### **KYOWA KIRIN**

# **Science That Heals**

Kyowa Hakko Kirin Co., Ltd.

Annual Report 2011 For the year ended December 31, 2011

### The Kyowa Hakko Kirin Group is...

...an R&D-based life sciences company with special strengths in biotechnology. The Kyowa Hakko Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies. We focus on science that heals in our core business segments of Pharmaceuticals and Bio-Chemicals. Innovation and integrity are strengths.

# Solid Support for

### Vision

The Kyowa Hakko Kirin Group aims to be a world-class R&Dfocused life sciences group of companies, based on biotechnology and with the pharmaceutical business at its core.

### **Pharmaceuticals**

### Kyowa Hakko Kirin

Creating innovative and effective drugs with a focus on oncology, nephrology and immunology/allergy

Our business vision is to be a Japan-based global specialty pharmaceutical company contributing to human health and well-being worldwide through innovative drug discovery and global commercialization, driven by state-of-the-art antibody technologies mainly in the core therapeutic areas of oncology, nephrology and immunology/allergy.

Kyowa Hakko Kirin is developing compounds with a focus on its POTELLIGENT<sup>®</sup> franchise of therapeutic antibodies, while maximizing its portfolio of existing products centered on market-leading anemia drugs that stimulate the production of red blood cells.

## **Our Commitment to**

### **Medical**

### Kyowa Medex

A leading global provider of advanced *in vitro* diagnostics and medical equipment

A global leader in areas including measurement of lipids and hemoglobin, Kyowa Medex is successfully creating diagnostic reagents that work with pharmaceuticals through Group collaboration from the earliest stages of development.

### **Health Care**

Kyowa Hakko Bio

Advanced technologies for high-valueadded pharmaceutical, medical and health care applications

Kyowa Hakko Bio uses sophisticated fermentation and synthesis technologies to maintain a leading position in global markets for products including amino acids, nucleic acids, vitamins and active pharmaceutical ingredients.

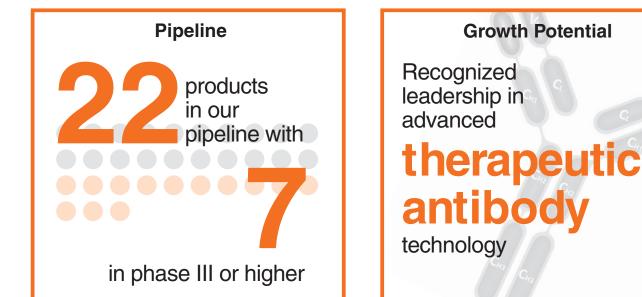
### Contents

Board of Directors	2
Financial Highlights	4
An Interview with President and Chief Executive Officer Nobuo Hanai	5
Feature: Science That Heals	13
LIFE	14
POTENTIAL	16
HEALTH	18
WORLDWIDE	20

Review of Operations	22
Main Segments	22
Pharmaceuticals	24
Bio-Chemicals	38
Intellectual Property	40
Sustainability	42
Corporate Social Responsibility	42
Organizational Governance	43
Human Rights and Labor Practices	47
Environment	48
Fair Operating Practices and Consumer Issues	49
Financial Section	51
Development Summary	95
Glossary	97
Principal Subsidiaries and Affiliates	99
Overseas Network	100
Corporate Data and Management Members	102
Investor Information	103

#### Note to Performance Forecasts

Forecasts contained in Annual Report 2011 represent judgments based on information available as of March 24, 2012. It should be noted that there is a possibility that actual results could differ significantly due to a variety of factors.



# **Science That Heals**

Clear Priorities in Growth Segments

- Oncology
- Nephrology
- Immunology
- Allergy



### Board of Directors (As of March 22, 2012)

Kyowa Hakko Kirin's management team has a deep philosophical commitment to serving stakeholders with science that heals.



### Nobuo Hanai

Executive Director of the Board, President and Chief Executive Officer

- Apr. 1976: Joined Kyowa Hakko Kogyo Co., Ltd. Feb. 2003: President and Chief Executive Officer, BioWa, Inc. Jun. 2006: Managing Officer, Kyowa Hakko Kogyo Co., Ltd. Oct. 2008: Managing Officer, Kyowa Hakko Kirin Co., Ltd. Apr. 2009: Executive Managing Officer, Kyowa Hakko Kirin Co., Ltd.
- Jun. 2009: Director of the Board, Executive Managing Officer, Kyowa Hakko Kirin Co., Ltd. Mar. 2010: Director of the Board, Senior Executive Managing Officer, Kyowa Hakko Kirin Co., Ltd. Mar. 2012: Appointed Executive Director of the Board, President and Chief Executive Officer. Kyowa Hakko Kirin Co., Ltd.

### Yoshiharu Furumoto

Executive Director of the Board, Executive Vice President

- Apr. 1973: Joined Kirin Brewery Co., Ltd. Apr. 2002: General Manager, Spirits and Wine Department of Sales and Marketing
- Division, Kirin Brewery Co., Ltd. Mar. 2004: Executive Officer,
- Kirin Brewery Co., Ltd. Mar. 2007: Managing Executive Officer, Kirin Brewery Co., Ltd.
- Jul. 2007: Managing Executive Officer, Kirin Holdings Company, Ltd.
- Mar. 2008: Managing Director, Kirin Holdings Company, Ltd. Mar. 2010: Managing Director,
- Waraging Director, Representative Director, Kirin Holdings Company, Ltd.
   Mar. 2012: Appointed Executive Director of the Board, Executive Vice President, Kyowa Hakko Kirin Co., Ltd. (to present)

### Kazuyoshi Tachibana

Director of the Board, Executive Managing Officer

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

### Hiroyuki Kawai

Director of the Board, Executive Managing Officer

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

(to present)

We believe that we can give patients life, potential and health, worldwide, and generate strong returns for shareholders by harnessing our scientific capabilities to solving unmet medical needs.



### Fumihiro Nishino

Director of the Board, Executive Managing Officer

- Nov. 1982: Joined Kyowa Hakko Kogyo Co., Ltd. Apr. 2004: General Manager, Pharmaceutical Sales Panning Department, Kyowa
- Hakko Kogyo Co., Ltd. Oct. 2006: General Manager, Pharmaceutical Marketing Department of Pharmaceutical Sales Division, Pharmaceuticals Business Unit, Kyowa Hakko Kogyo Co., Ltd.
- Apr. 2007: Managing Officer, Kyowa Hakko Kogyo Co., Ltd.
- Oct. 2008: Managing Officer, Kyowa Hakko Kirin Co., Ltd.
- Apr. 2011: Executive Managing Officer, Kyowa Hakko Kirin Co., Ltd.
- Mar. 2012: Appointed Director of the Board, Executive Managing Officer, Kyowa Hakko Kirin Co., Ltd. (to present)

### Mutsuyoshi Nishimura

Director of the Board

### Motoaki Kitayama

Director of the Board

- Apr. 1962: Joined Ministry of Foreign Affairs of Japan Jul. 1992: Director, Management and Coordination Division of Minister's Secretariat,
- Ministry of Foreign Affairs of Japan Aug.1997: Director-General, European and Oceanian Affairs Bureau, Ministry of
- Foreign Affairs of Japan Aug.1999: Ambassador Extraordinary and Plenipotentiary, Permanent Delegation of Japan to the Organisation for Economic
- Co-operation and Development Mar. 2003: Ambassador Extraordinary and Plenipotentiary, Permanent Mission of
- Japan to Mexico and Belize May. 2005: Ambassador for Global Environmental

Affairs Dec. 2007: Special Advisor to the Cabinet (Special Envoy of the Government of Japan for Climate Change) Mar. 2010: Appointed Director of the Board, Kyowa Hakko Kirin Co., Ltd. (to present)

- Apr. 1969: Appointed Judge
- Oct. 2006: President of Fukuoka High Court Apr. 2008: Admitted to the bar (to present) Task Force on Intellectual Property Systems in the Age of Digital Networks, Intellectual Property Strategy Headquarters,
- Cabinet Secretariat Apr. 2009: Professor, Nihon University Law School (to present)
- Mar. 2011: Member of Central Committee for Adjustment of Construction Work Disputes of the Ministry of Land, Infrastructure, Transport and Tourism (to present) Jun. 2011 Appointed Director of the Board, Kwwa Hakko Kirin Co. Ltd (to
  - Kyowa Hakko Kirin Co., Ltd. (to present) Member of Medical Malpractice Litigation Committee, Supreme Court of Japan (to present)

### Hajime Nakajima

Director of the Board

- Apr. 1977: Joined Kirin Brewery Co., Ltd. Mar. 2004: Member of the Board of Directors,
- San Miguel Corporation Mar. 2007: General Manager. Corporate Planning
- Department, Kirin Brewery Co., Ltd.
- Jul. 2007: General Manager, Corporate Planning Department, Kirin Holdings Company, Ltd. Mar. 2008: Managing Officer,
- Kirin Holdings Company, Ltd. Mar. 2009: Executive Managing Officer,
- Mar. 2009. Executive Mainaging Onicel, Kirin Holdings Company, Ltd. Mar. 2010: Appointed Director of the Board, Kyowa Hakko Kirin Co., Ltd. (to present) Managing Director, Kirin Holdings Company, Ltd. (to present)

### **Financial Highlights**

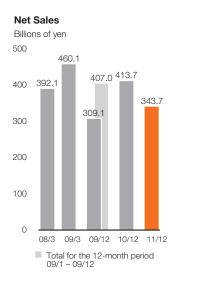
Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries

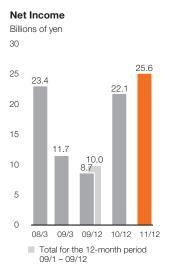
For the years ended December 31, 2011 and 2010, and the nine months ended December 31, 2009

- Slowing economies, the financial crisis in Europe and the continuing strength of the yen compounded the effects of the Great East Japan Earthquake.
- Competition remained intense in the Pharmaceuticals segment, especially in global new drug development.
- We achieved record earnings despite the challenging operating environment, demonstrating the effectiveness of our strategy of focusing on core strengths.

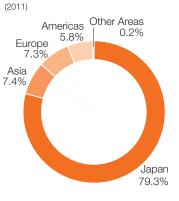
		Thousands of U.S. dollars <sup>1</sup>			
	2011	2010	2009	2011/2010	2011
For the Year: Net sales Operating income Net income Capital expenditures Depreciation and amortization R&D expenses	¥343,722 46,614 25,608 19,697 22,833 47,961	¥413,738 45,410 22,197 29,374 22,188 44,210	¥309,111 28,243 8,797 25,135 17,003 34,979	(16.9)% 2.7% 15.4% (32.9)% 2.9% 8.5%	\$4,421,442 599,621 329,409 253,378 293,717 616,950
At Year-End: Total assets Interest-bearing debt Total net assets Total shareholders' equity	658,873 6,042 540,023 554,856	695,862 7,515 544,992 553,172	695,268 13,228 540,343 539,304	(5.3)% (19.6)% (0.9)% 0.3%	8,475,350 77,726 6,946,527 7,137,331
		Y	en		U.S. dollars <sup>1</sup>
<b>Per Share Data:</b> Net income-basic <sup>2</sup> Net assets Cash dividends	¥45.16 970.2 20	¥38.96 954.6 20	¥15.40 940.8 15	15.9% 1.6% 0.0%	\$ 0.581 12.480 0.257
<b>Financial Ratios:</b> Return on assets (ROA) Return on equity (ROE)	3.78% 4.73%	3.19% 4.11%	1.26% 1.64%		

U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥77.74=U.S.\$1, the approximate exchange rate at December 31, 2011.
 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.











Molan States

Nobuo Hanai President and Chief Executive Officer

Nobuo Hanai became president and chief executive officer in March 2012. In this interview, he covers the progress and results of Medium-Term Management Plan – 2010 to 2012 and management strategies for the future.

### An Interview with President and Chief Executive Officer Nobuo Hanai

The Kyowa Hakko Kirin Group has entered a new phase by making solid progress in selecting and concentrating its business portfolio during fiscal 2011 ended December 31, 2011. In fiscal 2012, we will advance under a new management framework toward our vision of being a worldclass R&D-focused life sciences group of companies, based on biotechnology and with the pharmaceutical business at its core.

Q1. As the new president and chief executive officer, what are the keys to managing the Kyowa Hakko Kirin Group?

An entrepreneurial spirit is essential, and the Group needs to directly apply its unique capabilities in its businesses.

I was involved in pharmaceutical development as the vice president head of the Development Division since Kyowa Hakko Kirin's founding in 2008. I concentrated on a core theme of our current medium-term management plan: achieving rapid progress in our development pipeline through efficient use of management resources.

The Group's central strength is a vertically diversified pharmaceutical portfolio that is unique in its coverage of everything from pharmaceutical raw materials to pharmaceutical products. We need to directly apply this strength in our businesses. The Kyowa Hakko Kirin Group is entrepreneurial, not huge. Given our extremely challenging operating environment, my mission is to ensure continuous growth by leveraging our entrepreneurial spirit and our unique strengths as we take on new challenges.

### Q2: Please discuss performance during fiscal 2011 and the progress and results of Medium-Term Management Plan – 2010 to 2012.

### Bold, decisive management drove a major operational transformation and the Kyowa Hakko Kirin Group's evolution to a new phase.

Uncertainty dominated fiscal 2011, as slowing overseas economies, the financial crisis in Europe and the continuing strength of the yen compounded the effects of the Great East Japan Earthquake. In the Pharmaceuticals segment, conditions remained challenging due to the promotion of generic pharmaceuticals, aggressive moves by European and U.S. drug manufacturers and major specialist pharmaceutical companies, and intensifying global competition in new drug development.

In this environment, the Kyowa Hakko Kirin Group further strengthened domestic sales operations with the aims of expanding sales of core products and achieving rapid market penetration for new products. Targeting further progress in overseas

Basic Strategies	Progress under M	ediun	n-Term Mana	gement Pla	n – 2010 to 2012
Implementing the principles of selection and concentration in our business portfolio	April 2010 • Livestock and fisheries products of Bio-Chemicals transferred to ASKA Pharmaceutical Co., Ltd.		June 2010 • Alcohol sales operations of Bio-Chemicals integrated with Mercian Corporation		March 2011 • All shares of Kyowa Hakko Chemical Co., Ltd. transferred to KJ Holdings Inc.
Improving profitability by reorganizing production sites	January 2010 • Production base reorganization started; plan to invest ¥10 billion in new facilities through 2017		forms at the • Construction entities at I	n of a new plant for solid oral dosage 9 Ube Plant; completion in late 2012 20 of a plant for APIs for chemical DAIICHI FINE CHEMICAL; 1 in July 2012	
Further developing our world-class therapeutic antibody business	April 2011 • Acquisition of ProStrakan Group plc, which became a wholly owned subsidiary		March 2012  • Joint venture v Corporation to produce biosir	develop and	March 2012 • Nearly simultaneous approval for POTELIGEO <sup>®</sup> and companion diagnostic POTELIGEO <sup>®</sup> TEST

development, in April 2011 we acquired ProStrakan Group Plc (ProStrakan), a specialty pharmaceutical company in the United Kingdom, and made it a wholly owned subsidiary. In the Chemicals segment, we sold all shares of Kyowa Hakko Chemical Co., Ltd. in March 2011 with the objective of concentrating our operating resources in the Pharmaceuticals segment.

As a result, consolidated net sales decreased 16.9 percent compared with the previous fiscal year to ¥343.7 billion, partly due to the removal of the Chemicals segment from the scope of consolidation. However, we achieved record earnings despite the challenging operating environment, with operating income increasing 2.7 percent to ¥46.6 billion and net income increasing 15.4 percent to ¥25.6 billion.

Exemplifying the progress and results of Medium-Term Management Plan – 2010 to 2012, bold and decisive management during fiscal 2011 focused operations on the pharmaceuticals, medical and health care businesses and drove the Kyowa Hakko Kirin Group's evolution to a new phase.

In particular, the acquisition of ProStrakan created a framework for accelerating global growth by enhancing our sales network in Europe and the United States. We have been advocating global growth in the Pharmaceuticals segment as a global specialty pharmaceutical company since the creation of Kyowa Hakko Kirin in October 2008. While we have built pharmaceutical development capabilities in Europe and the United States and pharmaceutical development and sales capabilities in Asia, the addition of ProStrakan is a milestone in making the Group a global specialty pharmaceutical company.

The acquisition of ProStrakan helps us accelerate global growth as we prepare to market oncology therapies worldwide.

### Q3. What are the specific strengths of each Group segment?

### Each of our segments has unique technological strengths and outstanding growth potential driven by our strategies and policies.

In the Pharmaceuticals segment, our research and production technology capabilities center on world-class antibody technology that includes POTELLIGENT<sup>®</sup>, an antibody-dependent cellular cytotoxicity (ADCC) enhancing technology that is drawing attention as a revolutionary technology in the development of therapeutic antibodies. We have received domestic manufacturing and marketing approval for our first product using POTELLIGENT<sup>®</sup> technology, a treatment for adult T-cell leukemia-lymphoma (ATL) called POTELIGEO<sup>®</sup> (mogamulizumab) Injection ("POTELIGEO<sup>®</sup>"). We also have many other POTELLIGENT<sup>®</sup> therapeutic antibodies in development, including eight we are developing in-house and seven now in clinical trials among the seventeen companies that have licensed this technology. Thus we are building a framework for continuously creating new pharmaceuticals in an era in which launching breakthrough pharmaceuticals is extremely difficult.

Moreover, the Kyowa Hakko Kirin Group's diagnostic reagent subsidiary, Kyowa Medex Co., Ltd., received approval for POTELIGEO<sup>®</sup> TEST IHC and POTELIGEO<sup>®</sup> TEST FCM ("POTELIGEO<sup>®</sup> TEST"), a jointly developed companion

POTELIGEO<sup>®</sup> resolves an unmet medical need and demonstrates the sophistication of our research and technologies. diagnostic for POTELIGEO<sup>®</sup>. We submitted new drug applications (NDAs) for POTELIGEO<sup>®</sup> TEST and POTELIGEO<sup>®</sup> concurrently, which was an unprecedented innovation. This provides new business opportunities for Kyowa Medex given the move toward personalized medical care, which optimizes treatment by prescribing the pharmaceuticals that are the most effective with the fewest adverse reactions for each patient.

Our subsidiary in the Bio-Chemicals segment, Kyowa Hakko Bio Co., Ltd., was the first in the world to succeed at mass-producing amino

acids through fermentation, and is one of the few companies that has technology capable of producing virtually all amino acids this way. Amino acids are essential to patient nutrition and are widely used in health foods. They are also an essential nutrient in the culture media used to produce biopharmaceuticals and therapeutic antibodies. I see an important future role for Kyowa Hakko Bio in the Pharmaceuticals segment as our emphasis shifts from pharmaceuticals produced with conventional chemical synthesis to biopharmaceuticals. Q4: As an expert in therapeutic antibodies in Japan, you led the research and development of POTELIGEO<sup>®</sup> for 16 years. What does the approval and launch of POTELIGEO<sup>®</sup> mean for the Kyowa Hakko Kirin Group's therapeutic antibody business?

### Providing pharmaceuticals for unmet medical needs fulfills a social responsibility and enhances our credibility with society.

The launch of POTELIGEO<sup>®</sup> has two important ramifications. The first is its significance in terms of fulfilling our social responsibility to provide pharmaceuticals for unmet medical needs. The therapeutic antibody POTELIGEO<sup>®</sup> was approved for treating ATL, a terrible disease that used to quickly result in death because no treatment existed. Society shares the high expectations doctors and patients have for POTELIGEO<sup>®</sup>.

Second, this new pharmaceutical using revolutionary antibody technology shows the world the sophistication of the Kyowa Hakko Kirin Group's research and technological capabilities, which enhances our credibility with society. The launch of POTELIGEO® increases the trust doctors and patients place in us, which I expect will effectively increase their trust in our other pharmaceuticals.

### Q5: Please explain the Kyowa Hakko Kirin Group's prospects for global business development, including your expectations for ProStrakan.

### I expect that rapidly implementing our marketing strategies will allow us to quickly capture synergies.

We will look for synergies as we organically integrate our existing sales network in Europe with ProStrakan's infrastructure. In the United States, we will use ProStrakan's sales network to enhance the presence of Abstral<sup>®</sup>, a medication for managing breakthrough cancer pain, and Sancuso<sup>®</sup>, a treatment for chemotherapy-induced nausea and vomiting. We intend to build a powerful marketing foundation to prepare for global sales of cancer treatments including POTELIGEO<sup>®</sup> and other products, and I am looking forward to rapidly capturing synergies.

In Asia, we are already selling pharmaceuticals in China, Korea and ASEAN countries, but pharmaceutical markets and regulatory authorities differ by country and region. We will deploy our understanding of these countries and regions so that we can serve them profitably.





Q6: What was the rationale for forming a joint venture with FUJIFILM Corporation to develop, manufacture and sell biosimilars, and what are your expectations for this business?

This joint venture combines the technologies of both companies to enable global sales of biopharmaceuticals that are unrivaled in terms of quality and cost competitiveness.

We need to aggressively leverage our capabilities and our value chain to create new businesses when opportunities arise. Therapeutic antibody production requires an extremely high level of technology compared with the production of small molecular weight pharmaceuticals. The object of significant global attention, the biosimilars business presents an excellent opportunity for us to grow by using our world-class biopharmaceutical production technology.

We established a joint venture because we felt that we needed to establish biopharmaceutical production technologies of extremely high quality and cost competitiveness to compete globally in this business. We will deploy our biopharmaceutical manufacturing technologies with FUJIFILM's culturing and purification technologies to optimize production processes and raise the efficiency of cell culture processes. We will then combine innovative culturing technologies with technologies that apply the new manufacturing processes, assembling the innovative technologies that result to enable global sales of biopharmaceuticals that are unrivaled in terms of quality and cost competitiveness. I also have great expectations for broader application of the technologies we acquire in the development of new pharmaceuticals.

### Q7: What are the Kyowa Hakko Kirin Group's future challenges and policies?

In the Pharmaceuticals segment, we will further strengthen domestic sales capabilities through measures that include enhancing sales specialization. In the Bio-Chemicals segment, we will enhance profitability.

In the Pharmaceuticals segment, we will further enhance domestic sales capabilities. We have a high share in our core erythropoiesis stimulating agent (ESA) market, but competition is intensifying. We therefore need to maintain market share by expanding sales of core products while increasing sales specialization to achieve rapid market penetration for new products such as POTELIGEO<sup>®</sup>. We are emphasizing the Sales & Marketing Division in implementing a number of measures that include teaching sales personnel new approaches.

In the Bio-Chemicals segment, we will build global sales of amino acids, nucleic acids and related compounds with a continued focus on high-value-added pharmaceutical, medical and health care applications. We will also promote our own brands of health food materials such as ornithine in the domestic health care market. Concurrently, we will work to raise profitability.

## Q8: Do you plan to change the shareholder returns policy of a consolidated dividend payout ratio of at least 30 percent and stable, sustainable dividends? Our basic policy for profit distribution will not change.

The distribution of profits to shareholders through stable, sustainable dividends will remain a central priority for the Kyowa Hakko Kirin Group. Our dividend policy balances issues including the internal capital required for growth, annual consolidated results, the dividend payout ratio, and dividend return on net assets. I would like to assure shareholders of our continued commitment to a consolidated dividend payout ratio of at least 30 percent of earnings before amortization of goodwill. We will

Stable, sustainable dividends and a consolidated dividend payout ratio of at least 30 percent are central priorities.

also seek to improve capital efficiency through flexible, timely share repurchases. Based on this policy, for fiscal 2011 we paid an annual cash dividend per share of ¥20.00, consisting of an interim dividend of ¥10.00 and a year-end dividend of ¥10.00.

### Q9: What is your stance for strengthening corporate governance? Strengthening corporate governance is a central priority as we expand globally.

The Kyowa Hakko Kirin Group is committed to its Group Management Philosophy of striving 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." Above all, we have significant social responsibilities in the pharmaceuticals, medical and health care businesses, and we believe that strengthening governance is a central priority as we expand globally.

Although conditions and laws differ by country, the Group is improving corporate governance by increasing management transparency and reinforcing oversight functions to fulfill our social responsibilities and earn the trust of customers.

### Q10: What is your long-term vision for the Kyowa Hakko Kirin Group? How does it align with the expectations of shareholders and investors?

### We are committed to strength in the Pharmaceuticals segment, to innovation in our unique value chain, and to growth in global markets.

I would like to reiterate that we will not pursue size for the sake of size. Rather, we want to be a corporate group with a scale that lets us fully leverage our strengths as we take on challenges worldwide.

My approach to management prioritizes global expansion. Therefore, my goal is to have globally minded people working within an organization that embraces diversity, encourages them to take on challenges, and helps them achieve great things without regard for gender, age or similar distractions.

The Kyowa Hakko Kirin Group is undergoing a profound evolution to a new phase as a global specialty pharmaceutical company focused on the pharmaceuticals, medical and health care businesses. On behalf of our shareholders, we are committed to strength in the Pharmaceuticals segment, to innovation in our unique value chain, and to growth in global markets.

We are counting on your continued support.

## **Science That Heals**

## LIFE

## POTENTIAL 16

Kyowa Hakko Kirin is a research-based company that focuses on the power of science to heal. We are deploying our high-potential POTELLIGENT® franchise to create innovative and effective therapies for some of the most challenging diseases in the world. This feature article highlights our approach to providing life, potential and health, worldwide.

### HEALTH

18

14

## WORLDWIDE 20



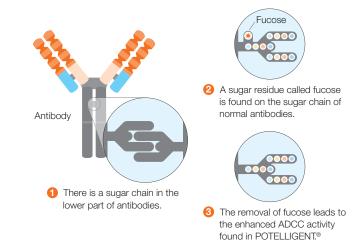
Demonstrating our commitment to life and health through new drug discovery, 20 of our therapeutic antibodies are at the clinical development stage: 10 in-house, 3 among licensees, and 7 within POTELLIGENT<sup>®</sup> technology alliances.

### **How Therapeutic Antibodies Work**

Therapeutic antibodies use the mechanisms and properties of antibodies, which have the distinctive feature of only recognizing specific targets. They bind to and attack specific antigens in the body, which makes them highly effective and much less likely to damage healthy cells than conventional synthetic pharmaceuticals. This in turn makes unexpected side effects much less likely.

### **ADCC Mechanism**

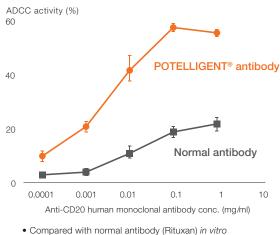
The basic structure of antibodies is a Y-shape. The tips of the "Y," which are called the hypervariable regions, bind to the pathogen's antigen. These tips have structures that differ by antigen, so the antibodies have the distinctive feature of binding only to a specific antigen, much like a lock and key.



### The Potential of POTELLIGENT<sup>®</sup>, a Powerful Technology for Enhancing Antibody-Dependent Cellular Cytotoxicity (ADCC)

A key feature of POTELLIGENT<sup>®</sup>, an original Kyowa Hakko Kirin technology, is its ability to remarkably increase ADCC activity by reducing the amount of fucose in the carbohydrate structure of antibodies. Animal studies have confirmed that POTELLIGENT<sup>®</sup> increases effectiveness in eliminating cancer cells and other targets by a factor of 100 or more.

#### ADCC Activity of POTELLIGENT<sup>®</sup> Antibody



- 1/100–1/1,000 conc. acquired same ADCC activity
- Max activity ophanood
- Max activity enhanced



**POTELLIGENT®** 

Technology

estimated global therapeutic antibody market in 2015



### antibody therapies now in clinical development

Kyowa Hakko Kirin is using its POTELLIGENT<sup>®</sup> technology to develop therapeutic antibodies in-house while also aggressively using this core technology in strategic alliances with other companies to quickly develop a broadly based antibody business. As of March 31, 2012, we have licensed POTELLIGENT<sup>®</sup> to 17 companies, and 7 licensees and alliance partners have related therapeutic antibodies in clinical development.

The stage during which we built the POTELLIGENT<sup>®</sup> franchise through contracts with major biopharmaceutical companies is now complete. The franchise will soon begin contributing to earnings because the new drugs our partners are developing using POTELLIGENT<sup>®</sup> technology should begin generating royalty income from 2015.

### Healing

Therapeutic antibodies are expected to effectively treat diseases that conventional pharmaceuticals cannot, with the use of POTELLIGENT® technology easing patient burden by enabling reduced dosage. We have received domestic manufacturing and marketing approval for POTELIGEO® (mogamulizumab), a treatment for adult T-cell leukemia-lymphoma (ATL) and our first POTELLIGENT®-based product. We expect POTELLIGENT® to drive the development of other pharmaceuticals that respond to the unmet medical needs of patients in a wide range of fields, including oncology, organ transplant rejection, and immunology and allergy conditions such as bronchial asthma.

### KM Mouse<sup>™</sup>

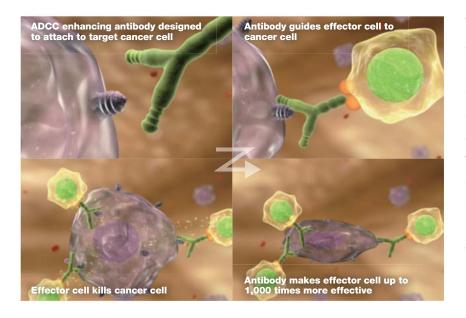
Kyowa Hakko Kirin pioneered technology for producing human artificial chromosomes (HACs) by transferring a fragment of a human chromosome into a mouse. We integrated this technique with the technology for producing human antibodies of Medarex Inc. (currently Bristol-Myers Squibb) to create KM Mouse<sup>™</sup> for producing fully human antibodies. This technology is recognized globally for its sophistication.

Today, KHK2898 is in phase I clinical trials in Singapore. We have high expectations for this oncology drug, which is a fully human antibody that symbolizes the benefits of the merger of Kyowa Hakko and Kirin Pharma because it uses both POTELLIGENT<sup>®</sup> technology and KM Mouse<sup>™</sup> technology.

# POTENTIAL

We received nearly simultaneous approval for the world's first POTELLIGENT<sup>®</sup> therapeutic antibody, POTELIGEO<sup>®</sup> (mogamulizumab), and for its companion diagnostic, POTELIGEO<sup>®</sup> TEST. This creates outstanding potential for Kyowa Hakko Kirin to grow while supporting tailored treatments.

### **POTELIGEO®: A Treatment for Adult T-Cell Leukemia-Lymphoma (ATL)**



We have received manufacturing and marketing approval for the therapeutic antibody, POTELIGEO®, which we discovered and developed entirely in-house. It is both our first and the world's first POTELLIGENT® therapeutic antibody. We expect this approval to enhance the potential of other POTELLIGENT®-based drugs now under development in-house and among licensees. POTELIGEO® is also important because it is designated as an orphan drug, which fulfills our objective of responding to unmet medical needs.

### **POTELIGEO® TEST: A Companion Diagnostic**



POTELIGEO® and POTELIGEO® TEST are complementary components for treating ATL that were approved nearly simultaneously. Using this drug and *in vitro* diagnostic in tandem is expected to contribute to personalized medical care that matches patients with the most appropriate therapies for them. We are now making the preparations that will enable us to quickly supply POTELIGEO® TEST to health care providers.



products in our development pipeline

### Oncology: ARQ 197

### Nephrology: RTA 402



### new cancer cases reported worldwide annually

ARQ 197 is an orally active small molecule. It inhibits c-Met, a receptor tyrosine kinase implicated in tumor cell migration, invasion and proliferation. In April 2007, we concluded an agreement with ArQule, Inc. for exclusive ARQ 197 development and marketing rights in Japan and certain countries of Asia. In the United States, ArQule has completed a phase II clinical trial for non-small cell lung cancer (NSCLC). In Japan, a phase I clinical trial of ARQ 197 started in February 2008, and a phase I clinical trial of ARQ 197 in combination with Erlotinib started in February 2010. A phase III clinical trial for NSCLC commenced in August 2011.

RTA 402 is an orally active small molecule. It is an inducer of the transcription factor Nrf2, which controls the production of many antioxidant and anti-inflammatory factors. Reata Pharmaceuticals, Inc. of the United States has been conducting clinical trials. Data from these trials show that RTA 402 achieves significant improvement in kidney function in chronic kidney disease (CKD) patients with type 2 diabetes. Reata is also conducting global phase III clinical trials in the United States and the European Union. In Japan, Kyowa Hakko Kirin began a phase II clinical trial in February 2012.

## Immunology: ASKP1240

ASKP1240 is a fully human monoclonal antibody that interferes with the CD40-CD40 ligand (CD154) interaction. We expect this antibody to satisfy unmet medical needs for organ transplants regulated by both cellular and humoral immunity. We concluded a co-development agreement with Astellas Pharma Inc. for this antibody in January 2007. Clinical trials are in phase II in the United States and phase I in Japan.

Kyowa Hakko Kirin supports earnings by gaining the trust of the pharmaceutical marketplace and contributing to patient treatment with outstanding products.

### **NESP®: A Strong Market Leader**



NESP<sup>®</sup> is an erythropoiesis stimulating agent (ESA) with longer-lasting effect than conventional erythropoietin drugs. It is effective for improving renal anemia with reduced administration frequency. Moreover, merits including outstanding effectiveness in correcting anemia during initial administration in dialysis and prior to the start of dialysis, along with a flexible dosage amount and regulation, have earned the trust of the pharmaceutical marketplace and given this useful drug a leading market share.

### **MR Training and Support for Comprehensive Therapeutic Proposals**



Kyowa Hakko Kirin's intense focus on renal disease and treatment also includes detailed education programs that ensure specialist renal knowledge among medical representatives (MRs), which empowers them to make comprehensive proposals in areas including dialysis drugs and patient care. In providing information to health care professionals, MRs benefit from the ability to draw on our database of valuable, leading-edge information from various media and the medical world that we add to daily using our global network.

Feature: Science That Heals



share of the ¥120 billion ESA market (price basis estimate)



### **ALLELOCK®** Oral Disintegrant (OD) Tablets

ALLELOCK<sup>®</sup> is an antiallergic agent that widely inhibits the factors involved in allergic reactions. Extensive clinical evidence demonstrates its potent antihistamine activity. It is available as a tablet; as a disintegrating tablet formulation that does not break during storage, which was developed using leading-edge technology; and as a powder that is easily administered to children.

### **CONIEL®** for Hypertension and Angina Pectoris

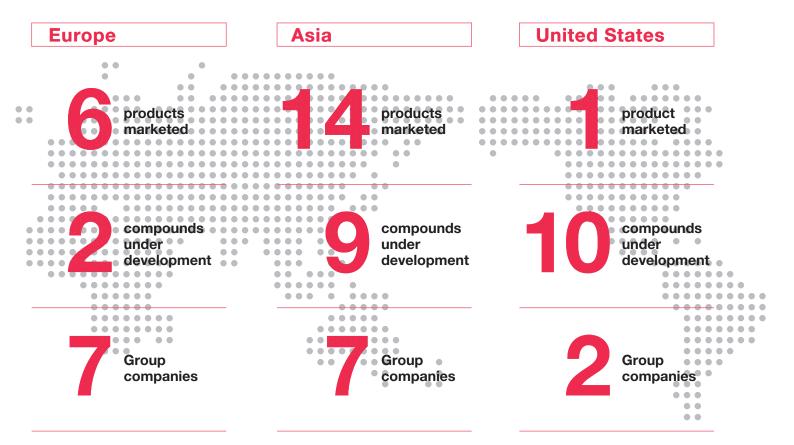
Extensive clinical testing has demonstrated the sustained efficacy and effectiveness of this calcium antagonist, which is the first drug in Japan for treating both hypertension and angina pectoris. Of note, a large body of evidence including clinical data and analyses demonstrates that CONIEL® protects the heart, kidneys and brain from the effects of hypertension and angina pectoris.

### **GRAN®** Granulocyte-Colony Stimulating Factor (G-CSF) Agent

This G-CSF agent is used to treat neutropenia occurring as a result of chemotherapy and other types of neutropenia. Moreover, health care professionals have praised the excellence of the syringe form of GRAN<sup>®</sup> in managing risk. As a result, GRAN<sup>®</sup> holds an estimated 55 percent share of its market on a drug price basis.



### **Development and Sales Network**



Our initiatives for maximizing the value of our therapeutic antibody business include aligning our production technologies for strong-acting antibodies with global standards, acquiring new antigens and antibodies through means including alliances, and quickly obtaining key patent rights. We have also strengthened our product lineup in the growth markets of Asia and created a long-term foundation for earnings in China. Moreover, we are formulating strategies for creating marketing channels in Europe and the United States to establish our own international marketing organization.



countries in which ProStrakan markets products



products marketed globally by Kyowa Hakko Kirin

### **United States**

In the United States, ProStrakan's salesforce of approximately 50 MRs focuses on building Sancuso<sup>®</sup>'s presence and a powerful marketing base. With the U.S. market launch of POTELIGEO<sup>®</sup> (mogamulizumab) in mind, we are also creating the organization needed to market new oncology-related pharmaceuticals globally.

Products Sancuso<sup>®</sup>: a treatment for chemotherapy-induced nausea and vomiting

### Europe

In Europe, Kyowa Hakko Kirin and ProStrakan are organically combining their sales infrastructures to enhance marketing capabilities.

#### Products

Abstral<sup>®</sup>: medication for managing breakthrough cancer pain Adcal-D3<sup>®</sup>: osteoporosis treatment / Rectogesic<sup>®</sup>: treatment for chronic anal fissures Tostran<sup>®</sup>: testosterone replacement therapy for hypogonadism Xomolix<sup>®</sup>: treatment of post-operative nausea and vomiting MITOMYCIN C<sup>®</sup>: cancer treatment

Asia

We tailor operations to conditions in each country and region to support profitability. In the growing Chinese market, we are concentrating on marketing our own products through our reorganized marketing organization, which we have enhanced by adding MRs.

#### Products

ESP0® and NESP®: erythropoiesis stimulating agents / Aranesp®: erythropoiesis stimulating agent Renagel®: hyperphosphatemia treatment / GRAN®: G-CSF agent / Peglasta®: G-CSF agent Neulasta®: G-CSF agent / Nplate®: treatment for idiopathic thrombocytopenic purpura Busulfex®: cancer treatment / REGPARA®: treatment for secondary hyperparathyroidism MITOMYCIN C®: cancer treatment / LEUNASE®: cancer treatment CONIEL®: hypertension and angina pectoris treatment / ALLELOCK®: antiallergic agent

### Science That Heals:

# Review of Operations

Main Segments 22

Pharmaceuticals 24

Bio-Chemicals 38

Intellectual Property 40



### Main Segments (As of December 31, 2011)

### **Pharmaceuticals**



R&D, production and sale of ethical drugs emphasizing oncology, allergies, renal anemia, hypertension and diagnostic reagents. Core technologies include therapeutic antibodies. Global clinical development complements international marketing capabilities. Sales Composition (Including intersegment transactions)



Net Sales\*/Segment Income Billions of yen



### **Bio-Chemicals**



Production and sale of amino acids, nucleic acids and related compounds for use in pharmaceuticals and their intermediates, health foods, dietary supplements and cosmetics. Mail-order sales of health care products in Japan show potential. 22.1%

eament trai

Sales Composition

(Including inter

Net Sales\*/Segment Income Billions of yen



#### **Core Products**

#### **Ethical Drugs:**

ESPO®/ NESP (ESA formulation) REGPARA (secondary hyperparathyroidism) **ALLELOCK**<sup>®</sup> (antiallergic agent) Patanol® (antiallergic eyedrops) **GRAN**<sup>®</sup> (G-CSF agent) 5-FU (anticancer agent) CONIEL (hypertension and angina pectoris) DEPAKENE (antiepileptic agent) Fentos (transdermal analgesic) Romiplate (chronic idiopathic thrombocytopenic purpura)

#### **Diagnostic Reagents:**

Determiner<sup>®</sup> series (clinical chemistry diagnostic reagents)

#### **Industry Trends**

- Innovation is essential because of intense competition created by generic drugs, the cost and difficulty of global new drug development, and government policies to control health care costs.
- Global development that optimizes resources and effective in- and out-licensing are strategically important. A strong pipeline and speed to market are critical.
- Drugs for unmet medical needs, personalized medicine using genomic information, and evidence-based medicine are key trends defining the direction and success of pharmaceutical companies.

#### **Fiscal 2011 Performance Review**

- Net sales increased 9.0 percent to ¥229.3 billion, and segment income increased 15.2 percent to ¥41.3 billion.
- Domestic sales of our core ethical drugs were significantly higher year on year.
   Sales of immunological reagents and exports were solid.
- POTELIGEO<sup>®</sup> (mogamulizumab), our first therapeutic antibody, and companion diagnostic POTELIGEO<sup>®</sup> TEST received nearly simultaneous manufacturing and marketing approval.
- The acquisition of ProStrakan supported growth in net sales and segment income.

### **Core Products**

### **Fine Chemical Products:**

Amino acids Nucleic acids Related compounds

#### **Health Care Products:**

Amino acids Vitamins Minerals Carotin Peptides Remake<sup>®</sup> series products Enguard<sup>®</sup> series products

#### Other:

Plant growth regulators

#### **Industry Trends**

- Global demand for amino acids and nucleic acids is increasing, driven by demand in emerging and developed countries in areas including pharmaceuticals, health care and dietary supplements.
- Technological innovation and efficient production are essential to counter rapidly rising raw material costs and profitably meet increased demand.
- Quality assurance, product safety, added value and cost competitiveness are primary themes that industrial customers and end-users continue to emphasize.

#### **Fiscal 2011 Performance Review**

- Net sales decreased 7.9 percent year on year to ¥77.5 billion, primarily because of the impact of the strong yen.
   Segment income decreased 11.6 percent to ¥2.8 billion.
- Pharmaceutical- and industrial-use amino acid and nucleic acid sales volume increased because of successful efforts to meet growing overseas demand.
- Mail-order sales of our own brands of health food materials grew steadily.
- Successful branding strategies in the U.S. supplements market generated positive results.

## Pharmaceuticals

### Research and Development



### **Fundamental Strategies**

- Leverage our leading-edge biotechnologies with emphasis on antibody technologies to promote discovery research in the focus areas (oncology, nephrology and immunology/ allergy) and enhance our development pipeline
- Accelerate new drug development through the effective use of overseas development bases to quickly acquire proof of concept (POC) for several products in development
- Obtain approval for two or more products every year (including additional indications)

### **Fiscal 2011 Achievements**

- POTELIGEO<sup>®</sup> (mogamulizumab), which is our first therapeutic antibody product, was approved for the treatment of adult T-cell leukemia-lymphoma (ATL).
- Companion diagnostic POTELIGEO® TEST was approved nearly simultaneously with POTELIGEO®.
- Apokyn<sup>®</sup> was approved for the treatment of Parkinson's disease.
- ALLELOCK<sup>®</sup> Granules was approved and launched.
- Romiplate<sup>®</sup> was approved for the treatment of chronic idiopathic thrombocytopenic purpura and launched.
- The prokinetic agent NAUZELIN® OD was approved and launched.

### **R&D Strategy and Organization**

Kyowa Hakko Kirin is focusing on leading-edge biotechnologies centered on the Company's original antibody technologies, such as POTELLIGENT<sup>®</sup> and KM Mouse<sup>™</sup>, which produces fully human antibodies from mice. Focusing on oncology, nephrology and immunology/allergy, we are accelerating R&D to enhance our development pipeline.

### **Research Organization**

Kyowa Hakko Kirin's research organization encompasses four laboratories that work together in close collaboration: Tokyo Research Park and Fuji Research Park in Japan, and Kyowa Hakko Kirin California, Inc. (KKC) and Hematech, Inc. overseas.

In April 2011, we merged the Antibody Research Laboratories and Innovative Drug Research Laboratories, which are located in the Tokyo Research Park, into the Biologics Research Laboratories. This research organization specializes in new biopharmaceutical discovery.

Due to the energy restrictions the government requested after the Great East Japan Earthquake in March 2011, we sent scientists to several overseas facilities from our two research facilities. This has given us an excellent opportunity to strengthen research collaboration among our laboratories and train our scientists. In addition, we strengthened collaboration with two non-profit research institutions, La Jolla Institute for Allergy & Immunology and the University of California at San Diego, which are located near KKC. We will continue to leverage internal and external relationships to enhance joint research and our product pipeline.

### **Development Organization**

Overseas clinical development bases include Kyowa Hakko Kirin Pharma, Inc. in the United States; Jeil-Kirin Pharmaceutical Inc. in Korea, which will change its name to Kyowa Hakko Kirin Korea Co., Ltd. in June 2012; Kyowa Hakko Kirin China Pharmaceutical Co., Ltd.; and Kyowa Hakko Kirin (Taiwan) Co., Ltd. Moreover, Kyowa Hakko Kirin dramatically strengthened its global strategy by adding UK-based ProStrakan Group Plc, which has a development and marketing network in Europe and the United States covering several therapeutic areas including oncology. This has accelerated the overseas development of new drugs in our core therapeutic areas.

### Manufacturing Technologies and Drug Production System

We have three laboratories that focus on researching synthetic pharmaceutical and biopharmaceutical processes: the Chemical Process Research and Development Laboratories, the Bio Process Research and Development Laboratories, and the Drug Formulation Research and Development Laboratories.

In addition, we proactively use contract manufacturing organizations (CMOs) in Japan and overseas for the production of small molecules. Moreover, we built one of the world's leading antibody production facilities at the Bio Process Research and Development Laboratories. The facility began operating in March 2010 and enables us to produce antibodies and other high molecular weight pharmaceuticals in-house and supply them globally.

### Developing the Therapeutic Antibody Business

### **Therapeutic Antibody Market Scale**

Therapeutic antibodies are innovative drugs that differ from small molecules. They help the antigenantibody interaction, which is a natural function of the human body, to target tumor and other cells with pinpoint accuracy. They are expected to have

**Therapeutic Antibody Market Trends** 

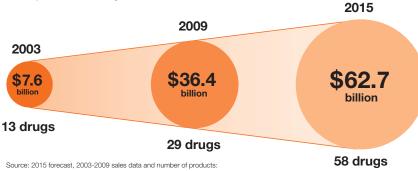
limited side effects and be highly effective against diseases that have been difficult to treat with conventional therapies.

The market for therapeutic antibodies has been growing rapidly in recent years. Approximately 30 types of therapeutic antibodies were available in a global market with sales of more than \$36 billion in 2009. Companies are aggressively entering the therapeutic antibody market, including large, financially strong pharmaceutical companies that were previously passive about in-house development of these drugs. A compound annual growth rate (CAGR) of 10 percent is expected for the global therapeutic antibody market. The number of products is expected to double and sales are expected to grow to more than \$60 billion by 2015.

### Kyowa Hakko Kirin's Antibody Technology

Kyowa Hakko Kirin has leveraged its genome research assets and research network to produce outstanding antibodies targeting cell surface proteins and other key druggable targets in the areas of oncology, nephrology and immunology/allergy.

Moreover, to enhance our presence in the field of therapeutic antibody technologies, we are expanding opportunities to acquire new antigens and accelerating therapeutic antibody development using our POTELLIGENT<sup>®</sup> and COMPLEGENT<sup>®</sup> ADCC enhancing technologies, our KM Mouse<sup>TM</sup> technology, and our bovine technology for producing fully human antibodies using animals. Our manufacturing processes complement these moves and enable us to create value chains.

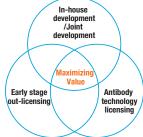


Datamonitor<sup>®</sup>, reprinted with permission. Published in *Monoclonal Antibodies: 2010 Update.* 

### Three Therapeutic Antibody Business Models

We maximize the value of the therapeutic antibodies in our development pipeline by assessing each drug candidate at the preclinical trial, clinical trial and application stages to decide whether we will out-license it at a given stage or complete the development process in-house until product launch. Out-licensing candidates at early stages and having antibody technology license contracts with other companies can generate royalty income according to development and marketing milestones and post-launch sales figures. Having multiple approaches to drug development allows us to accelerate the commercialization of therapeutic antibodies to achieve a core objective of the Medium-Term

Management Plan – 2010 to 2012, which is to develop a world-class therapeutic antibody business, while providing new drugs for diseases that still do not have effective treatments.



#### Model 1: In-House Development/Joint Development

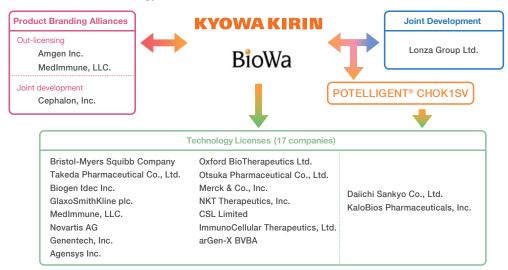
We are conducting clinical trials for 10 antibodies on our own and jointly. For ASKP1240, an anti-CD40 fully

human antibody generated using KM Mouse<sup>™</sup>, we concluded a worldwide joint development and marketing agreement with Astellas Pharma Inc. in January 2007. Clinical trials in Japan and the United States are steadily progressing. In addition, as described below in the section on early stage out-licensing, we are currently conducting a phase II clinical trial in Japan and Korea for KHK4563, for which the licensee has already moved ahead with development overseas. In 2010, we also repurchased global development and commercialization rights for anti-CCR4 humanized antibody KW-0761 in the field of oncology, for which we had previously licensed global development and commercialization rights excluding Japan, Korea, Taiwan and China to Amgen Inc.

Our joint R&D initiatives involve antibodies that we have discovered as well as combinations of our POTELLIGENT® and COMPLEGENT® technologies with the promising antigens/antibodies for oncology and inflammatory allergic therapies of biotech startups. We concluded a co-development agreement with Arana Therapeutics Limited in Australia (now Cephalon, Inc.) in April 2008, to develop an antibody therapy for colorectal cancer, and are now conducting joint development covering CEP-37250/KHK2804.

#### Model 2: Early Stage Out-Licensing

In certain cases we maximize value with accelerated out-licensing at early clinical or pre-clinical stages. We have licensed worldwide rights excluding certain Asian countries for the anti-IL-5 receptor humanized antibody



#### POTELLIGENT® Technology-Related Alliances (As of March 31, 2012)

\* To date seven out-licensed POTELLIGENT® antibodies have entered clinical trials, including those by Bristol-Myers Squibb and Genentech. KHK4563 (benralizumab), which uses POTELLIGENT<sup>®</sup> technology, to MedImmune, LLC. MedImmune is now conducting a phase IIb clinical trial of benralizumab with asthma patients. In addition, we have licensed KW-0761, which uses POTELLIGENT<sup>®</sup> technology, to Amgen Inc. In 2010, we repurchased the global development and commercialization rights for KW-0761 in the field of oncology from Amgen. Moreover, in 2009, we signed a research and marketing collaboration and licensing agreement under which Sanofi-Aventis received worldwide rights for our anti-LIGHT fully human monoclonal antibody, which utilizes KM Mouse<sup>™</sup> technology.

#### Model 3: Antibody Technology Licensing

Kyowa Hakko Kirin has been licensing out its POTELLIGENT<sup>®</sup> and COMPLEGENT<sup>®</sup> technologies through BioWa, Inc., our subsidiary in the United States. In 2007, we obtained the patent covering all antibodies with fucose-free mammalian sugar chains, irrespective of the antigen or type of production method, in the United States. As a result, a license from BioWa is essential to commercialize POTELLIGENT<sup>®</sup> antibodies in the U.S. This patent further strengthened the exclusive position of Kyowa Hakko Kirin and BioWa in the R&D of POTELLIGENT<sup>®</sup> antibodies. We have concluded POTELLIGENT<sup>®</sup> technology licensing contracts with 17 leading global therapeutic antibody companies and major pharmaceutical companies.

Further, joint research with Lonza Group Ltd. has allowed us to offer POTELLIGENT® CHOK1SV, a potent new cell line. In 2010, we concluded nonexclusive agreements with Daiichi Sankyo Co., Ltd., and KaloBios Pharmaceuticals, Inc. This new cell line features high productivity and also enables production of fucose-free mammalian sugar chains using POTELLIGENT® technology. It is therefore expected to become a standard for therapeutic antibody production.

In addition to POTELLIGENT<sup>®</sup>, we have also begun licensing activities for COMPLEGENT<sup>®</sup> technology that increases complement-dependent cytotoxicity (CDC) activity. We licensed COMPLEGENT<sup>®</sup> to Medarex, Inc. (currently Bristol-Myers Squibb) in 2008 and to GlaxoSmithKline plc. in 2010.

Therapeutic Area	Code Name	Country/Phase		Remarks
		Japan (Approved)	Adult T-cell leukemia-lymphoma (ATL)	
		Japan (Phase II)	ATL, combination therapy	POTELLIGENT <sup>®</sup> antibody
	KW-0761	Japan (Phase II)	Peripheral T/NK-cell lymphoma	Humanized monoclonal antibody
		U.S. (Phase I/II)	Peripheral T-cell lymphoma (PTCL) and cutaneous T-cell lymphoma (CTCL)	
	KRN330	U.S. (Phase I/IIa)	Cancer	●Uses KM Mouse™ ●Fully human monoclonal antibody
ONCOLOGY	BIW-8962	U.S. (Phase I/IIa)	Cancer	<ul> <li>POTELLIGENT<sup>®</sup> antibody</li> <li>Humanized monoclonal antibody</li> </ul>
	KHK2866	U.S. (Phase I)	Cancer	<ul> <li>POTELLIGENT<sup>®</sup> antibody</li> <li>Humanized monoclonal antibody</li> </ul>
	CEP-37250/ KHK2804	U.S. (Phase I)	Cancer	<ul> <li>POTELLIGENT<sup>®</sup> antibody</li> <li>Humanized monoclonal antibody</li> <li>Developing with Cephalon</li> </ul>
	KHK2898 Singapore (Phase		Cancer	●POTELLIGENT <sup>®</sup> antibody ●Uses KM Mouse <sup>™</sup> ●Fully human monoclonal antibody
	ASKP1240	Japan (Phase I)	Organ transplant rejection	●Uses KM Mouse™ ●Fully human monoclonal antibody
	ASKP1240	U.S. (Phase II)	organ transpiant rejection	•Co-development with Astellas Pharma
IMMUNOLOGY/ ALLERGY	KHK4563	Japan/Korea (Phase II)	Asthma	<ul> <li>POTELLIGENT<sup>®</sup> antibody</li> <li>Humanized monoclonal antibody</li> </ul>
	KW-0761	Japan (Phase I)	Asthma*	<ul> <li>POTELLIGENT<sup>®</sup> antibody</li> <li>Humanized monoclonal antibody</li> </ul>
	KHK4827	Japan (Phase I)	Psoriasis	<ul> <li>Fully human monoclonal antibody</li> <li>Licensed from Kirin-Amgen</li> </ul>
OTHER	KRN23	U.S./Canada (Phase I/II)	X-linked hypophosphatemic rickets/ osteomalacia (XLH)	•Uses KM Mouse™ •Fully human monoclonal antibody

#### Antibody Pipeline (As of March 31, 2012)

\*Additional indication

### Licensing

We also actively out-license and in-license to enhance our development pipeline and to maximize the value of our intellectual property.

#### **Out-Licensing**

In the field of oncology, we licensed tivozanib (in-house development code: KRN951), a VEGF receptor inhibitor, to AVEO Pharmaceuticals, Inc. in the United States. A phase III clinical trial is now in progress. In 2010, Astellas Pharma Inc. purchased the development and marketing rights of KRN951 from AVEO. In addition, the M phase kinesin Eg5 inhibitor that we licensed to Eli Lilly and Company in January 2006 is now in a phase II clinical trial as LY2523355.

In the central nervous system field, we licensed worldwide rights except for Japan and Asia for the adenosine A2a receptor antagonist KW-6356 to H. Lundbeck A/S.

In the immunology and allergy field, export sales and royalty income for olopatadine hydrochloride, the active ingredient in the antiallergic agent ALLELOCK<sup>®</sup>, are contributing significantly to our sales. Olopatadine hydrochloride licensee Alcon, Inc. markets it in more than 100 countries as ophthalmic formulations under the brand names of Patanol<sup>®</sup> and Pataday<sup>™</sup>. In the United States and some other countries, olopatadine hydrochloride is also marketed as a nasal spray. Other out-licensed therapeutic antibodies in the immunology and allergy field include KHK4563, KW-0761 and the anti-LIGHT fully human monoclonal antibody mentioned above.

Pre-clinical

Phase III

Phase II

Phase II

REGIMMUNE Phase I

Adenosine A2a

Cancer

receptor antagonist

Neuropathic pain Cancer (M phase

(VEGF receptor inhibitor)

kinesin Eg5 inhibitor)

Immunosuppressive

Status of Out-Licensed Compounds (As of March 31, 2012; excluding antibodies)

Lundbeck

AVEO

DARA

Eli Lilly

### In-Licensing

In December 2009, we entered into an exclusive global licensing agreement covering development, production and marketing rights for an anti-amyloidbeta peptide antibody with Immunas Pharma, Inc. of Japan. Also in December 2009, we concluded a licensing agreement with Reata Pharmaceuticals, Inc. covering Japan and Asian countries for RTA 402, which is in phase III clinical trials in the United States, the European Union and other non-Asian countries as a treatment for chronic kidney disease (CKD) in patients with type 2 diabetes. In January 2010, we entered into a research collaboration and license agreement with Dicerna Pharmaceuticals, Inc. for their Dicer Substrate siRNA (DsiRNA) pharmaceuticals and our drug delivery system. In March 2010, we concluded a licensing agreement with Solasia Pharma K.K. for exclusive marketing rights for SP-01, an extended release transdermal granisetron patch, for Taiwan, Hong Kong, Singapore and Malaysia. In January 2011, we concluded a licensing agreement with Kirin-Amgen, Inc. for exclusive development and marketing rights in Japan and Asian countries including China for AMG827, a fully human antibody that targets the IL-17 receptor.

In April 2010, we enhanced our product lineup by acquiring the sales rights for Japan of Permax<sup>®</sup>, a treatment for Parkinson's disease, from Eli Lilly Japan K.K. Moreover, we have steadily launched

		•	. ,
Development Code (Product Name)	Company		Remarks
HFT-290 (Fentos®)	Hisamitsu	Launched	Cancer pain (µ-opioid receptor agonist)
KW-6500	Britannia	Approved	Parkinson's disease (Dopamine receptor agonist)
KW-2246	Orexo	Phase III	Cancer pain (µ-opioid receptor agonist)
ARQ 197	ArQule	Phase III	Lung cancer (c-Met inhibitor)
ARQ 197		Phase II	Gastric cancer (c-Met inhibitor)
Z-206 (ASACOL®)	Zeria	Phase II	Crohn's disease Launched in Japan for the treatment of ulcerative colitis
RTA 402	Reata	Phase II	CKD in patients with type 2 diabetes

#### Status of In-Licensed Compounds (As of March 31, 2012)

### 28 KYOWA HAKKO KIRIN Annual Report 2011

KW-6356

Tivozanib

(KRN951)

**KRN5500** 

LY2523355

RGI2001

products that we have in-licensed. These include ASACOL<sup>®</sup>, for the treatment of inflammatory bowel disease, and Fentos<sup>®</sup>, a transdermal, sustainedrelease treatment for cancer pain. We concluded an agreement in January 2007 with Zeria Pharmaceutical Co., Ltd., for co-development and co-marketing of ASACOL<sup>®</sup>. For Fentos<sup>®</sup>, we concluded a co-marketing agreement in June 2008 with Hisamitsu Pharmaceutical Co., Inc.

We will enhance our in-house development pipeline using the strengths of our unique drug discovery technologies while collaborating with other companies and organizations such as the La Jolla Institute for Allergy & Immunology in alliances and partnerships to further intensify R&D in Japan, Asia, Europe and North America.

#### **Status of New Drug Development**

#### Oncology

In Japan, we started a phase III clinical trial for KRN125 targeting chemotherapy-induced febrile neutropenia in February 2011. In April 2011, we filed an NDA for POTELIGEO®, an anti-CCR4 humanized antibody that targets the hematological cancer ATL. POTELIGEO® was approved in March 2012. Also in March 2012, the Kyowa Medex companion diagnostic POTELIGEO® TEST was approved; it is used for prescribing POTELIGEO® for patients with relapsed or intractable ATL.

In Asia, we started an international phase III trial of ARQ 197, in combination with Erlotinib, in August 2011 in Japan, Korea and Taiwan for patients diagnosed with advanced or metastatic non-small cell lung cancer. In December 2011, we started a phase II trial of KRN321 (product name in Japan: NESP®) in Japan and Korea for anemia with myelodysplastic syndrome. In addition, Neulasta® was approved for the treatment of chemotherapy-induced febrile neutropenia in Taiwan in September 2011.

### Nephrology

In Japan, we started a phase III clinical trial of KRN321 in January 2011 for pediatric renal anemia. Also, we started a phase II clinical trial of RTA 402 for CKD patients with type 2 diabetes in February 2012.

In Asia, we started a phase III trial of KRN321 for

renal anemia on dialysis patients in India in September 2011. In January 2011, we filed an NDA in China for KRN1493 (product name in Japan: REGPARA®) as a treatment for secondary hyperparathyroidism.

#### Immunology/Allergy

In Japan, ALLELOCK<sup>®</sup> Granules was approved in July 2011 and launched in November 2011. Also, we started a phase II clinical trial of Z-206 (ASACOL<sup>®</sup>) for Crohn's disease in July 2011.

A phase II trial of KHK4563 for bronchial asthma was started in August 2011 in Japan and Korea.

#### **Central Nervous System**

In Japan, DEPAKENE<sup>®</sup>, an antiepileptic drug, was approved for suppressing the onset of migraines as a new indication in June 2011. We filed an NDA for Apokyn<sup>®</sup> to treat hyperanakinesia caused by Parkinson's disease-related motion complications in July 2011. Apokyn<sup>®</sup> was approved in March 2012. Also in March 2012, we filed an NDA for KW-6002 for the treatment of Parkinson's disease.

#### Other

In Japan, Romiplate<sup>®</sup> was approved for the treatment of chronic idiopathic thrombocytopenic purpura in January 2011 and launched in April 2011. We started a phase III clinical trial of KW-3357, which targets disseminated intravascular coagulation syndrome following a reduction of antithrombin (an anticoagulant component), in June 2011. Further, the prokinetic drug NAUZELIN<sup>®</sup> OD tablets was approved in July 2011 and launched in December 2011.

Overseas, Nplate<sup>®</sup> (product name in Japan: Romiplate<sup>®</sup>) was approved for the treatment of chronic idiopathic thrombocytopenic purpura in June 2011 in Korea. We acquired ProStrakan in April 2011. The company's Rectiv<sup>™</sup> was approved for the treatment of pain associated with chronic anal fissures in June 2011 in the United States.

### Pharmaceutical Pipeline (As of March 31, 2012)

Therapeutic Area	Code or Product Name	Generic Name	Туре	Mechanism of Action	Indications	Country	Formulation	1
	1			[	Adult T-cell leukemia-lymphoma (ATL)			
	1	!	Bio-pharmaceutical	1	Adult T-cell leukemia-lymphoma (ATL), combination therapy (for untreated patients)	Japan		
	KW-0761	Mogamulizumab	Antibody pharmaceutical	Anti-CCR4 humanized antibody	Peripheral T/NK-cell lymphoma		Injection	
	1		'		Peripheral T-cell lymphoma (PTCL) and cutaneous T-cell lymphoma (CTCL)	U.S.		
	2	2	Small molecular weight	5-HT3 serotonin receptor		Taiwan	Dutah	
	Sancuso®	Granisetron	pharmaceutical	antagonist	Chemotherapy-induced nausea and vomiting	Singapore	Patch	
	KW-2246	Fentanyl citrate	Small molecular weight pharmaceutical	µ-opioid receptor agonist	Cancer pain	Japan	Sublingual tablet	
						Taiwan		
	1	Pegfilgrastim	Bio-pharmaceutical	Long-acting granulocyte colony stimulating factor	Chemotherapy-induced febrile neutropenia	Korea	Injection	
	KRN125			Summaring rustor		Vietnam Japan		
	KRN1493	Cinacalcet	Small molecular weight	Calcium receptor agonist	Hyper calcemia with parathyroid carcinoma or	Japan	Oral	
ONCOLOGY		hydrochloride	pharmaceutical		intractable primary hyperparathyroidism Non-small cell lung cancer	Japan/Korea/Taiwan	Oral	
	ARQ 197	Tivantinib	Small molecular weight pharmaceutical	c-Met inhibitor	Gastric cancer	Japan/Korea	Oral	
	KRN321	Darbepoetin alfa	Bio-pharmaceutical	Long-acting erythropoiesis stimulating agent	Anemia with myelodysplastic syndrome	Japan/Korea	Injection	
	KW-2478		Small molecular weight pharmaceutical	HSP90 inhibitor	Multiple myeloma	U.K./U.S./Philippines	Injection	
	KW-2450		Small molecular weight	IGF-1 receptor signal inhibitor	Cancer	U.S.	Oral	
		<u> </u>	pharmaceutical Bio-pharmaceutical					
	KRN330	!	Antibody pharmaceutical	Anti-A33 fully human antibody	Cancer	U.S.	Injection	 
	BIW-8962		Bio-pharmaceutical Antibody pharmaceutical	Anti-GM2 humanized antibody	Cancer	U.S.	Injection	
	KRN951	Tivozanib	Small molecular weight pharmaceutical	VEGF receptor inhibitor	Cancer	Japan	Oral	
	LY2523355	Litronesib	Small molecular weight pharmaceutical	M phase kinesin Eg5 inhibitor	Cancer	Japan	Injection	
	KHK2866		Bio-pharmaceutical Antibody pharmaceutical	Anti-HB-EGF humanized antibody	Cancer	U.S.	Injection	
	CEP-37250/		Bio-pharmaceutical	Anti-tumor specific glycoprotein	Cancer	U.S.	Injection	
	KHK2804		Antibody pharmaceutical Bio-pharmaceutical	humanized antibody			-	
	KHK2898		Antibody pharmaceutical	Anti-CD98 fully human antibody	Cancer Rediatric ranal anomia	Singapore	Injection	
	1				Pediatric renal anemia	Japan Singapore		
	KENIGOT	Dest section offe	21. stranssting	Long-acting erythropoiesis		Thailand	l	
	KRN321 Da	Darbepoetin alfa	Bio-pharmaceutical	stimulating agent	Renal anemia on dialysis patients	Philippines	Injection 	
			'			India		
NEPHROLOGY			<sup>/</sup>	<u> </u> /		China China		
	1		'			Philippines		
	Cinacalcet hydrochloride	Small molecular weight pharmaceutical	Calcium receptor agonist	Secondary hyperparathyroidism	Malaysia	Oral		
	1		( ·			Thailand		
		Bardoxolone	Small molecular weight	Antioxidant inflammation		Singapore		-
	RTA 402	methyl	pharmaceutical	modulator	CKD in patients with type 2 diabetes	Japan	Oral	
	KHK4563	Benralizumab	Bio-pharmaceutical Antibody pharmaceutical	Anti-IL-5 receptor humanized antibody	Bronchial asthma	Japan/ Korea	Injection	ļ
	Z-206	Mesalazine	Small molecular weight pharmaceutical	pH dependant controlled release tablet	Crohn's disease	Japan	Oral	
IMMUNO- LOGY/	ASKP1240		Bio-pharmaceutical	Anti-CD40 fully human antibody	Organ transplant rejection	U.S.	Injection	
ALLERGY		ļ!	Antibody pharmaceutical Bio-pharmaceutical	Anti-IL-17 receptor fully human	Organ transplant rejection	Japan	-	
	KHK4827		Antibody pharmaceutical	antibody	Psoriasis	Japan	Injection	<u> </u>
	KW-0761	Mogamulizumab	Bio-pharmaceutical Antibody pharmaceutical	Anti-CCR4 humanized antibody	Asthma	Japan	Injection	
	KW-6500	Apomorphine hydrochloride	Small molecular weight pharmaceutical	Dopamine receptor agonist	Hyperanakinesia caused by Parkinson's disease-related motion complications	Japan	Injection	<b>_</b>
CENTRAL	KW-6002	Istradefylline	Small molecular weight pharmaceutical	Adenosine A2a receptor	Parkinson's disease	Japan	Oral	
NERVOUS SYSTEM			Small molecular weight	antagonist		U.S.		
	KW-6485	Topiramate	pharmaceutical	Antiepileptic drug	Pediatric epilepsy	Japan	Oral	
	KHK6188		Small molecular weight pharmaceutical	Cannabinoid CB2 receptor agonist	Neuropathic pain	Japan	Oral	
	1		'			Taiwan		
	AMG531	Rominlostim	Romiplostim Bio-pharmaceutical	Thrombopoietin receptor agonist	Chronic idiopathic thrombocytopenic	Hong Kong Malaysia	Injection	
	AWGGG.	nomprotan		III ombopolour rooopter agenet	purpura	Korea		
OTHER						Singapore		
	KW-3357	Antithrombin		Recombinant human antithrombin	Disseminated intravascular coagulation syndrome following a reduction of antithrombin	Japan	Injection	
			Bio-pharmaceutical		X-linked hypophosphatemic rickets/	Europe		
D' un stimund	KRN23		Antibody pharmaceutical	Anti-FGF23 fully human antibody	osteomalacia (XLH)	U.S./Canada	Injection	
Discontinued		<u> </u>	1			1		1
ONCOLOGY	KRN321	Darbepoetin alfa	Bio-pharmaceutical	Long-acting erythropoiesis stimulating agent	Chemotherapy-induced anemia	Japan	Injection	
	!	<u> </u>		1		/		

I	11	111	NDA Filed	Approved	Origin	Remarks
				Mar. 2012		
					In-house	POTELLIGENT <sup>®</sup> antibody
					Solasia Pharma	
					Solasia Pharma (ProStrakan)	
					Orexo	Launched by ProStrakan as Abstral®
				Sep. 2011		
					Kirin-Amgen	
					NPS	Launched in Japan for secondary hyperparathyroidism
					ArQule	
					In-house	Launched in Japan for anemia of CKD patients
					In-house	
					In-house	
					In-house	
					In-house	POTELLIGENT <sup>®</sup> antibody
					In-house	
					In-house	
					In-house	POTELLIGENT <sup>®</sup> antibody
					Cephalon	POTELLIGENT® antibody Joint development with Cephalon
					In-house	POTELLIGENT® antibody
				Jan. 2012		
 				May 2011 Jun. 2011	Kirin-Amgen	Launched in Japan for anemia of CKD patients
					NPS	
				Aug. 2011		
					Reata Pharmaceuticals	
					In-house	POTELLIGENT® antibody
					Zeria Pharmaceutical	Launched in Japan for ulcerative colitis Joint development with Zeria Pharmaceutical
					In-house	Joint development with Astellas Pharma
					Kirin-Amgen	
					In-house	POTELLIGENT® antibody
				Mar. 2012	Britannia Pharmaceuticals	
					In-house	
					Janssen Pharmaceutical	Launched in Japan for use as an antiepileptic drug
					In-house	
				Jul. 2011 Dec. 2011	Kirin-Amgen	
				Jun. 2011	<u> </u>	
				Feb. 2012		
					In-house	
					In-house	
 						The application was withdrawn after discussion with the Pharmaceuticals and Medical Devices Agency because the submitted data was insufficient to establish the evidence necessary to attain approval.

### Fujifilm Kyowa Kirin Biologics Co., Ltd. Established

In March 2012, FUJIFILM Corporation and Kyowa Hakko Kirin Co., Ltd. established Fujifilm Kyowa Kirin Biologics Co., Ltd., a joint venture for the development, manufacture and sale of biosimilars<sup>1</sup>.

Biopharmaceuticals have enabled notable progress in treating diseases that formerly lacked effective therapies, including cancer, heart disease, anemia and rheumatism. However, they are costly compared to conventional small molecular weight pharmaceuticals because of the sophisticated technology and production facilities required for their unique features and their substantial development costs, making the advent of low-cost biopharmaceuticals desirable. Against this background, the biosimilar market is forecast to grow to ¥200 billion by 2015, ten times the size of the market in 2010.

Fujifilm Kyowa Kirin Biologics will merge Kyowa Hakko Kirin's proprietary technologies and expertise in biopharmaceutical R&D and manufacturing with FUJIFILM's engineering technology for production, quality control and analysis, developed through businesses such as photographic film, to create revolutionary production processes that optimize the quality and reduce the cost of biosimilars. The joint venture aims to become a leader in the global biosimilars market.

Fujifilm Kyowa Kirin Biologics will first focus on developing a biosimilar of the fully human anti-TNF- $\alpha$  monoclonal antibody adalimumab, which is a highly effective therapy for diseases including rheumatoid arthritis. After introducing the producing cell<sup>2</sup> already established by Kyowa Hakko Kirin, Fujifilm Kyowa Kirin Biologics plans to start clinical trials in 2013. It will then proceed with development aiming for product launch several years after the start of clinical trials.

#### Overview of Fujifilm Kyowa Kirin Biologics Co., Ltd.

Fujifilm Kyowa Kirin Biologics Co., Ltd.
March 27, 2012
¥100 million (equity ownership:
Fujifilm 50%; Kyowa Hakko Kirin 50%)
Development, manufacture and sale of biosimilars

Number of employees: 27



### We Want to Be a Company That Society Needs

Our strength is that patients will be able to use our products with complete confidence because of our uncompromising commitment to quality and technologically advanced production. At the same time, we work to reduce manufacturing costs by leveraging our advanced technologies and expertise. In the biosimilars business, we will focus on superior quality in matching the safety and efficacy of innovator biopharmaceuticals while improving ease of use for patients. These approaches will allow us to accomplish our mission, which is to be a company that society needs.

Hideaki Nomura President & CEO Fujifilm Kyowa Kirin Biologics Co., Ltd.

Generic biopharmaceuticals. Follow-on biologics. Subsequent versions
of biotechnology based innovator biopharmaceuticals with new active
ingredients approved in the United States, the European Union and
Japan. The properties and quality in terms of efficacy and safety are
similar, but they are produced and marketed by a different sponsor.

Cells for biosimilar production introduced with adalimumab genes. Used to produce adalimumab biosimilars.

# **Production**

## **Fundamental Strategies**

- Increase productivity and efficiency by reorganizing production facilities and promoting outsourcing
- Begin operation of new manufacturing facilities with large-scale mammalian cell culture tanks for investigational therapeutic antibodies

## **Fiscal 2011 Achievements**

- Construction of a new plant for solid dosage forms at the Ube Plant moved toward completion at the end of 2012.
- Construction of a plant for active pharmaceutical ingredients (API) for chemical entities at DAIICHI FINE CHEMICAL CO., LTD. moved toward completion in July 2012.
- We overcame several delays caused by the Great East Japan Earthquake to bring preparations for product outsourcing back on schedule.

## **Production Facility Reorganization**

We are reorganizing all Kyowa Hakko Kirin Group production sites, solving problems with location and aging facilities to optimize our production system. The reorganization plan involves more than ¥10 billion in investment from 2010 through 2017 with the objective of further enhancing cost competitiveness by constructing a number of new plants that will be automated and achieve a high good manufacturing practice (GMP) level. We will complete a new plant for solid oral dosage forms at the Ube Plant at the end of 2012. After qualifying the facilities, we will successively transfer production to the Ube Plant from the Fuji Plant in 2013 and 2014. We expect full-scale operation from 2015. In addition, the Kyowa Hakko Bio Co., Ltd. subsidiary DAIICHI FINE CHEMICAL will complete a plant for APIs for chemical entities in July 2012, which should be fully operational in 2014. We are also preparing to build a new liquid pharmaceutical production facility at the Takasaki Plant that we expect to begin operating in 2016. Our plans are progressing steadily toward our 2017 target for completing the reorganization of our production facilities.

## Steady Operation of Facilities for Therapeutic Antibodies and Other Drugs

In March 2010, we completed a production facility for investigational therapeutic antibodies at the Bio Process Research and Development Laboratories in Takasaki, Gunma Prefecture. Its facilities for the cultivation of mammalian cells and for purification are among the largest in the world. Operations halted during summer 2011 due to the electricity shortage caused by the accident at the Fukushima Nuclear Power Plant. However, the facility is now back to normal operation and contributing to the stable supply of drugs for clinical trials and increased productivity.

# Building a New and Highly Competitive Production System

Building a new production system through the current reorganization of production facilities is extremely meaningful for Kyowa Hakko Kirin. Production facilities will be crucial as Kyowa Hakko Kirin further enhances its pipeline of therapeutic antibodies and enters a phase of projected strong growth, and we are making steady progress in creating a production system that can fulfill its important role. Our stakeholders can be confident that our production capabilities will be significantly stronger and extremely competitive when the plan is complete.

### Yutaka Osawa, MBA

Director Production Planning Department, Production Division Kyowa Hakko Kirin Co., Ltd.



# Marketing in Japan



### **Fundamental Strategies**

- Maintain and expand the market share of existing core products
- Achieve rapid market penetration for new products
- Reorganize the marketing organization to improve sales efficiency

## **Fiscal 2011 Achievements**

- NESP<sup>®</sup> and ESPO<sup>®</sup> together maintained the number one share of the erythropoiesis stimulating agent (ESA) market.
- We achieved market penetration and steady sales for new products including ALLELOCK®, an antiallergic agent, and Fentos®, a transdermal analgesic for persistent cancer pain, both launched in 2010; and Romiplate®, a treatment for chronic idiopathic thrombocytopenic purpura launched in 2011.
- We consolidated branches and sales offices.

## **Core Product Sales**

Further enhancing domestic marketing, we expanded sales of core products while working to rapidly increase market penetration for new products.

Combined sales of NESP® and ESPO® increased 17 percent year on year to ¥61.8 billion. The launch

of NESP® INJECTION PLASTIC SYRINGE in 10 a/1ml and other dosages in 2010 enabled administration for chronic renal disease from initial administration in dialysis through the dialysis period. NESP® and ESPO® therefore maintained their combined number one share of the ESA market.

REGPARA®, a treatment for secondary hyperparathyroidism, has steadily penetrated the market since its launch in January 2008. Sales increased a substantial 21 percent year on year to ¥11.5 billion.



REGPARA®

ALL FLOCK®

Sales of ALLELOCK® and antiallergic evedrops Patanol<sup>®</sup> expanded significantly year on year due to factors including higher levels of airborne pollen.

In March 2010, we transferred manufacturing, sales and other rights for Neu-up®, a neutropenia agent, to Yakult Honsha Co., Ltd. Subsequently, GRAN® has been our only neutropenia treatment agent. Sales increased 3 percent year on year to ¥14.8 billion.



**GRAN®** 

New products Permax<sup>®</sup>, a treatment for Parkinson's disease launched in 2010; Fentos®, a transdermal analgesic for persistent cancer pain launched in 2010; and Romiplate® launched in April 2011 all performed well.

Sales of CONIEL<sup>®</sup>, a treatment for hypertension and angina pectoris, decreased year on year due to changes in the market environment, the effects of reductions in National Health Insurance (NHI) reimbursement prices, and the influence of generics.

Revenues from exports were steady, centered on exports to Asia. Revenues from technology out-licensing decreased year on year.

### **Initiatives for Fiscal 2012**

We will work to expand sales of core products including NESP® while achieving rapid market penetration for new products. Other initiatives will include ensuring exacting compliance and increasing operating income by properly deploying marketing resources.

### **Diagnostic Reagents**

Subsidiary Kyowa Medex Co., Ltd. is responsible for manufacturing and marketing diagnostic reagents. Sales increased year on year due to strong sales of immune system diagnostic reagents and favorable exports.

Kyowa Medex deployed enzyme modification technology research to discover the principles for measuring serum high-density lipoprotein cholesterol (HDL-C) without the need for centrifugation, then developed and launched the world's first diagnostic reagent for this direct methodology, Determiner HDL-C<sup>®</sup>. Kyowa Medex has built on this achievement, becoming widely known as "Lipid Kyowa" by expanding its lineup of reagents for measuring lipids and providing them worldwide.

In addition, Kyowa Medex applied latex agglutination technology to monoclonal antibodies that respond specifically to glycated hemoglobin (HbA1c) to develop and commercialize a breakthrough method using changes in HbA1c turbidity to measure multiple specimens in less time than conventional methods.

Within the Kyowa Hakko Kirin Group, Kyowa Medex has been concentrating on the relationship between pharmaceuticals and diagnostic reagents in ways such as collaborating with Kyowa Hakko Kirin from the earliest stages of pharmaceutical development to create diagnostic reagents that work with pharmaceuticals. This focus resulted in nearly simultaneous approval for POTELIGEO® (mogamulizumab), Kyowa Hakko Kirin's first therapeutic antibody, and POTELIGEO® TEST, a companion diagnostic developed jointly by Kyowa Medex and Kyowa Hakko Kirin.

# Raising the Productivity of MRs as Health Care Professionals

Kyowa Hakko Kirin wants its MRs to see themselves as health care professionals who concentrate on ensuring that patients get the best treatment, rather than simply providing and gathering information.

At the same time, we are decisively enhancing MR productivity. We have consolidated branches and sales offices, accelerated decision-making processes, and worked to raise efficiency in sales territories. Also, we are providing specialized training for brand managers and MRs aimed at qualitatively improving sales, along with programs to enhance customer responsiveness and proposal capabilities.

Principal Drug	g Sales <sup>1</sup>	Billions of yen			
Product	Indication	2011	2010	2009 <sup>2</sup>	
NESP®/ESPO®	ESA formulation	¥61.8	¥52.6	¥48.9	
ALLELOCK®	Antiallergic	29.1	26.8	26.7	
CONIEL®	Cardiovascular (hypertension and angina pectoris)	19.7	21.0	23.3	
GRAN®/Neu-up®3	Neutropenia	14.8	14.4	17.0	
REGPARA®	Secondary hyperparathyroidism	11.5	9.5	6.8	
Patanol®	Antiallergic eyedrops	11.4	7.5	7.4	
DEPAKENE®	Antiepileptic	11.2	11.0	11.2	
NAUZELIN®	Gastrointestinal	4.8	5.3	5.1	
COVERSYL®	Cardiovascular (hypertension)	3.9	4.2	4.8	
5-FU	Anticancer	3.1	3.1	3.7	
Fentos <sup>®5</sup>	Cancer pain	3.1	0.8	-	
INOVAN® + PRe DOPA®	Cardiovascular	2.8	3.0	3.5	
ASACOL <sup>®6</sup>	Agent for ulcerative colitis	2.8	0.7	0.0	
CELTECT <sup>®</sup>	Antiallergic	2.5	2.7	3.3	
Permax <sup>®4</sup>	Parkinson's disease	2.1	2.0	-	
Navelbine®	Anticancer	1.7	2.0	2.9	
Exports and Technology Out-Licensing		22.3	24.1	18.0	

1. Non-consolidated basis

2. Reference: Restated total for the 12-month period ended 09/12, following change in fiscal year-end from March to December

As of March 1, 2010, manufacturing, sales and other rights for Neu-up<sup>®</sup> were transferred to Yakult Honsha. Therefore, GRAN<sup>®</sup>/Neu-up<sup>®</sup> figures after March 2010

tasteried to takult noisia. Therefore, dhaka include only sales figures for GRAN<sup>®</sup>.
 Sales of Permax<sup>®</sup> began April 1, 2010.
 Sales of Fentos<sup>®</sup> began June 24, 2010.
 Sales of ASACOL<sup>®</sup> began December 16, 2009.

# **Overseas Operations**



### **Fundamental Strategies**

- Expand sales in Asia by strengthening our marketing organization, and improve our reliability assurance system
- Improve organizations in the United States and Europe with a view to commencing new drug sales

### **Fiscal 2011 Achievements**

- ProStrakan became a wholly owned subsidiary. Its ethical drug development and sales organization covering Europe and the United States in fields including oncology is enabling major progress in the Kyowa Hakko Kirin Group's global strategy.
- Kyowa Hakko Kirin raised operating efficiency by consolidating its offices in the United Kingdom and Italy with ProStrakan offices.
- We increased products available for sale and enhanced our MR organization in China by integrating two Chinese subsidiaries to unify the sales organization.

# Accelerated Business Development in the United States and Europe

Kyowa Hakko Kirin acquired ProStrakan Group Plc with the goals of obtaining its own marketing organization in the United States and Europe, strengthening its internal global development organization, and accelerating and expanding global new drug development and marketing in key areas by acquiring development and marketing expertise. Synergies between the Group and ProStrakan are emerging as we move steadily toward these goals.

We also increased operating efficiency by integrating Kyowa Hakko Kirin offices in the United Kingdom and Italy with ProStrakan offices in those countries. ProStrakan's U.S. offices are shifting the focus of their marketing organization to oncology with a view to launching POTELIGEO<sup>®</sup> (mogamulizumab) in the United States. In Asia, ProStrakan made progress with the development of Sancuso<sup>®</sup>, a treatment for chemotherapy-induced nausea and vomiting, in Hong Kong, Singapore and Malaysia.

During fiscal 2011, Abstral<sup>®</sup>, a medication for managing breakthrough cancer pain, and Adcal-D3<sup>®</sup>, an osteoporosis treatment, contributed to results with steady gains in market share in Europe. For the six months ended December 31, 2011, ProStrakan sales trended upward compared with the previous fiscal year to £56 million (¥6.7 billion).



Abstral®



### Improved Efficiency in Asian Operations

The Kyowa Hakko Kirin Group has initiated sales of pharmaceuticals in China, Korea, the ASEAN countries and elsewhere in Asia, where subsidiaries employ approximately 200 MRs.

During fiscal 2011, we integrated two subsidiaries in the growing Chinese market to strengthen commercial operations and enhance the MR organization. Unifying the sales organization increased products available for sale by enabling sales of CONIEL®, a hypertension and angina pectoris treatment, and ALLELOCK®, an antiallergic agent.

The Kyowa Hakko Kirin Group is now shifting the emphasis of its marketing organization to selling in-house products from the former focus on marketing in-licensed products. Examples include ESAs: we formerly sold the Amgen product Aranesp<sup>®</sup>, but have switched to our own product NESP<sup>®</sup> and now market it in five Asian countries. In addition, we are marketing REGPARA<sup>®</sup>, a treatment for secondary hyperparathyroidism, in Korea, Hong Kong and Taiwan, and plan to launch it in Singapore and Malaysia.

## **Initiatives for Fiscal 2012**

We intend to enhance our marketing capabilities in Asia, and especially in China. Concurrently, we will work to accelerate development in Asia. In Europe and the United States, we will strengthen collaboration with our new partner ProStrakan in ways such as assigning Kyowa Hakko Kirin employees to its in-market operations as we energetically conduct global development and marketing.

# ProStrakan: Contributing to Group Performance

Since ProStrakan joined the Kyowa Hakko Kirin Group in April 2011, we have made significant progress. ProStrakan continues to drive the business forward and contributed operating income of £1.3 million to consolidated results in the second half of the year ended December 31, 2011. This was achieved through double digit growth in our portfolio of brands, with strong performance in the EU, spearheaded by the growth in sales of Abstral<sup>®</sup>, the re-establishment of Sancuso<sup>®</sup> in the U.S. market and increased product sales through partners.

Consistent with Kyowa Hakko Kirin's global oncology focus, in early 2011 ProStrakan launched Abstral<sup>®</sup> (fentanyl) Sublingual Tablets in the United States, for the management of breakthrough pain in cancer patients. The establishment of this product in the U.S. market received a boost with the FDA's approval in December of a shared Risk Evaluation and Mitigation Strategy for similar products. In February 2012 the European Medicines Agency's Committee for Medicinal Products for Human Use gave a positive recommendation for Sancuso<sup>®</sup>, ProStrakan's transdermal granisetron patch for chemotherapy-induced nausea and vomiting. This is expected to



result in formal EU approval in the first half of 2012.

With our partner, Endo Pharmaceuticals Inc., we launched in the U.S. Fortesta® (testosterone) gel for testosterone replacement therapy in male hypogonadism and in June we received FDA approval for Rectiv®, for the treatment of moderate to severe pain associated with chronic anal fissures. Our partner, Aptalis Pharma Inc., will launch Rectiv® in the U.S. in the first quarter of 2012.

The team at ProStrakan is working closely with our Kyowa Hakko Kirin colleagues in preparation for the introduction of the Group's exciting pipeline of high technology products, particularly KW-0761, into the European and U.S. markets.

Everyone at ProStrakan is proud and excited to be a part of the Kyowa Hakko Kirin Group and we are committed to contributing significantly to its global success.

Dr. Tom Stratford CEO, ProStrakan Group

# **Bio-Chemicals**



# Fundamental Strategies under Medium-Term Management Plan – 2010 to 2012

- Expand sales of core products, such as highvalue-added amino acids
- Strengthen alliances in health care areas within the Kirin Group
- Expand production infrastructure to ensure a steady supply of pharmaceutical raw materials and fine chemical products

# **Fiscal 2011 Achievements**

- In our global pharmaceutical- and medical use amino acid business, product quality enhanced reliability and market penetration.
- Sales of the mail-order Remake<sup>®</sup> series of health care products increased.
- We increased market penetration for our health care brands in the United States.
- DAIICHI FINE CHEMICAL CO., LTD. began constructing a production facility for active pharmaceutical ingredients (API) for chemical entities.

# **Overview of Fiscal 2011**

In the Bio-Chemicals segment, consolidated net sales decreased 7.9 percent compared with the previous year to ¥77.5 billion, primarily because of the impact of the strong yen. Segment income decreased 11.6 percent to ¥2.8 billion.

# **Fine Chemicals**

Sales decreased year on year due to the significant impact of the strong yen. However, the sales volume of pharmaceutical- and industrial-use materials, mainly amino acids, nucleic acids and related compounds, increased because of active efforts to expand sales to meet increased overseas demand.

# **Health Care Products**

Mail-order sales of health care products grew steadily, primarily our own brands of health food materials such as ornithine. However, overall health care product sales decreased year on year because raw material sales did not grow due to factors including the delay of the planned April renewal of products related to the Kirin Health Project *KIRIN Plus-I* as a result of the Great East Japan Earthquake.



In addition, successful branding strategies in the substantial U.S. market for supplements and related products began to generate steady results.

## Other

Sales at DAIICHI FINE CHEMICAL decreased because of a drop in sales volume and sales prices of certain bulk pharmaceuticals and intermediate products.

### Initiatives

The Bio-Chemicals segment targets consistent growth as a biotech group that has both fermentation and synthesis technology. The segment operates globally and is significantly affected by exchange rate movements. We intend to grow by aggressively promoting sales of amino acids, nucleic acids and related compounds for high-value-added pharmaceutical, medical and health care applications. In the health care market in Japan, under our slogan of "happy and healthy now and in 10 years because of fermentation," we will expand market scale and provide high-quality materials with a focus on further market development and penetration for our own brands of health food materials such as ornithine.

Moving to strengthen operating fundamentals, we are improving cost competitiveness by reorganizing and improving the Kyowa Hakko Kirin Group's overseas and domestic production facilities. This initiative includes a project to integrate facilities at the Yamaguchi Production Center slated for completion in 2018. We will also continue to enhance cost reduction through technological innovation. Additionally, strategies for responding accurately to increased global demand for high-performance amino acids will include strengthening production capacity and enhancing supply chain management.

# Higher Earnings and Better Collaboration with Kyowa Hakko Bio

DAIICHI FINE CHEMICAL's synthesis technologies give it crucial responsibilities as a consolidated subsidiary of Kyowa Hakko Bio Co., Ltd., which organically integrates fermentation and synthesis.

Reorganizing production facilities is a fundamental strategy of Medium-Term Management Plan – 2010 to 2012. As part of this strategy, the Group is shifting the production of APIs for chemical entities from Kyowa Hakko Kirin's Yokkaichi Plant and Sakai Plant to DAIICHI FINE CHEMICAL, which accommodated the shift and responded to the latest pharmaceutical regulations in Europe and the United States by starting construction of a new API production facility at its main plant in March 2011. The objective of this production shift is to transform DAIICHI FINE CHEMICAL into an organization that generates higher earnings and collaborates better with Kyowa Hakko Bio, with the integration of synthesis and fermentation technology creating new high-value-added products.

### Noriomi Sumida

Manager, Planning & Administration Department Kyowa Hakko Bio Co., Ltd.

### Yoshiyuki Yonetani

Group Manager, Planning & Administration Department Kyowa Hakko Bio Co., Ltd.



# **Intellectual Property**

## **Basic Stance**

Kyowa Hakko Kirin is an R&D-based company that considers intellectual property (IP) to be one of its key management resources. In particular, the Company aggressively pursues wide-ranging, robust, and effective rights to the IP that underpins its business strategies. Also, we respect the IP rights of third parties and refrain from infringing on them. This enables us to not only ensure compliance but also maintain a high degree of freedom in our research and business activities, which in turn contributes to the achievement of maximum value in each individual business.

Aiming to be a global specialty pharmaceutical company, Kyowa Hakko Kirin takes an international approach in strengthening its systems for activities such as acquiring and maintaining IP rights, acquiring and granting licenses, and monitoring third parties' rights. For example, in the Pharmaceuticals segment, the Company protects core technologies and prolongs the life of products through the strategic filing of relevant patents.

# Functions of the Intellectual Property Department

The Intellectual Property Department is responsible for the IP-related activities of the Company's Pharmaceuticals segment. The department is also working to make operations more efficient and to reinforce IP-related risk management through the provision of IP-related support to major subsidiaries.

The integration of business and IP strategies is an important Groupwide focus for Kyowa Hakko Kirin. The Intellectual Property Department is therefore enhancing coordination with regular meetings among the head offices of business divisions and research laboratories, and by frequently exchanging information and consulting with research laboratories. Moreover, department members participate in major projects related to development themes, existing products, licensing, and other relevant issues to ensure familiarity with the IP environment at the key stages of research and business decision making.

## **Enhanced IP Training for Employees**

The Intellectual Property Department serves the important function of educating employees on IP rights by developing and implementing systematic educational programs. During fiscal 2011, we complemented our recent focus on programs for specific fields and groups of employees by enhancing training for researchers, which included basic patent training for young scientists and training tailored to the needs of each laboratory.

The Company also has relationships worldwide with lawyers and patent attorneys with IP expertise who provide the counsel and advice needed to appropriately address highly specialized issues.

## **Support for Licensing Activities**

In the Pharmaceuticals segment, Kyowa Hakko Kirin selectively out-licenses products it has developed because of the challenges involved in continuously developing new products on its own.

The Company has accumulated numerous core technologies founded on unique and innovative research and technology. These include the proprietary POTELLIGENT<sup>®</sup> technology, which dramatically enhances the antibody-dependent cellular cytotoxicity (ADCC) of antibodies; COMPLEGENT<sup>®</sup>, which is a complement-dependent cytotoxicity (CDC) enhanced antibody technology; and KM Mouse<sup>™</sup> technology, which enables the development and evaluation of novel fully human monoclonal antibodies for cancer treatment.

The Company's aggressive focus on in-licensing has increased the number of candidate projects, which has raised the importance of IP assessment. Moreover, the Company is protecting its IP as it generates earnings from its numerous core technologies related to drug formulation.

## A Patent Portfolio Consistent with Business Strategy

The development of new drugs requires many years and substantial investment, but the success rate is extremely low. Products that reach the market are therefore a valuable asset that we protect with patents for as long as possible as one key to maximizing earnings.

In principle, the Company encourages the filing of patents based on discoveries created from research. The Intellectual Property Department helps the Company to structure a patent portfolio that is consistent with its business strategy by considering the strategic positioning of individual patent themes and their fit within business operations. In addition, the department helps ensure that Kyowa Hakko Kirin is concentrating IP-related resources on the most significant issues. It is also involved in organizational structuring that aggressively supports management initiatives to proactively assert patent rights.

### Number of Patents Owned (As of December 31, 2011)

	Kyowa Hakko Kirin	Rest of the Kyowa Hakko Kirin Group*	Total
Japan	166	145	311
Overseas	1,292	629	1,921

\*Excluding ProStrakan

# Science That Heals: Sustainability

### Group Management Philosophy

The Kyowa Hakko Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

Corporate Social Responsibility 42

Organizational Governance 43

Human Rights and Labor Practices 47

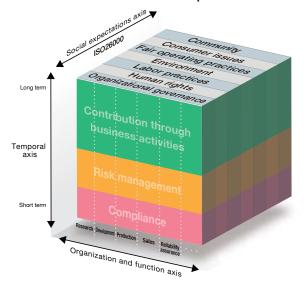
Environment 48

Fair Operating Practices and Consumer Issues 49 The Kyowa Hakko Kirin Group puts its Group Management Philosophy into practice through its business activities such as supplying new and unique pharmaceuticals and related products to patients. For us, CSR means being a trusted company that is valued by society as indispensable.

Our conventional CSR perspective for actionable outcomes employed a temporal axis and an organization and function axis. However, in 2011 ISO26000 clarified the definition of social responsibility as "business operations that influence society and the environment through transparent and ethical behavior." We therefore added a third axis for social expectations to incorporate the perspectives of customers, shareholders and investors, employees and other stakeholders as each Group company and organization practices CSR in its actions.



**Our Future CSR Perspective** 



# **Organizational Governance**

## **Corporate Governance**

### **Fundamental Approach**

Kyowa Hakko Kirin operates in accordance with its Group Management Philosophy of striving 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." Our basic goal in corporate governance is to clarify the responsibilities and duties of the management organization, to ensure compliance with the policies that we have in place, and to progress toward the realization of the Group Management Philosophy. We recognize the importance of increasing management transparency and reinforcing oversight functions in enhancing corporate governance to continually increase corporate value.

# **Corporate Governance Framework** (As of March 22, 2012)

Kyowa Hakko Kirin's management is organized around the Board of Directors and the Board of 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.

### Directors and Board of Directors

The Board of Directors has eight members, including three outside directors, and meets once a month in principle. The Board of Directors performs critical Groupwide management functions, including strategic planning, decision making, and monitoring of operational execution. The Company has not adopted a company-with-committees governance system, but the Company has established the Remuneration Consultative Committee and the Nomination Consultative Committee as advisory bodies to the Board of Directors. These committees consist of four directors each, including outside directors, and provide objective, impartial advice on compensation and nomination issues relevant to directors and company auditors. The Board of Directors met 14 times during fiscal 2011, to make decisions about management policies and other important matters and oversee the performance of directors. The Remuneration Consultative Committee and the Nomination Consultative Committee each met two times. These committees provided reports to the Board of Directors about compensation and nomination issues relevant to directors and company auditors.

### Company Auditors and the Board of Auditors

The Company has adopted the company auditor corporate governance system. The Board of Auditors has four members, including three outside auditors. Based on the audit policies established by the Board of Auditors, company auditors attend important meetings, including those of the Board of Directors, inspect operations and assets, and audit the work of directors.

Moreover, the Board of Auditors exchanges opinions with the Audit Department, which is a dedicated internal audit organization, regarding issues such as audit plans and important audit issues, and periodically receives reports on the results of audits. The Board of Auditors also periodically discusses audit plans, policies and status with the accounting auditors. Furthermore, the Board of Auditors receives reports from the Internal Control Department as needed regarding the status of the internal control system and related issues, and requests explanation if necessary. In performing these duties, the Board of Auditors met 12 times during fiscal 2011.

### Executive Committee and Executive Officer System

The Executive Committee is responsible for making accurate, effective and strategic management decisions. It met 18 times during fiscal 2011 to deliberate and decide on strategically important management issues. In addition, an executive officer system has been introduced to facilitate rapid decision making and strengthen operational execution. Four Executive Officers' Meetings took place during fiscal 2011.

# Risk Management System and Various Internal Committees

Various internal committees have been established to enhance risk management and corporate governance in order to address the variety of risks inherent in management issues. These committees regularly report on their activities to the Board of Directors. An overview of each committee follows.

### CSR Committee

Deliberates on important matters concerning CSR, such as basic policies and overall strategy for the entire Kyowa Hakko Kirin Group.

### Group Risk Management Committee

Deliberates on Group-wide risk management and the basic policy for protecting and handling confidential information in order to understand the risks relevant to Group management and to evaluate and respond to risk from a Group perspective. In addition, it deliberates on basic compliance policies and ensures thorough compliance.

### Crisis Management Committee

Convened by the head of the Group Risk Management Committee for crises and emerging risks that require an immediate response.

### Group Environmental Safety Committee

An advisory group to the President that deliberates on basic policies relating to environmental conservation and safety.

### Group Quality Assurance Committee

An advisory group to the President that deliberates on basic policies relating to quality assurance.

### Information Disclosure Committee

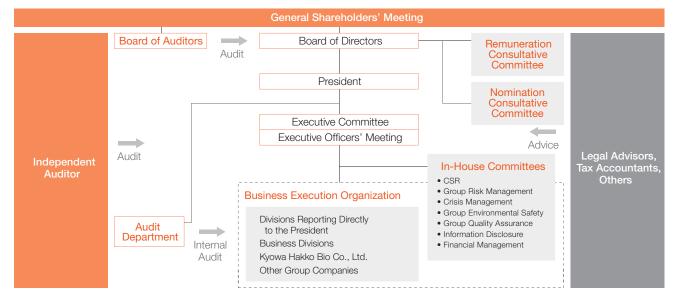
Deliberates comprehensively on basic information policies and important matters relating to information disclosure.

### Financial Management Committee

Deliberates on efficient financial activities and their accompanying risks.

## An Enhanced Global Governance Framework

The Kyowa Hakko Kirin Group is accelerating global operations, which makes enhanced global governance a management priority. We placed two Group employees on the Board of Directors of ProStrakan and two employees on its Executive Committee following our acquisition of that company. This framework provided the basis for various decisions as we organically integrated ProStrakan's marketing infrastructure in Europe with Kyowa Hakko Kirin's existing infrastructure. In the United States, we have been enhancing management from a global perspective through means including discussions about creating new organizations for development and marketing.



### Corporate Governance Structure (As of March 22, 2012)

# The Functions of Outside Directors and Outside Company Auditors

Kyowa Hakko Kirin believes that electing outside directors and outside company auditors improves management transparency and oversight, which are integral to our framework for supervising and auditing Group management independently, objectively and fairly.

Outside directors employ their backgrounds, specialized skills, deep experience and knowledge in Group management while exercising objective and fair oversight of Group management. Outside company auditors employ their specialized skills, knowledge and experience to supervise management from an objective, impartial perspective to help ensure sound, reliable management.

Kyowa Hakko Kirin's outside directors and outside company auditors have no personal, financial, business, or other vested interests in the Company.

# Compensation to Directors and Company Auditors

For directors, the Company has introduced systems for performance-linked compensation and for stock

options as stock-based compensation. The system for performance-linked compensation is an annual salary system that reflects company performance and individual performance in the determination of annual compensation. The system for stock options as stock-based compensation has the objective of enhancing motivation to increase enterprise value by aligning the interests of directors with those of shareholders in regard to changes in the Company's stock price. Outside directors and outside company auditors receive only fixed compensation to ensure they fulfill their management supervision function.

Kyowa Hakko Kirin has established suitable standards for compensation, including Group performance and scale and data from surveys of other companies conducted by external survey organizations. Maximum director compensation is ¥50 million in cash monthly and ¥55 million in stockbased compensation annually. Maximum company auditor compensation is ¥9 million in cash monthly. The General Shareholders' Meeting approves compensation for directors and company auditors.

### **Compensation to Directors and Company Auditors**

	Amount of	Total Compensation by Type			
	Remuneration, etc.	Regular Compensation	Stock Options		
Directors (6) (excluding outside directors)	324	289	34		
Company auditor (1) (excluding outside company auditors)	22	22	_		
Outside director and outside company auditors (7)	105	105	_		

(Millions of yen)

## Compliance

The Company has formulated the Kyowa Hakko Kirin Group Compliance Guidelines to clarify the Group's approach to compliance with corporate ethics in the conduct of business activities, and is working to ensure awareness of these guidelines among Group companies and all Group employees.

During fiscal 2011, Kyowa Hakko Kirin and several Group companies invited visiting speakers to ISO26000 seminars, initiated compliance training, and provided courses via e-learning. The Group also established four hotlines, including one for consulting with an outside attorney, to help ensure thorough compliance.



Compliance seminar



A poster that reminds employees of the existence of the hotlines

## **Risk Management**

The Group has created a risk management framework and Kyowa Hakko Kirin has established a Group Risk Management Committee in order to understand, evaluate and deal with risk from a Group-wide perspective. Specifically, the CSR Management Department monitors the progress of risk management programs, changes in risks, and actual risks confronting each division, and presents its findings quarterly to the Group Risk Management Committee. The committee also reports on its activities to the Board of Directors.

The Group Risk Management Committee recognized the Great East Japan Earthquake as a crisis on the day it occurred and immediately convened the Crisis Management Committee. This committee provided guidance to each division for confirming safety concerns, gathering information and helping people who had trouble returning home. Subsequently, we formed the Disaster Response Headquarters headed by the executive vice president and followed our manual in implementing countermeasures internally and externally.

In addition, we formulated a master business continuation plan (BCP) and BCP guidelines to respond to the issues the earthquake brought to our attention, and revised BCP documentation for various risks. Current moves include revising related regulations and manuals, and implementing disaster preparedness drills.

# **Human Rights and Labor Practices**

## **Basic Principles**

Kyowa Hakko Kirin respects human rights and diversity while creating a rewarding environment based on the Human Resources Philosophy it established to achieve its vision of becoming a global specialty pharmaceutical company, and to promote and embody the ideas set out in "Sharing Values, Aims, and Ideals; Team Kyowa Hakko Kirin."

### Kyowa Hakko Kirin's HR Philosophy

We value employees' self-initiative, encourage them to improve their abilities and creativeness, and will create a work environment in which they can pursue their own infinite possibilities and be fully motivated at work.

- Developing professionals We will provide employees with opportunities where they can proactively seek new challenges to acquire high expertise and a broad vision.
- Promoting diversity

We will provide employees with opportunities where diverse human resources can work well together by understanding and respecting different values.

• Clarification of mission and fair treatment We will share the company's vision and goals with employees to continuously enrich the value of their work, and clarify their expected roles. We will evaluate and reward employees fairly for their achievements and contributions to the company.

(Established in March 2009)

## **Promotion of Human Rights**

The Human Rights Training Program enhances awareness of the importance of human rights for all employees of all Group companies including affiliates. Other promotional activities include surveys on the human rights awareness of Group employees and human rights hotlines. During fiscal 2011, the Group distributed a brochure about preventing harassment and conducted workplace training using teaching materials.

## **Diversity and Inclusion Initiatives**

Kyowa Hakko Kirin has been conducting the Diversity & Inclusion Project since 2010 to ensure an organization of diverse employees who can express their individuality and live up to their full potential. In fiscal 2011, under the theme of creating a corporate culture in which gender presents no barrier to employees seeking to further their careers, we conducted 20 area forums in order to enhance employee understanding of diversity and inclusion and provide opportunities for communication.

## **Childcare Support Policy**

Kyowa Hakko Kirin promotes childcare support in cooperation with the labor union in order to create a work environment where all employees can pursue a full range of career options regardless of lifestyle or gender.

# Initiatives to Employ People with Disabilities

As of February 29, 2012, Kyowa Hakko Kirin employed 74 people with various disabilities. We will continue to implement employment programs for people with disabilities. In particular, we are helping people with intellectual disabilities find jobs through work experience programs and other means.

### **Development of a Globalized Workforce**

We offer optional training programs that provide employees with the opportunity to obtain the skills and mindset needed to work overseas, and also provide longer-term training under the Global Management Program to cultivate international personnel who can succeed globally as expatriate employees and international representatives. Moreover, in fiscal 2011, 15 people from three countries graduated from the borderless Global Executive Program, which is open to executive candidates from overseas subsidiaries and managers in Japan.

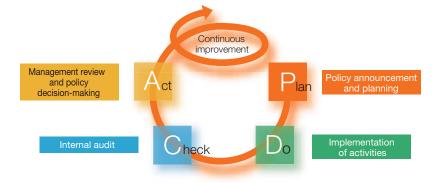


Global training participants

# Environment

# **Environmental and Safety Management**

The Kyowa Hakko Kirin Group employs the Plan-Do-Check-Act (PDCA) cycle for both its ISO14001accredited environmental management system and its occupational safety and health management system. Our environmental and safety activities comply with relevant laws and regulations and our own, more rigorous internal benchmarks. Our ongoing environmental activities have the goal of achieving low carbon corporate operations throughout the supply chain.



### **Environmental and Safety Management**

## **Declaration of Environmental Commitment**

As a member of the Kirin Group, which aspires to be a low carbon corporate group, Kyowa Hakko Kirin is working toward the environmental protection targets of its "Declaration of Environmental Commitment." Activities and results during fiscal 2011 are as follows.

Declaration	Fiscal 2011 Results
We aspire to become a low carbon corporate group.	<ul> <li>CO<sub>2</sub> emissions: 244 thousand tons (9.7% reduction from 2005)</li> <li>Reduced energy consumption among administrative divisions by 1% year on year</li> <li>Photovoltaic power generation facilities: installed at new Ube Plant building; installation planned at the Takasaki Plant</li> <li>Hybrid vehicles: cumulative total of 585 put into service</li> </ul>
We will promote resource conservation.	<ul> <li>Promoted green procurement throughout the supply chain</li> <li>Achieved zero waste emissions throughout the Group</li> </ul>
We will actively work on environmental conservation and protection.	<ul> <li>Conducted Kirin Takasaki Water Source Forest Conservation Activities since 2007</li> <li>Organized the Kirin Fuji-Sanroku Water Source Forest Conservation Activities jointly with Kirin Distillery</li> <li>Took part in various activities to protect water resources</li> </ul>
We will promote conservation of the environment and the ecological systems of local communities.	<ul> <li>Conducted activities to protect water resources used by our plants</li> <li>Conducted clean-up activities along the roads, harbors and rivers near each plant</li> </ul>

# Fair Operating Practices and Consumer Issues

# For Customers Our Customer Beliefs

Our goal is to manufacture safe, outstanding pharmaceuticals and steadily provide accurate information. We therefore comply with all laws and regulations at all stages from development to post-launch and conduct various quality assurance programs in putting the highest priority on customer safety.

### **Development Initiatives**

In the development of pharmaceuticals, manufacturers are required to ensure the reliability of application data and protect the safety and human rights of the people who participate in clinical trials by fully complying with the Good Laboratory Practice (GLP),<sup>1</sup> Good Clinical Practice (GCP),<sup>2</sup> and the Criteria for the Reliability of Application Data. At Kyowa Hakko Kirin, we have established Pharmaceutical Development Guidelines and Standard Operating Procedures (SOP) to meet these standards, as well as the Global Company Quality Assurance Policy. Under these governing documents, we strive to ensure reliability throughout the entire R&D process for new drugs, from preclinical studies using animals to human trials. We also conduct systematic quality assurance audits that encompass internal development departments, clinical testing facilities and development contractors.

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

2.Good Clinical Practice (GCP): Standard for the conduct of clinical trials for pharmaceuticals

## **Quality Assurance in Bio-Chemicals**

The amino acids and other fermentation products that Kyowa Hakko Bio provides are used in applica-



Quality control of bio-chemicals

tions ranging from pharmaceuticals and pharmaceutical synthetic intermediates to foods, food additives, health foods and cosmetics. Kyowa Hakko Bio manufactures these fermentation products in plants in Japan, the United States, and China and supplies to markets worldwide, ensuring that customers can use them with confidence by controlling production and quality with a system based on Good Manufacturing Practice<sup>3</sup> (GMP) for pharmaceuticals.

3. Good Manufacturing Practice (GMP): Standard for controlling pharmaceutical production and quality

## **Communication with Customers**

Our website provides detailed explanation of our strengths in therapeutic antibodies. In addition, our Chronic Kidney Disease (CKD) site provides an easily comprehensible introduction to the importance of early detection and early treatment of the disease.

The main task of our Medical Information Office is to respond to inquiries about our products from health care professionals and patients and their families. It received 38,688 inquiries during fiscal 2011. The office quickly shares information it gathers with medical representatives and relevant departments within

PERMIN (CK	0) e 🔿	0	-
もっていますかう	1.4	12 9	
CORPORTED ALL	- TA	1000	
*****	2 day	C.V	
			10 m
188-1 11.1894,7-67	108	TANKE	19-51 DID488
annasire.er	智性質血とは?	R.L.L.	1.1.2
1100m.	States and Street Stree	10.00	BALLAD BEATH
Manager and		- Di kut	cubi imar
	- 244517428 	0	
anani		A CITAR	BALBORN
P-STERE	00.01	× 653	Rancissi's and
areas torna	·T)-STROOMBREE	in ini	TRAC INCOME
data barriar	STREET BICK	CA DOW	-81
941934			Britket
	QAA	HCGRF272	- BOFFIRE

the company. This enhances our ability to collaboratively provide information on product safety, quality and other topics to stakeholders including medical institutions and patients.

Chronic Kidney Disease (CKD) site

# Communication Activities in Japan Local Science Experiment Classrooms

The BioAdventure vehicle is a mobile classroom equipped with microscopes and other scientific equipment that is operated by the Tokyo Research Park in Machida, Tokyo. Kyowa Hakko Kirin's researchers visit elementary, junior high, and senior high schools to demonstrate science to students and assist them in conducting experiments. In fiscal 2011, 144 students participated during four visits.

# **Kato Memorial Bioscience Foundation**

Established in 1988 in commemoration of Kyowa Hakko's founder, Dr. Benzaburo Kato, the Kato Memorial Bioscience Foundation supports creative bioscience research by providing grants to young scientists. In fiscal 2011, the foundation made 25 research grants in areas such as medical science and biotechnology, 31 international exchange grants, and 10 grants for academic conferences.



Keynote speaker at a research grant awards ceremony http://www.katokinen.or.jp/

# Communication Activities outside Japan

## Donation of Pharmaceuticals to Developing Countries

Kyowa Hakko Kirin has been donating highperformance liquid chromatographs (HPLCs) to organizations including the Cambodian Ministry of Health, the Laos Pharmaceutical Development Center, and the Thai Ministry of Public Health, via the Japan Pharmaceutical Manufacturers Association (JPMA). Moreover, we have been helping children in the developing countries of Asia since the 1970s by providing a steady supply of LEUNASE® Injection, an antitumor enzyme indispensable for treating pediatric hematological malignancies. Today, we supply this medicine in Asia, Europe and elsewhere around the world, including in developing countries.

# Table Tennis Classes Help Children Smile in Tohoku

The Kirin Group's Kirin Kizuna Project: Support for Rebuilding has included table tennis classes for 1,500 elementary, middle and high school students in Iwate, Miyagi and Fukushima prefectures. These classes provided the opportunity for head-tohead matches with top-class players from Kyowa Hakko Kirin's corporate team and Mr. Koji Matsushita, a former employee and



professional player who is currently president of table tennis products company Yamato Takkyu Co., Ltd. Wearing T-shirts saying "Give It All You Got, Tohoku," the participating students smiled enthusiastically, excited by exhibition matches, technical guidance, games with pros, the satisfaction of a blistering smash, autograph



A match in progress



Messages for participants of the next event

sessions, and a table tennis equipment raffle. We plan to continue holding these events through 2014, contributing to the growth and fulfillment of young people through the important life lesson of commitment that table tennis teaches, complemented by technical guidance.



# Science That Heals:

# **Financial Section**

Sound finances are essential to our ability to develop and deliver science that heals. Our financial objectives include stable cash flow that funds both strong investments in R&D and consistent, growing dividends.

Eleven-Year Selected Financial Data 52

Management's Discussion and Analysis 54

Risk Factors 60

Consolidated Balance Sheets 62

Consolidated Statements of Income 64

Consolidated Statement of Comprehensive Income 65

Consolidated Statements of Changes in Net Assets 66

Consolidated Statements of Cash Flows 67

Notes to the Consolidated Financial Statements 68

Report of Independent Auditors 94

# **Eleven-Year Selected Financial Data**

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries For the years ended December 31, 2011 and 2010, the nine months ended December 31, 2009 and years ended March 31, 2002 to 2009

	2011/12	2010/12	2009/12	2009/3	
For the Year:					
Net sales	¥343,722	¥413,738	¥309,111	¥460,183	
Gross profit	197,555	190,979	139,739	200,297	
Selling, general and administrative expenses	150,940	145,568	111,496	154,910	
Operating income	46,614	45,410	28,243	45,387	
Net income	25,608	22,197	8,797	11,726	
Capital expenditures	19,697	29,374	25,135	18,523	
Depreciation and amortization	22,833	22,188	17,003	18,779	
R&D expenses	47,961	44,210	34,979	48,389	
Cash Flows:					
Net cash provided by operating activities	¥ 40,634	¥ 64,189	¥ 24,203	¥ 41,069	
Net cash (used in) provided by investing activities	18,460	(32,373)	(13,246)	(3,981)	
Net cash used in financing activities	(30,740)	(14,446)	(16,906)	(20,978)	
Cash and cash equivalents at the end of the period	107,555	79,882	63,745	69,286	
	101,000	10,002	00,110		
At Year-End:					
Total current assets	¥284,217	¥288,852	¥276,587	¥279,475	
Total assets	658,873	695,862	695,268	699,041	
Total current liabilities	78,465	102,483	110,080	108,522	
Interest-bearing debt	6,042	7,515	13,228	13,540	
Total net assets	540,023	544,992	540,343	543,070	
Total shareholders' equity <sup>2</sup>	554,856	553,172	539,304	547,203	
Number of employees	7,229	7,484	7,436	7,256	
Per Share Data:					
Net income-basic <sup>3</sup>	¥45.16	¥38.96	¥15.40	¥20.42	
Net assets	970.2	954.6	940.8	938.4	
Cash dividends	20	20	15	20	
Common Stock Price Range (Per share):					
High	¥953	¥1,040	¥1,178	¥1,235	
Low	628	773	793	586	
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	567,029	569,711	570,935	574,083	
Financial Ratios:					
Return on assets (ROA)	3.78	3.19	1.26	1.62	
Operating return on assets	6.88	6.53	4.05	6.26	
Return on equity (ROE)	4.73	4.11	1.64	2.17	
Equity ratio	81.79	78.16	77.07	77.04	
Debt/equity ratio	1.12	1.38	2.47	2.51	
Operating income margin	13.56	10.98	9.14	9.86	
EBITDA₄ (Millions of yen)	69,153	64,687	37,876	50,241	
Payout ratio <sup>5</sup>	32.5	36.2	54.3	53.8	
	02.0	00.2	0.110	00.0	

U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥77.74=U.S.\$1, the approximate exchange rate at December 31, 2011.
 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. EBITDAE Income before income taxes and minority interests + Interest expenses + Depreciation and amortization
 5. The consolidated payout ratio is calculated using earnings before amortization of goodwill\* beginning with the fiscal year ended March 31, 2009.
 \* Earnings before amortization of goodwill: Net income before amortization of goodwill resulting from the April 2008 acquisition of Kyowa Hakko by Kirin Pharma through an exchange of shares.

Millions of yen							Thousands of U.S. dollars <sup>1</sup>
2008/3	2007/3	2006/3	2005/3	2004/3	2003/3	2002/3	2011/12
¥392,119	¥354,274	¥353,439	¥358,963	¥348,838	¥359,284	¥378,667	\$4,421,442
144,917	131,424	126,982	132,112	129,506	126,328	128,744	2,541,229
105,527	100,725	101,448	98,605	102,670	110,239	108,387	1,941,608
39,390	30,698	25,534	33,506	26,836	16,088	20,356	599,621
23,477	12,694	16,273	17,931	10,017	8,484	5,535	329,409
14,795	14,497	10,870	7,648	9,041	11,791	11,454	253,378
14,346	10,006	9,788	10,565	11,358	14,767	17,819	293,717
34,109	33,342	32,875	28,761	29,205	31,438	29,294	616,950
¥ 30,713	¥ 23,380	¥14,303	¥30,104	¥ 34,264	¥ 18,193	¥ 16,955	\$ 522,691
(9,492)	(8,493)	(1,795)	(8,104)	10,476	2,585	8,376	237,465
(13,499)	(24,417)	(5,139)	(9,116)	(44,226)	(38,748)	(16,843)	(395,427)
44,118	36,613	45,820	37,817	24,911	24,588	41,908	1,383,526
¥232,661	¥214,352	¥212,985	¥210,341	¥194,062	¥195,878	¥244,409	\$3,656,002
394,081	378,870	384,381	374,492	361,095	368,771	430,112	8,475,350
111,743	106,565	94,148	103,489	98,914	95,045	162,508	1,009,327
12,790	13,136	12,216	12,193	13,357	51,969	74,353	77,726
256,758	244,082	257,491	· _	· _	· _	· _	6,946,527
239,328	220,428	232,621	235,439	225,041	219,047	211,652	7,137,331
6,073	5,756	5,800	5,960	6,294	6,749	7,299	, , , , , , , , , , , , , , , , , , , ,
				-, -	- , -	,	
Yen							U.S. dollars
¥58.99	¥31.31	¥38.34	¥41.67	¥22.99	¥19.35	¥12.74	\$ 0.581
639.7	607.5	604.9	556.3	522.6	505.4	487.5	12.480
10	10	10	10	7.5	7.5	7.5	0.257
¥1,430	¥1,154	¥946	¥864	¥719	¥780	¥899	\$12.259
933	722	656	661	495	411	587	8.078
399,243	399,243	434,243	434,243	434,243	434,243	434,243	
397,716	405,270	422,919	427,635	431,497	433,747	434,243	
%, except EBITD							
6.07	3.33	4.29	4.88	2.74	2.12	1.28	
10.19	8.04	6.73	9.11	7.35	4.03	4.73	
9.47	5.1	6.63	7.79	4.51	3.94	2.72	
64.53	63.8	66.55	62.87	62.32	59.4	49.21	
5.03	5.43	4.78	5.18	5.94	23.73	35.13	
10.05	8.67	7.22	9.33	7.69	4.48	5.38	
53,162	33,771	34,846	40,707	27,539	33,477	33,396	
16.9	31.9	26.1	24.0	32.6	38.8	58.9	
. 510							

# **Management's Discussion and Analysis**

All amounts are rounded down from the fiscal year ended December 31, 2011.

### Subsidiaries Included in the Scope of Consolidation

As of December 31, 2011, the number of consolidated subsidiaries increased by seven from a year earlier to 38. Factors in the change are as follows.

On March 31, 2011, Kyowa Hakko Kirin divested all outstanding shares of Chemicals segment company Kyowa Hakko Chemical Co., Ltd. and excluded it from the scope of consolidation. As a result, the Chemicals segment was eliminated at the end of the first quarter, ended March 31, 2011. Also, in April 2011 we acquired all outstanding shares of UK specialty pharmaceutical company ProStrakan Group Plc (ProStrakan) and made it a wholly owned subsidiary. We included it in the scope of consolidation as of June 30, 2011, the deemed acquisition date. Consolidated results for the fiscal year ended December 31, 2011 therefore include the results of ProStrakan and its ten subsidiaries for the six months ended December 31, 2011 (net sales of ¥6.9 billion).

### Income and Expenses

### **Net Sales**

For the fiscal year ended December 31, 2011, net sales decreased 16.9 percent compared with the previous fiscal year to ¥343.7 billion. Sales rose steadily in the Pharmaceuticals segment, supported by higher sales of core products and the addition of ProStrakan's net sales. Sales decreased in the Bio-Chemicals segment due to the pronounced impact of the strong yen and business reorganization. Sales decreased substantially in the Chemicals segment, which was excluded from the scope of consolidation from the second quarter.

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

Cost of sales decreased 34.4 percent to ¥146.1 billion, while gross profit increased 3.4 percent to ¥197.5 billion. As a result, the gross margin improved 11.3 percentage points to 57.5 percent from 46.2 percent. This improvement was primarily the result of the exclusion of the Chemicals segment from the scope of consolidation.

Selling, general and administrative (SG&A) expenses increased 3.7 percent to ¥150.9 billion. Primary factors included higher R&D expenses due to increased depreciation following the completion of production facilities for investigational therapeutic antibodies at the Bio Process Research and Development Laboratories in Takasaki, Gunma Prefecture. Moreover, amortization of sales rights and goodwill increased as a result of the acquisition of ProStrakan. The ratio of SG&A expenses to net sales increased 8.7 percentage points to 43.9 percent from 35.2 percent.

As a result of the above, operating income increased 2.7 percent to ¥46.6 billion. The operating income margin increased 2.6 percentage points to 13.6 percent from 11.0 percent. The operating income margin before amortization of goodwill was 16.3 percent.

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

Net other expenses decreased substantially to ¥0.4 billion from ¥3.1 billion. Despite expenses including loss on valuation of investment securities of ¥2.3 billion and advisory fee of ¥1.0 billion, net other expenses improved because gain on sales of affiliates' stock totaled ¥7.2 billion, foreign exchange losses decreased, and loss on revision of retirement benefit plan did not recur.

Consequently, income before income taxes and minority interests increased 9.2 percent, to ¥46.1 billion.

### **Income Taxes**

Income taxes increased 2.2 percent to ¥20.4 billion. As a percentage of pretax income, the effective tax rate decreased 3.0 percentage points to 44.4 percent from 47.4 percent.

### **Net Income**

Consequently, net income increased 15.4 percent to ¥25.6 billion, and the net margin increased 2.1 percentage points to 7.5 percent from 5.4 percent.

### **Performance by Business Segment**

Net sales by business segment and segment income (loss) are shown below. Segment performance figures include intersegment transactions.

### **Pharmaceuticals**

In the core Pharmaceuticals segment, net sales increased 9.0 percent to ¥229.3 billion, which accounted for 66.7 percent of total net sales. Segment income increased 15.2 percent to ¥41.3 billion.

#### **Gross Profit**



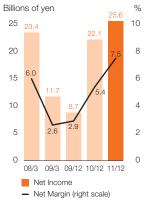








### Net Income



Domestic sales of our core ethical drug NESP®, a treatment for renal anemia, were robust while sales of ALLELOCK®, an antiallergic agent, and Patanol® antiallergic eye drops were significantly higher than in the previous fiscal year due to factors including higher levels of airborne pollen.

Sales at subsidiary Kyowa Medex Co., Ltd., which manufactures and sells diagnostic reagents, increased compared with the previous fiscal year because sales of immunological reagents and exports were solid.

Overseas, the consolidation of ProStrakan from the third quarter supported growth in net sales and segment income in the Pharmaceuticals segment.

### **Bio-Chemicals**

In the Bio-Chemicals segment, net sales decreased 7.9 percent to ¥77.5 billion, which accounted for 22.6 percent of total net sales. Segment income decreased 11.6 percent to ¥2.8 billion.

Sales declined due to the impact of the strong yen, although the sales volume of pharmaceutical- and industrial-use amino acids increased because of higher demand overseas. In Japan, mail-order sales of health care products grew steadily, primarily our own brands of health food materials such as ornithine, but product renewal delays resulting from the Great East Japan Earthquake cut into sales. Bio-Chemicals segment net sales and segment income therefore decreased year on year.

### Chemicals

Results for the Chemicals segment include only the first quarter of the consolidated fiscal year because Kyowa Hakko Kirin sold all outstanding shares of Kyowa Hakko Chemical Co., Ltd. to KJ Holdings Inc. on March 31, 2011. Growing demand in Asia, firm market conditions, and a recovery in demand in Japan supported results. Net sales increased 10.8 percent to ¥33.5 billion and accounted for 9.7 percent of total net sales. Segment income increased 216.6 percent to ¥2.1 billion. For reference, segment net sales were ¥130.0 billion and segment income was ¥5.6 billion for the previous fiscal year.

### Other

The Other segment includes transportation operations at subsidiaries. Net sales increased 1.5 percent to ¥10.6 billion, which accounted for 3.1 percent of total net sales. Segment income decreased 0.8 percent to ¥0.3 billion.

Teany mormation by business segme		Millions of yen						
	2011/12	2010/12	2009/12	2009/3	2008/3	2007/3	2011/12	
Net sales:								
Pharmaceuticals	¥229,339	¥210,362	¥158,273	¥210,449	¥138,377	¥131,525	\$2,950,086	
Bio-Chemicals	77,563	84,236	69,751	88,464	86,820	67,121	997,735	
Chemicals	33,550	130,018	52,326	89,204	108,007	98,649	431,567	
Food	—	_	_	42,468	43,324	42,589	—	
Other	10,659	10,499	49,500	68,733	48,998	48,480	137,121	
Adjustments	(7,390)	(21,377)	(20,740)	(39,135)	(33,407)	(34,091)	(95,068)	
Consolidated total	¥343,722	¥413,738	¥309,111	¥460,183	¥392,119	¥354,274	\$4,421,442	
Segment income (loss):								
Pharmaceuticals	¥41,314	¥35,857	¥26,657	¥34,832	¥19,961	¥15,745	\$531,444	
Bio-Chemicals	2,896	3,275	3,048	8,342	9,688	4,112	37,256	
Chemicals	2,135	5,678	(1,984)	(47)	7,169	7,973	27,470	
Food	—	_	—	1,086	1,576	1,831	—	
Other	360	363	400	1094	838	968	4,635	
Adjustments	(92)	235	121	(78)	155	66	(1,185)	
Consolidated total	¥46,614	¥45,410	¥28,243	¥45,387	¥39,390	¥30,698	\$599,621	

### Yearly Information by Business Segment

Note: U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥77.74=U.S.\$1, the approximate exchange rate at December 31, 2011.

### Quarterly Information by Business Segment

	Millions of yen									
			2011					2010		
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	12 months	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	12 months
Net sales:										
Pharmaceuticals	¥ 63,393	¥49,140	¥55,683	¥61,122	¥229,339	¥ 49,674	¥ 53,801	¥ 50,617	¥ 56,269	¥210,362
<b>Bio-Chemicals</b>	19,686	20,673	18,613	18,590	77,563	22,213	21,973	19,782	20,267	84,236
Chemicals	33,550	—	—	-	33,550	30,281	31,007	33,371	35,358	130,018
Other	2,651	2,655	2,549	2,804	10,659	2,493	2,589	2,623	2,794	10,499
Total	119,281	72,470	76,846	82,516	351,113	104,662	109,371	106,395	114,688	435,116
Adjustments	(4,419)	(965)	(855)	(1,152)	(7,390)	(5,406)	(5,161)	(5,408)	(5,402)	(21,377)
Consolidated total	¥114,862	¥71,505	¥75,991	¥81,364	¥343,722	¥ 99,256	¥104,209	¥100,987	¥109,286	¥413,738
Segment income (loss):										
Pharmaceuticals	¥18,419	¥6,726	¥7,979	¥8,189	¥41,314	¥ 9,678	¥ 8,314	¥ 8,474	¥ 9,390	¥35,857
<b>Bio-Chemicals</b>	1,272	1,247	495	(119)	2,896	1,010	843	991	430	3,275
Chemicals	2,135	—	—	—	2,135	674	914	1,953	2,136	5,678
Other	82	65	107	106	360	82	67	101	113	363
Total	21,909	8,039	8,582	8,176	46,706	11,446	10,140	11,520	12,069	45,175
Adjustments	0	(12)	(23)	(56)	(92)	81	23	13	117	235
Consolidated total	¥21,909	¥8,026	¥8,559	¥8,120	¥46,614	¥11,527	¥10,164	¥11,533	¥12,186	¥45,410

Note: First, second and third quarter data are from quarterly reports. Fourth quarter data are the total of the first three quarters subtracted from the 12-month total.

### Sales by Geographic Segment (Year ended December 31, 2011)

Japan	America*	Europe	Asia	Other areas**	Total
¥272,568	¥20,071	¥25,169	¥25,426	¥486	¥343,722

\*\* Oceania, Africa

### **ProStrakan Results\***

For the six months ended December 31, 2011, ProStrakan sales trended upward compared with the previous fiscal year to £56 million (¥6.8 billion). Sales increased in both Europe and the United States. Abstral® was the key growth driver in Europe. Sales and market share increased steadily for this product, which is used for managing episodes of breakthrough cancer pain. Sancuso®, a product for preventing chemotherapy-induced nausea and vomiting, performed well in the United States. In addition, Abstral® was launched in the United States in April 2011.

Operating income before amortization of goodwill and sales rights on consolidation was £1 million (¥189.8 million). Operating loss after amortization of goodwill and sales rights on consolidation was £16 million (¥2.0 billion). For the year ending December 31, 2012, ProStrakan forecasts sales of £142 million (¥17.0 billion), operating income before amortization of goodwill on consolidation of £14 million (¥1.7 billion) and operating loss after amortization of goodwill on consolidation of £17 million (¥2.1 billion).

\* British pound amounts are translated into Japanese yen, for convenience only, at the rate of ¥119.81=£1, the approximate exchange rate at December 31, 2011.

### **Cash Flow**

Cash and cash equivalents as of December 31, 2011 increased ¥27.6 billion from a year earlier to ¥107.5 billion. The main factors affecting cash flow during the fiscal year were as follows.

Net cash provided by operating activities decreased 36.7 percent compared with the previous fiscal year to ¥40.6 billion. The main source of cash was income before income taxes and minority interests of ¥46.1 billion. Depreciation and amortization totaled ¥22.8 billion, and amortization of goodwill totaled ¥10.7 billion. The main uses of cash included income taxes paid of ¥29.0 billion and a ¥12.8 billion increase in working capital resulting mainly from an increase in inventories.

Net cash provided by investing activities was ¥18.4 billion, compared with net cash used in investing activities of ¥32.3 billion for the previous fiscal year. Major uses of cash included ¥36.9 billion for purchase of investments in consolidated subsidiaries accompanying changes to the scope of consolidation and ¥16.3 billion for purchase of property, plant and equipment. Major sources of cash were ¥52.7 billion from proceeds from investments in consolidated subsidiaries accompanying changes to the scope of consolidation and ¥15.1 billion from proceeds from sales of affiliates' stock.

Net cash used in financing activities increased 112.8 percent compared with the previous fiscal year to ¥30.7 billion. The main uses of cash were ¥12.5 billion for purchase of treasury stock, ¥11.4 billion for cash dividends paid, and ¥6.5 billion for repayment of long-term loans payable.

### **Financial Position**

#### Assets

Total assets as of December 31, 2011 decreased 5.3 percent, or ¥36.9 billion, from a year earlier to ¥658.8 billion.

Total current assets decreased 1.6 percent, or ¥4.6 billion, to ¥284.2 billion. Factors such as the exclusion of the Chemicals segment from the scope of consolidation caused notes and accounts receivable and inventories to decrease. However, factors such as proceeds from sales of affiliates' stock were the primary cause of an increase in short-term loans receivable under the cash management system provided by Kyowa Hakko Kirin's parent company, Kirin Holdings, to all Group companies. Short-term loans to Kirin Holdings under this cash management system totaled ¥82.4 billion.

Total property, plant and equipment, net, decreased 23.0 percent, or ¥36.7 billion, to ¥122.9 billion. The primary reason was the exclusion of the Chemicals segment from the scope of consolidation, as discussed earlier.

Total investments and other assets, which include intangible assets, increased 1.8 percent, or ¥4.4 billion, to ¥251.7 billion. Factors including sales of affiliates' stock caused the sum of investment securities and investments in unconsolidated subsidiaries and affiliates to decrease ¥30.4 billion. The acquisition of ProStrakan was the primary reason goodwill, sales rights and other intangible assets included in other assets increased ¥38.0 billion.

### Liabilities

Total liabilities decreased 21.2 percent, or ¥32.0 billion, from the end of the previous fiscal year to ¥118.8 billion.

Total current liabilities decreased 23.4 percent, or ¥24.0 billion, to ¥78.4 billion. This was primarily the result of a significant decrease in notes and accounts payable due to the exclusion of the Chemicals segment from the scope of consolidation.

Total noncurrent liabilities decreased 16.5 percent, or ¥8.0 billion, to ¥40.3 billion. This was mainly the result of a ¥5.4 billion decrease in deferred tax liabilities and a ¥3.4 billion decrease in provision for retirement benefits. Interest-bearing debt decreased 19.6 percent, or ¥1.4 billion, to ¥6.0 billion.

Working capital (total current assets minus total current liabilities) increased ¥19.3 billion from a year earlier to ¥205.7 billion. Fiscal integrity strengthened as the current ratio improved to 362.2 percent from 281.9 percent.

### **Net Assets**

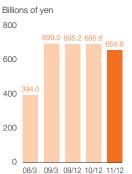
Total net assets decreased 0.9 percent, or ¥4.9 billion, from a year earlier to ¥540.0 billion, largely because foreign currency translation adjustments, purchases of treasury stock and cash dividends more than offset net income of ¥25.6 billion. However, the equity ratio increased 3.6 percentage points to 81.8 percent and the debt/equity ratio decreased to 1.1 percent from 1.4 percent. Fiscal integrity remained high as a result.

### **Performance Indicators**

Return on equity (ROE) improved to 4.73 percent from 4.11 percent for the previous fiscal year. Return on assets (ROA) improved to 3.78 percent from 3.19 percent. This was primarily due to the increase in net income and the decrease in total assets. Operating return on assets also improved to 6.88 percent from 6.53 percent.

Earnings before income tax, interest, depreciation, and amortization (EBITDA) for the fiscal year increased 6.9 percent to ¥69.1 billion.

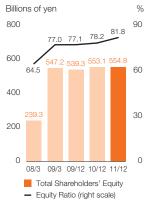
#### **Total Assets**



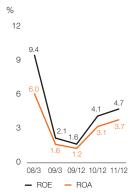
### Interest-Bearing Debt



**Total Shareholders' Equity** 







### **Capital Expenditures**

Our policy for capital expenditures is to invest strategically while considering the balance between capital expenditures and depreciation and amortization. During the fiscal year ended December 31, 2011, we invested aggressively to reorganize production bases, increase operating efficiency and expand leading-edge production facilities as the basis for future growth.

Capital expenditures during the fiscal year ended December 31, 2011 decreased 32.9 percent, or ¥9.6 billion, compared with the previous fiscal year to ¥19.6 billion. Investments included construction of a new formulating line at the Ube Plant in the Pharmaceuticals business and construction of a new production facility for small molecular weight active pharmaceutical ingredients at DAIICHI FINE CHEMICAL CO., LTD. in the Bio-Chemicals business. Capital expenditures were within the scope of depreciation and amortization, which increased 2.9 percent, or ¥0.6 billion, to ¥22.8 billion.

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

	Millions of yen									
	Ca	apital Expenditure	es	Depreciation and Amortization						
	2011/12	2010/12	2009/12	2011/12	2010/12	2009/12				
Pharmaceuticals	¥11,886	¥19,251	¥16,506	¥15,339	¥10,733	¥ 9,211				
<b>Bio-Chemicals</b>	7,482	7,604	5,000	6,457	6,731	4,321				
Chemicals	317	2,505	3,583	974	4,652	3,357				
Other	11	15	45	64	73	113				
Adjustments	—	(1)	(O)	(2)	(2)	(1)				
Consolidated total	¥19,697	¥29,374	¥25,135	¥22,833	¥22,188	¥17,003				

### **R&D Expenses**

R&D expenses, which are included in SG&A expenses, increased 8.5 percent to ¥47.9 billion. As a percentage of consolidated net sales, R&D expenses increased 3.3 percentage points to 14.0 percent from 10.7 percent for the previous fiscal year.

R&D expenses in the Pharmaceuticals segment totaled ¥44.5 billion and accounted for 92.9 percent of total R&D expenses. As a percentage of Pharmaceuticals segment net sales, R&D expenses increased 0.4 percentage points to 19.4 percent. Kyowa Hakko Kirin plans to maintain R&D expenses at approximately 20 percent of Pharmaceuticals segment sales to support research and development of new drugs.

### Per Share Data

Net income per share – basic was ¥45.16, compared with ¥38.96 for the previous fiscal year. Net income per share before amortization of goodwill was ¥61.50. Net assets per share as of December 31, 2011 increased to ¥970.2 from ¥954.6 a year earlier.

### Goodwill

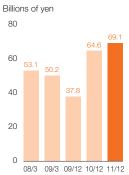
Kyowa Hakko Kirin recognized goodwill as a result of the April 1, 2008 exchange of shares in connection with the business combination through which Kirin Pharma Company Limited acquired Kyowa Hakko Kogyo Company, Limited because the acquisition cost exceeded the market value of Kyowa Hakko's net assets. In addition, Kyowa Hakko Kirin recognized goodwill as a result of the April 21, 2011 acquisition of all outstanding shares of ProStrakan because the acquisition cost exceeded the market value of ProStrakan's net assets.

### Goodwill from the business combination with Kirin Pharma:

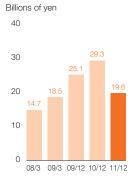
- Total goodwill generated: ¥191.9 billion
- Amortization method: Straight-line method
- Amortization period: 20 years (beginning the fiscal year ended March 31, 2009)

Amortization of goodwill during the fiscal year ended December 31, 2011 increased to ¥10.6 billion from ¥9.7 billion for the previous fiscal year, and included goodwill from the business combination with Kirin Pharma and six months of goodwill from the ProStrakan acquisition.

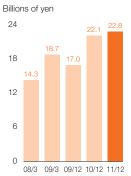
### EBITDA



**Capital Expenditures** 

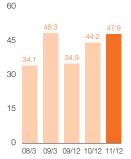


**Depreciation and Amortization** 



R&D Expenses





### **Management Plan**

The Kyowa Hakko Kirin Group's vision is to be a world-class R&D-focused life sciences company, based on biotechnology and with the pharmaceutical business at its core. We are aiming for global growth by providing new value that addresses diverse needs.

The theme of Medium-Term Management Plan – 2010 to 2012 is to accelerate progress in our development pipeline and efficiently allocate business resources in line with three key initiatives:

- Select and concentrate our business portfolio
- Strengthen profitability by reorganizing production facility locations
- Further develop our world-class therapeutic antibody business

During the fiscal year ended December 31, 2011 we selected and concentrated our business portfolio through major steps including the sale of our Chemicals business, Kyowa Hakko Chemical; securing a development and sales base to expand in Europe and the United States through the acquisition of U.K. specialty pharma business ProStrakan; and our recently announced entry into a joint venture with FUJIFILM Corporation, Fujifilm Kyowa Kirin Biologics Co., Ltd., for the development, manufacture and sale of biosimilars. Thus the Kyowa Hakko Kirin Group has advanced to a new stage in achieving its vision.

The Kyowa Hakko Kirin Group originally set targets for the fiscal year ending December 31, 2012, the final year of the Medium-Term Management Plan – 2010 to 2012, of ¥454.0 billion in net sales and ¥51.7 billion in operating income. However, due to factors including the elimination of the Chemicals segment as discussed above, the fiscal 2012 targets have been revised to net sales of ¥326.0 billion and operating income of ¥48.0 billion.

### **Outlook for Fiscal 2012**

In the fiscal year ending December 31, 2012 we expect the trend toward gradual improvement in the Japanese economy to continue. However, the outlook remains uncertain because factors such as a further worsening of fiscal and financial problems in Europe could cause overseas economies to underperform expectations, which would increase the risk of downward pressure on the domestic economy.

In this environment, for the fiscal year ending December 31, 2012 we forecast that net sales will decrease 5.2 percent year on year to ¥326.0 billion, operating income will increase 3.0 percent to ¥48.0 billion, and net income will decrease 21.9 percent to ¥20.0 billion.

In the Pharmaceuticals segment, we expect a pronounced impact from the reductions in National Health Insurance (NHI) reimbursement prices scheduled for April 2012. However, we anticipate that sales and earnings will increase year on year because of growth in sales of products such as Fentos<sup>®</sup>, a transdermal analgesic for persistent cancer pain; REGPARA<sup>®</sup>, a treatment for secondary hyperparathyroidism during dialysis therapy; ASACOL<sup>®</sup>, an ulcerative colitis treatment; and Romiplate<sup>®</sup>, a treatment for chronic idiopathic thrombocytopenic purpura. We also expect factors such as the full-year consolidated contribution from ProStrakan and licensing revenues from the biosimilar joint venture with FUJIFILM Corporation established in March 2012 to support results.

In the Bio-Chemicals segment, we forecast year-on-year sales growth due to higher sales volume for core amino acids, nucleic acids and related compounds and the mail-order Remake® series, although the impact of the strong yen will be significant. We forecast that operating income will decrease due to factors including the impact of the strong yen and an increase in depreciation and amortization resulting from large-scale capital expenditures at DAIICHI FINE CHEMICAL CO., LTD.

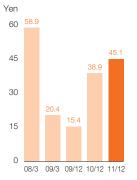
### **Profit Distribution**

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, the dividend payout ratio, and dividend return on net assets. We seek to improve capital efficiency through flexible, timely share repurchases. Kyowa Hakko Kirin deploys internal capital to fund future growth through investment in R&D and property, plant and equipment. Based on this policy, Kyowa Hakko Kirin paid cash dividends per share of ¥20.00 for the fiscal year ended December 31, 2011, as planned.

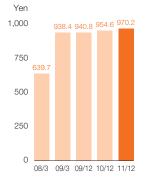
In Medium-Term Management Plan – 2010 to 2012, we will continue to target a consolidated dividend payout ratio of at least 30 percent of earnings before amortization of goodwill\*. For the fiscal year ending December 31, 2012, we expect to pay an annual cash dividend per share of ¥20.00, consisting of an interim dividend of ¥10.00 and a year-end dividend of ¥10.00.

\*Earnings before amortization of goodwill: Net income before amortization of goodwill resulting from the April 2008 acquisition of Kyowa Hakko by Kirin Pharma through an exchange of shares.

#### Net Income per Share-Basic



Net Assets per Share



# **Risk Factors**

The principal risks that may significantly affect the Kyowa Hakko Kirin Group's results and financial position and the confidence of its investors include the following.

The Group uses a risk management system to prevent the occurrence of risks that it can control. Should a risk event occur, the Group responds decisively to avert or minimize its impact.

Forward-looking statements or projections contained in this section reflect the judgments of the Group as of December 31, 2011

### 1. The Domestic Pharmaceutical Industry

Japan's National Health Insurance (NHI) system periodically reduces the official prices for ethical drugs, including many of the Group's pharmaceuticals. As a result, the Group cannot avoid reductions in the selling prices of drugs that are not awarded premiums for the development of new drugs or the elimination of off-label drug use. Inability to compensate for price reductions could affect the Group's results and financial position.

Factors including reforms of Japan's medical system aimed at promoting the use of generic drugs, intensified competition from European and American pharmaceutical companies, and the strategies of major specialist companies could also affect the Group's results and financial position.

### 2. Inability to Recover R&D Investment

The Group invests significantly in the development of new products and technologies, and in improving existing products and developing applications. In particular, breakthrough new drugs are essential for growth in the Group's core Pharmaceuticals segment. New drug development requires long periods of time and substantial R&D expenditures. Moreover, the development and sale of new pharmaceuticals is inherently complicated and uncertain. In the long-term development of new drugs, the Group may halt R&D when it cannot confirm the expected efficacy of particular compounds, and may discontinue successfully launched products that do not generate the expected level of sales or that exhibit serious unpredicted side effects. The Group may be unable to recover its investment in R&D because of these or other factors.

The Group also invests in businesses other than pharmaceuticals to develop new products and technologies to differentiate it from competitors, primarily using fermentation and other biotechnologies. The Group may be unable to recover these R&D investments if they do not produce results.

Inability to recover R&D investment may adversely affect the Group's growth, profitability, results and financial position.

### **3. Intellectual Property**

The Group may be subject to litigation claiming its products or technologies infringe on intellectual property rights. If successful, such litigation could require the Group to suspend product sales or pay compensation or settlement fees, which could adversely affect the Group's businesses, results and financial position. Conversely, competitors may infringe upon Group intellectual property rights and cause sales of the Group's in-house or outlicensed products or technology revenues to decline earlier than forecast, which could adversely affect the Group's results and financial position.

### 4. Side Effects

Pharmaceutical products undergo strict safety audits at the development stage and are approved only after close examination by the relevant authorities. However, post-launch usage data may reveal previously unknown side effects, which could adversely affect the Group's results and financial position.

### 5. Compliance

The Group rigorously complies with laws and regulations relevant to operations in Japan and overseas. In particular, the Pharmaceuticals segment is subject to the pharmaceutical-related regulations of the countries in which it operates at every stage from new drug development and manufacturing to importing and exporting, sales, distribution and use. The Group emphasizes full compliance with the numerous laws, business practices, and approval and permission systems relevant to its operations, and enhances internal control functions through means including audits.

However, the Group cannot completely eliminate the potential for noncompliance with relevant laws or regulations. Noncompliance may result in delay or cancellation of new product development or restrictions on manufacturing or sales activities, which could adversely affect the Group's credibility, results and financial position. Legal and regulatory changes in Japan and overseas could also adversely affect the Group's credibility, results and financial position.

### 6. Defective Products

The Group carries product liability insurance but cannot guarantee that it will completely cover damages for which the Group may be responsible. The Group may also be unable to obtain product liability insurance at acceptable terms. Issues including product defects that result in large-scale product recalls or product liability claims could significantly affect the Group's credibility and result in substantial losses, expenses and sales declines, which could adversely affect the Group's results and financial position.

### 7. Disasters and Accidents

The Group conducts periodic disaster prevention tests and maintenance at all production facilities to minimize operating exposure to negative impact from production line downtime. However, the Group cannot guarantee that it will be able to completely prevent production line downtime due to disasters such as earthquakes or fires, or problems such as electricity outages and boiler shutdowns. Further, the Group's head office, sales and distribution facilities may be unable to function properly if impacted by a disaster beyond the scope anticipated by the Group's disaster management systems, which could adversely affect Group operations.

The Group handles substances that are subject to various legal regulations and guidelines, and manages these substances at factories and research facilities in strict compliance with storage standards. However, natural disasters and accidents could cause leakage outside of Group facilities that damages the surrounding area.

Moreover, social disorder due to the spread of a new form of influenza or other infectious disease in the regions or countries where the Group operates could limit the Group's operating activities.

Scenarios such as the above could cause significant damage and adversely affect the Group's credibility, results and financial position.

### 8. Stronger Environmental Regulations

The Group generates effluent in the research and manufacture of biopharmaceuticals such as therapeutic antibodies and in the manufacture of amino acids and other products using fermentation technology. The Group processes and disposes of the effluent in accordance with the environmental regulations of host countries. However, environmental regulations in Japan and overseas tend to become more rigorous each year. The Group works to shift to raw materials that reduce environmental loading and to improve its effluent processing technology. However, regulatory changes could limit Group manufacturing activities and increase production costs, which could adversely affect the Group's results and financial position.

### 9. Overseas Operations

The Group operates in North America, Europe and Asia and is exposed to risks including the following:

- Unanticipated changes in laws and regulations and unfavorable changes in tax systems;
- Adverse political or economic factors;
- Difficulties hiring or retaining personnel;
- Social disorder as a result of terrorism, war or other factors;
- Changes in the operating or competitor landscape.

The Group may be unable to operate effectively overseas if these latent risks materialize, which could adversely affect the Group's results and financial position.

## 10. Impact of Raw Material and Fuel Price Volatility on Profitability

In the Bio-Chemicals segment, rising raw material prices caused by high fuel prices, growing demand from emerging countries, increased demand for bioethanol and poor harvests due to unseasonable weather have become a significant issue. Inability to quickly reflect raw material prices in product selling prices or compensate for them through cost reductions could adversely affect the Group's results and financial position.

### 11. Foreign Exchange Volatility

The Group has foreign currency-denominated cash flows including product sales, technology licensing income and overseas raw material purchases. Sudden changes in exchange rates could therefore adversely affect the Group's results and financial position. Exchange rate volatility could also affect the Group's price competitiveness in markets shared with overseas competitors.

The income, expenses, assets and liabilities of overseas consolidated subsidiaries are denominated in local currencies and translated into yen for consolidated financial reporting. The exchange rate at the time of translation could affect reported values.

### 12. Changes in the Price of Shares and Other Investment Securities

The Group holds investment securities with market values from issuers including business partners and financial institutions. A significant drop in the market value of these securities could cause loss on valuation that could adversely affect the Group's results and financial position.

The Group also invests a portion of its corporate pension assets in investment securities with market values. Changes to the market values of these assets could adversely affect the Group's results and financial position by changing the actuarial calculations used in retirement benefit accounting.

### 13. Impairment

Group assets including property, plant, equipment and investments are subject to impairment accounting for fixed assets. Events including a decline in operating profitability due to significant deterioration of the operating environment or a significant decrease in the market price of assets require the Group to recognize impairment loss, which could adversely affect the Group's results and financial position.

### **14. Raw Material Procurement**

The Group cannot easily change suppliers or use substitutes for certain raw materials, particularly those that are only available through a limited number of specialized suppliers. The Group has stockpiles of crucial raw materials sufficient to maintain uninterrupted production for a certain period of time. Unexpected contingencies could interfere with procurement of crucial raw materials for which there are no substitutes, which could halt manufacturing and adversely affect the Group's results and financial position.

# **Consolidated Balance Sheets**

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries As at December 31, 2011 and 2010

	Millions	of yen	Thousands of U.S. dollars (Note 3)	
ASSETS	2011	2010	2011	
Current Assets:				
Cash and deposits (Note 12)	¥ 27,063	¥ 33,128	\$ 348,124	
Notes and accounts receivable (Note 12):				
Trade	94,912	115,189	1,220,894	
Unconsolidated subsidiaries and affiliates	4,665	8,693	60,010	
Other	4,870	4,221	62,656	
	104,448	128,103	1,343,560	
Inventories (Note 6)	58,981	61,761	758,697	
Deferred tax assets (Note 9)	8,629	8,368	111,003	
Short-term loans receivable (Note 12):				
Parent company	82,473	53,199	1,060,893	
Other		284	6,238	
	82,958	53,483	1,067,131	
Other current assets		4,155	35,090	
Less: Allowance for doubtful accounts		4,155 (149)	(7,605)	
Total Current Assets	()	288,852	3,656,002	
Property, Plant and Equipment, at Cost (Note 17):		70.007		
Land (Note 18)		70,697	694,034	
Buildings and structures		153,135	1,661,826	
Machinery and equipment		211,317	1,798,260	
Other	,	51,584	604,167	
Construction in progress	6,221 376,130	10,578 497,313	80,024 4,838,313	
	570,130	497,313	4,030,313	
Less: Accumulated depreciation	(253,186)	(337,574)	(3,256,840)	
Total Property, Plant and Equipment, Net	122,943	159,738	1,581,473	
Investments and Other Assets:				
Investment securities (Notes 12, 13 and 18)	20,633	36,770	265,415	
Investments in unconsolidated subsidiaries and affiliates	20,000	00,770	200,410	
(Notes 12 and 13)	4,399	18,578	56,594	
Goodwill		162,659	2,280,257	
Sales rights	,	4,773	373,360	
Deferred tax assets (Note 9)		9,954	85,933	
Other assets.	-,	9,934 16,012	180,956	
Less: Allowance for doubtful accounts	,	(1,476)	(4,644)	
Total Investments and Other Assets	(001)	247,271	3,237,874	
		,		
Total Assets	¥ 658,873	¥ 695,862	\$ 8,475,350	
The accompanying notes are an integral part of the statements.				

	Millions	Thousands of U.S. dollars (Note 3)		
LIABILITIES AND NET ASSETS	2011	2010	2011	
Current Liabilities:				
Short-term loans payable (Notes 7 and 12)	¥ 5,943	¥ 7,253	\$ 76,455	
Current portion of long-term loans payable (Notes 7 and 12)	98	162	1,270	
Notes and accounts payable (Note 12):			-,	
Trade (Note 18)	20,845	42,048	268,150	
Unconsolidated subsidiaries and affiliates	1,628	5,631	20,942	
Construction and purchase of properties	7,016	6,346	90,251	
Other	29,657	20,338	381,495	
	59,147	74,366	760,838	
Income tayon navable				
Income taxes payable	7,821	15,379	100,609	
Accrued bonuses	161	100	2,074	
Other current liabilities	5,292	5,221	68,078	
Total Current Liabilities	78,465	102,483	1,009,327	
Noncurrent Liabilities:				
Long-term loans payable (Note 7)	-	99	-	
Deferred tax liabilities (Note 9)	10,926	16,379	140,553	
Provision for retirement benefits:				
Employees (Note 11)	20,654	24,109	265,691	
Directors and corporate auditors	94	134	1,213	
Asset retirement obligations (Note 24)	654	_	8,421	
Other noncurrent liabilities	8,055	7,663	103,616	
Total Noncurrent Liabilities	40,385	48,387	519,496	
Total Liabilities	118,850	150,870	1,528,823	
Commitments and Contingent Liabilities (Note 19)				
Net Assets:				
Shareholders' Equity (Note 20)				
Capital stock:				
Authorized: 987,900,000 shares at December 31, 2011 and 2010				
Issued: 576,483,555 shares at December 31, 2011 and 2010	26,745	26,745	344,031	
Additional paid-in capital	512,348	512,359	6,590,542	
Retained earnings				
5	34,956	20,744	449,661	
Treasury stock, at cost:				
21,037,327 shares at December 31, 2011 and	(10,10,1)	(0.070)	(0.4.0, 0.0.4)	
6,691,427 shares at December 31, 2010	(19,194)	(6,676)	(246,904)	
Total Shareholders' Equity	554,856	553,172	7,137,331	
Accumulated Other Comprehensive Income:				
Net unrealized holding loss on other securities (Note 13)	(3,144)	(2,195)	(40,454)	
Net deferred gain on hedges (Note 14)	—	0	—	
Foreign currency translation adjustments	(12,841)	(7,063)	(165,187)	
Total Accumulated Other Comprehensive Income	(15,986)	(9,258)	(205,641)	
Subscription rights to shares (Note 10)	250	207	3,223	
Minority interests	902	869	11,613	
Total Net Assets	540,023	544,992	6,946,527	
Total Liabilities and Net Assets	¥ 658,873	¥ 695,862	\$ 8,475,350	

# **Consolidated Statements of Income**

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

For the years ended December 31, 2011 and 2010 and the nine months ended December 31, 2009

		Millions of yen		Thousands of U.S. dollars (Note 3)
	2011	2010	2009	2011
Net Sales (Note 23)	¥343,722	¥413,738	¥309,111	\$4,421,442
Cost of Sales (Notes 11 and 15)	146,167	222,759	169,371	1,880,212
Gross Profit	197,555	190,979	139,739	2,541,229
Selling, General and Administrative				
Expenses (Notes 11 and 16)	150,940	145,568	111,496	1,941,608
Operating Income (Note 23)	46,614	45,410	28,243	599,621
Other Revenue (Expenses):				
Interest and dividend income	1,034	1,207	1,357	13,303
Interest expense	(135)	(199)	(244)	(1,744)
Foreign exchange losses	(154)	(1,280)	(112)	(1,989)
Equity in earnings of affiliates	199	1,074	1,558	2,560
Loss on sale and disposal of fixed assets (Note 17)	(1,292)	(1,633)	(288)	(16,626)
Impairment loss (Note 17)	(769)	(1,374)	(2,671)	(9,894)
Gain on sales of affiliates' stock	7,217		_	92,836
Gain on sales of investment securities (Note 13)	_	1,828	_	_
Gain on negative goodwill	_	854	_	_
Loss on valuation of investment securities	(2,374)	(1,473)	(537)	(30,549)
Advisory fee	(1,098)		_	(14,135)
Loss on sales of investment securities (Note 13)	(692)	(101)	(991)	(8,903)
Loss on disaster	(650)	_	_	(8,363)
Non-recurring depreciation on noncurrent assets	(477)	(1,225)	(3,299)	(6,142)
Loss on adjustment for changes of accounting standard				
for asset retirement obligations	(447)		_	(5,760)
Loss on disposal of business (operations)	(419)		_	(5,398)
Loss on revision of retirement benefit plan (Note 11)	_	(1,771)	_	_
Provision for environmental measures	_	(887)	_	_
Loss on dilution of equity interest in subsidiary	_		(1,379)	_
Other, net	(367)	1,872	(1,007)	(4,733)
	(430)	(3,110)	(7,615)	(5,540)
Income before Income Taxes and Minority Interests	46,183	42,299	20,628	594,080
Income Taxes (Note 9):				
Current	(22,539)	(21,363)	(16,450)	(289,928)
Deferred	2,049	1,323	4,819	26,368
	(20,489)	(20,040)	(11,631)	(263,560)
Income before Minority Interests	25,694	22,258	8,997	330,520
Minority Interests	(86)	(61)	(199)	(1,110)
Net Income	¥ 25,608	¥ 22,197	¥ 8,797	\$ 329,409

# **Consolidated Statement of Comprehensive Income**

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries For the year ended December 31, 2011

	Millions of yen	Thousands of U.S. dollars (Note 3)
	2011	2011
Income before Minority Interests	¥25,694	\$330,520
Other Comprehensive Income		
Net unrealized holding loss on other securities	(1,200)	(15,447)
Net deferred gain on hedges	2	31
Foreign currency translation adjustments	(5,799)	(74,600)
Share of other comprehensive income of associates		
accounted for using the equity method	(3)	(43)
Total Other Comprehensive Income	(7,001)	(90,059)
Comprehensive Income		
Comprehensive income attributable to:		
Owners of the parent	18,628	239,620
Minority interests	65	840
Total Comprehensive Income	¥18,693	\$240,461

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

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries For the years ended December 31, 2011 and 2010 and the nine months ended December 31, 2009

							Millions o	f yen					
			Shareh	olders' equ	ity		Accumula	ccumulated other comprehensive income					
	Number of shares issued	Capital stock	Additional paid-in capital	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Net unrealized holding gain (loss) on other securities	Net deferred gain (loss) on hedges	Foreign currency translation adjustments	Total accumu- lated other com- prehensive income	Subscription rights to shares	Minority interests	Total net assets
Balance at March 31, 2009	576,483,555	¥26,745	¥512,418	¥ 10,432	¥ (2,392)	¥547,203	¥(4,732)	¥ 4	¥ (3,920)	¥ (8,648)	¥188	¥4,326	¥543,070
Net income for the nine months													
ended December 31, 2009				8,797		8,797							8,797
Cash dividends				(11,434)		(11,434)							(11,434)
Purchases of treasury stock					(4,637)	(4,637)							(4,637)
Disposal of treasury stock			(19)		97	78							78
Decrease due to initial													
consolidation of subsidiaries				(878)		(878)							(878)
Increase due to exclusion of													
consolidated subsidiaries				67		67							67
Increase due to merger				109		109							109
Net changes during the year							5,208	(1)	(36)	5,170	7	(5)	5,172
Balance at December 31, 2009	576,483,555	26,745	512,398	7,093	(6,932)	539,304	475	3	(3,956)	(3,478)	196	4,321	540,343
Net income for the year ended													
December 31, 2010				22,197		22,197							22,197
Cash dividends				(8,546)		(8,546)							(8,546)
Purchases of treasury stock					(113)	(113)							(113)
Disposal of treasury stock			(39)		369	330							330
Net changes during the year							(2,670)	(3)	(3,106)	(5,779)	11	(3,451)	(9,219)
Balance at December 31, 2010	576,483,555	26,745	512,359	20,744	(6,676)	553,172	(2,195)	0	(7,063)	(9,258)	207	869	544,992
Net income for the year ended													
December 31, 2011				25,608		25,608							25,608
Cash dividends				(11,396)		(11,396)							(11,396)
Purchases of treasury stock					(12,582)	(12,582)							(12,582)
Disposal of treasury stock			(10)		64	54							54
Net changes during the year							(949)	(0)	(5,778)	(6,728)	42	33	(6,652)
Balance at December 31, 2011	576,483,555	¥26,745	¥512,348	¥ 34,956	¥(19,194)	¥554,856	¥(3,144)	¥ -	¥(12,841)	¥(15,986)	¥250	¥ 902	¥540,023

	Thousands of U.S. dollars (Note 3)											
		Shareh	uity		Accumulated other comprehensive income							
	Capital stock	Additional paid-in capital	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Net unrealized holding gain (loss) on other securities	Net deferred gain (loss) on hedges	Foreign currency translation adjustments	Total accumu- lated other com- prehensive income	Subscription rights to shares	Minority interests	Total net assets
Balance at December 31, 2010	\$344,031	\$6,590,675	\$266,844	\$ (85,877)	\$7,115,674	\$(28,236)	\$ 2	\$ (90,857)	\$(119,091)	\$2,673	\$11,188	\$7,010,445
Net income for the year ended												
December 31, 2011			329,409		329,409							329,409
Cash dividends			(146,592)		(146,592)							(146,592)
Purchases of treasury stock				(161,857)	(161,857)							(161,857)
Disposal of treasury stock		(133)		830	697							697
Net changes during the year						(12,217)	(2)	(74,329)	(86,550)	550	424	(85,575)
Balance at December 31, 2011	\$344,031	\$6,590,542	\$449,661	\$(246,904)	\$7,137,331	\$(40,454)	\$ -	\$(165,187)	\$(205,641)	\$3,223	\$11,613	\$6,946,527

# **Consolidated Statements of Cash Flows**

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

For the years ended December 31, 2011 and 2010 and the nine months ended December 31, 2009

	Thousands Millions of yen U.S. dollars (N					
	2011	2010	2009	U.S. dollars (Note 3) 2011		
Cash Flows from Operating Activities:						
Income before income taxes and minority interests	¥ 46,183	¥ 42,299	¥ 20,628	\$ 594,080		
Adjustments to reconcile income before income taxes and						
minority interests to net cash provided by operating activities:						
Depreciation and amortization	22,833	22,188	17,003	293,717		
Impairment loss	769	1,374	2,671	9,894		
Amortization of goodwill	10,713	9,928	7,181	137,811		
Increase (decrease) in provision for retirement benefits	(989)	(3,137)	576	(12,733)		
(Increase) decrease in prepaid pension costs	(1,869)	(251)	823	(24,045)		
Increase (decrease) in provision for bonuses	381	(1,122)	(2,891)	4,912		
Interest and dividend income	(1,034)	(1,207)	(1,357)	(13,303)		
Interest expenses	135	199	244	1,744		
Equity in earnings of affiliates	(199)	(1,074)	(1,558)	(2,560)		
Loss on sales and retirement of property, plant and equipment	315	624	277	4,063		
Loss (gain) on sales of investment securities	675	(1,726)	981	8,687		
Gain on sale of affiliates' stock	(7,217)	—	—	(92,836)		
Loss on valuation of investment securities	2,374	1,473	537	30,549		
Increase in notes and accounts receivable	(4,792)	(2,627)	(9,813)	(61,642)		
Increase (decrease) in inventories	(6,429)	476	4,588	(82,704)		
(Increase) decrease in notes and accounts payable	(1,656)	1,955	6,187	(21,303)		
Other	8,235	6,516	(1,467)	105,935		
Sub-total	68,431	75,890	44,612	880,267		
Interest and dividend income received	1,396	2,114	1,535	17,969		
Interest expenses paid	(133)	(204)	(258)	(1,711)		
Income taxes paid	(29,061)	(13,610)	(21,685)	(373,834)		
Net Cash Provided by Operating Activities	40,634	64,189	24,203	522,691		
Cash Flows from Investing Activities:						
Purchase of property, plant and equipment	(16,381)	(28,001)	(19,777)	(210,725)		
Proceeds from sales of property, plant and equipment	198	1,148	2,283	2,553		
Purchase of intangible assets	(1,108)	(7,471)	(1,085)	(14,258)		
Purchase of investment securities	(1,516)	(64)	(2,158)	(19,513)		
Proceeds from sales and redemption of investment securities	2,258	6,363	4,023	29,049		
Proceeds from sales of affiliates' stock	15,130	_	_	194,634		
Purchase of investments in consolidated subsidiaries	(36,979)	_	—	(475,678)		
Proceeds from investments in consolidated subsidiaries	52,745	_	_	678,485		
Purchase of investments in capital of subsidiaries		(2, 2, 2, 2)	(50)			
resulting in change in scope of consolidation	(70)	(3,880)	(59)	(900)		
Payments into time deposits	(2,122)	(7,012)	(4,135)	(27,307)		
Proceeds from withdrawal of time deposits	6,332	6,290	3,212	81,452		
Other	(25)	255	4,449	(326)		
Net Cash Provided by (Used in) Investing Activities	18,460	(32,373)	(13,246)	237,465		
Cash Flows from Financing Activities:		(5.000)	(000)	(222)		
Decrease in short-term loans payable	(76)	(5,380)	(383)	(982)		
Repayment of long-term loans payable	(6,509)	(248)	(202)	(83,738)		
Purchase of treasury stock	(12,582)	(113)	(4,637)	(161,857)		
Cash dividends paid	(11,433)	(8,568)	(11,372)	(147,079)		
Cash dividends paid to minority shareholders	(38)	(54)	(204)	(489)		
Other	(99)	(80)	(105)	(1,279)		
Net Cash Used in Financing Activities	(30,740)	(14,446)	(16,906)	(395,427)		
Effect of Exchange Rate Change on Cash and Cash Equivalents	(681)	(1,231)	(39)	(8,763)		
Net Increase (Decrease) in Cash and Cash Equivalents	27,672	16,137	(5,989)	355,966		
Cash and Cash Equivalents at the Beginning of the Period	79,882	63,745	69,286	1,027,559		
Increase in Cash and Cash Equivalents from Newly Consolidated Subsidiaries	—	—	393	—		
Decrease in Cash and Cash Equivalents Resulting from Exclusion of			(24.4)			
Subsidiaries from Consolidation	—	—	(214)	—		
Increase in Cash and Cash Equivalents Resulting from Merger			268			
Cash and Cash Equivalents at the End of Period	¥107,555	¥ 79,882	¥ 63,745	\$1,383,526		
Reconciliation between cash and cash equivalents at year end						
and the accounts booked in the consolidated balance sheets	¥ 07 000	N 00 100	V 00 150	<b>•</b> • • • • • • •		
Cash and deposits	¥ 27,063	¥ 33,128	¥ 30,159	\$ 348,124		
Time deposits whose maturity periods exceed 3 months	(1,981)	(6,445)	(6,592)	(25,491)		
Short-term loans receivable from parent company	82,473 ¥107,555	53,199 ¥ 79,882	40,177 ¥ 63,745	1,060,893 \$1,383,526		
Cash and Cash Equivalents						

# 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 from 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, 2011, 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 those for goodwill, actuarial differences and capitalized development costs.

### 2 Summary of Significant Accounting Policies

### (1) Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and significant companies that it controls directly or indirectly. As of December 31, 2011, the numbers of consolidated subsidiaries and affiliates accounted for by the equity method were 38 and 2 respectively (31 and 8 as of December 31, 2010). All significant intercompany balances and transactions are eliminated in consolidation.

Investments in subsidiaries and affiliates that are not consolidated or accounted for by the equity method are carried at cost or less. Where there has been a permanent decline in the value of such investments, the Company has written them down.

The closing date for all consolidated subsidiaries is December 31.

### (2) Cash and Cash Equivalents

Cash and cash equivalents in the consolidated statements of cash flows comprise cash on hand, bank deposits, which can be withdrawn on demand at any time, and short-term investments with an original maturity of 3 months or less, which are readily convertible into cash and considered to represent a low risk of market price fluctuation.

### (3) Securities

Securities other than equity securities issued by subsidiaries and affiliates are classified as either held-to-maturity or other securities. Held-to-maturity securities are carried at amortized cost. Marketable securities classified as other securities are carried at fair value with any changes in unrealized holding gain or loss, net of the applicable income taxes, included directly in net assets. Non-marketable securities classified as other securities are carried at cost.

For marketable securities classified as other securities, where the market value of each security has declined by more than 30%, which is deemed to be "significantly declined in value," the Company determines the necessity of a write-down by considering the recoverability of each security.

### (4) Inventories

Inventories are stated principally at cost, determined by the average-cost method. Book value is reduced when the contribution of inventories to profitability declines.

### (5) Property, Plant and Equipment (Except for leased assets)

Depreciation is computed mainly by the declining-balance method.

The Company and its domestic consolidated subsidiaries compute depreciation expense for buildings (other than related equipment and leasehold improvements) acquired on or after April 1, 1998, by the straight-line method.

The range of useful lives is principally as follows:

Buildings and structures: 15-50 years

Machinery and equipment: 4-15 years

### (6) Goodwill

Goodwill is amortized by the straight-line method over a period of 20 years unless the amounts are immaterial.

### (7) Intangible Assets (Except for leased assets)

Intangible assets, including capitalized computer software costs, are amortized by the straight-line method over their respective estimated useful lives.

### (8) Leases

Depreciation of assets under finance leases that do not transfer ownership of the leased assets to the lessee is calculated by the straight-line method over the lease period with a residual value of zero, except for the leases commencing on or before March 31, 2008, which are principally accounted for as operating leases.

#### (9) Allowance for Doubtful Accounts

An allowance for doubtful accounts is made against potential losses on collection at an amount measured using a historical bad debt ratio, plus specific amounts individually measured for receivables that are not expected to be collectible due to financial difficulties of the customer or insolvency.

#### (10) Accrued Bonuses

Accrued bonuses are provided for bonuses payable to employees based on the amount expected to be paid at the year end.

#### (11) Provision for Retirement Benefits

Provision for retirement benefits to employees and prepaid pension cost are recorded mainly at an amount calculated based on the retirement benefit obligations and the fair value of the pension plan assets at the balance sheet dates, as adjusted for unrecognized actuarial differences and unrecognized prior service costs.

Unrecognized prior service costs are amortized by the straight-line method mainly over 5 years from the year they occur. Unrecognized actuarial differences are amortized by the straight-line method mainly over 10 years from a year after they occur. A provision for retirement benefits to directors and corporate auditors is provided in accordance with each company's internal rules.

#### (12) Foreign Currency Translation

All monetary assets and liabilities of the Company and its domestic consolidated subsidiaries denominated in foreign currencies are translated into yen at the spot exchange rate prevailing at the year end. All revenue and expenses of the Company and its domestic consolidated subsidiaries denominated in foreign currencies are translated at the average exchange rate for each period. Resulting translation gains or losses are charged or credited to income.

Assets and liabilities of foreign consolidated subsidiaries, except for the components of net assets excluding minority interests, are translated into yen at the spot exchange rate in effect at the balance sheet date. The revenue and expense accounts are translated using the average exchange rate for each period. The components of net assets excluding minority interests are translated at their historical rates. Differences arising from the translation are presented as foreign currency translation adjustments and minority interests in net assets.

#### (13) Derivative Financial Instruments

The Company has entered into various derivatives transactions to manage certain risks arising mainly from adverse fluctuations in foreign currency exchange rates and interest rates. Derivative financial instruments are carried at fair value with any changes in unrealized gain or loss charged or credited to operations, except for those which meet the criteria for deferral hedge accounting under which unrealized gain or loss is deferred as a component of net assets ("Principle method"). Regarding forward exchange contracts that fulfilled certain conditions, the hedged foreign currency denominated receivables and payables are recorded using the Japanese yen amount of the contracted forward rate ("Exceptional method").

The validity assessment of hedging is based on the application of the ratio analysis.

#### (14) Research and Development Expenses

Research and development expenses are charged to income as incurred.

#### (15) Income Taxes

Income taxes of the Company and its domestic consolidated subsidiaries consist of corporate income taxes, local inhabitant's taxes and enterprise taxes.

Deferred tax assets and liabilities are determined based on the differences between financial reporting and the tax bases of the assets and liabilities and are measured using the statutory tax rates which will be in effect when the differences are expected to be realized.

#### (16) Appropriation of Retained Earnings

Under the Companies Act of Japan, the appropriation of retained earnings with respect to a given financial period is made by resolution of the shareholders at a general meeting held subsequent to the close of such financial period. The accounts for that period do not, therefore, reflect such appropriations.

#### (17) Net Income and Dividends per Share

Net income per share of common stock is based upon the weighted average number of shares of common stock outstanding, exclusive of treasury stock, during each year. Cash dividends per share represent dividends declared as applicable to the respective period.

#### (18) Reclassification

Certain amounts as of and for the fiscal year ended December 31, 2010 and the nine months ended December 31, 2009 have been reclassified to conform to the current period presentation.

#### (19) Accounting Changes

Effective January 1, 2011, the Company and its domestic consolidated subsidiaries have adopted ASBJ Statement No. 18, "Accounting Standard for Asset Retirement Obligations." This adoption negatively impacted operating income by ¥29 million (\$382 thousand) and income before income taxes and minority interests by ¥477 million (\$6,142 thousand) for the year ended December 31, 2011 compared to the amounts that would have been recognized under the previous method. The balance of the asset retirement obligations at the beginning of the year was ¥674 million (\$8,679 thousand). Also, ASBJ Statement No. 16 "Accounting Standard for Equity Method of Accounting for Investments" and Practical Issues Task Force No. 24 "Practical Solution on Unification of Accounting Policies Applied to Associates Accounted for Using the Equity Method," have been adopted. This adoption had no impact on the consolidated statements of income.

Effective January 1, 2010, the Company and its domestic consolidated subsidiaries have adopted ASBJ Statement No. 21, "Accounting Standard for Business Combinations," No. 22 "Accounting Standard for Consolidated Financial Statements," No. 23 "Partial amendments to Accounting Standard for Research and Development Costs," No. 7 "Accounting Standard for Business Divestitures," No. 16 "Accounting Standard for Equity Method of Accounting for Investments" and ASBJ Guidance No. 10 "Guidance on Accounting Standard for Business Combinations and Accounting Standard for Business Divestitures."

Effective April 1, 2009, the Company and its domestic consolidated subsidiaries have adopted ASBJ Statement No. 19, "Partial amendments to Accounting Standard for Retirement Benefits (Part 3)." This adoption had no impact on the consolidated statements of income.

For the reversal of the loss on valuation of investment securities at the end of the quarter, the Companies had conventionally adopted the quarterly cost or market method, which involved recalculating the book value at the end of the quarter after performing impairment accounting using the market value and thereby adjusting the purchase cost of the securities. For the purpose of standardizing the accounting procedures between the parent company and its subsidiaries, the Companies changed their accounting procedures to comply with those adopted by their parent company, Kirin Holdings Company, Limited (hereinafter "Kirin Holdings") in the first quarter of the period ended December 31, 2009, switching to the quarterly method of adding back the credited reserve amount in full to income in the following period. This method involves reversing the amount of the loss on valuation based on impairment accounting by comparing the book value after the reversal and the market value as at the end of the quarter. As a result of this change, income before income taxes and minority interests increased ¥41 million in the period compared to the amounts which would have been recorded under the previous method.

#### (20) Additional Information

# (a) Business Combination of a Subsidiary

At the meeting of the Board of Directors held on October 21, 2008, the Board passed a resolution to conclude an "Agreement to Integrate Food Products Businesses" aimed at integrating the food products businesses of the Company's wholly owned subsidiary Kyowa Hakko Food Specialties Co., Ltd. (the company's trade name was changed to Kirin Kyowa Foods Company, Limited on April 1, 2009) and Kirin Holdings' wholly owned subsidiary Kirin Food-Tech Company, Limited (hereinafter "Kirin Food-Tech"), and the Company entered into the agreement on the said date of the Board meeting. Under the agreement, the Company sold all of the remaining 474 shares of Kirin Kyowa Foods Company, Limited to Kirin Holdings at ¥14,987 million (\$192,794 thousand) on January 1, 2011. As a result of the merger, the Company recorded a ¥4,712 million (\$60,623 thousand) gain on sales of affiliates' stocks.

#### (b) Application of Accounting Standard

Effective January 1, 2011, the Company has adopted ASBJ Statement No. 25, "Accounting Standard for Presentation of Comprehensive Income." Under this accounting standard, "Accumulated Other Comprehensive Income" and "Total Accumulated Other Comprehensive Income" and "Total Accumulated Other Comprehensive Income" in the accompanying consolidated balance sheets and consolidated statements of changes in net assets as of December 31, 2011 and 2010 were newly presented in place of "Valuation and Translation Adjustments" in the prior years' consolidated financial statements.

Comprehensive income and other comprehensive income for the year ended December 31, 2010 were as follows.

	Millions of yen
	2010
Income before Minority Interests	¥22,258
Other Comprehensive Income	
Net unrealized holding loss on other securities	(2,633)
Net deferred loss on hedges	(3)
Foreign currency translation adjustments	(3,221)
Share of other comprehensive income of associates accounted for using the equity method	19
Total Other Comprehensive Income	(5,838)
Comprehensive Income	
Comprehensive income attributable to:	
Owners of the parent	16,478
Minority interests	(58)
Total Comprehensive Income	¥16,419

Effective January 1, 2010, the Company and its domestic consolidated subsidiaries have adopted ASBJ Statement No. 10, "Accounting Standard for Financial Instruments and its Implementation Guidance," and No. 19, "Guidance on Disclosures about Fair Value of Financial Instruments." Due to an increase in the estimated amount of environmental expenditures, the Company recognizes "Provision for environmental measures" of ¥888 million for the year ended December 31, 2010. As a result, income before income taxes and minority interests declined by the same amount. And the same amount is included in other noncurrent liabilities on the consolidated balance sheet.

# (c) Others

Effective January 1, 2011, Provision for point card certificates was newly recorded due to the growth of importance of amounts. The corresponding amount is based on the prospective points that customers who purchase from the mail-order business could use in the future and is based on the historical rate of actual utilization of points. This negatively impacted operating income by ¥39 million (\$504 thousand) and income before income taxes and minority interests by ¥167 million (\$2,153 thousand) for the year ended December 31, 2011.

Following the decision to reorganize plants, etc., the Company revised the useful lives of property, plant and equipment and recognized the difference between the book value before and after the change in the amounts of ¥477 million (\$6,142 thousand) for the year ended December 31, 2010 and ¥3,300 million for the nine months ended December 31, 2009 as non-recurring depreciation on noncurrent assets. As a result, income before income taxes and minority interests declined by the same amounts for each fiscal year.

# **3 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 ¥77.74=U.S.\$1, the approximate exchange rate at December 31, 2011. 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 ¥77.74=U.S.\$1 or at any other rate.

#### 4 Change in End of Fiscal Year

The Company changed its closing date of accounts on a consolidated basis (the Company's fiscal year end) from March 31 to December 31 of each year pursuant to the resolution of the ordinary General Shareholders' Meeting convened on June 25, 2009.

This was done to bring its fiscal year into line with that of its parent, Kirin Holdings, considering that Kirin Holdings' fiscal year ends on December 31 each year, to disclose its business performance and other such management information more appropriately and execute operations in an efficient manner.

Due to the change, the fiscal period ended December 31, 2009 served as a transitional period before the new full fiscal year and was therefore only nine months long, starting on April 1, 2009 and ending on December 31, 2009.

In conjunction with the change in the fiscal year end, all consolidated subsidiaries whose fiscal year ended on March 31 were also brought into line with the Company's close of accounts on December 31.

For the following 11 consolidated subsidiaries, whose financial statements as at their respective closing dates had been used due to their accounts conventionally being closed on December 31, which is three months before March 31. Effective April 1, 2009, the financial statements for the twelve-month accounting period from January 1, 2009 to December 31, 2009 have been used in preparing the consolidated financial statements for the nine-month period ended December 31, 2009.

The 11 subsidiaries that applied a full twelve-month accounting period are as follows:

BioWa, Inc., Kyowa Hakko Kirin America, Inc., Kyowa Hakko Kirin Pharma, Inc., Kyowa Hakko Bio U.S. Holdings, Inc., BioKyowa Inc., Kyowa Hakko Europe GmbH, Kyowa Italiana Farmaceutici S.r.I., Shanghai Kyowa Amino Acid Co., Ltd., Kyowa Hakko U.S.A., Inc., Kyowa Hakko (H.K.) Co., Ltd., Kashiwagi Corporation.

As a result, net sales increased ¥11,986 million, operating income ¥158 million and income before income taxes and minority interests ¥23 million.

# **5** Business Combinations

# 1. Acquisition of Shares of ProStrakan Group Plc

On February 21, 2011, the Company and ProStrakan Group Plc ("ProStrakan"), a UK-based specialty pharmaceuticals company, announced the reaching of an agreement on the terms of the recommended cash acquisition by the Company of the entire issued and to be issued share capital of ProStrakan (the "acquisition"). Subsequently, the Company acquired all outstanding shares of ProStrakan on April 21, 2011. As a result, ProStrakan and its ten subsidiaries were newly included in the scope of consolidation.

ProStrakan has an established development and marketing capability for cancer-related and other drugs in Europe and the United States and shares the business vision and the strategy for the Pharmaceuticals business with the Company. Looking ahead, the Company can dramatically advance its global strategy utilizing the business resources of ProStrakan and a mutually beneficial partnership.

#### (1) Description of the company

- (i) Name and business of the acquired company Name of the company: ProStrakan Group Plc Business of the company: Sales, marketing and development of pharmaceuticals
- (ii) Main reasons for the business combination Refer to the above
- (iii) Date of the business combination April 21, 2011
- (iv) Legal form of acquisition Share purchase by cash
- (v) Name of the company after acquisition ProStrakan Group Plc
- (vi) Percentage of voting rights acquired 100%

# (2) Period of results of acquired company included in the consolidated financial statements

From July 1, 2011 to December 31, 2011

# (3) Breakdown of acquisition cost of acquired company

	Millions of yen	Thousands of pounds
Share purchases	¥38,502	£284,122
Direct acquisition-related costs	409	3,012
Total	¥38,911	£287,143

(Note) Amount in pounds is converted into yen at the exchange rate as of the date of acquisition.

### (4) Description of goodwill

- (i) Amount of goodwill: ¥28,333 million (£218,317 thousand)
   (Note) Amount in pounds is converted into yen at the exchange rate as of June 30, 2011
- (ii) Reason for recognizing goodwill Goodwill was recognized as the excess of the acquisition cost over the net of acquired assets and assumed liabilities at fair value.
- (iii) Goodwill amortization method and period Amortized in equal amounts over 15 years

## (5) Amounts and breakdown of main components of assets acquired and liabilities assumed as of the date of acquisition

	Millions of yen	Thousands of pounds
Current assets	¥ 6,719	£ 51,773
Non-current assets	23,923	184,342
Total assets	¥ 30,643	£ 236,115
Current liabilities	¥(16,890)	£(130,148)
Non-current liabilities	(4,820)	(37,141)
Total liabilities	¥(21,710)	£(167,289)

(Note) Amount in pounds is converted into yen at the exchange rate as of June 30, 2011

# (6) Estimated amounts that would have an effect on the consolidated statement of income and the method of calculation, if the business combination had been completed at the beginning of the year.

	Willionio or your
Net sales	¥ 6,243
Operating income (loss)	(3,296)
Income (loss) before income taxes and minority interests	(5,864)
Net income (loss)	(5,695)
Net income (loss) per share (yen)	(10.04)

(The method of calculation)

The estimated amounts are the differences between net sales or income/loss information calculated assuming that the business combination had been completed at the beginning of the year and net sales or income/loss information had been recorded on the consolidated statement of income.

This note has not been audited by the Company's independent auditors.

# 2. Sale of Shares of Consolidated Subsidiary

At the meeting of the Board of Directors held on January 28, 2011, the Board passed a resolution to conclude the transfer of the entire 22,264,000 shares of Kyowa Hakko Chemical Co., Ltd. to KJ Holdings Inc., a special purpose company established and managed by Japan Industrial Partners, Inc. On the same day, the Company signed an assignment agreement for selling all these shares with KJ Holdings Inc. and Japan Industrial Partners, Inc.

After completing this agreement, the Company transferred all shares of Kyowa Hakko Chemical to KJ Holdings Inc. on March 31, 2011.

In accordance with the Group's Medium-term Business Plan for the period 2010 to 2012, against a background of intense competition in the market for pharmaceutical products, Kyowa Hakko Kirin aims to rapidly develop its product pipeline through efficient utilization of operating resources, while selecting and concentrating its business portfolio to create a business platform capable of achieving sustained growth.

Kyowa Hakko Chemical is the leading domestic producer of oxo alcohols and derivative products and has a high domestic market share. It also has several environmentally friendly products that are fast-growing and high-value-added products. As such, despite the presence of many large companies in the petrochemical industry, the Company believes that Kyowa Hakko Chemical has adequate business foundations to enable it to develop its position as a global niche player.

In order for Kyowa Hakko Chemical to achieve further growth, the Company decided to sell its entire stake in Kyowa Hakko Chemical to a business partner that can support Kyowa Hakko Chemical's further investments. As a result, Kyowa Hakko Kirin will be able to effectively focus its business resources on its pharmaceutical products business, while Kyowa Hakko Chemical can actively implement the capital expenditure required to meet diverse market demand, independent of Kyowa Hakko Kirin.

#### (1) Overview of the sale of shares

(i) Name and business of consolidated subsidiary and transferee

Consolidated subsidiary

Name: Kyowa Hakko Chemical Co., Ltd.

Business: Manufacturing and sales of petrochemical products

Transferee

Name: KJ Holdings Inc.

Business: A special purpose company established and managed by Japan Industrial Partners, Inc. The company was merged with Kyowa Hakko Chemical and changed its trade name to Kyowa Hakko Chemical Co., Ltd. on June 1, 2011.

- (ii) Main reasons for the sale of shares Refer to the above
- (iii) Date of shares transfer March 31, 2011

(iv) Overview of the sale of shares, including legal form

Legal form:	Acquisition of shares by cash
Number on shares:	22,264,000
Sales amount of shares*:	¥36,169 million (\$465,264 thousand)
Investment ratio after selling shares:	-%

\* ¥60,000 million of appraised business value of Kyowa Hakko Chemical plus the total amount of cash and deposits of both two companies; Kyowa Hakko Chemical and its subsidiary Miyako Kagaku Co., Ltd. at the date of selling the shares, minus the total amount of debt of those two companies at the same date and considering other adjustments.

## (2) Overview of accounting treatment

Gain on sales of affiliates' stock of ¥2,449 million (\$31,510 thousand) is recorded as other revenue for the year ended December 31, 2011 based upon the guidance set forth in "Accounting Standard for Business Divestitures" (ASBJ Statement No. 7) and "Guidance on Accounting Standard for Business Combinations and Accounting Standard for Business Divestitures" (ASBJ Guidance No. 10).

#### (3) Business segment of the subsidiary

Chemicals segment

(4) Estimated revenues and income from Kyowa Hakko Chemical recorded on the consolidated statement of income for the year ended December 31, 2011

	Millions of yen Thousands		
Net sales	¥33,550	\$431,567	
Operating income	2,135	27,470	

#### (5) Overview of ongoing involvement

The Company purchased 30,000 preferred shares for ¥1,500 million (\$19,295 thousand) issued by KJ Holdings Inc. on March 31, 2011.

# 6 Inventories

Inventories as of December 31, 2011 and 2010 are as follows:

	Millions	Thousands of U.S. dollars	
	2011	2010	2011
Merchandise and finished goods	¥36,840	¥40,803	\$473,899
Work in process	12,232	10,628	157,354
Raw materials and supplies	9,907	10,329	127,444
	¥58,981	¥61,761	\$758,697

# 7 Short-Term Borrowings and Long-Term Debt

# (1) Short-term borrowings at December 31, 2011 and 2010 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2011	2010	2011
Unsecured loans, principally from banks, with weighted average interest rates of 2.1% and 1.3% at December 31, 2011 and 2010, respectively	¥5,943	¥7,253	\$76,455

# (2) Long-term debt at December 31, 2011 and 2010 consisted of the following:

	Millions	Thousands of U.S. dollars	
	2011	2010	2011
Secured loans, principally from banks and other financial institutions,			
during 2012 at December 31, 2011 and due 2011 to 2012 at December 31,			
2010 with interest ranging from 6.0% to 6.9% per annum in 2011 and			
from 5.8% to 6.0% per annum in 2010	¥ 98	¥262	\$1,270
Less: Current portion of long-term debt	(98)	(162)	(1,270)
	¥ —	¥ 99	\$ —

# (3) The aggregate annual maturities of long-term debt subsequent to December 31, 2011 are as follows:

December 31,	Millions of yen	Thousands of U.S. dollars
2012	¥ 98	\$1,270
2013	—	—
2014	<u> </u>	<u> </u>
2015	<u> </u>	—
2016	—	-
	¥ 98	\$1,270

# 8 Leases

#### (1) Finance Leases

The Companies hold certain machinery, equipment and other fixed assets under finance leases that do not transfer ownership of the leased assets to the lessee. Lease transactions entered into on or before March 31, 2008 are not capitalized, but are accounted for as operating leases. If these leases had been capitalized, the purchase cost, accumulated depreciation and net book value of such leased assets at December 31, 2011 and 2010 would have been as follows:

	Millions of yen Thousands of U.S. dolla			ollars		
December 31, 2011	Machinery and equipment	Other	Total	Machinery and equipment	Other	Total
Purchase cost	¥ —	¥361	¥361	\$ —	\$4,650	\$4,650
Accumulated depreciation	—	328	328	—	4,231	4,231
Net book value	¥ —	¥ 32	¥ 32	\$ —	\$ 419	\$ 419

	1	Millions of yen		
December 31, 2010	Machinery and equipment	Other	Total	
Purchase cost	¥ —	¥671	¥671	
Accumulated depreciation	_	540	540	
Net book value	¥ —	¥130	¥130	

Lease payments relating to finance leases accounted for as operating leases amounted to ¥95 million (\$1,224 thousand) and the depreciation expense of the leased assets computed by the straight-line method over the lease terms amounted to ¥90 million (\$1,168 thousand), for the year ended December 31, 2011.

Future minimum lease payments subsequent to December 31, 2011 on finance leases accounted for as operating leases are summarized as follows:

	Millions of yen	Thousands of U.S. dollars
2012	¥31	\$401
Thereafter	1	17
-	¥32	\$419

#### (2) Operating Leases

Future minimum lease payments subsequent to December 31, 2011 on non-cancelable operating leases are summarized as follows:

(Lessee)	Millions of yen	Thousands of U.S. dollars
2012	¥ 301	\$ 3,880
Thereafter	2,973	38,244
-	¥3,274	\$42,124
Lessor)	Millions of yen	Thousands of U.S. dollars
2012	V 202	¢ 0,600

2012	¥ 202	\$ 2,602
Thereafter	2,687	34,573
	¥2,890	\$37,176

## 9 Income Taxes

Income taxes applicable to the Company and its domestic consolidated subsidiaries comprise corporation taxes, local inhabitants' taxes and enterprise taxes which, in the aggregate, resulted in a statutory tax rate of approximately 40.7% for the years ended December 31, 2011 and 2010, and the nine months ended December 31, 2009. Income taxes of the foreign consolidated subsidiaries are based generally on the tax rates applicable in their countries of incorporation.

(1) The effective tax rates reflected in the consolidated statements of income for the years ended December 31, 2011 and 2010, and the nine months ended December 31, 2009 differ from the statutory tax rate for the following reasons:

	2011	2010	2009
Statutory tax rate	40.7%	40.7%	40.7%
Amortization of goodwill	8.9	9.4	13.8
Permanently non-deductible expenses, such as entertainment expenses	3.2	4.0	6.2
Future deductible temporary differences deemed not to be realized	2.2	(2.4)	15.3
Undistributed profit of affiliates scheduled to be sold	1.4	8.5	_
Tax rate change	(2.2)	-	—
Special corporate tax credit	(9.4)	(9.6)	(13.4)
Permanently non-taxable income, such as dividend income	(0.5)	(1.2)	(2.8)
Equity in earnings of affiliates	(0.2)	(1.0)	(3.0)
Difference in statutory tax rate of subsidiaries	0.0	(1.5)	(2.0)
Loss on dilution of equity interest in a subsidiary	-	-	2.7
Other	0.3	0.5	(1.3)
Effective tax rates	44.4%	47.4%	56.4%

(2) The significant components of deferred tax assets and liabilities as of December 31, 2011 and 2010 are as follows:

	Million	Thousands of U.S. dollars	
Deferred tax assets:	2011	2010	2011
Non-deductible portion of depreciation of property, plant and equipment	¥ 10,291	¥12,027	\$ 132,389
Tax loss carried forward	7,960	—	102,394
Non-deductible portion of provision for retirement benefits to employees	7,179	9,843	92,348
Prepaid expenses for tax purposes	4,286	4,546	55,133
Investments in affiliates	1,828	—	23,515
Gain on sale of investments in affiliates	—	3,270	—
Other	13,112	14,757	168,675
Sub-total	44,658	44,446	574,456
Valuation allowance	(15,994)	(9,460)	(205,738)
Total deferred tax assets	¥ 28,664	¥34,985	\$ 368,718
Deferred tax liabilities:			
Valuation of land of the former Kyowa Hakko Group at the fair market			
value related to reverse acquisition	¥(14,304)	¥(19,866)	\$ (183,998)
Valuation of intangible assets related to business combinations	(4,190)	—	(53,901)
Deferred gain, mainly related to expropriation of fixed assets	(1,583)	(1,957)	(20,372)
Valuation of investment securities of the former Kyowa Hakko Group at the fair market value related to reverse acquisition	(1,562)	(2,918)	(20,096)
Undistributed gain on affiliates scheduled to be sold	_	(3,042)	_
Unrealized gains on marketable other securities	_	(2,691)	_
Prepaid pension expenses	_	(1,575)	_
Other	(2,640)	(989)	(33,965)
Total deferred tax liabilities	¥(24,280)	¥(33,041)	\$ (312,334)
Deferred tax assets (liabilities), net	¥ 4,383	¥ 1,943	\$ 56,384

(Note) Deferred tax assets (liabilities), net corresponds to the following items on the consolidated balance sheet as of December 31, 2011:

		Thousands of
	Millions of yen	U.S. dollars
Current Assets – Deferred tax assets	¥ 8,629	\$ 111,003
Noncurrent Assets — Deferred tax assets	6,680	85,933
Noncurrent Liabilities - Deferred tax liabilities	(10,926)	(140,553)

#### (3) Change in the effective corporate tax rate

Following the promulgation of the "Act for Partial Amendment of the Income Tax Act, etc. for the Purpose of Creating a Taxation System Responding to Changes in Economic and Social Structures" (Act No. 114, 2011) and the "Act on Special Measures for Securing Financial Resources Necessary to Implement Measures for reconstruction following the Great East Japan Earthquake" (Act No. 117, 2011) on December 2, 2011, the corporate tax rate will be reduced and a special corporate tax for reconstruction will be imposed from fiscal years beginning April 1, 2012. Therefore, the effective corporate tax rate that was used for calculating deferred tax assets and liabilities was 40.7% for temporary differences that will result in taxable amounts or deductible amounts in 2012, 38.0% for temporary differences from 2013 to 2015 and 35.6% for temporary differences after 2016. As a result of this change, deferred tax liabilities (net of deferred tax assets), income taxes deferred and net unrealized holding loss on other securities decreased ¥707 million (\$9,097 thousand), ¥968 million (\$12,457 thousand) and ¥261 million (\$3,359 thousand), respectively.

# **10** Stock Option Plans

Stock option expenses included in selling, general and administrative expenses for the years ended December 31, 2011, 2010 and the nine months ended December 31, 2009 were ¥86 million (\$1,107 thousand), ¥82 million and ¥78 million, respectively.

#### 1. The following table summarizes the information on stock options

(1) As	of De	cembe	er 31, 20	11
--------	-------	-------	-----------	----

	2011/12 Plan	2010/12 Plan	2009/12 Plan	2009/3 Plan	2008/3 Plan	2007/3 Plan	2006/3 Plan
Grantees' position	Directors and executive officers	Directors and executive officers	Directors and executive officers	Directors and executive officers	Directors and executive officers	Directors and executive officers	Directors and executive officers
Number of grantees	20	17	14	20	18	18	19
Type of stock	Common stock	Common stock	Common stock	Common stock	Common stock	Common stock	Common stock
Date of grant	April 1, 2011	April 1, 2010	June 26, 2009	June 25, 2008	June 21, 2007	June 29, 2006	June 28, 2005
Vesting condition	No provisions	No provisions	No provisions	No provisions	No provisions	No provisions	No provisions
Applicable period of service	No provisions	No provisions	No provisions	No provisions	No provisions	No provisions	No provisions
Exercisable period	April 2, 2011 – March 24, 2031	April 2, 2010 – March 24, 2030	June 27, 2009 – June 25, 2029	June 26, 2008 – June 24, 2028	June 22, 2007 – June 20, 2027	June 30, 2006 – June 28, 2026	June 29, 2005 – June 28, 2025

(2) As of December 31, 2010

	2010/12 Plan	2009/12 Plan	2009/3 Plan	2008/3 Plan	2007/3 Plan	2006/3 Plan
Grantees' position	Directors and executive officers	Directors and executive officers	Directors and executive officers			
Number of grantees	17	14	20	18	18	19
Type of stock	Common stock	Common stock	Common stock	Common stock	Common stock	Common stock
Date of grant	April 1, 2010	June 26, 2009	June 25, 2008	June 21, 2007	June 29, 2006	June 28, 2005
Vesting condition	No provisions	No provisions	No provisions	No provisions	No provisions	No provisions
Applicable period of service	No provisions	No provisions	No provisions	No provisions	No provisions	No provisions
Exercisable period	April 2, 2010 – March 24, 2030	June 27, 2009 – June 25, 2029	June 26, 2008 – June 24, 2028	June 22, 2007 – June 20, 2027	June 30, 2006 – June 28, 2026	June 29, 2005 – June 28, 2025

(3) As of December 31, 2009

	2009/12 Plan	2009/3 Plan	2008/3 Plan	2007/3 Plan	2006/3 Plan
Grantees' position	Directors and executive officers	Directors and executive officers	Directors and executive officers	Directors and executive officers	Directors and executive officers
Number of grantees	14	20	18	18	19
Type of stock	Common stock	Common stock	Common stock	Common stock	Common stock
Date of grant	June 26, 2009	June 25, 2008	June 21, 2007	June 29, 2006	June 28, 2005
Vesting condition	No provisions	No provisions	No provisions	No provisions	No provisions
Applicable period of service	No provisions	No provisions	No provisions	No provisions	No provisions
Exercisable period	June 27, 2009 – June 25, 2029	June 26, 2008 – June 24, 2028	June 22, 2007 – June 20, 2027	June 30, 2006 – June 28, 2026	June 29, 2005 – June 28, 2025

# 2. The following table summarizes the changes in stock options

(1) For the year ended December 31, 2011

(1) For the year ended becember 31, 20	511						
	2011/12 Plan	2010/12 Plan	2009/12 Plan	2009/3 Plan	2008/3 Plan	2007/3 Plan	2006/3 Plan
Non-vested (number of shares):							
Stock options outstanding							
at December 31, 2010		—	—	—	—	—	—
Granted during the period	119,000	-	—	—	—	—	—
Forfeited during the period	-	-	—	-	-	—	-
Vested during the period	119,000	—	—	—	—	—	—
Stock options outstanding							
at December 31, 2011	—	—	—	_	_	_	—
Vested (number of shares):							
Stock options outstanding							
at December 31, 2010	-	85,000	66,000	31,000	23,000	32,000	32,000
Vested during the period	119,000	—	—	—	—	—	—
Exercised during the period	—	10,000	14,000	9,000	5,000	6,000	7,000
Forfeited during the period	—	-	—	—	—	—	-
Stock options outstanding							
at December 31, 2011	119,000	75,000	52,000	22,000	18,000	26,000	25,000
(2) For the year ended December 31, 201	10						
(2) FOR THE YEAR ENDER DECEMBER 31, 201		010/10 0000	2000/10 000	2000/2 0000	2008/3 Plan	2007/2 0000	2006/3 Plan
Non vostad (number of charge):	2	2010/12 Plan	2009/12 Plan	2009/3 Plan	2000/3 Plan	2007/3 Plan	2000/3 191211
Non-vested (number of shares): Stock options outstanding							
at December 31, 2009		_					
			_	_	_	_	—
Granted during the period		65,000	—	—	—	—	—
Forfeited during the period			_	_	_	_	_
Vested during the period		85,000	_	_	_	_	_
Stock options outstanding							
at December 31, 2010		_	_				
Vested (number of shores)							
Vested (number of shares):							
Stock options outstanding at December 31, 2009			93,000	52 000	27 000	20,000	40.000
		- 85,000	93,000	53,000	37,000	39,000	40,000
Vested during the period		,		-	 14,000	7 000	-
Exercised during the period		—	27,000	22,000	14,000	7,000	8,000
Forfeited during the period		_	_	_	_	_	_
Stock options outstanding		05 000	00,000	01.000	00.000	00.000	00.000
at December 31, 2010		85,000	66,000	31,000	23,000	32,000	32,000
(3) For the nine months ended December	31 2009						
	01,2000		2009/12 Plan	2009/3 Plan	2008/3 Plan	2007/3 Plan	2006/3 Plan
Non-vested (number of shares):			2009/12 Fidi1	2009/3 Fian	2000/3 Fiall	200773 FIAIT	2000/3 Fidit
Stock options outstanding at March 31, 2009			_	_	_	_	_
Granted during the period			93,000	_	_	_	_
0			90,000	—	—	—	—
Forfeited during the period				—	_	—	—
Vested during the period			93,000	_	_	_	_
Stock options outstanding at December 31, 2009			_				
a. December 01, 2008			_	_	_	_	
Vested (number of shares):							
. ,							
Stock options outstanding at March 31, 2009			_	82,000	61,000	58,000	61,000
Vested during the period				02,000	01,000	56,000	01,000
0 1			93,000		-	10,000	21 000
Exercised during the period			_	29,000	24,000	19,000	21,000
Forfeited during the period			_	_	_	_	_
Stock options outstanding			00 000	E2 000	27 000	20.000	40.000
at December 31, 2009			93,000	53,000	37,000	39,000	40,000

# 3. The following table summarizes the price information of stock options

#### (1) As of December 31, 2011

	2011/12 Plan	2010/12 Plan	2009/12 Plan	2009/3 Plan	2008/3 Plan	2007/3 Plan	2006/3 Plan
Exercise price	¥ 1	¥ 1	¥ 1	¥ 1	¥ 1	¥ 1	¥ 1
Weighted average market price per stock							
at the time of exercise	-	777	777	777	777	777	777
Fair value per stock at the date of grant	741	940	1,014	1,038	1,140	705	_
(2) As of December 31, 2010							
		2010/12 Plan	2009/12 Plan	2009/3 Plan	2008/3 Plan	2007/3 Plan	2006/3 Plan
Exercise price ¥ 1			¥ 1	¥ 1	¥ 1	¥ 1	¥ 1
Weighted average market price per stock							
at the time of exercise		-	957	957	957	957	957
Fair value per stock at the date of grant		940	1,014	1,038	1,140	705	_
(3) As of December 31, 2009							
			2009/12 Plan	2009/3 Plan	2008/3 Plan	2007/3 Plan	2006/3 Plan
Exercise price			¥ 1	¥ 1	¥ 1	¥ 1	¥ 1
Weighted average market price per stock							
at the time of exercise			_	982	1,011	988	984
Fair value per stock at the date of grant			1,014	1,038	1,140	705	_

# 4. Method of estimating the fair value of stock options

1. Valuation method used: Black-Scholes model

2. The following table summarizes the principal basic numeric values and estimation methods:

	2011/12 Plan	2010/12 Plan	2009/12 Plan
Share price volatility <sup>1</sup>	6.4%	10.2%	8.8%
Expected remaining period <sup>12</sup>	2 years	2 years	3 years
Expected dividends <sup>3</sup>	¥20 per share	¥20 per share	¥20 per share
Risk-free interest rate <sup>-4</sup>	0.53%	0.69%	0.52%

\*1. Calculated based on share price results over 2 years (from April 2009 to March 2011).

\*2. Calculated by subtracting the average service years of present office holders from the average service years of retirees over the past 5 years.

\*3. Based on dividends for the year ended 2011/12.

\*4. The rate of return on Japanese government bonds over the expected remaining period.

# 5. Method of estimating the number of stock options vested

In principle, a method reflecting actual expirations is adopted, because it is not possible to estimate reasonably the number of shares forfeited in the future.

# 11 Provision for Retirement Benefits to Employees

The Company and its domestic consolidated subsidiaries operate various defined benefit plans, i.e., a corporate pension plan including a cash balance pension plan, a group contributory plan, and a severance payment plan. In addition, the Company and certain domestic consolidated subsidiaries have defined contribution pension plans. Certain foreign consolidated subsidiaries have defined benefit or defined contribution plans. The Company changed a part of its defined benefit plans to defined contribution plans from April 2010.

# (1) Details of the provision for retirement benefits to employees as of December 31, 2011 and 2010 are as follows:

	Millions	Thousands of U.S. dollars	
	2011	2010	2011
Retirement benefit obligations*	¥(78,296)	¥(74,749)	\$(1,007,164)
Plan assets at fair value	42,009	42,808	540,379
Unfunded retirement benefit obligations	(36,287)	(31,940)	(466,784)
Unrecognized actuarial differences	19,813	11,005	254,863
Unrecognized prior service costs	319	429	4,109
Prepaid pension expenses	4,499	3,604	57,878
Provision for retirement benefits to employees	¥(20,654)	¥(24,109)	\$ (265,691)

\* Certain subsidiaries calculate retirement benefit obligation by the simplified method permitted under the accounting standards generally accepted in Japan. (Note) Effects on the transition of a part of the Company's pension plans from defined benefit plan to defined contribution plan are as follows:

Decrease in retirement benefit obligations	¥2,966 million
Change in unrecognized actuarial differences	¥ (136) million
Decrease in provision for retirement benefit to employees	¥2,830 million

Plan assets of ¥3,761 million will be transferred to a defined contribution plan over four years beginning in 2010. Plan assets of ¥2,784 million that have not yet been transferred as of December 31, 2010 are presented as other long-term liabilities.

# (2) Retirement benefit expenses for the years ended December 31, 2011 and 2010, and the nine months ended December 31, 2009 are as follows:

	Millions of yen			Thousands of U.S. dollars
	2011	2010	2009	2011
Service cost*1	¥ 3,192	¥ 3,509	¥2,669	\$ 41,064
Interest cost	1,737	1,855	1,437	22,351
Expected return on plan assets	(1,022)	(1,013)	(902)	(13,156)
Amortization of unrecognized actuarial differences	1,123	1,656	1,239	14,456
Amortization of unrecognized prior service costs	111	111	1	1,433
Contribution to defined contribution pension plan	948	754	_	12,203
Special severance payment	_	_	22	
Other	<b>2</b> <sup>*4</sup>	25*3	182*2	29
Retirement benefit expenses	¥ 6,093	¥ 6,899	¥4,648	\$ 78,382
Loss on revision of retirement benefit plan	_	1,771*5	_	_
Total	¥ 6,093	¥ 8,670	¥4,648	\$ 78,382

\*1. Includes retirement benefit expenses incurred by the subsidiaries that apply the simplified method.

\*2. Includes contributions made under defined contribution plan and prepaid retirement benefit under prepaid pension plan.

\*3. Includes special severance payments and prepaid retirement benefits under prepaid pension plan.

\*4. Prepaid retirement benefits under prepaid pension plan.

\*5. Derived from the transition of a part of the Company's pension plans from defined benefit plan to defined contribution plan.

#### (3) Assumptions used in calculation of the above-mentioned information are as follows:

	2011	2010	2009
Discount rate	1.7%	2.5% (mainly)	2.5%
Expected rate of return on plan assets	2.5% (mainly)	2.5% (mainly)	3.0% (mainly)
Amortization period for prior service costs	5 years (mainly)	5 years (mainly)	5 years (mainly)
	(Straight-line method)	(Straight-line method)	(Straight-line method)
Amortization period for actuarial differences	10 years (mainly)	10 years (mainly)	10 years (mainly)
	(Straight-line method)	(Straight-line method)	(Straight-line method)

# 12 Financial Instruments

# 1. Qualitative information on financial instruments

# (1) Policies for financial instruments

The policy on cash investments of the Companies is to manage them by highly stable short-term bank deposits and short-term loans to the parent company, and to raise short-term working capital by obtaining bank loans and issuing commercial paper. It is also the Company's policy to use derivative financial instruments only for the purpose of hedging the risks described below and not to use derivative financial instruments for speculative purposes.

#### (2) Details of financial instruments and risks

Notes and accounts receivable are exposed to credit risks associated with customers. Receivables denominated in foreign currencies generated through business operations conducted globally are exposed to the risk of fluctuations in exchange rates. Investment securities, consisting mainly of the stocks of business partners, are exposed to the risk of fluctuations in stock prices. Notes and accounts payable that are due within one year, and denominated in foreign currencies, are generated through import of raw materials and are also exposed to the risk of fluctuations in exchange rates. Short-term loans payable are exposed to interest-rate risk.

Derivative transactions include forward foreign exchange contracts and currency swaps to hedge foreign exchange fluctuation risks associated with foreign currency denominated receivables and payables.

#### (3) Policies and processes for risk management

#### (a) Credit Risk Management (including risks of customers breaching contracts)

The Company manages credit risk according to the internal credit policy. Its sales management department monitors business and financial conditions of major customers regularly and controls their payment dates and credit balances by customer so that the Company can promptly recognize risks of incurrence of uncollectible accounts. The Companies enter into derivative trading contracts with only highly rated financial institutions in order to minimize credit risk.

#### (b) Market Risk Management (foreign exchange and interest rate risks)

As needed, the Company uses forward foreign exchange contracts to hedge foreign currency denominated operating receivables, and uses interest rate swaps for foreign currency denominated long-term loans to foreign subsidiaries. The Company regularly assesses the prices of marketable and investment securities and the financial positions of issuers (business partners). It factors in relationships with business partners in constantly reviewing the necessity of instruments other than held-to-maturity debt securities. Derivative transactions have been made in accordance with internal policies that regulate authority of processes.

#### (c) Funding-Related Liquidity Risk Management (risk of inability to settle obligations by payment dates)

The Company manages liquidity risk by making future cash flow plans in the accounting and finance section based on reports from each business section.

# (4) Supplemental information on fair values

The fair value of financial instruments is based on quoted market prices. If there are no market prices available, then the fair value is determined by using appropriate valuation techniques. Certain assumptions are considered in the calculations of such amounts and the results of such calculations may vary when different assumptions are used.

# 2. Fair values of financial instruments

The book value and fair value of the financial instruments on the consolidated balance sheets at December 31, 2011 and 2010 are described as follows. The table below excludes those financial instruments whose fair value estimation is extremely difficult and these are separately described below.

		Millions of yen	1	Tho	ars	
2011	Book value	Fair value	Difference	Book value	Fair value	Difference
(i) Cash and deposits	¥ 27,063	¥ 27,063	¥ —	\$ 348,124	\$ 348,124	\$ —
(ii) Notes and accounts receivable	104,448	104,448	-	1,343,560	1,343,560	—
(iii) Short-term loans receivable	82,958	82,958	-	1,067,131	1,067,131	_
(vi) Derivative financial instruments <sup>2</sup>	92	92	_	1,188	1,188	_

	Millions of yen		
2010	Book value	Fair value	Difference
(i) Cash and deposits	¥ 33,128	¥ 33,128	¥ —
(ii) Notes and accounts receivable	128,103	128,103	—
(iii) Short-term loans receivable	53,483	53,483	—
(iv) Investment securities	25,070	25,070	_
(v) Notes and accounts payable <sup>-1</sup>	(74,366)	(74,366)	—
(vi) Derivative financial instruments <sup>2</sup>	188	188	_

\*1. Liabilities are stated in parenthesis.

\*2. Amounts of derivative financial instruments are net amounts of assets and liabilities. Negative amounts stated in parentheses represent a net liability position of the financial instruments.

# (1) Basis of determining the fair value of financial instruments and matters relating to securities and derivative financial instruments are as follows:

(i) Cash and deposits, (ii) Notes and accounts receivable and (iii) Short-term loans receivable

The book value approximates fair value because of the short-term maturity of these instruments.

(iv) Investment securities

The fair value of securities is based on year-end quoted market prices. See Note 13.

(v) Notes and accounts payable

The book value approximates fair value because of short-term maturity of these instruments.

(vi) Derivative financial instruments

The fair value of derivative financial instruments is based on the quotes provided by financial institutions. See Note 14.

#### (2) Financial instruments whose fair value estimation is extremely difficult

The following items are excluded from (iv) Investment securities because their fair value is not available and their future cash flow cannot be estimated, and, accordingly, it is extremely difficult to estimate their fair value.

	Millions o	fyen	Thousands of U.S. dollars
	2011	2010	2011
Unlisted stocks	¥ —	¥ 30,143	\$ —
Other	—	134	—

#### (3) The redemption schedule for financial instruments and debt securities by contractual maturities at December 31, 2011 and 2010

		Millic	ons of yen	
2011	Within one year	Between one and five years	Between five and ten years	Total
Cash and deposits	¥ 27,063	¥ —	¥ —	¥ 27,063
Notes and accounts receivable	104,448	<u> </u>	<u> </u>	104,448
Short-term loans receivable	82,958	_		82,958
Total	¥214,470	¥ —	¥ —	¥214,470

	Thousands of U.S. dollars			
2011	Within one year	Between one and five years	Between five and ten years	Total
Cash and deposits	\$ 348,124	\$ -	\$ <b>—</b>	\$ 348,124
Notes and accounts receivable	1,343,560			1,343,560
Short-term loans receivable	1,067,131	_	_	1,067,131
Total	\$2,758,817	\$ -	\$ -	\$2,758,817

2010		Millio	ons of yen	
	Within one year	Between one and five years	Between five and ten years	Total
Cash and deposits	¥ 33,128	¥ —	¥ —	¥ 33,128
Notes and accounts receivable	128,103	_	_	128,103
Short-term loans receivable	53,483	—	—	53,483
Total	¥214,716	¥ —	¥ —	¥214,716

# 13 Securities

# (1) Marketable other securities as of December 31, 2011 and 2010 are as follows:

		2011		
	Millions of yen			
	Purchase cost	Carrying value	Unrealized gain (loss)	
Securities whose carrying value exceeds their purchase cost:				
Stocks	¥ 1,428	¥ 1,985	¥ 557	
Securities whose purchase cost exceeds their carrying value:				
Stocks	17,055	11,597	(5,457)	

		2011		
_	Thousands of U.S. dollars			
_	Purchase cost	Carrying value	Unrealized gain (loss)	
Securities whose carrying value exceeds their purchase cost: Stocks	\$ 18,379	\$ 25,546	\$ 7,166	
ecurities whose purchase cost exceeds their carrying value:	219,391	149,185	(70,206)	

	2010			
	Millions of yen			
	Purchase cost	Carrying value	Unrealized gain (loss)	
Securities whose carrying value exceeds their purchase cost:	¥ 4.225	¥ 5.122	¥ 897	
Stocks Securities whose purchase cost exceeds their carrying value:	ŧ 4,220	ŧ 0,122	∓ 097	
Stocks	24,501	19,947	(4,553)	

Unlisted stocks are excluded from the above table because their market value is not available, and it is extremely difficult to estimate their fair value.

#### (2) Sales of other securities for the years ended December 31, 2011 and 2010 are as below.

	Millions of yen		Thous	ands of U.S.	dollars	
	Sales amount	Gain	Loss	Sales amount	Gain	Loss
Year ended December 31, 2011	¥2,258	¥16	¥(692)	\$29,049	\$215	\$(8,903)
	I	Villions of yen				
	Sales amount	Gain	Loss			
Year ended December 31, 2010	¥6.363	¥1.828	¥(101)			

# (3) Impairment losses on valuation of investment securities

The Companies recognized ¥2,374 million (\$30,549 thousand) and ¥1,473 million in loss on valuation of investment securities for the years ended December 31, 2011 and 2010, respectively.

# **14** Derivative Transactions

#### (1) Hedge accounting not applied to derivative financial instruments

Year ended December 31, 2011	Millions of yen			Thousands of U.S. dollars		
Type of transaction	Notional amount	Fair value	Unrealized gain (loss)	Notional amount	Fair value	Unrealized gain (loss)
Foreign exchange forward contracts						
Selling U.S. dollar	¥ 2,727	¥ (2)	¥ (2)	\$ 35,086	\$ (25)	\$ (25)
Selling Euro	1,416	51	51	18,217	660	660
Currency swaps						
Receiving Japanese yen, Paying GBP	7,129	43	43	91,707	553	553
	¥11,273	¥92	¥92	\$145,010	\$1,188	\$1,188

Year ended December 31, 2010		Millions of yen			
Type of transaction	Notional amount	Fair value	Unrealized gain (loss)		
Foreign exchange forward contracts					
Selling U.S. dollar	¥3,229	¥ 60	¥ 60		
Selling Euro	2,155	58	58		
Currency swaps					
Receiving Japanese yen, Paying U.S. dollar	3,006	74	74		
	¥8,391	¥194	¥194		

(Note) The fair value of derivative financial instruments is based on the quotes provided by financial institutions.

# (2) Hedge accounting applied to derivative financial instruments

No relevant items for the year ended December 31, 2011

Year ended December 31, 2010	Million	is of yen
	Notional	
Type of transaction	amount	Fair value
Foreign exchange forward contracts (principle method)		
Selling U.S. dollar	¥ 60	¥ 1
Selling Euro	28	0
Buying U.S. dollar	251	(7)
Foreign exchange forward contracts (exceptional method)		
Selling U.S. dollar	1,007	*
Selling Euro	78	*
	¥1,426	¥(5)

(Note) The fair value of derivative financial instruments is based on the quotes provided by financial institutions. \* The amounts of fair value of gain (loss) on foreign exchange forward contracts (exceptional method) are

included in the fair value of accounts receivable.

# 15 Cost of Sales

The Companies recognized ¥(156) million (\$2,014 thousand) and ¥99 million in valuation loss on inventories in cost of sales for the years ended December 31, 2011 and 2010, respectively.

# 16 Research and Development Expenses

Research and development expenses, all of which were included in selling, general and administrative expenses for the years ended December 31, 2011 and 2010, and the nine months ended December 31, 2009 totaled ¥47,961 million (\$616,950 thousand), ¥44,210 million and ¥34,979 million, respectively.

# 17 Impairment Loss and Loss on Sale of Fixed Assets

# (1) Impairment loss

The Companies group fixed assets for impairment testing based on the management accounting unit. However, the Company classifies certain assets as an individual unit for impairment testing. The assets include assets held for lease, idle assets and assets held for sale or disposition.

The Companies recognized impairment loss and wrote down the book value to recovery value and accounted for its diminution in "impairment loss" for the following group of assets:

Year ended December 31, 2011 Location	Description	Classification	Millions of yen	Thousands of U.S. dollars
Takaoka City, Toyama Prefecture	Idle assets	Equipment, other	¥346	\$4,461
Ube City, Yamaguchi Prefecture	Idle assets	Land	173	2,234
Sakai City, Osaka Prefecture	Idle assets	Land and buildings	151	1,946
Hofu City, Yamaguchi Prefecture	Idle assets	Buildings and equipment, other	72	934
Bando City, Ibaraki Prefecture	Potential disposal assets	Land	24	316

Year ended December 31, 2010 Location	Description	Classification	Millions of yen
Osaka City, Osaka Prefecture	Lease assets	Land and equipment, other	¥581
Takaoka City, Toyama Prefecture	Idle assets	Buildings and equipment, other	558
Maebashi City, Gunma Prefecture	Idle assets	Land	223
Osaka City, Osaka Prefecture	Idle assets	Buildings	11
Nine months ended March 31, 2009	Description	Classification	Millions of yen
Takasaki City, Gunma Prefecture	Idle assets	Buildings and structures, other	¥2,559
Hofu City, Yamaguchi Prefecture	Idle assets	Equipment, other	111

#### (2) Loss on sale of fixed assets

Breakdown of loss on sale of fixed assets Year ended December 31, 2011 Sales rights: ¥635 million (\$8,176 thousand)

Year ended December 31, 2010 Land: ¥189 million

# 18 Pledged Assets

## (1) The following assets were pledged as collateral for debts and other liabilities at December 31, 2011 and 2010:

	Million	s of yen	Thousands of U.S. dollars
	2011	2010	2011
Land	¥ —	¥ 269	\$ —
Investment securities	—	1,150	—
Other	—	69	—
	¥ —	¥1,490	\$ —

#### (2) Such collateral secured the following obligations:

	Millions	s of yen	Thousands of U.S. dollars
	2011	2010	2011
Notes and accounts payable-trade	¥ —	¥1,583	\$ —
Other	—	100	-
	¥ —	¥1,683	\$ —

# **19** Contingent Liabilities

The Companies had contingent liabilities arising from notes discounted by banks in the amount of ¥83 million (\$1,070 thousand) at December 31, 2011.

# 20 Supplementary Information for Consolidated Statements of Changes in Net Assets

## (1) Type and Number of Outstanding Shares

Type of shares	Balance at beginning of year	Increase in shares during the year	Decrease in shares during the year	Number of shares Balance at end of year
Issued stock:				
Capital stock	576,483,555	—	-	576,483,555
Total	576,483,555	_	_	576,483,555
Freasury stock:				
Capital stock*1,2	6,691,427	14,410,738	64,838	21,037,327
Total	6,691,427	14,410,738	64,838	21,037,327

\*1. Treasury stock increased by 14,410,738 shares due to the acquisition of treasury stock (14,356,000 shares) and the repurchase of shares of less than one unit (54,738 shares).

\*2. Treasury stock decreased by 64,838 shares due to the stock options exercised (51,000 shares) and the sale of shares of less than one unit (13,838 shares).

## Year ended December 31, 2010

Type of shares	Balance at beginning of period	Increase in shares during the period	Decrease in shares during the period	Number of shares Balance at end of period
Issued stock:				
Capital stock	576,483,555	_	_	576,483,555
Total	576,483,555		_	576,483,555
Treasury stock:				
Capital stock*1,2	6,935,900	125,137	369,610	6,691,427
Total	6,935,900	125,137	369,610	6,691,427

\*1. Treasury stock increased by 125,137 shares due to the repurchase of shares of less than one unit.

\*2. Treasury stock decreased by 369,610 shares due to share exchanges in subsidiary (277,309 shares), the stock options exercised (78,000 shares), and the sale of shares of less than one unit (14,301 shares).

#### (2) Dividends

The Companies Act of Japan provides that an amount equal to 10% of cash appropriations of retained earnings shall be set aside as additional paid-in capital or legal earnings reserve until the total of such reserve and additional paid-in capital equals 25% of the stated capital.

The maximum amount that the Company can distribute as dividends is calculated based on the non-consolidated financial statements of the Company in accordance with Japanese laws and regulations.

#### 1. Dividends paid to shareholders

Date of approval	Resolution approved by	Type of shares	Amount (Millions of yen)	Amount (Thousands of U.S. dollars)	Per share (Yen)	Per share (U.S. dollars)	Record date	Effective date
March 24, 2011	Annual general meeting of shareholders	Common stock	¥5,697	\$73,294	¥10	\$0.129	December 31, 2010	March 25, 2011
August 2, 2011	Board of directors	Capital stock	5,698	73,298	10	0.129	June 30, 2011	September 1, 2011

2. Dividends with a record date during the current year but an effective date subsequent to the current fiscal year

Date of approval	Resolution approved by	Resource of dividends	Type of shares	Amount (Millions of yen)	Amount (Thousands of U.S. dollars)	Per share (Yen)	Per share (U.S. dollars)	Record date	Effective date
March 22, 2012	Annual general meeting of shareholders	Retained earnings	Common stock	¥5,554	\$71,449	¥10	\$0.129	December 31, 2011	March 23, 2012

# 21 Related Party Transactions

Significant transactions and balances with related parties as of and for the years ended December 31, 2011 and 2010 were as follows:

# (1) Parent Company

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

#### Year ended December 31, 2011

	Capital	Ratio of voting	atio of voting		Amounts		Amounts	
Name	Millions of yen	rights owning (owned)	Transactions	Millions of yen	Thousands of U.S. dollars	Closing balances	Millions of yen	Thousands of U.S. dollars
Kirin			Loan of funds*1	¥65,612	\$843,993	Short-term loans receivable	82,473	\$1,060,893
Holdings Company, Limited	¥102,045	Directly (52.4%)	Sales price of subsidiary's shares*2	14,987	192,794			
			Gain on sales of subsidiary's shares*2	4,712	60,623			

### Year ended December 31, 2010

	Capital	Ratio of voting rights owning Transactions Millions of yen		Closing	Amounts	
Name	Millions of yen			Millions of yen	balances	Millions of yen
Kirin Holdings Company, Limited	¥102,045	Directly (51.1%)	Loan of funds*1	¥41,287	Short-term loans receivable	¥53,199

\*1. Related to "Cash Management System" offered by Kirin Holdings, calculated the amount of transactions from the average amount of every month.

\*2. Related to sale of 474 shares of Kirin Kyowa Foods to Kirin Holdings.

#### (2) Directors of the Companies

No relevant items for the year ended December 31, 2011

Year ended December 31, 2010

	Ratio of voting rights		Amounts	
Name and position	owning (owned)	Transactions	Millions of yen	
Yoshiki Tsunekane Director	e Directly (0.0%)	Disposal of treasury stocks by exercise of stock options*	¥13	
Manabu Suzuki Corporate auditor	Directly (0.0%)	Disposal of treasury stocks by exercise of stock options*	¥14	

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

## 22 Supplementary Cash Flow Information

On April 21, 2011, the Company purchased shares of ProStrakan Group Plc. The assets and liabilities included in consolidation as of the date of acquisition were as follows:

	Millions of yen	Thousands of U.S. dollars
Current assets:	¥ 6,719	\$ 86,431
Noncurrent assets	23,923	307,742
Goodwill	28,333	364,462
Current liabilities	(16,890)	(217,270)
Noncurrent liabilities	(4,820)	(62,004)
Foreign currency translation adjustments	1,646	21,175
Acquisition costs	¥ 38,911	\$ 500,538
Cash and cash equivalents of ProStrakan	(1,932)	(24,859)
Cash disbursement	¥ 36,979	\$ 475,678

On March 31, 2011, Kyowa Hakko Chemical Co., Ltd. and Miyako Kagaku Co., Ltd. were excluded from the scope of consolidation because the Company's investments in these subsidiaries had been sold. The assets and liabilities as of the date of the sale and proceeds from sale and gain on the sale were as follows:

	Millions of yen	Thousands of U.S. dollars
Current assets:	¥ 49,396	\$ 635,402
Noncurrent assets	47,441	610,260
Current liabilities	(54,952)	(706,872)
Noncurrent liabilities	(8,165)	(105,036)
Gain on sales of affiliates' stock	2,449	31,510
Sales amount of shares	¥ 36,169	\$ 465,263
Collections on short-term loans receivable to subsidiaries	20,700	266,272
Cash and cash equivalents of subsidiaries	(4,124)	(53,050)
Proceeds from sale of investment	¥ 52,745	\$ 678,485

# 23 Segment Information

#### Segment information for the year ended December 31, 2011

The reporting 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 three reportable segments: "Pharmaceuticals Division", "Bio-Chemicals Division" and "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, nucleic acids and related compounds, healthcare products and others. The Chemicals Division manufactures and sells solvents, raw materials for plasticizers, functional products and others.

The Company sold all shares of Kyowa Hakko Chemicals on March 31, 2011. As a result, the "Chemicals Division" was consolidated until March 31, 2011 only.

# 1. Information on sales and income (loss), identifiable assets/liabilities and other items by business 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			
			- Adjustments*2	Consolidated			
	Pharmaceuticals	Bio-Chemicals	Chemicals	Other*1	Total	Adjustitionits	total
Sales							
Sales to outside customers	¥229,159	¥ 74,370	¥32,787	¥ 7,405	¥343,722	¥ —	¥343,722
Intersegment sales.	180	3,193	762	3,253	7,390	(7,390)	_
Net sales	229,339	77,563	33,550	10,659	351,113	(7,390)	343,722
Segment income	41,314	2,896	2,135	360	46,706	(92)	46,614
Segment assets	426,252	137,497	_	7,075	570,824	88,049	658,873
Other items							
Depreciation and amortization	¥ 15,339	¥ 6,457	¥ 974	¥ 64	¥ 22,835	¥ (2)	¥ 22,833
Amortization of goodwill	9,997	625	12	_	10,635	_	10,635
Investment to equity- method affiliates	69	_	_	1,186	1,255	_	1,255
Increase of property, plant and equipment and intangible assets	11,886	7,482	317	11	19,697	_	19,697

	Thousands of U.S. dollars							
			Business segmen	t		<ul> <li>Adjustments<sup>*2</sup></li> </ul>	Consolidated	
	Pharmaceuticals	Bio-Chemicals	Chemicals	Other*1	Total	Adjustinents	total	
Sales								
Sales to outside customers	\$2,947,766	\$ 956,653	\$421,755	\$95,266	\$4,421,442	\$ -	\$4,421,442	
Intersegment sales and transfer	2,319	41,081	9,811	41,855	95,068	(95,068)	_	
Net sales	2,950,086	997,735	431,567	137,121	4,516,510	(95,068)	4,421,442	
Segment income	531,444	37,256	27,470	4,635	600,806	(1,185)	599,621	
Segment assets	5,483,047	1,768,677	_	91,016	7,342,741	1,132,609	8,475,350	
Other items								
Depreciation and amortization	\$ 197,320	\$ 83,061	\$ 12,535	\$ 829	\$ 293,748	\$ (30)	\$ 293,717	
Amortization of goodwill	128,606	8,048	159	_	136,813	_	136,813	
Investment to equity- method affiliates	895	_	_	15,260	16,155	_	16,155	
Increase of property, plant and equipment and intangible assets.	152,904	96,248	4,078	146	253,378	_	253,378	

\*1 The Other segment is a business segment that is not included in the reportable segments. It includes logistics operations, etc.

\*2 (a) Segment as a balances significant at a not included in the reportable segments: it includes logistics operations, etc.
 \*2 (a) Segment income included in "Adjustments" consisted of the elimination of the intersegment transactions.
 (b) Segment assets included in "Adjustments" consisted of the elimination of the intersegment transactions and corporate assets that is not allocated to each reportable segment.
 The amounts were as follows.
 Elimination of the intersegment transactions: ¥ (10,544) million

Corporate assets:

¥ (10,544) million ¥ 98,593 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
¥272,568	¥20,071	¥25,169	¥25,426	¥486	¥343,722

	Thousands of U.S. dollars								
Japan America Europe Asia Other areas Total									
\$3,506,160	\$258,183	\$323,770	\$327,069	\$6,258	\$4,421,442				

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

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

As the balances of property, plant and equipment located in Japan accounted for more than 90% the balances of property, plant and equipment recognized in the consolidated balance sheet at December 31, 2011, information on property, plant and equipment at December 31, 2011 was omitted.

### 3. Information by major customer

	Millions of yen	
Customer name	Net sales	Related segment name
Alfresa Corporation	¥45,832	Pharmaceuticals

	Thousands of U.S. dollars	
Customer name	Net sales	Related segment name
Alfresa Corporation	\$589,563	Pharmaceuticals

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

\$7,947

			Mi	llions of yen			
	Pharmaceuticals	<b>Bio-Chemicals</b>	Chemicals	Other	Total	Adjustments	Consolidated total
Impairment losses	¥151	¥617	¥ —	¥ —	¥769	¥ —	¥769
_	Thousands of U.S. dollars						
	Pharmaceuticals	<b>Bio-Chemicals</b>	Chemicals	Other	Total	Adjustments	Consolidated total

**\$** –

\$9,894

**\$** –

\$9,894

**\$** –

Impairment losses

\$1,947

			Mi	llions of yen			
	Pharmaceuticals	<b>Bio-Chemicals</b>	Chemicals	Other	Total	Adjustments	Consolidated total
Amortization of							
goodwill	¥ 9,997	¥ 625	¥12	—	¥ 10,635	¥ —	¥ 10,635
Unamortized							
balance	167,100	10,166		_	177,267	—	177,267
			Thousar	nds of U.S. dollars	5		
	Pharmaceuticals	Bio-Chemicals	Chemicals	Other	Total	Adjustments	Consolidated total
Amortization of							
goodwill	\$ 128,606	\$ 8,048	\$159	-	\$ 136,813	\$ —	\$ 136,813
Unamortized							
balance	2,149,476	130,780	_	-	2,280,257	_	2,280,257

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

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

#### Supplemental information

Effective January 1, 2011, the Companies have adopted ASBJ Statement No. 17, "Accounting Standard for Disclosures about Segments of an Enterprise and Related Information" and ASBJ Guidance No. 20, "Guidance on Accounting Standard for Disclosures about Segments of an Enterprise and Related Information".

# Segment information for the year ended December 31, 2010

# 1. Business segment information

The Companies operate the same business segments as at December 31, 2011.

	Millions of yen						
		B	usiness segment			Corporate,	Consolidated
Year ended December 31, 2010	Pharmaceuticals	Bio-Chemicals	Chemicals	Other	Total	elimination and other	total
I. Sales and Operating income:							
Sales to outside customers	¥210,157	¥75,578	¥124,360	¥ 3,643	¥413,738	¥ —	¥413,738
Intersegment sales and transfers	205	8,658	5,657	6,855	21,377	(21,377)	_
Net sales	210,362	84,236	130,018	10,499	435,116	(21,377)	413,738
Operating expenses.	174,505	80,961	124,339	10,135	389,941	(21,613)	368,328
Operating income	¥ 35,857	¥ 3,275	¥ 5,678	¥ 363	¥ 45,175	¥ 235	¥ 45,410
II. Total assets, Depreciation and amortization, Impairment loss and Capital expenditures:							
Total assets	¥381,349	¥135,337	¥102,313	¥17,659	¥636,660	¥ 59,202	¥695,862
Depreciation and amortization	10,733	6,731	4,652	73	22,190	(2)	22,188
Impairment loss	804	558	11	_	1,374	_	1,374
Capital expenditures	19,251	7,603	2,504	15	29,375	(1)	29,374

(Note) In the fiscal year commencing on January 1, 2010, Miyako Kagaku Co., Ltd. and Kashiwagi Corporation, both of which are consolidated subsidiaries engaged in the wholesale of chemicals, etc., were brought under the control of Kyowa Hakko Chemical Co., Ltd., which is the core company in the Chemicals Division, primarily for the purpose of optimizing the business management structure within the Kyowa Hakko Kirin Group.

In line with this, the Company reviewed the segment classification of Miyako Kagaku Co., Ltd. and Kashiwagi Corporation, and consequently changed their business segment classification from "Other" to "Chemicals" in consideration of the management structure based on future policies, the current status of net sales and other such factors.

# 2. Geographic segment information

The classification of geographic segments is as follows:

Classification	Countries
Japan	Japan
Other	U.S.A., Germany, Italy, China, Korea, Hong Kong, Taiwan and Singapore

	Millions of yen						
_	Geographic segment			Corporate,	Consolidated		
Year ended December 31, 2010	Japan	Other	Total	elimination and other	total		
I. Sales and Operating Income:							
Sales to outside customers	¥374,382	¥39,356	¥413,738	¥ —	¥413,738		
Intersegment sales and transfers	24,952	10,543	35,495	(35,495)	_		
Net sales	399,334	49,899	449,234	(35,495)	413,738		
Operating expenses	357,350	45,967	403,318	(34,989)	368,328		
Operating income	¥ 41,984	¥ 3,932	¥ 45,916	¥ (505)	¥ 45,410		
II. Total assets	¥611,240	¥44,895	¥656,136	¥ 39,726	¥695,862		

# 3. Overseas sales

The classification of overseas sales is as follows:

Classification	Area					
America	North America, Latin Ame	rica				
Europe	All of Europe					
Asia	All of Asia					
Other areas	Oceania, Africa					
				Millions of yen		
Year ended December	31, 2010	America	Europe	Asia	Other areas	Total
I. Overseas sales		¥23,467	¥21,477	¥39,689	¥507	¥ 85,142
II. Consolidated net	sales					413,738
III. Ratio of overseas	sales to consolidated net sales	5.7%	5.2%	9.6%	0.1%	20.6%

# 24 Asset Retirement Obligations

# (1) Overview of asset retirement obligations

Obligations to restore property to its original state based on real estate lease contracts entered into on land for manufacturing facilities

## (2) Basis for calculating the asset retirement obligations

Asset retirement obligations are calculated on the assumption of prospective useful lives of 10 to 14 years with discount rates of 1.13% to 1.59%.

# (3) Changes in the asset retirement obligations in the fiscal year ended December 31, 2011

	Millions of yen	Thousands of U.S. dollars
Balance at beginning of year*	¥674	\$8,679
Accretion adjustment with the passing of time	6	80
Decrease due to fulfillment of obligations	(0)	(5)
Other	(25)	(332)
Balance at end of year	¥654	\$8,421

\* The balance of the asset retirement obligations at the beginning of the year was determined based upon the guidance set forth in "Accounting Standard for Asset Retirement Obligations" (ASBJ Statement No. 18) and "Guidance on Accounting Standard for Asset Retirement Obligations" (ASBJ Guidance No. 21).

# 25 Per Share Data

		Yen		U.S. dollars
	2011	2010	2009	2011
Net assets	¥970.2	¥954.6	¥940.8	\$12.480
Net income-basic	45.2	39.0	15.4	0.581
Net income-diluted	45.1	38.9	15.4	0.581

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, 2011 and 2010, and the nine months ended December 31, 2009 in the above table is as follows:

		Millions of yen		Thousands of U.S. dollars
	2011	2010	2009	2011
Net income-basic				
Net income used in the calculation of net income per share	¥25,608	¥22,197	¥8,797	\$329,409
Weighted average number of shares of common stock outstanding (Number of shares)	567,029,639	569,711,311	570,935,630	_
Net income-diluted				
Increasing number of common stock attributable to: (Number of shares)	324,056	266,959	265,826	—
Stock subscription rights (Number of shares)	324,056	266,959	265,826	_

The financial data used in the computation of net assets per share at December 31, 2011, 2010 and 2009 in the above table is as follows:

	Millions of yen			Thousands of U.S. dollars	
	2011	2010	2009	2011	
Total net assets	¥540,023	¥544,992	¥540,343	\$6,946,527	
Amounts deducted from total net assets attributable to	1,153	1,077	4,517	14,837	
Stock subscription rights	250	207	196	3,223	
Minority interests	902	869	4,321	11,613	
Net assets used in the calculation of net assets per share	¥538,869	¥543,914	¥535,826	\$6,931,690	
Number of shares used in the calculation of net assets per share (Number of shares)	555,446,228	569,792,128	569,547,655	_	

# 26 Subsequent Event

# Joint venture with FUJIFILM Co., Ltd.

At the meeting of the Board of Directors held on February 22, 2012, the Board passed a resolution to establish a joint venture for the development of biosimilars with FUJIFILM Co., Ltd. (hereinafter "Fujifilm"). On February 29, 2012, the Company and Fujifilm signed an agreement for setting up the joint venture.

The joint venture is a company that merges the Company's technologies and know-how with those of Fujifilm. This partnership, through the development and timely introduction of highly reliable, high-quality and cost-competitive biosimilars, will aim at establishing a position as the market leader in the fast-growing biosimilars market.

Overview of the joint venture

Name of the company	FUJIFILM KYOWA KIRIN Biologics Co., Ltd.		
Business of the company	Development of biosimilars		
Location of offices	Chiyoda-ku, Tokyo		
Capital stock	¥100 million (\$1,286 thousand)		
Planned timing of establishment and business launch	March 27, 2012 (Scheduled)		
Capitalization ratio	Kyowa Hakko Kirin Co., Ltd.: 50%		
	FUJIFILM Co., Ltd.: 50%		

# **Report of Independent Auditors**

ERNST & YOUNG Ernst & Young ShinNihon LLC Hibiya Kokusai Bidg. 2-2-3 Uchisaiwai-cho Chiyoda ku, Tokyo, Japan 100-0011 lei : +81 3 3503 1100 lax: +81 3 3503 1197 Report of Independent Auditors The Board of Directors Kyowa Hakko Kirin Co., Ltd. We have audited the accompanying consolidated balance sheets of Kyowa Hakko Kirin Co., Ltd. and consolidated subsidiaries as of December 31, 2011 and 2010, and the related consolidated statements of income, changes in net assets, and cash flows for the years ended December 31, 2011 and 2010 and the nine months ended December 31, 2009 and consolidated statement of comprehensive income for the year ended March 31, 2011, all expressed in yen. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in Japan. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion. In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Kyowa Hakko Kirin Co., Ltd. and consolidated subsidiaries at December 31, 2011 and 2010, and the consolidated results of their operations and their cash flows for the years ended December 31, 2011 and 2010 and the nine months ended December 31, 2009, in conformity with accounting principles generally accepted in Japan. The U.S. dollar amounts in the accompanying consolidated financial statements with respect to the year ended December 31, 2011 are presented solely for convenience. Our audit also included the translation of yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made on the basis described in Note 3. Ernst & young Shinnihon LLC March 16, 2012

her firm at Ernal & Young Gold Lin

# **Development Summary**

(As of March 31, 2012)

# Oncology

# KW-2246

KW-2246, a fentanyl citrate sublingual tablet, was in-licensed from Orexo AB of Sweden. It is expected to show rapid absorption and analgesic effects, and is being developed as a treatment for cancer breakthrough pain. We are now conducting a phase III clinical trial for cancer pain in Japan.

# **KRN125**

KRN125 (pegfilgrastim) is a pegylated form of the recombinant human granulocyte colony-stimulating factor (G-CSF) analog filgrastim, which has been marketed by Kyowa Hakko Kirin as GRAN<sup>®</sup>. Both KRN125 and GRAN<sup>®</sup> stimulate the growth of neutrophils, a type of white blood cell. KRN125 has a much longer half-life than GRAN<sup>®</sup>. Phase III clinical trials for chemotherapy-induced febrile neutropenia were initiated in Japan in February 2011.

# Neulasta®/Peglasta®

In Asia, we have developed pegfilgrastim as Neulasta®/ Peglasta® for chemotherapy-induced febrile neutropenia. Neulasta® has received NDA approval in Taiwan in September 2011, and is currently under NDA review in Korea. Further, Peglasta® is currently under NDA review in Vietnam.

# **ARQ 197**

ARQ 197 is an orally administered proprietary small molecule for treating malignant tumors. It selectively inhibits c-Met, a receptor tyrosine kinase, and shows anticancer activity through this inhibition. In April 2007, we entered into an agreement with ArQule for exclusive development and marketing rights for Japan and certain parts of Asia. We are now conducting phase III clinical trials for non-small cell lung cancer in Japan, Korea and Taiwan, and phase II clinical trials for gastric cancer in Japan and Korea.

# KW-2478

This compound was originally found through microbial screening and was developed through organic chemistry and X-ray crystallography technologies. The mechanism of action of KW-2478 is ATP competitive inhibition of heat shock protein 90 (HSP90). With this new type of anticancer action, this compound inhibits the functions of HSP90 client proteins, which are involved in the survival, proliferation, metastasis and other processes of cancer cells. We are now conducting a combination therapy phase I/II clinical trial for relapsed/refractory multiple myeloma in combination with Velcade<sup>®</sup> in the United States, the United Kingdom and the Philippines.

# KW-2450

This is a small molecule inhibitor of the IGF-1 receptor and insulin receptor, which are known to be involved in cancer proliferation and resistance to anticancer drugs. We are now conducting a phase I/II trial for HER2 positive advanced or metastatic breast cancer in combination with Tykerb<sup>®</sup> and Femara<sup>®</sup> in the United States.

# **KRN330**

This fully human monoclonal antibody recognizes the A33 antigen, which is expressed in 95 percent of colorectal cancers. KRN330 has antitumor effects with ADCC and CDC. We are now conducting a phase I/IIa clinical trial for metastatic colorectal cancer after first-line or adjuvant FOLFOX/CapOx failure in the United States.

# BIW-8962

This humanized monoclonal antibody specifically binds to ganglioside GM2, a glycolipid found in the cell membrane. It has shown promising antitumor effects by destroying GM2 positive cancer cells with ADCC enhanced by POTELLIGENT® technology. We are now conducting a phase I/IIa clinical trial for multiple myeloma in the United States.

# **KRN951**

KRN951 selectively inhibits the tyrosine kinase activity of vascular endothelial growth factor receptors (VEGFRs) to block angiogenesis. We are now conducting a phase I clinical trial for malignant tumors in Japan. Overseas, AVEO Pharmaceuticals, Inc. is conducting a phase III clinical trial for advanced renal cell carcinoma.

# KHK2866

This humanized monoclonal antibody specifically binds to the HB-EGF that cancer cells express; POTELLIGENT® technology enhances its ADCC. We are now conducting a phase I clinical trial for solid tumors and ovarian cancer in the United States.

# LY2523355

This compound specifically inhibits M phase kinesin Eg5. We out-licensed worldwide development rights, excluding Japan and Asia, to Eli Lilly in 2006. We are now conducting a phase I clinical trial for solid tumors in Japan.

#### CEP-37250/KHK2804

CEP-37250/KHK2804 is a proprietary humanized monoclonal antibody; POTELLIGENT® technology enhances its ADCC. The antibody binds to tumor-selective carbohydrate structures that are expressed on solid tumors and tumor cell lines targeting human colon cancer and potentially other solid tumors as clinical indications. In vitro CEP-37250/KHK2804 displayed potent tumor cell killing activities, and in vivo CEP-37250/ KHK2804 showed potent and significant efficacy against colon cancer in various mouse treatment models. We are now conducting a phase I clinical trial for advanced solid tumors in the United States.

# KHK2898

This fully human antibody specifically binds to the CD98 antigen that is highly expressed in many types of carcinomas. We are now conducting a phase I clinical trial for solid tumors in Singapore.

# Nephrology

#### **RTA 402**

RTA 402 is an orally active small molecule that is an activator of the transcription factor Nrf2, which controls the production of many antioxidant and anti-inflammatory factors. Clinical trials have been conducted by Reata Pharmaceuticals, Inc., of the United States. Data from these trials showed that RTA 402 achieved significant improvement in kidney function in CKD patients with Type 2 diabetes. In Japan, phase II clinical trials commenced in February 2012.

# Immunology/Allergy

### KHK4563

This humanized monoclonal antibody specifically binds to the human IL-5 receptor, which is expressed almost exclusively on eosinophils and basophils. Eosinophils are believed to play a key role in the pathogenesis of asthma. KHK4563 utilizes POTELLIGENT® technology to enhance ADCC activity on eosinophils, and is therefore expected to improve asthma symptoms by depleting eosinophils in airway tissues. We are now conducting a phase II clinical trial in Japan and Korea for bronchial asthma. In 2006, we licensed development and marketing rights, excluding Japan and certain Asian countries, to MedImmune.

#### **ASKP1240**

ASKP1240 is a fully human monoclonal antibody, which interferes with the CD40-CD40 ligand (CD154) interaction. We expect this antibody to satisfy unmet medical needs for organ transplants regulated by both cellular and humoral immunity. We concluded a co-development agreement with Astellas Pharma Co., Ltd. for this antibody in January 2007. Clinical trials are in Phase II in the United States and Phase I in Japan.

### KHK4827

This fully human monoclonal antibody targets the IL-17 receptor reported to play a key role in the pathogenesis of various autoimmune diseases. We are now conducting a phase I clinical study in Japan.

# Central Nervous System

# KW-6500

The dopamine D1 and D2 receptor agonist apomorphine is the active ingredient in KW-6500, which is self-administered as an injection. It improves the symptoms of patients in the final stage of Parkinson's disease and can be used when the effectiveness of existing treatments is wearing off or becoming inconsistent. In February 2006, we concluded an in-licensing agreement with Britannia Pharmaceuticals for exclusive development and sales rights in Japan and certain countries in Asia. We received manufacturing and marketing approval in Japan in March 2012.

### KW-6002

KW-6002 is the world's first selective adenosine A2a receptor antagonist for treating Parkinson's disease. In Japan, the results of clinical trials demonstrated improvement in Parkinson's disease under treatment with levodopa tablets and confirmed tolerability. The new drug application in Japan was filed in March 2012.

# KHK6188

This cannabinoid CB2 receptor agonist is expected to relieve neuropathic pain by activating CB2 receptors expressed on microglial cells and primary sensory neurons. We are now conducting a phase II clinical study for postherpetic neuralgia in Japan.

# Glossary

# Other

# KW-3357

KW-3357 is a recombinant human antithrombin, produced using the sugar chain control technology that we acquired during the development of POTELLIGENT® technology. Because the antithrombins currently marketed in Japan are all blood products, KW-3357 will have a key advantage as a substitute antithrombin treatment that eliminates any risk of infection. We are now conducting phase III clinical trials in Japan.

# KRN23

This fully human monoclonal antibody with neutralizing activity targets FGF23. In patients with X-linked hypophosphatemia, the excessive production of FGF23 impairs normal phosphate reabsorption in the kidney and causes a phosphate-wasting condition which is the major cause of XLH. By targeting FGF23, KRN23 is expected to normalize serum phosphorus levels and improve such disease conditions as underdevelopment of legs, small-stature syndrome, and osteomalasia. We are now conducting a phase I/II clinical trial for X-linked hypophosphatemia in the United States and Canada.

## Antibody

A type of protein the body produces to attack and eliminate foreign substances that enter the body. Antibodies therefore play an important role in the body's defense system, which is known as the immune system.

# Antigen

Antibodies find and destroy foreign substances by targeting antigens on their surface. Illnesses called autoimmune diseases cause the body's own component substances to become antigens that evoke an immune response. Antigens that cause allergic reactions are called allergens.

## **Therapeutic Antibody**

A pharmaceutical 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.

#### Antibody-Dependent Cellular Cytotoxicity (ADCC)

Cellular cytotoxicity refers to cell destruction. After an antibody binds to an antigen, effector cells such as macrophages and NK cells bind to the antibody. These effector cells depend on the antibody to find the antigen-bearing target cells they will destroy.

### Macrophage

A type of white blood cell that plays a role in the immune system. Macrophages engulf and digest dead cells and pathogens such as viruses and bacteria that have entered the body. They also function to "present" antigens, which involves notifying other cells of the antigens on the surface of the pathogens the macrophage has digested.

#### Natural Killer (NK) Cells

NK cells protect the body primarily by attacking cancer cells and cells infected with viruses.

# **POTELLIGENT®**

Kyowa Hakko Kirin's unique technology to produce antibodies with enhanced ADCC activity. This technique allows production of antibodies with reduced fucose in their carbohydrate structure. Non-clinical animal studies have confirmed that antibodies produced by this technology killed the target cells much more efficiently than existing antibodies and exhibited stronger antitumor effects.

# **Complement-Dependent Cytotoxicity (CDC)**

Cell destruction that depends on complements. An antibody binds to a cell or pathogen. This initiates rapid creation, known as a cascade, of the complements that activate pathogen or cell destruction.

#### Complements

Complements help antibodies bind to antigens; enhance antibody activity; encourage macrophages to engulf and digest pathogens, which is a process known as phagocytosis; and encourage lysis, or the rupturing of pathogenic cells.

#### **COMPLEGENT®**

A technology for producing antibodies that have enhanced therapeutic effect because of their powerful CDC. The use of COMPLEGENT® in conjunction with POTELLIGENT® technology enables the creation of breakthrough antibody therapies that powerfully enhance both ADCC and CDC.

#### KM Mouse™:

### A Mouse That Produces Human Antibodies

Kyowa Hakko Kirin created Human Artificial Chromosome (HAC) technology, which is a breakthrough technique for transferring a fragment of a human chromosome containing a very large cluster of genes into a mouse. We then created the KM Mouse<sup>™</sup>, which produces fully human antibodies, by fusing HAC with the technology of Medarex Inc. (currently Bristol-Myers Squibb). The creation of a mouse that can produce a diverse array of fully human antibodies offers benefits including continued antibody dosings, which broadens the potential for therapeutic antibodies.

#### **Biopharmaceuticals**

Pharmaceuticals expected to be highly effective with few adverse effects through the use of proteins and other biomolecules that have a complex structure and deliver pharmacological effects that were not possible to achieve with chemical synthesis.

### **Small Molecule Pharmaceuticals**

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

#### **Biosimilars**

Subsequent versions of biotechnology-based innovator biopharmaceuticals with new active ingredients approved in Japan. The properties and quality in terms of efficacy and safety are similar, but they are produced and marketed by a different sponsor.

# Orphan Drugs (Pharmaceuticals for Treating Intractable Diseases)

Pharmaceuticals for intractable diseases that affect fewer patients, such as AIDS. Japan's Minister of Health, Labour and Welfare specifies orphan drugs based on applications from pharmaceutical companies, using the following criteria:

- A. Fewer than 50,000 potential patients in Japan
- B. The need for the drug is high because appropriate alternative drugs or treatments are unavailable or the efficacy and safety of the drug is significantly better than other available drugs.
- C. The potential for development is strong because the applicant has an ethical rationale for the use of the drug and a valid product development plan.

#### **Companion Diagnostic**

An *in vitro* diagnostic reagent used for personalized medicine. Already used in the treatment of specific cancers, companion diagnostics identify genes and biomarkers in advance so that physicians can prescribe highly effective treatment for each patient with fewer adverse drug reactions and choose the best treatment and therapeutic agents.

#### **Contract Manufacturing Organization (CMO)**

A company that manufactures pharmaceutical products under contract to a pharmaceutical company. CMOs are specialized suppliers with technological capabilities and manufacturing facilities that meet stringent pharmaceutical manufacturing standards, and therefore offer advantages to pharmaceutical companies including excellent quality control and lower costs.

### **Good Clinical Practice (GCP)**

A set of guidelines for ethically and scientifically valid clinical tests involving humans that enhance data reliability and comply with pharmaceutical laws and regulations.

#### **Good Laboratory Practice (GLP)**

A set of guidelines for evaluating the safety and efficacy of pharmaceuticals particularly designed to enhance the reliability of safety data from various types of non-clinical animal studies.

#### **Good Manufacturing Practice (GMP)**

A set of guidelines to ensure the manufacture of pharmaceuticals with consistent quality in accordance with approved specifications by eliminating human error through control of all manufacturing processes, from receipt of raw materials to shipment of finished products, and the configuration of factory buildings, equipment and facilities.

### Proof of Concept (POC)

The clinical confirmation of the efficacy and safety of a new drug candidate compound to verify the validity of the concept. Generally refers to an early phase II clinical trial.

# **Principal Subsidiaries and Affiliates**

(As of December 31, 2011)

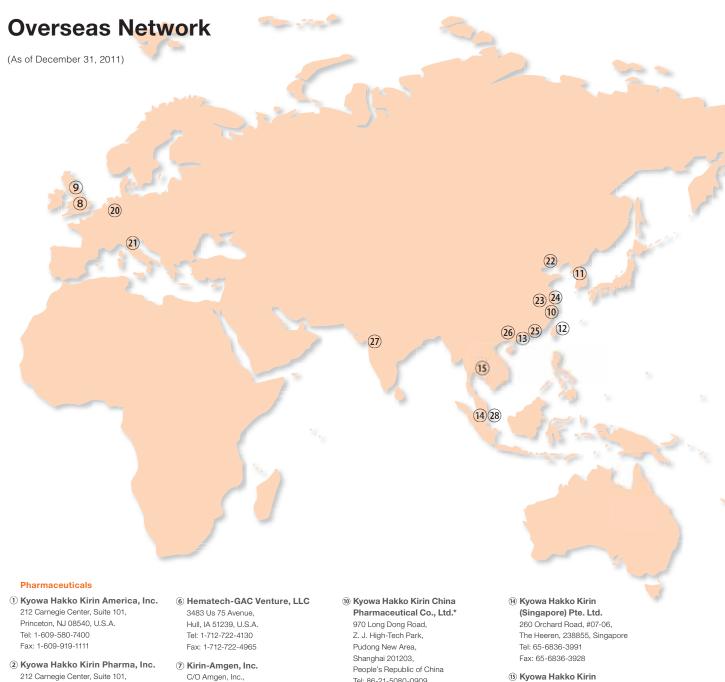
Name of Company	Percentage Owned Directly or Indirectly by the Company	Capital (Thousand)	Principal Business	
PHARMACEUTICALS				
Kyowa Medex Co., Ltd.	100.0%	¥450,000	Manufacture and sale of diagnostic reagents	
Kyowa Hakko Kirin China Pharmaceutical Co., Ltd. <sup>3</sup>	100.0%	CNY 246,794	Manufacture and sale of pharmaceuticals	
Kyowa Medical Promotion Co., Ltd.	100.0%	¥50,000	Sales promotion of pharmaceuticals	
Kyowa Hakko Kirin America, Inc.	100.0%	\$76,300	Holding company for managing subsidiaries in the United States	
BioWa, Inc.	100.0%	\$10,000	Licensing of antibody technology	
Kyowa Hakko Kirin Pharma, Inc.	100.0%	\$100	Development of pharmaceuticals	
Kyowa Hakko Kirin California, Inc.	100.0%	\$100	Discovery of new drug candidates	
ProStrakan Group Plc	100.0%	£10,771	Holding company for managing subsidiaries in Europe	
Strakan International S.a r.l.	100.0%	\$112,826	Sale, in-licensing and out-licensing of pharmaceuticals	
ProStrakan Limited	100.0%	£6,951	Sale of pharmaceuticals	
ProStrakan Pharma S.A.S	100.0%	€1,139	Sale of pharmaceuticals	
ProStrakan Farmaceutica SLU	100.0%	€216	Sale of pharmaceuticals	
ProStrakan Inc.	100.0%	\$235 <sup>2</sup>	Sale of pharmaceuticals	
Hematech, Inc.	100.0%	_	Research of base technology for production of therapeutic antibodies	
Hematech-GAC Venture, LLC	51.0%	_	Research of base technology for production of therapeutic antibodies	
Kyowa Hakko Kirin Korea Co., Ltd.4	90.0%	KRW 2,200,000	Sale of pharmaceuticals	
Kyowa Hakko Kirin (Taiwan) Co., Ltd.	100.0%	NT \$12,450	Sale of pharmaceuticals	
Kyowa Hakko Kirin (Hong Kong) Co., Ltd.	100.0%	HK \$6,000	Sale of pharmaceuticals	
Kyowa Hakko Kirin (Singapore) Pte. Ltd.	100.0%	\$1,000	Sale of pharmaceuticals	
Kyowa Hakko Kirin Italia S.r.I.	100.0%	€700	Sale of pharmaceuticals	
BIO-CHEMICALS			<u></u>	
Kyowa Hakko Bio Co., Ltd.	100.0%	¥10,000,000	Manufacture and sale of raw materials for pharmaceuticals and industrial use and health care products	
DAIICHI FINE CHEMICAL CO., LTD.	100.0%	¥6,276,000 Wanufacture and sale of bulk pharmaceuticals and intermediates		
Biokyowa Inc.	100.0%	\$20,000	Manufacture and sale of amino acids	
Shanghai Kyowa Amino Acid Co., Ltd.	70.0%	CNY 156,436	Manufacture and sale of amino acids	
Kyowa Hakko U.S.A., Inc.	100.0%	\$1,000	Import, export, and sale of amino acids and fine chemicals	
Kyowa Hakko Europe GmbH	100.0%	€1,030	Import, export, and sale of amino acids and fine chemicals	
Kyowa Hakko Bio Italia S.r.I.	100.0%	€700	Import, export, and sale of amino acids and fine chemicals	
Kyowa Hakko Bio Singapore Pte. Ltd.	100.0%	\$4,000	Import, export, and sale of amino acids and fine chemicals	
Kyowa Hakko (H.K.) Co., Ltd.	100.0%	HK \$1,200	Import, export, and sale of amino acids and fine chemicals	
Kyowa Hakko Bio U.S. Holdings, Inc.	100.0%	\$1	Holding company for managing subsidiaries in the United States	
Kyowa Wellness Co., Ltd.	100.0%	¥30,000	Sale of health care products	
Kyowa Engineering Co., Ltd.	100.0%	¥70,000	Design and installation of equipment and facilities	
OTHER				
Chiyoda Kaihatsu Co., Ltd.	100.0%	¥112,000	Logistics, insurance, and wholesale of foods	
Japan Synthetic Alcohol Co., Ltd. <sup>1</sup>	33.3%	¥480,000	Manufacture and sale of industrial-use alcohol	

1. All of the companies listed are consolidated subsidiaries except Japan Synthetic Alcohol Co., Ltd., which is an equity-method affiliate.

2. The unit for capital for all companies listed is thousands regardless of currency, except for ProStrakan Inc., for which capital is \$235.

3. Formerly Kirin Kunpeng (China) Bio-Pharmaceutical Co., Ltd. The company name changed in April 2012.

4. Formerly Jeil-Kirin Pharmaceutical Inc. The company name changed in June 2012.



212 Carnegie Center, Suite 101, Princeton, NJ 08540, U.S.A. Tel: 1-609-919-1100 Fax: 1-609-919-1111

- 3 BioWa, Inc. 212 Carnegie Center, Suite 101, Princeton, NJ 08540, U.S.A. Tel: 1-609-580-7500 Fax: 1-609-580-7534
- (4) Kyowa Hakko Kirin California, Inc. 9420 Athena Circle, La Jolla, CA 92037, U.S.A. Tel: 1-858-952-7000 Fax: 1-858-952-7001
- (5) Hematech, Inc. 4401 South Technology Drive, Sioux Falls, SD 57106, U.S.A. Tel: 1-605-361-6793 Fax: 1-605-361-9702

- C/O Amgen, Inc., One Amgen Center Drive, Thousand Oaks, CA 91320-1799, U.S.A. Tel: 1-805-447-1000 Fax: 1-805-447-1010
- 8 Kyowa Hakko Kirin UK Ltd. 258 Bath Road, Slough, Berkshire SL1 4DX, United Kingdom Tel: 44-1753-566000 Fax: 44-1753-566010
- 9 ProStrakan Group Plc Galabank Business Park, Galashiels TD1 1QH, United Kingdom Tel: 44-1896-664000 Fax: 44-1896-664001

- Tel: 86-21-5080-0909 Fax: 86-21-5080-0026
- 1) Kyowa Hakko Kirin Korea Co., Ltd.\*\* 5F, Poonglim Bldg, 124, Teheran-ro, Gangnam-gu, Seoul, 135-784, Korea Tel: 82-2-3471-4321 Fax: 82-2-3471-4322
- 12 Kyowa Hakko Kirin (Taiwan) Co., Ltd. 9F, No. 44, Sec 2, Chung Shan N. Road, Taipei 10448, Taiwan Tel: 886-2-2564-2800 Fax: 886-2-2560-1667
- (B) Kyowa Hakko Kirin (Hong Kong) Co., Ltd. Unit B. 13/F. Manulife Tower. 169 Electric Road, North Point, Hong Kong, People's Republic of China Tel: 852-2956-0828 Fax: 852-2956-1627

(Thailand) Co. Ltd. 20F, United Center Bldg., 323 Silom Road, Bangrak, Bangkok 10500, Thailand Tel: 66-2631-2126 Fax: 66-2631-2125

\* Formerly Kirin Kunpeng (China) Bio-Pharmaceutical Co., Ltd. The company name changed in April 2012.

\*\* Formerly Jeil-Kirin Pharmaceutical Inc. The company name changed in June 2012.



- (i) Kyowa Hakko U.S.A., Inc. 600 Third Avenue, 19th Floor, New York, NY 10016, U.S.A. Tel: 1-212-319-5353 Fax: 1-212-421-1283
- Wowa Hakko U.S.A., Inc. West Coast Office
   85 Enterprise, Suite 430, Aliso Viejo, CA 92656, U.S.A.
   Tel: 1-949-425-0707
   Fax: 1-949-425-0708
- (ii) Kyowa Hakko Bio U.S. Holdings, Inc.
   5469 Nash Road, P.O. Box 1550, Cape Girardeau,
   MO 63702-1550, U.S.A.
   Tel: 1-573-335-4849
   Fax: 1-573-335-1466
- Biokyowa Inc.
   5469 Nash Road, P.O. Box 1550, Cape Girardeau, MO 63702-1550, U.S.A.
   Tel: 1-573-335-4849
   Fax: 1-573-335-1466

Wyowa Hakko Europe GmbH Am Wehrhahn 50, D-40211 Düsseldorf, Germany Tel: 49-211-17545-0 Fax: 49-211-17545-441

17)4

56

(19)(18)

- ② Kyowa Hakko Bio Italia S.r.I. Viale Piero e Alberto Pirelli, no. 6, Milan, 20126, Italy Tel: 39-02-367-069-01 Fax: 39-02-644-704-44
- Wyowa Hakko Bio (Shanghai) Trading Co., Ltd. Beijing Branch Kyowa Hakko Bio Co., Ltd. Beijing Representative Office Room 720, Beijing Fortune Bldg., No. 5 Dong San Huan Bei Lu, Chao Yang District, Beijing 100004 People's Republic of China Tel: 86-10-6590-8515
- B. 60-10-6590-8515
   Fax: 86-10-6590-8517
   Kyowa Hakko Bio (Shanghai) Trading Co., Ltd.
- Kyowa Hakko Bio Co., Ltd. Shanghai Representative Office Room 1501, Metro Plaza, No. 555, Lou Shan Guan Road, Changning District, Shanghai 200051, People's Republic of China Tel: 86-21-6233-1919 Fax: 86-21-6233-6067

Shanghai Kyowa Amino Acid Co., Ltd. No. 158, Xintuan Road, Qingpu Industrial Zone, Shanghai 201700, People's Republic of China Tel: 66-21-5970-1998 Fax: 86-21-5970-1135

1 (2)(3)

- Wyowa Hakko (H.K.) Co., Ltd. Room 1501, 68 Yee Wo Street, Causeway Bay, Hong Kong, People's Republic of China Tel: 852-2895-6795 Fax: 852-2576-6142
- Kyowa Hakko Bio (Shanghai) Trading Co., Ltd. Guangzhou Branch Room 411, China Hotel Office Tower, Liu Hua Road, Guangzhou 510015, People's Republic of China Tel: 86-20-8667-5381 Fax: 86-20-8667-5472
- ⑦ Kyowa Hakko Bio India Pvt., Ltd. Kyowa Hakko Bio Co., Ltd. Mumbai Liaison Office 65, 3 North Avenue, Maker Maxity, Bandra Kurla Complex, Bandra (East), Mumbai 400051, India Tel: 91-22-6725-3457 Fax: 91-22-6725-3458
- Wyowa Hakko Bio Singapore Pte Ltd 47 Scotts Road, #12-05, Goldbell Towers, 228233 Singapore Tel: 65-6732-7889 Fax: 65-6732-7889

# **Corporate Data**

(As of December 31, 2011)

# 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.co.jp/english/index.html

Number of Employees 4,258 (Consolidated: 7,229)

Date of Foundation July 1, 1949

**Paid-in Capital** ¥26,745 million

# **Principal Plants**

Domestic

Pharmaceuticals Takasaki Plant Fuji Plant Yokkaichi Plant Sakai Plant Ube Plant Kyowa Medex Co., Ltd. Fuji Plant

Bio-Chemicals

Yamaguchi Production Center (Hofu, Ube) Healthcare Plant (Tsuchiura) Takaoka Plant

#### **Overseas**

Pharmaceuticals Kyowa Hakko Kirin China Pharmaceutical Co., Ltd.\* (China)

Bio-Chemicals Biokyowa Inc. (U.S.A.) Shanghai Kyowa Amino Acid Co., Ltd. (China)

# **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 Co., Ltd. Research Laboratories

Bio-Chemicals Technical Research Laboratories Tsukuba Development Center

#### Overseas

Pharmaceuticals Kyowa Hakko Kirin Pharma, Inc. (U.S.A.) Hematech, Inc. (U.S.A.) Kyowa Hakko Kirin California, Inc. (U.S.A.) ProStrakan Group Plc (UK) Kyowa Hakko Kirin China Pharmaceutical Co., Ltd.\* (China) Kyowa Hakko Kirin Korea Co., Ltd.\*\* (Korea) Kyowa Hakko Kirin (Taiwan) Co., Ltd. (Taiwan)

# **Management Members**

(As of March 22, 2012)

#### **Board Members**

Executive Director of the Board, President and Chief Executive Officer Nobuo Hanai\*

Executive Director of the Board, Executive Vice President Yoshiharu Furumoto\*

Directors of the Board Kazuyoshi Tachibana

Hiroyuki Kawai

Fumihiro Nishino

Mutsuyoshi Nishimura\*\*

Motoaki Kitayama\*\*

Hajime Nakajima\*\*

Company Auditors Hiroaki Nagai\*\*\*

Manabu Suzuki

Takahiro Kobayashi\*\*\*

Hiroyuki Takahashi\*\*\*

# **Managing Officers**

President and Chief Executive Officer Nobuo Hanai

Executive Vice President Yoshiharu Furumoto

Executive Managing Officers Kazuyoshi Tachibana

Hiroyuki Kawai Vice President Head Production Division

Fumihiro Nishino Vice President Head Sales & Marketing Division

Toshifumi Mikayama Director Overseas Business Department

Yoichi Sato Vice President Head Development Division

Yutaka Ouchi Director Human Resources Department

# Managing Officers

Shigeru Morotomi Director Corporate Communications Department

Nobuhisa Yamazaki Director Legal Department

Etsuo Ohshima Vice President Head Research Division

Toshiro Kawano Director Osaka Branch

Hiroshi Sugitani Director Strategic Product Planning Department

Masafumi Inoue Director Tokyo Branch

Shiro Akinaga Global Development Development Division

Hiroshi Okazaki Director Fiji Research Park

Kazuyoshi Adachi Vice President Head Pharmacovigilance and Quality Assurance Division

Kenya Shitara Director Intellectual Property Department

Masashi Miyamoto Director Regulatory Affairs Department

Takashi Oishi Director Sales Department

Satoshi Nakanishi Director Tokyo Research Park

Niro Sakamoto Director Corporate Strategy & Planning Department

\* Representative director \*\* Outside director \*\*\* Outside company auditor

\* Formerly Kirin Kunpeng (China) Bio-Pharmaceutical Co., Ltd. The company name changed in April 2012. \*\* Formerly Jeil-Kirin Pharmaceutical Inc. The company name changed in June 2012.

# **Investor Information**

(As of December 31, 2011)

Stock Listing Tokyo

Securities Code 4151

#### **Transfer Agent of Common Stock**

The Chuo Mitsui Trust and Banking Company, Limited 33-1, Shiba 3-chome, Minato-ku, Tokyo 105-8574, Japan

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

Number of Shareholders 42,858

## **Principal Shareholders**

	Number of Shares Held (Thousands)	Percentage of Total Shares Issued (%)
Kirin Holdings Company, Limited	288,819	50.10
The Master Trust Bank of Japan, Ltd. (Trust Account)	23,519	4.08
Japan Trustee Services Bank, Ltd. (Trust Account)	18,629	3.23
The Norinchukin Bank	10,706	1.86
Mizuho Trust & Banking Co., Ltd. (Retirement Benefit Trust for Mizuho Bank, Ltd.) <sup>1</sup>	4,781	0.83
The Nomura Trust and Banking Co., Ltd.	4,315	0.75
BBH/BlackRock Global Allocation Fund, Inc.	3,847	0.67
Juniper	3,440	0.60
Nipponkoa Insurance Co., Ltd.	3,246	0.56
Sompo Japan Insurance Inc.	3,135	0.54

1. The 4,781 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 21,037 thousand shares (3.65%) 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.co.jp/