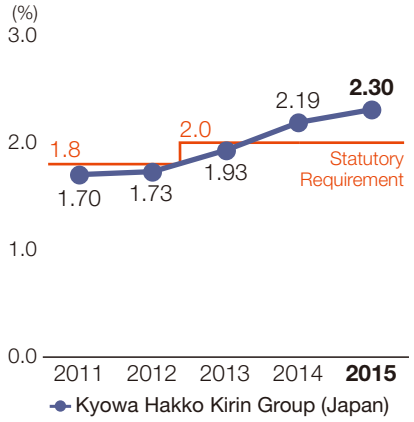
### Number of Employees/ Ratio of Overseas Employees



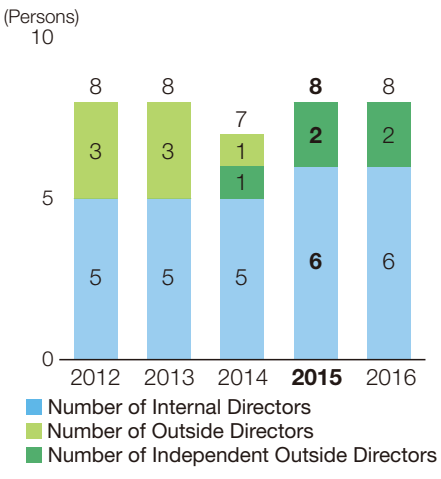

### Number of Female Managers/ Ratio of Female Managers [9]




### Ratio of Workers with Disabilities [10]




### Number of Directors




Please see ESG Data Collection for details. WEB

# Topics

## Important Topics of FY 2015

### Receiving the 2015 Pharmaceutical Society of Japan Award for Drug Research and Development

We received the award in recognition of our efforts with mogamulizumab (POTELIGEO®), the world's first humanized antibody drug that targets adult T-cell leukemia-lymphoma, for being the first of such drugs to be approved in Japan, for showing an example of epoch-making next-generation antibody technology from Japan, and for showing an example of university-industry cooperation.

### Completion of New Research Facility in Fuji Research Park

Drug discovery research and industrialization research have been consolidated in this facility. The facilities contain the laboratories needed for research and development as well as the production of synthetic drugs, with care taken to ensure proper safety and environmental management.

### Approval of ACOALAN® in Japan

ACOALAN®, a recombinant human antithrombin preparation, is expected to allow patients to avoid the risk of infection resulting from human blood. Kyowa Hakko Kirin has concluded an outsourcing agreement with the Japan Blood Products Organization to sell ACOALAN® and provide information to medical institutions.

### Conclusion of Option Agreement with AstraZeneca K.K. Concerning Benralizumab (KHK4563)

We have concluded an option contract for sales of Benralizumab (KHK4563) in Japan with AstraZeneca K.K.. This company has the exclusive development and commercialization rights outside of the countries in Asia for which Kyowa Hakko Kirin has sales rights.

### Conclusion of Partnership Agreement for Development Study of the Combination of Mogamulizumab and Opdivo (generic name: nivolumab) for Use in Cancer Immunotherapy

The company has entered into a clinical trial collaboration agreement with Bristol-Myers Squibb to conduct a phase 1/2 combination study in the U.S. concerning the combination of mogamulizumab and Opdivo as a potential treatment option for patients with advanced solid tumors.

### Change in Name from Daiichi Fine Chemical to Kyowa Pharma Chemical

In order to highlight the change from fine chemicals to the pharmaceuticals business and clarify the role of the company in the Kyowa Hakko Kirin Group, the name of the company has been changed.

**Mar.** | **Apr.** | **May** | **June** | **July** | **Aug.** | **Sep.** | **Oct.** | **Nov.** | **Dec.**

### Completion of Amino Acid Production Factory in Thailand

In preparation for the expected increase in demand for amino acids in Asia, Kyowa Hakko Bio constructed an amino acid production factory through a Thai subsidiary.

### Release of Calcium Receptor Agonist "REGPARA® Tablets 12.5mg"


Sales of REGPARA® Tablets 12.5mg for treatment of secondary hyperparathyroidism started. REGPARA® Tablet 12.5mg, a lower dosage form, is expected to allow doctors to more finely adjust the drug dose.

### Application for Approval of Brodalumab (KHK4827) in Japan

We applied to the Japanese Ministry of Health, Labour and Welfare (MLHW) for marketing approval of Brodalumab (KHK4827) for treatment of psoriasis*1 (plaque psoriasis*2, psoriatic arthritis*3), pustular psoriasis,*4 and psoriatic erythroderma*5.

*1 A chronic skin disorder. Generalized erythema with clear boundaries accompanied by invasion and thickening is apparent, and silver-white scales can be observed on the body of the patient.
*2 Approximately 90% of patients with psoriasis present with these symptoms, and erythema and scales appear on areas of the body that are susceptible to mechanical stimulation such as the elbow, knee, buttocks, and head.
*3 A disease in which skin symptoms are accompanied by arthritis.
*4 A type of psoriasis in which the patient experiences generalized reddening of the skin and many skin pustules accompanied by fever and fatigue. In some cases, the condition is life threatening, and it has therefore been designated as an intractable disease in Japan.
*5 A condition in which the psoriatic lesions are spread along the entire body, causing the skin to become red. In many cases, the patient experiences fever and fatigue.

### Receiving the Tokyo Labor Bureau Director's Excellence Award from MHLW at the 2015 Award for Equal Employment/Work and Family Harmonization


We received the award in recognition of our efforts to enable women to fully demonstrate their potential. We have also obtained a "Kurumin" certificate from MHLW as a company that supports child care through various measures such as enhanced support systems for employees who are raising children.

### Closing of Sakai Plant along with Reconstruction Plan of Production Sites

As part of the "reconstruction plan" to deal with aging facilities, to increase production efficiency, and to strengthen cost competitiveness, we closed Sakai Plant, which had started operation in 1949.

# Top Message

A Message from the President

## We aim to expand our global businesses and make a “leap” as a group.

From 2016, we started our new mid-term business plan. The theme of the plan is “leaping forward for Global Specialty Pharmaceutical company (GSP).” During the five-year plan, we aim for long-term growth while responding to significant changes in the medical environment. While taking advantage of our wide variety of business bases, the Kyowa Hakko Kirin Group will continue to widely contribute to the health and well-being of people around the world by continuing to produce further innovation.

Nobuo Hanai

President and CEO

# Top Message

**Review of the FY2013–2015 Mid-term Business Plan**

## We have continued development of the three global strategic products and prepared the base for our leap forward to become a GSP.

We express the growth of the Kyowa Hakko Kirin Group through the key phrase “global specialty pharmaceutical company (GSP).” Becoming a GSP means contributing to meeting medical needs by continually creating novel drugs, globally conducting business activities such as development, launch and sales, and delivering innovative new drugs to people all over the world.

Under the FY2013-2015 Mid-term Business Plan (previous mid-term business plan), this three-year period was the period of “striving toward” becoming a GSP, and we have solidified our foundations to prepare for a future leap.

In Japan, there was a significant change in governmental policy in 2014 to increase the target of market share of generic drugs to 60%. Therefore, the market penetration of generic drugs has advanced at a speed far exceeding our original forecasts, and has had a major impact on the sales of long-listed products. As a result of added investment to accelerate the development of the next new drugs, we achieved our sales target published in the previous mid-term business plan but, unfortunately, were unable to achieve our goal for operating profit.

Although we experienced such severe environmental changes, we have further strengthened the domestic sales capabilities of the Group through category-based strategies. Specifically, we have aimed to optimize and accelerate our business by focusing on the construction of an integrated system that can allow us to handle a series of processes of research/development, production, sales, and quality assurance in the four categories of nephrology, oncology, immunology/allergy, and central nervous system. As a result, we have launched many novel drugs in Japan such as NOURIAST®, an antiparkinsonian agent*1, ONGLYZA®, for treatment of type 2 diabetes, Dovobet®, a topical combination drug for the treatment of psoriasis vulgaris*2, and a sustained-duration G-CSF product*3 G-Lasta®.

Furthermore, as part of our strategic move toward global expansion, we acquired ProStrakan Group plc (U.K.) (hereinafter referred to as “ProStrakan”)*4 and Archimedes Pharma Limited (hereinafter referred to as “Archimedes”)*4 in 2011 and 2014, respectively, thereby allowing us to steadily expand our in-house sales network in Europe and the United States.

Our main strategic products developed with the aim of the company becoming a GSP are as follows: KW-0761, a therapeutic agent for treatment of adult T-cell leukemia/lymphoma*5, KW-6002, an antiparkinsonian agent, and KRN23, a treatment agent for X-linked hypophosphatemia (XLH)*6. We call these our “three global strategic products.” The development of these drugs in Europe and the United States has progressed smoothly over the past three years, and we have succeeded in the major achievement of entering the final-stage clinical trials. Based on these successes, we have achieved our aims of solidifying the foundations of the company generally in line with the previous mid-term business plan.

The three global strategic products (KW-0761, KW-6002, and KRN23) share the common characteristics of having novel mechanisms and being the first-in-class drugs in the world. We have strong pride in delivering promising new drugs based on the research of Kyowa Hakko Kirin to patients around the world who are suffering from diseases for which there is no current effective treatment.

*1 The decrease in the nerve cells of the region called the substantia nigra of the brain stem and the decrease in the chemical dopamine, which is used by the nerve cells to function, cause the onset of the disease. Although some cases of Parkinson’s disease are known to develop due to genetic factors, in many cases, the etiology of the condition is unknown and is not due to any genetic factor. It is said that this disease affects 100–150 out of every 100,000 persons.

*2 A disease in which the skin becomes red and swollen, and forms scales that thicken and flake off. Cases of psoriasis vulgaris account for approximately 90% of the total cases of psoriasis.* *Source: Japanese Dermatological Association (current as of February 2016).

*3 Protein formulation that is produced by recombinant DNA technology. Neutrophils, a type of white blood cell, are selectively increased by G-CSF in order to further improve their function. As a result, patients can quickly recover from neutropenia associated with cancer chemotherapy, and the various risks associated with neutropenia can be reduced.

*4 Currently, these two companies have been integrated.

*5 The retrovirus HTLV-1 is involved in the onset of peripheral T-cell tumors; onset is estimated to occur in approximately 1,150 persons each year in Japan. In general, combination chemotherapy such as mLSG15 therapy is performed, but no treatment method that is expected to be effective in cases other than transplantation has been established.

*6 A rare disease that causes disorder of the growth and maintenance of bone as a result of the onset of hypophosphatemia after phosphorus in the body is excessively excreted due to high concentrations of FGF23 in the blood.

# Top Message

### Overview of the FY2016-2020 Mid-term Business Plan

## During the runway approach, we will raise our altitude to make the leap in 2020.

The recently implemented mid-term business plan lays out our plans for the 2016–2020 period. Based on the key phrase “leaping forward for GSP,” we aim to respond to significant changes in global medical needs and achieve growth from a long-term perspective. We believe that it is important to especially focus on the improvement of operating income, a major issue in the previous mid-term business plan, and pursue improved profits of the entire Group through the international market launch of our three global strategic products and establishment of an in-house global sales network.

Our targets for 2020 are as follows: core operating profit of 100 billion yen, 50% overseas sales ratio, and 10% ROE or higher. These quantitative targets are challenging for the Group to meet, but we believe that we can absolutely achieve all targets by making all efforts to realize our policy of increasing operating income in international markets.

Under the FY2016-2020 Mid-term Business Plan (hereinafter referred to as the “new mid-term business plan”), the first half of the period (2016 and early 2017) is our “Investment Phase” of preparation. Our three global strategic products have reached the final stages of clinical trials, and we are going to apply for approval in Europe and the United States during this phase. This can be compared to an airplane that is traveling along a runway. During the latter half of the plan (from late 2017 to 2020), we plan to take off and increase altitude, which we refer to as the “Leaping Forward Phase.” Our mid-term business plan compares these stages to the runway approach, takeoff, and increasing altitude. I believe that, in this way, the term “leap” is most fitting to describe our plan.

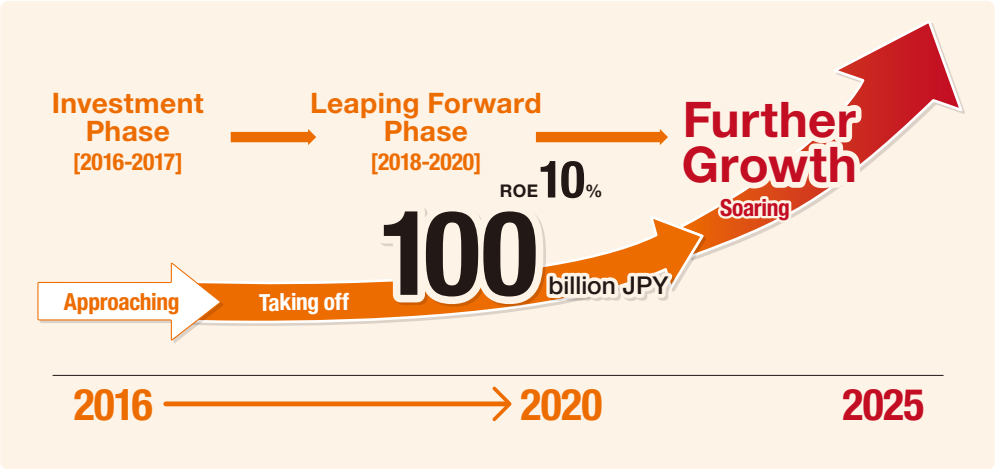
During the period in which we increase altitude, we will maintain the view of aiming for even greater growth through a further “leap” based on continued investment in development. For example, in the field of oncology, we are currently focused on developing immuno-oncology therapies*7, and have already begun investment. Furthermore, we have also been involved in research concerning small-molecule drug and therapeutic antibodies, and have been continuing our efforts in the new drug field of nucleic acid-based drugs*8.

In addition, regenerative medicine is our next target. We have commenced joint research with the Center for iPS Cell Research and Application, Kyoto University and begun development of immuno-oncology therapies. We aim to foster regenerative therapy as one of our future areas of research and development.

*7 Therapies that attempt to destroy cancer cells by controlling the body’s autoimmune system.

*8 A drug consisting of nucleic acids, constituents of DNA and RNA, which bind with macromolecules in the body to treat and prevent related diseases.

### Process of FY 2016-2020 Mid-term Business Plan




### Toward the Realization of the New Mid-term Business Plan

## We aim to promote the three global strategic products and maximize the value of local products.

In order to continue growing, it is necessary to place priority on steadily developing the three global strategic products so as to realize market launch in Europe and the United States. Each country has its own regulatory system; therefore, great time and effort will be needed to deal with the systems of each nation in Europe. We are aiming to launch KRN23 on the market in 2018. Our 2020 sales target for KRN23 is 60 billion yen, and the future peak sales potential is expected to be around 150 billion yen. We expect the drug to become a flagship strategic product of the company*9.

Approval and sales of global pharmaceutical products in each country are important and essential issues for the company. In addition, I believe that not only growth due to the launch of the global pharmaceuticals, but also maximization of the value of existing products, the foundation of sales and profits of the company, and further expansion of our product line-up are essential for the company.

*9 Please see the “Special Feature” on P19 for details.

# Top Message

### Toward the Creation of an Organization to Become a GSP

## Initiatives and actions taken to become borderless have become even more important.

As we work toward to become a GSP, there are many borderless tasks that are necessary in addition to the development process, such as the sharing of safety information following the launch of a product.

Furthermore, in order to achieve our leap forward towards becoming a GSP, we must not only be conscious of the reliability of our pharmaceutical products, but also to take sufficient consideration to "behave" as a company that contributes to global medical needs. Naturally, this means that it is necessary to strongly maintain a high awareness of compliance in following the rules of each country in the world.

We are also promoting globalization with regard to our human resources. Our workers, who possess a variety of personalities and abilities, share the intentions behind the "Group Philosophy" and "Commitment to Life," with each developing their respective strengths. We plan to further promote these initiatives in the future.

### Innovation created through Unified Group

## While using ingenuity to respond to changes in the environment, we will continue to evolve as a group.

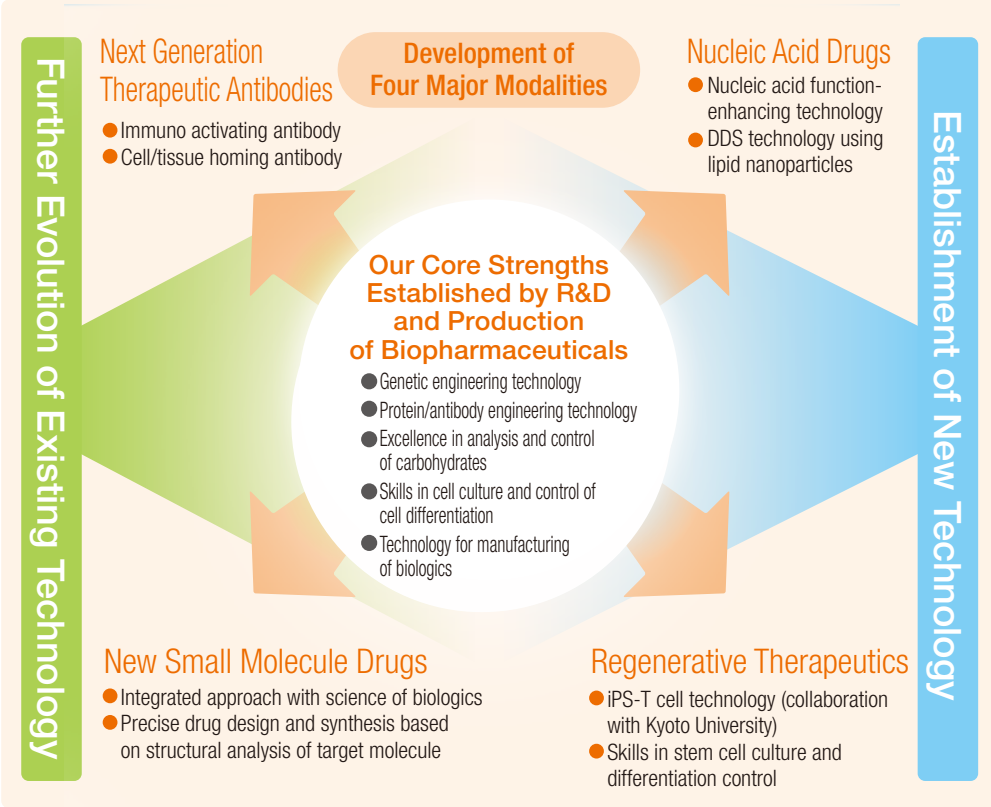
Under the new mid-term business plan, we have promoted the creation of innovation that takes advantage of the variety of business bases of the Kyowa Hakko Kirin Group, and plan to promote the further integration of the Group as well as expanding the synergy of our businesses. Medical practice is currently experiencing fragmentation and diversification of medical needs, and medical treatments have rapidly become more sophisticated and specialized. By contrast, the probability of success of drug discovery has lowered, and development time and costs have soared. Under these circumstances, we will be unable to grow if we do things as we always have done.

Our Group has bases in Japan, San Diego (U.S.A.), and Singapore, from which we globally conduct research. It is essential that we promote innovation as a group, ensure active communication among researchers within and outside the Group, and promote open innovation that will lead to the creation of synergy of knowledge and technology. It is also important for us to elucidate novel mechanisms and connect our innovation with the creation of novel drugs.

In addition, we believe it is also our responsibility to continue to create novel drugs from the perspective of the health care economy. One of such efforts is our biosimilars business. The field of biosimilar drugs is an area that meets the social demand for healthcare cost containment, and the market is expected to expand greatly. I regard this development as a type of innovation.

Furthermore, I believe that the Group should understand innovation not only from the narrow viewpoint of technological innovation, but rather in a larger sense. Innovation should not be limited to only research and development, but also production technology, sales, and back-office operations. Based on the understanding of innovation as ingenuity, it is important for us to speedily evolve in response to changes in the surrounding environment in order to survive. I believe that we must not forget the importance of continued ingenuity so that we can continue to evolve.

**Utilization of open innovation and development of four major modalities**



# Top Message

In Order to Increase Corporate Value

## We promote fairness, transparency, speed, and sensitivity in our management.

In June 2015, “Corporate Governance Code,” guidelines for the governance of the company as a listed corporation, came into effect in Japan. Based on the Code, we have established a corporate governance policy in our company, which was announced in February of 2016.

As we aim to leap forward to become a GSP, the most important issue when considering corporate governance is to show all stakeholders that we are a company that properly maintains governance from a global viewpoint.

I am always conscious of keeping “FTSS” as the basis of management of Kyowa Hakko Kirin. “FTSS” stands for fairness, transparency, speed, and sensitivity. Maintaining fairness and increasing transparency is the basis of the company.

It is our desire to increase fairness and transparency in accordance with the Corporate Governance Code to display to investors that Kyowa Hakko Kirin is a group fit for investment.

Furthermore, it is important for each and every employee to become highly sensitive to the needs of society and consider how best to expand our business in future and contribute to society while maintaining a sense of need for speedy action in responding to changes in the environment. “FTSS” forms the base of our new mid-term business plan and firmly guides our direction of management.

A message to investors

## Our products are a symbol of our stance of contributing to the medical needs of the world.

In comparison with major pharmaceutical companies in Japan and other countries, the Kyowa Hakko Kirin Group is by no means a large company. However, why is it that our group has been able to proceed to late-stage development of three compounds with novel mechanisms while other major pharmaceutical companies have been unable to produce so many novel drugs? I believe that this is due to the high basic research and development capabilities of Kyowa Hakko Kirin.

Furthermore, none of the indications of cancer, Parkinson’s disease, or XLH currently has an effective treatment; therefore, the creation of innovative new drugs to treat these diseases has long been hoped for. It is our sincere desire to contribute to the medical needs of the world by pooling the resources of our research and development forces that we have cultivated to focus on such difficult areas.

Furthermore, our Group not only focuses on current product development, but also heavily invests in development of drugs in the fields of chemotherapies, therapeutic antibodies and immuno-oncology therapies that deplete tumor cells by using the body’s autoimmune system. We are currently making progress in joint research focused on our products in development with large international pharmaceutical companies,

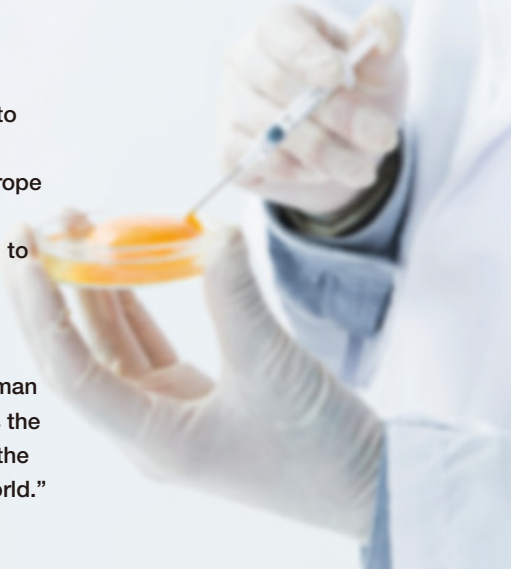
while keeping an eye on the growth of the company under the new mid-term business plan with a focus on the current and future periods. It is my hope that investors will view Kyowa Hakko Kirin as a company suitable for long-term investment.

Furthermore, I hope that all stakeholders, including investors, eagerly anticipate the future leap forward of Kyowa Hakko Kirin to become a GSP.

# Special Feature

The Story of Development of the Novel Drug KRN23

## Bringing the Global Strategic Product "KRN23" to the World, Contributing to Medical Needs Through Our Unique Antibody Technology



**We are currently aiming for sales of KRN23, a flagship product that we expect to contribute to our leap forward to become a global specialty pharmaceutical company, to commence in Europe in 2018. Development of the product has been progressing smoothly, and we expect the drug to become a pillar of our revenue in 2020 or later.**

**The research and development process of KRN23 represents an innovative fusion of outstanding technological capabilities and human resources with exploratory spirit, and contains the desire of Kyowa Hakko Kirin to "contribute to the health and well-being of people around the world."**

### KRN23 Leading the Move into European and U.S. Markets

We are developing KRN23 as a global strategic product that leads the drive to "Enhancement of Global Competitiveness," which is a pillar of the new mid-term business plan.

We have already initiated late-stage clinical trials in Europe and the United States and have been making smooth progress toward the 2018 launch in the European market and the planned subsequent U.S. approval and sales.

The development of KRN23 began with research focused on phosphorus metabolism.*1 We subsequently discovered FGF23,*2 a factor involved in diseases such as tumor-induced osteomalacia and X-linked hypophosphatemia (XLH). Utilizing the unique antibody technology of Kyowa Hakko Kirin, we created KRN23, an antibody, which inhibits the activity of FGF23.

XLH is a disease in which excess FGF23 decreases blood levels of phosphate and vitamin D which leads impairment of bone growth and maintenance; it is a rare disease that is said to occur in one out of every twenty thousand people in the world. The disease is treated symptomatically to replenish the deficiency of phosphorus and vitamin D, leading to the need for frequent medication and the side effect of renal calcification.*3 KRN23 has a high degree safety in contrast to the existing symptomatic treatment, and has been shown in clinical trials to possess superior efficacy to increase and maintain serum phosphorus concentration levels within the normal range; it is expected to be a therapeutic drug that will pave the way for fundamental treatment of the disease.

*1 In addition to absorption and excretion, optimal blood concentration of phosphorus is maintained by metabolic turnover that uses bone as storage.

*2 FGF23 (fibroblast growth factor 23), a polypeptide consisting of 251 amino acids that is produced mainly in bone tissue, acts on the kidneys to inhibit reabsorption of phosphate in the renal tubules. In recent years, FGF23 has been suggested to be involved in diseases such as X-linked hypophosphatemia, tumor-induced osteomalacia, and renal failure.

*3 If hypercalcemia continues, renal medullary nephrocalcinosis progresses, leading to renal dysfunction.

### Unending Innovation Leading to the Creation of Novel Drugs

Although there may be papers on rare diseases, such research may not lead to pharmaceutical companies aggressively developing and providing drugs for treatment of the diseases. However, Kyowa Hakko Kirin not only recognized the scientific significance of the discovery of FGF23, but also created therapeutic candidates KRN23 by utilizing antibody technology. This action was based on the desire of the company to develop novel drugs needed by patients suffering from diseases.

KRN23 is the fruit of deep understanding of the disease and the antibody technology of Kyowa Hakko Kirin. In addition, we have incorporated open innovation in the research process to take advantage of outside information and knowledge, which allowed us to speed up development.

### Working Together with Ultragenyx (U.S.) to Maximize Global Value

In order to achieve the sustainable growth of Kyowa Hakko Kirin in overseas markets, Global Phase III Clinical Trials of KRN23 are currently underway in the U.S., E.U., Canada, Japan and Korea.

One of the efforts to accelerate the global development of KRN23 is the joint development with Ultragenyx Pharmaceutical Inc. (Ultragenyx) located in America. Through the utilization of the company's strength, that is, its product development capabilities in the specialized area of rare genetic disease, we are working to maximize the value of KRN23 and for its early commercialization in the global market.

In the future, Ultragenyx and Kyowa Hakko Kirin will attempt market penetration of KRN23.

# Special Feature

Interviews with Developers

## I Desire to Create New Value for Medical Care and Health

In recent years, biopharmaceuticals have been established as one of the categories of therapeutics, but as a pioneer in the field, our company has been working on the research and development of biopharmaceuticals from early on. As I was studying bone metabolism, I applied acquired knowledge and experience to the field of nephrology, a core field of our business, and I focused on the regulation of calcium and phosphorus that are elements for bone formation. Research on phosphorus metabolism was lagging in comparison with calcium research, so I thought that we might discover a previously unknown mechanism essentially important for phosphorus regulation. As a result of an opportunity to conduct a collaboration on hypophosphatemia with Professor Fukumoto of the University of Tokyo Hospital, we succeeded in the identification*4 of FGF23, a humoral molecule that regulates phosphorus. In addition, by leveraging our antibody technologies, we succeeded in obtaining antibodies to FGF23 efficiently. It is my desire to continue to create new value for medical care and health of people as we continue to evolve and utilize advances in technology.

*4 Determination of the isolated substance

**Takeyoshi Yamashita, Ph.D.**
Director of Regulatory Affairs Department, Pharmacovigilance and Quality Assurance Division

## It is my hope to provide eagerly awaited drugs to patients across the globe as soon as possible

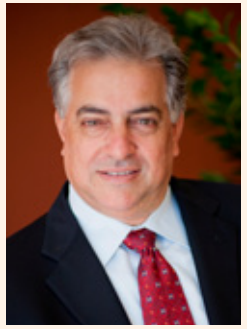
The development of KRN23 is proceeding smoothly, having overcome various difficulties many times. In the background is our challenging spirit to open up a path no matter how difficult it may be and perseverance with which to achieve success without giving up until the very end. Moreover, Ultragenyx, our development partner, has excellent human resources with rich expertise in the development of drugs for rare genetic metabolic diseases. We believe that collaboration with them is contributing considerably to the acceleration of the development in Europe and the United States. XLH is an intractable disease but not known widely to the public. Many XLH patients suffer from deficient growth and pains so severe as to keep them awake at night. As a person involved in its development, I have never felt so happy and proud of KRN23, when I read a letter from a patient who participated in the clinical trial, saying that the pain the patient had suffered had been greatly improved. We want to provide the medication as soon as possible to the patients all over the world who are suffering from the disease. It is our desire to help realize a society where as many people as possible can live a happy, healthy life.

**Hiroshi Hirose**
Manager/Project Leader, Nephrology R&D Management Office, Nephrology R&D Unit, R&D Division

## We hope to bring KRN23 to patients as soon as possible

The collaboration between Kyowa Hakko Kirin and Ultragenyx has been excellent and a model for generous and collaborative engagement with a common goal. More than two years into the collaboration since August 2013, we are encouraged by the Phase II interim clinical trial results in children with XLH, starting a Phase III program in adults, and planning to file a conditional marketing authorization application in Europe. We are so honored to have the opportunity to work on Kyowa Hakko Kirin's KRN23 program and hope to bring this therapy to patients as soon as possible.

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



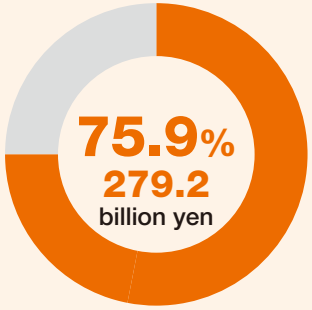
# Review of Operations

Pharmaceuticals Business/Bio-chemicals Business

## Our Strength Is Our Unique Business Structure That Integrates Various Businesses Related to New Drugs, Biosimilars, Diagnostics, and Bio-chemicals

### Pharmaceuticals Business

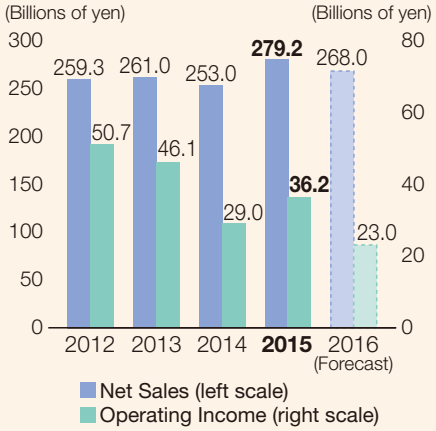
**Composition of sales**




**Details of business**

We have offices in various regions of Japan, Europe, the United States, and Asia that primarily focus on research, development, manufacturing, and sales of pharmaceutical products and diagnostic reagents in the fields of nephrology, oncology, immunology/allergy, and the central nervous system. Aiming to launch pharmaceutical products that meet the needs of those working in clinical practice as quickly as possible, we are also actively involved in partnering with international companies in the field of research and development.

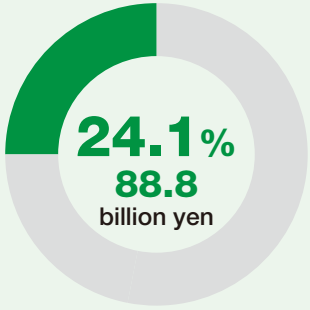
**Net sales/Operating income**




**Major products (pharmaceutical products)**

### Bio-Chemicals Business

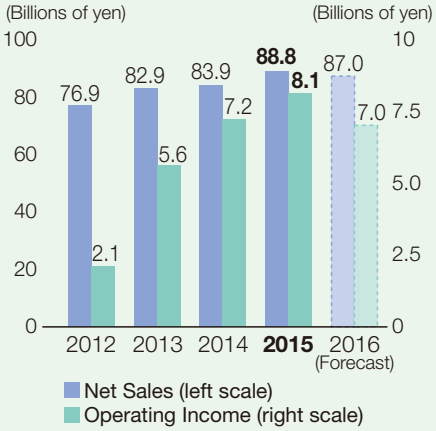
**Composition of sales**




**Details of business**

The bio-chemicals business is handled by Kyowa Hakko Bio and encompasses fine chemicals, healthcare, agribusiness. It also includes the production of active pharmaceutical ingredients for small molecule drugs which is handled by Kyowa Pharma Chemical. We have many products with a top share of the market, such as nucleic acids. In addition to mail-order sales in Japan, we also provide medical infusions, drugs, and health food products across the world.

**Net sales/Operating income**




**Major products (health food)**

# Pharmaceuticals Business

**As we "leap forward to become a global specialty pharmaceutical company (GSP)," we will continue to aggressively make investments aimed at further growth in Japan, Europe, the United States, and Asia.**

External Environment

## Problems related to increaseing medical expenses and the diversification of medical needs associated with the aging population

The increase in restructuring and formation of alliances between companies in the pharmaceutical industry, the decreasing probability of successfully developing novel drugs, and the steep rise in development costs have become serious global issues facing the industry.

In addition, there has been a rapid increase in Japan in the need for measures to lessen medical costs associated with the aging society, and expectations concerning preventive healthcare in Europe, the United States, and Asian countries are growing. At the same time, medical needs have become diversified into fields such as regenerative medicine and genetic diagnosis and treatment; therefore further sophistication and specialization of treatment is needed.

In response to this rapidly changing environment, the Kyowa Hakko Kirin Group must accelerate the late-stage development of highly innovative novel drugs and biosimilars in order to experience further growth while adopting countermeasures to handle the expiration of patents of major products. In addition, we must create unique value by collaboration within the group companies.

Countermeasures and Initiatives

## Promotion of globalization and operational efficiency of the organizational structure

In order to solve these issues and realize health and well-being, we will utilize the various business foundations of the Group and proceed with our unique CSV management* such as providing solutions to meet diverse medical needs.

We will launch three global strategic products that have been developed in-house in Europe and the United States, and create an organizational structure and sales infrastructure that can respond to changes in the field due to globalization. At the same time, we will strive to maximize the value of existing products and achieve sustainable growth overseas. We will also strengthen the international development of our bio-chemicals and diagnostic businesses and continue to foster an innovative corporate culture with the aim of further enhancing our pipeline through drug discovery utilizing advanced technology that is based on open innovation.

Furthermore, through improvement of operational efficiency, strengthening and restructuring of the organization, and improving the reliability of our operational processes, we can achieve more efficient asset management and ensure that we have a cash flow to support aggressive strategic investment.

Future Prospects

## Becoming innovators that create new value with social significance

Based on the mid-term business plan from 2016, we aim to launch our new drugs on European and the US markets, improve the profitability and brand power of our bio-chemicals business, and promote the strengthening of group management, to achieve our leap to becoming a GSP. Furthermore, in response to changes in the environment surrounding medical care and health, we will become an innovator to create new value with social significance in our areas of strength.

Kyowa Hakko Kirin Group is dedicated to its management philosophy of "contributing to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies."

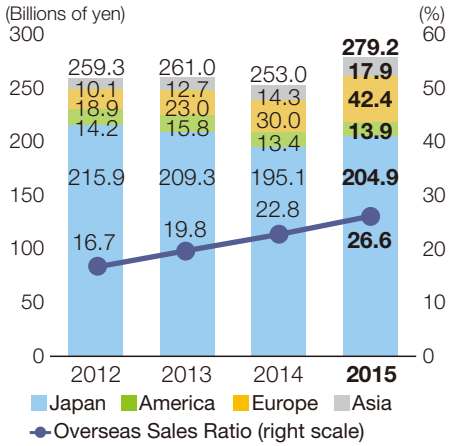
* creating shared value (CSV) is a new idea proposed by Harvard University's Professor Michael E. Porter to be an alternative philosophy to corporate social responsibility (CSR); it is the idea that a company should pursue economic value (profit) while simultaneously realizing social value.

### Number of Pharmaceuticals Business Sites

As of March 31, 2016

| | |
|---|---|
| Number of Domestic Sales Sites | 64 |
| Number of Overseas Subsidiaries and Affiliates | 34 |

### Pharmaceuticals Business Net Sales by Region



## Pharmaceuticals Business | Research and Development

Research and development is the driving force that will allow Kyowa Hakko Kirin to fulfill its mission. We aim to provide new drugs needed by patients as quickly as possible.

### External Environment

### Intensifying competition due to environmental changes and increasing demands on CSR initiatives

Due to the decrease in R&D efficiency associated with depletion of seeds and with swell of developmental cost, the governmental policy to promote generic drugs, and the responses to changes in future medical treatment systems, etc., the environment for pharmaceutical companies has become extremely challenging. As a result, the strategy of pharmaceutical companies has changed from conventional mergers and acquisitions, with the aim of expanding the company scale, to acquisition of bio-ventures to obtain drug discovery technology and seeds as well as large-scale exchanges between non-core businesses and core fields. Furthermore, the number of companies that have set the fields of nephrology, oncology, immunology/allergy, and the central nervous system as well as antibody and regenerative medical technology as core businesses has increased, leading to intensified competition.

On the other hand, there has been increased focus on the corporate social responsibility (CSR) of pharmaceutical companies concerning contributions to international drug trials, solving drug lag-related problems*1, and focusing on incurable, rare, and pediatric diseases in addition to neglected diseases in developing nations.

*1 The lag in time until new drugs from overseas are approved for use in Japan.

### R&D Division Organization


### Organization


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

### Countermeasures and Initiatives

### Promotion of reform in a wide range of fields such as the organizational structure, human resources, strategy, and technology

In the sharply changing and hardly predictable environment, we have taken various countermeasures in order to fulfill our mission as a company and to become a "global specialty pharmaceutical company" with a strong market presence.

Based on our medium- and long-term strategies, we will maximize our strengths through continuing our category-based strategy and through development and utilization of diverse human resources with the aim of creating a global organization.

We are also working to improve our success rate through translational research*2 while technology development that produces new value and promotion of open innovation with industry members, the government, and academia.

*2 This refers to the "bridge" between non-clinical and clinical trials. It refers to research to make use of the results of basic medical studies in actual clinical practice.

### Future Prospects

### Striving toward the creation of new value and the next innovation

From now on, 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.

# Pharmaceuticals Business | Research and Development

## Open Innovation

In order to continuously deliver innovative new drugs as soon as possible to patients, we believe that open innovation style of drug discovery is one of our most important strategies. For this reason, we are aiming to create novel drugs by utilizing external seeds and technologies, while actively promoting partnerships with academia and other companies in the industry. Currently, we are continuing joint research and development in multiple areas with domestic and international partners based on our category strategy of core therapeutic areas and technology strategy.

Furthermore, we are actively involved in enhancing our product pipelines for the fields of immunology/allergies and oncology through research sites of overseas subsidiaries in San Diego and Singapore in collaboration not only with laboratories inside our company, but also with overseas research institutions in academia.

### Status of Main Development for New Drugs

**Nephrology**

- Japan
  - Obtained approval of REGPARA® (the calcium receptor agonist) 12.5mg formulation (February) and launched (June)
  - Initiated phase III clinical study of KHK7580 (the calcium receptor agonist) for secondary hyperparathyroidism patients receiving hemodialysis (November)
  - Initiated phase II clinical study of RTA 402 for chronic kidney disease (CKD) with type 2 diabetes (March)

**Oncology**

- Japan
  - Ongoing phase III clinical study of ARQ 197 (c-Met inhibitor) for c-Met diagnostic-high inoperable hepatocellular carcinoma treated with one prior sorafenib therapy
- Japan/North America/Europe, etc.
  - Ongoing phase III clinical study of KW-0761 (the anti-CCR4 humanized monoclonal antibody, product name in Japan: POTELIGEO®) for cutaneous T-cell lymphoma (in Europe, the United States and Japan)
- North America/Europe, etc.
  - Ongoing phase II clinical study of KW-0761 for adult T-cell leukemia-lymphoma (in the US, Europe, etc.)

**Category-Based Strategies**

**Immunology/Allergy**

- Japan
  - Submitted application for approval of KHK4827 (the fully human anti-IL-17 receptor antibody) for the treatment of psoriasis (July)
  - Initiated phase III clinical study of KHK4563 (anti-IL-5 receptor humanized monoclonal antibody) for patients with chronic obstructive pulmonary disease as part of the multi-regional clinical study being conducted by AstraZeneca (July)
- Japan/Korea
  - Ongoing phase III clinical study of KHK4563 for asthma as part of the multi-regional clinical study being conducted by AstraZeneca

**Central Nervous System**

- North America/Europe, etc.
  - Ongoing phase III clinical study of KW-6002 (product name in Japan: NOURIAST®) for Parkinson's disease

**Other**

- Japan: Obtained approval of ACOALAN®, recombinant human antithrombin (AT), for indications of thrombophilia due to congenital AT deficiency and disseminated intravascular coagulation accompanied by a decrease in AT (July) and launched by The Japan Blood Products Organization (September)
- China: Initiated phase III clinical study of AMG531 (the thrombopoietin receptor agonist, product name in Jaapan: ROMIPLATE®) for chronic idiopathic (immune) thrombocytopenic purpura (September)
- North America/Europe/Japan/Korea: Initiated multi-regional phase III clinical study of KRN23 (the human monoclonal anti-Fibroblast Growth Factor 23 antibody) in adult patients with X-linked hypophosphatemia (December)
- North America/Europe: Ongoing phase II clinical study of KRN23 in pediatric X-linked hypophosphatemia

## Research and Development Ethics

There is a growing need for adequate ethical considerations, such as in the increasing importance of research using human-derived samples in the research and development process of drug discovery. Our company acts in compliance with relevant laws and regulations of both Japan and overseas such as the Pharmaceutical and Medical Device Act (former Pharmaceutical Affairs Act). Moreover, in order to protect personal information, respect human rights in accordance with the spirit of the Helsinki Declaration, and ensure the reliability of research, we have created education and training for employees, acquired third-party certification, and established opportunities for review from third parties.

### Main Initiatives

- Proper management of cellular, microbial, and chemical substances handled during research and development in compliance with related laws and regulations
- Proper management of animal breeding facilities and experimental conduct with consideration made for the welfare of animals in accordance with global standards
- Reviews by research ethics review committees that include outside members based on scientific and ethical viewpoints concerning medical and health research involving human subjects
- Implementation of clinical trials in compliance with the Pharmaceutical and Medical Device Act (former Pharmaceutical Affairs Act), GCP (Good Clinical Practice; i.e., standards concerning the conduct of clinical trials for drugs), and GPSP ( Good Post-marketing Study Practice; i.e., standards for the post-marketing study of pharmaceutical products)

## Pharmaceuticals Business | Production

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

### External Environment

### Structural transformation needed in response to the significant price reduction in long-term listed drugs

As shown in the "Comprehensive Strategy for Strengthening the Pharmaceutical Industry—Innovative Drug Development with an Eye on Global Expansion" laid out by the Ministry of Health, Labour and Welfare (MHLW) in September 2015, environment surrounding the pharmaceutical industry has undergone great changes in the past few years. In the future, it is expected that the replacement of long-term listed drugs with generic drugs will be accelerated based on the Japanese Cabinet basic policy*1 decision. Moreover, due to the governmental policy of limiting medical costs and the revision of drug price and its system, etc., significant decreases in the prices of long-term listed drugs can also be expected. The Japanese pharmaceutical industry is highly dependent on long-term listed drugs, therefore structural change is needed.

*1 Basic Policy on Economic and Fiscal Management and Reform 2015 —Without economic revitalization, there can be no fiscal consolidation—

### Countermeasures and Initiatives

### Increasing competitiveness through cost reduction and responding to medical needs through the acceleration of new product development

In order to respond to such a changing environment, we will review our production costs and accelerate the production of new products. We will be able to achieve higher efficiency and improved GMP*2 as well as improve cost competitiveness through reorganization plan of production and facilities that is currently underway. In addition, we will make continued efforts to improve production technology, while maintaining and increasing our competitive advantage. Kyowa Hakko Kirin works to reduce the environmental impact that results from its production activities through measures such as reducing $CO_2$ emissions*3, reducing the output of waste materials, and efficiently using water resources. Moreover, in order to deliver new products in development to patients as quickly as possible, we will not only promote the construction of a global production/supply system, but also make improvements to our BCP*4 to ensure stable and continued supply in time of emergency. Furthermore, by utilizing formulation techniques, we will proceed with product development in line with the needs of patients.

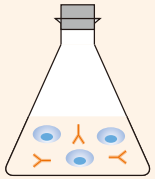
*2 Good Manufacturing Practice (criteria for manufacturing and quality control management of pharmaceutical products, etc.)

*3 The total amount of $CO_2$ emissions of the Kyowa Hakko Kirin Group in 2015 was 362 kilotons, which was 81% of the Fiscal 1990 level (goal: reduce our $CO_2$ emissions in Fiscal 2020 to no more than 85% of the Fiscal 1990 level).

*4 Business Continuity Plan

### Continuous Research on Production Technology

**Antibody production technologies**



Cell line creation

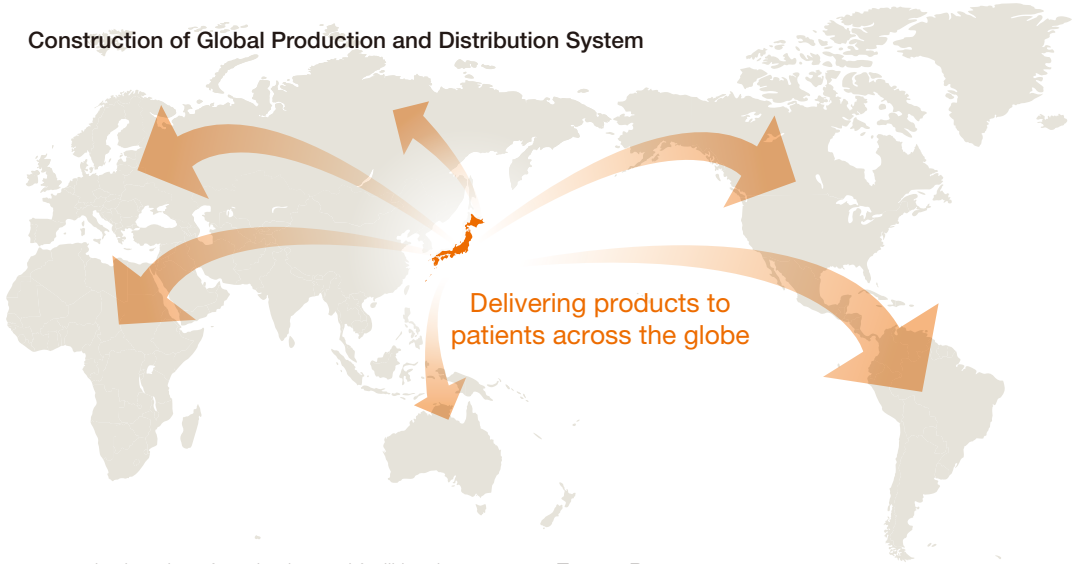
Cell culture

Purification

**Formulation technologies**


- Cost reduction
- Competitive advantage
- Construction of system for production of new products
- Responding to customer needs

### Construction of Global Production and Distribution System




### Future Prospects

### Promoting study of technology and development of human resources

Through the implementation of various initiatives, we will achieve top class product quality and productivity by utilizing our superior production technology used in making products such as antibodies. Moreover, in order to continue to deliver our products reliably to patients around the world, we will continue to promote the maintenance and improvement of our current global production and supply system.

In addition, we will aim for further growth as a GSP through responding to advances in technology and the development of key technology for the next-generation pharmaceuticals following antibodies such as nucleic acid medicines. In order to achieve this goal, we will continue to develop essential human resources and create a company with high organizational ability.

# Pharmaceuticals Business | Sales

Concerning sales in Japan, we will provide information to medical professionals with a focus on new products in our areas of strength, while responding to changes in the healthcare delivery system.

External Environment

## Transition to a sales structure that fits the regional healthcare vision

In order to establish a healthcare delivery system that can respond to the super-aged society that is expected to develop in the future, each prefecture in Japan has been examining a "Regional Healthcare Vision" since April 2015. These visions lay out specific healthcare delivery system plans for each region. As the providers of medical care have changed from "facilities" to "regions," in order for our company to work from the same viewpoint as medical institutions, from October 2015, we have started transition of our sales strategy from focusing on conventional private practice physicians and hospitals to secondary medical care zones* as our new sales base.

* Regional units to achieve a secure system that provides regional medical care in accordance with the hospital, while taking into account geographical and traffic conditions as well as trends in patient treatment.

Countermeasures and Initiatives

## Market penetration of new products

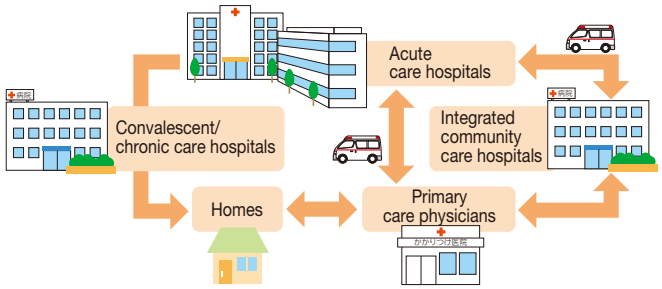
Although sales are predicted to greatly decrease due to the price revisions of conventional core products and the market penetration of generic drugs, we expect growth based on new products in our new mid-term business plan. G-Lasta®, the top-selling granulocyte-colony stimulating factor (G-CSF) agent which went on sale in November 2014, followed NESP®, the top-selling erythropoiesis stimulating agent (ESA), to become one of the growing pillars of sales of the company. Furthermore, the sales of new products such as the adult type 2 diabetes medication Onglyza®, antiparkinsonian agent NOURIAST®, anti-psoriasis vulgaris agent Dovobet®, and anti-psoriasis agent KHK4827 for which approval was applied in July 2015, have allowed us to make great strides in growth through our activities to provide and collect information of value to medical professionals.


Future Prospects

## Domestic (Japanese) sales as the foundation of a global specialty pharmaceutical company

Concerning our future domestic sales target, in response to the ever-changing healthcare delivery system, we believe that it is necessary to provide information to medical professionals in each region in order to meet their respective needs. Furthermore, our four strengths (the categories of nephrology, oncology, immunology/allergy, and the central nervous system) have been highly praised by medical professionals, and we believe that by continuing to provide new drugs in these categories, we can create the foundation to support the changeover of the company to a global specialty pharmaceutical company.

### Secondary Medical Care Zones Handled by the Sales Office




Secondary medical care zones are established as units encompassing multiple municipalities, thus the number of hospital beds in each zone is determined in consideration of how many beds are needed for each regional bloc. The regional healthcare vision aims to promote the sharing and coordination of the role of medical institutions in the secondary medical zones and allow for the smooth transition of patients from hospitalization to recovery and discharge.

Global/international sales

## Focus on the launch preparations to new products in Europe and the United States and sales activities in Asia

In Europe and the United States, through the acquisition of Archimedes Pharma Limited (U.K.) by ProStrakan Group plc (U.K.), not only the acquisition of new products such as PecFent®, a treatment for breakthrough cancer pain, but also other products has led to steady increase in sales. Furthermore, the new promising in-house products (KRN23, KW-0761 and KW-6002) that developed for global sales have smoothly proceeded to late-stage development. We will continue to focus on preparing the launch of these novel products to the market in the near future.

In Asia, we are paying efforts to expand our development pipeline and maximize sales of REGPARA®, which was launched in 2015 in China for the treatment of secondary hyperparathyroidism. In other Asian countries, we aim to grow continuously through the expansion and maintenance of our main products in the fields of nephrology and oncology while introducing new products to the market.

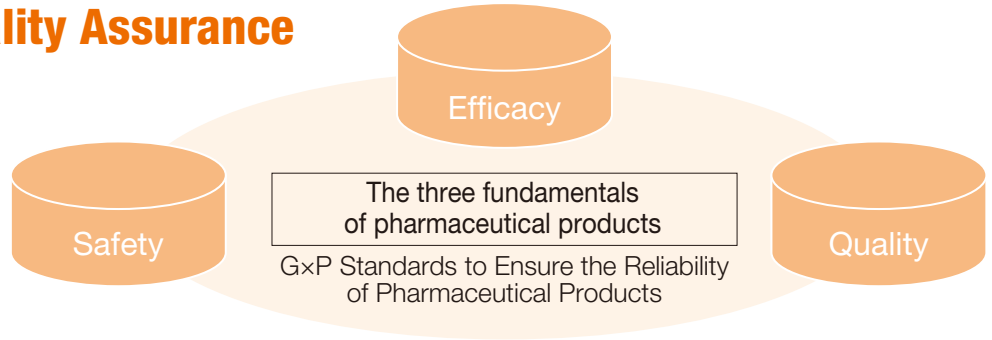
## Pharmaceuticals Business | Pharmacovigilance and Quality Assurance

We will supply products of excellent quality with reliable information to customers.
(Policy for Safety, Quality and Regulatory Affairs in Pharmaceutical Business since Oct. 1, 2008)

**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

**We ♥ 4C!**
Cordiality
Cooperation
Consistency
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 phase 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 fot 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 |

**External Environment**

### Optimization of our pharmacovigilance and quality assurance system to meet the needs of globalization

In order to market pharmaceutical products worldwide, it is necessary to comply strictly with regulations and conditions present in each region.

Regulations in Japan, the United States, and Europe concerning quality assurance of pharmaceutical products are gradually being harmonized, but at present, the regulatory requirement levels still differ by country and region.

Our company strives to construct a pharmacovigilance and quality assurance system so as not only to respond to global standards such as PIC/S*1 and GDP*2, but also to provide pharmaceutical products that satisfy the country-specific regulatory requirements in each regions.

*1 Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
*2 Standards for distribution of pharmaceutical products

**Countermeasures and Initiatives**

### Realization of the smooth collection and analysis of information through centralizing safety information

Considering the originality of Kyowa Hakko Kirin products and the environment surrounding the pharmaceutical industry, we are searching for original approaches to respond to globalization. In particular, in order to realize manufacturing and marketing of original new products in Europe and the United States, there is an urgent need to establish a pharmacovigirance and quality assurance system to meet the regulatory requirements of Japan, the United States, and Europe respectively. Thus, our company is currently developing a Global Safety Database to be shared throughout Japan, Europe, and the United States. Through globalization of pharmacovigilance activities, we will continue to develop a centralized drug safety information system that will allow us to smoothly collect, evaluate and provide relevant information.

**Future Prospects**

### Attempting to create new added value with the aim of realizing health and well-being

We continue to provide high-quality pharmaceutical products along with information with high added value to stakeholders*3, contributing to the realization of their health and well-being.

In order to achieve this goal, while striving to improve productivity and responding flexibly to changes in the global environment, all employees will continue to grow together to create new added value from the perspective of our customers.

*3 Stakeholders such as domestic and international patients and their families, physicians and healthcare professionals, and government agencies.

## Pharmaceuticals Business | Development Pipeline

As of January 22, 2016

| Area | Identification*1 | Code name/ Generic name | Indication | | Country or region of development | Development phases |
|---|---|---|---|---|---|---|
| | | | | | | Phase I / Phase II / Phase III / Filed |
| Nephrology | ○ | KRN321 | Renal anemia (on dialysis) | | China | |
| | | KHK7580 | Secondary hyperparathyroidism | | Japan | |
| | | RTA 402 | Chronic kidney disease in patients with type 2 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/Other | |
| | | | Adult T-cell leukemia/lymphoma | | U.S.A./Europe/Other | |
| | ● | BIW-8962 | Cancer | | Korea | |
| | | KHK2375 | Breast cancer | | Japan | |
| | ● | KHK2823 | Cancer | | U.K. | |
| | ● | KHK2898 | Cancer | | Singapore | |
| | | KRN951 | Cancer | | Japan | |
| | ● | KW-0761 | Solid tumor | (Combination with Durvalumab/Tremelimumab) | U.S.A. | |
| | | | | (Combination with PF-05082566) | U.S.A. | |
| | | | | (Combination with Nivolumab) | Japan | |
| | | | | (Combination with Docetaxel) | U.S.A. | |
| Immunology/ Allergy | ● | KHK4827 | Psoriasis | | Japan | |
| | ● | KHK4563 | Asthma | | Japan/Korea | |
| | | | Chronic obstructive pulmonary disease | | Japan | |
| | | Z-206 | Ulcerative colitis | | Japan | |

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

## Pharmaceuticals Business | Development Pipeline

As of January 22, 2016

| 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 | Autoimmune diseases | Canada | |
| Central Nervous System | | KW-6002 | Parkinson's disease | North America/Europe/Other | |
| | ● | KHK6640 | Alzheimer's disease | Europe/Japan | |
| Other | ○ | AMG531 | Idiopathic (Immune) thrombocytopenic purpura | Thailand/Malaysia | |
| | | | | China | |
| | | | Aplastic anemia | Korea | |
| | ● | KRN23 | X-linked hypophosphatemia in adult patients | North America/Europe/Japan/Korea | |
| | | | X-linked hypophosphatemia in pediatric patients | U.S.A./Europe | |
| | | | Tumor-induced osteomalacia/epidermal nevus syndrome | U.S.A. | |
| | ○ | KW-3357 | Disseminated intravascular coagulation, congenital antithrombin deficiency | Europe | |

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

**Glossary** Source: Medical Information Q&A 55 (Japan Pharmaceutical Manufacturers Association)

**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 | Diagnostics

We will continue to grow while fulfilling our social responsibility to provide new value for clinical testing and to sincerely keep our eyes focused on the health of people.

### External Environment

#### Negative revision of medical fees and the influence of changes in domestic regulations in Japan

Regarding the global in vitro diagnostics market, in addition to the expanding sales in the largest North American market, demand has also surged in emerging economies, and further growth is expected in the future.

On the other hand, growth in the Japanese market has remained largely unchanged with a slightly increasing trend. Due to governmental policies to reduce medical costs, the general reduction in drug prices in the 2014 revision of medical fees in Japan has had an impact on revenue*1.

In addition, due to the implementation of the revised Pharmaceutical Affairs Act in Japan (Pharmaceutical and Medical Device Act) and the changeover from orders to regulations in Europe, there have been regulatory changes relating to the quality assurance of diagnostic drugs and medical equipment while the deregulation of self-medication has become standard. Furthermore, companies from other industries have entered the field, bringing rapid change to the playing field.

*1 In Japan, medical fees are set for medical examinations. As diagnostic drugs and equipments comprise part of the cost for such examinations, there is intensified pressure to reduce the price of these products.

### Countermeasures and Initiatives

#### Aiming to strengthen our profit structure while maximizing the value of our products

In order to achieve growth in our business, it is necessary to strengthen our profit structure and keep up with these environmental changes. Therefore, we aim to strengthen our earnings structure through the pursuit of reducing the cost rate by increasing our bargaining power for purchasing as well as our production efficiency, including in-house and consignment production. In addition, it is possible to improve our performance by the proper allocation of research and development and sales resources, with the aim of strengthening our competitiveness. Furthermore, while ensuring overseas business revenue through the expansion of bulk sales of lipids and HbA1c*2 in emerging markets, we aim to first enter the US market in order to aggressively deploy our brand.

In order to maximize the value of the products that we provide to our customers, we will strengthen our product strategy functions and business development functions to create a collaborative model, including companies in other industries. We will also actively conduct in-licensing activities for the purpose of reinforcing our development and product pipelines. Furthermore, we aim to continuously create new products by reviewing the priority areas for research and development through the early establishment of a global development organization.

*2 Measuring reagent to monitor the blood sugar control in patients.

### Future Prospects

#### Striving toward the exploitation of international markets and the creation of business opportunities

We cannot expect large growth in the domestic sales of in vitro diagnostic reagents as long as we remain inside the framework of the public health insurance system. Due to developments in self-medication, the market is rapidly expanding outside the framework of public health insurance, and there have been many entrants to the field from other industries that are attempting to capitalize on the expanding market. This is a global trend in which the boundaries between industries and borders between countries continue to disappear.

In this environment, we will strive to realize the two primary goals of the new mid-term business plan: “pioneering exploitation in overseas markets through accelerated global development” and “creating business opportunities with a total view of healthcare, from personalized medicine to self-medication.”

### Main Products

Cholesterol measurement reagents contributing to the examination of lifestyle-related diseases

## Pharmaceuticals Business | Biosimilars

Fujifilm Kyowa Kirin Biologics creates world-class biosimilars*1 and has continued to grow as a Japan-based global biosimilar development company.

*1 Follow on biologics

**External Environment**

### Market expansion and intensified competition concerning off-patent of antibody drugs

In recent years, antibody drugs have become the focus of development of biosimilars because the patents of many blockbuster*2 antibody pharmaceutical products will expire in the next few years, leading to a predicted expansion of the market for biosimilars. In order to develop biosimilars, it is necessary to possess appropriate knowledge, technology and production facilities to produce the drugs, and a financial base to cover the huge development costs required. For this reason, in addition to global generic companies, mega-pharmaceutical companies have also entered the market, introducing to intensified competition.

*2 This refers to a novel drug with efficacy that can overturn conventional treatments and can be expected to generate over 100 billion yen (approximately 1 billion dollars) in sales per year and lead to huge profits as a result.

**Countermeasures and Initiatives**

### Striving toward low cost + high quality and enhancing our global development system

By utilizing and fusing together the technologies and know-how of our parent companies (Kyowa Hakko Kirin and Fuji Film), we have increased our market competitiveness by utilizing revolutionary technology that allows us to achieve the seemingly contradictory goals of producing high-quality products at low cost, while pursuing safety and security for patients and medical professionals.

In 2015, we promoted the phase III trial of our first product FKB327 (biosimilar of the antibody preparation adalimumab) and the phase I trial of second product FKB238 (biosimilar of the antibody preparation bevacizumab). In addition, in order to build a strong international development system with partner companies overseas, we have entered into a partnership with AstraZeneca Inc. (U.K.) concerning the development and sales of FKB238 as well as founding a 50-50 joint venture company (Centus Biotherapuetics).

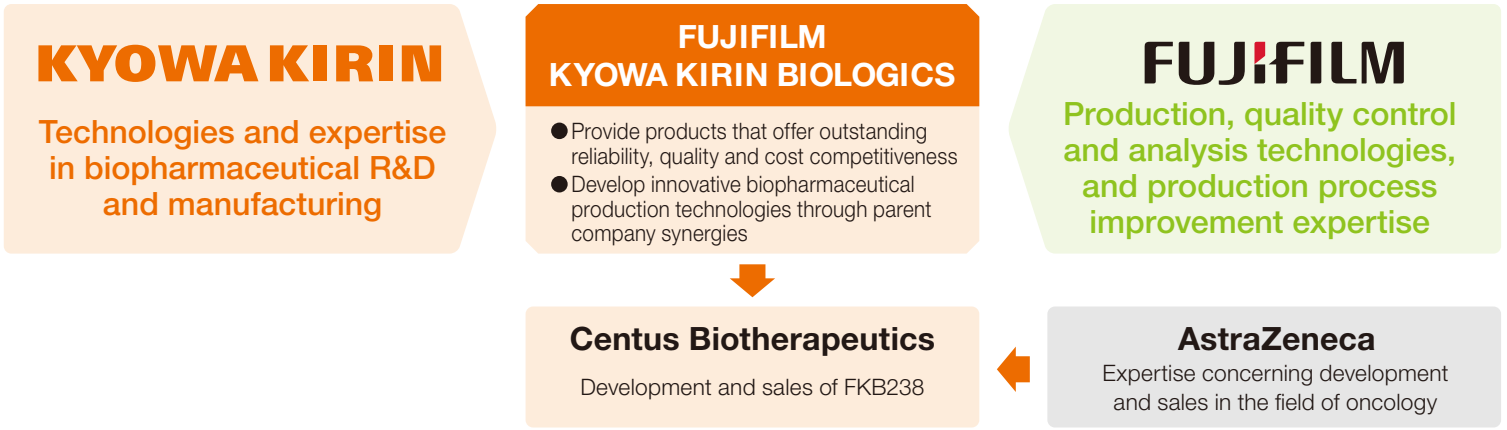
**Future Prospects**

### Contributing to a reduction of medical costs through a highly efficient and low-cost development system

We will continue the steady development of each product with an aim for early approval and product launch in Europe, the United States, and Japan. Furthermore, utilizing our past experience, we will establish an efficient development system and continue to reduce production costs.

The biosimilar business has played an important role in reducing medical costs around the world.

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



# Bio-chemicals Business

We have responded to the expanding market by strengthening our production and sales system of the existing products, through initiatives such as upgrading our production sites and constructing a new factory in Thailand. We will also continue our initiatives concerning new research on culture media for use in regenerative medicine.

## 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.**

External Environment

### Expanded demand due to the sophistication of medical treatment, increased health consciousness, and interest in safety and function

As the sophistication of medicine advances on a global scale, the demand for pharmaceutical amino acids, such as medical infusions, has increased. In addition, there has been much focus on materials utilized in health maintenance, strength enhancement, beauty, etc., due to growing interest in health. There has also been recent increased interest in safety and function, and demand has been concentrated in the small number of producers of amino acids for use in pharmaceutical products, including our company. In order to meet this demand, we believe that it is important to have a stable supply based on an efficient production system. Moreover, we believe that it is important to increase the added value of products by showing the evidence and basis for a strong quality assurance system and functionality.

Main Products

Countermeasures and Initiatives

### Improvements in production structure, function disclosure, and added value in order to respond to an expanded market

In order to respond to growing demand, we have been promoting the development of a production system for the past several years. By significantly shifting production overseas such as the United States, Thailand, and China, we can reduce costs and become a stronger organization that is less vulnerable to the impact of foreign exchange rates. Furthermore, we plan to continue to identify functions related to health maintenance and strength enhancement of our own materials, proceed with the registration of the brand and trademarks mainly in the United States, one of the largest health food markets, and expand our value adding activities. In order to maintain product reliability, we will continue to strengthen our safe and secure quality assurance system.

Kyowa Hakko Bio health foods

Future Prospects

### Striving to make culture media for use in regenerative medicine in addition to our existing materials and products

In the field of fine chemicals, we aim to continue to analyze the functions of amino acids, peptides, and sugars, and to supply products with added value to customers. In the field of healthcare, a part of the organization was transferred to the Fine Chemicals Sales Department. With our new sales structure, we will aim for further flexible expansion of mail order sales with a focus on ornithine one of amino acid. The types of crops for which the plant growth regulator Gibberellin is indicated have been increasing as the current usage market matures. In addition to these existing materials and products, we will continue to take advantage of our knowledge about our culture technology and will start research on culture media for new regenerative medicine treatments.

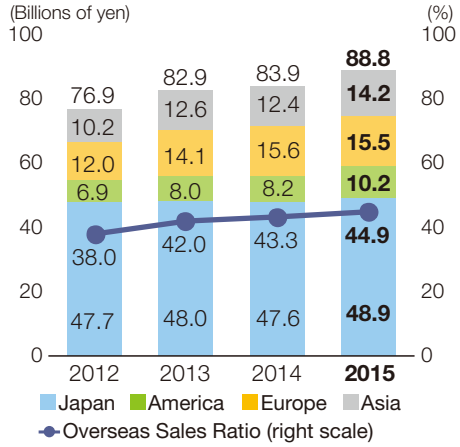
Gibberellin (plant growth regulator)

### Number of Bio-Chemicals Business Sites

As of March 31, 2016

| | |
|---|---|
| Number of Domestic Sales Sites | 3 |
| Number of Overseas Subsidiaries and Affiliates | 11 |

### Bio-Chemicals Business Net Sales by Region



## Bio-chemicals Business | Production

By increasing production efficiency through the development and enhancement of our production sites and facilities, we will provide bulk pharmaceutical products* for the global market.

*This refers to active pharmaceutical ingredients and intermediates.

### External Environment/Countermeasures and Initiatives/Future Prospects

**Consolidation of sites (e.g., factories) with the aim of improving production efficiency and ensuring a stable supply**

Currently, we are working on the consolidation of production facilities in order to improve the production efficiency and productivity of our bio-chemicals business. The main consolidation projects to be completed in the next few years are as follows:

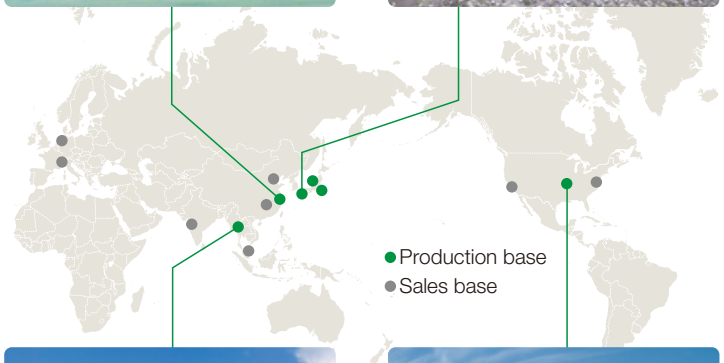
- Consolidation of Yamaguchi Production Center (Ube) into YPC (Hofu).
- Creation of new Fermentation Plant in Thailand (crude crystal manufacturing plant)
- Expansion of Shanghai Refinement Plant (final refinement process)

Due to the consolidation of Ube plant into Hofu, we have updated equipment and introduced new technology. In addition, the major amino acid products will be transferred to the new plant in Thailand. Furthermore, crude crystals of amino acid produced in Thailand are turned into high-purity crystals in Shanghai, and shipped to customers in the pharmaceutical and medical fields, especially in Europe. By introducing state-of-the-art equipment and technology, we will continue to supply products in a stable manner to the expanding global market.

### Global Production Centers

Shanghai Kyowa Amino Acid Company, Ltd. (Shanghai, China)

Kyowa Hakko Bio Yamaguchi Sales Office, Hofu (Yamaguchi Prefecture, Japan)

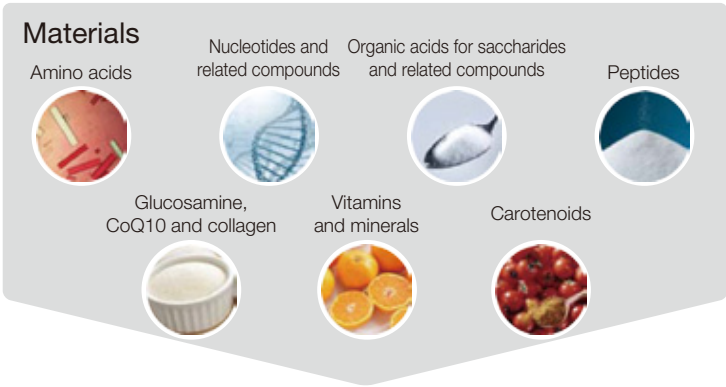


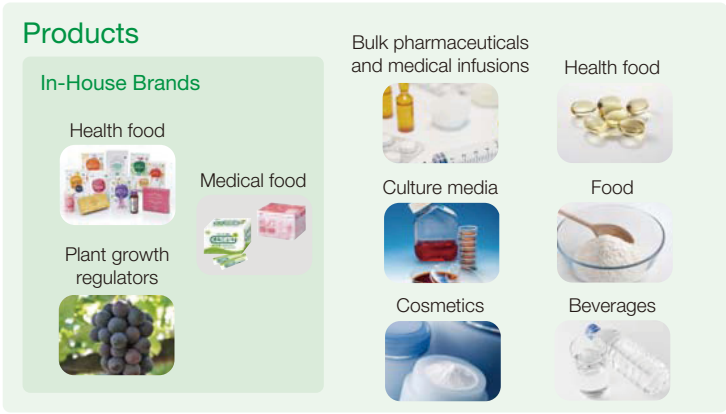

Thai Kyowa Biotechnologies Co., Ltd. (Rayong, Thailand)

Biokyowa Inc. (Cape Girardeau Mo, USA)

### 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

Board of Directors (As of March, 2016)

Director of the Board
Managing Executive Officer
Vice President Head, R&D Division

## Yoichi Sato

Apr. 1984: Joined Kirin Brewery Company, Limited
Sep. 2004: Director, Supervising Regulatory Affairs of Pharmaceutical Division, Kirin Brewery Company, Limited
Jul. 2007: Managing Officer, Vice Head and Director of Regulatory Affairs, Kirin Pharma Company, Limited
Oct. 2008: Director, Regulatory Affairs Department, Kyowa Hakko Kirin Co., Ltd.
Apr. 2009: Executive Officer, Kyowa Hakko Kirin Co., Ltd.
Mar. 2012: Managing Executive Officer, Kyowa Hakko Kirin Co., Ltd.
Mar. 2015: Director of the Board, Managing Executive Officer, Kyowa Hakko Kirin Co., Ltd. (to present)

Director 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, Kyowa Hakko Kirin Co., Ltd.
Mar. 2012: Managing Executive Officer, Kyowa Hakko Kirin Co., Ltd.
Mar. 2014: Director of the Board, Managing Executive Officer, Kyowa Hakko Kirin Co., Ltd. (to present)

Director 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)

Executive 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)

Executive 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)

Director 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)

Director 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 (to present)
Oct. 2013: President, Japan Industrial Track & Field Association (to present)
Mar. 2014: Director of the Board, Kyowa Hakko Kirin Co., Ltd. (to present)

Director of the Board

## Akihiro Ito

Apr. 1983: Joined Kirin Brewery Company, Limited
Jul. 2007: Director of Planning Department, Kirin Pharma Company, Limited
Oct. 2008: General Manager, Group Planning Department, Kyowa Hakko Kirin Co., Ltd.
Apr. 2009: General Manager, Strategy Planning Department, Kyowa Hakko Kirin Co., Ltd.
Mar. 2010: General Manager, Finance & Accounting Department, Kirin Business Expert Company, Limited, (January 1, 2011, trade name changed to Kirin Group Office Company, Limited)
Jan. 2013: Director and Executive Officer of Group Finance, Kirin Holdings Company, Limited
Mar. 2014: Director of the Board, Kirin Holdings Company, Limited and Lion Pty Ltd, Senior Executive Officer, Kirin Company, Limited(to present)
Mar. 2015: Director of the Board, Kyowa Hakko Kirin Co., Ltd. (to present)

# 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.

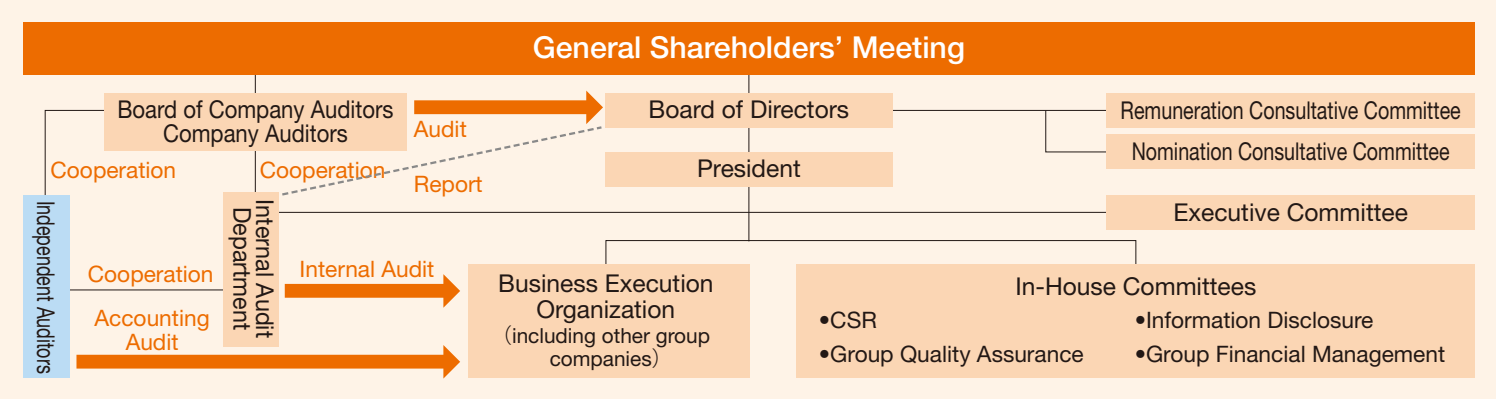
In addition, we have further enhanced the transparency of our management by voluntarily installing a "Nomination Consultative Committee" and "Remuneration Consultative Committee," as well as adopting a hybrid governance system that allows a balance between further enhancing the transparency of management 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 2015** | Number of meetings: 16<br>Director attendance: 100%<br>Company auditor attendance: 100% |

| | |
|---|---|
| **Board of Company Auditors meetings in 2015** | Number of meetings: 14<br>Company auditor attendance: 100% |
| **Director remuneration** | Total compensation for 2015 consisting of performance-linked base compensation and stock options as medium-term stock-based compensation (5 directors excluding outside directors): ¥277 million (base compensation, ¥229 million; stock options, ¥47 million) |
| **Company auditor remuneration** | Total compensation for 2015 (1 company auditor excluding outside company auditors): ¥24 million (base compensation: ¥24 million) |
| **Accounting auditor** | Ernst & Young ShinNihon LLC |

*As of March 24, 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-to-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

Company Auditors and Board of Auditors, conduct audits of the decision-making process and the execution of duties of the Board of Directors in accordance with the relevant laws (Companies Act, etc.), articles of incorporation and regulations, etc. Based on their respective abilities to gather information within the Group and maintain a neutral and objective point of view, the company auditors (full time) and outside company auditors actively report their opinions to the Board of Directors and cooperate with outside directors, independent auditors and the internal audit department to ensure the effectiveness of audits and the soundness of the management.

## 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 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.<br>• 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.<br>• 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.<br>• 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.<br>• 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." 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.

## Important Items Affecting Corporate Governance

Our company is a consolidated subsidiary of the pure holding company Kirin Holdings Co., Ltd., 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.

## Internal Control

Based on the basic policy of the parent company Kirin Holdings, 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.

## The Criteria for Independence of Outside Directors

In order to secure the requirements concerning the independence of outside directors, we have established our own election criteria based on the provisions for independent directors as 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.

## General Shareholders' Meeting

Convocation notifications concerning the General Shareholders' Meeting are 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, English translation of convocation notices and utilization of electronic voting platforms are offered. 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.

# 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.**

### A Message from the Executive Vice President

In order to realize the management philosophy of contributing to the health and well-being of people around the world, the Kyowa Hakko Kirin Group acts 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 to be the base of all of our corporate activities, and therefore have established appropriate rules and created an organizational structure that acts in compliance with all laws and ordinances, internal and external guidelines and rules, and social conventions. We also promote compliance by improving our understanding of important issues through surveys of compliance awareness.

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, protection of the environment, and information management. This policy has been translated into English, Chinese, and the other languages of the countries in which our sites are located as we attempt to inculcate this policy among all group members.

Under the mid-term business plan that starts from 2016, in order to leap forward to become a GSP, we are striving in good faith to meet the demands of society and to build and maintain healthy and favorable relationships with all stakeholders we reach through our business.

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

### Compliance Training

The Group is committed to cultivating workers and fostering an organizational culture that can respond 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. While improving awareness of issues such as "the prevention of corrupt practices," "human rights," and "the industry code" in 2015, we also created and distributed pamphlets concerning "inappropriate involvement in physician-led clinical research" in order to prevent the recurrence of a related incident that occurred in 2014.

In addition, as a member of the Kirin Group, our group administers a yearly "Awareness Survey of Human Rights and Compliance" to all of our domestic employees in the Group, and utilizes the results of the survey to improve education measures.

**Major training conducted, etc.** (targets: Kyowa Hakko Kirin domestic group companies)

- Anti-bribery Initiatives*1
- Proper Disposal of Waste Materials
- Handling of obtained information concerning side effects*2
- Training on human rights and compliance
- Social Security and Tax Number System
- Japan Pharmaceutical Manufacturers Association (JPMA) Code of Compliance 2015 "Promotion of Understanding the Code Month"
- Survey on compliance and human rights awareness in the Kirin Group in 2015

*1 Conducted in the entire Group, including international sites and subsidiaries
*2 Conducted only in Kyowa Hakko Kirin and Kyowa Medical Promotion

## Anti-bribery Initiatives

In order to be a company that is trusted and highly evaluated by society, it is necessary to operate the business with a high awareness of compliance. 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 the anti-bribery measures.

Kyowa Hakko Kirin Group has established Anti-Bribery policy and regulations, and has communicated them to Group companies together with communications from the president. The policy has been posted in Japanese and English on Kyowa Hakko Kirin website since April 2015.

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 prevent bribery 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, provided continuous training for executives and employees, and currently conduct monitoring and auditing of each company.

## Push for Transparency as a Pharmaceutical Company

Our Group has expanded its business activities while collaborating with other medical institutions in order to develop our life science business, including improvements in medical treatments, medicine and pharmacology. Furthermore, as patient participation in medicine has become popular, ensuring transparency in the relationships between pharmaceutical companies and patient organizations and respect for the independence of patient organizations has become increasingly important in recent years. With this background, Kyowa Hakko Kirin has established "Guidelines on Transparency in Corporate Activities and Relationships with Medical Institutions, Etc." and "Guidelines on Transparency in Corporate Activities and Relationships with Patient Organizations" in order to ensure transparency in relationships with medical institutions and patient organizations. Along with proper operation in line with the guidelines, we are increasing transparency through publishing information, such as payment to medical institutions and patient organizations on our website.

It is also important to promote compliance to increase the transparency of our business activities as we expand globally. Following the start of enforcement of the Physician Payments Sunshine Act (U.S.), as a corporation that handles pharmaceutical products in the United States, the Group has promoted efforts to disclose information about payments to physicians and medical institutions.

## "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.

## Internal Reporting System

In order to improve the correction, prevention, early detection and flexibility in the self-purification of unethical conduct (violations of rules or regulations, harassment, etc.), Kyowa Hakko Kirin (Japan) has established four internal reporting systems, including a lawyer hotline, to file reports or make consultations when an employee finds an unethical act.

In addition, we have established internal rules related to the internal reporting system, and clearly defined that informants and those cooperating with the investigation are to be protected. In 2015, there were 26 cases involving the internal reporting system.

# 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.**

## Concerning Risk Management

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

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

In addition, of the situations that inhibit the achievement of our business objectives, we have defined as crises those that require a serious and rapid response, in which we prioritize the 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 are also continually 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 BCP documents to perform PDCA cycle. In July of 2015, we held a BCP lecture conducted by outside experts for directors and executive officers and in September of the same year, we conducted BCP training to examine the supply system of our main products in the event of a disaster.

## Environmental Safety

Based on our "Basic Policy on the Environment, Safety, and Product Safety," we are promoting activities under both an ISO14001-accredited environmental management system and an occupational safety and health management system, and continuously improves them through a systematic Plan-Do-Check-Act (PDCA) cycle. Our environmental and safety activities are based not only on the relevant laws and regulations but on additional, more rigorous targets that we have voluntarily imposed on ourselves. We perform audits of all international production sites in order to directly understand the conditions facing each site. In our major domestic production sites and research center, we controll 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 administer surveys*1 as well as hold field surveys and networking events with the aim of improving the entire supply chain.

These activities have received high praise from outside the company: we won second place in the pharmaceutical industry in the 19th Nikkei Environmental Management Ranking Survey."*2

*1 We received answers from 259 companies (response rate: 87%) for the 2015 fiscal year.

*2 The survey of corporate initiatives for both environmental measures and manegement efficiency. Following the 12th survey, we have continued to be ranked as number two or higher in the pharmaceutical industry (we have won the first place award six times).

Environmental and safety audit of Thai plant
(Thai Kyowa Biotechnologies Co., Ltd.)

## Information Security

Kyowa Hakko Kirin recognizes that in order to improve reliability for customers and our competitiveness, the security of information assets is an important issue for management. To protect information assets, we have established a "Information Security policy" and under the policy, "Regulations for Confidential Information Management" has been established. A person is appointed as the manager in charge of the information security of the entire Group, and each department select a person in charge as well. Any important items related to the information security are to be discussed and reported in the CSR Committee. We have also implemented education to raise awareness of information security among employees and make all efforts to ensure the protection of information.

In addition, in response to the creation of the Japanese Social Security and Tax Number System, we have prepared a system to appropriately manage designated personal information.

# Outside Directors Message

## Koichiro Nishikawa
Director of the Board

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.

### By building common sense and global governance, I continue to support the “leap” of the company.

The 43 years that I was with the Hitachi Group reflects the history of Japan as an electronics-oriented country. During this period, I focused on negotiations with domestic and international companies as the business structure changed. As Kyowa Hakko Kirin aims to leap forward to become a global specialty pharmaceutical company (GSP), I would like to continue to contribute my experience in international business. I believe that the role of outside directors of the board is to provide “vitamin C.” “C” stands for “common sense.” What is common sense in Japan may not be so common in other countries. I would like to provide advice based on my experience that I have obtained to date concerning whether the methods and plans of the company are actually in line with the common sense of companies in Europe and the United States, so that the company can cultivate a true understanding of common sense.

One challenge from the viewpoint of governance is the absence of a foreign director as we attempt to expand our business overseas. I believe that it is essential to globalize both our human resources and our organizational structure before our global business comprises more than a half of our total business. The early inclusion of overseas human resources with a wide variety of international experience in the management team is desirable. By the same token, our greatest strength is our human resources. The abilities and strong determination of our workers far exceeds those found anywhere else. As all employees continue to maintain high aspirations, I also desire to support the management as a member of the Kyowa Hakko Kirin Group with the aim of realizing our target to leap forward to become a GSP.

## Yoshiko Leibowitz
Director of the Board

She had involved in nursing, education, and management for 30 years in the United States. 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.

### I support diversity while having the mindset to continue challenging new things.

Since becoming an outside director in 2015, I have visited various workplaces in the Kyowa Hakko Kirin Group, and by directly confirming the conditions in each location with my own eyes, I have spoken with many workers. During these experiences, I was reminded that the strengths of our company are technological capabilities such as antibody drugs and our human resources that are active across the globe.

I have been involved in nursing and medical care issues as well as the management of educational facilities in foreign country, which has allowed me to come into contact with thinking and cultures not limited by borders as I worked with a variety of people. I would like to utilize my past experiences to help the company become able to adopt more diverse human resources with diverse working styles and create an organizational structure that allows workers to continue to work in a healthy manner.

With the pharmaceutical business at its core, our unique business structure combines with the bio-chemicals and other businesses. It will allow us to foster a corporate culture in which each continues to improve itself by competing others and accepts diversity. I believe that this will connect to the leap toward becoming a global specialty pharmaceutical company.

My message to everyone is to aim for the sustained development of the company by uniting and continuing to strive to overcome difficulties through hard work while maintaining a positive attitude. There is a saying, “Don’t let perfect be the enemy of the good.” This means that if you aim for perfection from the start, you will be unable to complete anything. I would like workers to “just do it” and tackle challenges through what they can do, without the fear of failure.

# Financial Section

## Quick Search



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Financial Ratios


Financial Summary


Consolidated Statements of Cash Flows

# Eleven-Year Selected Financial Data

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries
For the years ended December 31, 2010 to 2015, the nine months ended December 31, 2009 and years ended March 31, 2005 to 2009

| | Millions of yen | | | | | | | | | | | Thousands of U.S. dollars[1] |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **2015/12** | 2014/12 | 2013/12 | 2012/12 | 2011/12 | 2010/12 | 2009/12 | 2009/3 | 2008/3 | 2007/3 | 2006/3 | **2015/12** |
| **For the Year:** | | | | | | | | | | | | |
| Net sales | **¥ 364,316** | ¥ 333,446 | ¥ 340,611 | ¥ 333,158 | ¥ 343,722 | ¥ 413,738 | ¥ 309,111 | ¥ 460,183 | ¥ 392,119 | ¥ 354,274 | ¥ 353,439 | **$ 3,022,366** |
| Gross profit | **225,393** | 205,904 | 212,761 | 210,690 | 197,555 | 190,979 | 139,739 | 200,297 | 144,917 | 131,424 | 126,982 | **1,869,865** |
| Selling, general and administrative expenses | **181,628** | 169,731 | 160,987 | 157,785 | 150,940 | 145,568 | 111,496 | 154,910 | 105,527 | 100,725 | 101,448 | **1,506,790** |
| Operating income | **43,765** | 36,173 | 51,773 | 52,905 | 46,614 | 45,410 | 28,243 | 45,387 | 39,390 | 30,698 | 25,534 | **363,074** |
| Net income | **29,774** | 15,898 | 30,078 | 24,199 | 25,608 | 22,197 | 8,797 | 11,726 | 23,477 | 12,694 | 16,273 | **247,012** |
| Capital expenditures (including intangible fixed assets) | **20,039** | 29,487 | 35,183 | 27,808 | 19,697 | 29,374 | 25,135 | 18,523 | 14,795 | 14,497 | 10,870 | **166,245** |
| Depreciation and amortization | **23,126** | 23,885 | 21,592 | 20,904 | 22,833 | 22,188 | 17,003 | 18,779 | 14,346 | 10,006 | 9,788 | **191,856** |
| R&D expenses | **51,604** | 47,737 | 43,682 | 44,808 | 47,961 | 44,210 | 34,979 | 48,389 | 34,109 | 33,342 | 32,875 | **428,112** |
| **Cash Flows:** | | | | | | | | | | | | |
| Net cash provided by operating activities | **¥ 66,526** | ¥ 19,377 | ¥ 56,884 | ¥ 59,134 | ¥ 40,634 | ¥ 64,189 | ¥ 24,203 | ¥ 41,069 | ¥ 30,713 | ¥ 23,380 | ¥ 14,303 | **$ 551,900** |
| Net cash peovided by (used in) investing activities | **(57,747)** | 16,805 | (77,163) | (98,772) | 18,460 | (32,373) | (13,246) | (3,981) | (9,492) | (8,493) | (1,795) | **(479,071)** |
| Net cash peovided by (used in) financing activities | **(14,060)** | (37,184) | (12,579) | (19,189) | (30,740) | (14,446) | (16,906) | (20,978) | (13,499) | (24,417) | (5,139) | **(116,647)** |
| Cash and cash equivalents at the end of the period | **12,784** | 17,013 | 19,242 | 50,334 | 107,555 | 79,882 | 63,745 | 69,286 | 44,118 | 36,613 | 45,820 | **106,063** |
| **At Year-End:** | | | | | | | | | | | | |
| Total current assets | **¥ 324,433** | ¥ 283,192 | ¥ 329,320 | ¥ 303,988 | ¥ 284,217 | ¥ 288,852 | ¥ 276,587 | ¥ 279,475 | ¥ 232,661 | ¥ 214,352 | ¥ 212,985 | **$ 2,691,497** |
| Total assets | **720,764** | 719,135 | 719,257 | 679,342 | 658,873 | 695,862 | 695,268 | 699,041 | 394,081 | 378,870 | 384,381 | **5,979,464** |
| Total current liabilities | **84,823** | 85,182 | 85,076 | 85,774 | 78,465 | 102,483 | 110,080 | 108,522 | 111,743 | 106,565 | 94,148 | **703,695** |
| Interest-bearing debt | **4,840** | 4,868 | 6,207 | 5,699 | 6,042 | 7,515 | 13,228 | 13,540 | 12,790 | 13,136 | 12,216 | **40,154** |
| Total net assets | **614,858** | 605,368 | 595,415 | 555,898 | 540,023 | 544,992 | 540,343 | 543,070 | 256,758 | 244,082 | 257,491 | **5,100,864** |
| Total shareholders' equity[2] | **594,989** | 580,499 | 578,329 | 560,663 | 554,856 | 553,172 | 539,304 | 547,203 | 239,328 | 220,428 | 232,621 | **4,936,033** |
| Number of employees | **7,435** | 7,424 | 7,152 | 7,243 | 7,229 | 7,484 | 7,436 | 7,256 | 6,073 | 5,756 | 5,800 | |
| **Per Share Data:** | | | | | Yen | | | | | | | U.S. dollars[1] |
| Net income–basic[3] | **¥ 54.40** | ¥ 29.05 | ¥ 54.95 | ¥ 44.12 | ¥ 45.16 | ¥ 38.96 | ¥ 15.40 | ¥ 20.42 | ¥ 58.99 | ¥ 31.31 | ¥ 38.34 | **$ 0.451** |
| Net assets | **1,122.8** | 1,105.4 | 1,085.2 | 1,013.6 | 970.2 | 954.6 | 940.8 | 938.4 | 639.7 | 607.5 | 604.9 | **9.320** |
| Cash dividends | **25** | 25 | 25 | 20 | 20 | 20 | 15 | 20 | 10 | 10 | 10 | **0.207** |
| **Common Stock Price Range (Per share):** | | | | | | | | | | | | |
| High | **¥ 2,321** | ¥ 1,510 | ¥ 1,256 | ¥ 970 | ¥ 953 | ¥ 1,040 | ¥ 1,178 | ¥ 1,235 | ¥ 1,430 | ¥ 1,154 | ¥ 946 | **$ 19.26** |
| Low | **1,094** | 1,006 | 833 | 757 | 628 | 773 | 793 | 586 | 933 | 722 | 656 | **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 | 399,243 | 399,243 | 434,243 | |
| Weighted average number of common stock issued | **547,285** | 547,348 | 547,391 | 548,449 | 567,029 | 569,711 | 570,935 | 574,083 | 397,716 | 405,270 | 422,919 | |
| **Financial Ratios:** | | | | | | %, except EBITDA | | | | | | |
| Return on assets (ROA) | **4.13** | 2.21 | 4.30 | 3.62 | 3.78 | 3.19 | 1.26 | 1.62 | 6.07 | 3.33 | 4.29 | |
| Operating return on assets | **6.07** | 5.03 | 7.40 | 7.91 | 6.88 | 6.53 | 4.05 | 6.26 | 10.19 | 8.04 | 6.73 | |
| Return on equity (ROE) | **4.90** | 2.65 | 5.24 | 4.43 | 4.73 | 4.11 | 1.64 | 2.17 | 9.47 | 5.1 | 6.63 | |
| Equity ratio | **85.20** | 84.13 | 82.58 | 81.68 | 81.79 | 78.16 | 77.07 | 77.04 | 64.53 | 63.8 | 66.55 | |
| Debt/equity ratio | **0.78** | 0.80 | 1.05 | 1.03 | 1.12 | 1.38 | 2.47 | 2.51 | 5.03 | 5.43 | 4.78 | |
| Operating income margin | **12.01** | 10.85 | 15.20 | 15.88 | 13.56 | 10.98 | 9.14 | 9.86 | 10.05 | 8.67 | 7.22 | |
| EBITDA[4] (Millions of yen) | **78,018** | 64,101 | 83,190 | 78,160 | 79,864 | 74,614 | 45,056 | 60,098 | 53,162 | 33,771 | 34,846 | |
| Payout ratio[5] | **35.1** | 54.4 | 34.8 | 32.8 | 32.5 | 36.2 | 54.3 | 53.8 | 16.9 | 31.9 | 26.1 | |

1. U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥120.54=U.S.$1, the approximate exchange rate at December 31, 2015.
2. Due to a change in accounting standards, figures for total shareholders' equity in the years ended March 31, 2007 and 2006 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, appropriately adjusted for subsequent free distributions of common stock.
4. EBITDA = Income before income taxes and minority interests + Interest expenses + Depreciation and amortization + amortization of goodwill
5. The consolidated payout ratio is calculated using net income before amortization of goodwill* beginning with the fiscal year ended March 31, 2009.
* "Net income before amortization of goodwill" refers to profits prior to the deduction of amortization of the goodwill arising on the reverse acquisition in April 2008 (Kirin Pharma share transfer).

# CFO Message

**Kazuyoshi Tachibana**
Director of the Board, Managing Executive Officer

### Concerning the Performance of the Group During the FY2015

## We saw a strong performance with an operating income of 43.7 billion yen, an increase of 21 percent year on year.

In comparison with the previous year, we experienced increases in revenue and profits for the 2015. In particular, net income rebounded to nearly that of 2013, our highest net income ever. Thus, it can be seen that our performance has been quite favorable. With regard to operating income, due to continued robust sales of prescription pharmaceutical products in the Japanese market, and the lump sum received from the conclusion of an option agreement for KHK4563 with AstraZeneca, we realized a profit of 43.7 billion yen, a 21% increase against the previous year, notwithstanding the costs related to the conclusion of the contract to introduce rituximab BS that occurred at the end of the year.

Stock prices at the end of 2015 significantly increased compared to the prices at the end of the 2014. We believe that this is a result of the improved pipeline value of Kyowa Hakko Kirin being positively evaluated by the securities market. It is important to continue investments for the future and enhance our corporate value to ensure the future growth of the Kyowa Hakko Kirin Group.

### Review of the FY2013-2015 Mid-term Biusess Plan

## Aiming to expand business in international markets, promoting aggressive investment

During the previous mid-term business plan, we aimed to “strive toward global specialty pharmaceutical company (GSP),” and accelerated our preparation to expand into international markets. ProStrakan Group Plc (UK), which joined the Group in 2011, similarly acquired Archimedes Pharma Limited (UK) in 2014, allowing us to strengthen the sales system of our products in international markets, especially Europe. We have also actively invested in clinical research in Europe and the United States with the goal of launching our own novel drugs in overseas markets. Being in a partnership since 2013, the joint development of KRN23 with Ultragenyx (US) and final clinical trials of the Kyowa Hakko Kirin-made antibody drug KW-0761 (mogamulizumab) for hematologic cancer have been progressing smoothly, and we have made great progress toward filing for approval in Europe and the United States. Furthermore, KW-6002 (NOURIAST®) has smoothly progressed to an additional phase III trial in Unites States.

For our pharmaceuticals business, we aggressively invested capital in the reconstruction of the production system for the launch of new drugs in overseas markets. For our bio-chemicals business, we have constructed a new factory in Thailand in order to expand our amino acid production capacity and reduce foreign exchange risks. Our tangible fixed assets have increased due to these capital investments conducted in response to the globalization of our pharmaceutical and bio-chemical businesses.

Looking back at the cash flow related to the above-mentioned activities for the previous three years, there has been a total of approximately 210 billion yen in cash inflow due to income after tax, amortization of tangible and intangible assets, and the sale of assets such as stocks. Of this, approximately 70 billion yen was used for capital investment and another 70 billion yen for purposes such as M&A, in-licensing products and strategic investments into the biosimilar business. Moreover, 40 billion yen was earmarked for dividends to shareholders. We believe that we can maintain a healthy and lean financial structure by proactively investing in future growth without increasing external debt.

### Financial Strategy of the FY2016–2020 Mid-term Biusess Plan

## We will work to improve the ROA as a whole to increase the ROE.

During the first three-year period, we will make new drug applications for approval and launch new drugs in the markets of Europe and the United States with the aim of expanding sales in overseas markets by 2020. For this reason, we will proceed with continued investment aimed at growth.

Our management goals for 2020 are as follows: core operating income of 100 billion yen or more, overseas sales ratio of 50%, and ROE of 10% or more.

“Core operating profit” refers to operating income with the addition of goodwill amortization and share of profit/loss of entities accounted for using equity method. As the Group expands and grows our business on a global scale, we regard core operating income to be a profit indicator that reflects the principles of the International Financial Reporting Standards (IFRS).* In the first three years, two or three drug price revisions in the Japanese market are expected, and with the increasing market share of generic drugs, pharmaceuticals segment in Japan must be prepared to face extremely severe business conditions. However, in this severe situation during the three-year period, we will aim to successfully apply to launch three global products in Europe and the United States and achieve a significant expansion of profits during the latter two-year period with the increase of our “overseas sales ratio” associated with the expansion of sales in Europe and the United States.

# CFO Message

Being said to have relatively low profitability, it is necessary for Japanese corporations to increase their return on equity (ROE). ROE can be expressed by multiplying the return on assets (ROA) by financial leverage (total assets/ownership equity). In order to increase ROE, our Group promotes business management focused on increasing this ROA. After-tax net income (the numerator of ROA) can be greatly increased through achieving our target of a core operating profit of 100 billion yen due to the expansion of our international business. Moreover, with regard to total assets (the denominator of ROA), we aim to further enhance the effects of investment by making strong strategic investment decisions and expand our overseas business while making utmost efforts to limit increases in liquid assets such as inventory and accounts receivable, thereby improving the entire ROA.

We have no plans to increase our debt for purposes of financial leverage. However, if we are unable to finance aggressive strategic investment using our own funds for M&A, pipeline enhancement, etc., we may flexibly consider taking out loans. Regarding shareholder returns as well, our dividend policy aims to payout 40% of the net income before amortization of goodwill for the next three years until 2018. Moreover, we will flexibly consider the purchase of treasury stock after comprehensively evaluating the market conditions. While maintaining our current sound financial position, we aim to perform growth investment through self-financing to the extent possible in order to ensure overseas business growth during the latter half of our business plan.

* The Kyowa Hakko Kirin Group is currently preparing to make the transition to use the International Financial Reporting Standards (IFRS) from 2017.

### The Kyowa Hakko Kirin Business Model

## Taking advantage of the strengths to expand overseas sales, we continue to implement our target business model.

The strengths of the Group are our development capabilities for bio-products (therapeutic antibodies, amino acids, etc.) and global business capabilities, including business partnerships with international pharmaceutical companies.

Kyowa Hakko Kirin is currently ranked at a mid-level position in the Japanese market in terms of sales, therefore the scale of the company is quite small in comparison with the larger pharmaceutical companies in Europe and the United States. However, we have reached the final clinical stages to apply for antibody drugs in Europe and the United States as a Japanese corporation because of the bio-technology that has been cultivated since the foundation of the company.

During the period of the new mid-term business plan, we expect that our nucleic acid drug candidates will advance to clinical development as next-generation drugs following our antibody drugs. On the other hand, cooperation with excellent companies that possess a variety of strengths enables us to expand our global business, for example, collaborations with Ultragenyx on KRN23, and FUJIFILM and AstraZeneca in our biosimilars business. All global manufacturing and sales of our bio-chemicals business is done in-house. Although we are a medium-sized company, our business model is to grow by fusing our strengths with the strengths of other companies with maintaining a view of the global market.

Under the new mid-term business plan, we will sell our in-house antibody drugs on the global market, thereby ensuring international profits from manufacturing and sales and increasing our operating profit. The realization of a business model to globally expand our in-house pharmaceutical development and sales system, which has been previously focused on the Japanese market, is a major goal for the Group.

Securing and developing human resources as a driving force for the achievement of management goals will also be an important issue for us. The pharmaceutical industry has been highly specialized and become fragmented recently, and its business has expanded globally in markets such as Europe, the United States, Asia, and China. Naturally, it is necessary to construct a competitive system of remuneration to ensure that we obtain excellent human resources. We spare no investment in the development of human resources, and also aim to further improve measures to increase the strength of these resources.

In addition, I believe that our total commitment to research and development makes the company an attractive place to work for many researchers. A balance is needed between an environment in which researchers can freely conduct research, and creating a company that possesses high research productivity.

However, as globalization progresses and we increase our international sales ratio, there is an increased financial risk of foreign exchange having a severe impact on the company's performance. For this reason, we have introduced a cash management system (CMS) for the yen, dollar, pound and euro, and are managing funds of whole group with the aim of reducing foreign exchange risks and improving the efficiency of fund management.

### A Message to Shareholders and Investors

## Aiming for a dividend payout ratio of 40% for the first three years

Under the new mid-term business plan, we plan to further implement shareholder returns while making growth investments with the aim of achieving our goals and ensuring our future. Specifically, we will aim for a dividend payout ratio of 40% of current net earnings before amortization of goodwill to provide stable dividends to the shareholders. The Kyowa Hakko Kirin Group will continue to put a focus on research and development while firmly investing in technology, products and human resources. Following antibody drugs, we will continue to promote research on products that will lead to growth in the next generation, such as nucleic acid-based drugs. It is my hope that you will look forward to these new initiatives in pre-clinical development.

As CFO, I plan to contribute to study not only the independent business models but also the models of international companies that perform development using external resources, which enable KHK to continuously grow from a financial standpoint. It is my hope that the shareholders and investors will pay close attention to our aggressive financial strategy.

# Management's Discussion and Analysis

All amounts are rounded down.

## Subsidiaries Included in the Scope of Consolidation

The number of our consolidated subsidiaries for the current fiscal year (the fiscal year ended December 31, 2015) stood at 46, a decrease of three compared to the end of the previous fiscal year.

## Income

(Billions of yen)

| | Fiscal year ended December 31, 2015 | Fiscal year ended December 31, 2014 | Change |
|---|---|---|---|
| Net sales | **364.3** | 333.4 | 30.8 |
| Operating income | **43.7** | 36.1 | 7.5 |
| Ordinary income | **39.2** | 29.5 | 9.6 |
| Net income | **29.7** | 15.8 | 13.8 |

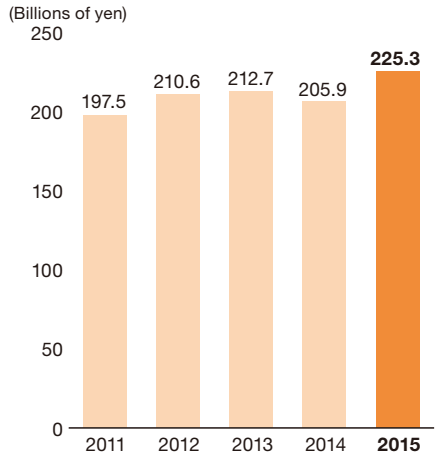
### Operating Income

Consolidated net sales and operating income for the current fiscal year increased due mainly to the growth in sales of new products as well as the impact of Archimedes Pharma Limited ("Archimedes"), which was acquired in August 2014.

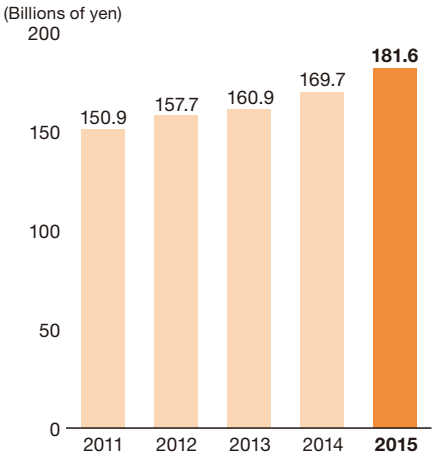
### Ordinary Income and Net Income

Ordinary income and net income respectively increased due to the increase in operating income. Ordinary income was affected by a decrease in share of loss of entities accounted for using equity method, while net income was affected by an increase in extraordinary income such as gain on sales of investment securities.

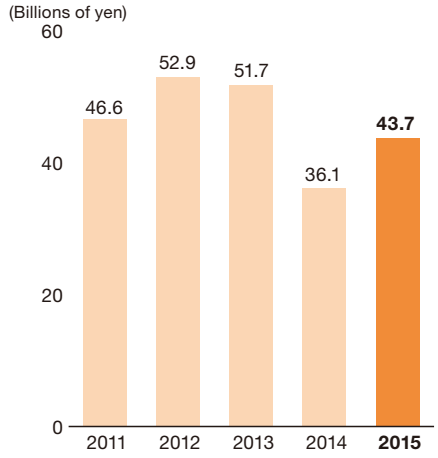
### Gross Profit



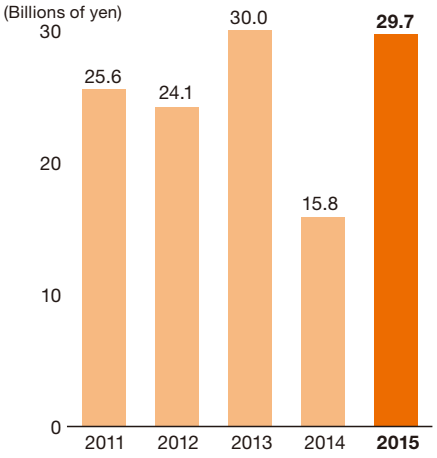

### Selling, General and Administrative Expenses




### Operating Income




### Net Income



## Performance by Business Segment

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

| | Millions of yen | | | Thousands of U.S. dollars* |
|---|---|---|---|---|
| | **2015/12** | 2014/12 | 2013/12 | **2015/12** |
| **Net sales:** | | | | |
| **Pharmaceuticals** | | | | |
| Sales to external customers | **¥ 278,402** | ¥ 251,882 | ¥ 259,584 | **$ 2,309,627** |
| Inter-segment sales and transfers | **894** | 1,129 | 1,423 | **7,419** |
| Total | **279,296** | 253,011 | 261,007 | **2,317,047** |
| **Bio-Chemicals** | | | | |
| Sales to external customers | **¥ 85,913** | ¥ 81,564 | ¥ 81,026 | **$ 712,738** |
| Inter-segment sales and transfers | **2,981** | 2,405 | 1,892 | **24,738** |
| Total | **88,895** | 83,970 | 82,919 | **737,476** |
| Adjustments | **(3,876)** | (3,535) | (3,315) | **(32,157)** |
| Consolidated total | **¥ 364,316** | ¥ 333,446 | ¥ 340,611 | **$ 3,022,366** |
| **Segment income (loss):** | | | | |
| Pharmaceuticals | **¥ 36,202** | ¥ 29,061 | ¥ 46,135 | **$ 300,337** |
| Bio-Chemicals | **8,127** | 7,277 | 5,667 | **67,426** |
| Adjustments | **(565)** | (165) | (29) | **(4,689)** |
| Consolidated total | **¥ 43,765** | ¥ 36,173 | ¥ 51,773 | **$ 363,074** |

* U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥120.54=U.S.$1, the approximate exchange rate at December 31, 2015.

### Pharmaceuticals Business

(Billions of yen)

| | **Fiscal year ended December 31, 2015** | Fiscal year ended December 31, 2014 | Change |
|---|---|---|---|
| Net sales | **279.2** | 253.0 | 26.2 |
| Operating income | **36.2** | 29.0 | 7.1 |

Domestic sales increased compared to the previous fiscal year due to such factors as the growth in sales of new products.

Sales of core product NESP®, a long-acting erythropoiesis stimulating agent for which approval for an additional indication for anemia with myelodysplastic syndrome was obtained in December 2014, were solid and increased from the previous fiscal year.

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

Sales of long term NHI products such as GRAN®, a G-CSF product, CONIEL®, a hypertension and angina pectoris drug, and ALLELOCK®, an anti-allergy agent, decreased due to the impacts of the market penetration of generics and reductions in drug price standards implemented in April 2014.

Overseas sales increased compared to the previous fiscal year due mainly to the impact of Archimedes, which was consolidated in August 2014.

In Europe and the U.S., sales of products such as Sancuso®, a treatment for chemotherapy-induced nausea and vomiting, and PecFent® and Abstral®, which are treatments for cancer pain, increased. Net sales of ProStrakan were ¥41.9 billion (up 33.7% year on year) and operating income was ¥1.1 billion (operating loss of ¥22 million in the previous fiscal year). Also, in licensing revenue, we booked sales from an up-front option fee (US$45 million) related to an option agreement for Benralizumab (KHK4563) signed with AstraZeneca.

In Asia, sales grew compared to the previous fiscal year, partly reflecting steady sales particularly in South Korea and China as well as further yen depreciation in foreign exchange.

### Bio-Chemicals Business

(Billions of yen)

| | Fiscal year ended December 31, 2015 | Fiscal year ended December 31, 2014 | Change |
|---|---|---|---|
| Net sales | **88.8** | 83.9 | 4.9 |
| Operating income | **8.1** | 7.2 | 0.8 |

Domestic sales increased compared to the previous fiscal year.

In the pharmaceutical and medical treatment fields, sales declined year on year partially due to a concentration of shipments of APIs for generics occurring in the previous fiscal year.

In the healthcare field, sales increased year on year due to firm growth in mail-order sales of Ornithine and other products.

Overseas sales increased compared to the previous fiscal year, partly reflecting further yen depreciation in foreign exchange.

In the U.S., sales increased year on year, due in part to growth in sales of amino acids for supplements.

In Europe, despite growth in sales of infusion-use amino acids, sales remained at the previous fiscal year level partially due to the effect of having transferred operations of raw materials for cosmetics ingredients business.

In Asia, the effect of the weaker yen in foreign exchange caused sales to increase year on year, even though there was no longer a concentration of API shipments as there had been in the previous fiscal year.

## Cash Flow

Cash and cash equivalents as of December 31, 2015 were ¥12.7 billion, a decrease of ¥4.2 billion compared to the balance of ¥17.0 billion as of December 31, 2014.

Net cash provided by operating activities was ¥66.5 billion, an increase of 243.3% over the previous fiscal year. The main factors included income before income taxes and minority interests of ¥41.4 billion, depreciation of ¥23.1 billion and amortization of goodwill of ¥13.4 billion, despite income taxes paid of ¥14.3 billion.

Net cash used in investing activities was ¥57.7 billion, compared to a net inflow of ¥16.8 billion in the previous fiscal year. Major outflows included a net increase of ¥54.4 billion in short-term loans receivable, purchase of property, plant and equipment, and intangible assets of ¥20.0 billion. Major inflows included proceeds from sales of investment securities of ¥17.9 billion.

Net cash used in financing activities was ¥14.0 billion, a 62.2% 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, 2015 were ¥720.7 billion, an increase of ¥1.6 billion compared to the end of the previous fiscal year. Current assets increased by ¥41.2 billion year on year to ¥324.4 billion as despite decreases in cash and deposits and inventories, there was an increase in short-term loans receivable from the parent company. Non-current assets decreased by ¥39.6 billion to ¥396.3 billion, affected by decreases in goodwill and sales right due to amortization, and a decrease in investment securities due to sales of shares.

### Liabilities

Liabilities as of December 31, 2015 were ¥105.9 billion, a decrease of ¥7.8 billion compared to the end of the previous fiscal year, due to decreases in notes and accounts payable - trade, deferred tax liabilities and other items, despite increases in income taxes payable and other items.

### Net Assets

Net assets as of December 31, 2015 were ¥614.8 billion, an increase of ¥9.4 billion compared to the end of the previous fiscal year, due to the booking of net income for the period and other items, which offset factors including payment of dividends and a decrease in foreign currency translation adjustment.

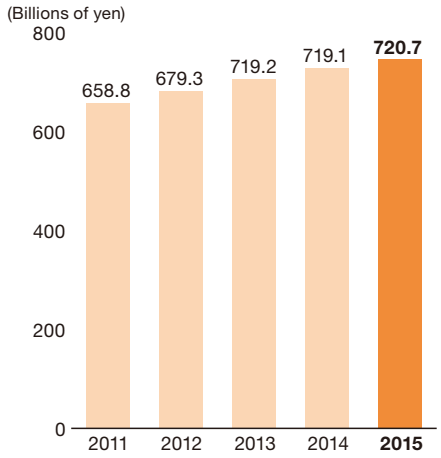
As a result, the equity ratio as of the end of the current fiscal year was 85.2%, an increase of 1.1 percentage points compared to the end of the previous fiscal year.

## Performance Indicators

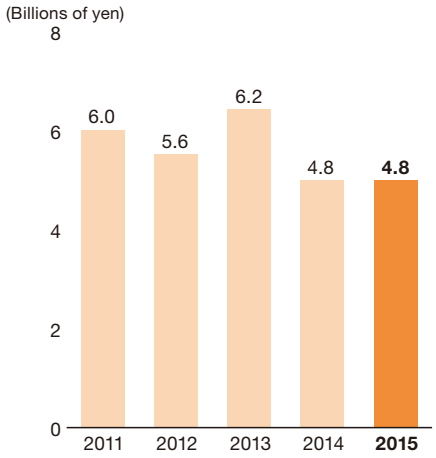
Return on equity (ROE) stood at 4.90%, an increase from 2.65% the previous fiscal year, and return on assets (ROA) at 4.13%, an increase from 2.21% the previous fiscal year. Operating return on total assets came to 6.07%, an increase from 5.03% the previous fiscal year.

EBITDA stood at 78.0 billion yen, an increase of 21.7% compared to the previous fiscal year.

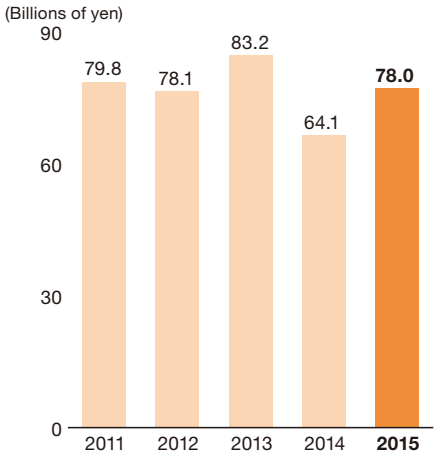
### Total Assets



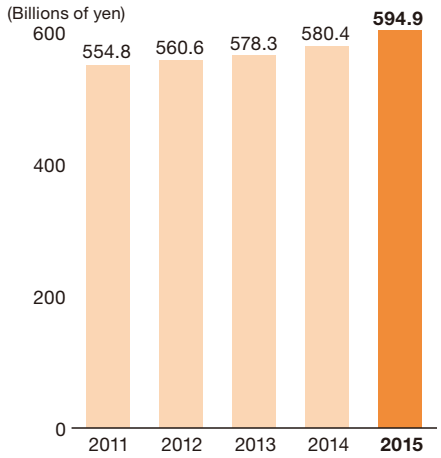

### Interest-Bearing Debt



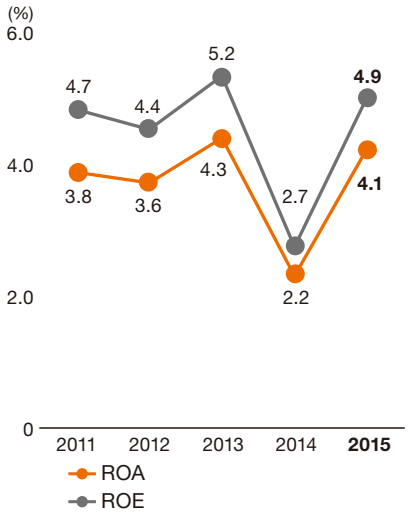

### EBITDA




### Shareholders' Equity




### Return (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, the Kyowa Hakko Kirin Group works to secure stable, low-cost capital primarily for Kyowa Hakko Kirin. We have introduced a global cash management system (CMS), which we use to support the efficient use of funds and reduction of financing costs for the Kyowa Hakko Kirin Group as a whole through approaches such as pooling of capital at Kyowa Hakko Kirin and domestic and overseas subsidiaries.

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 Expenditures (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, 2015 stood at ¥20.0 billion, a decrease of ¥9.4 billion (32.0%) compared to the previous fiscal year. Depreciation and amortization for the fiscal year amounted to ¥23.1 billion, a decrease of ¥0.7 billion (3.2%) compared to the previous fiscal year.

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

### Breakdown of Capital Expenditures and Depreciation and Amortization

**Capital Expenditure**

(Millions of yen)

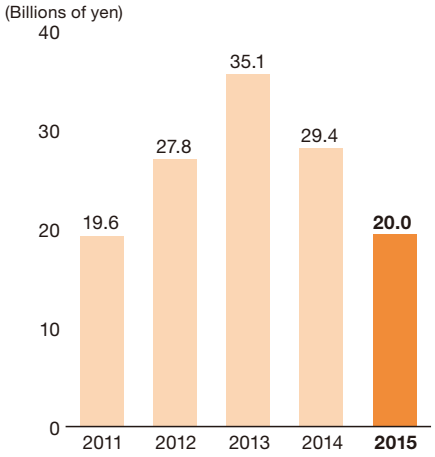
| | 2015/12 | 2014/12 | 2013/12 | 2012/12 | 2011/12 |
|---|---|---|---|---|---|
| Pharmaceuticals | ¥ **11,537** | ¥ 17,012 | ¥ 22,921 | ¥ 18,357 | ¥ 11,886 |
| Bio-Chemicals | **8,501** | 12,476 | 12,261 | 9,454 | 7,482 |
| Chemicals | **—** | — | — | — | 317 |
| Other | **—** | — | — | — | 11 |
| Adjustments | **—** | (1) | — | (3) | — |
| Consolidated total | ¥ **20,039** | ¥ 29,487 | ¥ 35,183 | ¥ 27,808 | ¥ 19,697 |

**Depreciation and Amortization**

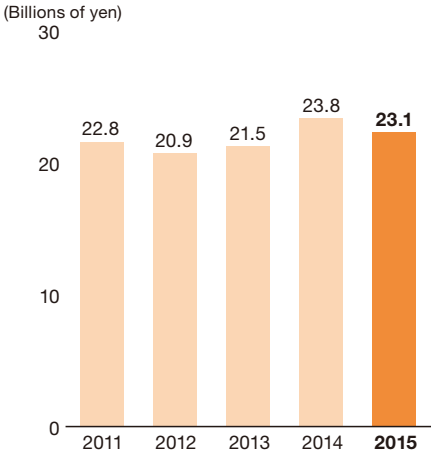
(Millions of yen)

| | 2015/12 | 2014/12 | 2013/12 | 2012/12 | 2011/12 |
|---|---|---|---|---|---|
| Pharmaceuticals | ¥ **16,569** | ¥ 17,075 | ¥ 14,966 | ¥ 14,625 | ¥ 15,339 |
| Bio-Chemicals | **6,558** | 6,811 | 6,627 | 6,280 | 6,457 |
| Chemicals | **—** | — | — | — | 974 |
| Other | **—** | — | — | — | 64 |
| Adjustments | **(1)** | (1) | (1) | (1) | (2) |
| Consolidated total | ¥ **23,126** | ¥ 23,885 | ¥ 21,592 | ¥ 20,904 | ¥ 22,833 |

### Capital Expenditure




### Depreciation and Amortization

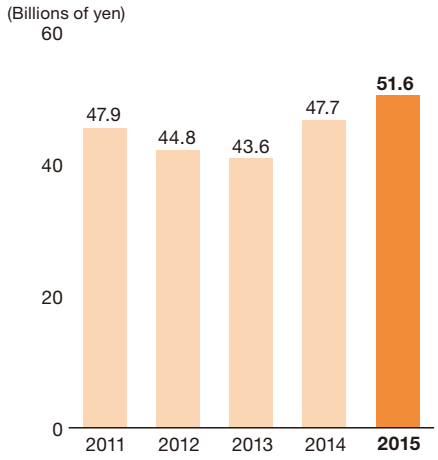


## R&D Expenses

R&D expenses for the fiscal year ended December 31, 2015 stood at ¥51.6 billion, an increase of 8.1% compared to the previous fiscal year. The ratio of R&D expenses to sales for the year came to 14.2%, a decrease of 0.1 percentage points from 14.3% the previous fiscal year.

R&D expenses in the Pharmaceuticals segment totaled ¥48.3 billion and accounted for 93.8% of total R&D expenses. The ratio of R&D expenses to sales in the pharmaceuticals business stood at 17.3%, a decline of 0.1 percentage points compared to the previous fiscal year. The R&D expenses of the biochemical business amounted to ¥3.2 billion.

R&D Expenses



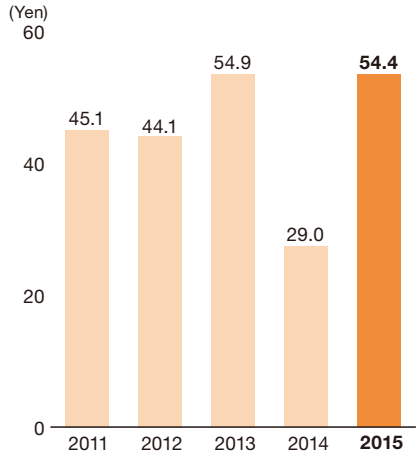

## Per Share Data

Net income per share (before dilution) for the fiscal year ended December 31, 2015 stood at ¥54.40 compared to ¥29.05 the previous fiscal year. Net income per share before goodwill amortization* amounted to ¥71.31.

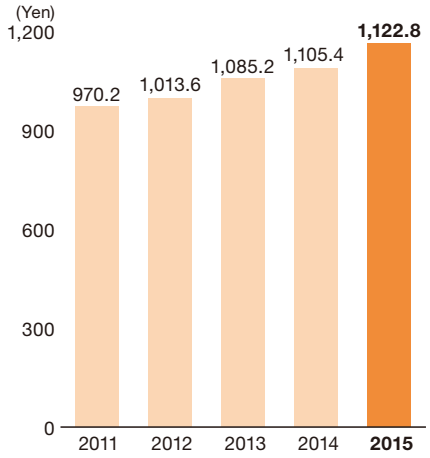
Net assets per share on December 31, 2015 totaled ¥1,122.8 compared to ¥1,105.4 on December 31, 2014.

* "Net income per share before goodwill amortization" refers to profits prior to the deduction of amortization of the goodwill arising on the reverse acquisition in April 2008 (Kirin Pharma share transfer).

Net Income per Share




Net Assets per Share




## Goodwill

Kyowa Hakko Kirin recognized goodwill as a result of the April 1, 2008 exchange of shares in connection with the business combination through which Kirin Pharma Company Limited acquired Kyowa Hakko Kogyo Company, Limited because the acquisition cost exceeded the market value of Kyowa Hakko's net assets.

**Goodwill from the business combination with Kirin Pharma Company Limited:**

- Total goodwill generated: ¥191.9 billion
- Amortization method: Straight-line method
- Amortization period: 20 years (beginning the fiscal year ended March 31, 2009)

Amortization of goodwill from the business combination with Kirin Pharma Company Limited totaled ¥9.2 billion for the fiscal year ended December 31, 2015, the same as in the previous fiscal year.

## 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 development at its core, the Group is pursuing a unique pharmaceutical business model that combines our biosimilars, diagnostics and bio-chemical businesses as it advances forward in becoming a global specialty pharmaceutical group, as set out in the new Mid-term Business Plan.

The Kyowa Hakko Kirin Group formulated the Group's five-year 2016 to 2020 Mid-term Business Plan with fiscal 2016 being the first year of the plan. Under our management targets for fiscal 2020, the final year of the plan, we aim to achieve core operating income*1 of at least ¥100.0 billion, an overseas sales ratio of 50% and ROE*2 of at least 10%, and in fiscal 2016, the initial year of the plan, we aim to achieve core operating income of ¥39.0 billion.

Note

*1 Core operating income: Operating income + Amortization of goodwill + Share of profit/loss of entities accounted for using equity method

*2 Net income before amortization of goodwill ÷ ((Equity at beginning of period + Equity at end of period) ÷ 2)

We expect that substantial changes with respect to the operating environment in the pharmaceuticals industry will pose even greater challenges, amid factors that are likely to include declining drug discovery success rates and increasingly stringent approval and review processes resulting in surging development costs, progress made with measures to reduce medical treatment costs, and increasingly diverse pharmaceutical needs. Meanwhile, amid slowing growth in the pharmaceutical market, particularly in Japan, the market share of generics has been steadily increasing. Due to this and other factors, research and development-oriented pharmaceutical manufacturers will have to pick up the pace in shifting their revenue sources from a reliance on existing long term NHI products and the domestic market to new pharmaceuticals and expansion into global markets.

In this environment, the Kyowa Hakko Kirin Group is taking steps to achieve our four strategic priorities of enhancing global competitive strengths, taking on challenges of innovation, making improvements resulting in unsurpassed operational processes, and contributing to people's health and well-being, all premised on the notion of becoming a global specialty pharmaceutical group, as set forth in our five-year Mid-term Business Plan released in January 2016.

Under the first pillar of our strategy set forth in the Mid-term Business Plan, that of enhancing global competitive strengths, we are working toward contributing to the health and well-being of people around the world by successfully launching in the U.S. and European markets our three global strategic products (KRN23, KW-0761 (product name in Japan: POTELIGEO®) and KW-6002 (product name in Japan: NOURIAST®)). We are aiming for early-stage launch of KRN23 and KW-0761 in particular, to which end we will forge ahead with the application process for the U.S. and Europe in 2016, and at the same time we will also continue to aggressively pursue ProStrakan's business model which involves introducing late-stage development and marketed products. Moreover, we intend to bring our U.S. and European sales locations all under the KYOWA KIRIN company name, which will thereby enable us to establish a framework for sales in the U.S. and Europe in conjunction with the market launch of our three global strategic products, while also making it possible to achieve worldwide penetration of the KYOWA KIRIN corporate brand. In Asia, the reorganization of our business base to achieve future stable growth in China is the most important issue. In addition, at local subsidiaries in Korea, Taiwan, Singapore, Thailand and other growing economies, we are implementing business strategies that reflect the unique characteristics and prevailing environment in each country.

Under the second pillar of our strategy, that of taking on challenges of innovation, we endeavor to create new value by linking our extensive knowledge of diseases and markets that we have developed in the four categories of nephrology, oncology, immunology/allergy and CNS, with cutting-edge technologies. We also aim to bring about further evolution of Kyowa Hakko Kirin's strengths involving antibody technology and small molecule drug discovery, while also establishing new technology platforms for discovery of nucleic acid medicines and other drugs, and also applying our expertise and know-how as a pharmaceutical manufacturer to the task of addressing opportunities in the realm of regenerative medicine in fields not being served by other firms. We are continuing our focus on fortifying our drug discovery strengths through open innovation that entails combining Kyowa Hakko Kirin's knowledge and technologies with those of external entities. Also, we are moving forward with efforts to upgrade our pipeline in the field of immuno-oncology, with efforts that include strategic partnering.

Under the third pillar of our strategy, that of making improvements resulting in unsurpassed operational processes, 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 are developing more reliable operational processes by building a global governance framework and engendering awareness of compliance. Particularly on the domestic front, we are pushing forward with efforts to implement our area marketing strategy in anticipation of the government's community medical care initiative, and are also moving ahead in having our medical science liaisons (MSLs) develop and provide appropriate scientific and academic information.

In 2016, the initial fiscal year of the Mid-term Business Plan, we aim to maximize the value of our products that are already on the market with initiatives including targeting growth of sustained-duration G-CSF product G-Lasta®. We expect tough-going in terms of business results due to factors that include the likelihood of lower net sales and earnings brought about by reductions in drug price standards, high levels of investment in late-stage development products, and

concentrated upfront investment largely involving expenses incurred in preparing for U.S. and European product launches. Nevertheless, we will persist with efforts going forward geared toward developing new drugs and nurturing other drugs.

Under the fourth pillar of our strategy, that of contributing to people's health and well-being, we are focusing on ensuring people's health through efforts that involve discovering innovative drugs that satisfy unmet medical needs, as well as expanding the scope of application of products and adding dosage forms. We will also ensure consistent supplies of high-quality products while taking action in response to societal demands for lower medical fees.

In our biosimilars business, which is a joint venture with FUJIFILM Corporation, we are making steady progress in clinical development with respect to top-quality pharmaceutical products that are highly cost-competitive in markets around the world. At the same time, we are also making steady progress with business partnerships encompassing our sales strategy, while going forward we intend to embark on preparations for application procedures in the U.S. and Europe.

In our diagnostics business, via Kyowa Medex Co., Ltd. we are providing advanced diagnostic products and instruments necessary for the treatment of various diseases, and are establishing a strong position in Japan while building a business base in overseas markets. We believe that diagnostics business will increasingly grow in importance going forward in line with further development with respect to individualized medicine and preventative medicine, thereby bringing about more new business opportunities for our diagnostics business in the healthcare field.

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. We will continue with efforts geared toward enhancing our cost competitiveness and create a business structure that is resistant to the impact of exchange rate volatility, while also supplying products of value besides just ingredients and substances, with respect to our customer enterprises and the health of their customers down the line, by branding, providing them with functionality data, and leveraging our intellectual property rights and others.

The Company will develop more socially reliable operational processes through efforts that include building a global governance framework and engendering awareness of compliance, with the aim of becoming a global specialty pharmaceutical group. We are promoting a Creating Shared Value (CSV) managerial approach where all those of the Kyowa Hakko Kirin Group act as members of the Kirin Group with respect to further contributing to the global community. To that end, we obviously act in compliance with amendments to Japan's Companies Act and Japan's Corporate Governance Code, while also encouraging initiatives regarding diversity and people's health in areas that include empowering women and ensuring mutual respect across cultures.

## Outlook for 2016

Consolidated financial earnings forecasts for fiscal 2016 (January 1, 2016 to December 31, 2016) are for net sales of ¥351.0 billion, a decrease of 3.7% compared to the current fiscal year, operating income of ¥30.0 billion, down 31.5%, ordinary income of ¥25.0 billion, down 36.2%, and profit attributable to owners of parent of ¥16.0 billion, a decrease of 46.3%.

In the Pharmaceuticals business, we anticipate increases in sales of new products such as G-Lasta®, a sustained-duration G-CSF product, Onglyza®, a treatment for type 2 diabetes, and NOURIAST®, an antiparkinsonian agent. Nevertheless, we forecast an overall downturn in sales year on year due to the likelihood that reductions in drug price standards slated for April 2016 will have a substantial negative impact on our financial performance. We also forecast a decrease in operating income given the likelihood of higher research and development expenses, expenses incurred in preparing for U.S. and European product launches, and others.

In the Bio-Chemicals business, despite our outlook for an increase in sales volumes of products that include core amino acids, nucleic acids and Ornithine, we forecast lower sales and profits due to factors such as a likely decrease in the volume of API sales.

Ordinary income and profit attributable to owners of parent are also forecast to decrease compared to the current fiscal year, due to the decrease of operating income.

## Profit Distribution

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

Our basic policy on profit distribution is to deliver stable dividends, while maintaining fully adequate internal reserves for business expansion and other developments, and considering factors such as our consolidated results 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, facilities, 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 2015 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 FY2016-2020 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 net income before amortization of goodwill. For the fiscal year ending December 2016, 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.

* 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, 2015).

# Risk Factors

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 expenditure. 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 ethical drug operations, 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 revenues from technology 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 from control on medical fees are high, 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.

# Risk Factors

### 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 changes 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 foreign 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 black outs and others events could result in suspension of business activities at our Group head quarters, factories, 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 risks

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) 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, suspension of supply of products and raw materials and information leaks.

# Investor Information

(As of December 31, 2015)

**Stock Listing**
Tokyo

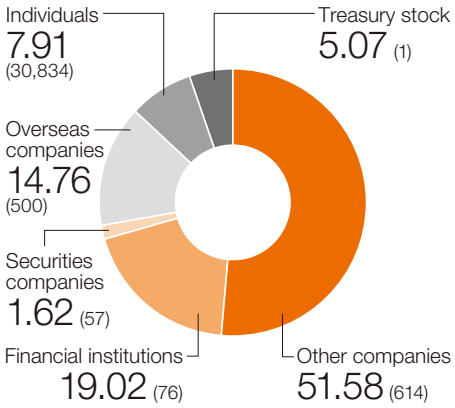
**Securities Code**
4151

**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**
32,082

**Shareholding by Type of Investor (Number)**

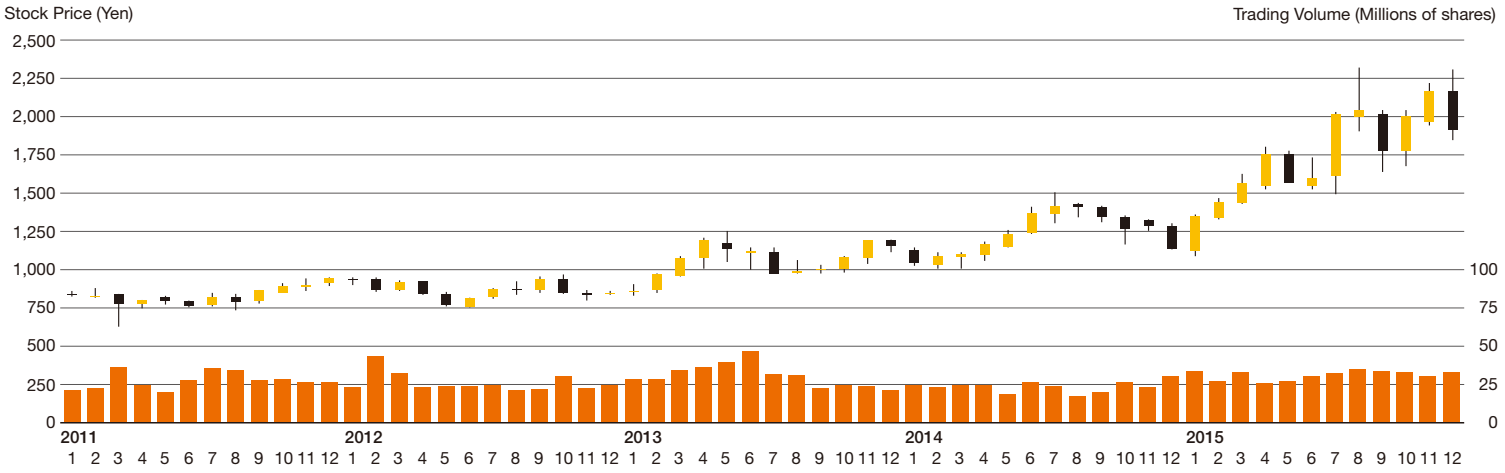



**Principal Shareholders**

| | 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) | 29,707 | 5.15 |
| Japan Trustee Services Bank, Ltd. (Trust Account) | 17,950 | 3.11 |
| The Norinchukin Bank | 10,706 | 1.86 |
| Mizuho Trust & Banking Co., Ltd. (Retirement Benefit Trust for Mizuho Bank, Ltd.)* | 6,809 | 1.18 |
| Nomura Trust and Banking Co., Ltd. (investment account) | 5,984 | 1.04 |
| State Street Bank West Client-Treaty 505234 (Standing Proxy: Mizuho, Ltd., Settlement & Clearing Services Division) | 5,352 | 0.93 |
| JPMorgan Chase Bank 385147 (Standing Proxy: Mizuho, Ltd., Settlement & Clearing Services Division) | 5,250 | 0.91 |
| State Street Bank and Trust Company 505223 (Standing proxy: Mizuho Bank, Ltd., Business Settlement Department) | 3,766 | 0.65 |
| Trust & Custody Services Bank, Ltd. (Securities Investment Trust Account) | 3,434 | 0.60 |

* 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.
※ The 29,256,749 shares (5.08%) held by the Company as treasury stock are excluded from the above because treasury stock has no voting rights.

**Stock Price and Trading Volume**



# Network

(As of December 31, 2015)

## Network*1

| Name of Company | Percentage Owned Directly or Indirectly by the Company | Capital*2 (Thousand) | 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 |
| Chiyoda Kaihatsu Co., Ltd. | 100.00% | ¥112,500 | Insurance, wholesale and retail |
| **America** | | | |
| Kyowa Hakko Kirin America, Inc. | 100.00% | US $76,300 | Holding company for administration and management of subsidiaries (U.S.A.) |
| BioWa, Inc. | 100.00% | US $10,000 | Out-licensing of antibody technology |
| Kyowa Hakko Kirin Pharma, Inc. | 100.00% | US $100 | Development of outsourced pharmaceutical products (U.S.A.) |
| Kyowa Hakko Kirin California, Inc. | 100.00% | US $100 | Contractor of generating new drug candidate substances etc. (U.S.A.)<br>Promotion of research alliance (U.S.A.) |
| ProStrakan Inc. | 100.00% | US $235 | Sales of pharmaceuticals (U.S.A.) |
| Archimedes Pharma US Inc. | 100.00% | US $1 | Licensing of pharmaceuticals (U.S.A.) |
| **Europe** | | | |
| ProStrakan Group plc | 100.00% | £13,848 | Supervision and management of special companies (U.K.) |
| Strakan International S.a r.l. | 100.00% | US $112,826 | Sales, licensing-in and licensing-out of pharmaceuticals (U.K.) |
| Strakan Pharmaceuticals Limited | 100.00% | £501 | Development of pharmaceuticals (U.K.) |
| ProStrakan Limited | 100.00% | £6,951 | Sales of pharmaceuticals (U.K.) |
| ProStrakan Pharma S.A.S | 100.00% | €1,139 | Sales of pharmaceuticals (France) |
| Kyowa Kirin Farmacéutica SLU | 100.00% | €216 | Sales of pharmaceuticals (Spain) |
| ProStrakan Pharma GmbH | 100.00% | €51 | Sales of pharmaceuticals (Germany) |
| ProStrakan Holdings B.V. | 100.00% | €105 | Holding company for special companies (Netherlands) |
| ProStrakan Pharma B.V. | 100.00% | €18 | Sales of pharmaceuticals (Netherlands) |
| ProStrakan S.r.l. | 100.00% | €10 | Sales of pharmaceuticals (Italy) |
| ProStrakan AB | 100.00% | SEK 200 | Sales of pharmaceuticals (Sweden) |
| Archimedes Pharma Limited | 100.00% | £542 | Supervision and management of special companies (U.K.) |
| Archimedes Development Limited | 100.00% | £113 | Sales and development of pharmaceuticals (U.K.) |
| Archimedes Holdings Limited | 100.00% | £10,501 | Holding company for special companies (U.K.) |
| Archimedes Pharma Europe Limited | 100.00% | £1,500 | Holding company for special companies (U.K.) |
| Archimedes Pharma UK Limited | 100.00% | £77 | Sales of pharmaceuticals (U.K.) |
| Archimedes Pharma Ibérica S.L. | 100.00% | €10 | Sales of pharmaceuticals (Spain) |
| Archimedes Pharma Ireland Limited | 100.00% | €0.1 | Sales of pharmaceuticals (Ireland) |
| **Asia** | | | |
| Kyowa Hakko Kirin China Pharmaceutical Co., Ltd. | 100.00% | US $29,800 | 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 $90,000 | 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 | Holding company for administration and management of US special companies (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% | US $18,900 | 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% | HK $1,200 | Sales of fine chemicals including amino acids (Hong Kong) |
| Kyowa Hakko Bio Singapore Pte. Ltd. | 100.00% | US $4,000 | Sales of fine chemicals including amino acids (Singapore) |

*1 All of the companies listed are consolidated subsidiaries except FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. and Centus Biotherapeutics Limited, which are equity-method affiliates.
*2 The unit for capital for all companies listed is thousands regardless of currency, except ProStrakan Inc., Archimedes Pharma US Inc. and Archimedes Development Limited.
※ The names of part of the Pharmaceuticals business subsidiaries have been changed as of February 2016.

# Corporate Data

## Corporate Data (As of December 31, 2015)

### Kyowa Hakko Kirin Co., Ltd.

**Head Office**
1-6-1, Otemachi, Chiyoda-ku, Tokyo
100-8185, Japan
* The head office has been transferred to new address as follows from July 2016.
1-9-2, Otemachi, Chiyoda-ku, Tokyo
100-0004, Japan
Tel: 81-3-5205-7200
Fax: 81-3-5205-7129
URL: http://www.kyowa-kirin.com/

**Number of Employees**
4,181 (Consolidated: 7,435)

**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.

### 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 Pharma, Inc. (U.S.A.)
Kyowa Hakko Kirin California, Inc. (U.S.A.)
ProStrakan Group plc (U.K.)
Kyowa Hakko Kirin China Pharmaceutical Co., Ltd.
Kyowa Hakko Kirin Korea Co., Ltd.
Kyowa Hakko Kirin (Singapore) Pte. Ltd.

* The names of part of the Pharmaceuticals business subsidiaries have been changed as of February 2016.

## Management Members (As of March 24, 2016)

### 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

**Yoichi Sato**
Vice President Head
R&D Division

Directors of the Board
**Akihiro Ito**

**Koichiro Nishikawa*2**

**Yoshiko Leibowitz*2**

*1 Concurrently serves as executive officer
*2 Outside director

### Company Auditors

Full-time Company Auditors
**Hiroaki Nagai*3**

**Nobuhisa Yamazaki**

**Akira Shimizu*3**

Company Auditors
**Motoyasu Ishihara**

**Kentaro Uryu*3**

*3 Outside company auditor

### Executive Officers

Managing Executive Officer
**Yutaka Ouchi**
Director
Human Resources Department

**Hiroshi Sugitani**
Vice President Head
Sales & Marketing Division

Executive Officers

**Shigeru Morotomi**
Director
Corporate Communications Department

**Masafumi Inoue**
Director
Nagoya Branch
Sales & Marketing Division

**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

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

**Takashi Oishi**
Director
Medical Affairs Department

**Satoshi Nakanishi, Ph.D.**
Director
CSR Management Department

**Niro Sakamoto**
Director
General Affairs Department

**Tamao Watanabe**
Director
Business Development Department

**Yutaka Osawa**
Vice President Head
Production Division

**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