

Kyowa Hakko Kirin Co., Ltd.



## About Annual Report 2014

#### **Editorial Policy**

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 2014 and part of 2015.

#### **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); Daiichi Fine Chemical Co., Ltd. (Daiichi Fine Chemical).

#### **Performance Forecasts**

Forecasts contained in Annual Report 2014 are assumptions based on reasonable judgments and information available at the time. Actual results could differ significantly due to a variety of factors.

#### **Numerical Data**

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

#### Cover

The cover presents images selected from the Company's "Commitment to Life Video Contest" held during 2014. Please refer to pages 9 and 10 for information about our "Commitment to Life."

A selection of videos will be available at the following website until the end of 2015.



http://www.kyowa-kirin.com/about\_us/ commitment\_to\_life/

#### Foreword

Kyowa Hakko Kirin has been publishing an integrated report since the year ended December 31, 2012. This report is designed to help readers understand Kyowa Hakko Kirin as a whole by selecting and combining key financial and non-financial data. We produced Annual Report 2014 with reference to the Integrated Reporting Framework issued in December 2013 by the International Integrated Reporting Council.

The 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." We bring smiles to all people who long for well-being through a sincere commitment to life that emphasizes cooperation with health care providers and continuously moving forward with life. Our "Commitment to Life," shared by all Group employees, is common to all of our activities.

In publishing Annual Report 2014, we reflected on the forms of capital that are most important to us and decided they are technology and human resources. We will maximize the deployment of these forms of capital, which are two of our strengths, and continue to provide new drugs to help address unmet medical needs worldwide, thus increasing our value to society.

Through this report, we hope that institutional investors and other stakeholders will take a long-term perspective and learn about our sustained growth and the strengths that help us create value.

April 2015 Shigeru Morotomi Executive Officer Director Corporate Communications Department Kyowa Hakko Kirin Co., Ltd.

## Inclusion in Socially Responsible Investment Indexes

Recognized by the global community for its management approach and active environmental efforts, Kyowa Hakko Kirin is included on the world's major socially responsible investment indexes, including the FTSE4Good and the MS-SRI (as of January 2015).



#### Websites

Our websites present activities and data that we could not include in Annual Report 2014.





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



#### Investors

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



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

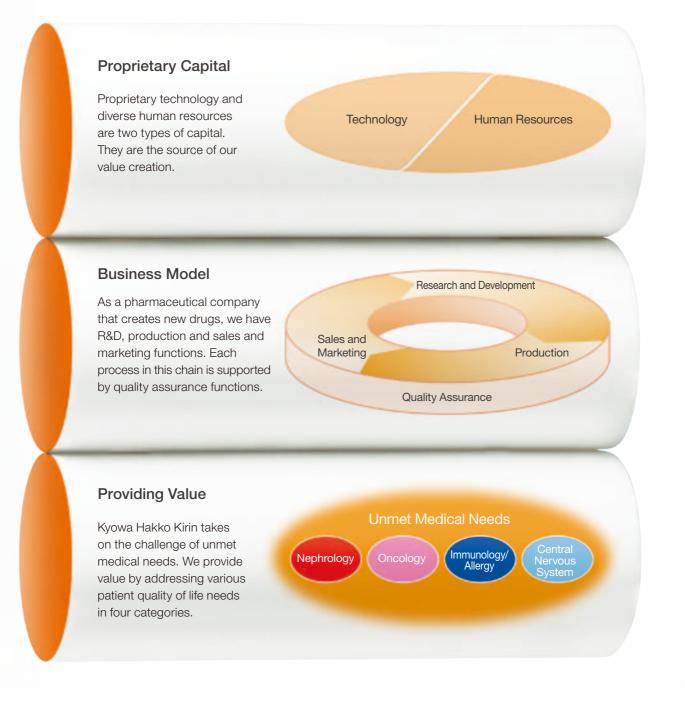
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### Kyowa Hakko Kirin's

All employees of the Kyowa Hakko Kirin Group share our "Commitment to Life" and the 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." Our biotechnology enhances the value we provide to address unmet medical needs and contributes to society.

# Value Creation Model



### **Providing New Value**

# A Unique Business Structure

The drug discovery business for ethical pharmaceuticals is at the core of the Kyowa Hakko Kirin Group. Our unique business structure that also 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 a Kyowa Hakko Kirin Group strength.

#### **Ethical Pharmaceuticals**

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 major player. 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 health care providers.

## Kyowa Hakko Kirin

## FUJIFILM KYOWA KIRIN BIOLOGICS

#### **Biosimilars**

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 biopharmaceutical manufacturing technologies with engineering technologies for manufacturing and quality control developed by FUJIFILM Corporation through its various businesses.

### Kyowa Medex

### Kyowa Hakko Bio

#### **Diagnostics**

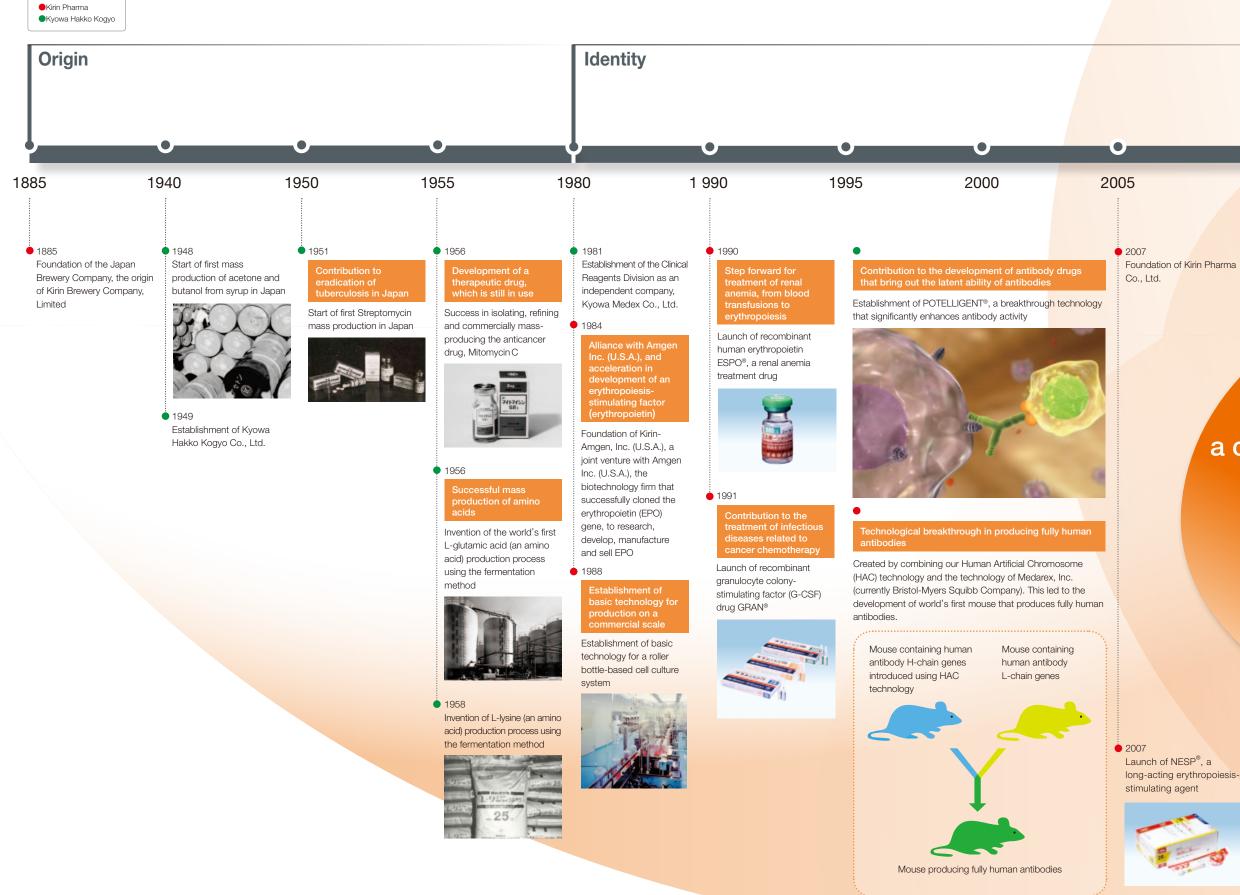
In cooperation with Kyowa Hakko Kirin's R&D operations, Kyowa Medex seeks to generate synergies with the pharmaceuticals business and enhance added value through the development and launch of *in vitro* diagnostic reagents, analyzers and companion diagnostics that contribute to personalized medicine.

#### **Bio-Chemicals**

Kyowa Hakko Bio supplies a range of products in Japan and overseas, including amino acids, nucleotides, vitamins, peptides and synthetic compounds. Using innovative fermentation and synthesis technologies, the company will continue to provide superior-quality, highvalue-added functional materials that satisfy needs in the pharmaceutical, medical and health care fields as it aims to become the world's premier bio-chemicals manufacturer.

## History of Kyowa Hakko Kirin: from fermentation technology to leading-edge biopharmaceuticals

Contributing to society with unique technologies, beginning with fermentation production technology



## Foundation of a company with a and strengths





## Future of Kyowa Hakko Kirin: global specialty pharmaceutical company

We aim to address unmet medical needs by maximizing the value of biotechnology.



## 2016

## Become a global specialty pharmaceutical company

Planned launch of three in-house products KW-0761, KW-6002 and KRN23 in Europe and the United **States** 

## **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.

KYOWA KIRIN Commitment to Life



## 自分たちを、自分たちが積み上げてきたものを信じよう。











Over 1,000 employees participated in the creation of our "Commitment to Life" when Kyowa Hakko Kirin was founded in 2008. It encapsulates our aspiration to face life with sincerity and continue to move ahead. In 2014, Kyowa Hakko Kirin held a video contest with the theme of our "Commitment to Life." Twenty three-minute videos were submitted. Scenes from the videos are presented here.

A selection of videos will be available at the following website until the end of 2015. http://www.kyowa-kirin.com/about\_us/commitment\_to\_life/











## 2014 Main Highlights

#### January

Launched renal anemia treatment NESP® Injection 5µg Plastic Syringe in Japan

#### February

Added new information covering pollinosis mechanisms and sublingual immunotherapy to the pollen information website, Pollinosis Navi

Received approval for additional dosage and administration indication for calcium receptor agonist REGPARA® Tablets 25mg and 75mg in Japan

#### March

Began construction of new research building IK8 at Fuji Research Park

Received approval for additional indication for anti-CCR4 humanized antibody POTELIGEO® for relapsed or refractory CCR4-positive peripheral T-cell lymphoma in Japan and cutaneous T-cell lymphoma in Japan

Started second season of web cartoon "New Antibody Story," which explains the mechanisms of antibodies and immunity

Kyowa Hakko Bio received 2014 JSBBA\* Award for Achievement in Technological Research for developing and commercializing dipeptide fermentation technology

\*JSBBA: Japan Society for Bioscience, Biotechnology, and Agrochemistry

#### April

Consolidated and reorganized the research and development divisions

Completed construction of the HA4 Plant, a biopharmaceutical API manufacturing facility, at the Takasaki Plant

Held the Kyowa Hakko Kirin Cup and fourth WASURENAI 3.11 *Kizuna* Four-Prefecture (Iwate, Miyagi, Ibaraki, Fukushima) Table Tennis Tournament. Set Guinness World Record® for most participants in a table tennis rally.

#### May

Launched a new formulation of Topina® (Topina® Fine Granules 10%), an antiepileptic agent in Japan

#### June

Received approval for additional indication of chronic pain for Fentos®, a transdermal longacting pain relief patch in Japan

#### July

Sakai Plant was awarded a Prime Minister's Commendation on Contributors to Public Safety

Concluded development alliance with AstraZeneca of the United Kingdom for cancer immunotherapy from the initial development phase

Signed domestic sales outsourcing agreement with Japan Blood Products Organization for recombinant human antithrombin preparation KW-3357

Kyowa Medex launched "A1c iGear K," glycated hemoglobin analysis equipment for diabetes testing in Japan

Submitted application for approval in Japan for recombinant human antithrombin preparation KW-3357

#### August

ProStrakan Group plc of the United Kingdom acquired Archimedes Pharma Limited of the United Kingdom

#### September

Launched Dovobet<sup>®</sup>, a treatment for psoriasis vulgaris in Japan

Concluded development alliance with Pfizer Inc. of the United States for cancer immunotherapy from the initial development phase

#### October

Initiated phase I trial for KHK6640 for Alzheimer's disease in Europe

Completed construction of the HA5 Plant, a drug product manufacturing facility, at the Takasaki Plant

#### November

Kyowa Hakko Bio launched renewal of the supplement "Fermented Coenzyme Q10 EX" in Japan

Added ITP Consultation Room, where medical specialists answer questions, to the ITP website

Launched sustained-duration G-CSF product G-Lasta® in Japan

#### December

Concluded development alliance with ONO PHARMACEUTICAL CO., LTD. of Japan and Bristol-Myers Squibb Company of the United States for cancer immunotherapy from the initial development phase

Received approval for additional indication of NESP® for anemia with myelodysplastic syndrome in Japan

Received approval for additional indication of the anti-CCR4 humanized antibody POTELIGEO® for chemotherapy-native CCR4-positive ATL in Japan

Concluded exclusive license agreement with Syndax Pharmaceuticals, Inc. of the United States to develop and commercialize Entinostat in Japan and Korea



#### Increasing Mogamulizumab's Value

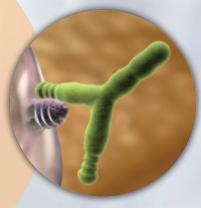
Kyowa Hakko Kirin is exploring the potential for using the anti-CCR4 humanized antibody Mogamulizumab, which uses our original POTELLIGENT® technology, for cancer immunotherapy. We therefore concluded development alliances with AstraZeneca of the United Kingdom in July 2014, with Pfizer Inc. of the United States in September 2014, and with ONO PHARMACEUTICAL CO., LTD. of Japan and Bristol-Myers Squibb Company of the United States covering combination therapy for solid tumors in December 2014.

Note: Please refer to "A Message from President and CEO Nobuo Hanai" on pages 17 and 18, and "Research and Development" on pages 27 and 28 for details.

•chimedes

PecFent

PHARMA



#### Acquisition of Archimedes Pharma Limited of the United Kingdom

U.K. subsidiary ProStrakan Group plc acquired privately held European company Archimedes Pharma Limited in August 2014. We expect ProStrakan Group plc to accelerate growth as a result of the acquisition of this specialty pharmaceutical company that serves the therapeutic areas of pain, oncology and critical care,\* supported by growth in sales of Archimedes Pharma's core product PecFent® and synergies among the products of the two companies.

\*Critical care: intensive treatment provided to patients in critical condition whose lives are at risk

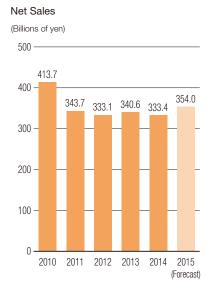
## **Financial and Non-Financial Highlights**

60

40

20

0



#### Operating Income/Operating Income Margin (Billions of yen)

52.9 51.7

15.9

2012

Operating Income (left scale)

15.2

2013

2014

41.5

11.7 10.8

0

2015

36.1

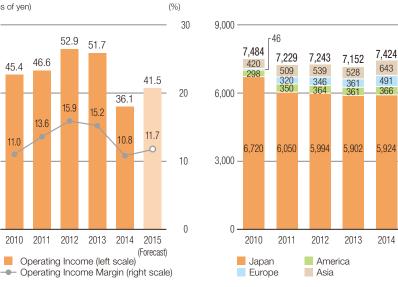
46.6

13.6

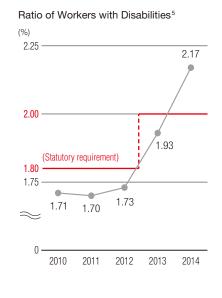
45.4

11.0

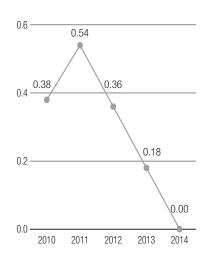
2010 2011 Number of Employees<sup>1</sup> (At year-end)



#### CO<sub>2</sub> Emissions<sup>2,3,4</sup> (1,000 tons) 400 356 354 335 331 314 92.7 94.7 300 88.6 86.2 71.0 32.8 29.3 31.5 29.1 33.9 200 161.0 164.2 169.2 156.2 165.1 100 49.3 56.5 61.0 64.7 0 2010 2011 2012 2013 2014 Kyowa Hakko Kirin (including Kyowa Medex) Kyowa Hakko Bio Daiichi Fine Chemical Overseas Bases



Accident Frequency Rate<sup>3,6,7</sup>



1. The figures for 2010 include Kyowa Hakko Chemical (currently KH Neochem Co., Ltd.).

- 2. The domestic plants and research laboratories of Kyowa Hakko Kirin, Kyowa Medex, Kyowa Hakko Bio and Daiichi Fine Chemical are covered. The overseas plants of Kyowa Hakko Kirin China Pharmaceutical Co., Ltd., BioKyowa Inc. (U.S.A.) and Shanghai Kyowa Amino Acid Co., Ltd. are also covered.
- 3. Data is for April to March 2010 to 2012, and January to December 2013 and 2014.
- 4. The figures for 2013 have been adjusted.
- 5. As of June each year. The figures for 2010 to 2013 are for Kyowa Hakko Kirin (non-consolidated). The figures for 2014 are for the Kyowa Hakko Kirin Group (domestic). The statutory requirement (domestic) was raised to 2.0% from April 1, 2013.
- 6. The number of fatal and lost time accidents per million working hours.

7. The domestic plants and research laboratories of Kyowa Hakko Kirin, Kyowa Medex, Kyowa Hakko Bio and Daiichi Fine Chemical are covered.

|   |          |          |          |          |          | %             | Thousands of<br>U.S. dollars <sup>8</sup> |
|---|----------|----------|----------|----------|----------|---------------|---|
|   | 2014     | 2013     | 2012     | 2011     | 2010     | 2014/2013     | <b>2014</b>                               |
| For the Year (Millions of yen):                                 |          |          |          |          |          |               |   |
| Net sales   | ¥333,446 | ¥340,611 | ¥333,158 | ¥343,722 | ¥413,738 | (2.1)%        | \$2,766,504                               |
| Sales by Region:  |          |          |          |          |          | . ,           |   |
| Japan   | 239,241  | 254,085  | 260,524  | 272,568  | 399,334  | (5.8)%        | 1,984,913                                 |
| America   | 21,695   | 23,948   | 21,207   | 20,071   | 23,467   | (9.4)%        | 180,004                                   |
| Europe  | 45,701   | 37,226   | 30,997   | 25,169   | 21,477   | 22.8 %        | 379,171                                   |
| Asia  | 25,886   | 24,420   | 19,880   | 25,426   | 39,689   | 6.0 %         | 214,772                                   |
| Other Regions   | 921      | 931      | 548      | 486      | 507      | (1.1)%        | 7,641                                     |
| Operating income  | 36,173   | 51,773   | 52,905   | 46,614   | 45,410   | (30.1)%       | 300,116                                   |
| Net income  | 15,898   | 30,078   | 24,199   | 25,608   | 22,197   | (47.1)%       | 131,902                                   |
| Capital expenditures (including intangible fixed assets)        | 29,487   | 35,183   | 27,808   | 19,697   | 29,374   | (16.2)%       | 244,648                                   |
| Depreciation and amortization                                   | 23,885   | 21,592   | 20,904   | 22,833   | 22,188   | 10.6 %        | 198,170                                   |
| R&D expenses  | 47,737   | 43,682   | 44,808   | 47,961   | 44,210   | 9.3 %         | 396,066                                   |
| At Year-End (Millions of yen):                                  |          |          |          |          |          |               |   |
| Total assets  | ¥719,135 | ¥719,257 | ¥679,342 | ¥658,873 | ¥695,862 | (0.0)%        | \$5,966,442                               |
| Interest-bearing debt   | 4,868    | 6,207    | 5,699    | 6,042    | 7,515    | (21.6)%       | 40,391                                    |
| Total net assets  | 605,368  | 595,415  | 555,898  | 540,023  | 544,992  | 1.7 %         | 5,022,556                                 |
| Total shareholders' equity                                      | 580,499  | 578,329  | 560,663  | 554,856  | 553,172  | 0.4 %         | 4,816,222                                 |
|   |          |          |          |          |          | %             | U.S. dollars <sup>8</sup>                 |
| Per Share Data (Yen):   |          |          |          |          |          | 70            | 0.0. 001113                               |
| Net income-basic <sup>9</sup>                                   | ¥ 29.05  | ¥ 54.95  | ¥ 44.12  | ¥45.16   | ¥38.96   | (47.1)%       | \$0.241                                   |
| Net assets  | 1,105.4  | 1,085.2  | 1,013.6  | 970.2    | 954.6    | 1.9 %         | 9.171                                     |
| Cash dividends  | 25       | 25       | 20       | 20       | 20       | 0.0 %         | 0.207                                     |
| Financial Ratios (%):   |          |          |          |          |          |               |   |
| Return on assets (ROA)  | 2.21     | 4.30     | 3.62     | 3.78     | 3.19     | (2.09) points |   |
| Return on equity (ROE)  | 2.65     | 5.24     | 4.43     | 4.73     | 4.11     | (2.59) points |   |
| Number of Employees:  |          |          |          |          |          |               |   |
| Total   | 7,424    | 7,152    | 7,243    | 7,229    | 7,484    | 3.8 %         |   |
| Japan   | 5,924    | 5,902    | 5,994    | 6,050    | 6,720    | 0.4 %         |   |
| America   | 366      | 361      | 364      | 350      | 298      | 1.4 %         |   |
| Europe  | 491      | 361      | 346      | 320      | 46       | 36.0 %        |   |
| Asia  | 643      | 528      | 539      | 509      | 420      | 21.8 %        |   |
| CO <sub>2</sub> Emissions <sup>2,3,4</sup> (1,000 tons):        |          |          |          |          |          |               |   |
| Total   | 354      | 356      | 335      | 314      | 331      | (0.6)%        |   |
| Kyowa Hakko Kirin (including Kyowa Medex)                       | 64.7     | 61.0     | 56.5     | 49.3     | 52.2     | 6.1 %         |   |
| Kyowa Hakko Bio   | 165.1    | 169.2    | 156.2    | 164.2    | 161.0    | (2.4)%        |   |
| Daiichi Fine Chemical   | 29.3     | 32.8     | 33.9     | 29.1     | 31.5     | (10.7)%       |   |
| Overseas bases  | 94.7     | 92.7     | 88.6     | 71.0     | 86.2     | 2.2 %         |   |
| Energy Consumption <sup>2,3</sup> (1,000 kl of oil equivalent): |          |          |          |          | . – .    |               |   |
| Total   | 148      | 148      | 144      | 142      | 151      | 0.0 %         |   |
| Kyowa Hakko Kirin (including Kyowa Medex)                       | 31.0     | 29.6     | 29.4     | 28.9     | 30.2     | 4.7 %         |   |
| Kyowa Hakko Bio   | 67.9     | 68.7     | 65.9     | 66.9     | 68.7     | (1.2)%        |   |
| Daiichi Fine Chemical   | 11.3     | 12.3     | 12.9     | 12.5     | 13.7     | (8.1)%        |   |
| Overseas bases  | 37.9     | 36.9     | 35.9     | 33.5     | 38.0     | 2.7 %         |   |
| Ratio of workers with disabilities <sup>5</sup>                 | 2.17     | 1.93     | 1.73     | 1.70     | 1.71     | 0.24 points   |   |
| Accident frequency rate <sup>3,6,7</sup>                        | 0.00     | 0.18     | 0.36     | 0.54     | 0.38     | (0.18) points |   |

8. U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥120.53=U.S.\$1, the approximate exchange rate at December 31, 2014.

9. 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.

## A Message from President and CEO Nobuo Hanai



We will fully leverage our unique biotechnology strengths to become a global specialty pharmaceutical company.

Strength in biotechnology defines the Kyowa Hakko Kirin Group. Our most important mission is to contribute to the health and well-being of people around the world by addressing an array of unmet medical needs using biotechnology. As we fulfill this mission, we intend to further enhance technology and human resources to generate sustained growth for the Group in global markets.

hobro Hanav

President and CEO



#### Biotechnology is our greatest strength.

Biopharmaceuticals can provide opportunities to treat diseases for which conventional small molecule pharmaceuticals have been ineffective, and the market for these biopharmaceuticals has been expanding worldwide over the past several years. Moreover, entry barriers are extremely high in this market because of the need for unconventional, advanced technology and experience. Using biotechnology to deliver biopharmaceuticals to patients requires a platform that integrates research aspects from initial discovery research to development research, and process research that creates production lines while assuring quality. We are an R&D-driven pharmaceutical company that is able to provide patients with new drugs by bringing together our technology and this unique platform. Our greatest strength is biotechnology; it is the source of drug discovery that drives sustained growth.

Newly developed KW-0761 (product name in Japan: POTELIGEO<sup>®</sup>) is a strategic product for our growth as a global specialty pharmaceutical company. It validates the increasing sophistication of the comprehensive capabilities supporting our biotechnology.

KW-0761 is a therapeutic antibody drug we created using POTELLIGENT<sup>®</sup>, an antibody-enhancing biotechnology unique to Kyowa Hakko Kirin. We are developing this

#### Glossary

#### Biopharmaceuticals

Pharmaceuticals that, through the use of complex proteins and other biomolecules, deliver pharmacological effects that cannot be achieved with chemical synthesis. They hold the promise of high efficacy with few side effects.

#### Small molecule pharmaceuticals

Conventional pharmaceuticals manufactured by chemically synthesizing molecules with relatively small molecular weight.

Antibody-enhancing biotechnology POTELLIGENT® See page 28 for details.

# Leading the way forward with our biotechnology

#### Glossary

#### Therapeutic antibody

A biopharmaceutical composed mainly of the antibodies that are central to the human immune system. These therapies employ the unique ability of specific antibodies to recognize only specific antigen targets.

#### CCR4

Chemokine (C-C motif) receptor 4

#### Adult T-cell leukemia-lymphoma (ATL)

HTLV1 (retrovirus)-induced peripheral T-cell lymphoma, Approximately 1,150 cases\* are estimated in Japan each year. It is generally treated with mLSG15 therapy and other types of combination chemotherapy. Transplantation is the only therapy available with the potential to cure this disease, and is currently the object of active investigation. For recurrent/relapsed ATL, different types of chemotherapies are performed based on the treatment of malignant lymphoma, but no effective treatment has been established. \* Source: Survey of and countermeasures to HTLV-1 infection and related diseases in Japan; 2010 summary research report by Kazunari Yamaguchi.

#### Solid tumors

Tumor mass composed of tumor cells, tumor blood vessels, and interstitium. Refers to hematopoietic tumors such as leukemia.

#### Unmet medical needs

Medical requirements that remain unfulfilled. The desire for breakthrough new drugs is urgent in representative areas such as cancer and Alzheimer's disease where treatment is unsatisfactory or unavailable. drug globally for hematological cancers, and launched it in Japan in May 2012 for relapsed or refractory CCR4-positive adult T-cell leukemialymphoma (ATL). In March 2014, we received approval in Japan for the additional indications of relapsed or refractory CCR4-positive peripheral T-cell lymphoma and CCR4-positive cutaneous T-cell lymphoma, and also received approval in Japan in December 2014 for the additional indication of chemotherapy-naive CCR4-positive adult T-cell leukemia-lymphoma.

Leading-edge research is particularly important for sustaining our strength in biotechnology. Apart from KW-0761, we have several antibody drugs in development that are the result of our leading-edge research and are now positioned to generate growth. The scientific acumen and vision

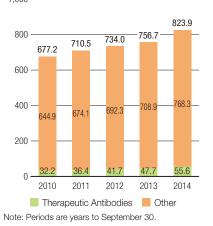
of our scientists, married to a corporate culture that values them, are central to our success in the future.

Building on newly reported data indicating that KW-0761 is efficacious against solid tumors, we concluded development alliance agreements with AstraZeneca of the United Kingdom in July 2014, with Pfizer Inc. of the United States in September 2014, and with ONO PHARMACEUTICAL CO., LTD. of Japan and Bristol-Myers Squibb Company of the United States in December 2014. These agreements involve collaborative studies of the possible efficacy of KW-0761 as an immunotherapy, which is a new class of cancer treatment designed to harness the body's own immune system in fighting cancer cells.

KW-0761 suppresses the regulatory T-cells that shield tumors from the immune system. The four companies we concluded development alliances with are taking a range of approaches in developing drugs that enhance the immune system's ability to attack cancer cells. We believe that combining KW-0761 with drugs these companies are developing will generate oncology treatment synergies that create new treatment options for patients and have the potential to address unmet medical needs.







Source: Copyright IMS Health based on MIDAS 2014 Q3 Data





Source: Copyright IMS Health based on MIDAS 2014 Q3 Data

### With the collective strength of our people underpinned by our mission of "Commitment to Life," we are striving to become a global specialty pharmaceutical company.

Kyowa Hakko Kirin was created from Kyowa Hakko Kogyo and Kirin Pharma, both of which had a background in biotechnology. The former was the first in the world to mass produce amino acids using the fermentation method in 1956, while the latter started by launching the erythropoiesis stimulating agent ESPO<sup>®</sup> in 1990. Both companies have subsequently overcome numerous challenges to develop an array of leading technologies. Today, we are committed to a management philosophy that values the capabilities of our people and our technologies, which are our core strengths.

Kyowa Hakko Kirin has various businesses and operations, but our "Commitment to Life" always serves as the common point of reference as we consider the approaches we should take while aiming to realize our management philosophy. Our employees are involved in the various stages of our value chain, from R&D to production, sales and marketing and quality assurance, and with "Commitment to Life" at the core they work to achieve our common goals. This shared understanding will enable us to make progress as we turn our attention to the world. I am very confident that the people at our Group operations around the world can be proud of their work on behalf of life as they engage in their

While focusing our energies on our shared ideas, we are also concentrating on promoting diversity. Our objective is to link diversity to innovation and harness it as a strength that enables even more meaningful global business development synergies. Moreover, we want to enhance our ability to respond to the changing business environment, and continue to meet the expectations and demands of society.

respective day-to-day responsibilities.

#### Glossary

#### Erythropoietin

A hormone that promotes erythrocyte production. It has a molecular weight of approximately 34,000 and consists of 165 amino acids.

Harnessing the collective strength of our people to become a global specialty pharmaceutical company





#### Glossary

#### Febrile neutropenia

Neutropenia caused by chemotherapy that is accompanied by fever. It is suspected to involve some type of infection, and complications may become severe if not immediately treated properly.

#### Psoriasis vulgaris

A skin disease characterized by raised red patches of skin covered by a thick layer of dry, dead skin cells called plaque. This plaque then falls off as ragged scales. About 90 percent\* of cases of psoriasis are psoriasis vulgaris. \* Source: Japanese Dermatological Association website (As of February 2015)

#### Myelodysplastic syndrome

A class of diseases characterized by a decrease in blood cells and the onset of acute myelocytic leukemia due to abnormalities in the pluripotent hematopoietic stem cells in bone marrow. Approximately 11,000 cases\* have been reported in Japan. Main clinical symptoms are anemia resulting from cytopenia, infection and bleeding. \* Source: Japan Intractable Diseases Information Center website (As of February 2015)

#### Adherence

Refers to active patient participation in formulating and following the treatment plan.

#### Category-based strategy

Strategy in which each category has its own portfolio management from R&D through to sales and marketing with the goal of achieving sustained growth while striving to improve productivity. The category-based strategy applies to the following four disease areas: nephrology, oncology, immunology/allergy and the central nervous system. In terms of the expectations and demands of society, in May 2014 inappropriate participation by Kyowa Hakko Kirin employees in clinical research led by doctors came to light. As president and CEO, I would like to deeply apologize for this compliance breach.

I immediately established an external committee of experts and commissioned an investigation of the facts and wrong-doing. I have received proposals for preventing recurrence and regaining trust from the committee (http://www.kyowa-kirin.co.jp/ report/20140711.pdf); (Japanese only). Based on issues the report uncovered regarding established internal rules, we are now steadily moving toward a resolution that involves both organizational and personnel reforms and improved employee awareness.\*

Today, modern society is scrutinizing more closely the relationship between pharmaceutical companies and health care providers and it is imperative that we come to grips with the compliance breach and prevent recurrence. The entire company is working in concert to further improve employee capabilities backed by a strong sense of ethics as we become a new Kyowa Hakko Kirin.

\*Please refer to "Compliance" on page 55 for details.

#### We contribute to addressing unmet medical needs through biotechnology.

In 2014, we successfully launched in Japan two new products to address unmet medical needs. One was sustained-duration G-CSF product G-Lasta® for decreasing the incidence of chemotherapy-induced febrile neutropenia, while the other was Dovobet®, a treatment for psoriasis vulgaris.

Moreover, we advanced KW-0761 to a new global stage, moved numerous new drugs into clinical trials, and submitted applications for additional indications of existing products. Sales of NESP<sup>®</sup>, a core biopharmaceutical for treatment of renal anemia, remained strong, and in December 2014 we received approval in Japan for the additional indication of anemia with myelodysplastic syndrome.

In 2015, our category-based strategy will remain central to discovering new drugs and expanding the application of existing products. At the same time, we will emphasize greater market penetration for G-Lasta<sup>®</sup> and Dovobet<sup>®</sup>. The overseas sales ratio in the

#### New Products Launched in 2014

G-Lasta®

G-Lasta® is a sustained-duration form of G-CSF product GRAN® for the treatment of chemotherapy-induced febrile neutropenia. G-CSF products thus far have required repeat dosing over consecutive days. However, a single dose of G-Lasta® per chemotherapy cycle is sufficient, and provides outstanding convenience for treatment. In particular, this is expected to lighten patient dosing burden and reduce visits for outpatient chemotherapy.

Dovobet<sup>®</sup>

Dovobet<sup>®</sup> is the first topical combination drug in Japan for psoriasis vulgaris that combines active vitamin D<sub>3</sub> and a corticosteroid, which are common treatments. Dovobet<sup>®</sup> achieves the chemically stable combination and complementary action of its ingredients, thus rapidly improving the skin symptoms of psoriasis and providing convenient once-daily application that contributes to increased patient adherence.

Pharmaceuticals business is currently 23 percent, but we expect to live up to our ambition as a global specialty pharmaceutical company in terms of quantitative results by raising this ratio even further during the period of the next medium-term business plan starting in 2016.

We want to be a Japan-based global specialty pharmaceutical company that contributes to the health and well-being of people around the world. We will fully leverage our biotechnology specialization and its growth potential to create drugs that address unmet medical needs, whether by treating diseases so people can live their lives normally or extending healthy lifespans.

I will continue to identify essential themes driving

he hly that e

scientific progress to help nurture ideas for new drugs. My rationale is that the managers of an R&D-driven company must have a deep understanding of and passion for science. "Commitment to Life" guides my determination to provide the leadership as president and CEO of the Kyowa Hakko Kirin Group that allows all employees to demonstrate capabilities befitting a global specialty pharmaceutical company with an open corporate culture, and to pursue individual and organizational growth.

# Biotechnology is taking us to a new global level

#### Road Map to Becoming a Global Specialty Pharmaceutical Company (GSP)

2016-2013-2015 2010-2012 2008-2009 STEP 4 STEP 3 Realize our Strive toward **GSP model** GSP Maximize value of Launch three products\* Integrated Divested Chemicals two business in Japan originated from KHK in companies business **U.S.A./Europe**  Promote \*KW-0761/KW-6002/KRN23 Transferred Acquired development in ProStrakan Food business U.S.A./Europe Make progress in global Entered **Biosimilars business** Biosimilars Improve revenue & business profitability of Expand worldwide Reorganized **Bio-Chemicals Bio-Chemicals business** production sites business Transferred alcohol & livestock related businesses

#### Glossary

#### Healthy lifespan

Period during which people can enjoy their daily lives without health problems.

### An Interview with the CFO



Aggressive investment to become a global specialty pharmaceutical company will create shareholder value.

> Kazuyoshi Tachibana Director of the Board Managing Executive Officer

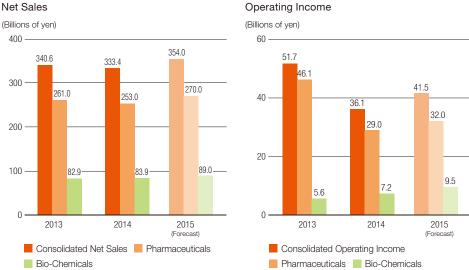
#### Q. 1 What are the key highlights of 2014?

In the Pharmaceuticals business, we successfully launched sustained-duration G-CSF product G-Lasta® and psoriasis vulgaris treatment Dovobet®. We also moved forward with joint development in Europe and the United States of KW-0761, which is gaining attention globally for cancer immunotherapy, and strengthened our business in Europe with the acquisition of Archimedes Pharma Limited of the United Kingdom. These initiatives represent steady progress toward achieving our goals as a global specialty pharmaceutical company.

Solid progress in the Bio-Chemicals business included the reorganization of the Yamaguchi Production Center and the construction of a new plant in Thailand. The depreciation of the yen is supporting improved profit margins, and in terms of the overall Group business portfolio we are taking full advantage of management synergies with the Pharmaceuticals business.

#### Q. 2 Please discuss results for 2014.

Earnings in the Pharmaceuticals business decreased year on year due to the impact of drug price revisions and an increase in R&D costs. Earnings in the Bio-Chemicals business increased significantly year on year despite flat sales because of a growth in APIs, steady performance in the core amino acids business and the effect of the weaker yen. For the year ended December 31, 2014, net sales were ¥333.4 billion, operating income was ¥36.1



Note: The figures for consolidated net sales and operating income are after elimination of intersegment transactions.

billion and net income was ¥15.8 billion.

We forecast that in 2015 net sales will increase 6.2 percent year on year to ¥354.0 billion, operating income will increase 14.7 percent to ¥41.5 billion, and net income will increase 16.4 percent to ¥18.5 billion.

Regarding our balance sheet, we benefited from increased asset efficiency as investment in the introduction of new drugs and mergers and acquisitions increased intangible assets and reduced cash reserves. Conversely, inventory increased as we hedged stock-out risk resulting from the reorganization of production operations. Once the new production organization is on track, however, inventory will decrease.

My personal assessment is that shifting our balance sheet to a pharmaceutical industry that is focused on intellectual property rather than industrial processes is a major step toward becoming a global specialty pharmaceutical company.

## Q. 3 Please discuss Kyowa Hakko Kirin's financial strategy and shareholder return policy.

We are currently using a global cash management system for the yen, the U.S. dollar, the pound and the euro, with Groupwide capital management reducing foreign exchange risk and enhancing capital management efficiency. Our next move is to extend this system to other Asian currencies. Additionally, in 2014 we established a new tax team in the Accounting Division. We intend to develop a global tax strategy that includes subsidiaries in Japan and overseas.

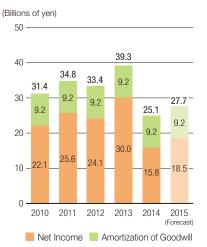
Under our medium-term business plan, our objective for shareholder returns is stable dividends with a target payout ratio of 40 percent of net income before amortization of goodwill.\* Dividends for 2014 were unchanged from the previous year at ¥25.00 per share, for a payout ratio (based on net income before amortization of goodwill) of 54.4 percent. \*Please refer to "Net income before amortization of goodwill" in the glossary.

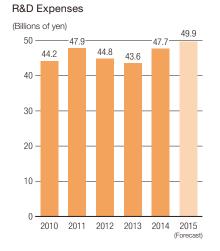
#### Q. 4 Please close with a comment for investors.

We have made various investments to date, and are now making investments that are fundamental to our growth strategy. In the Pharmaceuticals business, we plan to make investments encompassing development to obtain approvals in Europe and the United States, M&A to strengthen overseas businesses, and new drug introductions that support our category strategy. In the Bio-Chemicals business, we will invest in enhancing production capacity mainly in our amino acids business, and in development and production to reduce costs.

We have been nurturing KW-0761 and other drugs that will support shareholder value over the medium and long term. Confident that we will certainly be able to meet shareholder expectations, I am fully committed to investment decisions that prioritize pharmaceutical pipeline expansion.

#### Net Income/Net Income before Amortization of Goodwill\*





#### Note: Net income before amortization of goodwill = Net income + Amortization of goodwill \*Please refer to the glossary.

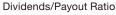
#### Glossary

#### Intangible assets

Assets without physical form such as patents, trademarks and expertise. Kyowa Hakko Kirin recognizes intangible assets acquired through investments in new drug introductions and M&A in sales rights and goodwill. (Please refer to the consolidated balance sheets on page 67 for data on sales rights and goodwill.)

## Net income before amortization of goodwill

"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).





#### Glossary

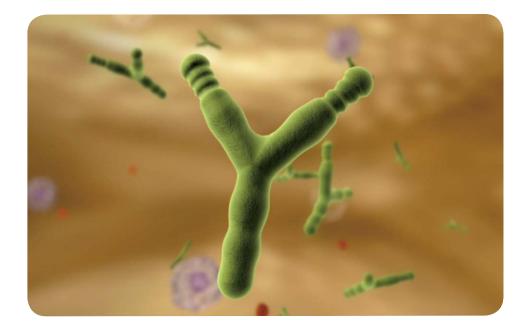
Product portfolio management (PPM) Strategy for appropriately allocating financial and human resources to R&D and sales; pinpointing the target patient segment for drug discovery research and setting quantitative targets; and in-licensing, out-licensing and partnering.

#### One Drug Development Organization (ODDO)

An organization that integrates the management of overseas bases to develop drugs.

#### Three in-house products

KW-0761 (anti-CCR4 humanized antibody); KW-6002 (adenosine A<sub>2A</sub> receptor antagonist); KRN23 (anti-FGF23 fully human antibody)



#### **Priorities**

The Pharmaceuticals business is taking on the challenge of becoming a global specialty pharmaceutical company (GSP) during the three years from 2013 through 2015. Our three core strategies are: (1) further strengthen competitiveness in Japan through our category-based strategy; (2) expand our business outside Japan, and aim to become a GSP; (3) create a corporate culture and organization appropriate for a GSP through reform and functional improvements.

We are promoting our category-based strategy, which revolves around enhancing coordination among our functions and PPM, and further strengthening the foundation of our business in Japan by accelerating drug discovery and increasing the value of the products we develop. In Europe and the United States, we are accelerating the speed of global development through our ODDO, while in Asia our subsidiaries are building the business foundation for responding flexibly to the intense changes in each country. We are also creating a worldclass system for earning trust and engendering awareness of compliance, both of which are requirements of a GSP.

Our key priority is the three in-house products we plan to launch from 2016 onward. We are steadily implementing the initiatives to do so.

#### Challenges

The Pharmaceuticals business sees 2016 onward as the time to make rapid progress in becoming a GSP. The launch of these three in-house products is just the start line, and we are fully committed to maximizing the value of these products. We also aim to generate sustained growth and maximize our corporate value as a GSP by continuously and globally launching new drugs following these three in-house products.

Moreover, we are implementing our category-based strategy to address unmet medical needs with a sense of urgency while further promoting collaboration through means including open innovation with a diverse array of business partners in Japan and overseas, and partnering. We are therefore transforming our corporate culture so that it can adapt to changes in the business environment in this age of diversity and global networks.

We are contributing to the health and well-being of people around the world by leveraging biotechnology, remaining committed to the unchanging values all employees share such as our corporate philosophy and "Commitment to Life," and constantly undertaking self-reform.

#### **Market Environment**

The operating environment of the Pharmaceuticals business remains challenging due to factors including decreasing drug discovery success rates, more stringent approval review processes and measures to reduce health care costs. The generic market is increasing steadily as growth slows in Japan's pharmaceutical market, necessitating a shift from dependence on long-selling listed products to new drugs, and from a domestic to a global focus.

The global pharmaceutical market continues to expand, primarily in emerging countries. The markets of advanced countries account for a large share of the global pharmaceutical market, but their growth is slowing. Moreover, generic drugs are driving growth in the global market, while the sale of new drugs is slowing. In this market environment, sales of biopharmaceuticals are increasing rapidly, primarily in the core Kyowa Hakko Kirin competency of therapeutic antibodies. In 2013, seven of the top ten global pharmaceuticals in terms of sales were

#### biopharmaceuticals (see below). The market of the future will be characterized by patent expirations and the shift to generic drug use among the many patients in the primary care market. Kyowa Hakko Kirin therefore intends to focus new drug development in specialty markets with pronounced unmet medical needs.

#### Top Ten Pharmaceuticals in Terms of Net Sales (2013) (Millions of U.S. dollars)

| Brand name (Company) |   | Main efficacy        | Sales     |
|----------------------|---|----------------------|-----------|
| 1.                   | Humira (AbbVie)                                 | Rheumatoid arthritis | 10,659    |
| 2.                   | Advair<br>(GlaxoSmithKline)                     | Asthma               | 8,244     |
| 3.                   | Lantus (Sanofi)                                 | Diabetes             | 7,588     |
| 4.                   | Rituxan (Roche)                                 | Cancer               | 7,499     |
| 5.                   | Avastin (Roche)                                 | Cancer               | 6,747     |
| 6.                   | Remicade (Janssen)                              | Rheumatoid arthritis | 6,673     |
| 7.                   | Herceptin (Roche)                               | Cancer               | 6,558     |
| 8.                   | Neulasta (Amgen)                                | Neutropenia          | 5,790     |
| 9.                   | Abilify (Otsuka<br>Pharmaceutical)              | Psychosis            | 5,744     |
| 10.                  | Crestor (AstraZeneca)                           | Hyperlipidemia       | 5,622     |
| Sou                  | rce: <i>Monthly MIX</i> 2014<br>Special Edition | Biopharm             | aceutical |

#### **Review of Operations**

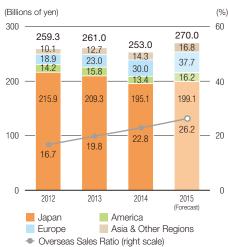
In the Pharmaceuticals segment, sales and earnings decreased due to the impact of National Health Insurance (NHI) drug price revisions in April 2014. Net sales decreased 3.1 percent year on year to ¥253.0 billion. Segment income decreased 37.1 percent to ¥29.0 billion.

We launched Dovobet<sup>®</sup>, a psoriasis vulgaris product in-licensed from LEO Pharma A/S of Denmark, in September 2014, and sustained-duration G-CSF product G-Lasta<sup>®</sup> in November 2014 to further strengthen business in Japan.

At ProStrakan Group plc of the U.K., growth of Abstral<sup>®</sup> and other core products supported 34.6 percent growth in net sales to ¥31.3 billion. Operating loss (post amortization of goodwill and sales rights) was ¥20 million. In addition, ProStrakan Group plc strengthened its European sales organization in August 2014 by acquiring Archimedes Pharma Limited of the U.K., which is strong in the therapeutic areas of pain, oncology and critical care. We also concluded development alliance agreements with four companies for KW-0761 (Mogamulizumab) with the goal of investigating its potential in cancer immunotherapy.\*

\* Please refer to "A Message from President and CEO Nobuo Hanai" on page 17 and "Research and Development" on page 27 for details.

#### Net Sales by Region



## Pharmaceuticals business net sales



Share of Pharmaceuticals business in net sales

75.1%

Pharmaceuticals business segment income\*

¥29.0 billion

\*Including intersegment transactions

Share of biopharmaceuticals in Pharmaceuticals business net sales

33.2%

#### Glossary

#### Open innovation

The creation of new value (products, technologies and services) through the combination of internal and external knowledge and technologies.

#### Translational research

Research on drug seeds, which are obtained from basic and discovery research, to enable forecasts for clinical results through collaboration with external medical research institutes.

#### Product lifecycle management

Process of increasing the value of drugs after their launch through means such as enhancing efficacy and safety, improving usage and expanding indications based on information acquired through actual treatment to support improved patient treatment.

#### Priorities

The R&D Division is strengthening its global network for both research and development. At the research stage, we use open innovation for the discovery of drug seeds and raise the efficiency of non-clinical research through translational research to improve clinical predictability. At the development stage, we are conducting multinational clinical trials in Europe, the United States and Asia, for which collaboration with overseas subsidiaries is essential. In alignment with our category strategy, we consolidated, reorganized and created a new organization on April 1, 2014, to coherently work on R&D and product lifecycle management (please refer to the R&D Division Organization chart on page 26). The collaboration of category-based R&D with disciplined core function members and external/internal parties enables us to work rigorously to meet the needs of actual medical practice. The new organization also enhances acceleration and improvement in success rates of R&D.

As a foundation to support these initiatives, we strengthen the management of intellectual property and emphasize ethical considerations relevant to R&D from an objective viewpoint.

#### Challenges

The next medium-term business plan we will initiate in 2016 targets regulatory approval and expanded sales in Europe and the United States of three in-house products: KW-0761, KW-6002 and KRN23. We will further unify our operations in Japan, the United States, Europe and Asia. By establishing a harmonious development organization, we expect to promote swift and efficient development of subsequent development candidates.

At the same time, we will focus on effectively enhancing our early-stage pipeline. We will leverage the strengths of our new organization to continuously address unmet medical needs and link them to drug discovery research. We will also continue to take on the challenge of drug discovery innovation for medical needs. In taking on the challenge of developing new technology, we will complement internal resources by proactively combining external ideas through open innovation.

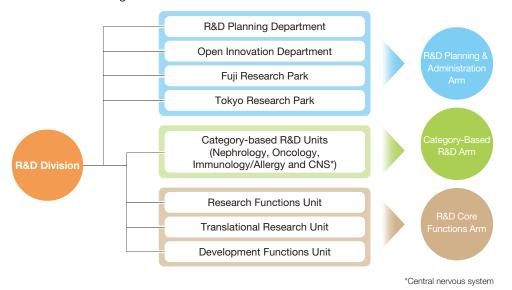
Going forward, we will use leading-edge biotechnology centered on our unique antibody technology to continuously discover and deliver breakthrough drugs that patients truly require as quickly as possible.

#### Organization



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

#### R&D Division Organization



#### Status of Main Development for New Drugs

#### Japan

- Initiated late-stage phase II clinical trial of calcium-sensing receptor agonist KHK7580 for secondary hyperparathyroidism (August)
- Planning to restart a phase II clinical trial of RTA 402 for chronic kidney disease (CKD) patients with type 2 diabetes

#### China

Nephrology

 Calcium-sensing receptor agonist KRN1493 (product name in Japan: REGPARA®) was approved for secondary hyperparathyroidism (June)

#### Japan

- POTELIGEO<sup>®</sup> was approved for relapsed or refractory CCR4-positive peripheral T-cell lymphoma and cutaneous T-cell lymphoma (March); and for untreated CCR4-positive adult T-cell leukemialymphoma (ATL) (December) as additional indications
- G-Lasta<sup>®</sup> was approved for chemotherapy-induced febrile neutropenia (September) and launched (November)
- NESP<sup>®</sup> was approved for anemia with myelodysplastic syndrome as an additional indication (December)
- Fentos<sup>®</sup>, a transdermal long-acting pain relief patch, was approved for chronic pain as an additional indication (June)

#### Category-

#### based Strategy

#### Japan and Korea

 Jointly initiated phase III clinical trial for anti-IL-5 receptor humanized antibody KHK4563 for asthma with the licensee, AstraZeneca PLC of the United Kingdom (April)

#### Japan

Immunology/Allergy

 Dovobet<sup>®</sup> for psoriasis vulgaris was approved (July) and was launched (September)

#### Japan

 New formulation of antiepileptic agent Topina<sup>®</sup> (fine granules) was approved (January) and launched (May)

#### Europe

 Initiated phase I clinical trial for KHK6640, an anti-amyloid beta (Aβ) peptide antibody for treatment of prodromal/mild/moderate Alzheimer's disease (October)

## Other Japan

U.S.A. and Europe Application for approval was submitted for recombinant human antithrombin KW-3357 (July) Phase II clinical trial began for anti-FGF23 fully human antibody KRN23 for pediatric X-linked R&D expenses



## R&D expenses as a percentage of net sales

14.3%

R&D personnel

980 people

(As of December 31, 2014)

The number of personnel includes research personnel in the production division.

#### Clinical trials in progress



The number of clinical trials in progess in 2014 (including trials continued from the previous year).

Phase II clinical that began for anti-FGF23 fully numan antibody KHN23 for pediatric X-linked hypophosphatemia (July)

#### Glossary

#### Cancer immunotherapy

Method for destroying cancer cells by regulating the body's immune system.

## Antibody-dependent cellular cytotoxicity (ADCC)

This mechanism is one of the human immune functions that permits white blood cells such as natural killer cells and monocytes to kill cancer cells via antibodies.

#### Web

#### Antibodies

http://www.kyowa-kirin.co.jp/antibody/ (Japanese only)

Research collaboration and licensing http://www.kyowa-kirin.com/research\_ and\_development/research\_collaboration\_ licensing/

#### **Partnering Activities**

We concluded a series of development collaboration agreements to explore the potential of KW-0761 (Mogamulizumab) for cancer immunotherapy in 2014. Under the agreement concluded in July, we partnered with AstraZeneca (U.K.) to study its anti-PD-L1 antibody MEDI4736 in combination with KW-0761, and its anti-CTLA-4 antibody tremelimumab in combination with KW-0761. Under the agreement concluded in September, we partnered with Pfizer Inc. (U.S.A.) to study the combination of Pfizer's PF-05082566, an anti-4-1BB antibody, with KW-0761. Under the agreement concluded in December, we partnered with ONO PHARMACEUTICAL CO., LTD. (Japan) and Bristol-Myers Squibb Company (U.S.A.) to study the combination of nivolumab (product name in Japan: *Opdivo®*), an anti-PD-1 antibody, with KW-0761.

We also strengthened the process for the creation of innovative new drugs and technologies by establishing the Open Innovation Department in April 2014 and launching proactive initiatives to partner with academia and other companies at earlier stages.

Main Compounds under Collaboration in the Development Phase (As of January 23, 2015)

| Therapeutic<br>Area       | Code<br>(Generic Name)                                  | Collaboration Partner                   | Indication  |
|---------------------------|---|---|---|
|                           | KHK7580   | Mitsubishi Tanabe Pharma<br>Corporation | Secondary<br>hyperparathyroidism                                |
| NEPHROLOGY                | RTA 402<br>(Bardoxolone methyl)                         | Reata Pharmaceuticals, Inc.             | CKD in patients with type 2 diabetes                            |
|                           | ♦ KW-0761<br>(Mogamulizumab)<br>+<br>MEDI4736           | AstraZeneca                             | Solid tumor   |
| ONCOLOGY                  | ♦ KW-0761<br>(Mogamulizumab)<br>+<br>Tremelimumab       | AstraZeneca                             | Solid tumor   |
|                           | ARQ 197<br>(Tivantinib)                                 | ArQule, Inc.                            | Hepatocellular carcinoma  |
|                           | ♦ KRN951 (Tivozanib)                                    | AVEO<br>Pharmaceuticals, Inc.           | Cancer  |
|                           | ASKP1240  | Astellas Pharma Inc.                    | Organ transplant rejection                                      |
|                           | <ul> <li>MEDI-563/KHK4563<br/>(Benralizumab)</li> </ul> | AstraZeneca PLC/<br>MedImmune, LLC      | Asthma, chronic obstructive pulmonary disease (COPD)            |
| IMMUNOLOGY/<br>ALLERGY    | ◆ RGI-2001  | REGIMMUNE Corporation                   | Immunosuppressive   |
|                           | ◆ SAR252067   | Sanofi                                  | Inflammatory bowel disease                                      |
|                           | Z-206 (ASACOL®)<br>(Mesalazine)                         | Zeria Pharmaceutical Co., Ltd.          | Ulcerative colitis  |
| CENTRAL<br>NERVOUS SYSTEM | KHK6640   | Immunas Pharma, Inc.                    | Alzheimer's disease   |
| OTHER                     | ♦ KRN23   | Ultragenyx Pharmaceutical Inc.          | X-linked hypophosphatemia                                       |
|                           | ♦ KRN5500   | DARA BioSciences, Inc.                  | Neuropathic pain  |
|                           | ♦ KW-3357   | Japan Blood Products<br>Organization    | Disseminated intravascular coagulation, congenital antithrombin |

## **Intellectual Property**

#### **Priorities**

For the key management resource of intellectual property (IP), we concentrate on protecting core technologies by acquiring wide-ranging, robust and effective rights and increasing product value through means such as lifecycle management. At the same time, we ensure compliance to avoid infringing on the rights of third parties and seek to maintain a high degree of freedom to operate in our research and business activities. We also enhance risk management by supporting the IP operations of main Group companies, and are strengthening IP collaboration among departments in Japan and overseas through means including meetings and online conferences to contribute to quick and appropriate decision making aligned with business strategies.

#### Challenges

We are reinforcing intellectual property management with a global perspective. The development of new drugs requires many years and substantial investment, but the success rate is extremely low. Products launched are therefore valuable assets that we need to protect with patents for as long as possible while acquiring as many kinds of rights as possible. This is one key to maximizing earnings. We will therefore structure a patent portfolio that is consistent with our business strategy. We are also involved in organizational structuring that aggressively supports management initiatives such as proactively asserting patent rights and providing human resources development that is essential for success.

#### Kyowa Hakko Kirin's Technology

ADCC enhanced antibody activity technology enables more effective elimination of target cells.

#### POTELLIGENT®

A key feature of POTELLIGENT®, a proprietary Kyowa Hakko Kirin technology, is its ability to remarkably increase antibody-dependent cellular cytotoxicity (ADCC) activity by reducing the amount of fucose in the sugar chain of antibodies. Animal and other testing has shown that POTELLIGENT® dramatically enhances effectiveness in attacking cancer cells and other targets compared with conventional therapeutic antibodies. World-class technology for producing fully human antibodies

#### Human Antibody Producing Mouse

Human Antibody Producing Mouse was created by combining Kyowa Hakko Kirin's Human Artificial Chromosome (HAC) technology and the human antibody producing technology of Medarex, Inc. (currently Bristol-Myers Squibb Company). This technology enables the rapid generation of fully human antibodies with the same diversity as naturally produced human antibodies, thus expanding the potential of clinical application.

#### **R&D Ethics**

The increasing importance of research using samples from humans in the R&D process for drug discovery is one of many factors increasing the need for well-grounded ethical considerations. Committed to compliance with the Pharmaceuticals and Medical Devices Act and other regulations, Kyowa Hakko Kirin provides employee training, acquires third-party certification, and creates opportunities for third-party audits in order to protect human rights and personal information and ensure the reliability of research.

#### Main Initiatives

- Appropriate management of cells, microorganisms, and chemical substances used in research that complies with relevant laws and regulations
- Breeding facility maintenance and appropriate experiment management that are aligned with global standards for animal welfare
- Scientific and ethical audits of research that uses human samples by the Research Ethics Audit Committee, which includes outside commissioners
- Execution and management of clinical trials that complies with the Declaration of Helsinki, the Pharmaceuticals and Medical Devices Act and Good Clinical Practice

## POTELLIGENT<sup>®</sup> technology licensees

14 licensees (As of December 31, 2014)

Number of patents owned

2,235 patents (As of December 31, 2014)

Excluding ProStrakan Group plc of the United Kingdom

#### Visitors to research labs

approximately 300 visitors

(2014 Uala)

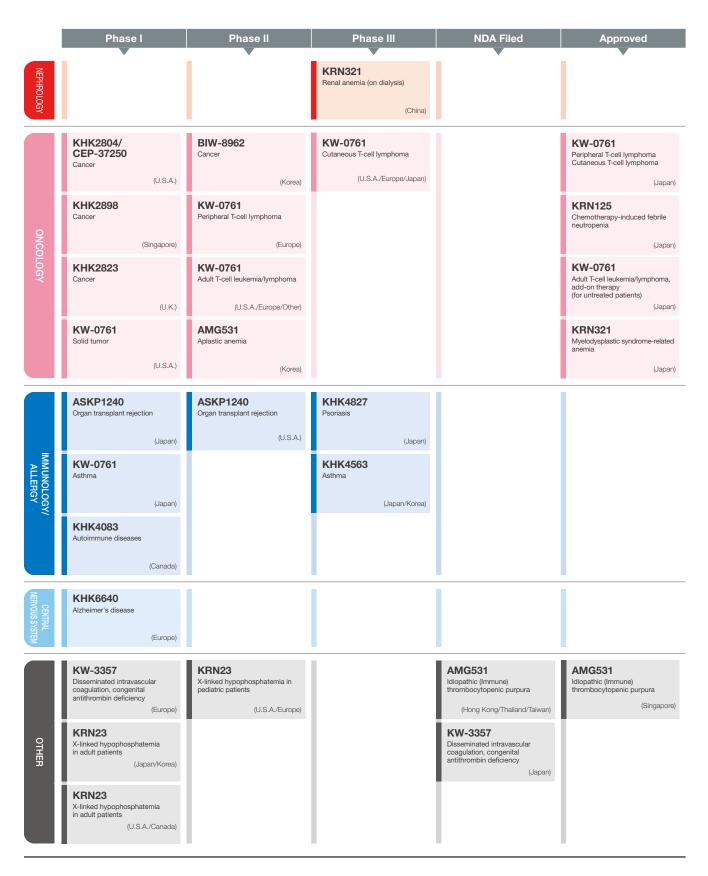
Kyowa Hakko Kirin's Tokyo Research Park conducts tours that meet the needs of students, corporate visitors and government institutions.

#### Science class participants

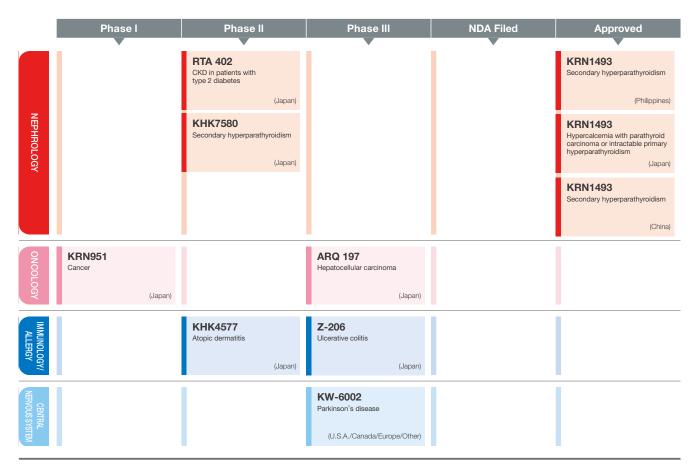
approximately 3,300 participants (Cumulative number since 2000)

Researchers at Kyowa Hakko Kirin's Tokyo Research Park visit elementary and junior high schools to conduct experiment programs covering subjects including DNA, microbes and immunity.

## Biopharmaceuticals (proteins, antibodies)



## **Small Molecule Pharmaceuticals**



Note: Cancelled projects (January 25, 2014 to January 23, 2015) ARQ 197 (lung cancer, gastric cancer) KW-2478 (multiple myeloma) Z-206 (Crohn's disease)

#### **Clinical Trial Phases**

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

| Phase I<br>Clinical Trial        | Phase II<br>Clinical Trial       | Phase III<br>Clinical Trial  |
|----------------------------------|----------------------------------|------------------------------|
| Studies in small numbers of      | Studies in small numbers of      | Studies in large numbers of  |
| healthy people* to verify safety | patients to verify effective and | patients to confirm efficacy |
| issues including side effects    | safe dosage and regimen          | and safety in comparison to  |
|                                  |                                  | standard drugs or placebo    |
| *Some studies include patients   |                                  |                              |

Source: Medicine Information Q&A 55 (Japan Pharmaceutical Manufacturers Association)

#### Glossary

Good manufacturing practice (GMP) International standard governing the manufacturing control and quality control of pharmaceuticals.

#### Business continuity plan (BCP)

A BCP covers issues such as organizational framework, advance preparation and response to disasters and other situations that may degrade essential operating resources and interrupt business activities. It prioritizes business operations in advance with the goals of maintaining an acceptable level of services and restoring operations within an acceptable time frame.

#### We

Production and production technologies

http://www.kyowa-kirin.co.jp/research\_ development\_production/approach/ production\_technology/ (Japanese only)

#### **Priorities**

Committed to the stable supply of highquality products, Kyowa Hakko Kirin is reinforcing its production and supply organization through measures that include reorganizing production sites and constructing new production facilities.

We are steadily moving ahead with various programs to reorganize production sites. These programs were initiated during Medium-Term Business Plan – 2010 to 2012, and completion is planned for 2017. We have completed new production facilities as planned at the Takasaki Plant, the Ube Plant, and Daiichi Fine Chemical. We have automated these production lines and equipped them with leading-edge facilities to meet GMP in Japan, the United States and Europe, and are moving forward with preparations for global supply.

In addition, we are creating an organization capable of producing and supplying the new products that we will launch in the future. We completed new production facilities for biopharmaceutical APIs at the Takasaki Plant in 2014. We are also revamping existing facilities to significantly improve productivity.

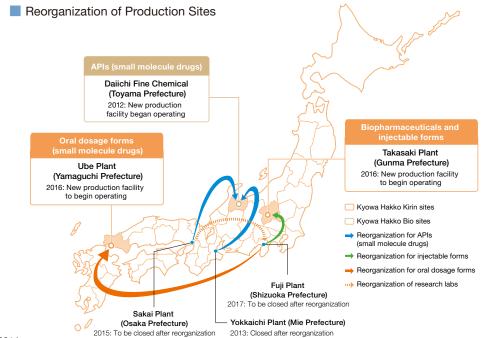
We will further reinforce the production and supply organization for all products during 2015.

#### Challenges

We are reinforcing our own production organization and also using contract manufacturers in Japan and overseas for certain pharmaceuticals to ensure the most appropriate production organization for all pharmaceuticals. We provide technological support and guidance to contract manufacturers to maintain the supply of pharmaceuticals that are of the same highquality as those we produce in-house. Moreover, we continuously review our BCP and proactively reinforce our product supply capabilities to be prepared for emergencies so that we can maintain stable supply without interruptions.

Kyowa Hakko Kirin implements environment, safety and health programs at its plants and other facilities to contribute to a sustainable society.

We are reinforcing our production and supply organization, implementing environment- and safety-oriented initiatives as a global specialty pharmaceutical company. Our objective is to maintain our identity as a company that consistently addresses the expectations of society by consistently producing and supplying highguality pharmaceuticals.



#### **Biopharmaceutical Production Technologies**

Kyowa Hakko Kirin also actively conducts development research for production and formulation technologies. This research results in new and improved technologies that are embodied in our products. We are therefore able to consistently deliver new value. In this context, we are developing even more innovative technologies based on our inherited strengths in fermentation technology, our historical point of origin, and in the biopharmaceutical technology that we subsequently developed through the Pharmaceuticals business. The Bio Process Research and Development Laboratories specialize in biopharmaceutical process research with a focus on high quality and productivity. Moreover, close cooperation between laboratories and plants helps us structure the optimal production organization for the biopharmaceuticals that we will launch from our development pipeline.



Biopharmaceutical production facility (Takasaki Plant)



New production facility for biopharmaceutical APIs (Takasaki Plant)

#### **Contract Manufacturer Audits**

Kyowa Hakko Kirin uses regularly scheduled quality audits to ensure that contract manufacturers are in compliance with production and quality control standards for pharmaceutical manufacturing, and to examine issues including contract fulfillment and compliance with the Pharmaceuticals and Medical Devices Act. We then communicate points for improvement and recognize excellence as means of improving the level of control at contract manufacturers. In the event of a major quality defect, we dispatch auditors to work with contract manufacturers to implement corrective measures and prevent recurrence. We share these measures with other contract manufacturers and with our own plants, thus enhancing the level of all parties associated with our manufacturing process. We also provide joint product recall training to prepare for emergencies.

#### Quality Audit Organization



#### Biopharmaceutical products developed using gene recombinant technology

products

(As of December 31, 2014)

- ESPO<sup>®</sup>
- ACTIVACIN<sup>®</sup>
- GRAN<sup>®</sup>
   NESP<sup>®</sup>
- INLOI
- Romiplate<sup>®</sup>
  POTELIGEO<sup>®</sup>
- G-Lasta®

Years we have been marketing biopharmaceutical products developed using gene recombinant technology

24 years

(As of December 31, 2014)

Erythropoiesis stimulating agent ESPO<sup>®</sup> launched in April 1990

Pharmaceutical and API production sites in our Group

Sites (As of December 31, 2014)

Domestic: Kyowa Hakko Kirin Takasaki Plant Fuji Plant Ube Plant Sakai Plant

Kyowa Iryo Kaihatsu Co., Ltd.

Kyowa Hakko Bio Yamaguchi Production Center

Daiichi Fine Chemical

Overseas: Kyowa Hakko Kirin China Pharmaceutical Co., Ltd.

#### Glossary

#### Environmental accounting

The Kyowa Hakko Kirin Group ascertains and numerically quantifies to the extent possible investments to conserve the environment and their economic benefit for all business activities.

Environmental initiatives

http://www.kyowa-kirin.co.jp/csr/ environment/ (Japanese only)

#### **Initiatives to Reduce Greenhouse Gas Emissions**

At Kyowa Hakko Kirin's production sites and laboratories, we introduce energy-saving equipment and improve operating procedures to reduce emissions of CO2 and other greenhouse gases. The amount of CO<sub>2</sub> emissions at Kyowa Hakko Kirin's production sites and laboratories in 2014 was 61,000 tons, which was 5% more than the previous year. The cause of this increase was the reorganization of production sites. We will steadily reduce CO2 emissions over the next several years. The Kyowa Hakko Kirin Group has set the global target, "Reduce our CO<sub>2</sub> emissions in fiscal 2020 to no more than 85% of the fiscal 1990 level." The total amount of CO2 emissions of the Kyowa Hakko Kirin Group in 2014 was 354,000 tons, which was 79% of the 1990 level.

#### Initiatives at the Ube Plant

A new production building and an administration building were constructed at the Ube Plant as a part of the reorganization of production sites. The Ube Plant has introduced energy-saving air conditioners and cooling machines based on the latest technology. This will contribute to saving energy and reducing CO2 emissions. We will achieve more detailed energy management and further save energy by introducing an energy monitoring system in 2015.



(Millions of ven)

#### **Environmental Accounting**

#### Environmental Acounting 1, 2, 3

|                                    | onmental Acounting <sup>1, 2, 3</sup>                          |            |          |            | (Millions of |
|------------------------------------|--|------------|----------|------------|--------------|
| Cost classification                |  | 2014       |          | 2013       |              |
|                                    | COSt Classification  | Investment | Expenses | Investment | Expenses     |
| (1) Business area cost             |  | 745        | 2,523    | 775        | 4,065        |
|                                    | (1)-1 Pollution prevention cost                                |            |          |            |              |
| Details                            | <ol> <li>Cost of preventing water<br/>contamination</li> </ol> | 476        | 1,125    | 310        | 1,262        |
|                                    | ② Cost of preventing air<br>pollution and other pollution      | 139        | 398      | 230        | 349          |
|                                    | (1)-2 Global environment conservation cost                     | 94         | 119      | 170        | 160          |
|                                    | (1)-3 Resource circulation cost                                | 37         | 881      | 66         | 2,294        |
| (2) Upst                           | tream/downstream cost  | 0          | 64       | 0          | 231          |
| (3) Administration cost            |  | 23         | 410      | 9          | 404          |
| (4) R&D cost                       |  | 0          | 144      | 0          | 144          |
| (5) Social activity cost           |  | 0          | 10       | 0          | 87           |
| (6) Environmental remediation cost |  | 0          | 1        | 0          | 0            |
| Total                              |  | 768        | 3,152    | 784        | 4,931        |

#### Economic Benefit of Environmental Protection Measures 1, 2

| Item   | Activities in 2014   | 2014   | 2013   |
|--|--|--------|--------|
| Total investment   | Expansion and rationalization of<br>production and research facilities | 11,807 | 19,324 |
| Total R&D cost   | R&D for new products and technologies                                  | 48,362 | 43,846 |
| Sales of valuables in connection with (1)-3 and (2)        | Sale of dried fungus fertilizer, used catalysts, and by-product oil    | 14     | 19     |
| Resource-saving effects in connection with (1)-2 and (1)-3 | Energy and resource conservation<br>and waste reduction                | 27     | 7      |

1. Figures pertain to production sites and laboratories of Kyowa Hakko Kirin, Kyowa Medex, Kyowa Hakko Bio and Daiichi Fine Chemical.

2. Data are calculated in accordance with the Environmental Accounting Guidelines 2005 published by the Ministry of the Environment.

3. The sum and breakdown of table data may not equal the total due to rounding down.

#### Initiatives for Environmental Conservation

Kyowa Hakko Kirin works to reduce the environmental impact that results from its production activities, through measures such as improving the quality of wastewater emitted by plants and reducing volatile organic compound emissions. We are particularly focused on reducing waste emissions, and reusing and recycling waste. We will continuously work for the reduction of waste emissions and final disposal volume. In addition to reducing environmental impact, we preserve the natural environment by protecting biodiversity, installing biotopes at laboratories, and conducting underbrush clearing and tree planting and thinning as water source forestation activities.

#### Initiatives at the Fuji Plant

The Fuji Plant conducts environmental conservation activities under its slogan, "We aim to keep the environment harmonizing with the nature of Mt. Fuji and Kise River by participation of everyone." Our environmental conservation activities don't just take place within the plant, but also include programs to clean up the Kise River along with local residents and release trout into the Momozawa River, which flows through the region.



#### **Community Relationships**

#### Commitment to Safety and Reliability

Kyowa Hakko Kirin continuously promotes safe, healthy activities to coexist harmoniously with communities. Sharing knowledge and technology through detailed internal education relevant to our operations is a core activity. In 2014, the Sakai Plant was recognized for its long-standing record of accident-free and disaster-free operations and contribution to improving industrial safety. In addition, the Takasaki Plant conducts tours to engender understanding of Kyowa Hakko Kirin's activities, and hosted approximately 30 groups during 2014.



Sakai Plant was awarded a Prime Minister's Commendation on Contributors to Public Safety

#### Continuous Relationship Building

Kyowa Hakko Kirin participates in local events and provides various communication opportunities in focusing on building trusting relationships through interaction with communities. The Fuji Plant holds an Autumn Festival each year, and in 2014 approximately 2,000 area residents participated. In addition, the Takasaki Plant conducts its Summer Vacation Science Classes for Children to communicate with local elementary school children through experimentation and to deepen their interest in science. Other activities include sporting events and lectures.

#### Other Examples of Activities

|                          | -                      |  |
|--------------------------|------------------------|--|
| Plant Name               | Number of Participants |  |
| Takasaki<br>Plant        | Approx. 100            | Table tennis lessons   |
|                          | Approx. 80             | Soccer lessons   |
| Fuji Plant               | Approx. 70             | Health improvement lectures  |
| Ube Plant                | Approx. 70*            | Participation in the<br>largest festival in Ube,<br>Yamaguchi Prefecture |
|                          | Approx. 30             | Science experiment classes   |
| Daiichi Fine<br>Chemical | Approx. 220            | Regional tournament of<br>boys and girls kickball<br>games               |

\*Kyowa Hakko Kirin Group employees

#### 18th Nikkei Environmental Management Ranking Survey in the Pharmaceutical Industry



The survey of corporate initiatives for both environmental measures and management efficiency. Kyowa Hakko Kirin ranked 1st in the pharmaceutical industry (72nd in the overall manufacturing industry).

#### Consecutive years achieving zero emissions\* (Kyowa Hakko Kirin Group)



(2011-2014)

\*The Kyowa Hakko Kirin Group defines zero emissions as the final disposal volume of less than 0.1 percent of waste emission volume.

Visitors on our factory tours

Approximately 500 visitors

(2014 data)

Kyowa Hakko Kirin's Takasaki Plant and Fuji Plant conduct factory tours for visitors including company customers, health care providers and students.

#### Glossar

#### Medical representative (MR)

A person whose main work includes visiting health care providers and collecting and providing safety management information to contribute to the appropriate use of drugs.

#### Orally disintegrating (OD) tablets

Tablets that dissolve in a small amount of saliva or water, and can therefore be swallowed without becoming stuck in the throat. Safe for people who have difficulties with tablets and children and the elderly without the strength to swallow.

#### Web

kksmile®

Website for health care providers http://www.kksmile.com/ (Japanese only)

#### **Priorities**

In 2014, we launched G-Lasta<sup>®</sup>, which offers new value by suppressing the incidence of chemotherapy-induced febrile neutropenia, and Dovobet<sup>®</sup>, a psoriasis vulgaris product that meets patient expectations.<sup>1</sup>

Kyowa Hakko Kirin places top priority on the appropriate use of our products, and therefore provides timely information to health care providers through various channels. We are enhancing education for medical representatives (MRs) and Sales & Marketing Division personnel including call center employees because we require a high level of specialized knowledge as a company that continuously launches new products. In addition, we are emphasizing an awareness of compliance as a result of inappropriate participation in clinical research.<sup>2</sup>

#### Challenges

We want to increase patient treatment options and improve the safety and efficacy of our products. MRs and Sales & Marketing Division personnel are enhancing their expertise about our products and therapeutic areas to meet the expectations of patients and health care providers. We also established the Area Marketing Strategy Department on April 1, 2015, to more closely respond to market needs, and are encouraging activities specific to therapeutic areas.

The domestic ethical pharmaceuticals market remains flat, but we will specialize in the four categories in which we are strong, provide a range of value, continuously supply new products, and build the business foundation for rapidly becoming a global specialty pharmaceutical company.

Please refer to "A Message from President and CEO Nobuo Hanai" on page 19 for details.
 Please refer to "Compliance" on page 55 for details.

#### Enhancing Competitiveness in Japan

NESP®, a treatment for renal anemia, is well recognized for its outstanding clinical efficacy and safety from predialysis through dialysis in adults and infants, and is used at many medical institutions. We expanded our lineup<sup>1</sup> in 2014 to contribute to treatments that earn even higher levels of satisfaction. In addition, we proposed the use of type 2 diabetes treatment ONGLYZA®, hypertension and angina pectoris treatment CONIEL®, and hypertension treatment COVERSYL® for preventive care to halt the progression of chronic kidney disease.

Nephrology

Immunology/Allergy

In the hematology market, we launched sustained-duration G-CSF product G-Lasta® and received approval for long-acting erythropoiesis-stimulating agent NESP® for the additional indication of anemia with myelodysplastic syndrome. As a result, our formulation lineup for hematopoietic blood cells<sup>2</sup> is contributing to higher levels of treatment satisfaction. We are focusing on providing information about cancer pain management with Abstral®, a treatment for managing breakthrough cancer pain, and Fentos®, a transdermal long-acting pain relief patch. In addition, we are broadening the contribution to treatment of anti-CCR4 humanized antibody POTELIGEO® by expanding indications.

Categorybased Strategy

Antiallergic agent ALLELOCK<sup>®</sup> and Patanol<sup>®</sup> antiallergic eyedrops have been used in dermatology, otolaryngology and ophthalmology for many years, and we continue to focus on patient convenience by launching new formulations such as orally disintegrating (OD) tablets and granules for ALLELOCK<sup>®</sup>. Moreover, in 2014 we launched Dovobet<sup>®</sup>

as a treatment for psoriasis vulgaris. It will contribute to improved patient quality of life (QOL) because of its rapid efficacy and convenient once-daily application. We are concentrating on the therapeutic areas of Parkinson's disease and epilepsy.

Our Parkinson's disease treatment proposals revolve around antiparkinsonian agents NOURIAST<sup>®</sup>, which has a unique nondopamine mechanism of action, and Apokyn<sup>®</sup>, a treatment for off-episode motor symptoms.

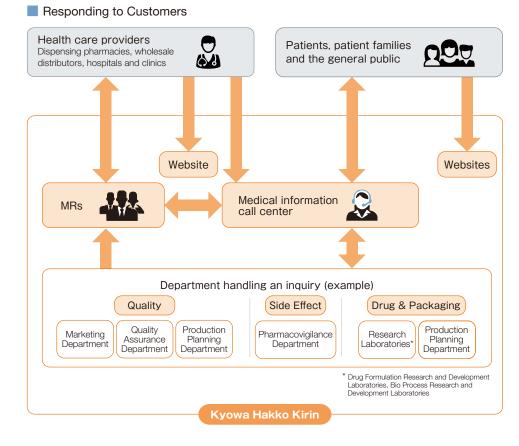
We are contributing to the treatment of epilepsy with antiepileptic agent Topina® and with DEPAKENE®, a treatment for epilepsy, the manic states of manic disorder and migraine headaches. These drugs are positioned as standard treatments.

1. NESP® Injection 5µg Plastic Syringe launched in January 2014 2. White blood cells, red blood cells and thrombocytes

#### **Providing and Collecting Customer Information**

Kyowa Hakko Kirin believes in the importance of quickly communicating the correct information to patients and health care providers from the vast amount of drugrelated data available. We take a multichannel approach that includes the activities of MRs, a medical information call center, and websites. As a result, we have been able to provide timely information that addresses changes in the health care environment over the past several years.

Moreover, we are sharing the data we collect internally among various departments to promote product lifecycle management that increases the value of our products.



#### Medical Representatives (MRs)

Our MRs leverage advanced specialization to provide information to health care providers that supports enhanced patient treatment. In particular, our MRs concentrate on providing information that addresses the expectations of health care providers and their questions about new product efficacy and safety, and adding value by expanding the scope of application of existing products.

#### Medical information call center

Our medical information call center addresses approximately 40,000 inquiries annually from health care providers such as pharmacists, and maintains a frequently asked questions (FAQ) website to provide information to a wide audience. We also continuously enhance capabilities through means including external evaluation and training to enable call center personnel to respond quickly and accurately to inquiries.

#### Websites

We maintain easy-to-understand disease-related information websites for patients, their families and the general public. We are enhancing convenience in ways such as developing smartphone applications. In addition, the kksmile® website for health care providers delivers content such as detailed information on Kyowa Hakko Kirin products and the latest scientific information.

## Sales and marketing sites (Domestic)

65 sites (As of December 31, 2014)

## Disease and health information websites (Domestic)



Number of products sold (Domestic)

135 products (As of April 1, 2015)

The number of products listed in "Kyowa Hakko Kirin's 2015 Product Guide for Health Care Providers." (Japanese only)

#### Glossary

#### **GRAN**<sup>®</sup>

Granulocyte-colony stimulating factor (G-CSF) drug. Used to suppress chemotherapy-induced febrile neutropenia.

#### Web

## Disease and health information websites

- CKD website
   http://www.kyowa-kirin.co.jp/ckd/
- Diabetes website http://www.kyowa-kirin.co.jp/ diabetes/
- Pollinosis website
   http://www.kyowa-kirin.co.jp/kahun/
- Parkinson's disease website
   http://www.kyowa-kirin.co.jp/
   parkinsons/
- Enuresis website
   http://www.kyowa-kirin.co.jp/onesho/
- ITP website http://www.kyowa-kirin.co.jp/itp/
- Pruritus website
   http://www.kyowa-kirin.co.jp/kayumi/
- Note: All of the websites noted above are in Japanese only.

#### **Disease and Health Information Programs**

Kyowa Hakko Kirin promotes the appropriate use of its products and provides disease and health information that contributes to helping patient families to provide support.

Parkinson's disease is designated as intractable. We publish and distribute through health care providers a biannual publication that supports the day-to-day activities of patients undergoing treatment for Parkinson's disease. In 2014, we also sponsored public lectures by medical specialists and health care providers on pathologies, the latest treatments and rehabilitation methods. Approximately 350 patients and their families attended.

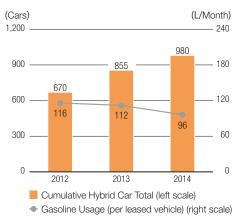


Pollinosis Navi (App version)

#### Addressing Environmental Impact

We are introducing hybrid cars for MR sales activities. Since 2009, we have been successively switching to low-emission gas vehicles, and hybrid cars accounted for 82.5 percent of our fleet as of the end of 2014. We are also reducing CO<sub>2</sub> emissions in ways such as cutting back the amount of fuel used in sales activities with No Car Days. We will continue to consider information provision activities and environmental impact to make Kyowa Hakko Kirin a low-carbon corporate group.

#### Number of Hybrid Cars and Gasoline Usage



#### **Employee Training**

We regularly and continuously provide compliance training to all employees in the Sales & Marketing Division. This training adheres to the guidelines for the Fair Competition Code in Ethical Pharmaceutical Drugs Marketing Industry and the Code of Practice of the JPMA,\* with a curriculum designed to help employees make correct judgments, and promote appropriate activities in accordance with rules. We also provide training to help employees incorporate our "Commitment to Life" and the pharmaceutical company employee mindset it sets forth in their daily conduct.



#### Compliance training

\*JPMA: Japan Pharmaceutical Manufacturers Association

#### **Priorities**

Kyowa Hakko Kirin's priority for overseas operations is to build a solid sales and marketing organization that will enable us to become a global specialty pharmaceutical company.

Acquired in 2011, ProStrakan Group plc of the United Kingdom has been steadily improving results by increasing sales of breakthrough cancer pain treatment Abstral<sup>®</sup> and other products. However, one issue that has arisen is that its core products are reaching the maturity stage of their lifecycles. In this context, ProStrakan Group plc acquired Archimedes Pharma Limited of the United Kingdom in August 2014 with the objective of acquiring products in strategic areas in Europe and strengthening its sales organization.

In Asia, a key priority is to establish the operating foundation to achieve sustained growth in China. Sales of GRAN® have been increasing and in June 2014 we received approval for REGPARA®, a treatment for secondary hyperparathyroidism. We have also received approval for multiple products in other Asian countries and expect them to become pillars of our operations.

#### Challenges

We are working on late-stage development and launch preparations for three in-house products (KW-0761, KW-6002, KRN23) in Europe and the United States. These inhouse products represent a major challenge. Our core business vision is to launch them quickly to generate sustained business growth.

We will achieve this vision by leveraging new products such as PecFent<sup>®</sup>, a treatment for breakthrough cancer pain, and the marketing infrastructure we obtained through the acquisition of Archimedes Pharma Limited of the United Kingdom to structure an even stronger marketing organization in Europe. In addition, we will strengthen our marketing foundation in the United States, which is the world's largest pharmaceutical market. We consider this extremely important in preparing for the launch of our three in-house products.

In China, we are targeting a smooth launch and maximum sales for REGPARA<sup>®</sup>. We aim to enhance our pipeline and to take on the challenge of accelerating development. In other parts of Asia, we will concentrate on quickly launching products under development, expanding sales, and generating sustained business growth.

### Pharmaceuticals business overseas sales ratio

22.8%

#### Approvals received (Overseas)



Six products approved in Asia, including NESP<sup>®</sup> and REGPARA<sup>®</sup>

#### Products acquired

15 products

Product lineup of Archimedes Pharma Limited

#### Number of overseas MRs

406 MRs (Total of all overseas subsidiaries as of December 31, 2014)

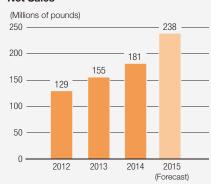
History of ProStrakan Group plc

2011: Became part of the Kyowa Hakko Kirin Group through an acquisition
2012: Kyowa Hakko Kirin and ProStrakan Group plc consolidated their bases in the United Kingdom and Italy
2013: Achieved operating profitability (post amortization of goodwill and sales rights) in the third year after the acquisition as a result of increased sales of core products and cost reductions

2014: Acquired Archimedes Pharma Limited of the United Kingdom



#### Net Sales



We view the nephrology category as broadly encompassing not only the treatment of the various diseases that affect the kidneys, but also the alleviation of their symptoms and the investigation of their causes. As a leading company in nephrology, we are committed to helping everyone who is battling chronic kidney disease (CKD).



#### NESP<sup>®</sup> 🗧

Nephrology

- Long-acting erythropoiesis-stimulating agent\*
- Darbepoetin alfa (genetic recombination)



\*A treatment for renal anemia since its launch. In 2014, additional indication as a treatment for anemia with myelodysplastic syndrome (hematological cancer).



#### **REGPARA®**

- Treatment for secondary hyperparathyroidism (Calcium receptor agonist)
- Cinacalcet hydrochloride





#### **ONGLYZA®**

- Treatment for diabetes
- Saxagliptin hydrate



In this category, we provide value from the standpoint of patients to improve their quality of life, primarily through products that are established in the market and have strong reputations. We are also advancing the development of new drugs to address unmet medical needs.



Newly

launched

#### Dovobet<sup>®</sup>

dipropionate

- Treatment for psoriasis vulgaris
- Calicipotrol hydrate/betamethasone



#### **ALLELOCK®**

- Treatment for allergic symptoms
- Olopatadine hydrochloride
  - ¥23.6 billion



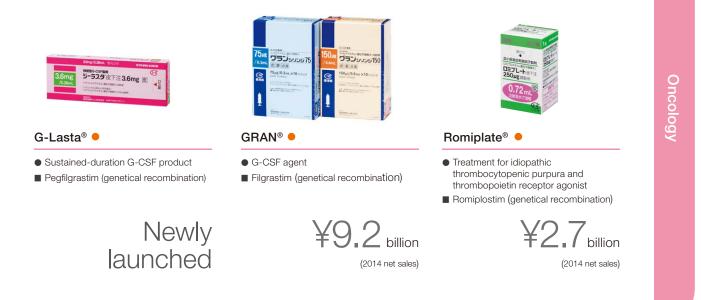
#### ASACOL®

- Treatment for ulcerative colitis
- Mesalazine



Therapeutic Category 
 Generic Name 
 Biopharmaceutical

In 2012, we launched therapeutic antibody POTELIGEO<sup>®</sup>, which was the world's first therapeutic antibody that applied our POTELLIGENT<sup>®</sup> technology for enhancement of antibody-dependent cellular cytotoxicity. Therapeutic antibodies will continue to be central to our efforts to address unmet medical needs and contribute to medical treatment.



Treatments for Parkinson's disease will drive sales growth in the central nervous system category. We expect this to grow into our fourth major category, centered on NOURIAST<sup>®</sup>, which we began marketing in Japan in May 2013.



#### Glossary

#### ICH Q10

(Pharmaceutical quality system) ICH is an acronym for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use conducted by regulatory authorities from Japan, the United States and the European Union. Its component Q10 is one of the guidelines for pharmaceutical quality that presents a pharmaceutical quality system model and includes the GMP guidelines for controlling pharmaceutical manufacturing and quality.

#### PIC/S

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme, a global standard for GMP inspections. Japan became a participating authority in 2014.

### Pharmaceutical risk management plan (RMP)

We evaluate pharmaceutical benefits and risks at every stage from development through post-marketing as the basis for implementing required safety measures. We target safety during manufacturing and postmarketing, and since April 2013 have implemented RMPs that incorporate a pharmacovigilance plan and a risk minimization plan.

#### **Priorities**

Our top priority is to guarantee both the safety and quality of our drugs in order to provide pharmaceuticals that patients can use with confidence. We therefore employ global quality standards and have created a safety management system.

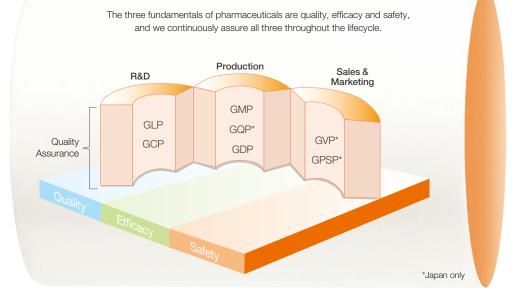
For quality, we have created a system that places the highest priority on implementing the ICH Q10 pharmaceutical quality management system and the international standard PIC/S. We have also adopted guidelines for implementing good distribution practice (GDP) standards, which are international standards for distributing pharmaceuticals.

#### Challenges

Kyowa Hakko Kirin is concentrating on building the business foundation to launch new products in the United States and Europe in taking on the challenge of becoming a global specialty pharmaceutical company.

We have implemented a safety information database shared among Japan, the United States and Europe with a view to launching antibody drug KW-0761, which we developed in-house to treat cutaneous T-cell lymphoma. This database enables unified management of safety information related to pharmaceuticals, and we are restructuring our safety management system based on the global standard to enable smooth data collection and analysis.

#### Pharmaceutical Quality Assurance



GLP (Good Laboratory Practice): Standard for the conduct of nonclinical laboratory studies for pharmaceuticals

GCP (Good Clinical Practice): Standard for the conduct of clinical trials for pharmaceuticals GMP (Good Manufacturing Practice): International standard governing the manufacturing control and quality control of pharmaceuticals

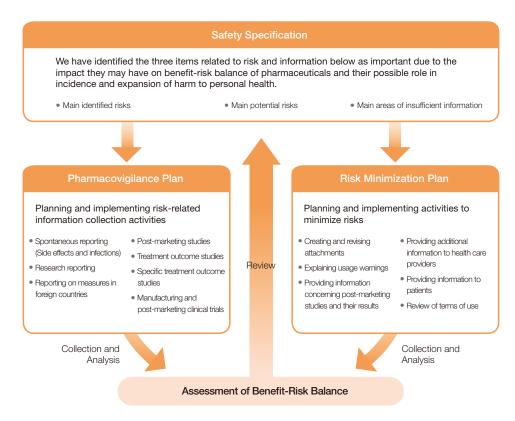
GQP (Good Quality Practice): Standards governing quality control of pharmaceutical products

GDP (Good Distribution Practice): Standards for distribution of pharmaceutical products GVP (Good Vigilance Practice): Standards governing post-marketing safety management of pharmaceutical products

GPSP (Good Post-marketing Study Practice): Standards governing post-marketing study of pharmaceutical products

#### Pharmacovigilance Based on Pharmaceutical Risk Management Plans

All pharmaceuticals have both efficacy (benefits) for treating patients and side effects (risks) that are undesirable for patients. The benefit-risk balance changes as a pharmaceutical product proceeds from development stages to approval review to manufacturing and post-marketing. Kyowa Hakko Kirin conducts appropriate benefitrisk assessments and reviews so that patients can use its pharmaceuticals safely and with confidence. In 2014, we initiated pharmaceutical risk management plans (RMPs) for four products. The consistent implementation of an array of activities and initiatives to maximize the benefits of these pharmaceuticals and minimize their risks is essential to product improvement within our quality assurance process, and we will proactively use RMPs in the future.



#### Preparing against Pharmaceutical Risks and Disasters

We fulfill our obligations as a pharmaceutical manufacturer and marketer by providing e-learning education annually about the harmful effects of medication.

As part of our quality assurance activities, we have also created a business continuity plan (BCP) for use in the case of a major disaster such as an earthquake, based on the assumption of a major earthquake beneath metropolitan Tokyo, to enable us to maintain our core responsibility as a pharmaceutical company to supply products and information. Specifically, we have created a detailed BCP Conduct Manual covering the collection, evaluation, announcement, and provision of important safety information as a part of pharmacovigilance activities and operations involved in product shipments in order to avoid interruptions in key operations in the event of a major disaster.

### Number of safety information resources Approximately 30,000 resources (2014 data)

#### Products covered by RMPs



(As of December 31, 2014) • G-Lasta<sup>®</sup> Subcutaneous Injection 3.6mg

- POTELIGEO<sup>®</sup> Injection 20mg
- REGPARA® Tablets 25mg and 75mg
- NESP<sup>®</sup> Injection
   5µg Plastic Syringe
  - 10µg Plastic Syringe 15µg Plastic Syringe 20µg Plastic Syringe 30µg Plastic Syringe 40µg Plastic Syringe 60µg Plastic Syringe
  - 120µg Plastic Syringe
  - 180µg Plastic Syringe

#### Glossary

#### Diagnostics

General term for drugs used in medical treatment to diagnose diseases.

#### Clinical analyzers

Automated analysis equipment that measures and visualizes test samples.

#### HbA1c

The combination of hemoglobin (Hb), a protein in red blood cells that carries oxygen within the human body, and glucose in the blood. HbA1c levels are notably higher in patients with diabetes.

#### Biosimilars

Subsequent versions of innovator biopharmaceuticals that have already been approved. The quality, efficacy and safety are similar, but they are produced and marketed by a different sponsor pursuant to the guidelines for biosimilars.

#### Hormone

A substance that specifically regulates the functions of other organs and tissue. Hormones are produced in endocrine organs such as the thyroid gland and the pancreas, and are circulated through blood and bodily fluids. Hormones include insulin, which is produced in the pancreas and secreted through the bloodstream to manage blood sugar that is used in muscle and fat cells. Other hormones include growth hormones and erythropoietin.

#### Cytokine

A protein that is produced and released by cells and has an important role in the generation of immune and inflammatory responses. Cytokines include interferons and interleukins.

#### **Priorities**

The management philosophy of Kyowa Medex is to contribute to the health and well-being of people throughout the world by providing advanced diagnostics and clinical analyzers based on scientific and technological progress.

To help put this philosophy into practice, Kyowa Medex's core initiatives during 2015 are to strengthen sales capabilities in Japan, promote business development overseas, enhance R&D, strengthen production and quality control systems, enhance its operating fundamentals in key therapeutic areas, promote product in-licensing and business alliances, and improve business process while reducing costs.

#### Challenges

As a member of the Kyowa Hakko Kirin Group, Kyowa Medex conducts R&D in line with the clinical test needs of Kyowa Hakko Kirin's drug discovery research. Kyowa Medex has earned trust through high-quality manufacturing of the products it develops and providing customers with accurate information. Kyowa Medex intends to further strengthen the business foundation supported by this trust by boldly taking on the challenge of overseas business development and establishing its own global brand. Kyowa Medex's diverse employees will earn customer trust and take on new challenges, which will sustain its growth as a company.

#### **Market Environment**

In Japan, government health insurance reimbursements are being lowered from the perspective of comprehensively reducing health care costs, and demand for reducing the reimbursements for testing with diagnostics and clinical analyzers is growing. On the other hand, factors such as policies for the prevention of disease are increasing demand for testing not reimbursed by health insurance. The future of Kyowa Medex's business in Japan will be determined by the emergence of new demand.

Overseas, the implementation of new health care reform laws in the United States has increased the number of insured. Markets are expected to expand in emerging countries due to factors such as rapidly increasing demand for testing.

#### **Product Overview**

Kyowa Medex's product lineup emphasizes diagnostic products that contribute to the diagnosis of lifestyle diseases such as hyperlipidemia, which causes arteriosclerosis, and diabetes.

International praise for reagents for measuring cholesterol including "Determiner HDL-C," "Determiner L LDL-C," and "MetaboLead RemL-C" has earned Kyowa Medex the nickname "Lipid Kyowa." Kyowa Medex is well known as a leader in testing because of its extensive product lineup, including tests for diabetes-related items such as HbA1c, and its experience with specialized equipment.



Cholesterol measuring reagents

#### Launch of New Equipment

#### A1c iGear K

In July 2014, Kyowa Medex launched HbA1c analysis equipment for diabetes testing. This equipment enables testing a small quantity of blood, which has reduced the burden on patients. Moreover, analysis results are available six minutes after placing a blood sample in this breakthrough equipment, which is compact and offers fast, simple measurement.



A1c iGear K

#### **Priorities**

FUJIFILM KYOWA KIRIN BIOLOGICS (FKB) merges Kyowa Hakko Kirin's well-developed technologies and expertise in biopharmaceutical R&D and manufacturing with FUJIFILM's production, quality control and analysis technologies. FKB leverages these capabilities to develop biosimilars that offer outstanding reliability and quality. In 2015, the fourth year since its establishment, FKB will move forward according to its development plan while targeting the realization of an organization that can consistently develop, submit applications for and obtain approval for products in Japan, the United States and Europe.

#### Challenges

FKB's value proposition involves the contradiction between low cost and high quality and it will continue to meet this challenge with innovative technology. At present, FKB is controlling production costs more effectively because of the use of Kyowa Hakko Kirin's well-developed technology. FKB will continue to reduce production costs using technology developed by drawing on the strengths of both parent companies. At the same time, FKB will emphasize quality for patients and health care providers, and develop high-quality products.

FUJIFILM

Production, guality control and

analysis technologies, and

production process

improvement expertise

#### **KYOWA KIRIN**

Technologies and expertise in biopharmaceutical R&D and manufacturing

- FUJIFILM KYOWA KIRIN BIOLOGICS
   Provide products that offer outstanding
- reliability, quality and cost competitiveness
   Develop innovative biopharmaceutical production technologies through parent company synergies

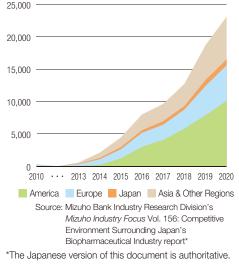
A joint venture established in March 2012 for development, manufacturing and sales of biosimilars

#### Market Environment

During the approximately nine years since the first biosimilar came to market, the focus has shifted from hormones and cytokines to antibodies. The biosimilars market is expected to grow because the patents for many antibody drugs that currently hold top spots in global pharmaceutical sales will expire over the next several years. On the other hand, the guidelines for biosimilars development in advanced countries have made it clear that sophisticated production technology and significant development expenses are necessary for approval. Moreover, competition is intensifying because not only major generic companies but also mega pharmaceutical companies have joined the market.



(Millions of U.S. dollars)



#### Progress in Product Development

Development is proceeding steadily. In 2014, FKB completed a phase I clinical trial of its first product, FKB327, a biosimilar of adalimumab, and launched a joint international phase III clinical trial. In addition, it initiated a phase I clinical trial for a second product, FKB238, a biosimilar of bevacizumab, and has made steady progress in developing production technology for a third product.

#### Diagnostics business net sales



Diagnostics business operating income

¥0.7

#### Gibberellin

A plant growth regulator that promotes plant development, flowering and corpulence in the fruit of trees.

2014 JSBBA\* Award for Achievement in Technological Research

http://www.kyowa-kirin.co.jp/news\_ releases/2014/20140214 01.html (Japanese only)

\* Japan Society for Bioscience, Biotechnology, and Agrochemistry

#### **Priorities**

The Bio-Chemicals business encompasses fine chemicals, health care, agribusiness and the production of active pharmaceutical ingredients (APIs) for small molecule drugs. Based on the Medium-Term Business Plan - 2013 to 2015, during 2014 we continued to concentrate on responding to strong demand for high-valueadded amino acids, expanding the health care field, raising production efficiency by reorganizing production bases, and developing new products and materials. In 2015, we aim to further increase earnings by further improving performance at Daiichi Fine Chemical, starting operations at our plant in Thailand, and taking advantage of stable domestic demand. This will underpin our goal of capturing growing international demand.

#### Challenges

The source of competitiveness in the Bio-Chemicals business is our fermentation technology. This technology has received very positive external recognition, including the 2014 JSBBA Award for Achievement in Technological Research. Targeting further improvements in profitability, we are concentrating on joint research with research institutes in Japan and overseas and with customers to develop new products and technologies and create new businesses. We are also enhancing productivity by introducing new production technologies while enhancing cost competitiveness. In the domestic health care market, we will raise awareness of our unique materials including ornithine, citrulline and arginine under the new functional labeling system.

#### Market Environment

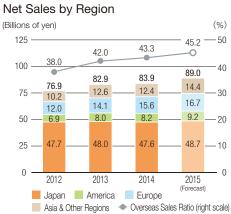
The market for high-value-added amino acids is growing, backed by expanding pharmaceutical, medical and health care markets worldwide. In particular, the market for infusion-use amino acids for pharmaceutical and medical applications is expected to grow further backed by the trend toward increasing medical sophistication around the world. Rising health

consciousness is also supporting growing global demand in the health food market, with sports nutrition leading standout growth in the United States, the world's largest health food market. In Japan, functional ingredients that help maintain health and strengthen the body are capturing awareness under the new functional labeling system.

#### **Review of Operations**

In the fine chemicals business, we transitioned to a stable earnings structure amid solid demand in Japan for pharmaceutical- and industrial-use materials. The entry of new competitors resulted in weaker prices in certain sectors of the overseas amino acid market, but we improved profitability with a focus on strong demand in the pharmaceutical and medical

### **Bio-Chemicals Business**



markets. In the domestic health care market. ornithine drove steady year-on-year mail-order sales growth backed by rising health consciousness. In the agribusiness market, we are concentrating on expanding new markets in ways such as registering expanded applications for gibberellin.

#### Net Sales by Market

(%)

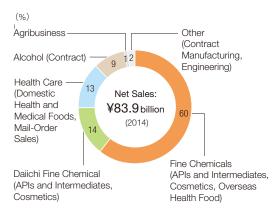
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40

30

-20

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#### A Wide Array of Amino Acid Products

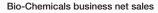
Our many materials are used in various products. We also sell in-house brands by mail order, and manufacture and market medical food and plant growth regulators.



#### Strengthening Our Production Organization

We are enhancing productivity at BioKyowa Inc. (U.S.A.) to address growing U.S. demand for amino acids used in health care. In addition, we are constructing a new plant at Thai Kyowa Biotechnologies Co., Ltd. to address rapidly growing demand in Asia. We are also increasing production capacity at Shanghai Kyowa Amino Acid Co., Ltd. to provide a stable supply of high-quality pharmaceutical- and medicaluse amino acids. Moreover, we are integrating production at the Yamaguchi Production Center to raise manufacturing efficiency for products including nucleotides and related compounds in conjunction with the construction of plants with leadingedge facilities.

Based on the reorganization of production sites announced during Kyowa Hakko Kirin's Medium-Term Business Plan – 2010 to 2012, Daiichi Fine Chemical has constructed a plant for and initiated commercial sales of APIs for small molecule drugs.





Share of Bio-Chemicals business in net sales

24.9%

Bio-Chemicals business segment income\*



#### Production Sites Worldwide



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### Original Technologies and Strategies for Addressing Unmet Medical Needs

Our People Discuss Drug Discovery and Unmet Medical Needs



#### Yoshinori Yamashita

Fellow Strategic Product Portfolio Department Corporate Strategy & Planning Department

#### Joined in 1985.

Experience in anticancer drug discovery research, then at a U.S. university. Joined the Business Development Department at the head office. Became a director at ProStrakan Group plc of the United Kingdom. Joined the Strategic Product Portfolio Department in 2012. Assumed current post in April 2015.

#### **Contending with Unmet Medical Needs**

Yamashita: Various new drugs have emerged during the past 20 or 30 years, and the likelihood of recovering from formerly incurable diseases has increased. In other words, the range of unmet medical needs has narrowed. Conversely, drugs have different effects on different people, and the problem of drug resistance remains. Research into disease has also advanced, with new understanding creating new needs. I would say that unmet medical needs have narrowed while becoming much deeper.

Kubota: Unmet medical needs have definitely changed along with the times. Kyowa Hakko Kirin quickly focused on using antibody molecules to create drugs, but a succession of new hurdles appeared precisely because expectations for antibody molecules are so high. Mizobata: The reality of unmet medical needs becomes painfully clear when doctors who want to do everything possible to heal their patients tell me that the drugs they prescribed did not help patients suffering from particular

> symptoms. I always think about the patients who health care professionals serve while providing information about drugs and understanding the needs of health care providers so that Kyowa Hakko Kirin can

address even more of the unmet medical needs of patients.

#### Interrelationships Drive Drug Discovery

Yamashita: Communicating the excellence of our products to health care providers is crucial, so we have created channels for accurately sharing R&D knowledge and information with everyone in the Sales & Marketing Division. Conversely, our MRs ensure that we learn about patient needs through feedback from health care providers, which enables us to create strategies for improving our products and developing new drugs.

Kubota: Knowing the key current issues for product development and for health care providers, such as whether drugs are safe and effective or whether dosing frequency should be reduced is critical for basic research. I always think about how we can address these needs with our technologies. **Mizobata:** Together we are taking on the challenge of addressing unmet medical needs with our "Commitment to Life" as the link between different operations.

I repeat passages from our "Commitment to Life" to myself when my work is difficult. This helps me realize that I love what I am doing. I always put patients first, so I don't simply provide information – I simultaneously collect information from health care providers with the knowledge that it will be used internally.



### We expect POTELIGEO<sup>®</sup> to become a new breakthrough.

Yoshinori Yamashita

#### **Credible Responses to Major Challenges**

Kubota: We created our unique POTELLIGENT® antibody enhancing technology and used it to launch POTELIGEO<sup>®</sup>. Also, we have provided POTELLIGENT<sup>®</sup> technology to many pharmaceutical companies to maximize its value while helping to address unmet medical needs. Yamashita: Increasing the indications of POTELIGEO<sup>®</sup> is also making an important contribution. In addition, we also launched G-Lasta<sup>®</sup> in November 2014, which is expected to reduce the side effects of cancer treatments. These developments allow us to help patients by taking different approaches to directly treating diseases, and give us opportunities to appreciate the importance of pharmaceutical development based on a broad understanding of unmet medical needs.

### **Unmet medical needs** change with the times.

Tsuguo Kubota



Tsuguo Kubota Innovative Technology Laboratories **B&D** Division

Joined in 2003. Has since been involved in technology development and antibody drug discovery research with a focus on protein engineering, primarily for antibodies. Experience with assignments at BioWa, Inc. of the United States.

#### An Exciting Time for Kyowa Hakko Kirin

Yamashita: I have been involved in the therapeutic area of cancer for about 30 years.

Innovative drugs have emerged along the way that were each a breakthrough in treating cancer. Today, the world is now looking to the potential efficacy of POTELIGEO® in immunooncology with the expectation that it will be an important breakthrough in cancer immunotherapy. This is a very exciting time for Kyowa Hakko Kirin in terms of both our business and science because of the drugs we have in hand that hold great hope for the near future.

Kubota: An antibody linked to the remarkable outcome we call POTELIGEO® was still in the initial research stage when I joined the company. Being part of this significant phase and of the development of antibody technology into a globally important field has been very exciting for me as a researcher. Mizobata: Launching a new product requires us to assimilate a huge body of specialized knowledge. That certainly poses challenges, but I am strongly motivated to study ways to deliver information as quickly as possible because I am driven by my awareness that patients and health care providers are waiting. I want to address unmet medical needs, so I am truly delighted to contribute to the health and well-being of people around the world by creating new drugs that are unique to Kyowa Hakko Kirin and excel in terms of safety and efficacy.

### Creating new drugs is a real delight!

Momoe Mizobata



Momoe Mizobata

Kyoto, Shiga and Hokuriku Branch Sales & Marketing Division In charge of Parkinson's disease portfolio

Joined in 2009. Experience as an MR responsible for hospitals at Kyoto Sales Office 1. Assumed responsibility for the Parkinson's disease portfolio in Kyoto, Shiga and Hokuriku in January 2015.

Note: Employee posts are as of April 1, 2015.



# Emphasizing Diversity as We Take on the Challenge of Becoming a Global Specialty Pharmaceutical Company

Our People Discuss Diversity as the Key to Our Transformation into a Global Specialty Pharmaceutical Company



Masahiro Hara

Manager Business Development Department

Joined in 1996. Studied in the United States after working as an MR. Began working at Kyowa Hakko Kirin America, Inc. in 2010 through the Development Planning Department and other head office organizations. Assumed current post in 2014.

**Global sensibilities are** 

important for each and

every one of us.

Masahiro Hara

#### **Diversity and Approaches to Work**

Yoshida: I am raising my child. My managers and colleagues have been very cooperative and I am able to leave work early. My life centered on work before my leave of absence, but upon returning I want to do an even better job in a limited time by working together with my colleagues, and I want to achieve results that give meaning to my life within that short time frame. The concept of time has a major influence on my work style.

Hara: While working in the United States, I was able to play with my children and spend quality time with my family even on weekdays. I would say this was because of a generally accepted atmosphere that encouraged me to handle my responsibilities at work and value my personal life. In Japan as well, a growing number of employees are using company support programs as a means to maintain their work-life balance.

Xu: Kyowa Hakko Kirin is recruiting foreign nationals, primarily in Asia. I am a recruiting

manager, and we need to enhance the workplace environment so that it facilitates work despite issues such as differing cultures. In doing so, we can broaden the regions in which we recruit.

#### The World Is Ever Closer

Yoshida: I am involved in supervising quality at Group companies, so I have many opportunities to work with people at Group companies. Company scale and situation, product lineup, and foreign and domestic regulations are all different, which means that work styles are also different. Providing quality assurance support under these conditions was unsettling at first, but now the differences are interesting. Also, learning about the Group through work is a valuable experience that truly broadens my horizons.

Hara: Group companies may have different corporate and work cultures in different countries. However, I saw during my four years at Kyowa Hakko Kirin America, Inc. that everyone keeps a steady eye on the head office in Japan, conscientiously taking messages from President Hanai to heart in considering seriously how best to achieve their goals. Group companies are also increasing opportunities to communicate their situation to Japan so that they are known. These initiatives are communicated through ways such as in-house newsletters. People in Japan are apt to focus on Japan. Increasing the number of people who work at the head office in Japan but follow initiatives around the world will allow us to further deepen our sense of Group unity.

Xu: I wanted to learn more about Japan as a student. My destiny was to enter Kyowa



### We are devising approaches to our work that enable continuous contribution.

#### Kumi Yoshida



#### Kumi Yoshida

Manager Corporate Quality Management Office Pharmacovigilance and Quality Assurance Division

Joined in 1999. Assumed current post after working at the Bio Process Research and Development Laboratories and the Regulatory Affairs Department at the head office. Returned to current post in 2012 after a year-long leave of absence to have a child.

Hakko Kirin, which was recruiting locally. My perception of Kyowa Hakko Kirin employees is that many have a strong sense of responsibility and work with enthusiasm. I also want to leverage my strengths, and I want to help build bridges between China and Japan.

#### Promoting Team Kyowa Hakko Kirin

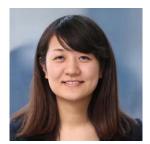
Hara: We have initiated global alliances in R&D, and globalization is moving forward within Kyowa Hakko Kirin. The next big step on the road to becoming a global specialty pharmaceutical company will be launching products in development overseas such as KW-0761, KW-6002 and KRN23. This course is shared among numerous employees around the world, and each employee in Japan must share it as well. That is an essential element of becoming a global specialty pharmaceutical company. **Yoshida:** The atmosphere at work is changing. There are now various ways to work, including systems for flexible working hours and working at home. Time flies when I am focusing on my work, and then suddenly a colleague reminds me that it's about time to go home. I feel strongly that we have an outstanding work environment that is filled with understanding. I am pleased the understanding and cooperation colleagues offer under an array of circumstances that help people to continue

working contributes to our becoming a global specialty pharmaceutical company. Xu: Our "Commitment to Life" is shared among Group companies overseas as well. I like the idea of building the best team ever. I came

to understand well the importance of cooperation by working as part of a team while gaining work experience. For example, I help with publicity programs to recruit new graduates, and conduct activities such as seminars at universities. These events cannot succeed without true cooperation among team members. I also believe we can achieve the goal of becoming a global specialty pharmaceutical company by building the best teams of Group employees from around the world.

### Let's build the best team ever.

Xiaobei Xu



Xiaobei Xu Human Resources Department

Joined in 2013. Born and raised in China, and began studying Japanese in junior high school. Experience studying in Japan while at university. Assigned to the Human Resources Department at the head office in Japan as one of the first employees recruited from abroad.

Note: Employee posts are as of April 1, 2015.



#### **Messages from Outside Directors**



Koichiro Nishikawa Director of the Board

# National Staff with High Competence Are the Key to Becoming a Global Specialty Pharmaceutical Company.

Since becoming a director in March 2014, I have been fulfilling my mission as an outside director by asking necessary questions at Board of Directors meetings from the viewpoint of general shareholders and increasing corporate value. Thanks to the sufficient information I asked for and was given by executive functions of Kyowa Hakko Kirin ("KHK") such as the Corporate Strategy and Planning Department, I was able to execute my responsibilities as an outside director.

During the past year, KHK has made use of my experience in decisions that increased its corporate value, such as the acquisition of Archimedes Pharma Limited. In addition, I visited major business facilities of KHK inside and outside Japan because I believe that first-hand knowledge is important to my participation in the management team. While deepening my understanding of KHK's businesses, I always sought chances to directly speak with employees. I strongly believe that people are KHK's greatest asset.

KHK is growing steadily while taking on the challenge of becoming a global specialty pharmaceutical company. Recruiting and developing national staff with high competence is key to facing this challenge. Fully making use of the talents of national staff is essential for KHK to become a global specialty pharmaceutical company. National staff with high managerial competence are not those who simply report that everything is fine to the head office in Japan, but those who have excellent cross-cultural communication skills and who are respected business leaders in their own country. To put it another way, the KHK Group's goal to become a global specialty pharmaceutical company means we offer national staff an exciting career path and I firmly believe we can do so.

#### I Will Share the "Commitment to Life" with All Employees to Increase Corporate Value.

I was involved in nursing care and medical problems in the United States for 30 years beginning in 1970. After returning to Japan, I became involved in education and management as president of Aomori University of Health and Welfare.

The U.S. population experienced rapid aging during the 1980s, and major health care reforms were implemented because of expanding health care costs. My experience in the U.S. coincided with the creation of a new health care framework, which parallels current developments in Japan. As health care reforms shortened patient hospital stays, I founded a home health care company and dealt with post-reform priorities and the social issues of an aging population.

When I returned to Japan, I taught at Oita Medical University and Aomori University of Health and Welfare. At the latter, I took part in education and university management as the first Chairperson of the Board of Trustees and President after privatization of the university. I implemented organizational reforms including personnel system reform, continuous quality improvement, and the introduction of third-party evaluations.

I am Kyowa Hakko Kirin's first female director. Moving beyond the lifetime employment system to create a flexible working environment is important to helping women excel and our company prosper. We need an environment where our employees and company are flexible. The goal of nurturing excellent employees has inarguable benefits for the company.

As an outside director of Kyowa Hakko Kirin, I want to harness my experience in taking on challenges in Japan and the United States to do everything I can to help the Kyowa Hakko Kirin Group increase its corporate value. I will use my varied experience to fulfill my responsibilities to the best of my ability.



Yoshiko Leibowitz Director of the Board

#### Board of Directors (As of April 1, 2015)



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

| NODU       | o Hanai, Th.D.  |
|------------|---|
| Apr. 1976: | Joined Kyowa Hakko Kogyo Co., Ltd.                    |
| Feb. 2003: | President and Chief Executive Officer,<br>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                       |

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



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



Executive Director of the Board Executive Vice President

#### Hiroyuki Kawai, Ph.D.

|            | Joined Kirin Brewery Company, Limited<br>General Manager, Development Division of<br>Pharmaceutical Division, Kirin Brewery |
|------------|---|
|            | Company, Limited  |
| Jul. 2007: | Director, Executive Officer,<br>Kirin Pharma Company, Limited   |
| Mar. 2008: | Representative Director, Executive Vice<br>President, Executive Officer,<br>Kirin Pharma Company, Limited                   |
| Oct. 2008: | Managing Executive Officer,<br>Kyowa Hakko Kirin Co., Ltd.  |
| Mar. 2010: | Director of the Board,<br>Managing Executive Officer,<br>Kyowa Hakko Kirin Co., Ltd.  |
| Mar. 2013: | Director of the Board, Senior Managing<br>Executive Officer, Kyowa Hakko Kirin Co., Ltd.                                    |
| Mar. 2014: | Executive Director of the Board, Executive Vice President, 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<br>Development Office, Hitachi, Ltd.  |
| Apr. 2001: | General Manager, Global Business<br>Development Division, Hitachi, Ltd.                               |
| Jun. 2003: | Executive Officer, Hitachi, Ltd.  |
| Jan. 2006: | Vice President and Executive Officer,<br>Hitachi, Ltd.  |
| Apr. 2007: | Senior Vice President and Executive<br>Officer, Hitachi, Ltd.   |
| Apr. 2010: | Senior Vice President and Executive<br>Officer, Hitachi Cable, Ltd.                                   |
| Apr. 2012: | Senior Advisor, Hitachi Research<br>Institute   |
| Jun. 2013: | International Affairs Committee member,<br>Japan Association of Athletics<br>Federations (to present) |
| Oct. 2013: | President, Japan Industrial Track & Field<br>Association (to present)                                 |
| Mar. 2014: | Director of the Board, Kyowa<br>Hakko Kirin Co., Ltd. (to present)                                    |



Director of the Board Managing Executive Officer

#### Kazuyoshi Tachibana

|            | Joined Kyowa Hakko Kogyo Co., Ltd.<br>General Manager, Pharmaceutical Strategic<br>Planning Division and Pharmaceutical<br>Manufacturing Strategy Department,<br>Kyowa Hakko Kogyo Co., Ltd. |
|------------|--|
| Jun. 2005: | Executive Officer,<br>Kyowa Hakko Kogyo Co., Ltd.  |
| Oct. 2008: | Executive Officer,<br>Kyowa Hakko Kirin Co., Ltd.  |
| Apr. 2009: | Managing Executive Officer,<br>Kyowa Hakko Kirin Co., Ltd.   |
| Jun. 2009: | Director of the Board,<br>Managing Executive Officer, Kyowa Hakko<br>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<br>Pharmaceutical Division, Kirin Brewery<br>Company, Limited |
| Jul. 2007: | Director, Executive Officer,<br>Kirin Pharma Company, Limited                                       |
| Oct. 2008: | Executive Officer,<br>Kyowa Hakko Kirin Co., Ltd.   |
| Mar. 2012: | Managing Executive Officer,<br>Kyowa Hakko Kirin Co., Ltd.  |
| Mar. 2014: | Director of the Board,<br>Managing Executive Officer, Kyowa Hakko<br>Kirin Co., Ltd. (to present)   |



Director of the Board (Outside Director)

#### Yoshiko Leibowitz

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



Director of the Board

#### Akihiro Ito

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

#### Glossary

#### **Diversity & Inclusion**

In 2010, we established an interdisciplinary, groupwide Diversity & Inclusion Project organization and have since implemented a variety of policies.

#### Web

#### Corporate governance

http://www.kyowa-kirin.com/about\_us/ corporate\_governance/

#### Disclosure policy

http://www.kyowa-kirin.com/investors/ disclosure\_policy/

#### Priorities

The Kyowa Hakko Kirin Group complies with relevant laws and regulations, and is further strengthening management functions and efficiency to become a global specialty pharmaceutical company (GSP). In recent years, we have appointed to the Board of Directors an outside director with extensive experience in managing global corporations and a female outside director who is a health care specialist. This has strengthened management supervision functions and enhanced our system for monitoring management from diverse perspectives. We also participate in executive committees and other functions at overseas subsidiaries. Other initiatives include using English as a working language and in publications.

In addition to these initiatives, we are responding to socioeconomic changes that have affected the Pharmaceuticals business over the past several years by strengthening management in terms of fairness and transparency. This will drive continuous growth in corporate value as a GSP that all stakeholders support. In particular, we are working to strengthen our governance system in compliance with the revised Companies Act and the Corporate Governance Code of Japan.

#### Challenges

Combining our resources and competencies and building a corporate governance system for maximizing their use are key to continuously increasing the corporate value of the Kyowa Hakko Kirin Group.

We want all stakeholders, from shareholders and investors to health care providers and patients, to benefit from increases in the corporate value of the Kyowa Hakko Kirin Group. We will therefore further enhance our websites and integrated reports to disclose appropriate, easily understood information at the appropriate time. We are also improving the quality of the dialogue through means such as bilaterally exchanging opinions.

Moreover, we intend to make use of the value of people with diverse and different backgrounds to energize our organization and engender innovation in order to succeed at enhancing corporate competitiveness. We will therefore further promote activities that contribute to diversity and inclusion.

The Kyowa Hakko Kirin Group will take full advantage of synergies to increase the Group's corporate value while continuing to enhance governance at Group companies.

#### Corporate Governance Summary

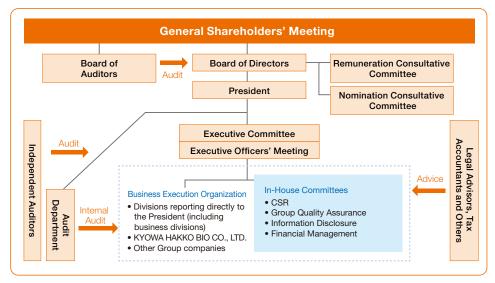
| Organizational structure                                    | Company with a board of company auditors  |
|---|---|
| Chairman of the Board of<br>Directors                       | Nobuo Hanai   |
| Number of directors*  | 8 (including 2 outside directors)   |
| Number of company auditors*                                 | 5 (including 4 outside company auditors)  |
| Number of independent<br>directors and company<br>auditors* | 2 outside directors, 2 outside company auditors   |
| Board of Directors meetings in 2014                         | Number of meetings: 18<br>Director attendance: 99 percent<br>Company auditor attendance: 99 percent   |
| Board of Company Auditors meetings in 2014                  | Number of meetings: 14<br>Company auditor attendance: 98.57 percent   |
| Director remuneration                                       | Total compensation for 2014 consisting of performance-linked base<br>compensation and stock options as medium-term stock-based compensation<br>(6 directors excluding outside directors): ¥250 million (base compensation: ¥220<br>million, stock options: ¥30 million) |
| Company auditor remuneration                                | Total compensation for 2014 (2 company auditors excluding outside company auditors): ¥22 million (base compensation: ¥22 million)   |
| Accounting auditor  | Ernst & Young ShinNihon LLC   |

\* As of March 20, 2015

#### Framework

Kyowa Hakko Kirin's management is organized around the Board of Directors and the Board of Company Auditors, which together carry out the functions stipulated by the Companies Act of Japan. The following governance entities have been established to enhance management functions and efficiency.

#### Corporate Governance Structure



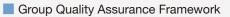
#### Quality Assurance Initiatives Based on the Group Quality Assurance Committee

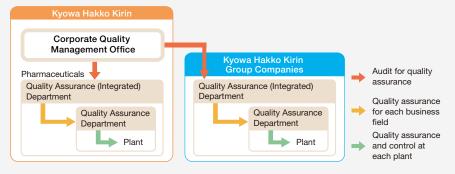
The Kyowa Hakko Kirin Group operates and improves its quality assurance system based on the deliberations and decisions of the Group Quality Assurance Committee. In addition, we confirm that our quality assurance system is functioning soundly using a three-tier structure that involves a quality assurance department at each plant, a quality assurance department for each business field, and the Corporate Quality Management Office that serves as a Groupwide quality supervision organization. In addition, the results of this system are reported to the Group Quality Assurance Committee. We implement quality assurance activities with a mindset that places the highest priority on customer safety while responding to changes in the business environment.

#### Kyowa Hakko Kirin Group Quality Policy

• We will maintain high quality and provide products and services that satisfy customers.

 We will comply with relevant laws and regulations and place the highest priority on safety to provide products and services that earn customer trust as a result of trustworthy quality assurance activities.





### Number of shareholders with voting rights

7,123 shareholders 92nd General Shareholders' Meeting (March 2015)

### Percentage of voting rights exercised

88,3% 92nd General Shareholders' Meeting (March 2015)

Number of individual interviews covering Kyowa Hakko Kirin (securities analysts, etc.)

237 cases

Meetings with overseas investors



#### Web

Clinical research policy

http://www.kyowa-kirin.co.jp/csr/fair\_ operating\_practices/clinical\_research\_ policy/ (Japanese only)

#### **Priorities**

The Kyowa Hakko Kirin Group recognizes the importance of dealing with social change as well as complying with laws and regulations as it works to maintain sound and normal relationships with the stakeholders it reaches through its businesses.

With business partners in more and more regions around the world, complying with each country's different laws and regulations and meeting the demands of a diverse international community have become crucial issues. As our globalization progresses, we have been addressing antibribery laws that have become more stringent and extraterritorial in recent years. We have also implemented CSR procurement to enable the stable supply of quality drugs.

In Japan, we are implementing reforms, education and awareness programs after reflecting upon issues concerning inappropriate participation in clinical research led by doctors. We are reconfirming our ethics as a corporate group associated with life and focusing on regaining trust so that patients can use our products with confidence.

#### Challenges

The global business environment is becoming more diverse and complex. The Kyowa Hakko Kirin Group is enhancing its competitiveness through an organization structured according to global standards and growing employee diversity.

In addition to promoting risk mitigation and more thorough compliance, our next mediumterm business plan, which begins in 2016, will enhance the organization, mechanisms and strengths that promote resilience in the face of internal and external changes. Specifically, we are further strengthening our globally capable risk management and compliance organization, and are steadily implementing the Groupwide risk management system we have formulated. Moreover, using objective indicators such as awareness surveys, we work to foster a corporate culture and workforce that can deal with changing social norms. We will continue to enhance the broadly based compliance mindset of executives and employees with the management philosophy and code of conduct set forth in our "Commitment to Life" as a foundation

#### Issues Concerning Inappropriate Participation in Clinical Research

Inappropriate participation by Kyowa Hakko Kirin personnel in clinical research related to renal anemia treatment NESP® came to light. The research was being conducted by doctors at a medical institute in Japan. We therefore established an external, third-party audit committee to objectively determine the facts of the case, identify wrong-doing, and prevent recurrence.

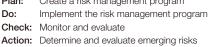
The audit did not identify any data manipulation or fabrication, or the use of the results of the clinical research in promotional activities. However, the audit did point out issues including provision of work despite the clinical research led by doctors, provision of research funds, and receipt of patient information. Moreover, the audit indicated that Kyowa Hakko Kirin was late to recognize the significance of this matter and passive in addressing it. Kyowa Hakko Kirin has formulated a Clinical Research Policy that incorporates the external audit committee's proposals to prevent recurrence. This involved restructuring the approach to funding and clinical research audits and formulating clear internal rules for supporting clinical research. Other revisions included enhancing the independence of the organization that internally audits promotional activities and materials.

Kyowa Hakko Kirin has reaffirmed the fundamentals of improving health care, advancing medicine and pharmaceutical science, and contributing to the health and well-being of people through clinical research. We will embrace transparency more than ever to prevent such incidents in the future, and will enforce thorough compliance.

#### **Risk Management**

The Kyowa Hakko Kirin Group is implementing a risk management system for all Group companies in order to consistently determine emerging risks and continue to evolve. The CSR Committee considers risk management basic policy and important measures and reports to the Board of Directors. In particular, the CSR Committee assesses key areas including quality, environment and safety, compliance, and information security in all Group companies. The CSR Committee also continuously improves the Group's business continuity plan (BCP) and programs to prevent crisis.





#### **Inculcating a Compliance Mindset**

As a member of the Kirin Group, each year we survey compliance and human rights awareness among all employees in Japan, and use the survey results for training and inculcation measures. Over the past three years, we have seen positive results in the survey comments of senior workplace managers, who have a major impact on the creation of the appropriate organizational culture, and in the direct comments and specific conduct of managers and leaders. In 2014, we also received guidance on handling personal information from an outside audit committee associated with the issue of inappropriate participation in clinical research led by doctors. We are working to prevent recurrence by rethinking relevant rules and standards and reconsidering the role of managers responsible for personal information in each division, and by enhancing education with e-learning and group training.

#### **Antibribery Initiatives**

We are enhancing our antibribery organization. Each Group company complies with Japan's Unfair Competition Prevention Law, the U.S. Foreign Corrupt Practices Act,<sup>1</sup> the U.K. Bribery Act,<sup>2</sup> 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.

The Kyowa Hakko Kirin Group has formulated an Antibribery and Anticorruption Policy and Antibribery Regulations, and has communicated them to Group companies together with communications from the president. In 2014, we assigned an antibribery manager and established a help desk at each Group company, established rules for each company, and provided implementation training for executives and employees. In July 2014, we initiated an antibribery and anticorruption organization, which we are now monitoring and auditing.



Asking a question at a lecture on preventing bribery 1. Foreign Corrupt Practices Act (FCPA)

2. Bribery Act (BA)

### Group companies with risk management systems

35 companies

(As of December 31, 2014)

The number of consolidated subsidiaries implementing risk management systems, excluding Archimedes Pharma Limited of the United Kingdom, which was acquired in August 2014.

### Number of consecutive years conducting a supplier survey

3 years

(2012-2014)

The goal of this survey is to better understand current conditions in order to promote CSR initiatives throughout the entire supply chain.

Number of compliance hotline inquiries

34 inquiries

### **Eleven-Year Selected Financial Data**

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries

For the years ended December 31, 2014, 2013, 2012, 2011 and 2010, the nine months ended December 31, 2009 and years ended March 31, 2005 to 2009

|  | 2014/12          | 2013/12       | 2012/12                 | 2011/12       |  |
|--|------------------|---------------|-------------------------|---------------|--|
| For the Year:  |                  |               |                         |               |  |
| Net sales  | ¥333,446         | ¥340,611      | ¥333,158                | ¥343,722      |  |
| Gross profit   | 205,904          | 212,761       | 210,690                 | 197,555       |  |
| Selling, general and administrative expenses             | 169,731          | 160,987       | 157,785                 | 150,940       |  |
| Operating income   | 36,173           | 51,773        | 52,905                  | 46,614        |  |
| Net income   | 15,898           | 30,078        | 24,199                  | 25,608        |  |
| Capital expenditures (including intangible fixed assets) | 29,487           | 35,183        | 27,808                  | 19,697        |  |
| Depreciation and amortization                            | 23,885           | 21,592        | 20,904                  | 22,833        |  |
| R&D expenses   | 47,737           | 43,682        | 44,808                  | 47,961        |  |
|  |                  |               |                         |               |  |
| Cash Flows:  |                  |               |                         |               |  |
| Net cash provided by operating activities                | ¥ 19,377         | ¥ 56,884      | ¥ 59,134                | ¥ 40,634      |  |
| Net cash (used in) provided by investing activities      | 16,805           | (77,163)      | (98,772)                | 18,460        |  |
| Net cash used in financing activities                    | (37,184)         | (12,579)      | (19,189)                | (30,740)      |  |
| Cash and cash equivalents at the end of the period       | 17,013           | 19,242        | 50,334                  | 107,555       |  |
| At Yoor End  |                  |               |                         |               |  |
| At Year-End:<br>Total current assets                     | ¥283,192         | ¥329,320      | ¥303,988                | ¥284,217      |  |
| Total assets   | 719,135          | 719,257       | 679,342                 | 658,873       |  |
| Total current liabilities                                | 85,182           | 85,076        | 85,774                  | 78,465        |  |
|  | 4,868            | 6,207         | 5,699                   | 6,042         |  |
| Interest-bearing debt<br>Total net assets                | 4,000<br>605,368 | 595,415       | 555,898                 | 540,023       |  |
|  |                  | 578,329       | ,                       | ,             |  |
| Total shareholders' equity <sup>2</sup>                  | 580,499          | ,             | 560,663                 | 554,856       |  |
| Number of employees                                      | 7,424            | 7,152         | 7,243                   | 7,229         |  |
| Per Share Data:  |                  |               |                         |               |  |
| Net income-basic <sup>3</sup>                            | ¥ 29.05          | ¥ 54.95       | ¥ 44.12                 | ¥45.16        |  |
| Net assets   | 1,105.4          | 1,085.2       | 1,013.6                 | 970.2         |  |
| Cash dividends   | 25               | 25            | 20                      | 20            |  |
|  |                  |               |                         |               |  |
| Common Stock Price Range (Per share):                    | ¥1,510           | ¥1,256        | ¥970                    | ¥953          |  |
| High<br>Low  | 1,006            | \$33          | <sup>+</sup> 970<br>757 | ÷955<br>628   |  |
|  | 1,000            | 000           | 101                     | 020           |  |
| Stock Information (Thousands of shares):                 |                  |               |                         |               |  |
| Number of common stock issued                            | 576,483          | 576,483       | 576,483                 | 576,483       |  |
| Weighted average number of common stock issued           | 547,348          | 547,391       | 548,449                 | 567,029       |  |
| Financial Ratios:  |                  |               |                         |               |  |
| Return on assets (ROA)                                   | 2.21             | 4.30          | 3.62                    | 3.78          |  |
| Operating return on assets                               | 5.03             | 7.40          | 7.91                    | 6.88          |  |
| Return on equity (ROE)                                   | 2.65             | 5.24          | 4.43                    | 4.73          |  |
|  | 84.13            | 82.58         | 4.43<br>81.68           | 4.73<br>81.79 |  |
| Equity ratio   | 04.13            | 02.50<br>1.05 | 1.03                    | 1.12          |  |
| Debt/equity ratio  |                  |               |                         |               |  |
| Operating income margin                                  | 10.85            | 15.20         | 15.88                   | 13.56         |  |
| EBITDA <sup>4</sup> (Millions of yen)                    | 64,101           | 83,190        | 78,160                  | 79,864        |  |
| Payout ratio⁵  | 54.4             | 34.8          | 32.8                    | 32.5          |  |

U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥120.53=U.S.\$1, the approximate exchange rate at December 31, 2014.
 Due to a change in accounting standards, figures for total shareholders' equity in the years ended March 31, 2007 and 2006 have been restated.
 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 intervent 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).

| Millions of yen  |          |          |          |          |          |          | Thousands of U.S. dollars <sup>1</sup> |
|------------------|----------|----------|----------|----------|----------|----------|--|
| 2010/12          | 2009/12  | 2009/3   | 2008/3   | 2007/3   | 2006/3   | 2005/3   | 2014/12                                |
|                  |          |          |          |          |          |          |  |
| ¥413,738         | ¥309,111 | ¥460,183 | ¥392,119 | ¥354,274 | ¥353,439 | ¥358,963 | \$2,766,504                            |
| 190,979          | 139,739  | 200,297  | 144,917  | 131,424  | 126,982  | 132,112  | 1,708,327                              |
| 145,568          | 111,496  | 154,910  | 105,527  | 100,725  | 101,448  | 98,605   | 1,408,210                              |
| 45,410           | 28,243   | 45,387   | 39,390   | 30,698   | 25,534   | 33,506   | 300,116                                |
| 22,197           | 8,797    | 11,726   | 23,477   | 12,694   | 16,273   | 17,931   | 131,902                                |
| 29,374           | 25,135   | 18,523   | 14,795   | 14,497   | 10,870   | 7,648    | 244,648                                |
| 22,188           | 17,003   | 18,779   | 14,346   | 10,006   | 9,788    | 10,565   | 198,170                                |
| 44,210           | 34,979   | 48,389   | 34,109   | 33,342   | 32,875   | 28,761   | 396,066                                |
|                  |          |          |          |          |          |          |  |
| ¥ 64,189         | ¥ 24,203 | ¥ 41,069 | ¥ 30,713 | ¥ 23,380 | ¥ 14,303 | ¥ 30,104 | \$ 160,766                             |
| (32,373)         | (13,246) | (3,981)  | (9,492)  | (8,493)  | (1,795)  | (8,104)  | 139,432                                |
| (14,446)         | (16,906) | (20,978) | (13,499) | (24,417) | (5,139)  | (9,116)  | (308,507)                              |
| 79,882           | 63,745   | 69,286   | 44,118   | 36,613   | 45,820   | 37,817   | 141,158                                |
|                  |          |          |          |          |          |          |  |
| ¥288,852         | ¥276,587 | ¥279,475 | ¥232,661 | ¥214,352 | ¥212,985 | ¥210,341 | \$2,349,557                            |
| 695,862          | 695,268  | 699,041  | 394,081  | 378,870  | 384,381  | 374,492  | 5,966,442                              |
| 102,483          | 110,080  | 108,522  | 111,743  | 106,565  | 94,148   | 103,489  | 706,732                                |
| 7,515            | 13,228   | 13,540   | 12,790   | 13,136   | 12,216   | 12,193   | 40,391                                 |
| 544,992          | 540,343  | 543,070  | 256,758  | 244,082  | 257,491  | _        | 5,022,556                              |
| 553,172          | 539,304  | 547,203  | 239,328  | 220,428  | 232,621  | 235,439  | 4,816,222                              |
| 7,484            | 7,436    | 7,256    | 6,073    | 5,756    | 5,800    | 5,960    |  |
|                  |          |          |          |          |          |          |  |
| Yen              |          |          |          |          |          |          | U.S. dollars <sup>1</sup>              |
| ¥38.96           | ¥15.40   | ¥20.42   | ¥58.99   | ¥31.31   | ¥38.34   | ¥41.67   | \$0.241                                |
| 954.6            | 940.8    | 938.4    | 639.7    | 607.5    | 604.9    | 556.3    | 9.171                                  |
| 20               | 15       | 20       | 10       | 10       | 10       | 10       | 0.207                                  |
|                  |          |          |          |          |          |          |  |
| ¥1,040           | ¥1,178   | ¥1,235   | ¥1,430   | ¥1,154   | ¥946     | ¥864     | \$12.53                                |
| 773              | 793      | 586      | 933      | 722      | 656      | 661      | 8.35                                   |
|                  |          |          |          |          |          |          |  |
| 576,483          | 576,483  | 576,483  | 399,243  | 399,243  | 434,243  | 434,243  |  |
| 569,711          | 570,935  | 574,083  | 397,716  | 405,270  | 422,919  | 427,635  |  |
| %, except EBITDA |          |          |          |          |          |          |  |
| 3.19             | 1.26     | 1.62     | 6.07     | 3.33     | 4.29     | 4.88     |  |
| 6.53             | 4.05     | 6.26     | 10.19    | 8.04     | 6.73     | 9.11     |  |
| 4.11             | 1.64     | 2.17     | 9.47     | 5.1      | 6.63     | 7.79     |  |
| 78.16            | 77.07    | 77.04    | 64.53    | 63.8     | 66.55    | 62.87    |  |
| 1.38             | 2.47     | 2.51     | 5.03     | 5.43     | 4.78     | 5.18     |  |
| 10.98            | 9.14     | 9.86     | 10.05    | 8.67     | 7.22     | 9.33     |  |
| 74,614           | 45,056   | 60,098   | 53,162   | 33,771   | 34,846   | 40,707   |  |
| 36.2             | 54.3     | 53.8     | 16.9     | 31.9     | 26.1     | 24.0     |  |
|                  |          |          |          |          |          |          |  |

### **Management's Discussion and Analysis**

All amounts are rounded down.

#### Subsidiaries Included in the Scope of Consolidation

As of December 31, 2014, the number of consolidated subsidiaries increased by 13 from a year earlier to 49. Archimedes Pharma Limited of the United Kingdom and its 12 subsidiaries were added to the scope of consolidation as a result of the acquisition of all Archimedes Pharma Limited shares.

#### **Income and Expenses**

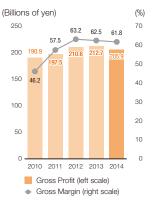
#### **Net Sales**

For the year ended December 31, 2014, net sales decreased 2.1 percent, or ¥7.1 billion, compared with the previous year to ¥333.4 billion. Sales decreased in the Pharmaceuticals segment due to reductions in NHI reimbursement prices and lower revenue from technology out-licensing. In the Bio-Chemicals segment, domestic sales of active pharmaceutical ingredients (APIs) were firm, and sales increased due to the foreign exchange impact of the deprecation of the yen.

#### Cost of Sales, SG&A Expenses and Operating Income

Cost of sales decreased 0.2 percent to ¥127.5 billion, while gross profit decreased 3.2 percent to ¥205.9 billion. The gross margin decreased 0.7 percentage points to 61.8 percent from 62.5 percent in the previous year.

#### **Gross Profit**



#### SG&A Expenses



Selling, general and administrative (SG&A) expenses increased 5.4 percent to ¥169.7 billion due to factors including the consolidation of Archimedes Pharma and higher R&D expenses, which increased 9.3 percent compared with the previous year to ¥47.7 billion. The ratio of R&D expenses to net sales increased 1.5 percentage points to 14.3 percent from 12.8 percent.

As a result of the above, operating income decreased 30.1 percent compared with the previous year to ¥36.1 billion. The operating income margin decreased 4.4 percentage points to 10.8 percent from 15.2 percent.

#### **Other Revenue (Expenses)**

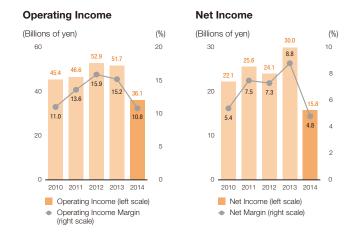
Net other expenses increased to ¥8.9 billion from ¥2.0 billion. Net other expenses increased in fiscal 2014 absent the gain of ¥3.2 billion on sales of affiliates' stock in 2013.

#### **Income Taxes**

Income taxes decreased 42.1 percent to ¥11.3 billion. The effective tax rate calculated using income before income taxes increased 2.2 percentage points to 41.6 percent from 39.4 percent. The effective tax rate calculated using income before income taxes and amortization of goodwill decreased 3.7 percentage points to 28.3 percent from 32.0 percent.

#### Net Income

Consequently, net income decreased 47.1 percent to  $\pm$ 15.8 billion, and the net margin decreased 4.0 percentage points to 4.8 percent from 8.8 percent.



#### **Performance by Business Segment**

Net sales by reportable segment and segment income (loss) are presented in the table below. Segment performance figures include intersegment transactions.

The Kyowa Hakko Kirin Group revised its business segments in 2013. The Other segment was eliminated and the affiliates formerly included in this segment are now included in the Pharmaceuticals segment.

#### Yearly Information by Reportable Segment

|                        |          |          | Millions of yen   |          |          | Thousands of<br>U.S. dollars <sup>1</sup> |
|------------------------|----------|----------|-------------------|----------|----------|---|
|                        | 2014     | 2013     | 2012 <sup>2</sup> | 2011     | 2010     | 2014                                      |
| Net sales:             |          |          |                   |          |          |   |
| Pharmaceuticals        | ¥253,011 | ¥261,007 | ¥259,365          | ¥229,339 | ¥210,362 | \$2,099,160                               |
| Bio-Chemicals          | 83,970   | 82,919   | 76,966            | 77,563   | 84,236   | 696,676                                   |
| Chemicals              | _        | —        | —                 | 33,550   | 130,018  | -   |
| Other                  | _        | —        | —                 | 10,659   | 10,499   | —   |
| Adjustments            | (3,535)  | (3,315)  | (3,172)           | (7,390)  | (21,377) | (29,332)                                  |
| Consolidated total     | ¥333,446 | ¥340,611 | ¥333,158          | ¥343,722 | ¥413,738 | \$2,766,504                               |
|                        |          |          |                   |          |          |   |
| Segment income (loss): |          |          |                   |          |          |   |
| Pharmaceuticals        | ¥29,061  | ¥46,135  | ¥50,749           | ¥41,314  | ¥35,857  | \$241,111                                 |
| Bio-Chemicals          | 7,277    | 5,667    | 2,127             | 2,896    | 3,275    | 60,379                                    |
| Chemicals              | _        | —        | _                 | 2,135    | 5,678    | —   |
| Other                  | _        | —        | —                 | 360      | 363      | _   |
| Adjustments            | (165)    | (29)     | 28                | (92)     | 235      | (1,374)                                   |
| Consolidated total     | ¥36,173  | ¥51,773  | ¥52,905           | ¥46,614  | ¥45,410  | \$300,116                                 |

Notes: 1. U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥120.53=U.S.\$1, the approximate exchange rate at December 31, 2014.

2. Segment information for 2012 has been restated to reflect the change in business segments discussed above.

#### Pharmaceuticals

In the core Pharmaceuticals segment, net sales decreased 3.1 percent to ¥253.0 billion. Segment income decreased 37.0 percent to ¥29.0 billion.

Domestic sales decreased year on year due to the impact of downward drug price revisions. Sales of our core ethical drug NESP®, a long-acting erythropoiesis-stimulating agent, were solid. However, sales decreased year on year because of the effect of less airborne pollen on the sales of ALLELOCK®, an antiallergic agent, and Patanol® antiallergic eyedrops as well as the downward drug price revisions on ALLELOCK®, and the impact of ongoing market penetration for generic pharmaceuticals. Sales also decreased for other long-listed products including CONIEL®, a treatment for hypertension and angina pectoris; GRAN®, a G-CSF product; and DEPAKENE®, an entiepileptic.

Sales of other products increased steadily. These included NOURIAST®, an antiparkinsonian agent; REGPARA®, a calcium receptor agonist; Abstral®, a treatment for managing breakthrough cancer pain; Fentos®, a transdermal long-acting pain relief patch; ASACOL®, a treatment for ulcerative colitis; and ONGLYZA®, a treatment for type 2 diabetes.

Market penetration proceeded well for Dovobet<sup>®</sup>, a treatment for psoriasis vulgaris that we launched jointly with LEO Pharma K.K in September 2014. We also launched G-Lasta<sup>®</sup>, a sustained-duration G-CSF product, in November 2014.

Revenues from exports of pharmaceuticals and technology outlicensing decreased from the previous year. Exports were steady but out-licensing revenue decreased.

At ProStrakan, sales of core products including Abstral®, a treatment for managing breakthrough cancer pain, were steady. ProStrakan acquired Archimedes Pharma and its 12 subsidiaries on August 5, 2014, meaning ProStrakan's results for fiscal 2014 include these 13 companies for the period from August 5, 2014 to December 31, 2014. As a result, ProStrakan's net sales after the consolidation of Archimedes Pharma increased 34.6 percent compared with the previous fiscal year to ¥31.3 billion. Operating loss (post amortization of goodwill and sales rights) was ¥22 million, compared with operating income of ¥0.2 billion for the previous fiscal year.

#### **Bio-Chemicals**

In the Bio-Chemicals segment, sales increased 1.3 percent to ¥83.9 billion, and segment income increased 28.4 percent to ¥7.2 billion.

In Japan, sales of APIs in pharmaceutical and medical markets increased.

In the health care business, mail-order sales of *ornithine* and other products grew steadily. We also launched "Fermented Coenzyme Q10 EX," a high-potency supplement, in November 2014.

Sales of food and beverage ingredients decreased because unseasonable summer weather cut into sales of beverage ingredients.

Overseas sales increased from the previous year mainly due to the foreign exchange impact of the depreciation of the yen. Sales in the United States increased year on year supported by higher sales of amino acids for supplements. In Europe, infusion-use amino acid sales volume was essentially unchanged year on year, but sales of APIs and products for other applications increased. The depreciation of the yen also contributed to the year-on-year increase in sales. In Asia, the depreciation of the yen resulted in year-on-year sales growth, even though infusion-use amino acid sales volume in China decreased because customer response to pharmaceutical business regulations reduced production, which cooled the rapidly growing demand of 2013.

#### **Quarterly Information by Reportable Segment**

|             | Millions of yen   |  |  |   |  |  |   |   |   |  |  |  |  |
|-------------|---|--|--|---|--|--|---|---|---|--|--|--|--|
|             |   | 2014   |  |   |  |  | 2013  |   |   |  |  |  |  |
| 1st Quarter | 2nd Quarter   | 3rd Quarter  | 4th Quarter  | 12 months   | 1st Quarter  | 2nd Quarter  | 3rd Quarter   | 4th Quarter   | 12 months   |  |  |  |  |
|             |   |  |  |   |  |  |   |   |   |  |  |  |  |
| ¥63,182     | ¥56,355   | ¥59,135  | ¥74,338  | ¥253,011  | ¥67,422  | ¥62,527  | ¥62,831   | ¥68,225   | ¥261,007  |  |  |  |  |
| 23,589      | 20,465  | 18,706   | 21,208   | 83,970  | 19,997   | 21,209   | 20,378  | 21,333  | 82,919  |  |  |  |  |
| 86,771      | 76,820  | 77,842   | 95,547   | 336,982   | 87,420   | 83,737   | 83,210  | 89,559  | 343,927   |  |  |  |  |
| (692)       | (1,001)   | (804)  | (1,037)  | (3,535)   | (750)  | (699)  | (814)   | (1,051)   | (3,315)   |  |  |  |  |
| ¥86,079     | ¥75,819   | ¥77,037  | ¥94,510  | ¥333,446  | ¥86,669  | ¥83,037  | ¥82,396   | ¥88,507   | ¥340,611  |  |  |  |  |
|             |   |  |  |   |  |  |   |   |   |  |  |  |  |
|             |   |  |  |   |  |  |   |   |   |  |  |  |  |
| ¥ 9,437     | ¥4,741  | ¥6,433   | ¥ 8,447  | ¥29,061   | ¥13,061  | ¥11,064  | ¥12,837   | ¥9,172  | ¥46,135   |  |  |  |  |
| 3,052       | 1,168   | 1,444  | 1,611  | 7,277   | 1,480  | 1,622  | 1,406   | 1,158   | 5,667   |  |  |  |  |
| 12,490      | 5,910   | 7,878  | 10,059   | 36,338  | 14,541   | 12,686   | 14,243  | 10,330  | 51,803  |  |  |  |  |
| (43)        | 53  | (11)   | (164)  | (165)   | (76)   | 24   | (11)  | 33  | (29)  |  |  |  |  |
| ¥12,447     | ¥5,964  | ¥7,866   | ¥ 9,895  | ¥36,173   | ¥14,465  | ¥12,711  | ¥14,232   | ¥10,364   | ¥51,773   |  |  |  |  |
|             | ¥63,182<br>23,589<br>86,771<br>(692)<br>¥86,079<br>¥ 9,437<br>3,052<br>12,490<br>(43) | ¥63,182         ¥56,355           23,589         20,465           86,771         76,820           (692)         (1,001)           ¥86,079         ¥75,819           ¥9,437         ¥4,741           3,052         1,168           12,490         5,910           (43)         53 | 1st Quarter         2nd Quarter         3rd Quarter           ¥63,182         ¥56,355         ¥59,135           23,589         20,465         18,706           86,771         76,820         77,842           (692)         (1,001)         (804)           ¥86,079         ¥75,819         ¥77,037           ¥9,437         ¥4,741         ¥6,433           3,052         1,168         1,444           12,490         5,910         7,878           (43)         53         (11) | 1st Quarter         2nd Quarter         3rd Quarter         4th Quarter           ¥63,182         ¥56,355         ¥59,135         ¥74,338           23,589         20,465         18,706         21,208           86,771         76,820         77,842         95,547           (692)         (1,001)         (804)         (1,037)           ¥86,079         ¥75,819         ¥77,037         ¥94,510           ¥         9,437         ¥4,741         ¥6,433         ¥8,447           3,052         1,168         1,444         1,611           12,490         5,910         7,878         10,059           (43)         53         (11)         (164) | 2014           1st Quarter         2nd Quarter         3rd Quarter         4th Quarter         12 months           ¥63,182         ¥56,355         ¥59,135         ¥74,338         ¥253,011           23,589         20,465         18,706         21,208         83,970           86,771         76,820         77,842         95,547         336,982           (692)         (1,001)         (804)         (1,037)         (3,535)           ¥86,079         ¥75,819         ¥77,037         ¥94,510         ¥333,446           #         4         4         4         4         4           ¥9,437         ¥4,741         ¥6,433         ¥ 8,447         ¥29,061           3,052         1,168         1,444         1,611         7,277           12,490         5,910         7,878         10,059         36,338           (43)         53         (11)         (164)         (165) | 2014         2014           1st Quarter         2nd Quarter         3rd Quarter         4th Quarter         12 months         1st Quarter           ¥63,182         ¥56,355         ¥59,135         ¥74,338         ¥253,011         ¥67,422           23,589         20,465         18,706         21,208         83,970         19,997           86,771         76,820         77,842         95,547         336,982         87,420           (692)         (1,001)         (804)         (1,037)         (3,535)         (750)           ¥86,079         ¥75,819         ¥77,037         ¥94,510         ¥333,446         ¥86,669           ¥         9,437         ¥4,741         ¥6,433         ¥ 8,447         ¥29,061         ¥13,061           3,052         1,168         1,444         1,611         7,277         1,480           12,490         5,910         7,878         10,059         36,338         14,541           (43)         53         (11)         (164)         (165)         (76) | 2014         1st Quarter         2nd Quarter         3rd Quarter         4th Quarter         12 months         1st Quarter         2nd Quarter           ¥63,182         ¥56,355         ¥59,135         ¥74,338         ¥253,011         ¥67,422         ¥62,527           23,589         20,465         18,706         21,208         83,970         19,997         21,209           86,771         76,820         77,842         95,547         336,982         87,420         83,737           (692)         (1,001)         (804)         (1,037)         (3,535)         (750)         (699)           ¥86,079         ¥75,819         ¥77,037         ¥94,510         ¥333,446         ¥86,669         ¥83,037           ¥         9,437         ¥4,741         ¥6,433         ¥ 8,447         ¥29,061         ¥13,061         ¥11,064           3,052         1,168         1,444         1,611         7,277         1,480         1,622           12,490         5,910         7,878         10,059         36,338         14,541         12,686           (43)         53         (11)         (164)         (165)         (76)         24 | 2014         2013           1st Quarter         2nd Quarter         3rd Quarter         4th Quarter         12 months         1st Quarter         2nd Quarter         3rd Quarter           ¥63,182         ¥56,355         ¥59,135         ¥74,338         ¥253,011         ¥67,422         ¥62,527         ¥62,831           23,589         20,465         18,706         21,208         83,970         19,997         21,209         20,378           86,771         76,820         77,842         95,547         336,982         87,420         83,737         83,210           (692)         (1,001)         (804)         (1,037)         (3,535)         (750)         (699)         (814)           ¥86,079         ¥75,819         ¥77,037         ¥94,510         ¥33,446         ¥86,669         ¥83,037         ¥82,396           ¥         9,437         ¥4,741         ¥6,433         ¥ 8,447         ¥29,061         ¥13,061         ¥11,064         ¥12,837           3,052         1,168         1,444         1,611         7,277         1,480         1,622         1,406           12,490         5,910         7,878         10,059         36,338         14,541         12,686         14,243 | 2014         2013           1st Quarter         2nd Quarter         3rd Quarter         4th Quarter         12 months         1st Quarter         2nd Quarter         3rd Quarter         4th Quarter           ¥63,182         ¥56,355         ¥59,135         ¥74,338         ¥253,011         ¥67,422         ¥62,527         ¥62,831         ¥68,225           23,589         20,465         18,706         21,208         83,970         19,997         21,209         20,378         21,333           86,771         76,820         77,842         95,547         336,982         87,420         83,737         83,210         89,559           (692)         (1,001)         (804)         (1,037)         (3,535)         (750)         (699)         (814)         (1,051)           ¥86,079         ¥75,819         ¥77,037         ¥94,510         ¥333,446         ¥86,669         ¥83,037         ¥82,396         ¥88,507           ¥9,437         ¥4,741         ¥6,433         ¥ 8,447         ¥29,061         ¥13,061         ¥11,064         ¥12,837         ¥9,172           3,052         1,168         1,444         1,611         7,277         1,480         1,622         1,406         1,158           12,490         < |  |  |  |  |

#### Sales by Geographic Segment (Year ended December 31, 2014)

|          | Millions of yen      |         |         |                          |          |  |  |  |  |  |  |
|----------|----------------------|---------|---------|--------------------------|----------|--|--|--|--|--|--|
| Japan    | America <sup>1</sup> | Europe  | Asia    | Other areas <sup>2</sup> | Total    |  |  |  |  |  |  |
| ¥239,241 | ¥21,695              | ¥45,701 | ¥25,886 | ¥921                     | ¥333,446 |  |  |  |  |  |  |
|          |                      |         |         |                          |          |  |  |  |  |  |  |

1. North America, Latin America

2. Oceania, Africa

#### **Cash Flow**

Cash and cash equivalents as of December 31, 2014 decreased ¥2.2 billion from a year earlier to ¥17.0 billion.

Net cash provided by operating activities was ¥19.3 billion, a decrease of 65.9 percent compared with the previous year. The main source of cash was income before income taxes and minority interests of ¥27.2 billion. Depreciation and amortization totaled ¥23.8 billion and amortization of goodwill totaled ¥12.8 billion. The main uses of cash were contribution to employee's retirement benefits trust of ¥19.0 billion, income taxes paid of ¥16.8 billion, and an increase of ¥12.0 billion in inventories.

Net cash provided by investing activities was ¥16.8 billion,

compared with net cash used in investing activities of ¥77.1 billion in the previous fiscal year. Principal uses of cash included ¥34.6 billion for the purchase of property, plant, and equipment, and intangible assets, and ¥14.5 billion for purchase of shares of subsidiaries resulting from the acquisition of Archimedes Pharma. Principal sources of cash included a decrease of ¥68.3 billion in short-term loans receivable.

Net cash used in financing activities increased 195.6 percent to ¥37.1 billion. Principal uses of cash included a net decrease of ¥23.4 billion in short-term loans payable resulting from the acquisition of Archimedes Pharma, and cash dividends paid of ¥13.6 billion.

Total net assets increased ¥9.9 billion from the previous year-end to ¥605.3 billion, largely reflecting net income and foreign currency

As a result, the equity ratio increased 1.5 percentage points to

84.1 percent. Fiscal integrity remained high, as the debt/equity ratio

translation adjustments. Factors reducing net assets included

Return on equity (ROE) decreased to 2.65 percent from 5.24

decreased to 2.21 percent from 4.30 percent. Operating return on assets decreased to 5.03 percent from 7.40 percent. Earnings

before income tax, interest, depreciation, and amortization (EBITDA)

percent for the previous year, while return on assets (ROA)

#### **Financial Position**

#### Assets

Total assets as of December 31, 2014 decreased ¥0.1 billion from a year earlier to ¥719.1 billion. Total current assets decreased ¥46.1 billion to ¥283.1 billion. Principal factors were a decrease in short-term loans receivable to parent company Kirin Holdings Company, Limited, offset by increases in inventories and notes and accounts receivable – trade.

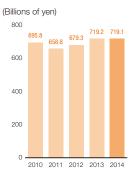
Total property, plant and equipment, net, increased ¥13.9 billion, to ¥151.8 billion. Investments and other assets increased ¥32.0 billion to ¥284.0 billion because of an increase in intangible assets including goodwill and sales rights resulting from the acquisition of Archimedes Pharma.

#### Liabilities

Total liabilities decreased ¥10.0 billion from the end of the previous year to ¥113.7 billion. Factors including a decrease in provision for retirement benefits due to cash contribution of ¥19.0 billion to retirement benefits trusts more than offset an increase in deferred tax liabilities.

Interest-bearing debt decreased 21.5 percent, or ¥1.3 billion, to ¥4.8 billion.

#### **Total Assets**



#### Interest-Bearing Debt



#### Total Shareholders' Equity

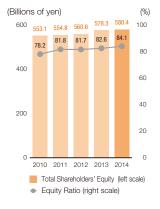
**Net Assets** 

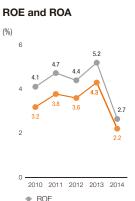
payment of cash dividends.

was unchanged at 0.8 percent.

**Performance Indicators** 

decreased 22.9 percent to ¥64.1 billion.





<sup>+</sup> ROA



0

2010 2011 2012 2013 2014

#### **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)**

Our policy for capital expenditures is to invest strategically while considering the balance between capital expenditures and depreciation and amortization.

Capital expenditures during the year ended December 31, 2014 decreased 16.2 percent, or ¥5.6 billion, compared with the previous year to ¥29.4 billion. Significant investments included the acquisition of sales rights in the Pharmaceuticals business. Depreciation and amortization increased 10.6 percent, or ¥2.2 billion, to ¥23.8 billion.

The table below presents a breakdown of capital expenditures and depreciation and amortization.

#### **R&D Expenses**

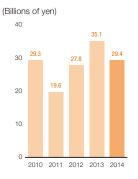
R&D expenses increased 9.3 percent to ¥47.7 billion. As a percentage of consolidated net sales, R&D expenses increased 1.5 percentage points to 14.3 percent from 12.8 percent for the previous year.

R&D expenses in the Pharmaceuticals segment totaled ¥44.0 billion and accounted for 92.3 percent of total R&D expenses. As a percentage of Pharmaceuticals segment sales, R&D expenses increased 1.9 percentage points to 17.4 percent. R&D expenses in the Bio-Chemicals segment were ¥3.6 billion.

#### Breakdown of Capital Expenditures and Depreciation and Amortization

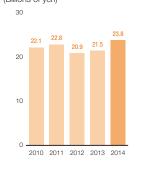
|                    |         | Millions of yen |            |         |         |                               |         |         |         |         |  |  |  |  |
|--------------------|---------|-----------------|------------|---------|---------|-------------------------------|---------|---------|---------|---------|--|--|--|--|
|                    |         | Capital Ex      | penditures |         |         | Depreciation and Amortization |         |         |         |         |  |  |  |  |
|                    | 2014    | 2013            | 2012       | 2011    | 2010    | 2014                          | 2013    | 2012    | 2011    | 2010    |  |  |  |  |
| Pharmaceuticals    | ¥17,012 | ¥22,921         | ¥18,357    | ¥11,886 | ¥19,251 | ¥17,075                       | ¥14,966 | ¥14,625 | ¥15,339 | ¥10,733 |  |  |  |  |
| Bio-Chemicals      | 12,476  | 12,261          | 9,454      | 7,482   | 7,603   | 6,811                         | 6,627   | 6,280   | 6,457   | 6,731   |  |  |  |  |
| Chemicals          | -       | _               | _          | 317     | 2,504   | -                             | _       | _       | 974     | 4,652   |  |  |  |  |
| Other              | -       | —               | _          | 11      | 15      | -                             | _       | _       | 64      | 73      |  |  |  |  |
| Adjustments        | (1)     | _               | (3)        | _       | (1)     | (1)                           | (1)     | (1)     | (2)     | (2)     |  |  |  |  |
| Consolidated total | ¥29,487 | ¥35,183         | ¥27,808    | ¥19,697 | ¥29,374 | ¥23,885                       | ¥21,592 | ¥20,904 | ¥22,833 | ¥22,188 |  |  |  |  |

#### **Capital Expenditures**

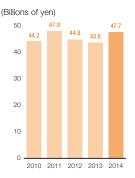


#### **Depreciation and Amortization**



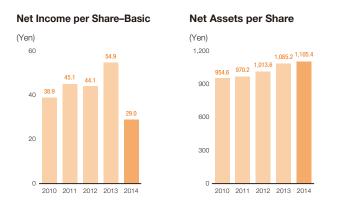


#### **R&D** Expenses



#### **Per Share Data**

Net income per share – basic was ¥29.05, compared with ¥54.95 for the previous year. Net income per share before amortization of goodwill was ¥45.95. Net assets per share as of December 31, 2014 increased to ¥1,105.4 from ¥1,085.2 a year earlier.



#### **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. Under this philosophy, through new drug development we are aiming to become a global specialty pharmaceutical company.

The Kyowa Hakko Kirin Group formulated its three-year Medium-Term Business Plan – 2013 to 2015 with the year ended December 31, 2013 as the first year of the plan. Our targets for the year ending December 31, 2015, the final year of the plan, were net sales of ¥355.0 billion and operating income of ¥55.0 billion. However, we have revised our targets for the year ending December 31, 2015 to net sales of ¥354.0 billion and operating income of ¥41.5 billion because revenue from technology out-licensing is below plan and R&D expenses have increased.

The theme of Medium-Term Business Plan – 2013 to 2015 is to become a global specialty pharmaceutical company as we implement three key initiatives:

- Further strengthen competitiveness in Japan through our categorybased strategy
- Expand our business base in the United States, Europe and Asia and aim to become a global specialty pharmaceutical company
- Strengthen the revenue base of our Bio-Chemicals business The operating environment of the pharmaceuticals industry is

changing significantly and rapidly, and becoming increasingly competitive due to factors including a decrease in drug discovery success rates and stricter approval review processes in Japan and overseas, and progress with measures to reduce health care costs. In particular, measures to promote generic drug use in Japan are causing generic drugs to replace long-listed drugs more rapidly than assumed. Moreover, the share of generic drugs is steadily increasing as growth slows in the domestic pharmaceutical market. R&D-driven pharmaceutical companies must transform their source of earnings from existing long-listed drugs to new drugs and from the domestic market to global markets.

In this environment, Kyowa Hakko Kirin will promote its categorybased strategy to further strengthen competitiveness in Japan and support global business development and sustained growth. In the four categories of nephrology, oncology, immunology/allergy and CNS, we will strengthen cooperation consistently on every function from R&D to manufacturing and sales. In addition to steadily launching new drugs from our extensive pipeline, we are aiming to build an effective marketing system using our high level of expertise to maximize sales

#### 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 year ended December 31, 2014, the same as in the previous year.

and win trust among medical practitioners.

With the hurdles in launching new drugs becoming ever higher, Kyowa Hakko Kirin launched psoriasis vulgaris treatment Dovobet<sup>®</sup>, which is in-licensed from Leo Pharma, in September 2014, and launched sustained-duration G-CSF product G-Lasta<sup>®</sup> in November 2014. Aiming to maximize the value of drugs we are already marketing, we launched NESP<sup>®</sup> Injection 5µg Plastic Syringe in January 2014, which we expect to contribute to meticulous, individually-targeted therapy for anemia. We also launched Topina<sup>®</sup> Fine Granules 10%, an antiepileptic agent expected to improve drug adherence<sup>1</sup> among children, elderly people and other patients who may have trouble swallowing tablets. We intend to rely on our category-based strategy to accurately determine the unmet medical needs of health care providers in developing new drugs and nurturing existing products.

On April 1, 2014, we consolidated and reorganized our research and development divisions to establish the R&D Division, which has unified responsibility for operations from research through development. In this division, we have established R&D units for different categories, which will operate under a unified structure in drug discovery research, clinical development and nurturing drugs in their respective categories. We believe that this organizational reform will speed up research and development and enhance our success rate. By creating new drugs and nurturing existing products that address the needs of health care providers, we will more quickly maximize the value of our products.

We are steadily maximizing the value of our strength in antibody drugs through progress and cooperation in clinical development in Japan and overseas. We will also maintain our focus on strengthening drug discovery by combining Kyowa Hakko Kirin's knowledge and technologies with those of external entities and implementing open innovation to address unmet medical needs.

In overseas business, we are expanding our business bases in Europe, the United States and Asia with the aim of becoming a global specialty pharmaceutical company. In August 2014, we further strengthened our business in Europe by acquiring Archimedes Pharma and its strength in the therapeutic areas of pain, oncology and critical care<sup>2</sup> through ProStrakan. We will actively promote ProStrakan's business model of in-licensing late-stage development and marketed products while also building a marketing organization in the United States that is aligned with launches of products we are developing globally such as POTELIGEO<sup>®</sup>, Kyowa Hakko Kirin's first therapeutic antibody. In Asia, our top priority is the reorganization of our business base for stable future growth in China. We are implementing business strategies at subsidiaries in Korea, Taiwan, Singapore, Thailand and other growing economies. These strategies reflect the prevailing conditions in each country.

We are energetically developing the biosimilars business, a joint venture with FUJIFILM Corporation, by carefully considering changes in the market environment with the objective of globally marketing drugs that offer outstanding reliability, quality and cost effectiveness.

In our diagnostics business, we will provide advanced diagnostics products and instruments necessary for the treatment of various illnesses through Kyowa Medex, and will work to strengthen our business in Japan while moving forward in building a foundation in the Chinese market. Personalized medicine and preventive treatment are key trends that will become increasingly important in the diagnostics business, which aims to expand the value of its operations by developing companion diagnostics through synergy with the Pharmaceuticals business.

In the Bio-Chemicals business, we aim for sustained growth in the pharmaceutical, medical and health care fields as a biotech group that has both fermentation and synthesis technologies. We will therefore create new value and strengthen our revenue base by developing innovative technologies.

We are steadily reinforcing, reorganizing and improving the Group's overseas and domestic production facilities, including the Yamaguchi Production Center, Daiichi Fine Chemical Co., Ltd. and BioKyowa Inc. in the United States in order to enhance cost competitiveness, create a business structure that is resistant to the impact of exchange rate movements, and strengthen production capacity to respond to increased global demand for amino acids. Among these initiatives, we are making steady progress in constructing a new manufacturing facility in Thailand with the aim of starting commercial operations in the second half of 2015.

In April 2015, Japan will introduce a new system based on scientific evidence for making functional claims about products such as health foods. Our domestic health care business will address this new system by developing materials that are functional and safe. In addition, we will cooperate with other Kirin Group companies to devise approaches for making functional claims that customers can easily understand. In the mail-order business centered on *ornithine*, we will work to further enhance product awareness through effective advertising and provide unique materials that customers can use with confidence.

Kyowa Hakko Kirin must cultivate an organization and corporate culture to conscientiously fulfill corporate social responsibilities, such as compliance and quality assurance, to realize its goal of becoming a global specialty pharmaceutical company. In addition, we have responded to the problem of improper involvement by Kyowa Hakko Kirin employees in clinical research led by doctors, which came to light in May 2014. Having received recommendations for the prevention of a recurrence from an external investigation committee composed of outside experts, we established a policy on clinical research and clarified the restructuring of our system for examining monetary donations and clinical research, and internal company rules to regulate support for clinical research. We also carried out a variety of reviews on matters such as increasing the independence of our internal body to examine promotional activities and materials. We will continue working to promote transparency and to thoroughly implement compliance.

The Kyowa Hakko Kirin Group is well-recognized for its technological capabilities as a R&D-driven company. In the Pharmaceuticals business, we received the Pharmaceutical Society of Japan Award for Drug Research and Development for our research and development of the novel anti-cancer drug Mogamulizumab (humanized anti-CCR4 antibody using high ADCC POTELLIGENT® technology) for adult T-cell leukemia-lymphoma. The work was selected as a successful example of original Japanese next-generation antibody technology, the use of such technology, and collaboration between industry and academia.

Furthermore, in the Bio-Chemicals business, we received the Japan Society for Bioscience, Biotechnology, and Agrochemistry Award for Achievement in Technological Research for the development and industrialization of our dipeptide fermentation technology, which was selected as a noteworthy technical achievement in the field of agrochemistry. Under 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" and with the drug discovery business at its core, the Kyowa Hakko Kirin Group will pursue a unique pharmaceutical business model that combines biosimilars, diagnostics and bio-chemicals as it advances toward becoming a global specialty pharmaceutical company.

- 1. Drug adherence refers to voluntary patient compliance with the drug usage and dosage prescribed by a doctor.
- Critical care is intensive treatment provided to patients in critical condition whose lives are at risk.

#### Outlook for 2015

In the year ending December 31, 2015, we forecast that net sales will increase 6.2 percent year on year to ¥354.0 billion, operating income will increase 14.7 percent to ¥41.5 billion, and net income will increase 16.4 percent to ¥18.5 billion.

In the Pharmaceuticals segment, we forecast that sales and profits will increase because of higher sales of new products such as G-Lasta®, a sustained-duration G-CSF product; Dovobet®, a treatment for psoriasis vulgaris; NOURIAST®, an antiparkinsonian agent; and ONGLYZA®, a treatment for type 2 diabetes. Segment results should also benefit from the full-year contribution of Archimedes Pharma. These factors should more than compensate for lower revenue from technology out-licensing and increased R&D expenses.

In the Bio-Chemicals segment, we forecast that sales and profits will increase due to factors including higher sales of core amino acids, nucleotides and *ornithine*, improved earnings at Daiichi Fine Chemical Co., Ltd., and further deprecation of the yen.

We also forecast a year-on-year increase in net income.

#### **Profit Distribution**

The distribution of profits to shareholders through stable and sustainable dividends is a central priority for Kyowa Hakko Kirin. Our dividend policy balances issues including internal capital required for growth, annual consolidated results, and the dividend payout ratio. We seek to improve capital efficiency through flexible, timely share repurchases. Kyowa Hakko Kirin allocates internal capital to research and development and capital expenditures that will contribute to enhancing future corporate value, and to expansion of the development pipeline and other investments that lead to new growth.

Based on this policy, Kyowa Hakko Kirin paid cash dividends per share of ¥25.00 for the year ended December 31, 2014, consisting of an interim dividend of ¥12.50 per share and a year-end dividend of ¥12.50 per share.

In addition, during Medium-Term Business Plan – 2013 to 2015 we are targeting stable dividends with a payout ratio of 40 percent of net income before amortization of goodwill.<sup>3</sup> Currently, we plan to pay cash dividends per share of ¥25.00 for the year ending December 31, 2015, consisting of an interim dividend of ¥12.50 per share and a year-end dividend of ¥12.50 per share.

 "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).

### **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. Items in this section dealing with future events reflect the assessment of the Group as of December 31, 2014.

#### 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.

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.

#### 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) 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.

### **Consolidated Balance Sheets**

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries As at December 31, 2014 and 2013

|   | Millions  | s of yen  | Thousands of<br>U.S. dollars (Note 2) |  |
|---|-----------|-----------|---------------------------------------|--|
| ASSETS  | 2014      | 2013      | 2014                                  |  |
| Current Assets:   |           |           |                                       |  |
| Cash and deposits   | ¥ 20,657  | ¥ 20,190  | \$ 171,390                            |  |
| Notes and accounts receivable:                            |           |           |                                       |  |
| Trade   | 104,509   | 98,147    | 867,078                               |  |
| Unconsolidated subsidiaries and affiliates                | 4,533     | 970       | 37,615                                |  |
| Other   | 5,143     | 4,431     | 42,672                                |  |
|   | 114,186   | 103,549   | 947,366                               |  |
|   |           |           |                                       |  |
| Inventories   | 91,284    | 75,701    | 757,361                               |  |
| Deferred tax assets                                       | 10,611    | 10,409    | 88,042                                |  |
| Short-term loans receivable:                              |           |           |                                       |  |
| Parent company  | 41,561    | 113,133   | 344,823                               |  |
| Other   |           | -         | 922                                   |  |
|   | 41,672    | 113,133   | 345,745                               |  |
| Other current assets                                      |           | 6,834     | 42,692                                |  |
| Less: Allowance for doubtful accounts                     |           | (497)     | (3,041)                               |  |
| Total Current Assets                                      |           | 329,320   | 2,349,557                             |  |
|   |           |           |                                       |  |
| Property, Plant and Equipment, at Cost:                   |           |           |                                       |  |
| Land  | 54,271    | 54,620    | 450,277                               |  |
| Buildings and structures                                  | 134,423   | 132,861   | 1,115,267                             |  |
| Machinery and equipment                                   | 153,286   | 146,935   | 1,271,767                             |  |
| Other   | 50,284    | 47,795    | 417,191                               |  |
| Construction in progress                                  | 23,371    | 13,501    | 193,905                               |  |
|   | 415,636   | 395,715   | 3,448,409                             |  |
| Less: Accumulated depreciation                            | (263,745) | (257,795) | (2,188,212)                           |  |
| Total Property, Plant and Equipment, Net                  | 151,891   | 137,919   | 1,260,196                             |  |
|   |           |           |                                       |  |
| Investments and Other Assets:                             |           |           |                                       |  |
| Investment securities                                     | ,         | 20,588    | 176,519                               |  |
| Investments in unconsolidated subsidiaries and affiliates | -,        | 4,149     | 13,519                                |  |
| Goodwill  |           | 163,713   | 1,437,331                             |  |
| Sales rights  |           | 46,519    | 557,801                               |  |
| Deferred tax assets                                       | -,        | 3,893     | 67,003                                |  |
| Net defined benefit assets                                |           |           | 53,465                                |  |
| Other assets  |           | 13,343    | 52,507                                |  |
| Less: Allowance for doubtful accounts                     | (         | (191)     | (1,459)                               |  |
| Total Investments and Other Assets                        | 284,051   | 252,016   | 2,356,688                             |  |
|   |           |           |                                       |  |
| Total Assets  | ¥ 719,135 | ¥ 719,257 | \$ 5,966,442                          |  |

|  | Millions | s of yen | Thousands of<br>U.S. dollars (Note 2) |  |
|--|----------|----------|---------------------------------------|--|
| LIABILITIES AND NET ASSETS                 | 2014     | 2013     | 2014                                  |  |
| Current Liabilities:                       |          |          |                                       |  |
| Short-term loans payable                   | ¥ 4,868  | ¥ 6,207  | \$ 40,391                             |  |
| Notes and accounts payable:                |          |          |                                       |  |
| Trade                                      | 22,657   | 22,517   | 187,981                               |  |
| Unconsolidated subsidiaries and affiliates | 187      | 171      | 1,553                                 |  |
| Construction and purchase of properties    | 6,435    | 9,942    | 53,394                                |  |
| Other                                      | 34,353   | 27,823   | 285,022                               |  |
|  | 63,633   | 60,455   | 527,951                               |  |
| Income taxes payable                       | 7,718    | 10,483   | 64,040                                |  |
| Provision for sales rebates                | 1,753    | 1,217    | 14,547                                |  |
| Other current liabilities                  | 7,207    | 6,712    | 59,801                                |  |
| Total Current Liabilities                  | 85,182   | 85,076   | 706,732                               |  |
| Noncurrent Liabilities:                    |          |          |                                       |  |
| Deferred tax liabilities                   | 16,235   | 11,807   | 134,697                               |  |
| Provision for retirement benefits:         |          |          |                                       |  |
| Employees                                  | _        | 19,196   | _                                     |  |
| Directors and corporate auditors           | 149      | 134      | 1,243                                 |  |
| Net defined benefit liabilities            | 3,714    | _        | 30,816                                |  |
| Asset retirement obligations               | 268      | 374      | 2,223                                 |  |
| Other noncurrent liabilities               | 8,216    | 7,253    | 68,173                                |  |
| Total Noncurrent Liabilities               | 28,584   | 38,765   | 237,153                               |  |
| Total Liabilities                          | 113,766  | 123,841  | 943,886                               |  |
|  |          |          |                                       |  |

| Net Assets:  |          |          |             |
|--|----------|----------|-------------|
| Shareholders' Equity:  |          |          |             |
|  |          |          |             |
| Capital stock:   |          |          |             |
| Authorized: 987,900,000 shares at December 31, 2014 and 2013 |          |          |             |
| Issued: 576,483,555 shares at December 31, 2014 and 2013     | 26,745   | 26,745   | 221,895     |
| Additional paid-in capital                                   | 512,326  | 512,328  | 4,250,616   |
| Retained earnings  | 68,103   | 65,888   | 565,031     |
| Treasury stock, at cost:                                     |          |          |             |
| 29,157,158 shares at December 31, 2014 and                   |          |          |             |
| 29,143,513 shares at December 31, 2013                       | (26,675) | (26,632) | (221,320)   |
| Total Shareholders' Equity                                   | 580,499  | 578,329  | 4,816,222   |
| Accumulated Other Comprehensive Income:                      |          |          |             |
| Net unrealized holding gain on other securities              | 2,753    | 1,414    | 22,843      |
| Foreign currency translation adjustments                     | 24,414   | 14,214   | 202,561     |
| Remeasurements of defined benefit plans                      | (2,631)  | _        | (21,833)    |
| Total Accumulated Other Comprehensive Income                 | 24,536   | 15,628   | 203,571     |
| Subscription rights to shares                                | 332      | 306      | 2,762       |
| Minority interests   | _        | 1,150    | _           |
| Total Net Assets   | 605,368  | 595,415  | 5,022,556   |
|  |          |          |             |
| Total Liabilities and Net Assets                             | ¥719,135 | ¥719,257 | \$5,966,442 |

### **Consolidated Statements of Income**

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries For the years ended December 31, 2014 and 2013

|   | Millions | of yen   | Thousands of<br>U.S. dollars (Note 2) |
|---|----------|----------|---------------------------------------|
|   | 2014     | 2013     | 2014                                  |
| Net Sales (Note 5)                                    | ¥333,446 | ¥340,611 | \$2,766,504                           |
| Cost of Sales (Note 3)                                | 127,542  | 127,850  | 1,058,176                             |
| Gross Profit  | 205,904  | 212,761  | 1,708,327                             |
| Selling, General and Administrative Expenses (Note 3) | 169,731  | 160,987  | 1,408,210                             |
| Operating Income (Note 5)                             | 36,173   | 51,773   | 300,116                               |
| Other Revenue (Expenses):                             |          |          |                                       |
| Interest and dividend income                          | 1,070    | 1,445    | 8,884                                 |
| Interest expense                                      | (145)    | (259)    | (1,206)                               |
| Foreign exchange gains                                | 101      | 2,098    | 838                                   |
| Equity in losses of affiliates                        | (6,055)  | (4,163)  | (50,239)                              |
| Gain (loss) on sale and disposal of fixed assets      | (735)    | 130      | (6,099)                               |
| Insurance Income                                      | 308      | _        | 2,556                                 |
| Impairment loss                                       | (1,342)  | (207)    | (11,141)                              |
| Compensation expenses                                 | (400)    | _        | (3,318)                               |
| Loss due to fire                                      | (309)    | _        | (2,566)                               |
| Business structure improvement expenses               | (289)    | _        | (2,404)                               |
| Loss on sales of affiliates' stock                    | (233)    | _        | (1,933)                               |
| Gain on sales of affiliates' stock                    | _        | 3,217    | -                                     |
| Gain on sales of investment securities                | _        | 687      | -                                     |
| Provision for loss on plant reorganization            | _        | (3,390)  | -                                     |
| Special extra retirement payments                     | _        | (630)    | -                                     |
| Loss on a liquidation of affiliates                   | _        | (190)    | -                                     |
| Loss on valuation of investment securities            | _        | (150)    | -                                     |
| Loss on sales of investment securities                | _        | (131)    | -                                     |
| Other, net  | (897)    | (455)    | (7,442)                               |
|   | (8,927)  | (2,000)  | (74,072)                              |
| Income before Income Taxes and Minority Interests     | 27,245   | 49,773   | 226,044                               |
| Income Taxes:   |          |          |                                       |
| Current   | (13,568) | (17,490) | (112,576)                             |
| Deferred  | 2,221    | (2,112)  | 18,434                                |
|   | (11,346) | (19,603) | (94,141)                              |
| Income before Minority Interests                      | 15,898   | 30,169   | 131,902                               |
| Minority Interests                                    | _        | (91)     | _                                     |
| Net Income  | ¥ 15,898 | ¥ 30,078 | \$ 131,902                            |

### **Consolidated Statements of Comprehensive Income**

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries For the years ended December 31, 2014 and 2013

|   | Millions | s of yen | Thousands of<br>U.S. dollars (Note 2) |  |  |
|---|----------|----------|---------------------------------------|--|--|
|   | 2014     | 2013     | 2014                                  |  |  |
| Income before Minority Interests                | ¥15,898  | ¥30,169  | \$131,902                             |  |  |
| Other Comprehensive Income                      |          |          |                                       |  |  |
| Net unrealized holding gain on other securities | 1,338    | 3,678    | 11,108                                |  |  |
| Foreign currency translation adjustments        | 9,981    | 17,978   | 82,813                                |  |  |
| Total Other Comprehensive Income                | 11,320   | 21,656   | 93,921                                |  |  |
| Comprehensive Income                            |          |          |                                       |  |  |
| Comprehensive income attributable to:           |          |          |                                       |  |  |
| Owners of the parent                            | 27,218   | 51,499   | 225,824                               |  |  |
| Minority interests                              | _        | 326      | -                                     |  |  |
| Total Comprehensive Income                      | ¥27,218  | ¥51,826  | \$225,824                             |  |  |

### **Consolidated Statements of Changes in Net Assets**

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries For the years ended December 31, 2014 and 2013

|   |                               |                  |                                  |                   |                               |                                  | Millions  | of yen  |  |  |                                     |                       |                        |
|---|-------------------------------|------------------|----------------------------------|-------------------|-------------------------------|----------------------------------|---|---|--|--|-------------------------------------|-----------------------|------------------------|
|   |                               |                  | Share                            | eholders' eq      | quity                         |                                  | Accum   | ulated other co                                   | omprehensive                                       | income   |                                     |                       |                        |
|   | Number of<br>shares<br>issued | Capital<br>stock | Additional<br>paid-in<br>capital | Retained earnings | Treasury<br>stock,<br>at cost | Total<br>shareholders'<br>equity | Net unrealized<br>holding gain<br>(loss) on other<br>securities | Foreign<br>currency<br>translation<br>adjustments | Remeasure-<br>ments of<br>defined<br>benefit plans | Total<br>accumulated<br>other com-<br>prehensive<br>income | Subscription<br>rights to<br>shares | Minority<br>interests | Total<br>net<br>assets |
| Balance at<br>January 1, 2013                         | 576,483,555                   | ¥26,745          | ¥512,329                         | ¥ 48,127          | ¥(26,538)                     | ¥560,663                         | ¥(2,264)  | ¥ (3,528)   |  | ¥ (5,792)  | ¥203                                | ¥ 823                 | ¥555,898               |
| Net income for<br>the year ended<br>December 31, 2013 |                               |                  |                                  | 30,078            |                               | 30,078                           |   |   |  |  |                                     |                       | 30,078                 |
| Cash dividends  |                               |                  |                                  | (12,316)          |                               | (12,316)                         |   |   |  |  |                                     |                       | (12,316)               |
| Purchases of<br>treasury stock                        |                               |                  |                                  |                   | (126)                         | (126)                            |   |   |  |  |                                     |                       | (126)                  |
| Disposal of<br>treasury stock                         |                               |                  | (1)                              |                   | 32                            | 30                               |   |   |  |  |                                     |                       | 30                     |
| Net changes<br>during the year                        |                               |                  |                                  |                   |                               |                                  | 3,678   | 17,743  |  | 21,421   | 103                                 | 326                   | 21,851                 |
| Balance at January 1, 2014                            | 576,483,555                   | 26,745           | 512,328                          | 65,888            | (26,632)                      | 578,329                          | 1,414   | 14,214  | -  | 15,628   | 306                                 | 1,150                 | 595,415                |
| Net income for<br>the year ended<br>December 31, 2014 |                               |                  |                                  | 15,898            |                               | 15,898                           |   |   |  |  |                                     |                       | 15,898                 |
| Cash dividends  |                               |                  |                                  | (13,683)          |                               | (13,683)                         |   |   |  |  |                                     |                       | (13,683)               |
| Purchases of treasury stock                           |                               |                  |                                  |                   | (116)                         | (116)                            |   |   |  |  |                                     |                       | (116)                  |
| Disposal of<br>treasury stock                         |                               |                  | (1)                              |                   | 73                            | 72                               |   |   |  |  |                                     |                       | 72                     |
| Net changes<br>during the year                        |                               |                  |                                  |                   |                               |                                  | 1,338   | 10,200  | (2,631)  | 8,907  | 26                                  | (1,150)               | 7,783                  |
| Balance at December 31, 2014                          | 576,483,555                   | ¥26,745          | ¥512,326                         | ¥ 68,103          | ¥(26,675)                     | ¥580,499                         | ¥ 2,753   | ¥24,414   | ¥(2,631)   | ¥24,536  | ¥332                                | -                     | ¥605,368               |

|   |                  | Thousands of U.S. dollars (Note 2) |                   |                               |                                  |   |   |  |  |                                     |                       |                        |
|---|------------------|------------------------------------|-------------------|-------------------------------|----------------------------------|---|---|--|--|-------------------------------------|-----------------------|------------------------|
|   |                  | Share                              | eholders' ec      | quity                         |                                  | Accum   | ulated other c                                    | omprehensive                                       | income   |                                     |                       |                        |
|   | Capital<br>stock | Additional<br>paid-in<br>capital   | Retained earnings | Treasury<br>stock,<br>at cost | Total<br>shareholders'<br>equity | Net unrealized<br>holding gain<br>(loss) on other<br>securities | Foreign<br>currency<br>translation<br>adjustments | Remeasure-<br>ments of<br>defined<br>benefit plans | Total<br>accumulated<br>other com-<br>prehensive<br>income | Subscription<br>rights to<br>shares | Minority<br>interests | Total<br>net<br>assets |
| Balance at January 1, 2014                      | \$221,895        | \$4,250,627                        | \$ 546,658        | \$(220,964)                   | \$4,798,216                      | \$11,734  | \$117,932   | -  | \$129,667  | \$2,543                             | \$9,547               | \$4,939,975            |
| Net income for the year ended December 31, 2014 |                  |                                    | 131,902           |                               | 131,902                          |   |   |  |  |                                     |                       | 131,902                |
| Cash dividends                                  |                  |                                    | (113,529)         |                               | (113,529)                        |   |   |  |  |                                     |                       | (113,529)              |
| Purchases of treasury stock                     |                  |                                    |                   | (969)                         | (969)                            |   |   |  |  |                                     |                       | (969)                  |
| Disposal of treasury stock                      |                  | (11)                               |                   | 613                           | 602                              |   |   |  |  |                                     |                       | 602                    |
| Net changes during the year                     |                  |                                    |                   |                               |                                  | 11,108  | 84,628  | (21,833)   | 73,904   | 218                                 | (9,547)               | 64,576                 |
| Balance at December 31, 2014                    | \$221,895        | \$4,250,616                        | \$ 565,031        | \$(221,320)                   | \$4,816,222                      | \$22,843  | \$202,561   | \$(21,833)   | \$203,571  | \$2,762                             | -                     | \$5,022,556            |

### **Consolidated Statements of Cash Flows**

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries For the years ended December 31, 2014 and 2013

|  | Millions o | f ven    | Thousands of<br>U.S. dollars (Note 2) |  |  |
|--|------------|----------|---------------------------------------|--|--|
|  | 2014       | 2013     | 2014                                  |  |  |
| Cash Flows from Operating Activities:  |            |          |                                       |  |  |
| Income before income taxes and minority interests         Adjustments to reconcile income before income taxes and           minority interests to net cash provided by operating activities:         Adjustments | ¥ 27,245   | ¥ 49,773 | \$ 226,044                            |  |  |
| Depreciation and amortization  | 23,885     | 21,592   | 198,170                               |  |  |
| Impairment loss  | 1,342      | 207      | 11,141                                |  |  |
| Amortization of goodwill   | 12,826     | 11,577   | 106,419                               |  |  |
| Increase (decrease) in provision for retirement benefits   | -          | (274)    | —                                     |  |  |
| Increase (decrease) in net defined benefit liabilities   | (696)      | —        | (5,777)                               |  |  |
| Decrease (increase) in prepaid pension costs   | -          | (1,157)  | -                                     |  |  |
| Decrease (increase) in net defined benefit assets  | (292)      | -        | (2,425)                               |  |  |
| Contribution to employee's retirement benefits trust   | (19,000)   | —        | (157,637)                             |  |  |
| Interest and dividend income   | (1,070)    | (1,445)  | (8,884)                               |  |  |
| Interest expenses  | 145        | 259      | 1,206                                 |  |  |
| Equity in (earnings) losses of affiliates  | 6,055      | 4,163    | 50,239                                |  |  |
| Loss (gain) on sales and retirement of property, plant and equipment   | 224        | (685)    | 1,866                                 |  |  |
| Loss (gain) on sales of investment securities  | (76)       | (556)    | (630)                                 |  |  |
| Loss (gain) on sale of affiliate's stock   | 233        | (3,214)  | 1,933                                 |  |  |
| Decrease (increase) in notes and accounts receivable   | (6,426)    | 5,955    | (53,317)                              |  |  |
| Decrease (increase) in inventories   | (12,018)   | (8,708)  | (99,709)                              |  |  |
| Increase (decrease) in notes and accounts payable  | (1,720)    | (2,915)  | (14,276)                              |  |  |
| Other  | 4,766      | 3,856    | 39,548                                |  |  |
| Sub-total  | 35,424     | 78,428   | 293,909                               |  |  |
| Interest and dividend income received  | 1,072      | 1,874    | 8,898                                 |  |  |
| Interest expenses paid   | (300)      | (242)    | (2,494)                               |  |  |
| Income taxes paid  | (16,819)   | (23,175) | (139,546)                             |  |  |
| Net Cash Provided by Operating Activities  | 19,377     | 56,884   | 160,766                               |  |  |
| Cash Flows from Investing Activities:  |            |          |                                       |  |  |
| Purchase of property, plant and equipment  | (30,466)   | (21,599) | (252,767)                             |  |  |
| Proceeds from sales of property, plant and equipment   | 186        | 1,748    | 1,547                                 |  |  |
| Purchase of intangible assets  | (4,186)    | (13,126) | (34,731)                              |  |  |
| Purchase of investment securities  | (4,556)    | (3,801)  | (37,799)                              |  |  |
| Proceeds from sales and redemption of investment securities  | 1,252      | 3,957    | 10,392                                |  |  |
| Proceeds from sales of affiliates' stock   | 1,000      | 3,747    | 8,296                                 |  |  |
| Purchase of shares of subsidiaries resulting in change in scope of consolidation   | (14,510)   | -        | (120,390)                             |  |  |
| Payments into time deposits  | (1,166)    | (4,251)  | (9,681)                               |  |  |
| Proceeds from withdrawal of time deposits  | 1,300      | 2,922    | 10,785                                |  |  |
| Decrease (increase) in short-term loans receivable   | 68,388     | (43,000) | 567,400                               |  |  |
| Other  | (436)      | (3,759)  | (3,619)                               |  |  |
| Net Cash Provided by (Used in) Investing Activities  | 16,805     | (77,163) | 139,432                               |  |  |
| Cash Flows from Financing Activities:  |            |          |                                       |  |  |
| Net increase (decrease) in short-term loans payable  | (23,405)   | 12       | (194,191)                             |  |  |
| Purchase of treasury stock   | (116)      | (126)    | (969)                                 |  |  |
| Cash dividends paid  | (13,683)   | (12,310) | (113,529)                             |  |  |
| Other  | 22         | (155)    | 183                                   |  |  |
| Net Cash Used in Financing Activities  | (37,184)   | (12,579) | (308,507)                             |  |  |
| Effect of Exchange Rate Change on Cash and Cash Equivalents  | (1,227)    | 1,765    | (10,180)                              |  |  |
| Net Increase (Decrease) in Cash and Cash Equivalents   | (2,228)    | (31,091) | (18,488)                              |  |  |
| Cash and Cash Equivalents at the Beginning of the Period   | 19,242     | 50,334   | 159,647                               |  |  |
| Cash and Cash Equivalents at the End of Period   | ¥ 17,013   | ¥ 19,242 | \$ 141,158                            |  |  |
| Reconciliation between cash and cash equivalents at year end   |            |          |                                       |  |  |
| and the accounts booked in the consolidated balance sheets   |            |          |                                       |  |  |
| Cash and deposits  | ¥ 20,657   | ¥ 20,190 | \$ 171,390                            |  |  |
| Time deposits whose maturity periods exceed 3 months   | (3,705)    | (3,448)  | (30,741)                              |  |  |
| Short-term loans receivable from parent company not exceeding three months   | 61         | 3,133    | 510                                   |  |  |
| Current loans payable as negative cash equivalents (short-term loans payable)  | _          | (633)    | _                                     |  |  |
| Cash and Cash Equivalents  | ¥ 17,013   | ¥ 19,242 | \$ 141,158                            |  |  |

### **Notes to the Consolidated Financial Statements**

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries

#### Basis of Presenting Consolidated Financial Statements

The accompanying consolidated financial statements have been prepared from accounts and records maintained by Kyowa Hakko Kirin Co., Ltd. (the "Company") and its consolidated subsidiaries (hereinafter collectively referred to as the "Companies"). The Company and its domestic consolidated subsidiaries have maintained their accounts and records in accordance with the provisions set forth in the Financial Instruments and Exchange Act and in conformity with generally accepted accounting principles and practices prevailing in Japan, which are different in certain respects as to the application and disclosure requirements of International Financial Reporting Standards (hereinafter "IFRS").

Effective April 1, 2008, the Company has adopted the "Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for Consolidated Financial Statements" (Practical Issues Task Force No. 18 (hereinafter "PITF No. 18"), issued by the Accounting Standards Board of Japan (hereinafter "ASBJ")). In accordance with the new accounting standard, the accompanying consolidated financial statements for the year ended December 31, 2014, have been prepared by using the accounts of foreign consolidated subsidiaries prepared in accordance with either IFRS or accounting principles generally accepted in the United States as adjusted for certain items including goodwill, actuarial differences and capitalized development costs.

#### **2** U.S. Dollar Amounts

The accompanying consolidated financial statements are prepared in Japanese yen. The U.S. dollar amounts included in the consolidated financial statements and notes thereto represent the arithmetical results of translating yen to dollars on the basis of ¥120.53=U.S.\$1, the approximate exchange rate at December 31, 2014. The inclusion of such dollar amounts is solely for convenience and is not intended to imply that yen amounts can be converted into dollars at ¥120.53=U.S.\$1 or at any other rate.

#### **3** Research and Development Expenses

Research and development expenses, all of which were included in selling, general and administrative expenses and production cost for the years ended December 31, 2014 and 2013 totaled ¥47,737 million (\$396,066 thousand) and ¥43,682 million, respectively.

#### Related Party Transactions

Significant transactions and balances with related parties as of and for the years ended December 31, 2014 and 2013 are as follows:

#### **1. Parent Company**

Kirin Holdings Co., Ltd. is listed on the first section of the Tokyo, Nagoya, Fukuoka and Sapporo Stock Exchanges.

#### Year ended December 31, 2014

|  | Capital         | Ratio of voting     |                   | Amo             | unts                         |                                   | Amounts         |                              |  |
|--|-----------------|---------------------|-------------------|-----------------|------------------------------|-----------------------------------|-----------------|------------------------------|--|
| Name                                     | Millions of yen | rights<br>(owned)   | Transactions      | Millions of yen | Thousands of<br>U.S. dollars | Closing<br>balances               | Millions of yen | Thousands of<br>U.S. dollars |  |
| Kirin<br>Holdings<br>Company,<br>Limited | ¥102,045        | Directly<br>(53.2%) | Loan of<br>funds* | ¥82,921         | \$687,974                    | Short-term<br>loans<br>receivable | ¥41,561         | \$344,823                    |  |

#### Year ended December 31, 2013

|  | Capital         | Ratio of voting     |                   | Amounts         |                                   | Amounts         |
|--|-----------------|---------------------|-------------------|-----------------|-----------------------------------|-----------------|
| Name                                     | Millions of yen | rights<br>(owned)   | Transactions      | Millions of yen | Closing<br>balances               | Millions of yen |
| Kirin<br>Holdings<br>Company,<br>Limited | ¥102,045        | Directly<br>(53.2%) | Loan of<br>funds* | ¥101,661        | Short-term<br>loans<br>receivable | ¥113,133        |

\* A "Cash Management System" offered by Kirin Holdings is used to calculate transaction amounts, which are the average amounts of every month. The interest rates on loans are reasonably decided in consideration of market interest rates.

#### 2. Director and auditor of the Company

#### Year ended December 31, 2014

|                                      | Ratio of voting rights |  | Amounts         |
|--------------------------------------|------------------------|--|-----------------|
| Name and position                    | (owned)                | Transactions   | Millions of yen |
| Toshifumi Mikayama<br>Director       | Directly (0.0%)        | Disposal of treasury stocks<br>by exercise of stock options* | ¥21             |
| Nobuhisa Yamazaki<br>Company Auditor | Directly (0.0%)        | Disposal of treasury stocks<br>by exercise of stock options* | ¥26             |

\* Calculated the amount of transactions from the book value of treasury stocks at the time of disposal.

#### 3. Financial summary of the significant corporate affiliate

FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. is a significant corporate affiliate. The financial summary for the years ended December 31, 2014 and 2013 is as follows:

|                          | Millions of yen |          | Thousands of<br>U.S. dollars |  |
|--------------------------|-----------------|----------|------------------------------|--|
|                          | 2014            | 2013     | 2014                         |  |
| Current assets:          | ¥ 1,054         | ¥ 2,073  | \$ 8,746                     |  |
| Noncurrent assets        | 893             | 1,129    | 7,413                        |  |
| Current liabilities      | 4,372           | 832      | 36,276                       |  |
| Noncurrent liabilities   | 27,800          | 20,500   | 230,647                      |  |
| Net assets               | (30,224)        | (18,129) | (250,764)                    |  |
| Sales                    | -               | —        | -                            |  |
| Loss before income taxes | (12,092)        | (8,361)  | (100,330)                    |  |
| Net loss                 | (12,095)        | (8,362)  | (100,348)                    |  |

#### **5** Segment Information

The reportable segments for the Companies are based on the financial data available for discrete operating units and for the purpose of periodic review by the Board of Directors in regard to the decision-making on proper allocation of business resources and the evaluation of business performance.

The Companies are made up of business groups formed on the basis of similarities in the products and services handled by each company. A core company in each business group, serving as the headquarters of that individual business, formulates comprehensive strategies for domestic and overseas markets and develops business activities in accordance with such strategies. Therefore, the Companies have two reportable segments: "Pharmaceuticals Division" and "Bio-Chemicals Division." The Pharmaceuticals Division manufactures and sells ethical pharmaceuticals, diagnostic reagents and others. The Bio-Chemicals Division manufactures and sells raw materials for pharmaceutical and industrial use, primarily amino acids, nucleotides and related compounds, healthcare products and others.

#### Segment information for the year ended December 31, 2014

**1. Information on sales and income (loss), identifiable assets/liabilities and other items by reportable segment** The accounting method for reportable segments is based on the accounting method and information provided in "Summary of Significant Accounting Policies."

Segment income is based on operating income. Intersegment sales are mainly based on transaction prices with third parties.

|   | Millions of yen    |               |          |              |              |
|---|--------------------|---------------|----------|--------------|--------------|
|   | Reportable segment |               |          |              | Consolidated |
|   | Pharmaceuticals    | Bio-Chemicals | Total    | Adjustments* | total        |
| Sales   |                    |               |          |              |              |
| Sales to outside customers                                      | ¥251,882           | ¥ 81,564      | ¥333,446 | ¥ —          | ¥333,446     |
| Intersegment sales and transfers                                | 1,129              | 2,405         | 3,535    | (3,535)      | _            |
| Net sales   | 253,011            | 83,970        | 336,982  | (3,535)      | 333,446      |
| Segment income  | 29,061             | 7,277         | 36,338   | (165)        | 36,173       |
| Segment assets  | 524,281            | 168,943       | 693,224  | 25,910       | 719,135      |
| Other items   |                    |               |          |              |              |
| Depreciation and amortization                                   | ¥ 17,075           | ¥ 6,811       | ¥ 23,886 | ¥ (1)        | ¥ 23,885     |
| Amortization of goodwill  | 11,893             | 933           | 12,826   | _            | 12,826       |
| Investment in equity method affiliates                          | _                  | _             | _        | _            | _            |
| Increase of property, plant and equipment and intangible assets | 17,012             | 12,476        | 29,489   | (1)          | 29,487       |

|   | Thousands of U.S. dollars |                      |             |              |              |
|---|---------------------------|----------------------|-------------|--------------|--------------|
|   |                           | Reportable segment   |             |              | Consolidated |
|   | Pharmaceuticals           | <b>Bio-Chemicals</b> | Total       | Adjustments* | total        |
| Sales   |                           |                      |             |              |              |
| Sales to outside customers                                      | \$2,089,789               | \$ 676,715           | \$2,766,504 | \$           | \$2,766,504  |
| Intersegment sales and transfers                                | 9,371                     | 19,961               | 29,332      | (29,332)     | -            |
| Net sales   | 2,099,160                 | 696,676              | 2,795,836   | (29,332)     | 2,766,504    |
| Segment income  | 241,111                   | 60,379               | 301,491     | (1,374)      | 300,116      |
| Segment assets  | 4,349,800                 | 1,401,670            | 5,751,470   | 214,971      | 5,966,442    |
| Other items   |                           |                      |             |              |              |
| Depreciation and amortization                                   | \$ 141,668                | \$ 56,512            | \$ 198,180  | \$ (10)      | \$ 198,170   |
| Amortization of goodwill  | 98,677                    | 7,742                | 106,419     | _            | 106,419      |
| Investment in equity method affiliates                          | _                         | _                    | _           | _            | _            |
| Increase of property, plant and equipment and intangible assets | 141,149                   | 103,512              | 244,661     | (12)         | 244,648      |

\* (a) Segment income included in "Adjustments" consisted of the elimination of intersegment transactions.
(b) Segment assets included in "Adjustments" consisted of the elimination of intersegment transactions and corporate assets that were not allocated to each reportable segment.

The amounts are as follows.

Elimination of intersegment transactions: ¥(23,370) million

Corporate assets: ¥49,281 million

Corporate assets consist of surplus operating funds (cash, deposits and short-term loans receivable) and long-term investments (investment securities).

#### 2. Related information

#### (1) Information on sales by product and service

As information on sales by product and service is the same as segment information, it was omitted.

#### (2) Geographical information

#### (a) Net sales

The classification of overseas sales is as follows:

| Classification | Area                         |
|----------------|------------------------------|
| America        | North America, Latin America |
| Europe         | All of Europe                |
| Asia           | All of Asia                  |
| Other areas    | Oceania, Africa              |

|          |         | Millions | of yen  |             |          |
|----------|---------|----------|---------|-------------|----------|
| Japan    | America | Europe   | Asia    | Other areas | Total    |
| ¥239,241 | ¥21,695 | ¥45,701  | ¥25,886 | ¥921        | ¥333,446 |

| Thousands of U.S. dollars |           |           |           |             |             |
|---------------------------|-----------|-----------|-----------|-------------|-------------|
| Japan                     | America   | Europe    | Asia      | Other areas | Total       |
| \$1,984,913               | \$180,004 | \$379,171 | \$214,772 | \$7,641     | \$2,766,504 |

(Note) Net sales information above is classified by country or region based on the location of customers.

#### (b) Property, plant and equipment

|          |         | Millions of yen |         |          |
|----------|---------|-----------------|---------|----------|
| Japan    | America | Europe          | Asia    | Total    |
| ¥126,926 | ¥10,851 | ¥662            | ¥13,452 | ¥151,891 |

|             |          | Thousands of U.S. dollars |           |             |
|-------------|----------|---------------------------|-----------|-------------|
| Japan       | America  | Europe                    | Asia      | Total       |
| \$1,053,073 | \$90,033 | \$5,494                   | \$111,607 | \$1,260,196 |

#### 3. Information by major customer

| Millions of yen     |           |                      |  |  |
|---------------------|-----------|----------------------|--|--|
| Customer name       | Net sales | Related segment name |  |  |
| Alfresa Corporation | ¥42,633   | Pharmaceuticals      |  |  |

|                     | Thousands of U.S. dollars |                 |
|---------------------|---------------------------|-----------------|
| Customer name       | Related segment name      |                 |
| Alfresa Corporation | \$353,961                 | Pharmaceuticals |

#### 4. Information regarding impairment losses on fixed assets by reportable segment

|                   |                 |                      | Millions of yen |             |                    |
|-------------------|-----------------|----------------------|-----------------|-------------|--------------------|
|                   | Pharmaceuticals | <b>Bio-Chemicals</b> | Total           | Adjustments | Consolidated total |
| Impairment losses | ¥1,123          | ¥219                 | ¥1,342          | ¥ —         | ¥1,342             |

|                   | Thousands of U.S. dollars                              |         |          |      |          |  |
|-------------------|--|---------|----------|------|----------|--|
|                   | Pharmaceuticals Bio-Chemicals Total Adjustments Consol |         |          |      |          |  |
| Impairment losses | \$9,321  | \$1,820 | \$11,141 | \$ — | \$11,141 |  |

#### 5. Information regarding amount of amortization of goodwill and unamortized balance by reportable segment

|                          |                 |                      | Millions of yen |             |                    |
|--------------------------|-----------------|----------------------|-----------------|-------------|--------------------|
|                          | Pharmaceuticals | <b>Bio-Chemicals</b> | Total           | Adjustments | Consolidated total |
| Amortization of goodwill | ¥ 11,893        | ¥ 933                | ¥ 12,826        | ¥ —         | ¥ 12,826           |
| Unamortized balance      | ¥163,560        | ¥9,681               | ¥173,241        | ¥ —         | ¥173,241           |

|                          | Thousands of U.S. dollars |                    |             |      |             |  |
|--------------------------|---------------------------|--------------------|-------------|------|-------------|--|
|                          | Pharmaceuticals           | Consolidated total |             |      |             |  |
| Amortization of goodwill | \$ 98,677                 | \$ 7,742           | \$ 106,419  | \$ — | \$ 106,419  |  |
| Unamortized balance      | \$1,357,011               | \$80,320           | \$1,437,331 | \$   | \$1,437,331 |  |

## 6. Information regarding gain on recognition of negative goodwill by reportable segment No relevant items.

#### Segment information for the year ended December 31, 2013

**1. Information on sales and income (loss), identifiable assets/liabilities and other items by business segment** Reportable segment information for the year ended December 31, 2013 was as follows:

|   |                    |               | Millions of yen |              |        |              |
|---|--------------------|---------------|-----------------|--------------|--------|--------------|
|   | Reportable segment |               |                 | _            |        | Consolidated |
|   | Pharmaceuticals    | Bio-Chemicals | Total           | Adjustments* |        | total        |
| Sales   |                    |               |                 |              |        |              |
| Sales to outside customers                                      | ¥259,584           | ¥ 81,026      | ¥340,611        | ¥            | _      | ¥340,611     |
| Intersegment sales and transfers                                | 1,423              | 1,892         | 3,315           | (3           | 3,315) | —            |
| Net sales   | 261,007            | 82,919        | 343,927         | (3           | 3,315) | 340,611      |
| Segment income  | 46,135             | 5,667         | 51,803          |              | (29)   | 51,773       |
| Segment assets  | 460,732            | 158,404       | 619,136         | 100          | ),120  | 719,257      |
| Other items   |                    |               |                 |              |        |              |
| Depreciation and amortization                                   | ¥ 14,966           | ¥ 6,627       | ¥ 21,593        | ¥            | (1)    | ¥ 21,592     |
| Amortization of goodwill  | 10,951             | 625           | 11,577          |              | _      | 11,577       |
| Investment in equity method affiliates                          | 2,426              | —             | 2,426           |              | _      | 2,426        |
| Increase of property, plant and equipment and intangible assets | 22,921             | 12,261        | 35,183          |              | _      | 35,183       |

\* (a) Segment income included in "Adjustments" consisted of the elimination of intersegment transactions.

(b) Segment assets included in "Adjustments" consisted of the elimination of intersegment transactions and corporate assets that were not allocated to each reportable segment.

The amounts were as follows. Elimination of the intersegment transactions: ¥(16,983) million Corporate assets: ¥117,103 million

Corporate assets consist of surplus operating funds (cash, deposits and short-term loans receivable) and long-term investments (investment securities).

#### 2. Related information

#### (1) Information on sales by product and service

As information on sales by product and service is the same as segment information, it was omitted.

#### (2) Geographical information

#### (a) Net sales

The classification of overseas sales is as follows:

| Classification | Area                         |
|----------------|------------------------------|
| America        | North America, Latin America |
| Europe         | All of Europe                |
| Asia           | All of Asia                  |
| Other areas    | Oceania, Africa              |

| Millions of yen |         |         |         |             |          |
|-----------------|---------|---------|---------|-------------|----------|
| Japan           | America | Europe  | Asia    | Other areas | Total    |
| ¥254,085        | ¥23,948 | ¥37,226 | ¥24,420 | ¥931        | ¥340,611 |

(Note) Net sales information above is classified by country or region based on the locations of customers.

#### (b) Property, plant and equipment

| _ |          |         | Millions of yen |        |          |
|---|----------|---------|-----------------|--------|----------|
|   | Japan    | America | Europe          | Asia   | Total    |
|   | ¥121,862 | ¥9,160  | ¥212            | ¥6,684 | ¥137,919 |

#### 3. Information by major customer

|                     | Millions of yen |                      |
|---------------------|-----------------|----------------------|
| Customer name       | Net sales       | Related segment name |
| Alfresa Corporation | ¥45,352         | Pharmaceuticals      |

#### 4. Information regarding impairment losses on fixed assets by reportable segment

|                   |                 |               | Millions of yen |             |                    |
|-------------------|-----------------|---------------|-----------------|-------------|--------------------|
|                   | Pharmaceuticals | Bio-Chemicals | Total           | Adjustments | Consolidated total |
| Impairment losses | ¥146            | ¥61           | ¥207            | ¥ —         | ¥207               |

#### 5. Information regarding amount of amortization of goodwill and unamortized balance by reportable segment

|                          |                 |                      | Millions of yen |             |                    |
|--------------------------|-----------------|----------------------|-----------------|-------------|--------------------|
|                          | Pharmaceuticals | <b>Bio-Chemicals</b> | Total           | Adjustments | Consolidated total |
| Amortization of goodwill | ¥ 10,951        | ¥ 625                | ¥ 11,577        | ¥ —         | ¥ 11,577           |
| Unamortized balance      | ¥154,798        | ¥8,915               | ¥163,713        | ¥ —         | ¥163,713           |

## 6. Information regarding gain on recognition of negative goodwill by reportable segment No relevant items.

#### **6** Per Share Data

|                    | Y        | U.S. dollars |         |
|--------------------|----------|--------------|---------|
|                    | 2014     | 2013         | 2014    |
| Net assets         | ¥1,105.4 | ¥1,085.2     | \$9.171 |
| Net income-basic   | 29.0     | 54.9         | 0.241   |
| Net income-diluted | 29.0     | 54.9         | 0.240   |

Basic net income per share is computed based on the net income available for distribution to shareholders of common stock and the weighted average number of shares of common stock outstanding during the year. Diluted net income per share is computed based on the net income available for distribution to the shareholders and the weighted average number of shares of common stock outstanding each year after giving effect to the dilutive potential of shares of common stock to be issued upon the exercise of share subscription rights.

Net assets per share are computed based on the net assets excluding stock subscription rights and minority interests and the amount of common stock outstanding at the year end.

The financial data used in the computation of basic net income per share for the years ended December 31, 2014 and 2013 in the above table is as follows:

|   | Millions of yen |             | Thousands of<br>U.S. dollars |
|---|-----------------|-------------|------------------------------|
|   | 2014            | 2013        | 2014                         |
| Net income-basic  |                 |             |                              |
| Net income used in the calculation of net income per share                          | ¥15,898         | ¥30,078     | \$131,902                    |
| Weighted average number of shares of<br>common stock outstanding (Number of shares) | 547,348,362     | 547,391,705 |                              |
| Net income-diluted  |                 |             |                              |
| Increase in number of common stock (Number of shares) attributable to:              | 400,243         | 359,114     |                              |
| Stock subscription rights (Number of shares)  | 400,243         | 359,114     |                              |

The financial data used in the computation of net assets per share at December 31, 2014 and 2013 in the above table is as follows:

|  | Millions of yen |             | Thousands of<br>U.S. dollars |
|--|-----------------|-------------|------------------------------|
|  | 2014            | 2013        | 2014                         |
| Total net assets   | ¥605,368        | ¥595,415    | \$5,022,556                  |
| Amounts deducted from total net assets attributable to                             | 332             | 1,457       | 2,762                        |
| Stock subscription rights  | 332             | 306         | 2,762                        |
| Minority interests   | _               | 1,150       | _                            |
| Net assets used in the calculation of net assets per share                         | ¥605,035        | ¥593,957    | \$5,019,793                  |
| Number of shares used in the calculation ofnet assets per share (Number of shares) | 547,326,397     | 547,340,042 |                              |

### **Network**<sup>1</sup> (As of December 31, 2014)

10 11 12 13 20 22 29 16 28 42 14 27 19 43 15 26

 31
 37

 44
 38

 30
 Kyowa Hakko Kirin Co., Ltd.

 33
 46
 32

 1
 2
 3
 35

45

| Name of Company                              | Percentage<br>Owned Directly<br>or Indirectly by<br>the Company | Capital <sup>2</sup><br>(Thousand) | 34 47<br>Principal Business  |
|--|---|------------------------------------|--|
| PHARMACEUTICALS                              |   |                                    |  |
| Japan  |   |                                    |  |
| Kyowa Medex Co., Ltd.                        | 100.00%   | ¥450,000                           | Manufacturing and sales of diagnostic reagents                             |
| 2 Kyowa Medical Promotion Co., Ltd.          | 100.00%   | ¥50,000                            | Promotion and sales of pharmaceuticals                                     |
| <sup>3</sup> Chiyoda Kaihatsu Co., Ltd.      | 100.00%   | ¥112,500                           | Insurance, wholesale and retail  |
| America                                      |   |                                    |  |
| 4 Kyowa Hakko Kirin America, Inc.            | 100.00%   | US \$76,300                        | Holding company for administration and management of subsidiaries (U.S.A.) |
| 5 BioWa, Inc.                                | 100.00%   | US \$10,000                        | Out-licensing of antibody technology and research alliance (U.S.A.)        |
| 6 Kyowa Hakko Kirin Pharma, Inc.             | 100.00%   | US \$100                           | Development of outsourced pharmaceutical products (U.S.A.)                 |
| 7 Kyowa Hakko Kirin California, Inc.         | 100.00%   | US \$100                           | Generate new candidate substances and develop<br>pharmaceuticals (U.S.A.)  |
| 8 ProStrakan Inc.                            | 100.00%   | US \$235                           | Sales of pharmaceuticals (U.S.A.)  |
| 9 Archimedes Pharma US Inc.                  | 100.00%   | US \$1                             | Licensing of pharmaceuticals (U.S.A.)                                      |
| Europe                                       |   |                                    |  |
| 10 ProStrakan Group plc                      | 100.00%   | £13,848                            | Supervision and management of special companies (U.K.)                     |
| 11 Strakan International S.a r.l.            | 100.00%   | US \$112,826                       | Sales, licensing-in and licensing-out of pharmaceuticals (U.K.)            |
| 12 Strakan Pharmaceuticals Limited           | 100.00%   | £501                               | Development of pharmaceuticals (U.K.)                                      |
| 13 ProStrakan Limited                        | 100.00%   | £6,951                             | Sales of pharmaceuticals (U.K.)  |
| 14 ProStrakan Pharma S.A.S                   | 100.00%   | €1,139                             | Sales of pharmaceuticals (France)  |
| 15 ProStrakan Farmaceutica SLU               | 100.00%   | €216                               | Sales of pharmaceuticals (Spain)   |
| 16 ProStrakan Pharma GmbH                    | 100.00%   | €51                                | Sales of pharmaceuticals (Germany)   |
| 17 ProStrakan Holdings B.V.                  | 100.00%   | €105                               | Holding company for special companies (Netherlands)                        |
| 18 ProStrakan Pharma B.V.                    | 100.00%   | €18                                | Sales of pharmaceuticals (Netherlands)                                     |
| 19 ProStrakan S.r.I.                         | 100.00%   | €10                                | Sales of pharmaceuticals (Italy)   |
| 20 ProStrakan AB                             | 100.00%   | SEK 200                            | Sales of pharmaceuticals (Sweden)  |
| 21 Archimedes Pharma Limited                 | 100.00%   | £542                               | Supervision and management of special companies (U.K.)                     |
| 22 Archimedes Development Limited            | 100.00%   | £113                               | Development of pharmaceuticals (U.K.)                                      |
| 23 Archimedes Holdings Limited               | 100.00%   | £10,501                            | Holding company for special companies (U.K.)                               |
| 24 Archimedes Pharma Europe Limited          | 100.00%   | £1,500                             | Holding company for special companies (U.K.)                               |
| 25 Archimedes Pharma UK Limited              | 100.00%   | £77                                | Sales of pharmaceuticals (U.K.)  |
| <sup>26</sup> Archimedes Pharma Ibérica S.L. | 100.00%   | €0.1<br>€9.9                       | Sales of pharmaceuticals (Spain)   |
| 27 Archimedes Pharma France SAS              | 100.00%   | €250                               | Sales of pharmaceuticals (France)  |
|  |   |                                    |  |



39 41

40 4 9

| Name of Company                                     | Percentage<br>Owned Directly<br>or Indirectly by<br>the Company | Capital <sup>2</sup><br>(Thousand) | Principal Business  |
|---|---|------------------------------------|---|
| 28 Archimedes Pharma Germany GMBH                   | 100.00%   | €25                                | Sales of pharmaceuticals (Germany)  |
| 29 Archimedes Pharma Ireland Limited                | 100.00%   | €0.1                               | Sales of pharmaceuticals (Ireland)  |
| Asia  |   |                                    |   |
| Kyowa Hakko Kirin China Pharmaceutical<br>Co., Ltd. | 100.00%   | RMB 246,794                        | Manufacturing and sales of pharmaceuticals (China)  |
| 31 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)  |
| 34 Kyowa Hakko Kirin (Singapore) Pte. Ltd.          | 100.00%   | SG \$1,000                         | Sales of pharmaceuticals and research (Singapore)   |
| Japan (Equity-method affiliate)                     |   |                                    |   |
| 55 FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.         | 50.00%  | ¥100,000                           | Development, manufacturing and sales of biosimilar<br>pharmaceuticals                               |
| BIO-CHEMICALS                                       |   | 25                                 |   |
| Japan   |   |                                    |   |
| 36 KYOWA HAKKO BIO CO., LTD.                        | 100.00%   | ¥10,000,000                        | Manufacturing and sales of pharmaceutical and industrial rav<br>materials, and health care products |
| 22 Daiichi Fine Chemical Co., Ltd.                  | 100.00%   | ¥6,276,000                         | Manufacturing and sales of active pharmaceutical ingredients<br>and pharmaceutical intermediates    |
| 38 Kyowa Engineering Co., Ltd.                      | 100.00%   | ¥70,000                            | Design and installation of plant facilities and equipment   |
| America   |   |                                    |   |
| 39 BioKyowa Inc.                                    | 100.00%   | US \$20,000                        | Manufacturing and sales of amino acids (U.S.A.)   |
| W Kyowa Hakko U.S.A., Inc.                          | 100.00%   | US \$1,000                         | Sales of fine chemicals including amino acids (U.S.A.)  |
| 41 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  |   |                                    |   |
| 42 Kyowa Hakko Europe GmbH                          | 100.00%   | €1,030                             | Sales of fine chemicals including amino acids (Germany)   |
| 🛽 Kyowa Hakko Bio Italia S.r.I.                     | 100.00%   | €700                               | Sales of fine chemicals including amino acids (Italy)   |
| Asia  |   |                                    |   |
| 44 Shanghai Kyowa Amino Acid Co., Ltd.              | 100.00%   | RMB 156,436                        | Manufacturing and sales of amino acids (China)  |
| 45 Thai Kyowa Biotechnologies Co., Ltd.             | 100.00%   | THB 2,000,000                      | Manufacturing and sales of amino acids (Thailand)   |
| 46 Kyowa Hakko (H.K.) Co., Ltd.                     | 100.00%   | HK \$1,200                         | Sales of fine chemicals including amino acids (Hong Kong)   |
| 47 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., which is an equity-method affiliate.

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.

### Management Members (As of April 1, 2015)

#### Kyowa Hakko Kirin Co., Ltd.

#### Head Office

1-6-1, Ohtemachi, Chiyoda-ku, Tokyo 100-8185, Japan Tel: 81-3-3282-0007 Fax: 81-3-3284-1968 URL: http://www.kyowa-kirin.com/

Number of Employees 4,214 (Consolidated: 7,424)

**Date of Foundation** July 1, 1949

Paid-in Capital ¥26,745 million

#### **Principal Plants**

#### Domestic

Pharmaceuticals

Takasaki Plant Fuji Plant Ube Plant Sakai Plant Kyowa Medex Fuji Plant

#### **Bio-Chemicals**

Yamaguchi Production Center (Hofu, Ube) Healthcare Plant (Tsuchiura) Daiichi Fine 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 Chemical Process Research and Development Laboratories Drug Formulation Research and Development Laboratories 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.

#### **Board Members**

Executive Director of the Board President and Chief Executive Officer Nobuo Hanai, Ph.D.<sup>1</sup>

#### 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 Head Development Functions Unit

#### **Directors of the Board**

Koichiro Nishikawa<sup>2</sup> Yoshiko Leibowitz<sup>2</sup> Akihiro Ito

Concurrently serves as executive officer
 Outside director

#### **Company Auditors**

#### **Full-time Company Auditors**

Hiroaki Nagai<sup>3</sup> Takahiro Kobayashi<sup>3</sup> Nobuhisa Yamazaki

#### **Company Auditors**

Motoyasu Ishihara<sup>3</sup> Kentaro Uryu<sup>3</sup> 3. Outside company auditor

#### **Executive Officers**

#### Managing Executive Officer

Yutaka Ouchi Director Human Resources Department

#### Executive Officers

Shigeru Morotomi Director Corporate Communications Department

Hiroshi Sugitani Vice President Head Sales & Marketing Division

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

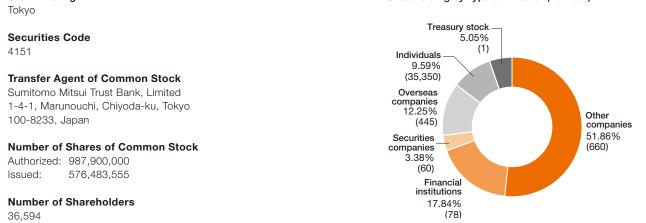
Wataru Murata Director Corporate Strategy & Planning Department

Yukihiro Noda Director

Osaka Branch Sales & Marketing Division

Hiroshi Sonekawa Director Area Marketing Strategy Department Sales & Marketing Division Stock Listing

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



| Principal Shareholders   |         | Percentage of Total<br>Shares Issued (%) |
|--|---------|--|
| Kirin Holdings Company, Limited  | 288,819 | 50.10                                    |
| The Master Trust Bank of Japan, Ltd. (Trust Account)   | 23,442  | 4.07                                     |
| Japan Trustee Services Bank, Ltd. (Trust Account)  | 12,727  | 2.21                                     |
| The Norinchukin Bank   | 10,706  | 1.86                                     |
| Trust & Custody Services Bank, Ltd. (Securities Investment Trust Account)                                    | 7,403   | 1.28                                     |
| Mizuho Trust & Banking Co., Ltd. (Retirement Benefit Trust for Mizuho Bank, Ltd.) <sup>1</sup>               | 6,809   | 1.18                                     |
| JPMorgan Chase Bank 385147 (Standing Proxy: Mizuho, Ltd., Settlement & Clearing Services Division)           | 5,250   | 0.91                                     |
| Nomura Securities Co., Ltd. (Private Transfer Account)   | 4,640   | 0.80                                     |
| State Street Bank West Client-Treaty (Standing Proxy: Mizuho, Ltd., Settlement & Clearing Services Division) | 4,523   | 0.79                                     |
| BNP Paribas Securities Limited   | 4,387   | 0.76                                     |
| BNP Paribas Securities Limited   | /       |  |

1. 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.

2. The 29,157,158 shares (5.06%) held by the Company as treasury stock are excluded from the above because treasury stock has no voting rights.

#### Stock Price and Trading Volume



### Kyowa Hakko Kirin Co., Ltd.

1-6-1, Ohtemachi, Chiyoda-ku, Tokyo 100-8185, Japan TEL: 81-3-3282-0007 FAX: 81-3-3284-1968 URL: http://www.kyowa-kirin.com/