KYOWA KIRIN

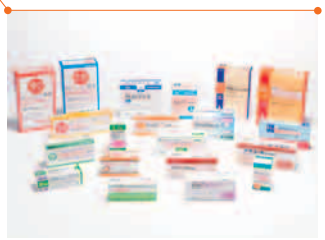
Innovation That Sustains

Kyowa Hakko Kirin

Annual Report 2012

For the year ended December 31, 2012

Contents

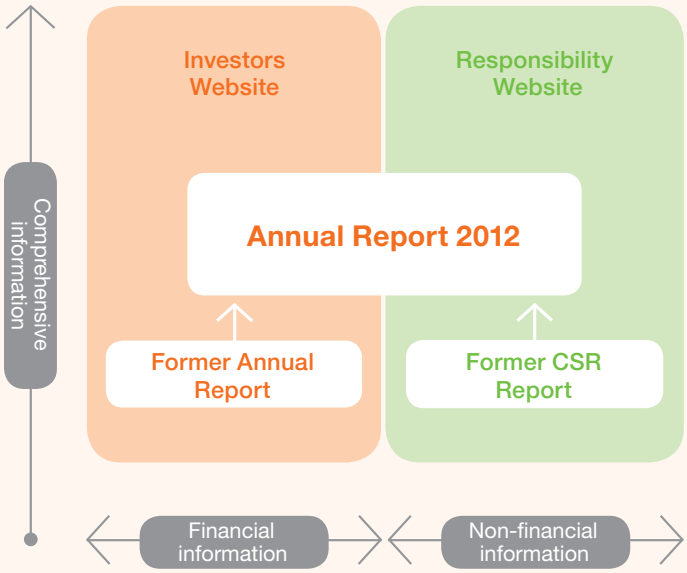


Note to Performance Forecasts
Forecasts contained in Annual Report 2012 represent judgments based on information available as of January 31, 2013. It should be noted that there is a possibility that actual results could differ significantly due to a variety of factors.

Annual Report 2012: An Integrated Publication

The Kyowa Hakko Kirin Group formerly published separately its Annual Report covering a comprehensive range of issues including management philosophy, vision, business strategy and finances, and its CSR Report covering CSR initiatives. However, we have identified the key information in these two publications and integrated it in a single publication, Annual Report 2012.

We will also redo our websites so that they present activities and data that we could not include in Annual Report 2012.



- **Investors Website (http://www.kyowa-kirin.com/investors/index.html)**
- **Responsibility Website (http://www.kyowa-kirin.com/responsibility/index.html)**

Editorial Policy

Scope

- This report covers Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries in Japan and overseas, as well as certain non-consolidated subsidiaries and affiliates.
- Environmental data is annotated for the convenience of readers.

Reporting Period

- The reporting period includes calendar 2012 and part of 2013.
- The reporting period is April 2012 to March 2013 for certain domestic environmental data.

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.

Kyowa Hakko Kirin

Ethical Drugs

We create innovative, efficacious ethical drugs in the categories of nephrology, oncology, immunology/allergy and central nervous system.

Focusing on the categories of nephrology, oncology, immunology/allergy and central nervous system, we are enhancing cooperation and consistency from research and development to manufacturing and marketing to rapidly evolve into a major player. We will steadily launch products from our well-stocked pipeline while creating an effective, highly specialized sales organization with the objective of earning the trust of health care providers.

FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.

Biosimilars

Providing biosimilars that offer high quality at lower costs

The mission of FUJIFILM KYOWA KIRIN BIOLOGICS is to deliver reliable, high-quality and cost-competitive biosimilars by using new technologies that merge Kyowa Hakko Kirin's world-class biopharmaceutical manufacturing technologies with engineering technologies for manufacturing and quality control developed by FUJIFILM Corporation through its various businesses.

Kyowa Hakko Bio Co., Ltd.

Bio-Chemicals

Providing advanced technologies for high-value-added pharmaceutical, medical and health care applications

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

Kyowa Medex Co., Ltd.

Diagnostics

Contributing to the advancement of personalized medical care through companion diagnostics

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

The Kyowa Hakko Kirin Group's Strengths

We have a unique Pharmaceuticals business model that centers on the drug discovery business and encompasses a Diagnostics business that contributes to personalized medical care, a Biosimilars business that leverages Kyowa Hakko Kirin's manufacturing capabilities, and a Bio-Chemicals business that includes the manufacture of the amino acids and the active pharmaceutical ingredients needed to produce therapeutic antibodies. This model allows us to respond flexibly to the operating environment while growing as a global specialty pharmaceutical company.

Operations and CSR Centered on Medium-Term Business Plans

Since the creation of the Kyowa Hakko Kirin Group in 2008, we have energetically executed the strategies of our medium-term business plans and steadily implemented our target business structure and CSR activities to realize our Group Management Philosophy. We will implement the policies of Medium-Term Business Plan – 2013 to 2015, initiated in 2013, with a sense of urgency to take on the challenge of becoming a global specialty pharmaceutical company.

CSR

- June: Formulated the Declaration of Environmental Commitment
- August: Published CSR Report 2010 (formerly called Sustainability Report)
- October: Launched the Diversity & Inclusion Project

- March: Donated money and daily necessities to support victims of the Great East Japan Earthquake
- May: Received ISO 14001 certification for all Kyowa Hakko Bio operations
- August: Established the Kyowa Hakko Kirin Group CSR Policy (approved by the CSR Committee)
- November: Held Kyowa Hakko Kirin Table Tennis Lessons at five sites in Iwate, Miyagi and Fukushima prefectures as part of the Kirin *Kizuna* Relief-Support Project, a recovery support program

- October: Established Basic Policy on the Environment, Safety and Product Safety

- January: Developed "Commitment to Life" after receiving ideas from 1,000 people
- March: Established Kyowa Hakko Kirin Group Compliance Guidelines
  Established Kyowa Hakko Kirin's Human Resources (HR) Philosophy
- May: Received companywide ISO 14001 certification (including the Kyowa Medex Fuji Plant)
- August: Announced plan to complete the changeover of all field sales vehicles in the Pharmaceuticals business to hybrid cars by 2014

2011

- January: Sold all shares of Kirin Kyowa Foods Company, Limited to Kirin Holdings Company, Limited
- March: Sold all shares of Kyowa Hakko Chemical Co., Ltd. to KJ Holdings Inc.
- April: Launched Romiplate®, a platelet producer stimulating thrombopoietin receptors
  Acquired U.K. company ProStrakan Group plc as a wholly owned subsidiary
  Submitted new drug application in Japan for KW-0761, a treatment for ATL
- July: Submitted new drug application in Japan for KW-6500 (apomorphine)
- November: Launched ALLELOCK® Granules

2010

2009

2008

Kyowa Hakko Kirin Group inaugurated

- May: Launched long-acting erythropoiesis stimulating agent NESP® INJECTION PLASTIC SYRINGE
- June: Began phase II clinical trial in Japan for in-house developed KW-0761 for adult T-cell leukemia-lymphoma (ATL)
- December: Launched ASACOL® for ulcerative colitis jointly with Zeria Pharmaceutical Co., Ltd.

- January: Initiated reorganization of production bases (estimated investment of approximately ¥10 billion by 2017)
- March: Completed one of Japan's leading facilities for producing investigational therapeutic antibodies at the Bio Process Research and Development Laboratories
- April: Sold the livestock and fisheries product operations of the Bio-Chemicals business to ASKA Pharmaceutical Co., Ltd.
  Completed a new laboratory at the Tokyo Research Park
  Licensed antiparkinsonian agent Permax® from Eli Lilly Japan K.K.
- June: Launched transdermal analgesic Fentos® Tape for cancer pain treatment
- July: Integrated alcohol sales operations of the Bio-Chemicals business with Mercian Corporation
- November: Launched ALLELOCK® orally disintegrating tablets for the treatment of allergic symptoms

2008 – 2009: **Integrate Strengths**

2010 – 2012:
Selection and Concentration

Kyowa Hakko Kirin

Kyowa Hakko Kirin Group

Global Specialty Pharmaceutical Company

2012

March: Revised Basic Policy on the Environment, Safety and Product Safety

May: Announced Kyowa Hakko Kirin Table Tennis Lessons at 10 sites in Iwate, Miyagi and Fukushima prefectures as part of the fiscal 2012 Kirin *Kizuna* Relief-Support Project: Support for Rebuilding

August: Initiated the Tohoku Bio Education Project at high schools in the Tohoku region to nurture the next generation of biological researchers

2013 2014 2015

- Maximize the value of businesses in Japan
- Promote product development in Europe and the United States
- Improve revenue & profitability in the Bio-Chemicals business

March: Launched a biosimilars joint venture with FUJIFILM Corporation, FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.

Submitted new drug application in Japan for antiparkinsonian agent KW-6002

May: Launched POTELIGEO®, a therapeutic antibody for ATL, and its companion diagnostic, POTELIGEO® TEST, at nearly the same time

June: Launched a strategic alliance with Otsuka Pharmaceutical Co. Ltd. in the fields of diabetes and oncology

July: Completed a production facility for small molecular weight active pharmaceutical ingredients at Daiichi Fine Chemical Co., Ltd.

Launched antiparkinsonian agent Apokyn® Subcutaneous Injection 30 mg

August: Began phase II clinical trial in Europe and the United States for mogamulizumab (KW-0761) for ATL

October: Announced the Bio-Chemicals business would establish a subsidiary in Thailand and build a new amino acids plant

Announced FUJIFILM KYOWA KIRIN BIOLOGICS would develop a biosimilar of bevacizumab, an anti-VEGF humanized monoclonal antibody

November: Submitted new drug application in Japan for KW-2246 for managing breakthrough cancer pain

December: Completed a plant for solid dosage forms within the Ube Plant

Began phase III clinical trial in the United States for mogamulizumab (KW-0761) for cutaneous T-cell lymphoma (CTCL)

- Launch three products* originated by KHK in Europe and the United States
- Progress rapidly in the Biosimilars business
- Expand the Bio-Chemicals business internationally

*KW-0761, KW-6002 & KRN23

Business Development

Medium-Term Business Plan – 2013 to 2015:

Become a Global Specialty Pharmaceutical Company

2016 Onward:

Global Specialty Pharmaceutical Company

Board of Directors

(As of April 1, 2013)

1 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. (to present)

2 Yoshiharu Furumoto

Executive Director of the Board,
Executive Vice President

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

3 Hiroyuki Kawai

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

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

4 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)

5 Fumihiro Nishino

Director of the Board,
Executive Managing Officer,
Vice President
Head Sales & Marketing Division

Nov. 1982: Joined Kyowa Hakko Kogyo Co., Ltd.
Apr. 2004: General Manager, Pharmaceutical Sales Planning 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)

6 Mutsuyoshi Nishimura

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)

7 Motoaki Kitayama

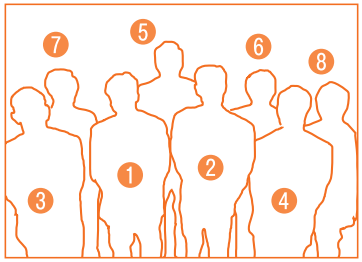
Director of the Board

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
Professor, Nihon University Law School (to present)
Apr. 2009: Member of Central Committee for Adjustment of Construction Work Disputes of the Ministry of Land, Infrastructure, Transport and Tourism (to present)
Mar. 2011: Appointed Director of the Board, Kyowa Hakko Kirin Co., Ltd. (to present)
Jun. 2011: Member of Medical Malpractice Litigation Committee, Supreme Court of Japan (to present)

8 Hajime Nakajima

Director of the Board

Apr. 1977: Joined Kirin Brewery Company, Limited
Mar. 2004: General Manager, Supply Chain Management Division, Kirin Brewery Company, Limited
Mar. 2006: General Manager, Nagoya Plant Production Division, Domestic Alcohol Beverages Company, Kirin Brewery Company, Limited
Mar. 2007: Executive Officer, Kirin Brewery Company, Limited
Mar. 2009: Managing Director, Kirin Brewery Company, Limited
Mar. 2011: Managing Director, Kirin Holdings Company, Limited (to present)
Mar. 2012: Appointed Director of the Board, Kyowa Hakko Kirin Co., Ltd. (to present)
Managing Director, Representative Director, Kirin Holdings Company, Limited (to present)



Highlights

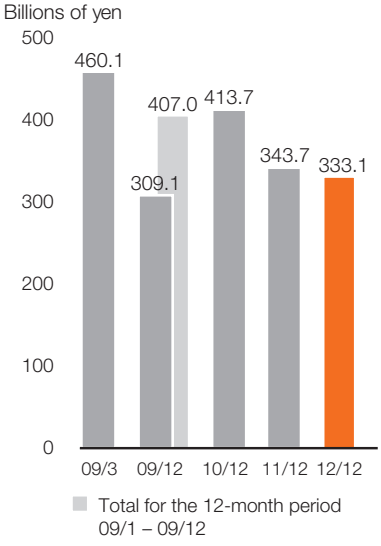
Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries
For the years ended December 31, 2012, 2011 and 2010

- The operating environment remains challenging. Issues include more rigorous approval processes, the promotion of measures to restrain health care costs, the growing share of generic pharmaceuticals and NHI drug price revisions.
- The Pharmaceuticals business generated record earnings because of the robust performance of core products coupled with the introduction of technologies through the development of biosimilars and the full-year contribution of ProStrakan.
- We have achieved record operating income for the past three consecutive fiscal years, largely because of the strong performance of core products in the Pharmaceuticals business.

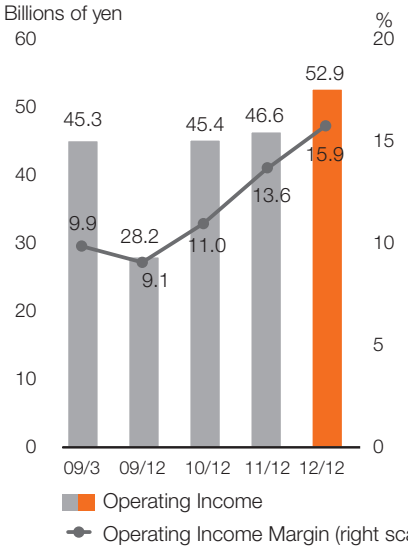
	Millions of yen				Thousands of U.S. dollars[1]
	2012	2011[3]	2010	2012/2011	**2012**
For the Year:					
Net sales	**¥333,158**	¥343,722	¥413,738	(3.1)%	**$3,847,987**
Operating income	**52,905**	46,614	45,410	13.5 %	**611,055**
Net income	**24,199**	25,608	22,197	(5.5)%	**279,505**
Capital expenditures	**27,808**	19,697	29,374	0.4 %	**321,188**
Depreciation and amortization	**20,904**	22,833	22,188	(8.4)%	**241,449**
R&D expenses	**44,808**	47,961	44,210	(6.6)%	**517,544**
At Year-End:					
Total assets	**679,342**	658,873	695,862	3.1 %	**7,846,409**
Interest-bearing debt	**5,699**	6,042	7,515	(5.7)%	**65,830**
Total net assets	**555,898**	540,023	544,992	2.9 %	**6,420,630**
Total shareholders' equity	**560,663**	554,856	553,172	1.0 %	**6,475,669**
	Yen				U.S. dollars[1]
Per Share Data:					
Net income–basic[2]	**¥ 44.12**	¥45.16	¥38.96	(2.3)%	**$ 0.509**
Net assets	**1,013.6**	970.2	954.6	4.5 %	**11.707**
Cash dividends	**20**	20	20	0.0 %	**0.231**
Financial Ratios:					
Return on assets (ROA)	**3.62%**	3.78%	3.19%		
Return on equity (ROE)	**4.43%**	4.73%	4.11%		

1. U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥86.58=U.S.$1, the approximate exchange rate at December 31, 2012.
2. 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.
3. Results for 2011 include Kyowa Hakko Chemical Co., Ltd. results for the three months ended March 31, 2011.

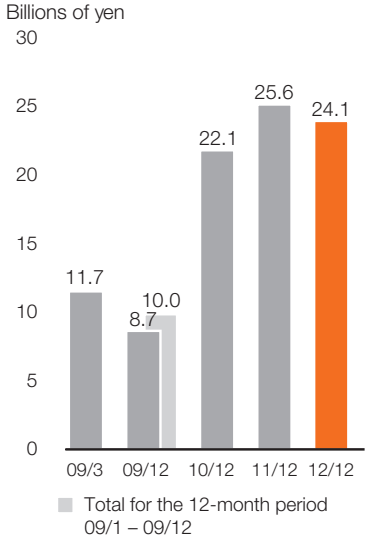
Net Sales



Operating Income



Net Income



Note: 09/12 data is for the nine months ended December 31, 2009 because the Kyowa Hakko Kirin Group changed its fiscal year-end.

Millions of yen

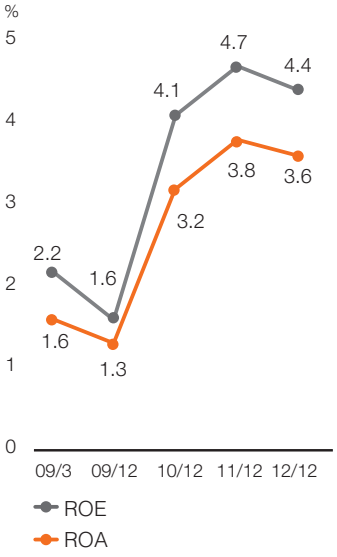
	2012	2011[3]	2010	2012/2011
Overseas Sales	**¥72,632**	¥71,152	¥85,140	2.1 %
Ratio of Overseas Sales to Net Sales	**21.8%**	20.7%	11.1%	1.1 points
Sales by Region:				
Japan	**260,524**	272,568	399,334	(4.4)%
United States	**21,207**	20,071	23,467	5.7 %
Europe	**30,997**	25,169	21,477	23.2 %
Asia	**19,880**	25,426	39,689	(21.8)%
Other Regions	**548**	486	507	12.8 %

	2012	2011	2010[4]	2012–2011
Number of Employees:				
Japan	**5,994**	6,050	6,720	(56)
United States	**364**	350	298	14
Europe	**346**	320	46	26
Asia	**539**	509	420	30
Total	**7,243**	7,229	7,484	14

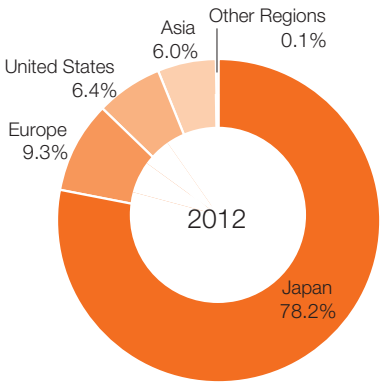
	2012	2011	2010[4]	2012/2011
Environmental Data[5]:				
Energy used (1,000 kl of oil equivalent)	**145**	143	352	1.4 %
CO_2 emissions (1,000 tons)	**337**	333	791	1.2 %
SO_x (Tons)	**11**	13	12	(15.4)%
NO_x (Tons)	**30**	32	317	(6.3)%

4. Number of employees and environmental data for 2010 include Kyowa Hakko Chemical Co., Ltd.
5. The domestic plants and research laboratories of Kyowa Hakko Kirin Co., Ltd., Kyowa Medex Co., Ltd., Kyowa Hakko Bio Co., Ltd. and Daiichi Fine Chemical Co., Ltd. are covered. The overseas plants of Kyowa Hakko Kirin China Pharmaceutical Co., Ltd. (China), BioKyowa Inc. (U.S.A.) and Shanghai Kyowa Amino Acid Co., Ltd. (China) are also covered.

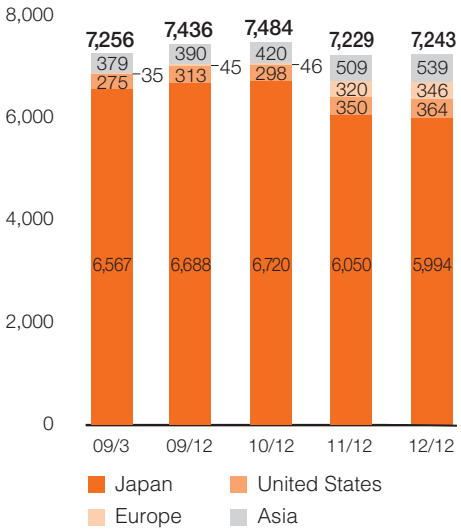
ROA and ROE



Sales Composition by Geographic Area



Number of Employees



An Interview with President and CEO Nobuo Hanai

The Kyowa Hakko Kirin Group will leverage its unique operating foundation to decisively become a global specialty pharmaceutical company.

Nobuo Hanai

Nobuo Hanai
President and Chief Executive Officer

Q1. Please begin by discussing results for 2012.

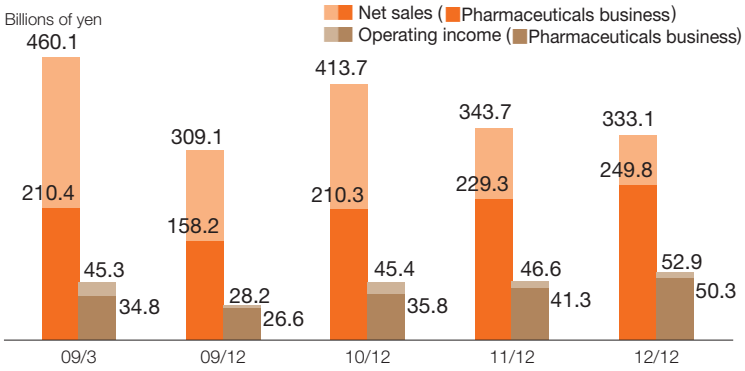
We achieved record income for the third consecutive year because of strong sales of core products in the Pharmaceuticals business and other factors.

The operating environment for the Pharmaceuticals business during 2012 remained challenging due to factors including the implementation of policies to reduce health care costs, the increasing share of generic drugs, and National Health Insurance (NHI) drug price revisions. In this environment, the Kyowa Hakko Kirin Group moved ahead with drug development in Europe, the United States and Asia while focusing on Japan in expanding sales of core products and quickly penetrating markets for new products. We also made steady progress in building the operating foundation for global growth in the future in ways such as strengthening cooperation with ProStrakan Group plc (ProStrakan), which we acquired in 2011, and participating in the Biosimilars business by establishing a joint venture with FUJIFILM Corporation.

In the Bio-Chemicals business, the impact of the strong yen was pronounced because overseas activities account for a comparatively large share of the overall business. However, we worked to expand sales of and revise prices for high-value-added products such as amino acids, nucleic acids and related compounds with a focus on high-demand pharmaceutical and medical applications. We also took steps to strengthen mail-order sales of our own brands of health food materials such as ornithine in the health care products business.

Net sales decreased due to the impact of removing the Chemicals business from the scope of consolidation in March 2011. This business had sales of ¥33.5 billion and operating income of ¥2.1 billion in the first quarter of 2011. However, operating income increased to a record high for the third consecutive year due largely to strong sales of core products in the Pharmaceuticals business. Net income decreased absent the gain on sales of affiliates' stock in 2011.

2009 to 2012 Results



Q2. Please provide an overview of Medium-Term Business Plan – 2010 to 2012, which the Group completed in 2012.

A key outcome of the plan was that we built a globally unique operating foundation through business portfolio selection and concentration.

Selection and Concentration of Business Portfolio

Kyowa Hakko Kogyo Co., Ltd., which was strong in therapeutic antibody technology, merged with strategic alliance partner Kirin Pharma Company, Limited in 2008 to create Kyowa Hakko Kirin Co., Ltd. Rapid selection and concentration of our businesses has been a top priority since then. In 2008, Kyowa Hakko Kogyo was involved in the diverse businesses of pharmaceuticals, chemical products and food products, but the Kyowa Hakko Kirin Group needed to concentrate its resources to support its vision of becoming a global specialty pharmaceutical company taking on challenges worldwide. The Group's chemicals and food products

businesses had difficulty responding flexibly to a variety of market needs, so we began looking for buyers that could enable these businesses to grow. We therefore implemented decisive policies during Medium-Term Business Plan – 2010 to 2012 with a focus on business portfolio selection and concentration.

We sold all shares of our chemicals and food products businesses because we felt that would best allow them to make use of their respective operating strengths. We found partners best able to provide future growth potential while preserving the jobs of employees, which was a condition of sale.

At the same time, when the merger created the Kyowa Hakko Kirin Group we did not have an adequate sales force outside Japan except in Asia. In considering the development plan for KW-0761, which became the therapeutic antibody POTELIGEO® and was positioned as a strategic product for becoming a global specialty pharmaceutical company, a key priority was quickly establishing operating bases in Europe and the United States. We therefore added ProStrakan to the Group in 2011, which allowed us to achieve our long-held objective of acquiring a sales network in Europe and the United States. ProStrakan has approximately 150 medical representatives (MRs) in Europe and approximately 50 in the United States, an optimal scale for sales of KW-0761 in these markets and a base that perfectly satisfies the functional parameters we sought. The acquisition opened a new epoch for the Group's growth and development. It also brought ProStrakan's talented employees to the Group, and working with them will be extremely significant because we are emphasizing diversity in becoming a global specialty pharmaceutical company.

Strengthened Profitability by Reorganizing Production Facilities

The reorganization of domestic production sites is also proceeding steadily according to plan because of the understanding and support of our employees. This challenging long-term program under way until 2017 is maintaining stable supply while shifting production to new bases. In the Pharmaceuticals business, we plan to enable the efficient production of high-quality pharmaceuticals by making the

Achievements of Medium-Term Business Plan – 2010 to 2012

Strategy Execution

Selection and concentration of business portfolio
- Divested Chemicals and other businesses
- Acquired ProStrakan, ensuring penetration of U.S. and European pharmaceutical markets
- Entered Biosimilars business through joint venture with FUJIFILM Corporation

Strengthened profitability by reorganizing production facilities
- Reorganized production facilities including those of the Bio-Chemicals business
- Constructed new production facilities with automated equipment

Developed highest global standards for antibody technology business
- Launched POTELIGEO®, the world's first POTELLIGENT® therapeutic antibody
- Promoted out-licensing and advanced therapeutic antibodies through development stages

Building a globally unique operating foundation to become a global specialty pharmaceutical company

Pipeline Achievements

10 Drugs Entered Clinical Trials*

KHK4563	KHK2866	LY2523355	CEP-37250/KHK2804	KHK2898
RTA 402	KHK4827	KHK6188	KHK4577	KHK7580

11 Drugs Launched in Japan
(New Drugs, Expanded Applications, Additional Dosages/Changes)

2010	2011	2012
NESP® subcutaneous	Romiplate®	Apokyn®
ALLELOCK® (infants)	ALLELOCK® Powder	POTELIGEO®
ALLELOCK® OD	NAUZELIN® OD	Change to liquid volumes of NESP®
DESMOPRESSIN® (Room temperature)		MINIRINMELT® OD

New drugs　Expanded applications　Additional dosages/changes

*Phase I as defined by First Patient In (FPI)

Filed
KW-6002
KW-2246
NESP® (infants)
TOPINA® (infants)
Dacarbazine®
Leunase®
ACTIVACIN®
Pasetocin®

Takasaki Plant in Gunma Prefecture a production base for injectable formulations including biopharmaceuticals while consolidating solid oral dosage forms at the Ube Plant in Yamaguchi Prefecture.

Developed Highest Global Standard for Antibody Technology Business

We have steadily built our therapeutic antibody technology business. Kyowa Hakko Kirin has quickly taken advantage of the unique benefits of the merger that created it, with crucial outcomes including the launch of the new in-house therapeutic antibody POTELIGEO®. At present, pharmaceutical companies worldwide have licensed POTELLIGENT® technology and used it to develop seven therapeutic antibodies that have advanced to the clinical trial stage. In addition, four therapeutic antibodies we developed in-house and licensed to other companies have advanced to the clinical trial stage. We believe that our therapeutic antibody business will begin contributing to earnings from 2015.

Looking back on the past three years, we have implemented a succession of initiatives to select and concentrate our business portfolio with a sense of urgency. As a result, we have built a globally unique operating foundation.

Q3. Please explain the creation of a globally unique operating foundation in greater detail.

We have become a corporate group that can respond flexibly to changes in the external environment while opening up business opportunities.

The core of the Kyowa Hakko Kirin Group is Kyowa Hakko Kirin and its Pharmaceuticals business involving new drug research, development, production and sales. The Group also encompasses Kyowa Medex Co., Ltd. and its Diagnostics business expected to contribute to personalized medical care; FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. and its Biosimilars business that develops, manufactures and sells generic biopharmaceuticals; and Kyowa Hakko Bio Co., Ltd. and its broadly based Bio-Chemicals business that uses world-class fermentation and synthesis technologies for operations ranging from amino acids, active pharmaceutical ingredients and pharmaceutical intermediates to supplements. Thus, complementing our Pharmaceuticals business with ancillary operations allows the Group to capture a broad array of business opportunities while also responding appropriately and flexibly to an uncertain and volatile external environment.

Exemplifying the value of our unique operating foundation, in May 2012 we launched the first therapeutic antibody that we handled from research through development, POTELIGEO®, and its companion diagnostic, POTELIGEO® TEST, at nearly the same time. This outcome was uniquely possible for the Group because it encompasses pharmaceuticals and diagnostics, which enables the exchange of information from the early stages of development.

In addition, the cell culture processes used in the production of therapeutic antibodies such as POTELIGEO® require high-quality amino acids. Pharmaceutical-grade amino acids are one category of Kyowa Hakko Bio's amino acids business, which gives the Group access to a stable supply of the high-quality amino acids necessary to produce therapeutic antibodies. This business portfolio is a Group strength, and we must maximize corporate value by actualizing the potential of synergies among our businesses.

Q4. What are your expectations for the newly launched Medium-Term Business Plan – 2013 to 2015?

We will thrive and become a global specialty pharmaceutical company in an evolving external business environment that we expect to become increasingly challenging.

The three years of Medium-Term Business Plan – 2013 to 2015 will be crucial to the Group's global specialty pharmaceutical company aspirations from 2016 onward. The various uncertainties we face in Japan include lower drug prices and higher consumption taxes. Given this kind of environment, steadily

increasing earnings and establishing the foundation for significant progress overseas are critical.

Becoming a global specialty pharmaceutical company will be our theme during the coming three years as we implement our three core strategies: further strengthen competitiveness in Japan through our category-based strategy; expand our business base in the United States, Europe and Asia and aim to become a global specialty pharmaceutical company; and strengthen the revenue base of our Bio-Chemicals business. We will implement these policies with a sense of urgency.

While the external environment will be challenging, the Group is united in its intent to press forward vigorously to become a global specialty pharmaceutical company. Moreover, our outlook for 2016 onward involves selling in Europe and the United States the pharmaceuticals we create in-house during the first step toward becoming a global specialty pharmaceutical company.

Our approach will consistently emphasize global employees with diverse personalities and capabilities who share the principles of the Group Management Philosophy and "Commitment to Life," while Group companies will exercise their diverse strengths and synergies. We will therefore focus energetically on employee diversity.

We have set numerical targets in our business plan for 2013 and guidance for 2015. Over the coming three years, we expect various changes in the operating environment in Japan. For starters, the NHI drug price revisions for 2014 are not yet clear because of the large variety of pending issues. For example, we do not know the extent to which the revisions will incorporate the promotion of generic drug use, the degree to which prices for long-term listed drugs will be revised downward, or if the premium to promote the development of new drugs and eliminate off-label use will be permanently implemented. Past examples also suggest irregular decreases in drug prices due to the increase in the consumption tax. The numerical targets we announced in our guidance for 2015 are based on this environment, and we plan to announce revised figures annually. On the other hand, the numbers we announced for the plan are numerical targets that have the full commitment of management.

Overview of Medium-Term Business Plan – 2013 to 2015

Become a Global Specialty Pharmaceutical Company

Basic strategy

1. Further strengthen competitiveness in Japan through our category-based strategy
2. Expand our business base in the United States, Europe and Asia and aim to become a global specialty pharmaceutical company
3. Strengthen the revenue base of our Bio-Chemicals business

Targets

Leveraging synergies to achieve sustainable growth by responding to changes in the operating environment

(Billions of yen except where noted)

	2012 Results	2013 Planned	2015 Guidance[1]
Net sales	333.1	338.0	358.0
Operating income	52.9	55.0	60.0
(Operating income to sales ratio	15.9%	16.3%	16.8%)
Ordinary income[2]	49.0	49.0	53.0
Net income[2]	24.1	30.0	30.0
EPS (¥)[3]	61.0	71.7	71.7

1. To be updated annually
2. Income after amortization of goodwill
3. EPS calculated using net income before amortization of goodwill

Q5. What specific initiatives will Medium-Term Business Plan – 2013 to 2015 involve?

Maximizing the Value of Our Drugs to Earn the Trust of Health Care Providers

Further Strengthen Competitiveness in Japan through Our Category-Based Strategy

We have a strong, comprehensive presence that spans research and development to production, sales and reliability assurance in the four categories of nephrology, oncology, immunology/allergy and central nervous system. We will structure functionally linked product portfolio management (PPM) for these categories and appropriately maximize the value of domestic sales. Domestic operations account for about 75 percent of earnings, so further strengthening them is essential for building the operating foundation for becoming a global specialty pharmaceutical company.

In addition to steadily launching new drugs from our well-stocked pipeline, we will build an effective marketing organization that makes use of our extensive expertise to maximize sales and earn the trust of health care providers.

Our commitment does not end once we launch a pharmaceutical. The creation of a system for nurturing drugs is extremely important. This system involves feedback and evidence from health care providers and patients that substantiates efficacy, while research, development, sales and manufacturing divisions share information to maximize the value of drugs with additional formulations and indications.

Accelerating Development with a One Drug Development Organization[1] and Building a Development and Marketing Organization for Global In-House Drugs

Expand Our Business Base in Europe, the United States and Asia and Aim to Become a Global Specialty Pharmaceutical Company

We plan to aggressively invest increased earnings from the domestic Pharmaceuticals business in European and U.S. research and development.

We will make Kyowa Hakko Kirin Pharma, Inc. (KKP) the central base for development in Europe and the United States within a one drug development organization that melds the development capabilities of KKP and ProStrakan. This one drug development organization is already functional for the development of KW-0761 and is reporting accelerated development.

In the United States, we see programs supporting the launch of KW-0761 as crucial to significant progress toward becoming a global specialty pharmaceutical company. We are therefore building a global in-house drug development and marketing organization to achieve self-sustaining growth in the enormous U.S. market.

In addition, ProStrakan is executing a business model for aggressively licensing late-stage development projects and launched products, which will enhance our market presence and product lineup in key countries in Europe and the United States.

Our top priority in Asia is reorganizing our operating foundation for consistent growth in China. Meanwhile, subsidiaries in countries and regions with sustained economic growth, including South Korea, Taiwan, Singapore and Thailand, are implementing business strategies in accordance with their respective national conditions and circumstances.

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

Creating a Powerful Business Structure That is Resistant to the Impact of Exchange Rates

Strengthen the Revenue Base of Our Bio-Chemicals Business

Exchange rate fluctuations significantly impact earnings in our Bio-Chemicals business. We will appropriately allocate resources to insulate this business against the impact of exchange rates and implement decisive reforms to strengthen its business structure. Specifically, we will reorganize and revamp production bases in Japan and overseas, including the Yamaguchi Production Center, Daiichi Fine Chemical Co., Ltd., and BioKyowa Inc. in the United States, to further enhance cost competitiveness. We will also create a global operating foundation through means including the construction of a new production base in Thailand to meet strong global demand for high-value-added amino acids.

In the domestic health care products business, the company handling raw material and mail-order sales, Kyowa Wellness Co., Ltd., joined the Kyowa Hakko Bio organization in January 2013 through an absorption merger. The new organization will use effective advertising and promotion activities to stimulate mail-order sales, exemplified by ornithine.

Q6. The Group's research and development aims include drug discovery using a global network. What are some specific initiatives?

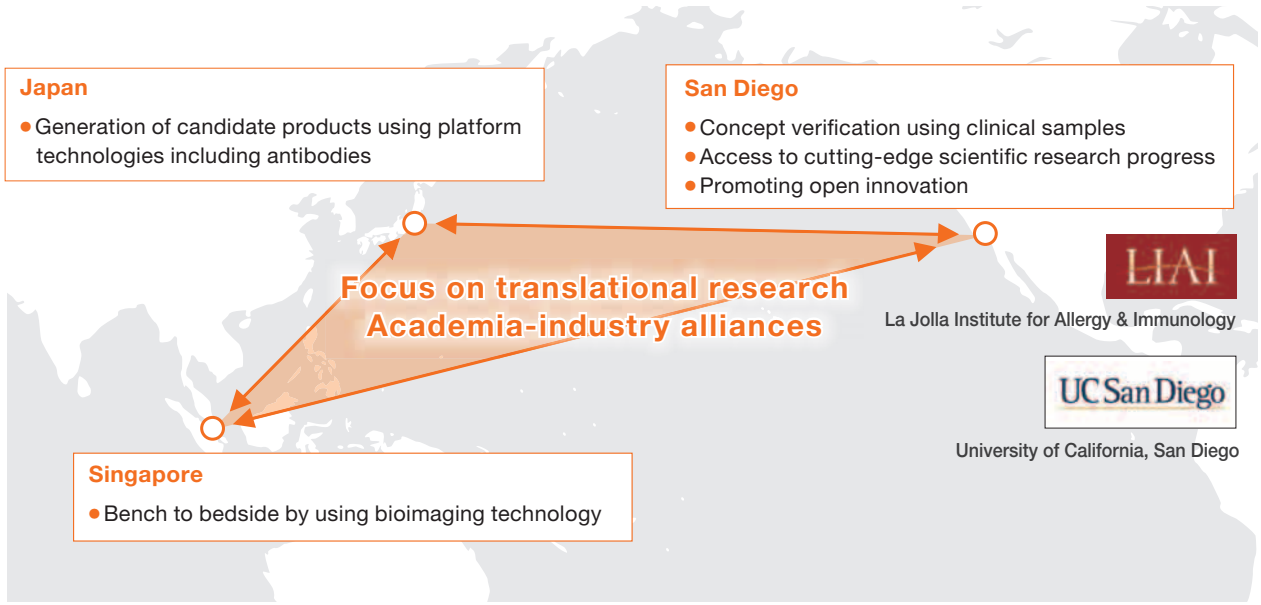
We will promote drug discovery using open innovation and translational research.

Open innovation involves the use of information and knowledge from outside Kyowa Hakko Kirin, and we have always incorporated open innovation in our drug discovery process. Creating new drugs using only our internal capabilities requires extraordinary effort. We therefore seek knowledge globally and focus on incorporating the results of leading-edge research generated by universities and research institutes. A rapid succession of medical innovations is expected for induced pluripotent stem (iPS) cells and other areas that are the focus of attention today. We will therefore promote closer open innovation at earlier stages of research through energetic communication between external researchers and our scientists to create knowledge and technology synergies.

We also observe that the drug discovery success rate is decreasing. Drugs that are effective in nonclinical studies often turn out to be ineffective in clinical studies, or safety problems arise. These and other issues commonly bring development to a halt. We will therefore cooperate with health care providers to introduce clinical trials that use translational research from early stages to predict efficacy and safety for patients with the intention of raising the success rate of new drugs.

We will devote our global network of research activities to drug discovery that uses this kind of open innovation and translational research. Centered on our strengths in antibody technology, we will deploy leading-edge biotechnology as we work passionately to create new breakthrough drugs that address unmet medical needs.

Global Network-Based Drug Discovery Research



Q7. Medium-Term Business Plan – 2013 to 2015 includes the creation of a corporate culture and organization appropriate for a global specialty pharmaceutical company. What are Kyowa Hakko Kirin's views and initiatives regarding CSR?

We will integrate CSR into our business activities to quickly establish the foundation for rapid progress toward becoming a global specialty pharmaceutical company.

The Kyowa Hakko Kirin Group truly contributes to society through its business activities in accordance with its Management Philosophy to "contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies." We therefore emphasize the creation of new value for society by integrating CSR with our business activities.

We also stress the establishment of a foundation for aligning all aspects from quality assurance and safety to human resources with global standards to support rapid progress toward becoming a global specialty pharmaceutical company from 2016 onward. Medium-Term Business Plan – 2013 to 2015 therefore prescribes a system that enables appropriate quality assurance and a stable supply of core pharmaceutical products; thorough compliance on a global level and business promotion in accordance with the laws and regulations of each country and region we serve; and CSR initiatives appropriate for a global specialty pharmaceutical company that meet the expectations of society.

In particular, we are upgrading and strengthening our global framework for audits and quality assurance based on our recognition that accelerated global development necessitates compliance with differing national and regional regulatory systems along with initiatives that accommodate these varying circumstances. We are also deploying people to overseas subsidiaries including ProStrakan to enhance global corporate governance and support CSR initiatives.

In addition, we are energetically involved with human resource diversity. Our Global Executive Program for training employees selected from Europe, the United States, Japan and elsewhere in Asia immerses participants in true diversity through an enhanced one-year program that we intend to continue. We are also concentrating on ensuring an environment in which women are better able to exercise their capabilities.

Q8. Medium-Term Business Plan – 2013 to 2015 raises the consolidated payout ratio[2] to 40 percent. Please discuss this increase.

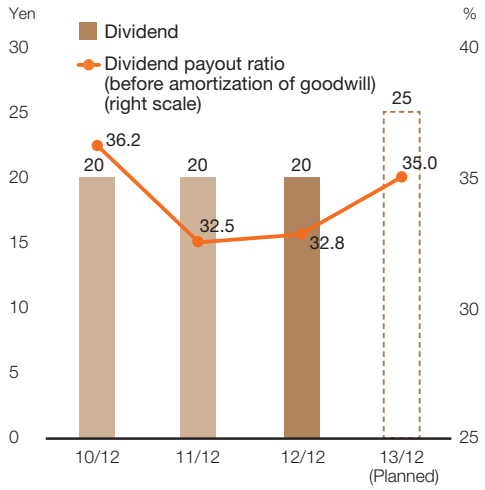
We will respond to the expectations of shareholders and investors to achieve even greater progress for the Kyowa Hakko Kirin Group.

Kyowa Hakko Kirin positions shareholder returns as a top management priority. Our medium-term business plan has raised the target for shareholder returns for 2013 from a payout ratio of 30 percent or higher under the previous medium-term business plan to a payout ratio of 40 percent. This target is based on our belief that meeting the expectations of shareholders and investors to the best of our ability further encourages them to support the Group's development.

We therefore intend to increase cash dividends per share for 2013 to ¥25 from ¥20 for 2012.

2. Based on earnings before amortization of goodwill

Consolidated Dividend and Dividend Payout Ratio



Q9. Please conclude by commenting on the Group's commitment to achieving its medium-term business plan and to its stakeholders.

Our watchwords will be fairness, transparency and speed as we accelerate management and respond to stakeholder expectations.

The 2015 guidance targets for net sales of ¥358 billion and operating income of ¥60 billion will not be easy to achieve. Naturally, my job is to provide leadership to implement various measures and guide the Group in the right direction.

Putting the fundamentals of fairness, transparency and speed into practice will vitalize our organization and enhance communication. While simultaneously realizing these three elements will entail conflicts and will require imagination and creativity, I am committed to increasing management speed by eliminating the unreasonable, the inefficient and the inconsistent.

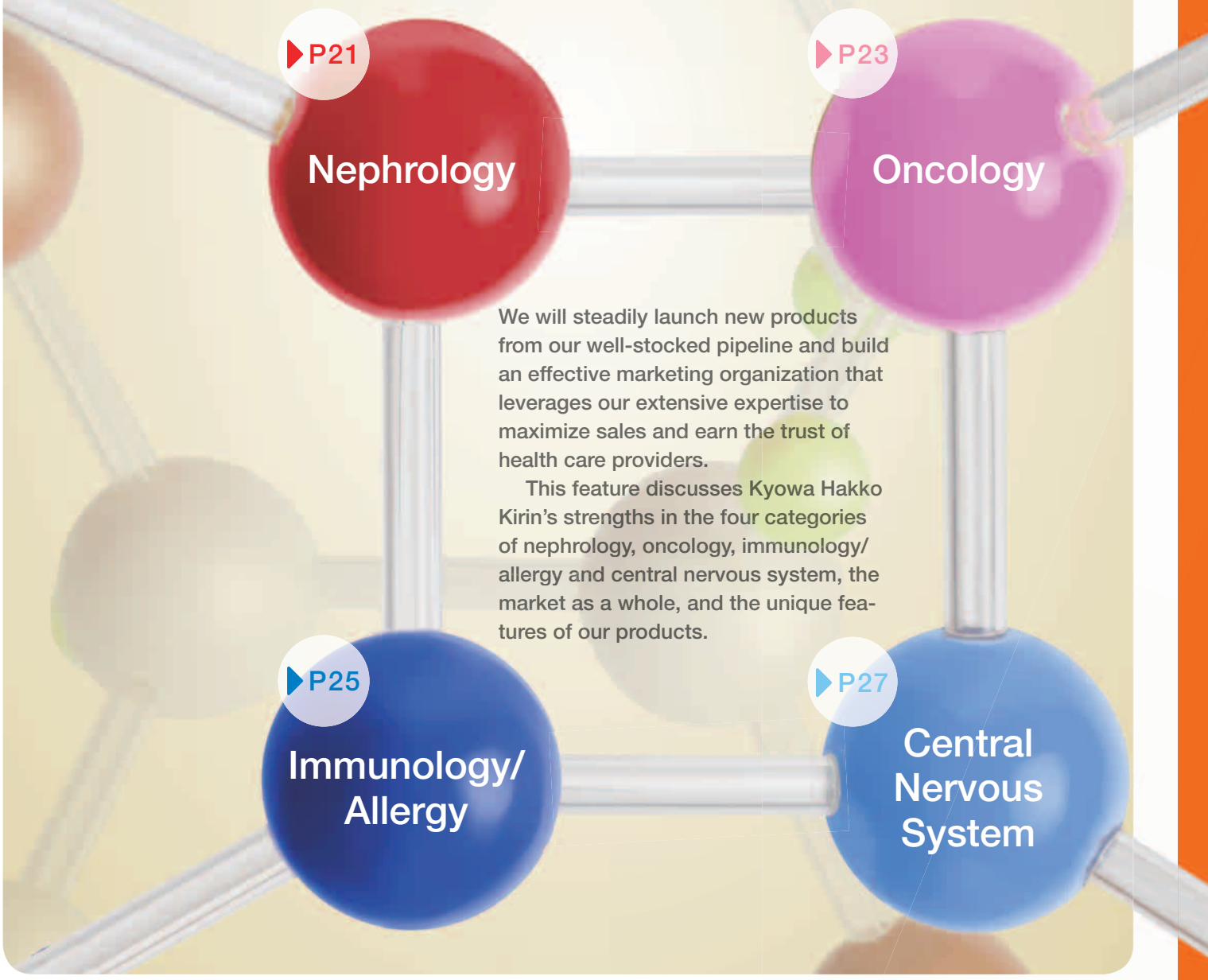
The Kyowa Hakko Kirin Group has built a unique Pharmaceuticals business that encompasses biosimilars, diagnostics and bio-chemicals around a core of drug discovery. Our operating structure incorporates a high-risk, high-return drug discovery business model coupled with stable businesses centered on amino acids, which makes us a company that stakeholders can have confidence in over the long term.

We intend to achieve the targets of our medium-term business plan, fulfill our corporate responsibilities, and make rapid progress toward becoming a global specialty pharmaceutical company as a life-sciences company that society trusts.

The Kyowa Hakko Kirin Group will be counting on the support and understanding of its stakeholders as it takes on these challenges.

Innovation for Strong Growth

One of the fundamental strategies of Medium-Term Business Plan – 2013 to 2015 is further strengthening competitiveness in Japan through a category-based strategy. We will focus on four categories to make rapid progress toward becoming a global specialty pharmaceutical company by strengthening consistent coordination among all of our capabilities from research and development to manufacturing and sales.



We will steadily launch new products from our well-stocked pipeline and build an effective marketing organization that leverages our extensive expertise to maximize sales and earn the trust of health care providers.

This feature discusses Kyowa Hakko Kirin's strengths in the four categories of nephrology, oncology, immunology/allergy and central nervous system, the market as a whole, and the unique features of our products.

Nephrology

A leader in treating kidney disease, we will further enhance our strengths in the therapeutic areas of anemia and bone mineral metabolism disorders to take on the challenge of kidney disease and related maladies.

Basic Strategies of Medium-Term Business Plan – 2013 to 2015

In the dialysis market, which is the core of our nephrology category, we are maintaining and expanding the markets for our erythropoiesis stimulating agent (ESA) NESP® and our secondary hyperparathyroidism treatment REGPARA®. In the predialysis market, we will aggressively promote NESP® as an anemia therapy while researching and developing drugs for metabolic bone disease as a complication of chronic kidney disease (CKD-MBD), nephrosis and nephritis. In addition, we are taking on the new challenge of launching the DPP-4 inhibitor saxagliptin during 2013 to treat diabetes, which is the most common cause of chronic kidney disease.

Chronic Kidney Disease (CKD) Market Scale

CKD afflicts 13.3 million* patients in Japan, or one in eight people over the age of 20, and is called the new national disease. More than 300 thousand patients in Japan are undergoing dialysis, and CKD is closely linked to metabolic syndrome and lifestyle diseases such as high blood pressure and diabetes. Anyone can develop CKD.

Kyowa Hakko Kirin is expanding its presence as a leading provider of drugs to treat various complications associated with dialysis and predialysis.

* Japanese Society of Nephrology, *Evidence-Based Practice Guideline for the Treatment of CKD*, 2009

ESA Market

No.1

share in Japan

Copyright 2013 IMS Japan K.K., *IMS JPM December 2012*

Maintaining and Expanding Core Product Sales

NESP® was designed to be highly effective for all CKD patients from predialysis through dialysis as an anemia therapy

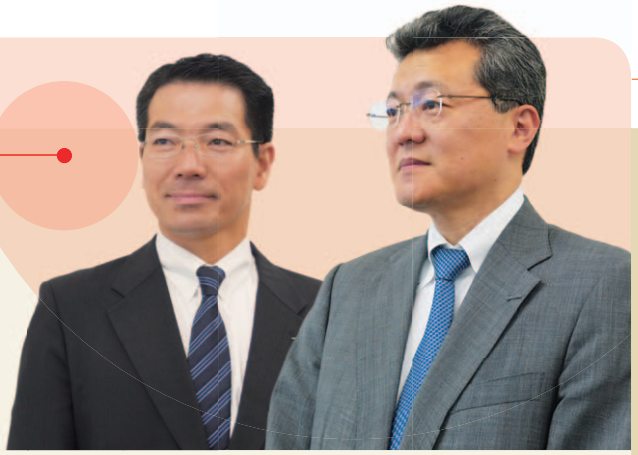
NESP® (Launched July 2007)

Not complacent because we have number one brands, we are committed to further enhancing our strengths by forging ahead with our category-based strategy.

Not complacent because we have number one brands, we see the challenge of research and development to improve treatments as a key priority. We are proud of our nephrology portfolio we pioneered by working with many people both internally and externally, but we still have improvements to make that will require our creativity. We will further enhance our strengths in the areas of anemia and CKD-MBD to propose even better therapies. Considering available treatments for kidney disease, many unmet medical needs still exist. We intend to take on the challenge of deploying our research and development capabilities to find therapies in the difficult fields of nephrosis and nephritis.

During Medium-Term Business Plan – 2013 to 2015, we will complement the activities I mentioned above with

Initiatives to Enhance Our Marketing Organization and Improve Treatment



Ken Unemoto
Associate Director
Nephrology Product Group
Marketing Department
Sales & Marketing Division

Kenji Shimamura
Associate Director
Metabolism, Endocrine and Cardiovascular Product Group
Marketing Department
Sales & Marketing Division

Kyowa Hakko Kirin is the only pharmaceutical company in Japan with an MR organization that specializes in nephrology. We leverage it fully and earn the praise of health care providers by deploying a broad understanding of the dialysis treatment environment to make comprehensive treatment proposals that are not limited to therapies using Kyowa Hakko Kirin products.

We enable our MRs to make these comprehensive proposals by emphasizing programs that are structured to provide detailed MR education.

We will also coordinate the information dissemination activities of MRs in the cardiovascular and diabetes areas within both the Sales & Marketing Division and among relevant divisions throughout the Group.

Kyowa Hakko Kirin does not simply sell the pharmaceuticals it has launched. We also look for ways to improve CKD treatment methods by cooperating with numerous doctors to support large-scale cohort studies.[1] Specifically, we have supported the CKD Japan Cohort (CKD-JAC) study for predialysis and the Dialysis Outcomes and Practice Patterns Study[2] (DOPPS) Mineral and Bone Disorders Outcomes in Stage 5D of Chronic Kidney Disease (MBD-5D) study for dialysis. These approaches were unique to Kyowa Hakko Kirin, and we will use the data we acquired as the basis for working with nephrology doctors to improve the results of CKD treatment.

1. A research technique that involves follow-up surveys of many people over a long period of time for use in epidemiology
2. Study of dialysis patient treatment and disease progression. Please refer to page 65 for additional details.

that allows flexible dosing regimens according to patient condition and hospital visit frequency. NESP® has received strong support from the medical community since its launch in 2007 because of its safety, effectiveness and other benefits in correcting anemia, and its share of the ESA market in 2012 was approximately 60 percent. We will further enhance our strength in the dialysis market while expanding in the underserved predialysis market to provide even better approaches for treating anemia.

We launched REGPARA®, a treatment for secondary hyperparathyroidism, in 2008. Featuring a breakthrough mechanism of action, it is the only calcium receptor agonist approved in Japan. It has received wide market acceptance because it has increased treatment options for secondary hyperparathyroidism and contributed to the effectiveness of treatment. Similar to NESP®, REGPARA® has played a key role in driving our performance in the nephrology category since its launch, and we will continue to expand the market.

Kyowa Hakko Kirin offers two other drugs for CKD-MBD besides REGPARA®: the secondary hyperparathyroidism treatment ROCALTROL® and the hyperphosphatemia treatment PHOSBLOCK®.

Our core cardiovascular products are hypertension and angina pectoris treatment CONIEL® and hypertension treatment COVERSYL®. They are widely used in nephrology and various other categories, making them key products for building our business.

Tomohiro Sudo
General Manager
Nephrology Strategy Group
Strategic Product Portfolio Department

additional initiatives. We will maximize the value of saxagliptin, a diabetes treatment that is a global sales leader, to contribute to therapies in this challenging and competitive field.

While emphasizing our core strengths, we will avoid complacency in constantly and repeatedly taking on new challenges. We will therefore promote cooperation among research, development, manufacturing, sales and many other divisions.

Nephrology is a powerful Kyowa Hakko Kirin franchise that we will strengthen further. We need a medium-to-long-term viewpoint and concrete actions to continue to offer society the value that only we can provide. This will take us to the next level.

2012 Sales of Our Kidney Disease Franchise

¥80 billion

Oncology

Our focus will be GRAN®, POTELIGEO® and Fentos® as we enhance our status in the area of hematology and build our presence in the field of supportive cancer therapy, including cancer pain relief.

Basic Strategies of Medium-Term Business Plan – 2013 to 2015

In the area of hematology, we will concentrate on enhancing our status and establishing the brands GRAN®, our core neutropenia agent; Romiplate®, a treatment for chronic idiopathic thrombocytopenic purpura; and POTELIGEO®, a treatment for adult T-cell leukemia-lymphoma (ATL) and our first drug to use POTELLIGENT® antibody technology.

We will also comprehensively help oncology patients alleviate pain to enhance our cancer pain relief presence. We have launched Fentos®, a transdermal analgesic for persistent cancer pain, and will soon launch KW-2246, a treatment for breakthrough cancer pain for which we filed a new drug application.

Market Penetration for the Next Generation of GRAN®

A biogeneric version of core product GRAN® will be approved in 2013. Our strategies for maintaining GRAN®'s presence and stable market share will therefore be important. One strategy is enhancing communication with healthcare providers to ensure they fully understand the sophistication of our biopharmaceutical technologies and our experience with them spanning more than two decades. Another of our responses is KRN125, a long-acting pegylated form of GRAN® that stimulates the growth of neutrophils. Expected to be highly effective, KRN125 only needs to be administered once per chemotherapy cycle to treat neutropenia occurring as a result of chemotherapy, unlike the daily dosings needed when using GRAN®. KRN125 enables simple and effective neutropenia management, so we expect its cancer treatment benefits to include keeping chemotherapy and dosing on schedule. In Japan, we have completed a phase III clinical trial for KRN125, and plan to file a new drug application in 2013.

We will also contribute to improved quality of life for patients suffering from cancer pain by applying our experience marketing Fentos® in Japan to KW-2246, which ProStrakan already sells in Europe as Abstral®.

Initiatives to Build the POTELIGEO® Brand

Promotional Activities

POTELIGEO® is Kyowa Hakko Kirin's bellwether therapeutic antibody technology. It is the first therapeutic antibody that we handled in-house from research and clinical trials to marketing. POTELIGEO® is truly a strategic global product that is crucial to our aspirations to become a global specialty pharmaceutical company because overseas

Oncology Pipeline

16 products

GRAN® Estimated Market Share on a Drug Price Basis

Over 55%

We will succeed in building the foundation for becoming a global specialty pharmaceutical company by strengthening our position in Japan and around the world.

Two oncology category strategies are critical to our goal of becoming a global specialty pharmaceutical company.

The first is further strengthening our competitiveness in Japan through our category strategy. In the oncology category, over the coming three years we plan to introduce three new drugs in Japan in the form of additional indications for KRN125, KW-2246 and KW-0761 (POTELIGEO®). This will be crucial for enhancing Kyowa Hakko Kirin's presence and marketing capabilities. My primary mission is implementing these initiatives with a focus on increasing the value of the new products while strengthening the fundamentals needed to

Steady Market Penetration for Romiplate®

Romiplate® is a treatment for chronic idiopathic thrombocytopenic purpura. An orphan drug, it treats thrombocytopenia by stimulating thrombopoietin receptors. Romiplate® and one other type of drug that stimulates thrombopoietin receptors are now in clinical use. However, Romiplate® is steadily becoming the new therapy of choice among patients with treatment complexities because controlling thrombocytopenia with steroid therapy and pancreas extracts is difficult.

Yasusuke Utsunomiya
Associate Director
Oncology Product Group
Marketing Department
Sales & Marketing Division

Romiplate® (Launched April 2011)

development proceeded concurrently with its launch in Japan. This contrasts with the recent trend for overseas development to proceed first.

Brand strategy is critical. We are therefore ensuring consistent global use of brand-name logos and color under a strategy that ensures awareness of the Kyowa Hakko Kirin POTELIGEO® brand at a glance. We are also concentrating on building awareness among health care providers through venues including regular lectures and POTELIGEO® presentation booths at conferences. The core theme is the major contribution POTELIGEO® can make in treating patients with refractory ATL.

Additional POTELIGEO® Indications (Code Name: KW-0761)

Kyowa Hakko Kirin will expand the medical contribution of ATL treatment POTELIGEO® by quickly implementing a development strategy.

We are currently conducting clinical trials and studies of POTELIGEO® in first-line patients with untreated ATL, with the goal of submitting an application during 2013. Concurrently, we are moving forward with additional indications that will allow patients with peripheral T-cell lymphoma (PTCL) and cutaneous T-cell lymphoma (CTCL) to use POTELIGEO®. Development is also proceeding in Europe and the United States as we work to maximize the value of POTELIGEO® as a global in-house product.

KW-0761 Development Status

	Japan	United States	Europe
ATL	Combination therapy (untreated patients) Phase Ⅱ	Phase Ⅱ	Phase Ⅱ
PTCL	Phase Ⅱ		Phase Ⅱ
CTCL	Phase Ⅱ	Phase Ⅲ	

Accelerating ARQ 197 Development

ARQ 197 is a small molecular weight drug we licensed from ArQule, Inc. It is now in clinical trials for hepatocellular cancer and EGF-receptor mutated non-small cell lung cancer.

We entered into an agreement with ArQule for exclusive development and marketing rights for Japan and certain parts of Asia, and are promoting development with the objective of rapidly launching products for the many patients in Asia.

Yoshinori Yamashita
General Manager
Oncology Strategy Group
Strategic Product Portfolio Department

become a global specialty pharmaceutical company.

The second is expanding our business foundation in Europe, the United States and Asia. In the oncology category, we are accelerating development by coordinating the overseas teams that are involved in global product development while consulting with ProStrakan concerning issues such as the marketing organization and branding strategy for product launches. Our objective in the oncology category is to build the business foundation for becoming a global specialty pharmaceutical company by 2015 with consistent policies spanning research and development to manufacturing and marketing.

Immunology/Allergy

We will further enhance our presence in the immunology/allergy category by increasing the value of existing products and launching new drugs as early as possible.

Basic Strategies of Medium-Term Business Plan – 2013 to 2015

Generic versions of ALLELOCK®, our main antiallergic agent, are now available. We therefore expect category sales to decrease slightly over the next three years. We have been leveraging the strength of the ALLELOCK® brand and will continue to concentrate on adding value with new formulations such as orally disintegrating (OD) tablets and granules. We will also work to maximize synergies between Patanol® antiallergic eyedrops and ALLELOCK®, which share the same active ingredient. Moreover, clinical studies have demonstrated the efficacy of KHK4827 for psoriasis, and KHK4563 for asthma. We will accelerate development of these agents with the intention of launching them in 2016 and beyond to maintain our solid position in the fields of dermatology and otolaryngology and establish our presence in new markets.

Cooperative Development Pipeline with Leading Global Pharmaceutical Companies

5 products

Sustained ALLELOCK® and Patanol® Value Propositions

ALLELOCK® features potent antihistamine activity supported by a large volume of evidence. It excels at rapidly inhibiting a broad range of factors that trigger allergic reactions.

The antiallergy market is intensely competitive, but ALLELOCK® has received strong support from health care providers and patients since its launch more than a decade ago. While a generic version of ALLELOCK® hit the market in December 2012, we will continue to increase the value of this brand with formulations that fully meet patient needs and marketing that focuses on specialists. We will leverage the strengths of ALLELOCK® by continuing to offer product value

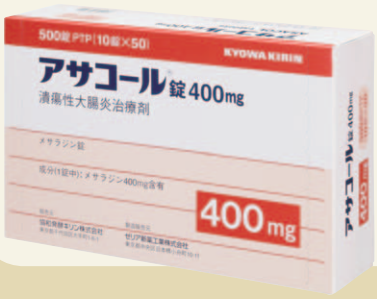
ALLELOCK®
(Launched November 2011)

In global markets, we will focus even more intently on increasing the value of our business through joint development with leading international drug companies.

A key feature of expansion in our immunology/allergy category is that we are increasing the value of our business through a strategy of joint development in global markets with leading pharmaceutical companies that recognize the sophistication of our drug discoveries technologies. Companies working with us include licensee AstraZeneca of the United Kingdom, which is developing KHK4563, and licensee Amgen Inc. of the United States, which is developing KHK4827 and additional indications for KW-0761 in the allergy area. This strategy helps us use our resources efficiently and also allows us to learn a great deal from our partners, so I believe it is an extremely effective approach to becoming a global specialty pharmaceutical company.

ASACOL®: Steady Growth Potential and a Focus on Market Penetration

ASACOL® has an active ingredient, mesalazine, that demonstrates outstanding anti-inflammatory effect. An oral formulation, the drug has an enteric coating that features pH-dependent controlled release. Approved and used in more than 60 countries and regions, it holds the leading market share in its category. In Japan, we market ASACOL® jointly with Zeria Pharmaceutical. Anticipating steady market expansion, we are consistently supporting ASACOL®'s market penetration.



ASACOL® (Launched December 2009)

Takashi Kawakami
Associate Director
Anti-allergic Product Group
Marketing Department
Sales & Marketing Division

aligned with the diverse needs of health care providers.

Patanol® antiallergic eyedrops are approved in 105 countries worldwide including Japan. Overseas, licensee Alcon, Inc. is known for excellence and is deeply experienced as a developer, manufacturer and marketer. Sales in Japan are growing robustly each year and the market for Patanol® is forecast to continue expanding. Patanol® quickly relieves red, itchy eyes and is recognized for long-lasting effectiveness for the major symptoms of allergic conjunctivitis centering on hay fever.

Patanol® (Launched October 2006)

Kyowa Hakko Kirin expects to capture synergies as it widely shares the value of ALLELOCK® and Patanol®.

Accelerated Development of New Therapeutic Antibodies

KHK4563 is a humanized monoclonal antibody that specifically binds to the human IL-5 receptor, which is expressed almost exclusively on eosinophils. We are developing it as a therapy for asthma. Eosinophils are believed to play a key role in the pathogenesis of asthma, so 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 asthma.

KHK4827 is a fully human monoclonal antibody that targets the IL-17 receptor reported to play a key role in the pathogenesis of various autoimmune diseases. We are now conducting a phase II clinical study in Japan for psoriasis.

Development has already advanced further in Europe and the United States, with excellent efficacy reported. Clinical trials in Japan are proceeding steadily with the enthusiastic participation of patients. We expect to launch KHK4827 in 2016.

Mitsuo Sato
General Manager
Immunology Strategy Group
Strategic Product Portfolio Department

Our category strategy for capturing value is that domestic sales will steadily generate the resources needed for rapid progress in becoming a global specialty pharmaceutical company while we take timely advantage of new drug leads and business opportunities in tandem with the most advantageous partners.

Our partners see Kyowa Hakko Kirin as a company with many talented employees, including the scientists who are developing our fascinating chemical entities and our licensing specialists. A key issue is further strengthening horizontal cooperation to holistically harmonize the components of our category strategy. I am totally committed to my role as the catalyst for that cooperation.

Patanol®'s Share of Estimated Patient Prescriptions for Antiallergic Eyedrops in Japan

No.1

Source: Japan Medical Data Center
(December 2011 to November 2012)

Central Nervous System

We will penetrate the markets for our expanded lineup of Parkinson's disease treatments to generate steady growth in our fourth category.

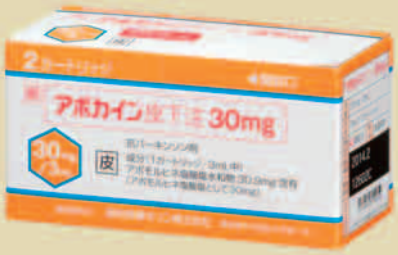
Basic Strategies of Medium-Term Business Plan – 2013 to 2015

The antiepileptic agents DEPAKENE® and Topina® are currently a core component of earnings, but we will concentrate on positioning treatments in the 150,000-patient antiparkinsonian market as key growth drivers. Adding to our existing antiparkinsonian agents EC-DOPARL® and Permax®, we launched Apokyn® in 2012 and received approval in March 2013 for the new antiparkinsonian agent NOURIAST®. Our expanded four-product lineup will give us a powerful competitive advantage. The plan is to immediately penetrate the market for NOURIAST®, which stands out as a new first-in-class drug, by communicating its unique non-dopamine mechanism of action to specialists.

A Focus on Parkinson's Disease in the Field of Neurology

The central nervous system category encompasses a wide range of diseases, but our fundamental strategy primarily targets diseases in the field of neurology. Three features characterize this field. One, neurology encompasses a large number of rare and intractable diseases for which the causes are unknown. Two, patients with neurological disorders and their families therefore face a considerable burden because they must live with the disease for a long time after its onset. Three, neurological disorders impact quality of life because they afflict the mind.

Among diseases in the field of neurology, Parkinson's disease follows Alzheimer's disease in number of patients. Extended ongoing treatment is necessary for Parkinson's disease when it develops in people around the age of 50. Drugs must be varied according to factors including disease progression. We will therefore support our solid product lineup by leveraging the relationships with key opinion leaders and neurologists that we developed with Apokyn® to clearly emphasize Kyowa Hakko Kirin's commitment to treating Parkinson's disease with the launch of its four neurological products.



Apokyn® (Launched July 2012)

Apokyn® is a dopamine agonist that patients can self-administer subcutaneously using a specially designed injector. This drug has been shown to rapidly improve "off" episodes of Parkinson's disease that cannot be effectively treated by conventional drug therapy. In March 2011, Apokyn® was designated an orphan drug in Japan.

Central Nervous System Products and Development Pipeline

7 products

We want to help patients with central nervous system disorders by developing new drugs through clinical research.

Our vision for the central nervous system category is helping patients with various rare and intractable neurological diseases, with a focus on Parkinson's disease. In view of this, the 2012 launch of the orphan drug Apokyn® and subsequent approval for the novel antiparkinsonian agent NOURIAST® were significant achievements.

As the world's first A_{2A} receptor antagonist to receive approval, NOURIAST® is a breakthrough first-in-class drug. We built up a lead in the field of A_{2A} receptor antagonists over more than 20 years of research, with the data we collected supporting our competitive advantage. I have been

NOURIAST®: A New Option for Parkinson's Disease

NOURIAST® (generic name: istradefylline) is an antiparkinsonian agent with a novel mechanism of action that Kyowa Hakko Kirin discovered. It is the world's first A_{2A} receptor antagonist to receive approval in Japan. Dopamine replacement therapy is the mainstream in treating Parkinson's disease, but over the long term this therapeutic approach can result in motor complications. One such complication is the wearing-off phenomenon,* which poses serious problems that interfere with the daily lives of Parkinson's disease patients because their condition changes repeatedly. A therapy with a non-dopamine mechanism of action was needed. The launch of NOURIAST® with a non-dopamine mechanism of action that improves the wearing-off phenomenon is expected to broaden treatment options for Parkinson's disease.

*Adverse side effect from long-term use of levodopa drugs. Patient condition is good for a short time after medication, but Parkinsonism begins to appear prior to the next dosing because the effectiveness of the drug begins to wear off quickly.

Shigeyuki Yamamoto

Associate Director
CNS and Gastroenterology Product Group
Marketing Department
Sales & Marketing Division

NOURIAST®
(Launched May 2013)

KHK6188 under Development In-House

We are developing KHK6188 in the central nervous system category. This cannabinoid CB2 receptor agonist for relieving neuropathic pain is now in a phase II clinical study in Japan. Aiming to become a global specialty pharmaceutical company, we expect to launch KW6188 in Japan, Asia, Europe and the United States because we hold worldwide marketing rights to this drug.

The Effect of Portfolio Management

Our category-based strategy involves portfolio management. We will strengthen interdivisional cooperation to share information immediately among multiple divisions, including research, development, manufacturing and sales. This has significantly enhanced transparency and decision-making speed by establishing channels for discussion. Judging from initial results, we believe building an organization that moves decisively toward consensus has created a framework that allows timely response to market demands.

Lineup of Antiparkinsonian Agents in Japan

No.1

Akihisa Mori

General Manager
Central Nervous System Strategy Group
Strategic Product Portfolio Department

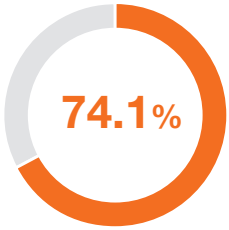
involved with NOURIAST® for many years, from discovery research through development in Japan and overseas. Developing the product strategy for it has therefore been a profound experience for me as the person in the central nervous system category responsible for product launch timing. Going forward, we want to help patients with central nervous system disorders by ensuring the broad penetration of our new drugs. Portfolio management will therefore include providing sales departments with scholarly papers that use the research data we have accumulated along with clinical research that provides product and sales support.

Main Segments (As of December 31, 2012)

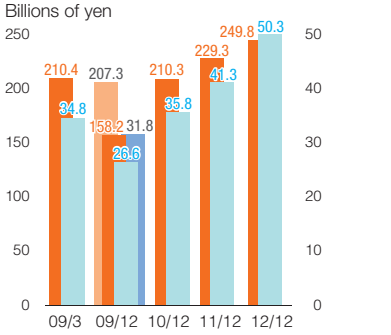
Pharmaceuticals

R&D, production and sale of ethical drugs emphasizing renal anemia, oncology, allergies, hypertension and *in vitro* 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

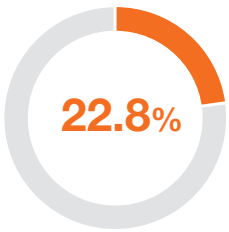


* Including intersegment transactions

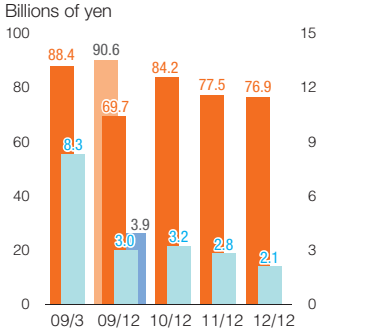
Bio-Chemicals

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.

Sales Composition
(Including intersegment transactions)



Net Sales*/Segment Income
Billions of yen



* Including intersegment transactions

Core Products

Ethical Drugs:

ESPO®/ NESP® (ESA formulation)

REGPARA® (secondary hyperparathyroidism)

ALLELOCK® (antiallergic agent)

Patanol® (antiallergic eyedrops)

GRAN® (G-CSF agent)

5-FU (anticancer agent)

CONIEL® (hypertension and angina pectoris)

DEPAKENE® (antiepileptic agent)

Fentos® (transdermal analgesic)

Romiplate® (chronic idiopathic thrombocytopenic purpura)

POTELIGEO® (adult T-cell leukemia-lymphoma)

***In Vitro* Diagnostic Reagents:**

POTELIGEO® TEST

Determiner® series (clinical chemistry diagnostic reagents)

Industry Trends

- Competition continues due to factors including the spread of generic drugs and revisions to the National Health Insurance drug price system.
- The growth rate of global pharmaceuticals sales is declining with the expiration of patents for core products and a growing market for generic drugs.
- Drugs for unmet medical needs, personalized medical care using genomic information, and evidence-based medicine are key trends defining the direction and success of pharmaceutical companies.
- Cancer treatments remain a therapeutic area that is attracting significant investment, including the introduction of companion diagnostics for selecting treatments as a result of progress in personalized medical care.

2012 Performance Review

- Net sales increased 9.0 percent year on year to ¥249.8 billion, and segment income increased 22.0 percent to ¥50.3 billion.
- Domestic sales of ethical drugs benefited from steady sales of core products but were impacted by factors including NHI drug price reductions.
- Solid exports and revenues from biosimilar development technology were main factors supporting revenues from exports and revenues from technology licensing.
- *In vitro* diagnostic reagents benefited from strong sales of immune system diagnostic reagents and favorable exports.
- ProStrakan performed well according to plan.

Core Products

Fine Chemical Products:

Amino acids

Nucleic acids

Related compounds

Health Care Products:

Amino acids

Vitamins

Minerals

Carotin

Peptides

Enguard® 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.

2012 Performance Review

- Net sales decreased 0.8 percent year on year to ¥76.9 billion, primarily because of the impact of the strong yen. Segment income decreased 26.6 percent to ¥2.1 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 Business

Research and Development

2012 Achievements

- POTELIGEO®, a treatment for adult T-cell leukemia-lymphoma (ATL) and our first therapeutic antibody, received manufacturing and marketing approval in Japan in March 2012 and launched in May 2012
- POTELIGEO® TEST, the companion diagnostic for POTELIGEO®, also received approval in March 2012 and launched in May 2012
- Antiparkinsonian agent Apokyn® received approval in March 2012 and launched in July 2012
- MINIRINMELT®, an antidiuretic hormone, received approval in March 2012 and launched in May 2012, and received approval for the additional indication of central diabetes insipidus in December 2012
- Long-acting ESA NESP® INJECTION PLASTIC SYRINGE with unified injection volume received approval and launched in December 2012

Basic Strategies of Medium-Term Business Plan – 2013 to 2015

- Enhance our ability to create and launch new drugs that address unmet medical needs
- Maximize value by moving forward with therapeutic antibody clinical trials in Japan and overseas and promoting antibody technology agreements
- Take on the challenge of new drug discovery approaches including drugs created through RNA interference (RNAi)
- Implement translational research that leverages our global research network to raise the success rate of clinical development
- Energetically conclude alliances from the early stages of research emphasizing open innovation that actively uses external information and knowledge

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® and KM Mouse, which produces fully human antibodies from mice. Our goal is to address unmet medical needs through breakthrough new drug discovery.

Research Strategy and Organization

In research, we are enhancing drug discovery. While promoting antibody technology agreements to maximize value, we are taking on the challenge of new drug discovery approaches including RNAi drugs.

The pharmaceutical industry is grappling with a low drug discovery success rate. Kyowa Hakko Kirin is approaching this issue in cooperation with health care providers, aggressively introducing translational research using clinical specimens at early stages of research to raise the new drug discovery success rate by forecasting patient efficacy and safety. We are also promoting open innovation to take advantage of knowledge and technology synergies. This involves energetic communication between external scientists and our researchers to gain access to cutting-edge research results generated by universities and research institutions.

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

In Japan, we concentrate on using drug discovery platforms such as antibodies to generate development candidates.

In the United States, Kyowa Hakko Kirin has supported research at La Jolla Institute for Allergy & Immunology (LIAI) for more than 20 years within an industry-academia alliance. Centered on this alliance, we intend to strengthen a translational research agreement with nearby University of California, San Diego School of Medicine. Having drug discovery research bases in the United States, which generates leading-edge research results, gives us an advantage. Moreover, we will bridge clinical and non-clinical research at our research base in Singapore, which systematically employs bioimaging technology. For example, we plan to implement bridge research that forecasts clinical efficacy and safety by examining the distribution of antibodies within the body.

These activities will support robust new drug discovery research that uses regional features and networks with a global perspective.

Development Organization

Clinical development in Europe and the United States will center on U.S. development subsidiary Kyowa Hakko Kirin Pharma, Inc. as the core of our one drug development organization (ODDO) that includes ProStrakan. We are using this organization to accelerate the speed of global in-house product development.

In Asia, Kyowa Hakko Kirin will take the lead in strengthening a development organization that encompasses Kyowa Hakko Kirin Korea Co., Ltd., Kyowa Hakko Kirin China Pharmaceutical Co., Ltd., and Kyowa Hakko Kirin (Taiwan) Co., Ltd. to accelerate joint international clinical trials.

Manufacturing Technologies and Drug Production System

We have three laboratories that focus on researching small molecule 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 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.

Therapeutic Antibody Business

Therapeutic Antibody Market Scale

Therapeutic antibodies are innovative drugs that differ from small molecules. They help the antigen-antibody interaction, which is a natural function of the human body, to target tumor and other cells with pinpoint accuracy. They are expected to have limited side effects and be highly effective against diseases that have been difficult to treat with conventional therapies.

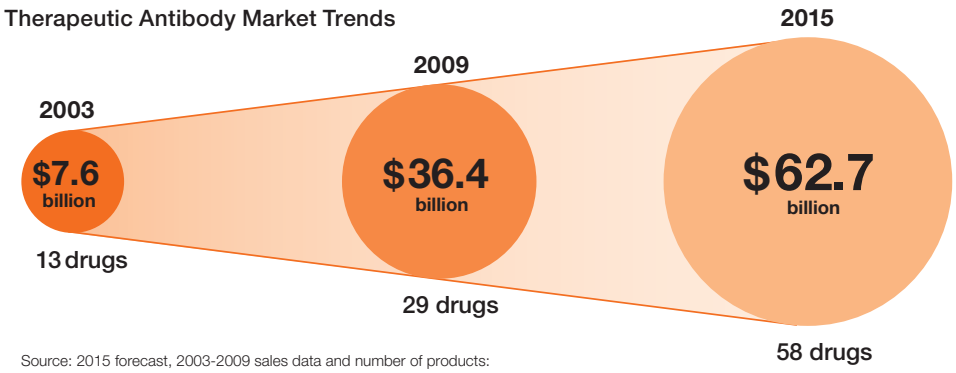
The market for therapeutic antibodies has been growing rapidly in recent years. Approximately 30 types of therapeutic antibodies were available in a global market with sales of more than $36 billion in 2009. Companies are entering the therapeutic antibody market, including large, financially strong pharmaceutical companies that were previously passive about in-house development of these drugs. A compound annual growth rate 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, we are expanding opportunities to acquire new antigens and accelerating therapeutic antibody development by enhancing our presence in the field of therapeutic antibody technologies using our POTELLIGENT® and COMPLEGENT® ADCC enhancing technologies and our KM Mouse genetic engineering technology for producing fully human antibodies using animals. Our manufacturing processes complement these technologies and enable us to create value chains.

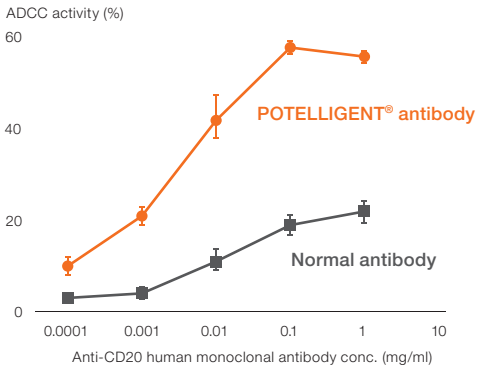
A key feature of POTELLIGENT®, an original Kyowa Hakko Kirin technology, is its ability to remarkably increase ADCC activity by reducing the amount of fucose in the carbohydrate structure of antibodies. Non-clinical studies have confirmed that POTELLIGENT® increases effectiveness in eliminating cancer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



Source: 2015 forecast, 2003-2009 sales data and number of products: Datamonitor©, reprinted with permission. Published in *Monoclonal Antibodies: 2010 Update.*

technology for therapeutic antibodies also significantly reduces patient burden by enabling reduced dosage.

ADCC Activity of POTELLIGENT® Antibody



- Compared with normal antibody (Rituxan) *in vitro*
- 1/100–1/1,000 conc. acquired same ADCC activity
- Max. activity enhanced

In 2012, we received domestic manufacturing and marketing approval for and launched POTELIGEO® (mogamulizumab; development name: KW-0761), a treatment for ATL and the world's first therapeutic antibody using POTELLIGENT® technology. We are now pressing forward with development in a wide range of fields, including peripheral T/NK-cell lymphoma and other forms of cancer and immunology and allergy conditions such as asthma, to maximize the value of KW-0761. We therefore expect the use of POTELLIGENT® technology to result in new drugs to address the unmet medical needs of patients.

POTELLIGENT® Technology Licensing

We are not limiting our use of POTELLIGENT® technology to the development of in-house therapeutic antibodies. We are also aggressively and strategically forming alliances covering this core technology with other companies to rapidly build a broadly-based antibody business.

Kyowa Hakko Kirin is maximizing the value of its POTELLIGENT® and COMPLEGENT® franchises by licensing them out through BioWa, Inc., a subsidiary in the United States. In 2007, we obtained the U.S. patent covering all antibodies with fucose-free mammalian sugar chains, irrespective of the antigen type or production method. As a result, a license from BioWa is essential to commercialize POTELLIGENT® antibodies in the United States. This patent further strengthened the exclusive position of Kyowa Hakko Kirin and BioWa in the research and development of POTELLIGENT® antibodies.

We have concluded technology licensing contracts related to POTELLIGENT® with leading global therapeutic antibody start-ups and major pharmaceutical companies, and expect royalty income to begin contributing to earnings as our alliance partners are forecast to begin launching new drugs from 2015.

Antibody Pipeline

(As of January 24, 2013)

Therapeutic Area	Code	Country/Phase	Indication	Remarks
ONCOLOGY	KW-0761	Japan (Phase II)	Adult T-cell leukemia-lymphoma (ATL), combination therapy	·POTELLIGENT® antibody
		Japan (Phase II)	Peripheral T/NK-cell lymphoma	
		Europe (Phase II)	Peripheral T-cell lymphoma	
		U.S./Europe (Phase II)	ATL	
		U.S. (Phase III)	Cutaneous T-cell lymphoma (CTCL)	
	BIW-8962*	U.S. (Phase I/IIa)	Cancer	·POTELLIGENT® antibody
	KHK2866*	U.S. (Phase I)	Cancer	·POTELLIGENT® antibody
	CEP-37250/ KHK2804*	U.S. (Phase I)	Cancer	·POTELLIGENT® antibody ·Joint development with Teva (formerly Cephalon)
	KHK2898*	Singapore (Phase I)	Cancer	·POTELLIGENT® antibody ·Uses KM Mouse ·Fully human monoclonal antibody
IMMUNOLOGY/ ALLERGY	ASKP1240*	Japan (Phase I)	Organ transplant rejection	·Uses KM Mouse ·Fully human monoclonal antibody ·Joint development with Astellas Pharma
		U.S. (Phase II)		
	KHK4563*	Japan/Korea (Phase II)	Asthma	·POTELLIGENT® antibody
	KHK4827*	Japan (Phase II)	Psoriasis	·Fully human monoclonal antibody ·Licensed from Kirin-Amgen
	KW-0761	Japan (Phase I)	Asthma	·POTELLIGENT® antibody
	KHK4083*	Canada (Phase I)	Autoimmune diseases	·POTELLIGENT® antibody ·Uses KM Mouse ·Fully human monoclonal antibody
OTHER	KRN23*	U.S./Canada (Phase I/II)	X-linked hypophosphatemic rickets/osteomalacia (XLM)	·Uses KM Mouse ·Fully human monoclonal antibody

* New molecular entity

All BioWa employees are dedicated to achieving our two missions.

Yasunori Yamaguchi, PhD
President and CEO
BioWa, Inc.

As we celebrate our tenth anniversary as a company in 2013, our primary mission is to provide even better therapeutic antibodies that help even more patients by licensing the breakthrough POTELLIGENT® and COMPLEGENT® technologies that Kyowa Hakko Kirin developed to enhance the effectiveness of therapeutic antibodies and by out-licensing development projects to maximize the value of these antibody technologies. At present, 16 pharmaceutical and biotechnology companies worldwide have licensed these technologies, and alliance partners have seven antibodies in the clinical development stage.

Moreover, AstraZeneca subsidiary MedImmune, LLC has licensed the therapeutic antibody MEDI-563/KHK4563, which has moved steadily forward to phase II clinical trials globally.

Under Medium-Term Business Plan – 2013 to 2015, BioWa has an additional mission. We are charged with enhancing Kyowa Hakko Kirin's pipeline by using the entrepreneurial network we have built through our licensing activities and our flexibility to seek and acquire exciting drug discovery ideas and technology in-licensing opportunities. We think of ourselves as an external innovation engine that will help the Kyowa Hakko Kirin Group grow steadily as it becomes a global specialty pharmaceutical company by adding to the quality and number of drug discovery projects.

BioWa further enhanced its activities in March 2013 by moving from Princeton, New Jersey to San Diego, California, a world-class center of academic institutions and biotechnology companies involved in basic and drug discovery research. Approximately half of the 252 drugs approved by the FDA from 1998 to 2007 were originally discovered in the United States, with over 60 percent coming from academic institutions or biotechnology companies. Working with them to acquire opportunities to create new drugs has therefore become more important than ever. In addition, we hope to maximize results by cooperating with Kyowa Hakko Kirin California, which has long been involved in discovery and translational research in California.

All BioWa employees are dedicated to achieving our two missions. In our second decade, we are committed to outstanding patient therapies and Kyowa Hakko Kirin's growth.

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 is contributing significantly to earnings through export sales and royalty income for olopatadine hydrochloride, the active ingredient in the antiallergic agent ALLELOCK®. Olopatadine hydrochloride licensee Alcon, Inc. markets it in more than 100 countries as ophthalmic formulations under the brand names of Patanol™ and Pataday™. In the United States and some other countries, olopatadine hydrochloride is also marketed as PATANSE™ nasal spray.

The tables below present the status of other in- and out-licensed chemical entities.

Status of Main Out-Licensed Compounds

(As of January 24, 2013)

Code	Company	Stage	Indication	Remarks
Tivozanib (KRN951)	AVEO Astellas Pharma	NDA filed	Cancer	In 2011, Astellas Pharma Inc. purchased the development and marketing rights from AVEO. (VEGF receptor inhibitor)
KW-2871 (Low-fucose antibody)	Life Science	Phase II	Cancer	(Anti-GD3 antibody)
MEDI-563 (KHK4563)	MedImmune	Phase II	Asthma	POTELLIGENT® (Anti-IL-5R antibody)
RGI-2001	REGiMMUNE	Phase I/II	Immunosuppressive	
KRN5500	DARA	Phase II	Neuropathic pain	
SAR252067	Sanofi	Phase I	Ulcerative colitis	(Anti-LIGHT antibody)

Status of In-Licensed Compounds

(As of January 24, 2013, except Kirin-Amgen)

Therapeutic Area	Code (Product Name)	Company	Stage	Indication	Remarks
ONCOLOGY	KW-2246	Orexo	NDA filed	Cancer pain	
	ARQ 197	ArQule	Phase III	Lung cancer (EGF-receptor wild type)	Development discontinued in October 2012
			Phase II	Lung cancer (EGF-receptor mutated)	
			Phase II	Gastric cancer	
			Phase I	Lung cancer	
NEPHROLOGY	RTA 402	Reata	Phase II	CKD in patients with type 2 diabetes	Development suspended in October 2012
	KHK7580	Mitsubishi Tanabe	Phase I	Secondary hyperparathyroidism	
IMMUNOLOGY/ ALLERGY	Z-206 (ASACOL®)	Zeria	Phase II	Crohn's disease (Launched in Japan for the treatment of ulcerative colitis)	Concluded a joint development and marketing agreement for ulcerative colitis treatment ASACOL® in January 2007
CENTRAL NERVOUS SYSTEM	KW-6500 (Apokyn®)	Britannia	Launched	Parkinson's disease	

In December 2009, we entered into an exclusive global licensing agreement with Immunas Pharma, Inc. of Japan covering development, production and marketing rights for an anti-amyloidbeta peptide antibody. 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 in Taiwan, Hong Kong, Singapore and Malaysia for SP-01, an extended release transdermal granisetron patch. In October 2010, 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.

Status of New Drug Development

Oncology

In Japan, we filed an NDA in November 2012 for KW-2246 (overseas product name: Abstral®), an agent for managing breakthrough cancer pain. In addition, POTELIGEO® received approval in March 2012 for the treatment of the hematological cancer ATL and launched in May 2012. Kyowa Medex Co., Ltd. received nearly simultaneous approval in March 2012 for POTELIGEO® TEST, an *in vitro* diagnostic reagent used to make

decisions about treating patients with POTELIGEO®, and launched this product in May 2012 as well. This diagnostic is used for deciding whether to prescribe POTELIGEO® for patients with relapsed or intractable ATL.

Overseas, Neulasta® received approval for the treatment of chemotherapy-induced febrile neutropenia in Korea in May 2012. Sancuso® (generic name: granisetron) received approval for the treatment of chemotherapy-induced nausea and vomiting in Taiwan in October 2012, and we filed applications for the drug in Malaysia and Hong Kong. In the United States, KW-0761 entered a phase III clinical trial for patients with previously treated cutaneous T-cell lymphoma (CTCL) in December 2012. Moreover, phase II clinical trials began in the United States and Europe for KW-0761 in patients with relapsed or intractable ATL in August 2012.

ProStrakan received approval for Sancuso® for the treatment of chemotherapy-induced nausea and vomiting in Europe in April 2012.

Nephrology

In Japan, we filed an NDA for an additional pediatric indication of anemia agent NESP® in September 2012. We also started phase II clinical trials for RTA 402 for treating CKD patients with type 2 diabetes in February 2012, but decided to discontinue the trial in October 2012 after Reata Pharmaceuticals, Inc. of the United States terminated an overseas phase III clinical trial for this compound because of safety concerns. In addition, we started a phase I clinical trial for KHK7580 for treating secondary hyperparathyroidism in December 2012.

Overseas, changes in the operating environment and other factors led us to revise our product portfolio. As a result, we decided to suspend a phase III clinical trial in India for KRN321 for renal anemia in dialysis patients.

Immunology/Allergy

In Japan, psoriasis treatment KHK4827 entered a phase II clinical trial in December 2012. We also initiated a phase I clinical trial for anti-inflammatory agent KHK4577 in December 2012.

Overseas, we started a phase I clinical trial for autoimmune disease treatment KHK4083 in Canada in January 2013.

Central Nervous System

In Japan, antiparkinsonian agent Apokyn® was approved in March 2012 and launched in July 2012. We filed NDAs for an additional pediatric indication and an additional fine granule formulation of antiepileptic agent Topina® in December 2012. In addition, we began a phase II clinical trial for KHK6188 in patients with postherpetic neuralgia in May 2012.

Other

Nplate® (product name in Japan: Romiplate®) received approval for the treatment of chronic idiopathic thrombocytopenic purpura in Taiwan in October 2012.

Initiatives for 2013

During 2013, the first year of Medium-Term Business Plan – 2013 to 2015, our top priority will be steady progress in the development of the in-house products KW-0761, KW-6002 and KRN23 in Europe and the United States in order to support a quantum leap in becoming a global specialty pharmaceutical company.

In Japan, we will implement plans to expand the indications of KW-0761 to combination therapy at the onset of ATL and peripheral T/NK-cell lymphoma, while moving steadily toward filing an NDA for KRN125 during 2013. In Asia, we will make use of local subsidiaries and other resources to move forward with development tailored to the state of medical care in each country.

We will implement product portfolio management in line with our category-based strategy to direct resources to key products under development and make rapid decisions to continue or terminate development projects. Moreover, we will use the valuable experience we gained in obtaining approval for companion diagnostic POTELIGEO® TEST to work with Kyowa Medex in creating drugs for personalized medical care. We will also continue to address unmet medical needs by creating new drugs.

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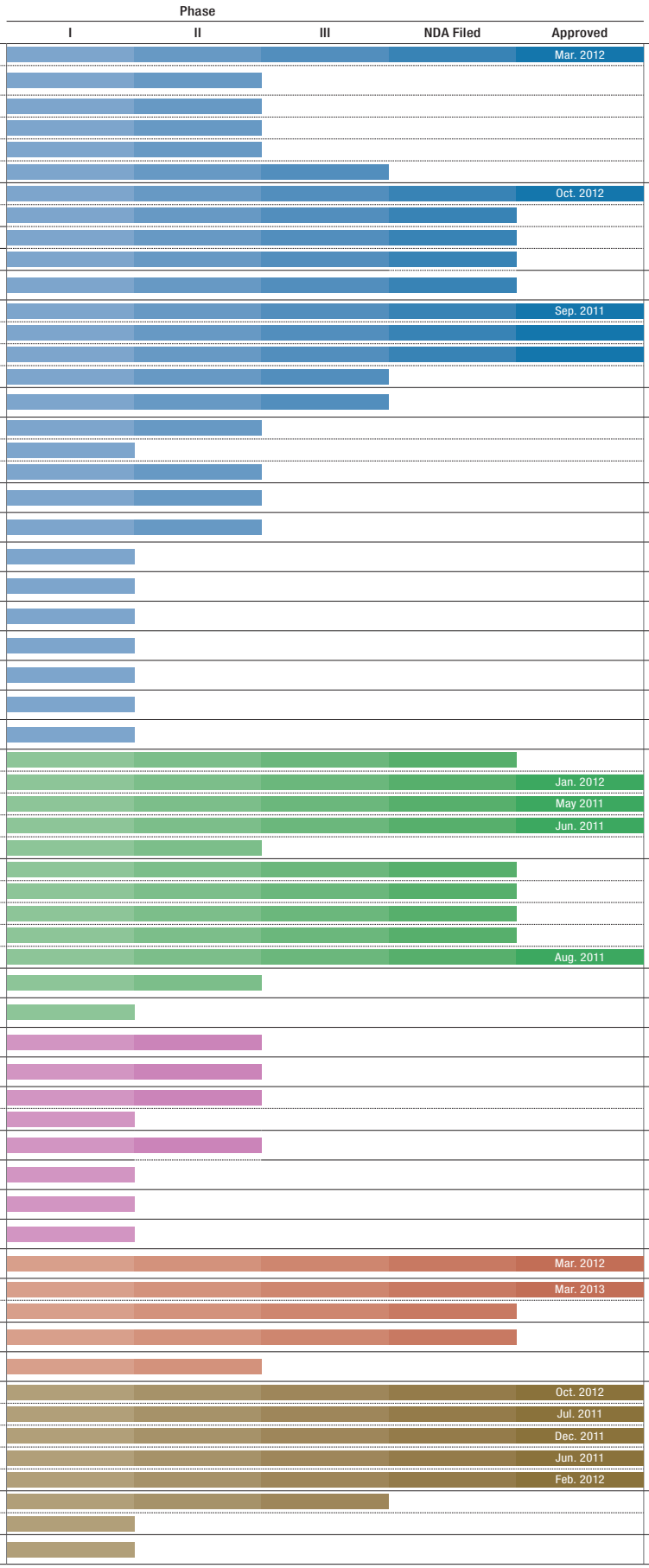
Pharmaceutical Pipeline (As of January 24, 2013)

Therapeutic Area	Code or Product Name	Generic Name	Type	Mechanism of Action	Indications	Country	Formulation
ONCOLOGY	KW-0761	Mogamulizumab	Bio-pharmaceutical Antibody pharmaceutical	Anti-CCR4 humanized antibody	Adult T-cell leukemia-lymphoma (ATL)	Japan	Injection
					Adult T-cell leukemia-lymphoma (ATL), combination therapy (for untreated patients)		
					Peripheral T/NK-cell lymphoma		
					Peripheral T-cell lymphoma (PTCL)	Europe	
					Adult T-cell leukemia-lymphoma (ATL)	U.S./Europe	
					Cutaneous T-cell lymphoma (CTCL)	U.S.	
	Sancuso®	Granisetron	Small molecular weight pharmaceutical	5-HT_3 serotonin receptor antagonist	Chemotherapy-induced nausea and vomiting	Taiwan	Patch
						Singapore	
						Malaysia	
						Hong Kong	
	KW-2246	Fentanyl citrate	Small molecular weight pharmaceutical	μ-opioid receptor agonist	Cancer pain	Japan	Sublingual tablet
		Pegfilgrastim	Bio-pharmaceutical	Long-acting granulocyte colony stimulating factor	Chemotherapy-induced febrile neutropenia	Taiwan	Injection
						Korea	
						Vietnam	
	KRN125					Japan	
	KRN1493	Cinacalcet hydrochloride	Small molecular weight pharmaceutical	Calcium receptor agonist	Hyper calcemia with parathyroid carcinoma or intractable primary hyperparathyroidism	Japan	Oral
	ARQ 197	Tivantinib	Small molecular weight pharmaceutical	c-Met inhibitor	Non-small cell lung cancer (EGF-receptor mutated)	Japan	Oral
					Hepatocellular cancer	Japan	
					Gastric cancer	Japan/Korea	
	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 pharmaceutical	IGF-1 receptor signal inhibitor	Cancer	U.S.	Oral
	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/ KHK2804		Bio-pharmaceutical Antibody pharmaceutical	Anti-tumor specific glycoprotein humanized antibody	Cancer	U.S.	Injection
	KHK2898		Bio-pharmaceutical Antibody pharmaceutical	Anti-CD98 fully human antibody	Cancer	Singapore	Injection
NEPHROLOGY	KRN321	Darbepoetin alfa	Bio-pharmaceutical	Long-acting erythropoiesis stimulating agent	Pediatric renal anemia	Japan	Injection
					Renal anemia on dialysis patients	Singapore	
						Thailand	
						Philippines	
						China	
		Cinacalcet hydrochloride	Small molecular weight pharmaceutical	Calcium receptor agonist	Secondary hyperparathyroidism	China	Oral
						Philippines	
						Malaysia	
						Thailand	
						Singapore	
	RTA 402	Bardoxolone methyl	Small molecular weight pharmaceutical	Antioxidant inflammation modulator	CKD in patients with type 2 diabetes	Japan	Oral
	KHK7580		Small molecular weight pharmaceutical	Calcium receptor agonist	Secondary hyperparathyroidism	Japan	Oral
IMMUNOLOGY/ ALLERGY	KHK4563	Benralizumab	Bio-pharmaceutical Antibody pharmaceutical	Anti-IL-5 receptor humanized antibody	Asthma	Japan/Korea	Injection
	Z-206	Mesalazine	Small molecular weight pharmaceutical	pH dependant controlled release tablet	Crohn's disease	Japan	Oral
	ASKP1240		Bio-pharmaceutical Antibody pharmaceutical	Anti-CD40 fully human antibody	Organ transplant rejection	U.S.	Injection
						Japan	
	KHK4827		Bio-pharmaceutical Antibody pharmaceutical	Anti-IL-17 receptor fully human antibody	Psoriasis	Japan	Injection
	KW-0761	Mogamulizumab	Bio-pharmaceutical Antibody pharmaceutical	Anti-CCR4 humanized antibody	Asthma	Japan	Injection
	KHK4083		Bio-pharmaceutical Antibody pharmaceutical	Immunomodulator	Autoimmune diseases	Canada	Injection
	KHK4577		Small molecular weight pharmaceutical	Anti-inflammatory agent	Inflammatory diseases	Japan	Oral
CENTRAL NERVOUS SYSTEM	KW-6500	Apomorphine hydrochloride	Small molecular weight pharmaceutical	Dopamine receptor agonist	Hyperanakinesia caused by Parkinson's disease-related motion complications	Japan	Injection
	KW-6002	Istradefylline	Small molecular weight pharmaceutical	Adenosine A_{2A} receptor antagonist	Parkinson's disease	Japan	Oral
						U.S.	
	KW-6485	Topiramate	Small molecular weight pharmaceutical	Antiepileptic drug	Pediatric epilepsy	Japan	Oral
	KHK6188		Small molecular weight pharmaceutical	Cannabinoid CB2 receptor agonist	Neuropathic pain	Japan	Oral
OTHER	AMG531	Romiplostim	Bio-pharmaceutical	Thrombopoietin receptor agonist	Chronic idiopathic thrombocytopenic purpura	Taiwan	Injection
						Hong Kong	
						Malaysia	
						Korea	
						Singapore	
	KW-3357	Antithrombin	Bio-pharmaceutical	Recombinant human antithrombin	Disseminated intravascular coagulation syndrome following a reduction of antithrombin	Japan	Injection
						Europe	
	KRN23		Bio-pharmaceutical Antibody pharmaceutical	Anti-FGF23 fully human antibody	X-linked hypophosphatemic rickets/ osteomalacia (XLH)	U.S./Canada	Injection
Discontinued							
ONCOLOGY	KRN321	Darbepoetin alfa	Bio-pharmaceutical	Long-acting erythropoiesis stimulating agent	Chemotherapy-induced anemia	Japan	Injection
	ARQ 197	Tivantinib	Small molecular weight pharmaceutical	c-Met inhibitor	Non-small cell lung cancer (EGF-receptor wild type)	Japan/Korea/Taiwan	Oral
	KRN330		Bio-pharmaceutical Antibody pharmaceutical	Anti-A33 fully human antibody	Cancer	U.S.	Injection



Origin	Remarks
In-house	POTELLIGENT® antibody
Solasia Pharma (ProStrakan)	
Orexo	Launched by ProStrakan as Abstral®
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	POTELLIGENT® antibody
In-house	Filed in the U.S. by AVEO as AV-951
In-house	Eli Lilly is developing LY2523355 in regions other than Japan
In-house	POTELLIGENT® antibody
Teva (formerly Cephalon)	POTELLIGENT® antibody Joint development with Teva
In-house	POTELLIGENT® antibody Uses KM Mouse
Kirin-Amgen	Launched in Japan for anemia of CKD patients
NPS	
Reata Pharmaceuticals	
Mitsubishi Tanabe Pharma	
In-house	POTELLIGENT® antibody
Zeria Pharmaceutical	Launched in Japan for ulcerative colitis Joint development with Zeria Pharmaceutical
In-house	Joint development with Astellas Pharma Uses KM Mouse
Kirin-Amgen	
In-house	POTELLIGENT® antibody
In-house	POTELLIGENT® antibody Uses KM Mouse
In-house	
Britannia Pharmaceuticals	
In-house	
Janssen Pharmaceutical	Launched in Japan for use as an antiepileptic drug
In-house	
Kirin-Amgen	
In-house	
In-house	Uses KM Mouse

Kirin-Amgen	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.
ArQule	Following the safety review committee recommendation due to higher frequency of interstitial lung disease cases in the study as a drug-related adverse reaction
In-house	Discontinued when oncology development portfolio was re-prioritized

Production

2012 Achievements

- Completed a new plant for solid oral dosage forms within the Ube Plant at the end of 2012
- Completed a new production facility for small molecular weight active pharmaceutical ingredients (APIs) at Daiichi Fine Chemical in July 2012
- Began preparing to build a new liquid pharmaceutical production facility at the Takasaki Plant as scheduled

Basic Strategies of Medium-Term Business Plan – 2013 to 2015

- Advance the plan to reorganize production bases slated for completion by the end of 2017
- Promote outsourcing

Reorganization of Production Bases

Targeting completion in 2017, we are reorganizing all Kyowa Hakko Kirin Group production sites, solving problems with location and aging facilities to optimize production. The reorganization plan involves more than ¥10 billion in investment from 2010 through 2017 with the objective of further enhancing cost competitiveness by constructing state-of-the-art automated plants that are Good Manufacturing Practice compliant at a number of bases. Reorganization initiatives proceeded according to plan during 2012.

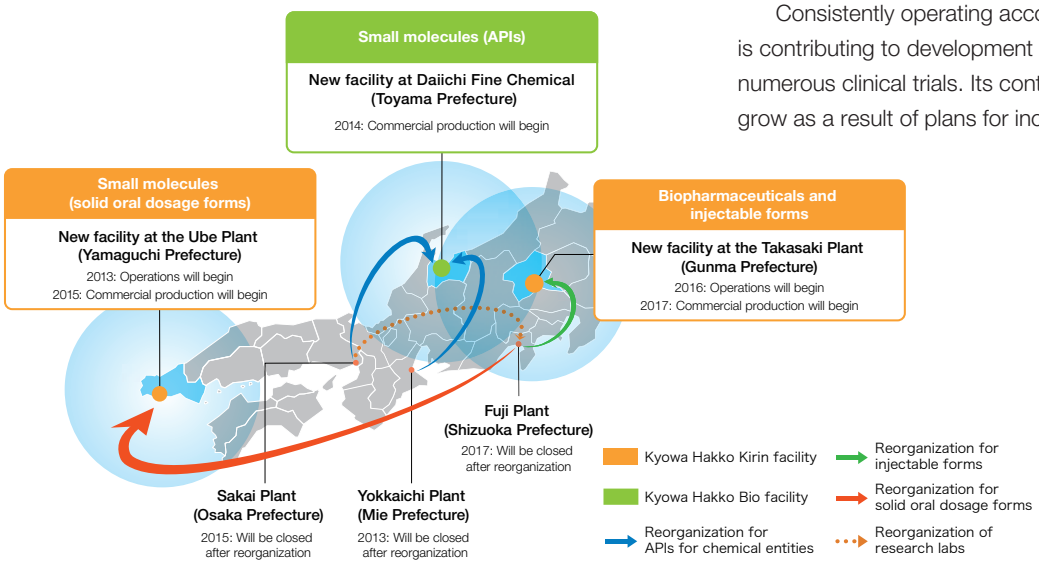
We completed a new plant for solid oral dosage forms at the Ube Plant at the end of fiscal 2012. After receiving GMP verification of the facilities, we will transfer production to the Ube Plant from the Fuji Plant in 2013 and 2014. We expect full-scale operation from 2015. In addition, in July 2012 the Kyowa Hakko Bio Co., Ltd. subsidiary Daiichi Fine Chemical completed a plant for APIs for chemical entities, which should be fully operational in 2014. We also began preparing to build a new liquid pharmaceutical production facility at the Takasaki Plant that we expect to begin operating in 2016. Moreover, we have begun preparing to decommission the Yokkaichi Plant, which we plan to shut down by the end of 2013.

During 2013, our plans will continue to progress steadily toward our 2017 target for completing the reorganization of our production bases.

Facilities for Investigational Therapeutic Antibodies Now Contributing to Development

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.

Consistently operating according to plan, this facility is contributing to development by supplying drugs for numerous clinical trials. Its contribution is expected to grow as a result of plans for increased production.



Marketing in Japan

2012 Achievements

- Continued to expand share for NESP®, an ESA, to maintain its market leadership
- Strengthened the antiallergic brand ALLELOCK® and increased market share
- Generated sales growth for REGPARA®, a treatment for secondary hyperparathyroidism, by providing safety information
- Steadily increased sales of new drugs such as Fentos®, a transdermal analgesic for persistent cancer pain, and Asacol®, an ulcerative colitis treatment, through initiatives to drive rapid market penetration
- Strengthened our sales organization as needed in ways such as establishing the Distribution Support Department to strengthen our relationship with distributors

Basic Strategies of Medium-Term Business Plan – 2013 to 2015

- Further strengthen competitiveness in Japan through our category-based strategy
- Maximize sales with an effective marketing organization that leverages specialized expertise and earns the trust of health care providers

Core Product Sales

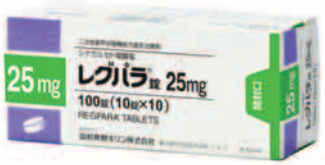
Our operating environment remains challenging due to factors including policies to contain health care costs and the expanding share of generics. In Japan, we targeted increased sales of core products and rapid market penetration for new products.

We have created a sales organization that efficiently delivers detailed information about core product NESP®. Consequently, sales increased 3 percent year on year during 2012 to ¥58.1 billion, and market share continued to expand.

Erythropoiesis stimulating agent NESP®

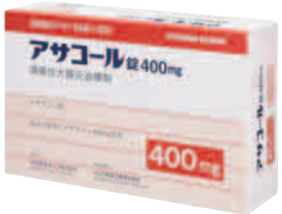
Sales of antiallergic agent ALLELOCK® increased 3 percent year on year to ¥29.9 billion. Leveraging its pronounced clinical effect, we increased market share by enhancing this brand's mindshare. In addition, sales of REGPARA®, a treatment for secondary hyperparathyroidism, increased 16 percent year on year to ¥13.4 billion because we promoted this drug with a focus on providing safety information.

Antiallergic agent ALLELOCK®



Secondary hyperparathyroidism treatment REGPARA®

We also steadily increased sales of new drugs such as Fentos®, a transdermal analgesic for persistent cancer pain launched in June 2010, and Asacol®, an ulcerative colitis treatment launched in December 2009, through initiatives to drive rapid market penetration.



Ulcerative colitis treatment Asacol®

Principal Drug Sales[1]

Billions of yen

Product	Indication	2012	2011	2010
NESP®/ESPO®	ESA formulation	¥62.0	¥61.8	¥52.6
ALLELOCK®	Antiallergic	29.9	29.1	26.8
CONIEL®	Cardiovascular (hypertension and angina pectoris)	17.1	19.7	21.0
GRAN®[2]	Neutropenia	13.5	14.8	14.4
REGPARA®	Secondary hyperparathyroidism	13.4	11.5	9.5
DEPAKENE®	Antiepileptic	10.7	11.2	11.0
Patanol®	Antiallergic eyedrops	10.2	11.4	7.5
NAUZELIN®	Gastrointestinal	4.9	4.8	5.3
Fentos®[3]	Cancer pain	4.6	3.1	0.8
ASACOL®	Agent for ulcerative colitis	4.1	2.8	0.7
Rocaltrol®[4]	Secondary hyperparathyroidism	3.6	3.2	—
COVERSYL®	Cardiovascular (hypertension)	3.5	3.9	4.2
5-FU	Anticancer	2.8	3.1	3.1
INOVAN®/PRe DOPA®	Cardiovascular	2.4	2.8	3.0
CELTECT®	Antiallergic	1.9	2.5	2.7
Permax®[5]	Parkinson's disease	1.7	2.1	2.0
Romiplate®[6]	Chronic idiopathic thrombocytopenic purpura	1.7	0.7	—
Navelbine®	Anticancer	1.3	1.7	2.0
Exports and Technology Out-Licensing		34.2	22.3	24.1

Marketing Organization and Policies

We have raised marketing efficiency by flexibly upgrading our marketing organization in step with changes in our operating environment. Initiatives have included restructuring our sales branch network and establishing the Distribution Support Department to strengthen our relationship with distributors.

We have also tightened compliance and allocated resources appropriately. Industry rules for generating operating income have changed, so we have energetically conducted in-house training and set up help lines to ensure thorough compliance. Appropriately allocating resources has involved a focus on core and new products, an area-based network of sales offices, and personnel assignments, thus earning the praise of the medical institutions for our proprietary products. Operating income was strong in 2012 as a result.

1. Non-consolidated basis
2. Includes sales of Neu-up® for January and February 2010. As of March 1, 2010, manufacturing, sales and other rights for Neu-up® were transferred to Yakult Honsha.
3. Sales of Fentos® began on June 24, 2010.
4. As of April 1, 2012, manufacturing, sales and other rights for Rocaltrol® were transferred to Chugai Pharmaceutical Co., Ltd.
5. Sales of Permax® began on April 1, 2010.
6. Sales of Romiplate® began on April 13, 2011.

Fumihiro Nishino
Vice President Head
Sales & Marketing Division
Director of the Board

Collaboration will be our theme as we further enhance our competitiveness in Japan in a challenging environment.

We are now in the first year of Medium-Term Business Plan – 2013 to 2015. Our external operating environment has become increasingly challenging because of escalating market offensives by large U.S., European and Japanese drug companies, the penetration of generic drugs, and the NHI drug price reductions coming up in 2014. These circumstances raise the importance of the Sales & Marketing Division – and the expectations for the division. We are committed to meeting these high expectations by further enhancing our competitiveness in Japan through our category-based strategy to steadily execute the new medium-term business plan and achieve its goals.

The Sales & Marketing Division will focus on collaboration to smoothly execute its category-based strategy. That is, we will configure our marketing organization to effectively deploy the extensive expertise of our people, which will help us maximize sales.

As a pharmaceutical company, we will also be conscientious about compliance in our marketing activities so that we can earn the trust of health care providers.

In 2013, we will follow up on the 2012 launch of two new drugs – POTELIGEO® and Apokyn® – with first-in-class NOURIAST® and Onglyza®.

The Sales & Marketing Division will leverage its organizational strengths while our MRs provide information as health care providers.

Approaches in 2013

Kyowa Hakko Kirin expects its MRs to be both sales representatives and health care providers. This policy means that our MRs go beyond simply providing information. Rather, as medical professionals our MRs use their knowledge of customer circumstances, medical treatments, and Kyowa Hakko Kirin to provide information that helps health care providers deliver outstanding patient care.

During 2013, the first year of Medium-Term Business Plan – 2013 to 2015, our Commitment to Life will be at the core of initiatives to enhance our strengths and marketing capabilities through multitasking that harnesses the advantages of multiple viewpoints and responsibilities as we work to improve as an organization. We will also continue to emphasize conscientious compliance in working to be the ideal partner for health care providers.

Diagnostic Reagents

Kyowa Medex is responsible for the diagnostic reagents business. 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-CR. 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 hemoglobin to latex that had not been sensitized to it in deploying latex agglutination technology to develop and commercialize a breakthrough method using changes in HbA1c turbidity to measure multiple specimens in less time than conventional methods.

The Kyowa Hakko Kirin Group also cooperates internally on development projects, such as the collaboration between Kyowa Hakko Kirin and Kyowa Medex from the earliest stages of pharmaceutical development to create diagnostic reagents that work with pharmaceuticals. In 2012, this approach resulted in nearly simultaneous approval for and launch of POTELIGEO® (mogamulizumab), Kyowa Hakko Kirin's first therapeutic antibody, and POTELIGEO® TEST (*in vitro* diagnostic reagents POTELIGEO® TEST IHC and POTELIGEO® TEST FCM), a companion diagnostic developed jointly by Kyowa Medex and Kyowa Hakko Kirin.

In 2013, we will build a powerful position in Japan and a foundation in the Chinese market. Targeting synergies with the Pharmaceuticals business and greater added value, we will cooperate with Kyowa Hakko Kirin's research and development departments to develop and launch *in vitro* and other diagnostic reagents and analysis instruments.

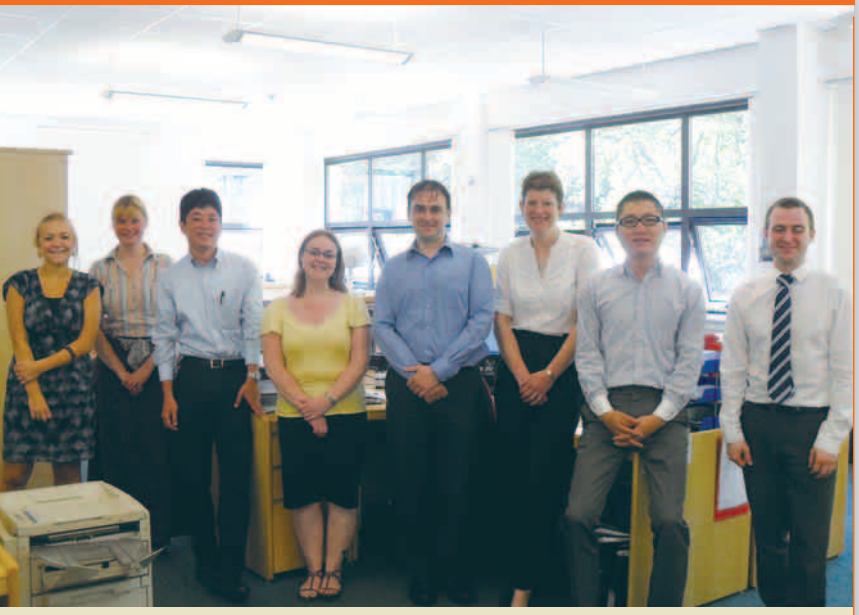
Diagnostic Reagents That Contribute to Personalized Medical Care

POTELIGEO® TEST attracted a great deal of attention prior to launch as a breakthrough diagnostic reagent slated for nearly simultaneous launch with a pharmaceutical. Post launch, we were pleasantly surprised by the unequivocal praise POTELIGEO® TEST received from the pharmaceutical industry and the many inquiries it elicited from health care providers we had not done business with before. POTELIGEO® TEST motivated our employees because of our success in developing and launching a companion diagnostic that contributes directly to both personalized medical care that matches patients with the most appropriate therapies for them and lower medical costs.

We will take advantage of Group synergies and share information with Kyowa Hakko Kirin from the initial stages of new drug development to develop companion diagnostics.

Masahito Yamaguchi
President and CEO
Kyowa Medex Co., Ltd.

Overseas Operations



2012 Achievements

- Sancuso® received approval for the treatment of chemotherapy-induced nausea and vomiting in Europe in April 2012
- Neulasta® received approval for the treatment of neutropenia in Korea in May 2012
- Sancuso® received approval for the treatment of chemotherapy-induced nausea and vomiting in Taiwan in October 2012
- Nplate® (product name in Japan: Romiplate®) received approval for the treatment of chronic idiopathic thrombocytopenic purpura in Taiwan in October 2012
- A phase III clinical trial began in the United States in December 2012 for KW-0761 (product name in Japan: POTELIGEO®) for relapsed or refractory cutaneous T-cell lymphoma
- A phase II clinical trial began in the United States and Europe in August 2012 for KW-0761 (product name in Japan: POTELIGEO®) for adult T-cell leukemia-lymphoma

Basic Strategies of Medium-Term Business Plan – 2013 to 2015

- Use ProStrakan's existing marketing network in Europe and the United States to build and expand a marketing organization that accommodates new product sales
- Fully leverage operating fundamentals in Asia to maximize sales by rapidly launching products under development

Expansion in Europe and the United States

Kyowa Hakko Kirin acquired ProStrakan with the goals of establishing our own marketing organization in the United States and Europe, strengthening our 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.

In 2012, we made progress in optimizing our European marketing organization by completing the integration of 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 KW-0761 (product name in Japan: POTELIGEO®) in the United States. Our marketing organization in Europe and the United States is cooperating with ProStrakan in building our One Drug Development Organization led by Kyowa Hakko Kirin Pharma, which has initiated the development of KW-0761.

Raising the Efficiency of Our Organization in Asia

Kyowa Hakko Kirin was the first Japanese pharmaceutical company to sell drugs in China, South Korea, the ASEAN nations and other Asian countries. Our sales operations center on six local subsidiaries with 200 MRs.

During 2012, we integrated two subsidiaries in the rapidly growing Chinese market to strengthen commercial operations and enhance the MR organization.

We are building a development organization in Asia led by Kyowa Hakko Kirin with the support of local subsidiaries. Sancuso® received approval for the treatment of chemotherapy-induced nausea and vomiting in Taiwan in October 2012, and development progressed in Hong Kong, Singapore and Malaysia.

Enhancing Brand Awareness

We will enhance awareness of the Kyowa Hakko Kirin brand in Asian pharmaceutical markets while changing company names with the goal of growth for a unified Kyowa Hakko Kirin Group as a global specialty pharmaceutical company.

In China, Kirin Kunpeng (China) Bio-Pharmaceutical Co., Ltd. changed its name to Kyowa Hakko Kirin China Pharmaceutical Co., Ltd. on April 23, 2012. This company develops, manufactures and markets ethical drugs.

In Korea, JEIL-KIRIN PHARMACEUTICAL INC. changed its name to Kyowa Hakko Kirin Korea Co., Ltd. on June 1, 2012. This company develops and markets ethical drugs.

Initiatives for 2013

Our region- and country-based global operating strategy revolves around deploying ProStrakan, a key Group company acquired in 2011.

In the United States, we see moves toward the launch of POTELIGEO®, our first therapeutic antibody, as

Our Pharmaceuticals Business in Asia

Consolidated Subsidiaries (Date Established)	MRs*	Sales* (Billions of Yen)	Products	Basic Strategies
1. Kyowa Hakko Kirin China Pharmaceutical Co., Ltd. (Established June 1997)	124	2.9	GRAN®, ESPO®, Busulfex®, CONIEL®, Mitomycin-C, LEUNASE®, ALLELOCK®	• Accelerate development (NESP® and other products under multinational development) • Increase sales by strengthening marketing capabilities • Initiate *in vitro* diagnostics business
2. Kyowa Hakko Kirin Korea Co., Ltd. (Established May 1991)	27	2.9	NESP®, GRAN®, Renagel®, REGPARA®, Busulfex®, LEUNASE®, Mitomycin-C, Nplate®	• Build strong presence in the targeted therapeutic areas of cancer, nephrology and hematology • Accelerate multinational studies by strengthening development capabilities
3. Kyowa Hakko Kirin (Taiwan) Co., Ltd. (Established April 1992)	19	2.1	NESP®, GRAN®, REGPARA®, Mitomycin-C, Busulfex®, LEUNASE®, Neulasta®	• Launch new products and penetrate market (Sancuso® and Nplate®) • Modify sales organization to support upcoming biosimilar launch
4. Kyowa Hakko Kirin (Hong Kong) Co., Ltd. (Established August 1993)	6	0.5	Aranesp®, Renagel®, REGPARA®, Mitomycin-C, LEUNASE®, Busulfex®, Nplate®	• Strengthen marketing capabilities in targeted therapeutic areas and increase sales of existing products • Launch new products and penetrate market (Sancuso® and Nplate®)
5. Kyowa Hakko Kirin (Singapore) Pte. Ltd. (Established March 2005)	7	0.3	GRAN®, NESP®, Busulfex®, Mitomycin-C, REGPARA®, Peglasta®, LEUNASE®, Nplate®	• Promote sales in Malaysian market • Launch new products and penetrate market (REGPARA®, Sancuso® and Nplate®)
Non-Consolidated Subsidiary				**Basic Strategies**
6. Kyowa Hakko Kirin (Thailand) Co., Ltd.				• Launch new products and penetrate market (REGPARA®) • Enhance presence in the nephrology category

*As of December 31, 2012

an important opportunity to make a quantum leap toward becoming a global specialty pharmaceutical company. We will therefore build the drug development and marketing organization for self-sustaining growth in the enormous U.S. market. Moreover, we will energetically incorporate ProStrakan's late-stage development and launched products into our business model to expand our product lineup in the United States and key European countries while enhancing our market presence.

In Asia, our top priority is restructuring our operating fundamentals to achieve stable future growth in China. In growing countries such as Korea, Taiwan, Singapore and Thailand, local subsidiaries will implement business strategies tailored to conditions in their respective countries.

Steady Market Penetration for NESP® and REGPARA®

NESP® and other ESAs are our core products in Asia, where customers appreciate our reliable, high quality and sophisticated marketing activities. Health care systems and competitive conditions differ among Asian countries, but NESP® sales are growing steadily in the intensely competitive ESA market. Also in the nephrology category, Asian dialysis patients want the first-in-class REGPARA®, which we now market in Korea, Taiwan, Hong Kong and Singapore and plan to launch in China, Thailand and Malaysia.

Teamwork with local subsidiaries will drive rapid penetration for these products in Asia and further increase product value.

Hideaki Matsumoto
Manager
Sales & Marketing Group
Overseas Business Department

Biosimilars Business

2012 Achievements

- Completed preparations for development and clinical trial of FKB327 (a biosimilar of the fully human anti-TNF-α monoclonal antibody adalimumab)
- Decided to initiate development of FKB238 (a biosimilar of the anti-VEGF humanized monoclonal antibody bevacizumab)
- Opened the Production & Development Centre and began operations

Basic Strategies of Medium-Term Business Plan – 2013 to 2015

- Develop four biosimilar products

Operating Objective of FUJIFILM KYOWA KIRIN BIOLOGICS

Kyowa Hakko Kirin and FUJIFILM Corporation launched a joint venture in March 2012, FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd., to handle the biosimilars business.

FUJIFILM KYOWA KIRIN BIOLOGICS merges Kyowa Hakko Kirin's proprietary technologies and expertise in biopharmaceutical R&D and manufacturing with the production, quality control and analysis technologies that FUJIFILM developed through businesses such as photographic film. Targeting leadership in the global biosimilars market, the joint venture will create revolutionary biosimilar production processes for the development, manufacture and timely launch of highly reliable, high-quality, low-cost biosimilars.

The Biosimilars Market

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 their substantial development costs and the sophisticated technology and production facilities required for their unique features, making the advent of cost-competitive biopharmaceuticals desirable. Given these expectations, the biosimilar market is forecast to grow to $5.2 billion by 2015, and $37.5 billion in 2020.

Review of 2012

We basically completed preparations for the start of FKB327 clinical trials in 2013, by conducting various studies, setting up the internal and external organization, and consulting with regulatory authorities. We also started development of a second candidate compound, FKB238.

Additionally, we opened the Production & Development Centre in December 2012 to conduct biosimilar production process research and development. Equipped to develop cultivation and purification processes and perform analysis, the facility serves as the core of research, development and creation of the manufacturing processes for high-quality, cost-competitive biosimilars.

Overview of the Production & Development Centre

Address: 100-1 Hagiwara-cho, Takasaki-shi,
Gunma Prefecture, Japan
(located within Kyowa Hakko Kirin's Takasaki Plant)
Scale: Two-storey ferroconcrete building.
Building area: approximately 2,100m^2
Total floor area: approximately 2,500m^2

Initiatives for 2013

We plan to make steady progress in several initiatives. These include a phase I clinical trial for FKB327 and organizational work for its phase III clinical trial, various studies to initiate a phase I clinical trial for FKB238, and the start of development of a third candidate entity.

The biosimilar pharmaceutical market is expanding, which is also attracting a succession of new entrants. We will contribute to the Kyowa Hakko Kirin Group by steadily moving forward with development that accommodates widely varying regulations, concentrating on pricing power through lower costs, entering markets according to plan, and launching competitive products that capture market share.

Bio-Chemicals Business

2012 Achievements

- Increased market penetration by developing markets for our own health food brands led by ornithine
- The project to integrate facilities at the Yamaguchi Production Center moved steadily forward
- Completed a new production facility for small molecule drugs in July 2012 at Daiichi Fine Chemical
- Steadily enhanced cost competitiveness by improving and reorganizing production bases and innovating technology
- Decided to construct a new amino acid plant in Thailand to address further growth in demand

Basic Strategies of Medium-Term Business Plan – 2013 to 2015

- Structure operations to minimize the impact of exchange rates
- Reorganize and improve Group production bases in Japan and overseas to further raise cost competitiveness
- Further upgrade the global operating foundation to aggressively meet strong international demand
- Enhance consumer awareness of mail-order products such as ornithine and provide our own health food materials

Overview of 2012

In the Bio-Chemicals business, net sales decreased 0.8 percent compared with the previous year to ¥76.9 billion, primarily because of the impact of the strong yen. Segment income decreased 26.6 percent to ¥2.1 billion, largely because of the impact of the strong yen and increased investment in pharmaceutical research and development.

Fine Chemicals

In Japan, sales of pharmaceutical- and medical-use materials increased year on year due to solid sales of products including pharmaceutical-use amino acids, nucleic acids and related compounds such as adenosine triphosphate, and other active pharmaceutical ingredients (APIs).

Overseas, U.S. sales of amino acids for supplements were firm. In Europe and Asia, sales of amino acids remained steady for infusions, while the API citicoline and other amino acids, nucleic acids and related compounds continued to sell well. Given these conditions, sales volume increased as we maintained high capacity utilization rates at our plants to meet strong demand and revised prices. However, sales were essentially unchanged year on year due to the pronounced impact of the strong yen.

Health Care Products

Mail-order sales of health care products grew steadily, including our own brand ornithine. Raw material sales were also robust because ornithine is an ingredient used for healthy *Kirin Plus-i* brand products such as beverages, yogurt and rice porridge, and synergy with mail-order advertising has greatly enhanced consumer awareness. However, overall sales were flat year on year because sales of other food and beverage ingredients were weak.

Overseas Premium Quality Science-Backed Brand

Kyowa Quality

Overseas Brands

Cognizin

Setria

Lumistor
Renewed Radiance through Advanced Nutrition

SUSTAMINE

Pantesin

Initiatives for 2013

During the first year of Medium-Term Business Plan – 2013 to 2015, we will improve profitability by restructuring operations and configuring operating fundamentals to minimize the impact of exchange rates.

Restructuring Operations

Several initiatives in the API business will support improved profitability. We will ramp up to full-scale production of tranexamic acid at Daiichi Fine Chemical and full-scale operation of a recently completed facility for small molecule drug production. Moreover, we will continue construction of a facility to produce APIs for small molecule drugs while preparing for the launch of generic products. The project to integrate facilities at the Yamaguchi Production Center, which is scheduled for completion in 2018, will progress steadily, and we will introduce new technologies to reduce costs. In addition, we will raise the efficiency of existing businesses, communicate with customers worldwide for future sales expansion, and build customer trust by providing high-quality products and services.

Configuring Operating Fundamentals

In Japan, we will further enhance consumer awareness of ornithine and make steady progress in upgrading mail-order sales promotion. We will also expand the health care business by increasing sales of our own materials such as citrulline. Overseas, we will increase production at existing manufacturing bases while moving forward with a project to construct a production base in Thailand. This plant will begin operating in the latter half of 2015, in which we expect to expand international transactions and minimize the impact of exchange rates. Moreover, we will upgrade the logistics organization that supports the globalization of our operations and enhance our quality assurance system.

Initiatives Designed for Higher Product Prices, Improved Profitability and Our Growth Strategy

Shuichi Ishino

President and CEO
Kyowa Hakko Bio Co., Ltd.

Our goals for the three years of the former medium-term business plan involved operating reforms that included expanding sales of high-value-added amino acids and other core products, developing health care products, and expanding our production infrastructure. We achieved our goals ahead of schedule. However, profitability suffered from challenging developments in the operating environment including the impact of the strong yen and the rapid emergence of major competitors from China and elsewhere, in addition to depreciation expenses arising from capital expenditures to reorganize operations.

During the three years of Medium-Term Business Plan – 2013 to 2015, we intend to achieve the identity we have targeted in our Vision 21 plan by enhancing and fine tuning the assets in which we have invested.

We will start with a focus on improving earnings by making the assets in which we have invested profitable. We intend to transform Bio-Chemicals into a highly profitable business through initiatives that include upgrading the efficiency of our production infrastructure to achieve high productivity and low costs, operating steadily in the API business, and introducing a global supply chain management system. Our growth strategy involves accelerating R&D to discover next-generation materials and develop new products in order to achieve sustained growth in the pharmaceutical, medical and health care markets. We will also enhance cooperation among Group companies, employ a reliable quality assurance system and powerful branding to supply safe products that customers can use confidently, and enhance product value.

Intellectual Property

Kyowa Hakko Kirin takes an international approach to strengthening its organization for acquiring and maintaining intellectual property rights, acquiring and granting licenses, and monitoring the rights of third parties.

Basic Stance

Intellectual property (IP) is a key management resource. Kyowa Hakko Kirin therefore aggressively acquires 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 those rights. 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 business, 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 Group's Pharmaceuticals business. 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 2012, 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.

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, 2012)

	Kyowa Hakko Kirin	Rest of the Kyowa Hakko Kirin Group*	Total
Japan	172	164	336
Overseas	1,270	618	1,888

*Excluding ProStrakan

Quality Assurance

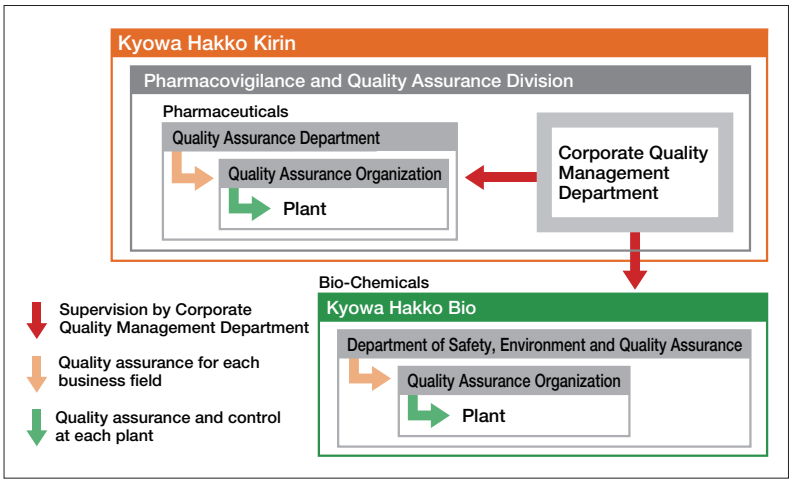
We will take steps to establish a quality assurance system suitable for global operation.

Quality Assurance Activities

The Kyowa Hakko Kirin Group utilizes a three-tier structure to ensure sound operation of its quality assurance system. The first tier consists of quality assurance organizations at each plant. Above that, we have quality assurance organizations overseeing each of our two business fields. Finally, supervising the quality assurance activities of the entire Group is the Corporate Quality Management Department. In all quality assurance activities, we ensure full regulatory compliance and make customer safety our number one priority.

Since 2010, we have been implementing the ICH Q10[1] pharmaceutical quality system throughout the Group. In 2012, we promoted implementation of the system at each plant, and confirmed that ICH Q10 had steadily taken root. In addition, management reviews are conducted in accordance with the ICH Q10 system, which facilitates continual improvement in manufacturing and quality control. The Kyowa Hakko Kirin Group will continue its current quality assurance activities and expand them to include knowledge management, one of the elements of ICH Q10.

The Kyowa Hakko Kirin Group's Quality Assurance Organization



New Initiatives in Quality Assurance

We are promoting two initiatives toward establishing a quality assurance system suitable for global operation, which is part of one of the core strategies of Medium-Term Business Plan – 2013 to 2015.

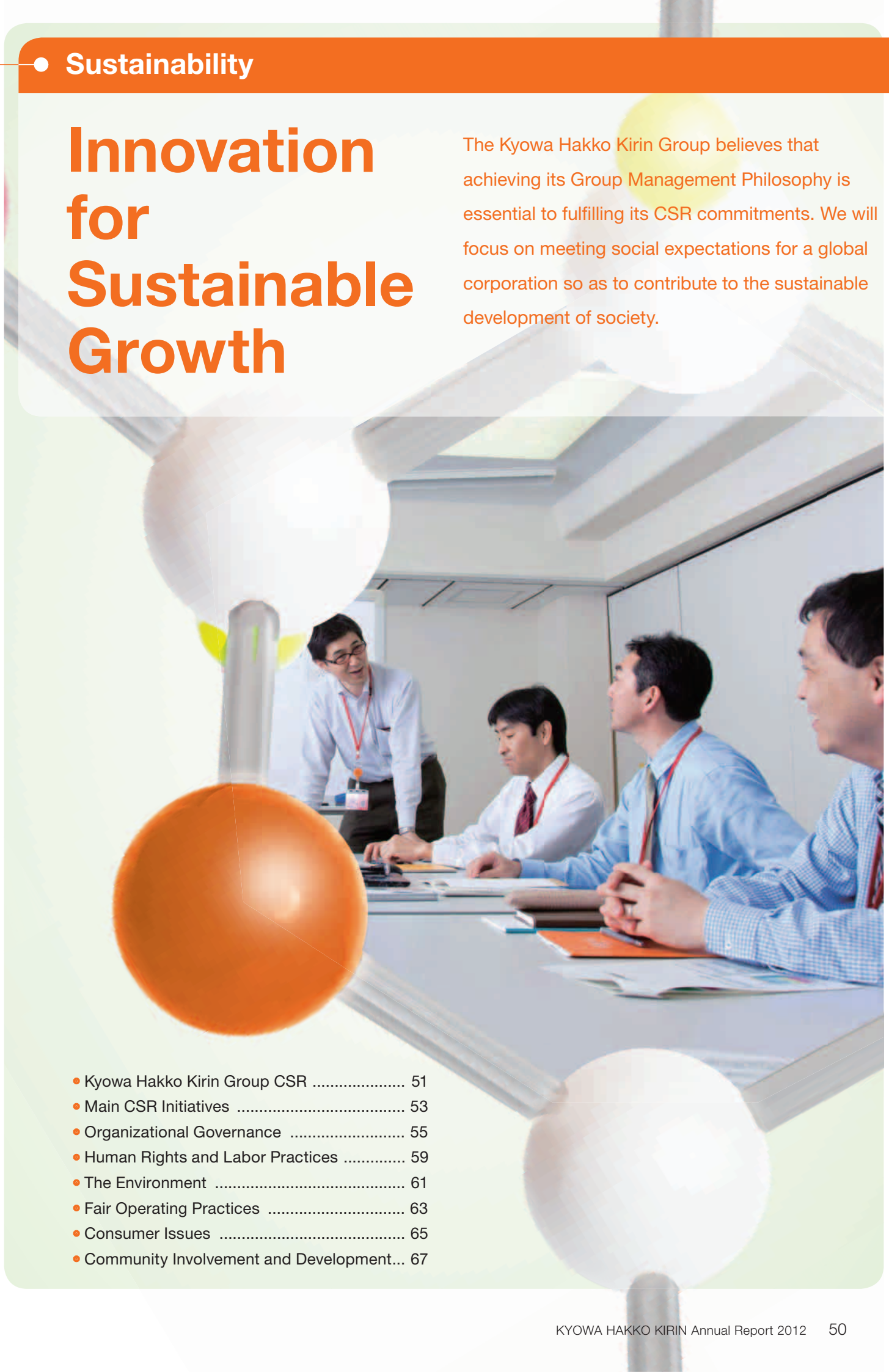
First, with the progress in global harmonization of good manufacturing practice (GMP) in recent years, we plan to make all of Kyowa Hakko Kirin's pharmaceutical plants compliant with PIC/S[2] GMP guidelines, which are becoming the global GMP standard.

Second, good distribution practice (GDP) guidelines are being drawn up by the EU and the World Health Organization (WHO) to reflect the increasing importance of logistics stemming from the globalization of pharmaceuticals. We will therefore work to strengthen quality control of pharmaceuticals in the shipping process. Biopharmaceuticals generally must be stored at low temperatures, so we are looking at the issues involved in low-temperature distribution and will make necessary improvements in areas such as temperature control during transit. We are also preparing our own guidelines to further upgrade our GDP management system in cooperation with overseas subsidiaries.

1. ICH is the abbreviation for International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. Q10 is a model quality system that incorporates GMP guidelines for pharmaceuticals.
2. PIC/S is the abbreviation used to describe both the Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Co-operation Scheme. The Pharmaceutical Inspection Convention is an informal cooperative arrangement of pharmaceutical regulatory authorities, mainly from European countries. It created GMP and quality control guidelines to ensure consistency and has been working since 1995 to facilitate reciprocity in GMP inspections. As of 2012, there were 38 participating authorities. Japan applied for PIC/S membership in March 2012, and its application is currently under review.

Innovation for Sustainable Growth

The Kyowa Hakko Kirin Group believes that achieving its Group Management Philosophy is essential to fulfilling its CSR commitments. We will focus on meeting social expectations for a global corporation so as to contribute to the sustainable development of society.



Kyowa Hakko Kirin Group CSR

The Kyowa Hakko Kirin Group believes that achieving its Group Management Philosophy is essential to fulfilling its CSR commitments. We will focus on meeting social expectations for a global corporation so as to contribute to the sustainable development of society.

Management Philosophy and CSR of the Kyowa Hakko Kirin Group

In its Group Management Philosophy, the Kyowa Hakko Kirin Group promises "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." Based on this philosophy, all employees perform their daily tasks in accordance with the Group's Action Guidelines: "We will work together in a sincere and mutually respectful manner," "We will take a forward-looking, energetic approach to change," "We will do our utmost to add value and contribute to a brighter future around the world" and "We will always act with integrity in everything that we do." We consider it part of our CSR to realize our management philosophy through activities consistent with these action guidelines.

We will strengthen our ties with society while remaining conscious of our "Commitment to Life."

The Kyowa Hakko Kirin Group's CSR encompasses Group-wide efforts aimed at realizing our management philosophy. It underpins the daily work of all employees. I believe the most important thing is to maximize the Kyowa Hakko Kirin Group's brand value, an intangible asset; that is, we should focus on increasing our corporate value. To do so, we must earn the trust of society by responding sincerely to feedback from our stakeholders, not by taking a corporate-centered approach.

In 2013, the first year of our new medium-term business plan, we will continue to work in line with the core subjects of ISO 26000, a set of global standards for CSR, and will promote CSR from the perspectives of protection and creation. "Protection" refers to improving the effectiveness of compliance and risk management, which form the backbone for the Company's continued existence. Specifically, we will focus on having employees adopt and enforce the systems we have put in place. We will revise our business continuity plan drawing on lessons from the Great East Japan Earthquake, enhance compliance awareness and comply with the regulations that apply to global companies. "Creation," on the other hand, means focusing on activities that strengthen our ties with society. Our strong determination to do so is clearly spelled out in our mission statement, "Commitment to Life." We have therefore gone back to the basics and launched an internal cross-organizational project to create new value by aligning our goal of making people smile with the requirements and expectations of society.

We will continue to maintain active communication with our stakeholders while executing CSR activities unique to the Kyowa Hakko Kirin Group as a socially oriented enterprise.

Yoshiharu Furumoto

Executive Director of the Board
Executive Vice President

Our mission statement Commitment to Life

"Commitment to Life" is printed in card form and distributed to all employees.

"Commitment to Life" is the mission statement of Kyowa Hakko Kirin, created when the company was established in October 2008. It reflects our aspirations, as employees of a pharmaceutical company, for facing up to life with sincerity and continuing to move ahead with life, along with medical practitioners, in order to bring smiles to all people who are fighting against diseases.

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

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

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

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

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

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

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

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

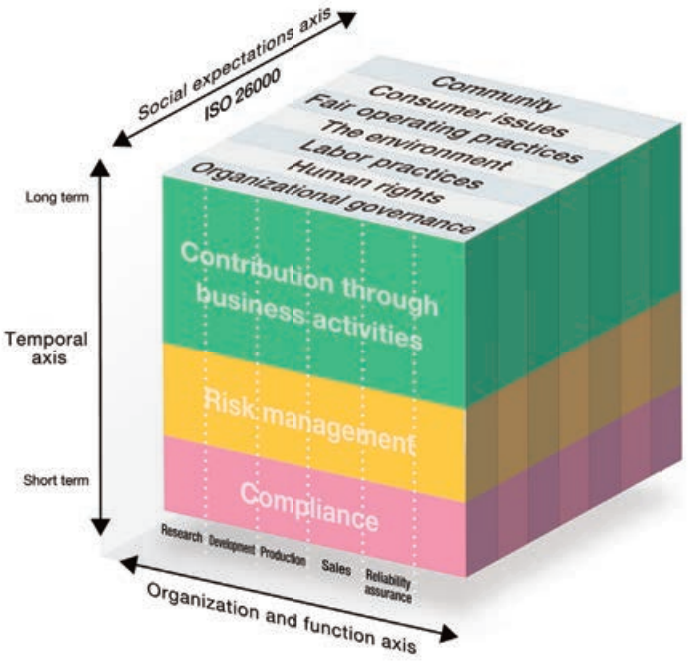
CSR Promotion Policy

CSR activities have been reorganized from a global perspective as shown in the figure below according to the 7 core subjects defined in ISO 26000.

Before the reorganization, our top priorities were compliance and risk management in terms of temporal urgency and, from a mid- to long-term perspective, contribution through business activities in response to changes in the social landscape in terms of organization and function.

In addition to these two axes, the temporal axis and the axis of organization and function, the new policy includes the 7 core subjects proposed by ISO 26000 as the axis of social expectation. Under this revised policy, more emphasis will be placed on dialogue with stakeholders as a means of strengthening our contribution to developing a sustainable society.

Kyowa Hakko Kirin Group CSR Perspective



Main CSR Initiatives

7 core subjects	Issues
Organizational governance	—
Human rights/ Labor practices	**Human Rights** 1 Due diligence 2 Human rights risk situations 3 Avoidance of complicity 4 Resolving grievances 5 Discrimination and vulnerable groups 6 Civil and political rights 7 Economic, social and cultural rights 8 Fundamental principles and rights at work
The environment	1 Prevention of pollution 2 Sustainable resource use 3 Climate change mitigation and adaptation 4 Protection of the environment, biodiversity and restoration of natural habitats
Fair operating practices	1 Anti-corruption 2 Responsible political involvement 3 Fair competition 4 Promoting social responsibility in the value chain 5 Respect for property rights
Consumer issues	1 Fair marketing, factual and unbiased information and fair contractual practices 2 Protecting consumers' health and safety 3 Sustainable consumption
Community involvement and development	1 Community involvement 2 Education and culture 3 Employment creation and skills development 4 Technology development and access

ISO 26000 is an international standard providing guidelines to help organizations meet their social responsibilities. Launched in November 2010, this guidance document offers a range of advice and applies to all types of organizations, including corporations, governments, schools and NGOs. It was prepared with input from a variety of stakeholders, including governments, corporations, workers, consumers, NGOs and experts from more than 40 organizations in over 90 countries, both in the developed and developing world. One of the reasons for undertaking such a large-scale project to establish this international standard for social responsibility is the increasing expectations held by stakeholders toward the international activities of various organizations.

	Results in 2012	
	• Enhanced corporate governance and the internal control system → **p. 55, 56, 57** • Used risk management system to prevent materialization of serious risks → **p. 58** • Held results presentation meetings, conference calls, lectures and other events for institutional investors and securities analysts (6 times) → **p. 58**	• Formulated business continuity plan for head office and key business sites • Issued "To Our Shareholders" and Annual Report • Conducted facility tours and held press conferences (3 times)
Labor Practices 1 Employment and employment relationships 2 Conditions of work and social protection 3 Social dialogue 4 Health and safety at work 5 Human development and training in the workplace	• Promoted hiring of people with disabilities (people with disabilities employed: 87; percentage of total employees: 1.9%; students with disabilities accepted for internships: 12) → **p. 59, 60** • Promoted diversity and inclusion (foster corporate culture in which diverse people can fulfill their potential) → **p. 60** • Conducted human rights training throughout the Company (248 sessions; percentage of employees receiving training: 96.3%) • Conducted human rights awareness survey (response rate: 93.4%) • Sent out president's message for Harassment Elimination Month and solicited human rights slogans during Human Rights Week • Conducted thorough ethical reviews in research and development and protected human rights in clinical trials	• Provided childcare and nursing care support (employees taking childcare leave: 86; publicized the nursing care support system) • Supported employees' career development with programs such as the self-development support system • Conducted global human resource development training • Addressed mental health (conduct stress checks) • Occupational safety and health (risk assessments) (lost worktime incidence rate: 0.45%) • Traffic safety measures (installed drive recorders in vehicles with higher accident risk, conducted risk prediction training) • Conducted emergency drills at each site (27 times)
	• Reduced CO_2 emissions (reduction of 3.2% vs. 2007) → **p. 62** • Took measures to preserve biodiversity → **p. 62** • Promoted shift to hybrid vehicles in sales fleet • Promoted Green Office Plan • Reduced waste generation (maintained zero landfill waste)	• Promoted reuse and recycling (recover phosphate from fermentation wastewater) • Reduced discharge of chemical substances • Prevented air and water pollution • Conducted environmental protection activities at each site
	• Conducted questionnaire survey of suppliers on their CSR efforts (companies responding: 271; response rate: 91%) → **p. 63** • Received a certificate of conformity from the Center for Accreditation of Laboratory Animal Care and Use → **p. 64**	• Compliance education activities: Presented two corporate ethics lectures and conducted compliance training (group training: total of 248 sessions and 6,540 participants; attendance rate: 96.3%; e-learning participation rate: 97.5%) → **p. 64** • Provided education on the Anti-Monopoly Act and prevention of insider trading
4 Consumer service, support, and complaint and dispute resolution 5 Consumer data protection and privacy 6 Access to essential services 7 Education and awareness	• Supported DOPPS (an international study) to advance dialysis therapy → **p. 65** • Provided measures for preventing chronic kidney disease, pollinosis and other illnesses on our website → **p. 66** • Number of product-related inquiries handled by the Medical Information Office: approximately 40,000 → **p. 66**	• Renewed global website to enhance convenience for users • Conducted training on Personal Information Protection Act by e-learning (participation rate: 96%)
5 Wealth and income creation 6 Health 7 Social investment	• Promoted Kirin *Kizuna* (bonding) Relief-Support Project for post-disaster reconstruction in areas affected by the Great East Japan Earthquake (table tennis lessons, table tennis meets, etc.: 22 times) → **p. 67, 68** • Held science classes for young students (6 times) → **p. 68** • Participated in community dialogue activities promoted by the Japan Responsible Care Council • Interns accepted: 53 • Supported La Jolla Institute for Allergy & Immunology, a nonprofit research institute	• Donated to the Kato Memorial Bioscience Foundation • Participated in and donated to community events (Seoul Citizen Marathon to help pediatric cancer patients: 82 participants; marathon sponsored by support organization of Parkinson's disease patient groups in the U.S.: 15 participants) • Distributed Braille calendars for the visually impaired (70 schools; 3,850 calendars) • Held health promotion lectures for local residents (about 70 people attended)

Organizational Governance

We aim to earn the trust of society by maintaining a transparent organization and sound operations. To achieve this, we are taking measures to enhance corporate governance, implement thorough risk management and appropriately disclose information in a timely manner.

Mutsuyoshi Nishimura
Outside Director of the Board

I am struck by the Company's earnest approach to fulfilling its social responsibilities under its mission statement, "Commitment to Life."

When I was working at the Ministry of Foreign Affairs, I became very interested in corporate governance and the social responsibilities of corporations. Part of this interest came from serving as ambassador to the Organization for Economic Cooperation and Development, an international body comprising 34 developed countries, including European nations, Japan and the United States. I am now in my fourth year as an outside director of Kyowa Hakko Kirin. The Board of Directors is not merely a formality. We engage in friendly but candid discussions, so I believe the board serves its purpose well. I ask many questions at the meetings to fulfill my role. The management team at Kyowa Hakko Kirin is very cognizant of corporate governance, and I feel they address it sincerely.

I also think the Company compares favorably even at the international level in its earnest approach to fulfilling its social responsibilities. Companies often get too caught up in legal compliance, which tends to restrain their efforts. CSR, however, is essentially the concept of living and growing together with society. It is a positive idea. I also think it is a valuable concept for unifying a company internally. Kyowa Hakko Kirin's mission statement, "Commitment to Life," is wonderful. It is the result of employees' in-depth discussions of what they should value. I am impressed that people here share this commitment in their actions.

On the other hand, if there is one thing we can learn from Western countries, it is employing and promoting women. Not just Kyowa Hakko Kirin but Japanese society as a whole has lagged in this area. Going forward, we need to step up our efforts. At the same time, as a global specialty pharmaceutical company, Kyowa Hakko Kirin needs to focus its efforts on developing a globalized workforce.

Drawing on my specialized knowledge and experience, I try to make appropriate judgments that are consistent with social norms.

Motoaki Kitayama
Outside Director of the Board

In addition to my role as director, I am a member of the Remuneration Consultative Committee and the Nomination Consultative Committee. The Board of Directors in particular engages in vigorous debate, and I have the opportunity to speak my mind freely. Business transactions that require a board resolution normally involve two perspectives: management and legal. For the former, I respect the business judgment of the inside directors, who are management specialists. I fulfill my duty with a determination to make governance work from a legal perspective by drawing on my specialized knowledge and experience to make reasonable judgments consistent with social norms.

My benchmark for those judgments is whether or not the transaction in question could cause the Company to suffer damage. If the Company suffers damage, then by extension it will harm all stakeholders, including shareholders, business partners and employees. Therefore, my main priority is to prevent damage to the Company. Protection of intellectual property such as patents and utility model rights is also vitally important for a pharmaceutical company, so I have to meet expectations in that area as well. I receive occasional reports and give advice on pending lawsuits over intellectual property rights in Japan, the United States and other countries.

Kyowa Hakko Kirin is accelerating its global business expansion to become a global specialty pharmaceutical company, but it is also aiming for global standards in the area of governance. From that standpoint, I think Kyowa Hakko Kirin should actively work to increase the number of women in senior positions by cultivating future management candidates from among the many talented women working as researchers and in other areas of the Company. Furthermore, as the environment has become a key public issue, the Company needs to continue to show consideration for the environment in all its operations.

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 April 1, 2013)

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

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 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 15 times during 2012, to make decisions about management policies and other important matters and oversee the performance of directors. The Remuneration Consultative Committee met two times and the Nomination Consultative Committee met three times. These committees provided reports to the Board of Directors about compensation and nomination issues relevant to directors and company auditors.

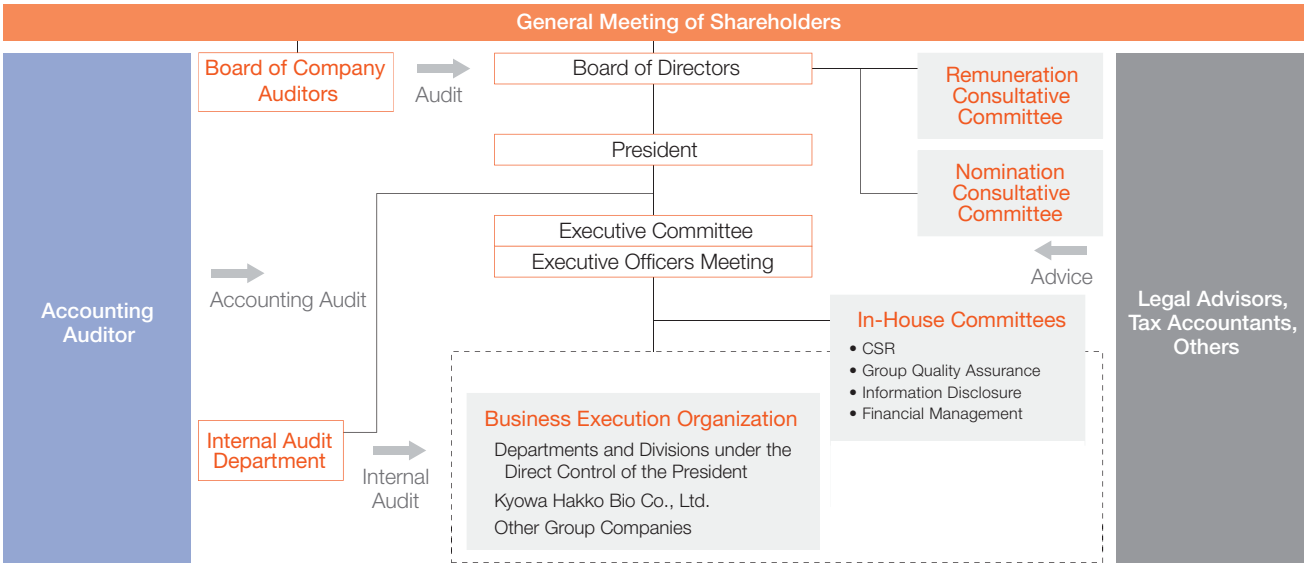
Company Auditors and the Board of Company Auditors

The Company has adopted the company auditor corporate governance system. The Board of Company Auditors has five members, including four outside auditors. Based on the audit policies established by the Board of Company Auditors, company auditors attend important meetings, including those of the Board of Directors, and inspect operations and assets to audit the performance of duties by directors. Moreover, the Board of Company Auditors exchanges opinions with the Internal 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 Company Auditors also periodically discusses audit plans, policies and status with the independent auditors. Furthermore, the Board of Company Auditors receives reports from internal control sections 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 Company Auditors met 14 times during 2012.

Executive Committee and Executive Officer System

The Executive Committee is responsible for making accurate, effective and strategic management decisions. It met 23 times during 2012 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 2012.

Corporate Governance Structure (As of April 1, 2013)



Risk Management System and 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 basic policies and important matters associated with CSR; overall Group strategy and action policies for CSR; and basic policies and important matters related to risk management and the environment.
- **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.

Internal Control System

The Company resolved to establish the following policy to ensure a system for appropriate business operations (the "internal control system"). The Company has the following internal control system policy to ensure appropriate business operations. The Board of Directors periodically confirms its effectiveness.

1. System to ensure that the duties performed by the directors and employees comply with laws and the Company's articles of incorporation.
2. System to ensure the proper preservation and maintenance of information regarding the performance of duties by the directors.
3. Regulations and systems related to the control of risks of loss.
4. System to ensure the effective performance of duties by the directors.
5. System to ensure the appropriate operations of the corporate group that comprises the Company, its parent company and its subsidiaries.
6. Matters concerning employees appointed on request to assist company auditors with their duties and the independence of these employees from directors.
7. System to ensure reporting by the directors and employees to the company auditors, and other systems to ensure reporting to the company auditors.
8. Other systems to ensure effective auditing by the company auditors.

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

Ensuring the Independence of Outside Directors and Outside Auditors

Kyowa Hakko Kirin has established its own Standards for the Independence of Outside Officers with reference to standards and other criteria including those of the Tokyo Stock Exchange for independence qualification. In light of the standards, the Company has notified the Tokyo Stock Exchange that it has appointed four officers as outside officers under Tokyo Stock Exchange regulations (two outside directors: Mutsuyoshi Nishimura and Motoaki Kitayama; and two outside auditors: Hiroaki Nagai and Hiroyuki Takahashi).

Compensation to Directors and Company Auditors

The Company has fundamentally designed director compensation to retain quality executives who are motivated to contribute to the Company through the execution of their duties.

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 the Company's 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 that they fulfill their management supervision function.

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

Compensation to Directors and Company Auditors (Millions of yen)

	Amount of Compensation, etc.	Total Compensation by Type	
		Performance-Linked Compensation	Stock Options
Directors (8) (excluding outside directors)	275	245	29
Company auditor (1) (excluding outside company auditors)	25	25	—
Outside officers (7)	83	83	—

Risk Management

Kyowa Hakko Kirin has established the CSR Committee to understand, evaluate and deal with risk from a Group-wide perspective and to build and operate a risk management system.

Specifically, the CSR Committee conducts a risk census to identify critical risks and then creates and executes programs to manage them. The CSR Management Department monitors the quarterly progress of risk management programs, changes in risks, and actual risks confronting each division, and presents its findings to the CSR Committee. The committee also reports on its activities to the Board of Directors. (Please refer to page 80 for additional risk factor details.)

In addition, we are applying what we learned from the Great East Japan Earthquake in continuously improving our business continuity plan (BCP). We have formulated a BCP master plan and companywide BCP guidelines, and revised BCP documentation for particular risks. Other initiatives have included rewriting related rules and manuals and conducting emergency drills.

Basic Policy regarding Information Disclosure

The Kyowa Hakko Kirin Group regards investor relations (IR) as an important management issue and endeavors to provide timely, accurate disclosure of information to shareholders and other investors in accordance with the Financial Instruments and Exchange Act and the timely disclosure rules of the Tokyo Stock Exchange (TSE). In addition, Kyowa Hakko Kirin is committed to the timely, active disclosure of other information that, in the judgment of the company, will be effective in helping shareholders and other investors to understand Kyowa Hakko Kirin.

Communication with Shareholders and Investors

Annual General Meeting of Shareholders

The 90th Annual General Meeting of Shareholders was held on March 22, 2013. The Notice of Convocation sent prior to the meeting was both easy on the environment and easy for shareholders to understand because it used environmentally friendly paper and ink and a universal design font, and also featured color photographs and graphs. Moreover, business reports presented at the meeting made use of visuals such as narrated videos.

Shareholder attendance at the general shareholders' meeting was higher than in 2012. All proposals were approved as resolutions after lively deliberation involving questions and answers.

- Time: 10:00-11:42
- Attendees: 455
- Questioners: 7
- Number of questions: 17

For the record, 8,220 shareholders exercised their voting rights, representing 85.0 percent of total voting rights.

The environmentally friendly Notice of Convocation

Investor Relations (IR) Activities

The president and other senior managers attend information meetings and conference calls held four times each year when results are announced to explain management strategies and operating performance to institutional investors and securities analysts. We also conduct overseas IR activities in Europe, the United States and Asia. In addition, we conducted various programs during 2012 to address issues of interest to shareholders. These included a March 2012 facility tour of the world-class plant for producing investigational therapeutic antibodies at the Bio Process Research and Development Laboratories; lectures in June 2012 on POTELIGEO®, the first therapeutic antibody for which Kyowa Hakko Kirin had an NDA approved; and the Development Forum held in December 2012.

Other IR activities include sending shareholders a business report titled "To Our Shareholders," and the distribution of our annual report to shareholders in Japan and overseas. Moreover, we are enhancing the contents of our website to disclose information to shareholders and investors quickly and fairly, and in 2012 renewed the Investors section of our global website. We are using the website to distribute videos of information meeting presentations and question-and-answer sessions, along with information such as news releases, financial updates, information meeting materials, annual reports, and our IR calendar.

Global Recognition

Recognized by the global community for its management approach and active environmental efforts, Kyowa Hakko Kirin is included on the world's major socially responsible investment indexes, including the FTSE4Good Index Series and the MS-SRI (as of January 2013).

FTSE4Good
FTSE4Good Index

MS-SRI
Morning Star Socially Responsible Investment Index

Human Rights and Labor Practices

Paying special attention to the human rights of workers, we strive to create a work environment that values diversity. Our goal as a corporate group is to develop a diverse workforce made up of broadminded and fully engaged individuals.

Our Human Resources Philosophy promotes diversity. We also actively provide employment for people with disabilities.

The Kyowa Hakko Kirin Group is taking steps to promote workplace diversity. As part of our efforts, in September 2012 we launched a project to promote employment of people with disabilities in Japan. Group companies had previously acted on their own in hiring people with disabilities, but increasing demands from society have made it necessary to speed up this effort. Therefore, we have made it a Group-wide initiative in Japan.

In this project, we recognized the need to cultivate understanding in the workplaces that would be accepting these employees. Accordingly, in January 2013, we established the Declaration on Employment of People with Disabilities for the Kyowa Hakko Kirin Group in Japan. Based on this declaration, we are conducting in-house awareness activities. In addition to the Human Resources Department, people from across the Group, including the CSR Department, Legal Department and Group companies in Japan, came together to debate various aspects of the project. In discussing how to position the declaration, we initially considered the term “charter,” but ultimately decided to use the term “declaration” because of the consensus that the name should encourage a more proactive approach.

Since 2011, we have been conducting joint work experience programs[1] with a Tokyo Metropolitan Special Support School.[2]

Kentaro Takahashi
Chiyoda Kaihatsu Co., Ltd.
Formerly Manager, Human Resources Department

We feel this is a mutually beneficial program because it has changed our perceptions while allowing the students in the program to experience what it is like to have a job. We hope to continue the program next year and beyond.

In 2013, we intend to execute project plans to expand employment opportunities for people with disabilities as stated in the declaration and to arrange barrier-free work environments.

1. On-the-job training that includes computer-based data entry, filing, mail collection and delivery, and copier paper replenishing.
2. High schools that include vocational programs to prepare intellectually disabled students for work in the private sector.

Maki Imada
CSR Management Department

In formulating the Kyowa Hakko Kirin Group Declaration on Employment of People with Disabilities, we were very conscious of its links with the Kyowa Hakko Kirin Group Management Philosophy, Action Policies and the spirit of our “Commitment to Life” and participated with a view to promoting CSR. This reaffirmed our belief that all employees need to understand those connections in their workplaces. I want to help make the Kyowa Hakko Kirin Group a place where people can work with a smile whether they have a disability or not.

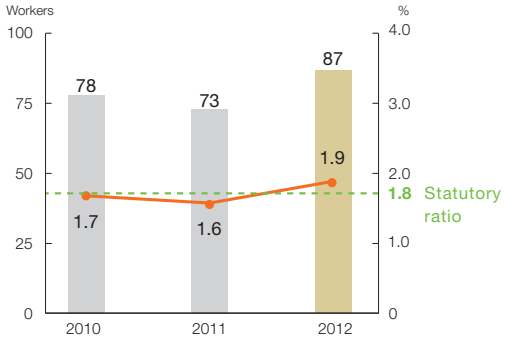
Right after launching the project, we visited a Special Support School that helps students with intellectual disabilities prepare for employment. This visit gave the team members a shared awareness, which will serve as a foundation for smooth operation of the project. As a member of the Legal Department, I would like to continue to support programs for the employment of people with disabilities while monitoring the legal situation, including the Constitution, relevant laws and regulations, treaties related to people with disabilities, and their revisions and ratifications.

Tomoko Fukuda
Manager, Legal Department

Initiatives to Employ People with Disabilities

Kyowa Hakko Kirin employs people with disabilities as part of its emphasis on diversity. As of the end of December 2012, we employ 87 such workers in Japan. This constitutes 1.9 percent of our total workforce, meeting the Japanese statutory requirement of 1.8 percent. The statutory requirement increased to 2.0 percent in April 2013, reflecting demands from society to speed up employment of persons with disabilities. The Kyowa Hakko Kirin Group is further strengthening its initiatives accordingly.

Ratio of Workers with Disabilities

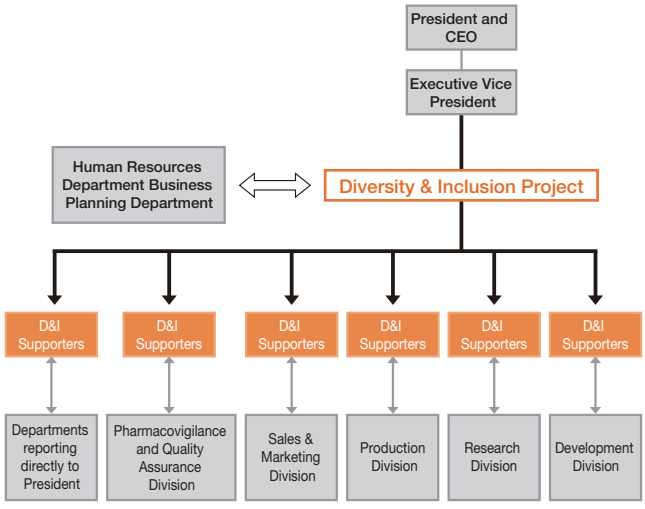


Diversity and Inclusion Initiatives

An organization that encourages mutual acceptance among employees with different backgrounds so they can achieve their full potential is crucial to human rights and labor practices. We are therefore committed to creating a work environment where diversity is respected and valued.

In October 2010, Kyowa Hakko Kirin launched the Company-wide Diversity & Inclusion (D&I) Project with members from every division. The D&I Project has been implementing a range of measures aimed at raising the company's competitiveness and producing results by leveraging the value of differences among employees with diverse backgrounds to vitalize our organization and drive innovation. The project is currently focusing on five themes: gender, nationality, differing career histories, life events and disabilities. Project activities will continue through 2015 to support a corporate culture that encourages consistent employee enthusiasm for their work.

Diversity & Inclusion Project Organization



Initiatives in 2012

Six cross-organizational working teams implemented various measures to create a culture that embraces diversity. To help female employees struggling with child-rearing widen the circle of colleagues they can talk to easily, the Networking Team held a D&I Discussion Meeting attended by female employees and senior employees who are pursuing successful careers while raising children. In the discussion, the senior employees shared their own experiences such as relationships with other people in their careers, time management and ways of overcoming anxiety, and talked with the other participants. After the meeting, the female employees appeared more positive. One commented that she hoped to find a balance between her work and raising her children, and another said that she wanted to actively establish career goals.

D&I Discussion Meeting

Action Plans for 2013

We will continue working to resolve issues related to employee gender and life events, as in 2012. In addition, we plan to focus on initiatives for the Sales & Marketing Division and on increasing the number of women in management positions.

In our new medium-term business plan, we set the challenge of becoming a global specialty pharmaceutical company. This will require us to enhance the individual abilities and motivation of our employees. One of our core strategies for doing so is to create a corporate culture in which diverse people can work together and fulfill their potential. The D&I Project has been an essential program for Kyowa Hakko Kirin, which is preparing to expand its business globally. We will promote the project even more strongly as we work to achieve the goals of our medium-term business plan.

The Environment

We are contributing to the realization of a sustainable society by assessing and reducing the impact of the Group's business activities, with preventing global warming and conserving biodiversity as our core themes.

As a corporate group aiming to be a global specialty pharmaceutical company, we will extend our environmental initiatives worldwide.

Takayuki Tanaka

Director, CSR Management Department
Formerly Director, Environment and Safety Department

Initiatives to address environmental issues around the world are carried out under the principal theme of sustainable development, based on agreements such as the Framework Convention on Climate Change and the Convention on Biological Diversity adopted at the United Nations Conference on Environment and Development (also known as the Earth Summit) held in Rio de Janeiro in 1992. The Kyowa Hakko Kirin Group is also actively engaged in initiatives for the environment, one of the core subjects of ISO 26000. However, it is important that we stay on top of world trends, carefully determine how we should respond as a corporate group and incorporate that response in our action policies, targets and measures.

With the start of the Medium-Term Business Plan – 2013 to 2015, we also set new targets for our environmental activities. In measures to prevent global warming, we are extending our initiatives worldwide. We have set a global target[1] of reducing our CO_2 emissions in fiscal 2020 to no more than 85 percent of the fiscal 1990 level. In addition to the domestic Group companies the target applied to in the past, it will also apply to four overseas manufacturing subsidiaries.[2] Until now, we have visited overseas manufacturing subsidiaries once a year to discuss compliance and environmental initiatives. Beginning this year, however, the entire Group will work to achieve shared targets. In addition, we will confirm the impact of the business activities of our overseas marketing and development subsidiaries on global warming, and respond accordingly.

We will continue to contribute to the realization of a sustainable society by conducting environmental initiatives worldwide as a corporate group aiming to be a global specialty pharmaceutical company.

1. The target applies to Kyowa Hakko Kirin Co., Ltd. and the domestic manufacturing and research facilities and overseas manufacturing facilities of its consolidated subsidiaries
2. Kyowa Hakko Kirin China Pharmaceutical Co., Ltd., Shanghai Kyowa Amino Acid Co., Ltd., BioKyowa Inc. (U.S.A.), and Kyowa Hakko Kirin (Thailand) Co., Ltd.

Environment and Safety Assessment and Management

Based on its own Basic Policy on the Environment, Safety, and Product Safety, as well as under the Responsible Care initiative for environmental protection and safety, the Kyowa Hakko Kirin Group operates rigorous assessments at each stage of the product life cycle, from R&D to use and disposal.

The Kyowa Hakko Kirin Group has both an ISO 14001-certified environmental management system and an occupational safety and health management system centered on risk assessment, and continuously improves them through a systematic Plan-Do-Check-Act (PDCA) cycle. Moreover, our environmental and safety activities comply with relevant laws and regulations while also aiming to help us earn the trust of society by supporting resource recycling, ensuring and enhancing environmental and safety management, and minimizing risk.

Basic Policy on the Environment, Safety and Product Safety

Based on Kyowa Hakko Kirin Group Management Philosophy, we will exert ourselves to realize an affluent society by conducting business activities with scientific consideration for health, safety, the environment and product safety throughout the entire life cycle of each of our products, that extends from research and development through production, marketing, use, and disposal, at the same time, we are making efforts to ensure the quality and safety of our products, taking the safety of consumers as a matter of the greatest importance.

(Revised March 22, 2012)

Environmental Accounting

In 2012, environmental investment totaled ¥1,274 million and environmental costs totaled ¥3,354 million. Main investments included renovation of air conditioning equipment and high-efficiency freezers, additional equipment to process and reduce sludge, new wastewater processing equipment, installation and renovation of equipment to recycle volatile organic chemicals, changeover to LED lighting, and the installation of photovoltaic power generation systems. This environmental investment generated an economic benefit of ¥101 million.

Environmental Accounting

Unit: Millions of yen

Cost classification		Major activities in 2012	2011		2012	
			Investment	Investment Expense	Investment	Investment Expense
(1) Business area cost			1,467	2,923	1,200	2,779
Details	(1)-1 Pollution prevention cost					
	① Cost of preventing water contamination	Investment and maintenance cost for water contamination control facilities	660	1,431	386	1,334
	② Cost of preventing air pollution and other pollution	Investment and maintenance cost for air pollution control facilities, deodorization facilities, etc.	278	440	223	312
	(1)-2 Global environment conservation cost	Investment and maintenance cost for photovoltaic power generation facilities and chlorofluorocarbon-alternative freezers	413	271	526	178
	(1)-3 Resource circulation cost	Investment and maintenance cost for water-saving equipment, waste recycling and treatment facilities, etc.	116	781	64	956
(2) Upstream /downstream cost		Cost of green purchasing and recycling containers and packaging	0	33	17	36
(3) Administration cost		Cost of operating an environmental management system, monitoring environmental impact, and other activities	19	387	51	379
(4) R&D cost		Cost of developing environmentally friendly products and curtailing environmental impact	1	476	5	142
(5) Social activity cost		Cost of environmental conservation activities and of participating and cooperating in nature preservation activities	0	16	0	17
(6) Environmental remediation cost		Marine accident remediation, etc.	0	1	0	1
Total			1,487	3,836	1,274	3,354

Economic Benefit

Unit: Millions of yen

Item	Activities in 2012	2011	2012
Total investment	Expansion and rationalization of production and research facilities	9,797	17,810
Total R&D cost	R&D for new products and technologies	47,998	44,987
Sales of valuables in connection with (1)-3 and (2)	Sale of dried fungus fertilizer, used catalysts, and by-product oil	45	2
Resource-saving effects in connection with (1)-2 and (1)-3	Energy and resource conservation and waste reduction	82	99

* The figures pertain to production sites and laboratories of Kyowa Hakko Kirin (including Kyowa Medex), Kyowa Hakko Bio and Daiichi Fine Chemical.
* The data were calculated in accordance with the Environmental Accounting Guidelines 2005 published by the Ministry of the Environment.
* Green purchasing statistics represent the purchase amount of environmentally friendly products, including Eco Mark products, and have been included as reference information.
* The sum of table data may not equal the total due to rounding.

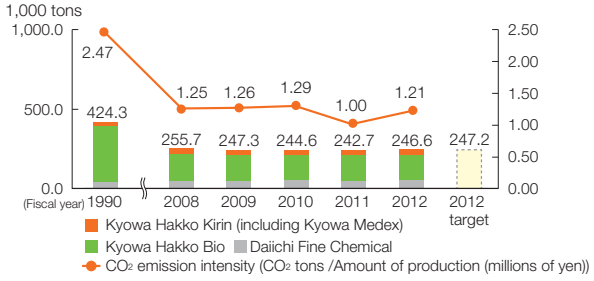
Our Activities for Reducing CO_2 Emissions

The Kyowa Hakko Kirin Group worked to achieve the fiscal 2012 goal of its Medium-Term Environmental Plan of reducing CO_2 emissions among Group companies in Japan by 3 percent from the level in fiscal 2007 to 247,200 tons.

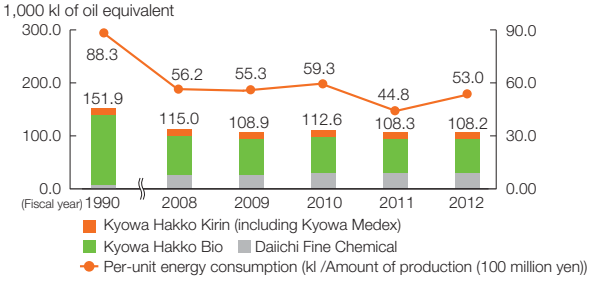
We achieved our fiscal 2012 goal. CO_2 emissions at domestic Group plants and laboratories totaled 246,600 tons, a reduction of 3.2 percent compared with fiscal 2007. The CO_2 emissions coefficient for power generation increased due to the suspension of nuclear power generation in Japan. However, Eco Project activities including the phase-out of facilities that use heavy oil, the introduction of the latest energy-efficient equipment at new facilities, and the improvement of operating techniques contributed to reducing CO_2 emissions by 4,181 tons. The Group's energy consumption in 2012 was unchanged year on year at 108,000 kiloliters of oil equivalent.

Renewable energy remain a focus. Photovoltaic power generation systems have been operating at the Fuji Plant, Tokyo Research Park and Ube Plant, and should begin operating at the Takasaki Plant during 2013.

CO_2 Emissions / CO_2 Emission Intensity



Energy Consumption/Per Unit Energy Consumption



*The 2011 figures for CO_2 emissions and CO_2 emission intensity in the above graph were reported erroneously in Corporate Social Responsibility Report 2012 and have been corrected.

Initiatives for Conserving Biodiversity

The Kyowa Hakko Kirin Group is taking steps to maintain ecosystems and conserve biodiversity. We have participated in the Kirin Group's water-source protection project at the Kyowa Hakko Kirin Takasaki Plant since fiscal 2007 and at the Kyowa Hakko Kirin Fuji Plant, Kyowa Medex Fuji Plant, Kyowa Hakko Bio Yamaguchi Production Center and Kyowa Hakko Kirin Ube Plant since fiscal 2009. In fiscal 2012, employees at these five plants participated in underbrush clearing and tree planting and thinning as part of our Water Source Forest Conservation Activities.

The third-party review of Corporate Social Responsibility Report 2012 identified the need to give appropriate consideration to and take the necessary action for access and benefit sharing (ABS) for local residents near raw material and sample collection sites. We will address this by following the Kirin Group's guidelines on access to genetic resources.

In 2013, we will begin using bioassay-based whole effluent toxicity (WET) testing of wastewater as part of our efforts to preserve biodiversity. This will enable us to verify, examine and analyze the extent of the impact of the Kyowa Hakko Kirin Group's business sites on ecosystems.

Fair Operating Practices

We strive for open and fair business transactions and CSR procurement, promote compliance and conduct our business based on sound ethics.

We promote CSR procurement based on open and fair business transactions with suppliers and a spirit of equal partnership.

Kinya Kubo
Director, Procurement Department

Our social mission as a pharmaceutical company is to deliver safe and reliable medicines to patients who need them. The mission of the Procurement Department is fulfilling social responsibilities including the stable supply of Kyowa Hakko Kirin pharmaceuticals by developing and maintaining multiple and reliable procurement routes through good relationships with several suppliers for each of our products.

In addition, we believe it is important to promote CSR throughout the supply chain, including suppliers and the companies that supply them. We therefore endeavor to maintain open dialogue with our suppliers.

In 2012, we surveyed the CSR efforts of domestic suppliers of raw materials, packaging materials and other materials to the Kyowa Hakko Kirin Group. We also published the Kyowa Hakko Kirin Group Procurement Policy on our website. This policy declares our commitment to open and fair procurement and to the promotion of CSR procurement with our suppliers to contribute to the advancement of a sustainable society.

In 2013, we will perform a follow-up survey of the suppliers we surveyed in 2012. Furthermore, we will set up face-to-face meetings with them to exchange opinions, share awareness of issues and consider solutions at each end. Based on these activities, we plan to specify our standards for CSR procurement and announce them in CSR procurement guidelines by the end of 2013.

We will work to ensure that suppliers understand our Group's commitment to CSR. In our relationships with them, we will keep in mind that we are equal partners based on the premise of open and fair business transactions. In this way, we hope to steadily spread the practice of CSR procurement.

Promoting CSR Procurement

Questionnaires on CSR Initiatives

In May and October 2012, we surveyed 299 suppliers about their CSR activities and received responses from 271 companies (a response rate of 91 percent). Our purpose was to promote CSR such as environmental consciousness and legal compliance throughout the supply chain, including the suppliers related to the Kyowa Hakko Kirin Group.

We asked suppliers 51 questions in 12 categories to determine the current situation concerning their CSR efforts, with a focus on compliance, corporate governance, risk management, human rights, occupational safety and environmental conservation. While supplier characteristics vary according to their industry, 85 percent or more of the companies are addressing human rights and labor practices, quality and safety, compliance, and risk management. We also reconfirmed that suppliers needed to improve efforts in three categories: green procurement (environmentally friendly procurement), environmental audits of their suppliers, and consideration for biodiversity.

In December 2012, we sent a summary of the survey results with the newly established Kyowa Hakko Kirin Group Procurement Policy to the suppliers who participated, and requested their cooperation in promoting CSR procurement.

This questionnaire survey was a part of our effort to encourage suppliers to implement CSR initiatives based on the third-party review of CSR Report 2012, which stated that further efforts were expected regarding this point.

Next Steps in Adopting CSR Procurement

In 2013, we will continue to work proactively to establish CSR procurement as quickly as possible.

To maintain communication with suppliers, we will conduct interviews and follow-up questionnaire surveys to determine the

progress of their CSR efforts and identify other issues to be resolved. In addition, we will set up face-to-face meetings with suppliers to exchange opinions so that we can mutually consider CSR objectives and measures to promote CSR based on our respective circumstances.

We will also draw up the guidelines that specify standards for promoting CSR procurement, as stated in the procurement policy formulated last year. We plan to announce the guidelines during 2013.

These various guidelines will be shared not just with the people involved in procurement but among all Group employees. We will work to educate employees to ensure that they comply with the guidelines.

Compliance

Strengthening and enforcing compliance is the basis of social responsibility. We have formulated the Kyowa Hakko Kirin Group Compliance Guidelines to clarify the Group's commitment to compliance with corporate ethics and are working to promote awareness of the guidelines among Group companies by providing compliance training and e-learning. We have also set up four hotlines, including one to an outside attorney, for reporting and providing consultation on any legal or ethical violations that are discovered in the Kyowa Hakko Kirin Group.

Main Training Provided in 2012

- **Corporate Ethics Lectures:** Two lecture presentations by outside experts were held in 2012. The lectures were recorded on DVD and streamed over the Group intranet to give employees at every business site the opportunity to view them.

  1. Theme: Social Responsibility Has Significance Not for Society but for the Company Itself
     Presenter: Hideto Kawakita, CEO, International Institute for Human, Organization and the Earth (IIHOE)
  2. Theme: Leaders Are the Key to Instilling Compliance
     Presenter: Kazutaka Okubo, CSR Promotion Officer, Ernst & Young ShinNihon LLC

The lectures were well attended.

- **Human Rights and Compliance Training:** Organized jointly by the Human Resources Department and CSR Management Department. The training consists mainly of group work and is designed to encourage participation in various activities. In 2012, a total of 248 sessions took place in the Group, with 6,540 employees participating (a participation rate of 96.3 percent).
- **E-learning Instruction:** Topics in 2012 included information security, copyright compliance and security trade controls.
- **Survey on Attitudes toward Compliance and Human Rights:** We conducted this survey as a member of the Kirin Group and provided feedback on the results.

We conduct our pharmaceutical business activities in a highly transparent manner consistent with the letter and spirit of relevant standards such as the Charter for Good Corporate Conduct and guidelines established by the Japan Pharmaceutical Manufacturers Association (JPMA). In addition, we agree with the policies of the Transparency Guideline for the Relation between Corporate Activities and Medical Institutions, which the JPMA formulated in 2011 to increase transparency in relationships between the pharmaceutical industry and medical institutions. Kyowa Hakko Kirin has formulated and published its own corresponding guidelines under the same title.

In 2013, we will start providing information on monetary payments to medical institutions in Japan during the previous year via our Japanese website and other means.

Position on Animal Welfare

Animal testing is essential to evaluate the safety and effectiveness of pharmaceuticals. Kyowa Hakko Kirin has established its own animal testing standards in line with relevant laws and guidelines. Based on these standards, we have worked to properly care for laboratory animals and conduct animal testing in a way that promotes animal welfare as well as scientific benefit.

Kyowa Hakko Kirin was evaluated as properly conducting animal testing in accordance with the guidelines of the Ministry of Health, Labour and Welfare. As a result, in March 2012 Tokyo Research Park, Fuji Research Park and Takasaki Plant received a certificate from the Center for Accreditation of Laboratory Animal Care and Use established by the Japan Health Sciences Foundation.

Certification of animal testing practices

Consumer Issues

To deliver safe, trustworthy products, we ensure reliability in all work processes and focus on activities that contribute to better treatment and on communication with patients.

By supporting DOPPS, we are working to realize a better future for everyone involved in dialysis therapy.

DOPPS (Dialysis Outcomes and Practice Patterns Study) is a study on practice patterns and outcomes in hemodialysis patients. It is the first international collaborative epidemiological study ever conducted, with 19 countries participating as of the end of 2012.

Kyowa Hakko Kirin has been serving as the coordinating center for DOPPS in Japan since 1999. We cooperate with medical institutions in Japan in conducting the study and collecting data from approximately 2,000 patients at 58 facilities. Our report on the care of dialysis patients in Japan has informed the world of the excellent outcomes of dialysis therapy in Japan and has helped identify new challenges and improve treatment in other countries.

In Japan, the data are used in the guidelines of the Japanese Society for Dialysis Therapy and have shown a correlation between the duration of dialysis therapy and better prognosis for patients. This has led to revision of the National Health Insurance policy on dialysis therapy. Moreover, medical institutions are able to refer to data from around the world and from individual facilities and reflect it in individual treatment plans for their patients.

Yasuhiro Nishikawa / Chizu Togawa
Clinical Research Management Department, Development Division

We faced some difficulties in collecting the DOPPS survey forms, but are proud to be part of an important project in the field of nephrology, one of our core therapeutic areas. We will continue our sincere efforts to realize a better future for patients and everyone involved in dialysis therapy.

Overview of DOPPS and Kyowa Hakko Kirin's Initiatives

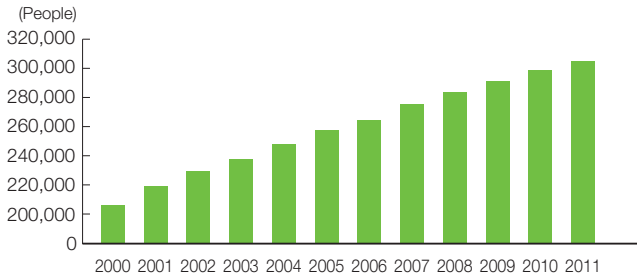
Dialysis therapy plays an important role in treating patients with chronic renal failure. More than one million patients around the world are currently receiving dialysis. While significant advances have been made recently in the technology and devices used in dialysis therapy, there are still many issues to address, such as improvement of treatment methods to reduce the burden on patients.

Launched in 1999, DOPPS is the first international collaborative study in the field of dialysis. It is coordinated by the Arbor Research Collaborative for Health, a U.S.-based nonprofit research organization. Kyowa Hakko Kirin provides funding to this organization and support for the study surveys in Japan.

Many valuable data that have been collected through DOPPS have been used to improve treatment methods and reduce the burden on patients. In addition to its supportive role in surveys, Kyowa Hakko Kirin contributes to the progress of dialysis therapy in ways such as organizing joint symposiums with the Japanese Society for Dialysis Therapy and disseminating relevant information.

Kyowa Hakko Kirin also provides support for research on treatment methods for chronic kidney disease and the influence of dialysis on bone and the parathyroid glands. We will continue to focus on activities aimed at elucidating diseases in addition to conducting research and development of pharmaceuticals.

Change in the Number of Chronic Dalysis Patients in Japan



Source: Currents States of Chronic Dialysis Treatments in Japan (as December 31, 2011), Statistics and Research Committee, The Japanease Society for Dialysis Therapy

Communication with Customers

Information and drug counseling available on our website help us communicate with customers and respond to their inquiries.

Sharing Useful Information on the Web

Kyowa Hakko Kirin provides information on the web tailored to different customer segments to assist and encourage them in fighting disease.

At kksmile.com, a website for physicians, pharmacists and other health care professionals in Japan, the content focuses on in-depth information about our products related to the fields of nephrology, circulatory system and diabetes; oncology and hematology; immunology and allergies; and central nervous system and gastroenterology. The site also provides the latest scientific information presented at conferences and in publications.

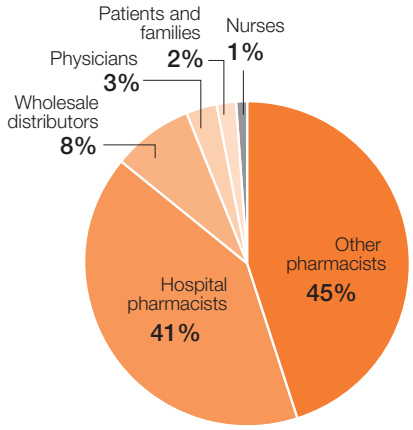
On our websites for patients, their families and the general public, we present detailed, easy-to-understand information on disease causes, symptoms and treatments, as well as tips for healthy living. (All of the websites noted above are in Japanese only.)

Medical Information Office

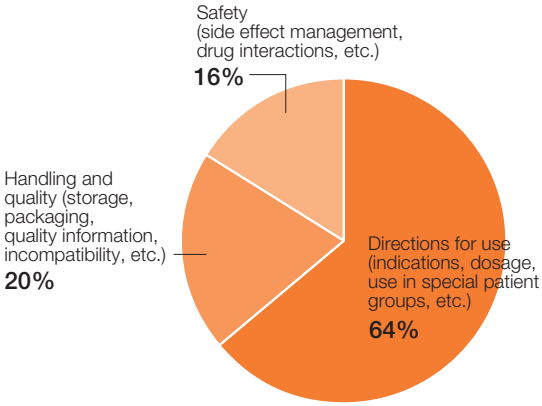
The Medical Information Office responds to inquiries about our products from medical doctors, pharmacists, patients and their families. The number of inquiries has been increasing year by year, with nearly 40,000 in 2012. Information received by the office is immediately provided to MRs and relevant departments. Through enhanced cooperation, the information is not only used within the Sales & Marketing Division, but also to supplement our safety management and quality knowledge.

Among its new initiatives in 2012, the office compiled a list of frequently asked questions and answers, and posted them on the kksmile.com website. The office also makes suggestions at internal liaison conferences based on the comments it receives, and has begun setting up a structure for quickly reflecting end-user feedback in products.

Number of Inquiries



Number of Inquiries by Subject



Community Involvement and Development

Our efforts to contribute to communities include ongoing activities to bring smiles back to children's faces in Japan's disaster-affected region and support for science education for the young people who will lead the next generation.

Kirin *Kizuna* Relief-Support Project for Post-Disaster Reconstruction

We are bringing smiles to children and fostering ties in communities.

Masumi Horikoshi
Corporate Communications Department

Under the theme "fostering ties," the Kirin Group is carrying out its Kirin *Kizuna* Relief-Support Project to assist in the recovery of the region affected by the Great East Japan Earthquake. Three activities are the pillars of this project: helping restore the local food culture and food industry, bringing smiles to children, and helping people enhance their mental and physical wellness.

Kyowa Hakko Kirin is focusing mainly on activities to bring cheer and smiles back to the faces of children affected by the disaster. Our efforts include table tennis lessons for children, support for science education and a scholarship program for high school students studying agriculture. The table tennis lessons have been ongoing since November 2011.

This is my second year of involvement as an operations staff member. During the table tennis lessons, when I witness the smiles of the children as they interact with players from our company's table tennis club, and the delight of their caregivers, I feel that the circle of ties is steadily widening. In our support for science education, we do more than provide research materials and assistance for experimental methods. We also establish a framework for independent research even after our support ends by creating research networks that link the schools we supported with each other and with the research institutions such as universities.

These activities may be minor, but I believe that sustaining them brings smiles to more people's faces. We will continue to engage in community activities that bring people together.

Table Tennis Club Cooperates in Project in Disaster-Affected Region

Kyowa Hakko Kirin's table tennis club was founded in 1974, and has remained active under the motto "Balancing work and table tennis." The club has produced many players who have competed in international tournaments and other events. It has conducted various programs to contribute to society, including holding table tennis lessons and supporting physical fitness programs for people with disabilities as well as for elementary school children.

We are conducting our table tennis program in the region affected by the Great East Japan Earthquake with the full cooperation of the Company's table tennis club. In the Kyowa Hakko Kirin Table Tennis Lessons project, we try to bring smiles to the faces of as many children as we can by imparting not only table tennis skills but also the joy and appeal of sports. In 2012, table tennis lessons were held at 10 facilities for elementary, junior and senior high school students in Iwate, Miyagi and Fukushima prefectures. Members of the Company's table tennis club, all top players in the Japan Table Tennis League, worked directly with the students, providing skill instruction, engaging in rallies and arranging matches.

As a new initiative, we also held a table tennis event twice last year specifically set up for people of all ages with disabilities. In Fukushima Prefecture, we held nine table tennis meets at temporary housing facilities and other places in an effort to spread cheer in the community. Besides providing an opportunity for local residents to enjoy this indoor sport, we also donated 80 table tennis tables via the Social Welfare Council. In addition, we held the Kyowa Hakko Kirin Cup and 2nd WASURENAI 3.11 *Kizuna* Four-Prefecture (Iwate, Miyagi, Fukushima and Ibaraki) Table Tennis Tournament.

Table Tennis Lessons Held in 2012

May 19	Oshu City, Iwate Pref.	(190 participants)
May 20	Kitakata City, Fukushima Pref.	(350 participants)
Jul. 28	Shiwa Town, Iwate Pref.	(230 participants)
Jul. 29	Watari Town, Miyagi Pref.	(140 participants)
Aug. 1	Nihonmatsu City, Fukushima Pref.	(250 participants)
Aug. 19	Soma City, Fukushima Pref.	(150 participants)
Sept. 22	Miyako City, Iwate Pref.	(260 participants)
Sept. 23	Kesennuma City, Miyagi Pref.	(145 participants)
Oct. 27	Shichigahama Town, Miyagi Pref.	(210 participants)
Nov. 23	Ishinomaki City, Miyagi Pref.	(330 participants)

Total: 10 locations (total participants: 2,255)

On the Scene

Yasushi Toya, Deputy Manager, Men's Table Tennis Club

When I participate in table tennis lessons and see the children eagerly trying to learn, I feel this program really is helpful in cheering up the people in the disaster-affected region.

I didn't start participating until about a year and a half after the disaster, but the damage along the coast was still very evident. The situations of the children are different depending on the area – some lost their families, some were forced to evacuate their homes – but when they are in the gym playing table tennis, they play with innocent smiles. That is what I enjoy most, and what makes this project so rewarding. I will continue to help out in activities that energize people in the region.

Bringing people together with a smile

Support for Science Education in the Disaster Region

Through the Japan Society for Bioscience, Biotechnology, and Agrochemistry, Kyowa Hakko Kirin is supporting science education at junior and senior high schools in Iwate, Miyagi and Fukushima prefectures, which suffered heavy damage from the earthquake and tsunami. In 2012, we provided support that included visiting workshops and experiments and donating laboratory and other equipment to nine junior high schools and 16 senior high schools in these three prefectures.

In August 2012, we started the Tohoku Bio Education Project. This project gives students at participating schools the opportunity to attend hands-on learning workshops on biological research. The goals of the project are to nurture biological researchers and future human resources in the disaster-affected region and build research networks. The students choose their own research themes and take the initiative in performing the research. We provide them with a program of step-by-step research support, from proposal of research plans to announcement of findings. In addition to building research networks among the participating schools, we also assist in the formation of networks among the schools and research institutions of universities and other organizations. The three schools below participated in fiscal 2012, the first year of the program. Each of their themes evoked images of a new future for the disaster-affected region.

Participating Schools and Research Themes in 2012

- Takata Senior High School, Iwate Prefecture: "Exploration of Biofuel-Producing Algae from Soil and Seawater in the Tsunami-Affected Region"
- Miyagi Fisheries High School, Miyagi Prefecture: "Analysis of Microbial Succession during High-Temperature Fermentation of Fish Sauce"
- Shinchi Senior High School, Fukushima Prefecture: "Research of Culture Media in Environmentally Controlled Agriculture"

Note: With the addition of three more schools in May 2013, we plan to continue this project through March 2014 with a total of six schools.

Science Classes for Young Students

Our plants and laboratories in Japan conduct science experiment classes to create opportunities to share the excitement of science with large numbers of children. The Tokyo Research Park started the Bio-Adventure Project in 2000, sending its research staff equipped with microscopes and other experimental equipment to local elementary, junior and senior high schools to conduct science experiments related to genetics, microbiology and immunology. A total of 4 classes with 114 attending students were held in 2012.

In addition, the Ube Plant, Takasaki Plant and Bio Process Research and Development Laboratories use the summer break to hold science classes led by employees.

Financial Section

Sound finances are essential to our ability to develop and deliver patient therapies. Our financial objectives include stable cash flow that funds both strong investments in R&D and sustained dividends.

A Message from the CFO

Kyowa Hakko Kirin has balanced its finances. We will build the foundation for further growth while maintaining a high level of profitability.

Overview of Medium-Term Business Plan – 2010 to 2012

Over the past three years, we implemented various measures to concentrate on the Pharmaceuticals business. We sold the Chemicals business and the Food Products business and acquired ProStrakan of the United Kingdom, while simultaneously raising asset efficiency. For example, under the management plan we scrutinized idle land and portfolio securities, sold assets we did not need, and deployed that capital to generate growth in the Pharmaceuticals business.

As a result, we built a balance sheet appropriate for a pharmaceutical manufacturer, with less property, plant and equipment, more intangible assets including goodwill and sales rights, and a higher equity ratio. Moreover, the profitability indicators of gross margin and operating margin have improved because our sales are also focused on pharmaceuticals.

Financial Strategy for Medium-Term Business Plan – 2013 to 2015

Looking at the coming three years, we will be competing with well-known global pharmaceutical companies in the categories of nephrology, oncology, immunology/allergy and the central nervous system. We therefore need to focus on therapeutic areas in which we are strong so that we can leverage the Kyowa Hakko Kirin Group's unique advantages in terms of knowledge, flexibility and teamwork rather than competing on the basis of size.

During Medium-Term Business Plan – 2013 to 2015, our management priority will be maintaining current levels of profitability while making the investments required to enhance our new product pipeline. We have selected and concentrated our business portfolio, but we still need to make new investments to further strengthen both our Pharmaceuticals business and our Bio-Chemicals business. We will deploy capital effectively and emphasize a flexible financial strategy that hedges risk while ensuring that we do not fall behind other companies in capturing business opportunities. We will use the cash management system we have introduced to support capital-efficient activities and reduce inefficient assets throughout the Group to strengthen the foundation for growth as a global specialty pharmaceutical company.

Policies for Shareholder Returns and Capital Deployment

Kyowa Hakko Kirin's policy for shareholder returns emphasizes stable, sustained dividends. Medium-Term Business Plan – 2013 to 2015 raises our target for the consolidated payout ratio to 40 percent. At the same time, we are emphasizing proactive investment in a promising pipeline while maintaining high profitability so that we can address shareholder expectations.

We respond to our stakeholders sincerely because we must earn their trust. We intend to meet their expectations while energetically investing in sustained growth as a global specialty pharmaceutical company.

Kazuyoshi Tachibana

Director of the Board
Executive Managing Officer

Eleven-Year Selected Financial Data

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries
For the years ended December 31, 2012, 2011 and 2010, the nine months ended December 31, 2009 and years ended March 31, 2002 to 2009

	2012/12	2011/12	2010/12	2009/12
For the Year:				
Net sales	¥333,158	¥343,722	¥413,738	¥309,111
Gross profit	210,690	197,555	190,979	139,739
Selling, general and administrative expenses	157,785	150,940	145,568	111,496
Operating income	52,905	46,614	45,410	28,243
Net income	24,199	25,608	22,197	8,797
Capital expenditures	27,808	19,697	29,374	25,135
Depreciation and amortization	20,904	22,833	22,188	17,003
R&D expenses	44,808	47,961	44,210	34,979
Cash Flows:				
Net cash provided by operating activities	¥ 59,134	¥ 40,634	¥ 64,189	¥ 24,203
Net cash (used in) provided by investing activities	(98,772)	18,460	(32,373)	(13,246)
Net cash used in financing activities	(19,189)	(30,740)	(14,446)	(16,906)
Cash and cash equivalents at the end of the period	50,334	107,555	79,882	63,745
At Year-End:				
Total current assets	¥303,988	¥284,217	¥288,852	¥276,587
Total assets	679,342	658,873	695,862	695,268
Total current liabilities	85,774	78,465	102,483	110,080
Interest-bearing debt	5,699	6,042	7,515	13,228
Total net assets	555,898	540,023	544,992	540,343
Total shareholders' equity[2]	560,663	554,856	553,172	539,304
Number of employees	7,243	7,229	7,484	7,436
Per Share Data:				
Net income–basic[3]	¥ 44.12	¥45.16	¥38.96	¥15.40
Net assets	1,013.6	970.2	954.6	940.8
Cash dividends	20	20	20	15
Common Stock Price Range (Per share)**:**				
High	¥970	¥953	¥1,040	¥1,178
Low	757	628	773	793
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	548,449	567,029	569,711	570,935
Financial Ratios:				
Return on assets (ROA)	3.62	3.78	3.19	1.26
Operating return on assets	7.91	6.88	6.53	4.05
Return on equity (ROE)	4.43	4.73	4.11	1.64
Equity ratio	81.68	81.79	78.16	77.07
Debt/equity ratio	1.03	1.12	1.38	2.47
Operating income margin	15.88	13.56	10.98	9.14
EBITDA[4] (Millions of yen)	78,160	79,864	74,614	45,056
Payout ratio[5]	32.8	32.5	36.2	54.3

1. U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥86.58=U.S.$1, the approximate exchange rate at December 31, 2012.
2. Due to a change in accounting standards, figures for total shareholders' equity in the years ended March 31, 2007 and 2006 have been restated.
3. Net income per share–basic is based upon the weighted average number of shares of common stock outstanding during each year, appropriately adjusted for subsequent free distributions of common stock.
4. EBITDA= Income before income taxes and minority interests + Interest expenses + Depreciation and amortization + amortization of goodwill
5. The consolidated payout ratio is calculated using 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[1]
2009/3	2008/3	2007/3	2006/3	2005/3	2004/3	2003/3	**2012/12**
¥460,183	¥392,119	¥354,274	¥353,439	¥358,963	¥348,838	¥359,284	**$3,847,987**
200,297	144,917	131,424	126,982	132,112	129,506	126,328	**2,433,483**
154,910	105,527	100,725	101,448	98,605	102,670	110,239	**1,822,427**
45,387	39,390	30,698	25,534	33,506	26,836	16,088	**611,055**
11,726	23,477	12,694	16,273	17,931	10,017	8,484	**279,505**
18,523	14,795	14,497	10,870	7,648	9,041	11,791	**321,188**
18,779	14,346	10,006	9,788	10,565	11,358	14,767	**241,449**
48,389	34,109	33,342	32,875	28,761	29,205	31,438	**517,544**
¥ 41,069	¥ 30,713	¥ 23,380	¥14,303	¥30,104	¥ 34,264	¥ 18,193	**$ 683,004**
(3,981)	(9,492)	(8,493)	(1,795)	(8,104)	10,476	2,585	**(1,140,825)**
(20,978)	(13,499)	(24,417)	(5,139)	(9,116)	(44,226)	(38,748)	**(221,635)**
69,286	44,118	36,613	45,820	37,817	24,911	24,588	**581,359**
¥279,475	¥232,661	¥214,352	¥212,985	¥210,341	¥194,062	¥195,878	**$3,511,069**
699,041	394,081	378,870	384,381	374,492	361,095	368,771	**7,846,409**
108,522	111,743	106,565	94,148	103,489	98,914	95,045	**990,701**
13,540	12,790	13,136	12,216	12,193	13,357	51,969	**65,830**
543,070	256,758	244,082	257,491	—	—	—	**6,420,630**
547,203	239,328	220,428	232,621	235,439	225,041	219,047	**6,475,669**
7,256	6,073	5,756	5,800	5,960	6,294	6,749	
Yen							U.S. dollars[1]
¥20.42	¥58.99	¥31.31	¥38.34	¥41.67	¥22.99	¥19.35	**$ 0.509**
938.4	639.7	607.5	604.9	556.3	522.6	505.4	**11.707**
20	10	10	10	10	7.5	7.5	**0.231**
¥1,235	¥1,430	¥1,154	¥946	¥864	¥719	¥780	**$11.20**
586	933	722	656	661	495	411	**8.74**
576,483	399,243	399,243	434,243	434,243	434,243	434,243	
574,083	397,716	405,270	422,919	427,635	431,497	433,747	
%, except EBITDA							
1.62	6.07	3.33	4.29	4.88	2.74	2.12	
6.26	10.19	8.04	6.73	9.11	7.35	4.03	
2.17	9.47	5.1	6.63	7.79	4.51	3.94	
77.04	64.53	63.8	66.55	62.87	62.32	59.4	
2.51	5.03	5.43	4.78	5.18	5.94	23.73	
9.86	10.05	8.67	7.22	9.33	7.69	4.48	
60,098	53,162	33,771	34,846	40,707	27,539	33,477	
53.8	16.9	31.9	26.1	24.0	32.6	38.8	

All amounts are rounded down.

Subsidiaries Included in the Scope of Consolidation

As of December 31, 2012, the number of consolidated subsidiaries was 38, the same as a year earlier. The Kyowa Hakko Kirin Group acquired additional shares of ProStrakan AB, which had been accounted for by the equity method, and included it in the scope of consolidation. Newly established Thai Kyowa Biotechnologies Co., Ltd. is also included in the scope of consolidation.

On the other hand, Kyowa Hakko Kirin Italia S.r.l. was dissolved in a merger with consolidated subsidiary ProStrakan S.r.l., and is therefore excluded from the scope of consolidation. Hematech-GAC Venture, LLC is also excluded from the scope of consolidation because the Kyowa Hakko Kirin Group sold all of its shares in that company.

Income and Expenses

Net Sales

For the year ended December 31, 2012, net sales decreased 3.1 percent compared with the previous year to ¥333.1 billion. Sales increased in the Pharmaceuticals segment due to higher sales of core products and solid growth in exports. Also supporting growth were licensing revenues for biosimilar development from FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd., and the full-year contribution of the ProStrakan Group plc (ProStrakan), which was added to the scope of consolidation on June 30, 2011. However, net sales decreased overall due to the exclusion of the Chemicals segment (which contributed sales of ¥33.5 billion in the previous year) from the scope of consolidation.

Cost of Sales, SG&A Expenses and Operating Income

Cost of sales decreased 16.2 percent to ¥122.4 billion, while gross profit increased 6.6 percent to ¥210.6 billion. As a result, the gross margin improved 5.7 percentage points to 63.2 percent from 57.5 percent in the previous year. 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 4.5 percent to ¥157.7 billion. Key factors included the effect from the inclusion of ProStrakan in the scope of consolidation. The ratio of SG&A expenses to net sales increased 3.5 percentage points to 47.4 percent from 43.9 percent.

As a result of the above, operating income increased 13.5 percent to ¥52.9 billion, reaching a record high level for the third consecutive year. The operating income margin increased 2.3 percentage points to 15.9 percent from 13.6 percent.

Other Revenue (Expenses)

Net other expenses increased to ¥7.8 billion from ¥0.4 billion. Key factors included equity in losses of affiliates of ¥4.8 billion associated with the establishment of FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd., impairment loss of ¥1.3 billion, and loss on transfer of assets of ¥1.0 billion. In the previous year, we recorded a gain of ¥7.2 billion on sales of affiliates' stock.

As a result, income before income taxes and minority interests decreased 2.5 percent to ¥45.0 billion.

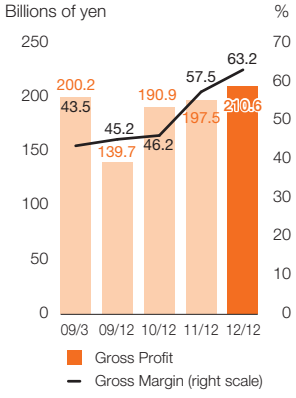
Income Taxes

The effective tax rate increased 1.4 percentage points to 45.8 percent from 44.4 percent.

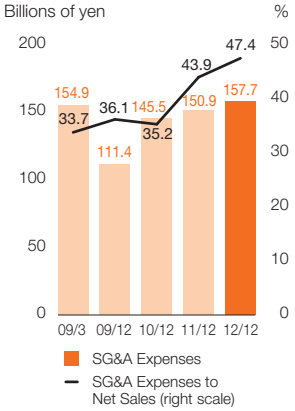
Net Income

Consequently, net income decreased 5.5 percent to ¥24.1 billion, and the net margin decreased 0.2 percentage points to 7.3 percent from 7.5 percent.

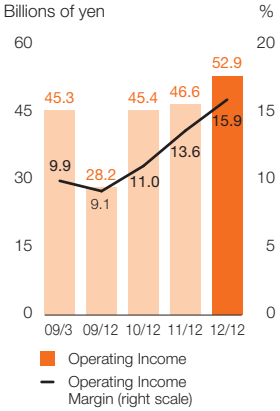
Gross Profit



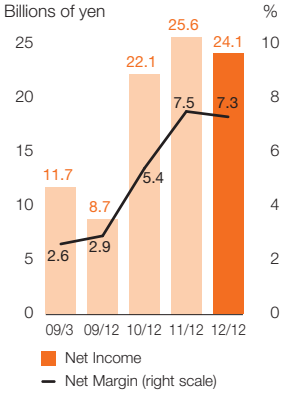
SG&A Expenses



Operating Income



Net Income



Note: 09/12 data is for the nine months ended December 31, 2009 because the Kyowa Hakko Kirin Group changed its fiscal year-end.

Performance by Business Segment

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

Yearly Information by Reportable Segment

	Millions of yen						Thousands of U.S. dollars
	2012/12	2011/12	2010/12	2009/12	2009/3	2008/3	**2012/12**
Net sales:							
Pharmaceuticals	**¥249,891**	¥229,339	¥210,362	¥158,273	¥210,449	¥138,377	**$2,886,245**
Bio-Chemicals	**76,966**	77,563	84,236	69,751	88,464	86,820	**888,962**
Chemicals	**—**	33,550	130,018	52,326	89,204	108,007	**—**
Food	**—**	—	—	—	42,468	43,324	**—**
Other	**10,429**	10,659	10,499	49,500	68,733	48,998	**120,457**
Adjustments	**(4,127)**	(7,390)	(21,377)	(20,740)	(39,135)	(33,407)	**(47,676)**
Consolidated total	**¥333,158**	¥343,722	¥413,738	¥309,111	¥460,183	¥392,119	**$3,847,987**
Segment income (loss):							
Pharmaceuticals	**¥50,392**	¥41,314	¥35,857	¥26,657	¥34,832	¥19,961	**$582,033**
Bio-Chemicals	**2,127**	2,896	3,275	3,048	8,342	9,688	**24,573**
Chemicals	**—**	2,135	5,678	(1,984)	(47)	7,169	**—**
Food	**—**	—	—	—	1,086	1,576	**—**
Other	**338**	360	363	400	1,094	838	**3,915**
Adjustments	**46**	(92)	235	121	(78)	155	**533**
Consolidated total	**¥52,905**	¥46,614	¥45,410	¥28,243	¥45,387	¥39,390	**$611,055**

Notes: 1. U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥86.58=U.S.$1, the approximate exchange rate at December 31, 2012.
2. 09/12 data is for the nine months ended December 31, 2009 because the Kyowa Hakko Kirin Group changed its fiscal year-end.

Pharmaceuticals

In the core Pharmaceuticals segment, net sales increased 9.0 percent to ¥249.8 billion. Segment income increased 22.0 percent to ¥50.3 billion.

Domestic sales were impacted by the biennial reductions in National Health Insurance (NHI) reimbursement prices, although core products performed well. Sales of our core ethical drug NESP®, a treatment for renal anemia, and ALLELOCK®, an antiallergic agent, were strong. However, sales of CONIEL®, a treatment for hypertension and angina pectoris, decreased due in part to the impact of generic pharmaceuticals.

Other products that recorded sales growth included REGPARA®, a treatment for secondary hyperparathyroidism during dialysis therapy, Fentos®, a transdermal analgesic for persistent cancer pain, ASACOL®, an ulcerative colitis treatment, and Romiplate®, a treatment for chronic idiopathic thrombocytopenic purpura.

Sales of POTELIGEO® for CCR4-positive adult T-cell leukemia-lymphoma (ATL) and Apokyn®, a treatment for Parkinson's disease, advanced steadily following their respective launches in May and July 2012.

Revenues from exports of pharmaceuticals and technology out-licensing increased from the previous year. In addition to solid growth in exports, we recorded out-licensing revenue from FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. for the development of biosimilars.

Sales of diagnostic reagents increased because of the solid performance of immunological reagents and exports.

ProStrakan, which was consolidated as of June 30, 2011, generally performed well and in line with expectations, with net sales of ¥16.2 billion and an operating loss (after amortization of goodwill) of ¥2.5 billion.

Bio-Chemicals

In the Bio-Chemicals segment, net sales decreased 0.8 percent to ¥76.9 billion, and segment income decreased 26.6 percent to ¥2.1 billion.

In Japan, sales of pharmaceutical-use amino acids, nucleic acids such as adenosine triphosphate (ATP) and other active pharmaceutical ingredients (API) were solid. Tranexamic acid sales volume rose substantially following the completion of production facilities in the previous year. As a result, overall sales of pharmaceutical and medical products increased from the previous year.

Sales of health care products were essentially unchanged from the previous year. Mail-order sales, primarily sales of ornithine, grew steadily. As an ingredient in Kirin Health Project *Kirin Plus-i* brands, ornithine is used in beverages, yogurt and rice porridge. While awareness of the product has greatly increased due to synergy with mail-order sales advertising, sales as a raw ingredient have also increased. On the other hand, sales of other materials used as raw ingredients for beverages and foods were weak.

Overseas, sales of amino acids for use as supplements were solid in the United States. In Europe and Asia, sales of amino acids and nucleic acids, including infusion-use amino acids and citicoline, an API, continued to grow steadily. Our factories maintained a high operating rate, and we adjusted selling prices in response to this buoyant demand. However, overseas sales were flat overall due to the significant impact of the strong yen.

Other

Net sales in the Other segment, principally distribution, decreased 2.2 percent to ¥10.4 billion, while segment income fell 6.1 percent to ¥0.3 billion.

Quarterly Information by Reportable Segment

Millions of yen

	2012					2011				
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	12 months	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	12 months
Net sales:										
Pharmaceuticals	¥64,870	¥57,963	¥59,572	¥67,484	¥249,891	¥ 63,393	¥49,140	¥55,683	¥61,122	¥229,339
Bio-Chemicals	20,589	19,493	17,405	19,478	76,966	19,686	20,673	18,613	18,590	77,563
Chemicals	—	—	—	—	—	33,550	—	—	—	33,550
Other	2,557	2,615	2,530	2,725	10,429	2,651	2,655	2,549	2,804	10,659
Total	88,016	80,072	79,509	89,689	337,286	119,281	72,470	76,846	82,516	351,113
Adjustments	(905)	(893)	(1,107)	(1,223)	(4,127)	(4,419)	(965)	(855)	(1,152)	(7,390)
Consolidated total	¥87,111	¥79,178	¥78,401	¥88,467	¥333,158	¥114,862	¥71,505	¥75,991	¥81,364	¥343,722
Segment income (loss):										
Pharmaceuticals	¥16,638	¥6,725	¥11,473	¥15,555	¥50,392	¥18,419	¥6,726	¥7,979	¥8,189	¥41,314
Bio-Chemicals	1,303	737	173	(86)	2,127	1,272	1,247	495	(119)	2,896
Chemicals	—	—	—	—	—	2,135	—	—	—	2,135
Other	94	61	104	79	338	82	65	107	106	360
Total	18,036	7,524	11,750	15,547	52,859	21,909	8,039	8,582	8,176	46,706
Adjustments	3	20	7	14	46	0	(12)	(23)	(56)	(92)
Consolidated total	¥18,039	¥7,545	¥11,758	¥15,562	¥52,905	¥21,909	¥8,026	¥8,559	¥8,120	¥46,614

Sales by Geographic Segment (Year ended December 31, 2012)

Millions of yen

Japan	America*	Europe	Asia	Other areas**	Total
¥260,524	¥21,207	¥30,997	¥19,880	¥548	¥333,158

* North America, Latin America
** Oceania, Africa

Cash Flow

Cash and cash equivalents as of December 31, 2012 decreased ¥57.2 billion from a year earlier to ¥50.3 billion.

Kyowa Hakko Kirin participates in the cash management system of its parent company, Kirin Holdings Company, Limited. Under this system, short-term loans to Kirin Holdings with maturities over three months are not included in cash and cash equivalents. These loans increased by ¥67.0 billion, which significantly decreased cash and cash equivalents at the end of the year.

Net cash provided by operating activities was ¥59.1 billion, an increase of 45.5 percent compared with the previous year. The main source of cash was income before income taxes of ¥45.0 billion. Depreciation and amortization totaled ¥20.9 billion and amortization of goodwill totaled ¥12.0 billion. The main use of cash was income taxes paid of ¥15.9 billion.

Net cash used in investing activities was ¥98.7 billion, compared with net cash provided by investing activities of ¥18.4 billion in the previous year. Principal uses of cash included a net increase of ¥66.9 billion in short-term loans receivable and payment of ¥17.5 billion for purchase of property, plant and equipment. Principal sources of cash included proceeds from sales and redemption of investment securities totaling ¥2.4 billion.

Net cash used in financing activities decreased 37.6 percent to ¥19.1 billion. Principal uses of cash were payment of ¥7.5 billion for purchase of treasury stock and ¥11.0 billion for cash dividends paid.

Financial Position

Assets

Total assets as of December 31, 2012 increased 3.1 percent, or ¥20.4 billion, from a year earlier to ¥679.3 billion. Total current assets increased ¥19.7 billion to ¥303.9 billion. Principal factors included an increase in short-term loans receivable to parent company Kirin Holdings Company, Limited.

Total property, plant and equipment, net, increased 3.2 percent, or ¥3.9 billion, to ¥126.8 billion. Investments and other assets decreased 1.3 percent, or ¥3.2 billion, to ¥248.4 billion. Sales rights increased, but goodwill decreased due to amortization.

Liabilities

Total liabilities increased 3.9 percent, or ¥4.5 billion, from the end of the previous year to ¥123.4 billion.

Total current liabilities increased 9.3 percent, or ¥7.3 billion, to ¥85.7 billion. This was primarily the result of a ¥7.9 billion increase in income taxes payable.

Total noncurrent liabilities decreased 6.7 percent, or ¥2.7 billion, to ¥37.6 billion. This was primarily the result of a decrease in provision for retirement benefits.

Interest-bearing debt decreased 5.7 percent, or ¥0.3 billion, to ¥5.6 billion.

Working capital (total current assets minus total current liabilities) increased ¥12.4 billion from the previous year-end to ¥218.2 billion. The current ratio decreased to 354.4 percent from 362.2 percent.

Net Assets

Total net assets increased 2.9 percent, or ¥15.8 billion, from the previous year-end to ¥555.8 billion, largely reflecting net income and foreign currency translation adjustments. Factors reducing net assets included the purchase of treasury stock and payment of cash dividends.

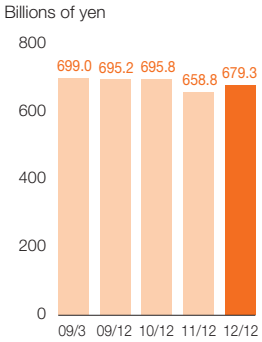
As a result, the equity ratio decreased 0.1 percentage point to 81.7 percent. Fiscal integrity remained high, as the debt/equity ratio decreased to 1.0 percent from 1.1 percent.

Performance Indicators

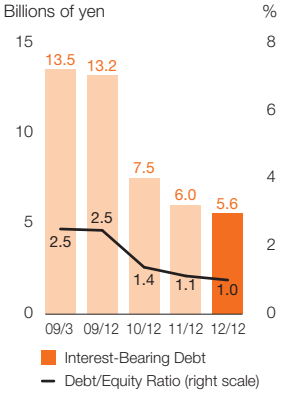
Return on equity (ROE) decreased to 4.43 percent from 4.73 percent for the previous year, while return on assets (ROA) decreased to 3.62 percent from 3.78 percent. Operating return on assets improved to 7.91 percent from 6.88 percent.

Earnings before income tax, interest, depreciation, and amortization (EBITDA) decreased 2.1 percent to ¥78.1 billion.

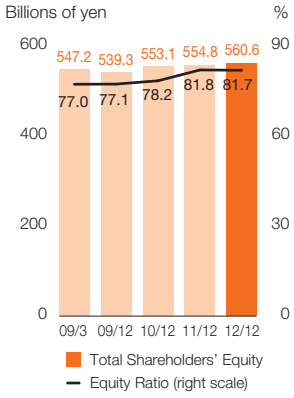
Total Assets



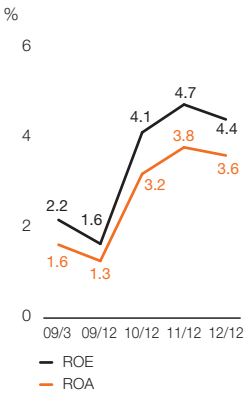
Interest-Bearing Debt



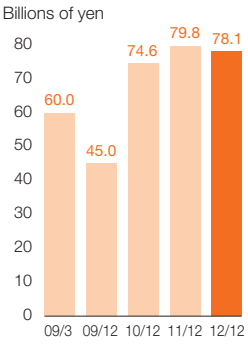
Total Shareholders' Equity



ROE and ROA



EBITDA



Note: 09/12 data is for the nine months ended December 31, 2009 because the Kyowa Hakko Kirin Group changed its fiscal year-end.

Capital Requirements and Financing

The Kyowa Hakko Kirin Group's capital requirements mainly consist of purchases of raw materials for manufacturing products, purchases of goods and supplies, and operating expenses such as manufacturing expenses and selling, general and administrative expenses. Principal operating expenses consist of payroll costs such as wages and bonuses, research and development expenses and promotional expenses. The Kyowa Hakko Kirin Group continuously makes capital investments for purposes such as expanding and streamlining production facilities and strengthening research and development capabilities.

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

Kyowa Hakko Kirin maintains a short-term credit rating sufficient for meeting its funding requirements and is able to raise short-term funds through the flexible issuance of domestic commercial paper. We are also taking measures to improve our financial strength and increase our creditworthiness while considering the funding environment and other factors.

Capital Expenditures

Our policy for capital expenditures is to invest strategically while considering the balance between capital expenditures and depreciation and amortization. During the year ended December 31, 2012, 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 year ended December 31, 2012 increased 41.2 percent, or ¥8.1 billion, compared with the previous year to ¥27.8 billion. Significant investments included construction of a new formulating line at the Ube Plant in the Pharmaceuticals business and a new production facility for small molecular weight active pharmaceutical ingredients at Daiichi Fine Chemical Co., Ltd. in the Bio-Chemicals business. Depreciation and amortization decreased 8.4 percent, or ¥1.9 billion, to ¥20.9 billion.

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

R&D Expenses

R&D expenses, which are included in SG&A expenses, decreased 6.6 percent to ¥44.8 billion. As a percentage of consolidated net sales, R&D expenses decreased 0.6 percentage point to 13.4 percent from 14.0 percent for the previous year.

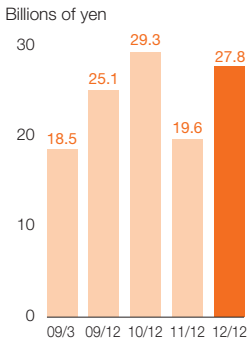
R&D expenses in the Pharmaceuticals segment totaled ¥41.3 billion and accounted for 92.3 percent of total R&D expenses. As a percentage of Pharmaceuticals segment sales, R&D expenses decreased 2.8 percentage points to 16.6 percent. R&D expenses in the Bio-Chemicals segment were ¥3.4 billion.

Breakdown of Capital Expenditures and Depreciation and Amortization

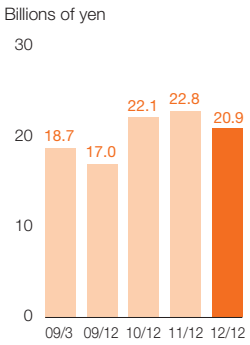
Millions of yen

	Capital Expenditures			Depreciation and Amortization		
	2012/12	2011/12	2010/12	2012/12	2011/12	2010/12
Pharmaceuticals	¥18,333	¥11,886	¥19,251	¥14,573	¥15,339	¥10,733
Bio-Chemicals	9,454	7,482	7,603	6,280	6,457	6,731
Chemicals	—	317	2,504	—	974	4,652
Other	24	11	15	52	64	73
Adjustments	(3)	—	(1)	(1)	(2)	(2)
Consolidated total	¥27,808	¥19,697	¥29,374	¥20,904	¥22,833	¥22,188

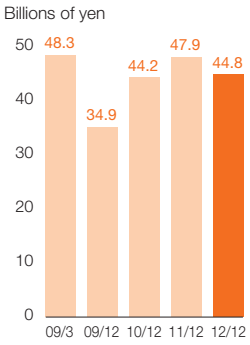
Capital Expenditures



Depreciation and Amortization



R&D Expenses

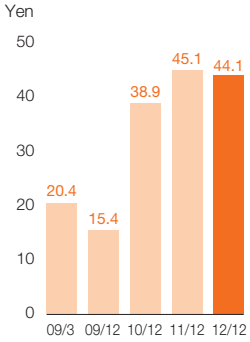


Note: 09/12 data is for the nine months ended December 31, 2009 because the Kyowa Hakko Kirin Group changed its fiscal year-end.

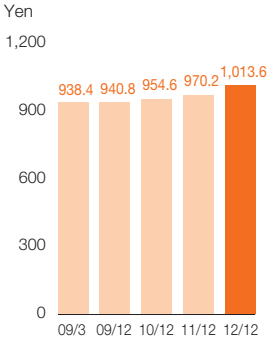
Per Share Data

Net income per share – basic was ¥44.12, compared with ¥45.16 for the previous year. Net income per share before amortization of goodwill was ¥61.00. Net assets per share as of December 31, 2012 increased to ¥1,013.6 from ¥970.2 a year earlier.

Net Income per Share – Basic



Net Assets per Share



Note: 09/12 data is for the nine months ended December 31, 2009 because the Kyowa Hakko Kirin Group changed its fiscal year-end.

Goodwill

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

Goodwill from the business combination with Kirin Pharma:

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

Amortization of goodwill from the business combination with Kirin Pharma Company Limited totaled ¥9.2 billion for the year ended December 31, 2012, the same as in the previous year.

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.

We formulated the three-year Medium-Term Business Plan – 2013 to 2015, which started in the year ending December 31, 2013, to achieve our vision. Our targets for the final year of this plan (the year ending December 31, 2015) are consolidated net sales of ¥358.0 billion and consolidated operating income of ¥60.0 billion.

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

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

In the Pharmaceuticals business, the outlook for the operating environment is becoming increasingly unclear, impacted by a decline in drug discovery success rates and stricter approval review processes in Japan and overseas, progress with measures to reduce health care costs, and the rising market share of generic drugs. Competition between companies has undergone a major shift and is now a test of comprehensive strengths such as information collection and sharing capabilities, network strength and the ability to coordinate diverse functions. In particular, front-line medical professionals are demanding a higher level of expertise on the information provided.

In this environment, Kyowa Hakko Kirin will aim for an accelerated competitive advantage and sustainable growth by further strengthening competitiveness in Japan through its category strategy. Focusing on four categories in which we already have a strong presence – nephrology, oncology, immunology/allergy and CNS – we will take strides toward becoming a truly major player and strengthen cooperation consistently on every function from R&D to manufacturing and sales. In addition to steadily launching new drugs from our extensive pipeline, we are aiming to build an effective marketing system using our high level of expertise to maximize sales and win trust among medical practitioners.

In R&D, we will sharpen our ability to create and bring to market new drugs that address unmet medical needs. In addition, we will advance antibody drugs through domestic and international clinical development, maximize value by promoting alliances in antibody technology, and try new approaches to drug discovery with nucleic acid drugs and others. Moreover, to increase our probability of success in the clinical development stage, we are driving translational research using our global research network, emphasizing open innovation, taking advantage of external information and knowledge, and actively promoting research collaboration from the earliest stages of development.

In overseas business, we will pursue global growth in accordance with region- and country-specific strategies with the help of ProStrakan, which we acquired in 2011 and is now an important constituent of the Group, to expand our business bases in Europe, the United States and Asia with the aim of becoming a global specialty pharmaceutical company.

We regard activities to prepare for the U.S. launch of POTELIGEO®, Kyowa Hakko Kirin's first therapeutic antibody, as an important opportunity for a major step toward becoming a global specialty pharmaceutical company. We are building a framework for the development and sale of global drugs with a view to achieving self-sustaining growth in the huge U.S. market.

Furthermore, through a business model of in-licensing late-stage development and marketed products from ProStrakan, we will enhance our product range and expand our presence in major Western markets.

In Asia, our top priority is the reorganization of our business base for stable future growth in China. We are implementing business strategies at subsidiaries in Korea, Taiwan, Singapore, Thailand and other growing economies that reflect the prevailing conditions in each country.

In the biosimilars business, FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd., a joint venture with FUJIFILM Corporation, will leverage our world-class biopharmaceutical production technology to energetically advance development activities aimed at the timely launch of biosimilars with a view to expansion in the global market. FUJIFILM KYOWA KIRIN BIOLOGICS seeks to provide reliable, high-quality and cost-competitive biosimilars using new production technologies. While challenging ourselves in the biosimilars market, in which significant growth is expected globally, we are hoping to help deal with health care-related economic issues, including the problem of rising costs.

In our diagnostics business, we will provide advanced diagnostic products and instruments necessary for the treatment of various illnesses via Kyowa Medex Co., Ltd., and will work to establish a firm position in Japan while building a foundation in the Chinese market. By developing and launching *in vitro* diagnostics (reagents for clinical trials), analytical instruments and companion diagnostics (*in vitro* diagnostic reagents used for personalized medical care) in cooperation with our R&D department, we will strive to achieve synergy between this business and the Pharmaceuticals business and improve added value.

In the Bio-Chemicals business, we will aim for sustained growth in the pharmaceutical, medical and health care areas while strengthening our revenue base as a biotech group that has both fermentation and synthesis technologies. Current issues to be addressed are the creation of a business structure that is resistant to the impact of exchange rate movements and expansion of production capacity to meet rising global demand for amino acids. We will enhance cost-competitiveness by reorganizing and improving the Kyowa Hakko Kirin Group's overseas and domestic production facilities, including the Yamaguchi Production Center, Daiichi Fine Chemical Co., Ltd. and BioKyowa Inc. in the United States. At the same time, we will further develop our global business foundation with measures including the establishment of a new production base in Thailand to respond to robust global demand.

In the health care market in Japan, Kyowa Wellness Co., Ltd., which had been responsible for raw material sales and the mail-order sales business, was absorbed into Kyowa Hakko Bio Co., Ltd. in January 2013 to accurately address customer needs. In the mail-order business centered on ornithine, we will work to further enhance product awareness through effective advertising and provide unique materials that customers can use with confidence.

With the new drug business at its core, the Kyowa Hakko Kirin Group will pursue a unique pharmaceutical business model that combines biosimilars, diagnostics and bio-chemicals as it advances toward becoming a global specialty pharmaceutical company.

Outlook for 2013

In the year ending December 31, 2013, we forecast that net sales will increase 1.5 percent year on year to ¥338.0 billion, operating income will increase 4.0 percent to ¥55.0 billion, and net income will increase 24.0 percent to ¥30.0 billion.

In the Pharmaceuticals segment, we forecast that sales growth will be driven by higher sales volume of products including NESP®, a treatment for renal anemia, Patanol® antiallergic eyedrops, Fentos®, a transdermal analgesic for persistent cancer pain, ASACOL®, an ulcerative colitis treatment, and REGPARA®, a treatment for secondary hyperparathyroidism during dialysis therapy. Overseas, we also expect growth in sales at ProStrakan. However, segment income is projected to decline, mainly due to a decrease in licensing revenue.

In the Bio-Chemicals segment, we forecast year-on-year sales and income growth due to higher sales volume for core amino acids, nucleic acids and ornithine, and progress in the business restructuring of Daiichi Fine Chemical Co., Ltd. In addition, the yen is projected to be weaker relative to 2012.

Despite an expected increase in equity in losses of affiliates, we forecast that net income will increase due to factors including extraordinary gains on sales of affiliates' stock and other items as well as a decrease in extraordinary losses.

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 allocates internal capital to research and development and capital expenditures that will contribute to enhancing future corporate value, and to expansion of the development pipeline and other investments that lead to new growth.

Based on this policy, Kyowa Hakko Kirin paid cash dividends per share of ¥20.00 for the year ended December 31, 2012, as planned. As a result, the payout ratio was 45.3 percent of consolidated earnings, or 32.8 percent of earnings before amortization of goodwill.*

In Medium-Term Business Plan – 2013 to 2015, we will continue to target a dividend payout ratio of at least 40 percent of earnings on a consolidated basis before amortization of goodwill. For the year ending December 31, 2013, we expect to pay an annual cash dividend per share of ¥25.00, consisting of an interim dividend of ¥12.50 and a year-end dividend of ¥12.50.

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

Risk Factors

With respect to Kyowa Hakko Kirin Group's business performance and financial position, the major risks that may significantly affect investors' judgments include, but are not limited to, those described below. The Group recognizes that these risk events may occur, and the Group uses a risk management system to prevent the occurrence of those risk events that can be controlled by the Group. At the same time, the Group will do its utmost to respond in the event of the occurrence of a risk event. Items in this section dealing with future events reflect the judgment of the Group as of December 31, 2012.

1. Risks associated with R&D investment

In ethical drug operations, the development of new drugs requires long periods of time and substantial R&D expenditure. The process of development and sale of new pharmaceuticals is inherently complicated and uncertain. In the long-term development of new drugs, there may be cases where the expected efficacy or stability is not confirmed.

In addition, in non-pharmaceutical operations, the Group invests R&D resources in the development of new products and new technologies to differentiate the Group from its competitors. However, as with R&D for ethical drug operations, there is no guarantee that these investments will produce results, and as above, in cases where expected R&D results are not realized, the Group's future growth and profitability may decline and our business performance and financial position may also be adversely affected.

2. Risks related to intellectual property assets

In cases where the Group is subject to litigation as a result of our products or technology being in violation of intellectual property rights, the Group may be required to cease such activities, and pay compensation and/or settlement, and our business activities, business performance and financial position may be adversely affected. Conversely, in cases where the Group's intellectual property rights are infringed upon by competitive products to the Group's products or out-licensed products, sales of the Group's products or revenues from technology could decline earlier than forecast and similarly, the Group's business performance and financial position could be adversely affected.

3. Risk of side effects

Pharmaceutical products undergo strict safety audits at the development stage and following checks by the relevant national authorities are approved. However, following launch, on occasion previously unknown side effects based on the accumulated results of users may become apparent. In such cases where an unexpected side effect is discovered following launch, the Group's business performance and financial position, etc., could be adversely affected.

4. Risks related to pharmaceutical regulations

The Pharmaceuticals business, KHK Group's core business, operates under the pharmaceutical regulatory authorities of the countries in which we operate. In Japan, Kyowa Hakko Kirin Group's business performance and financial position could also be affected by factors including future trends in the reform of Japan's system of medical treatment aimed at promoting the use of generic drugs, in addition to price reductions under the domestic public pharmaceutical price system. Overseas, pressure from control on medical fees is high, and in cases where a price reduction cannot be compensated for by an increase in volumes, the Group's business performance and financial position could be adversely affected.

5. Legal regulation risk

In the course of carrying out its operations in Japan and overseas, the Group must strictly comply with legal regulations. The Group emphasizes compliance to try to ensure that it does not violate the laws to which it is subject, and the Group is working to bolster internal control functions through such means as administrative oversight. However, there is no guarantee that the Group will be able to completely eliminate the possibility of committing a violation of these legal regulations. If, because we are unable to observe these legal regulations, new product development is delayed or stopped, or manufacturing or sales activities are restricted, the Group's credibility could be damaged. In such cases, the Group's business performance and financial position could be negatively impacted.

Furthermore, in the future, if laws and regulations that must be observed in Japan and overseas change, the Group's business performance and financial position could be adversely affected.

6. Risk of changes to foreign exchange rate

The Group conducts foreign currency denominated transactions such as receiving income from overseas sales, licensing-out of technologies overseas and acquiring raw materials overseas. Therefore, any sudden change in exchange rates could adversely affect the Group's business performance and financial position. Fluctuations to the foreign exchange rate could also affect our ability to be price competitive on products sold in markets shared with overseas competitors.

The gains and losses, and assets and liabilities of overseas-consolidated subsidiaries denominated in local currencies are translated into yen for the preparation of the consolidated financial report. The exchange rate at the time of translation could have an effect on values following currency translation.

7. Disaster-related and accident-related risks

Earthquakes, fires, pandemics such as influenza, terrorism, large-scale electrical blackouts and other events could result in suspension of business activities at our Group headquarters, factories, research facilities or offices. The Group handles substances that are subject to various legal regulations and guidelines, and as a result of natural disasters, etc., these substances could enter the external environment and cause damage to the surrounding area.

Although KHK Group maintains a disaster prevention system and has prepared a business continuity plan, should an event or accident as described above occur it might result in significant damage and negatively impact the Group's position of trust in society. Additionally, the Group's business performance and financial position could be adversely affected.

8. Other risks

In addition to the above, there are other risks that could adversely affect the Group's business performance and financial position and they include changes to the price of raw materials and fuel prices, changes to share prices and interest rates, impairment of fixed assets, suspension of supply of products and raw materials and information leaks.

Consolidated Balance Sheets

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries
As at December 31, 2012 and 2011

	Millions of yen		Thousands of U.S. dollars (Note 3)
ASSETS	2012	2011	2012
Current Assets:			
Cash and deposits (Note 11)	¥ 21,577	¥ 27,063	$ 249,225
Notes and accounts receivable (Note 11):			
Trade	99,885	94,912	1,153,683
Unconsolidated subsidiaries and affiliates	3,028	4,665	34,980
Other	3,178	4,870	36,711
	106,093	104,448	1,225,376
Inventories (Note 5)	63,442	58,981	732,763
Deferred tax assets (Note 8)	10,369	8,629	119,770
Short-term loans receivable (Note 11):			
Parent company	98,189	82,473	1,134,095
Other	4	484	48
	98,194	82,958	1,134,144
Other current assets	4,692	2,727	54,197
Less: Allowance for doubtful accounts	(381)	(591)	(4,406)
Total Current Assets	303,988	284,217	3,511,069
Property, Plant and Equipment, at Cost (Note 16):			
Land	53,386	53,954	616,611
Buildings and structures	134,875	129,190	1,557,812
Machinery and equipment	143,595	139,796	1,658,528
Other	48,166	46,967	556,322
Construction in progress	7,360	6,221	85,010
	387,383	376,130	4,474,285
Less: Accumulated depreciation	(260,511)	(253,186)	(3,008,906)
Total Property, Plant and Equipment, Net	126,872	122,943	1,465,378
Investments and Other Assets:			
Investment securities (Notes 11 and 12)	18,248	20,633	210,771
Investments in unconsolidated subsidiaries and affiliates (Notes 11 and 12)	5,552	4,399	64,134
Goodwill (Note 16)	168,850	177,267	1,950,224
Sales rights (Note 16)	36,214	29,025	418,272
Deferred tax assets (Note 8)	7,724	6,680	89,217
Other assets	12,167	14,067	140,529
Less: Allowance for doubtful accounts	(276)	(361)	(3,188)
Total Investments and Other Assets	248,481	251,712	2,869,961
Total Assets	¥ 679,342	¥ 658,873	$ 7,846,409

The accompanying notes are an integral part of the statements.

LIABILITIES AND NET ASSETS	Millions of yen 2012	2011	Thousands of U.S. dollars (Note 3) 2012
Current Liabilities:			
Short-term loans payable (Notes 6 and 11)	¥ 5,699	¥ 5,943	$ 65,830
Current portion of long-term loans payable (Notes 6 and 11)	—	98	—
Notes and accounts payable (Note 11):			
Trade	22,429	20,845	259,059
Unconsolidated subsidiaries and affiliates	267	1,628	3,090
Construction and purchase of properties	7,763	7,016	89,667
Other	25,843	29,657	298,489
	56,303	59,147	650,307
Income taxes payable	15,777	7,821	182,229
Provision for sales rebates	771	667	8,910
Other current liabilities	7,222	4,785	83,424
Total Current Liabilities	85,774	78,464	990,701
Noncurrent Liabilities:			
Deferred tax liabilities (Note 8)	11,262	10,926	130,079
Provision for retirement benefits:			
Employees (Note 10)	19,503	20,654	225,260
Directors and corporate auditors	114	94	1,322
Asset retirement obligations (Note 22)	383	654	4,424
Other noncurrent liabilities	6,405	8,055	73,989
Total Noncurrent Liabilities	37,668	40,386	435,076
Total Liabilities	123,443	118,850	1,425,778
Commitments and Contingent Liabilities (Note 18)			
Net Assets:			
Shareholders' Equity (Note 19)			
Capital stock:			
Authorized: 987,900,000 shares at December 31, 2012 and 2011			
Issued: 576,483,555 shares at December 31, 2012 and 2011	26,745	26,745	308,905
Additional paid-in capital	512,329	512,348	5,917,412
Retained earnings	48,127	34,956	555,870
Treasury stock, at cost:			
29,062,630 shares at December 31, 2012 and 21,037,327 shares at December 31, 2011	(26,538)	(19,194)	(306,518)
Total Shareholders' Equity	560,663	554,856	6,475,669
Accumulated Other Comprehensive Income:			
Net unrealized holding loss on other securities (Note 12)	(2,264)	(3,144)	(26,149)
Foreign currency translation adjustments	(3,528)	(12,841)	(40,755)
Total Accumulated Other Comprehensive Income	(5,792)	(15,986)	(66,904)
Subscription rights to shares (Note 9)	203	250	2,350
Minority interests	823	902	9,515
Total Net Assets	555,898	540,023	6,420,630
Total Liabilities and Net Assets	¥679,342	¥658,873	$7,846,409

Consolidated Statements of Income

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries
For the years ended December 31, 2012 and 2011

	Millions of yen		Thousands of U.S. dollars (Note 3)
	2012	2011	2012
Net Sales (Note 21)	¥333,158	¥343,722	$3,847,987
Cost of Sales (Notes 10, 14 and 15)	122,467	146,167	1,414,504
Gross Profit	210,690	197,555	2,433,483
Selling, General and Administrative Expenses (Notes 10 and 15)	157,785	150,940	1,822,427
Operating Income (Note 21)	52,905	46,614	611,055
Other Revenue (Expenses):			
Interest and dividend income	1,598	1,034	18,460
Interest expense	(205)	(135)	(2,368)
Foreign exchange gains (losses)	1,224	(154)	14,148
Equity in losses (earnings) of affiliates	(4,861)	199	(56,152)
Loss on sale and disposal of fixed assets	(825)	(1,292)	(9,535)
Impairment loss (Note 16)	(1,341)	(769)	(15,499)
Gain on sales of affiliates' stock	—	7,217	—
Loss on transfer of assets (Note 17)	(1,035)	—	(11,957)
Loss on valuation of investment securities	(1,007)	(2,374)	(11,636)
Loss on sales of investment securities (Note 12)	(344)	(692)	(3,973)
Loss on reorganization of business (operations)	(247)	—	(2,860)
Advisory fee	—	(1,098)	—
Loss on disaster	—	(650)	—
Non-recurring depreciation on noncurrent assets	—	(477)	—
Loss on adjustment for changes of accounting standard for asset retirement obligations	—	(447)	—
Loss on disposal of business (operations)	—	(419)	—
Other, net	(834)	(367)	(9,638)
	(7,877)	(430)	(91,010)
Income before Income Taxes and Minority Interests	45,025	46,183	520,040
Income Taxes (Note 8):			
Current	(24,095)	(22,539)	(278,303)
Deferred	3,485	2,049	40,258
	(20,609)	(20,489)	(238,045)
Income before Minority Interests	24,415	25,694	281,995
Minority Interests	(215)	(86)	(2,490)
Net Income	¥ 24,199	¥ 25,608	$ 279,505

The accompanying notes are an integral part of the statements.

Consolidated Statements of Comprehensive Income

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries
For the years ended December 31, 2012 and 2011

	Millions of yen		Thousands of U.S. dollars (Note 3)
	2012	2011	2012
Income before Minority Interests	¥24,415	¥25,694	$281,995
Other Comprehensive Income (Note 4)			
Net unrealized holding gain or loss on other securities	874	(1,200)	10,099
Net deferred gain on hedges	—	2	—
Foreign currency translation adjustments	9,413	(5,799)	108,727
Share of other comprehensive income of associates accounted for using the equity method	6	(3)	75
Total Other Comprehensive Income	10,294	(7,001)	118,902
Comprehensive Income			
Comprehensive income attributable to:			
Owners of the parent	34,393	18,628	397,246
Minority interests	316	65	3,651
Total Comprehensive Income	¥34,709	¥18,693	$400,898

The accompanying notes are an integral part of the statements.

Consolidated Statements of Changes in Net Assets

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries
For the years ended December 31, 2012 and 2011

Millions of yen

		Shareholders' equity					Accumulated 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 accumulated other comprehensive income	Subscription rights to shares	Minority interests	Total net assets
Balance at January 1, 2011	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 January 1, 2012	576,483,555	26,745	512,348	34,956	(19,194)	554,856	(3,144)	–	(12,841)	(15,986)	250	902	540,023
Net income for the year ended December 31, 2012				24,199		24,199							24,199
Cash dividends				(11,028)		(11,028)							(11,028)
Purchases of treasury stock					(7,511)	(7,511)							(7,511)
Disposal of treasury stock			(19)		167	148							148
Net changes during the year							880	–	9,313	10,194	(47)	(79)	10,068
Balance at December 31, 2012	576,483,555	¥26,745	¥512,329	¥ 48,127	¥(26,538)	¥560,663	¥(2,264)	¥ –	¥ (3,528)	¥ (5,792)	¥203	¥823	¥555,898

Thousands of U.S. dollars (Note 3)

	Shareholders' equity					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 accumulated other comprehensive income	Subscription rights to shares	Minority interests	Total net assets
Balance at January 1, 2012	$308,905	$5,917,634	$403,750	$(221,695)	$6,408,595	$(36,323)	$ –	$(148,321)	$(184,645)	$2,894	$10,427	$6,237,272
Net income for the year ended December 31, 2012			279,505		279,505							279,505
Cash dividends			(127,384)		(127,384)							(127,384)
Purchases of treasury stock				(86,753)	(86,753)							(86,753)
Disposal of treasury stock		(222)		1,930	1,708							1,708
Net changes during the year						10,174	–	107,566	117,740	(544)	(912)	116,284
Balance at December 31, 2012	$308,905	$5,917,412	$555,870	$(306,518)	$6,475,669	$(26,149)	$ –	$ (40,755)	$ (66,904)	$2,350	$ 9,515	$6,420,630

The accompanying notes are an integral part of the statements.

Consolidated Statements of Cash Flows

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries
For the years ended December 31, 2012 and 2011

	Millions of yen		Thousands of U.S. dollars (Note 3)
	2012	2011	2012
Cash Flows from Operating Activities:			
Income before income taxes and minority interests	¥ 45,025	¥ 46,183	$ 520,040
Adjustments to reconcile income before income taxes and minority interests to net cash provided by operating activities:			
Depreciation and amortization	20,904	22,833	241,449
Impairment loss	1,341	769	15,499
Amortization of goodwill	12,026	10,713	138,905
Decrease in provision for retirement benefits	(1,173)	(989)	(13,554)
Decrease in prepaid pension costs	(450)	(1,869)	(5,202)
Increase in provision for bonuses	59	381	688
Interest and dividend income	(1,598)	(1,034)	(18,460)
Interest expenses	205	135	2,368
Equity in earnings (losses) of affiliates	4,861	(199)	56,152
Loss on sales and retirement of property, plant and equipment	248	315	2,868
Loss on sales of investment securities	321	675	3,711
Gain on sale of affiliates' stock	(0)	(7,217)	(1)
Loss on valuation of investment securities	1,007	2,374	11,636
Increase in notes and accounts receivable	(708)	(4,792)	(8,185)
Increase in inventories	(2,647)	(6,429)	(30,582)
Decrease in notes and accounts payable	(2,522)	(1,656)	(29,134)
Other	(3,545)	8,235	(40,952)
Sub-total	73,354	68,431	847,246
Interest and dividend income received	1,844	1,396	21,300
Interest expenses paid	(122)	(133)	(1,410)
Income taxes paid	(15,942)	(29,061)	(184,132)
Net Cash Provided by Operating Activities	59,134	40,634	683,004
Cash Flows from Investing Activities:			
Purchase of property, plant and equipment	(17,587)	(16,381)	(203,135)
Proceeds from sales of property, plant and equipment	446	198	5,161
Purchase of intangible assets	(9,339)	(1,108)	(107,870)
Purchase of investment securities	(10)	(1,516)	(122)
Proceeds from sales and redemption of investment securities	2,466	2,258	28,490
Proceeds from sales of affiliates' stock	0	15,130	1
Purchase of investments in consolidated subsidiaries	(111)	(36,979)	(1,293)
Proceeds from investments in consolidated subsidiaries	—	52,745	—
Purchase of corporate bonds of an affiliate	(6,450)	—	(74,497)
Increase (decrease) in short-term loans receivable	(66,998)	196	(773,834)
Payments into time deposits	(3,224)	(2,122)	(37,242)
Proceeds from withdrawal of time deposits	3,051	6,332	35,243
Other	(1,015)	(292)	(11,726)
Net Cash Provided by (Used in) Investing Activities	(98,772)	18,460	(1,140,825)
Cash Flows from Financing Activities:			
Net decrease in short-term loans payable	(374)	(76)	(4,320)
Repayment of long-term loans payable	(100)	(6,509)	(1,165)
Purchase of treasury stock	(7,511)	(12,582)	(86,753)
Cash dividends paid	(11,029)	(11,433)	(127,393)
Cash dividends paid to minority shareholders	(44)	(38)	(512)
Other	(128)	(99)	(1,489)
Net Cash Used in Financing Activities	(19,189)	(30,740)	(221,635)
Effect of Exchange Rate Change on Cash and Cash Equivalents	1,606	(681)	18,550
Net Increase (Decrease) in Cash and Cash Equivalents	(57,221)	27,672	(660,906)
Cash and Cash Equivalents at the Beginning of the Period	107,555	79,882	1,242,265
Cash and Cash Equivalents at the End of Period	¥ 50,334	¥107,555	$ 581,359
Reconciliation between cash and cash equivalents at year end and the accounts booked in the consolidated balance sheets			
Cash and deposits	¥ 21,577	¥ 27,063	$ 249,225
Time deposits whose maturity periods exceed 3 months	(2,433)	(1,981)	(28,110)
Short-term loans receivable from parent company within 3 months	31,189	82,473	360,244
Cash and Cash Equivalents	¥ 50,334	¥107,555	$ 581,359

The accompanying notes are an integral part of the statements.

Notes to the Consolidated Financial Statements

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

1 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 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, 2012, 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, 2012, the numbers of consolidated subsidiaries and affiliates accounted for by the equity method were 38 and 2, respectively (38 and 2 as of December 31, 2011). 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 an effective period within 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 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) Provision for Sales Rebates
Provision for sales rebates is recorded by multiplying accounts receivable of pharmaceutical products at the year end by the estimated percentage of rebates to provide for possible sales rebates expected to be paid after the year end date.

(11) Provision for Retirement Benefits
Provision for retirement benefits to employees and prepaid pension cost is 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 fulfill 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, 2011 have been reclassified to conform to the current period presentation.

(19) Accounting Changes

Adoption of "Accounting Standard for Earnings Per Share"

Effective January 1, 2012, the Company and its domestic consolidated subsidiaries have adopted "Accounting Standard for Earnings Per Share" (ASBJ Statement No. 2, issued on June 30, 2010) and the "Guidance on Accounting Standard for Earnings Per Share" (ASBJ Guidance No. 4, issued on June 30, 2010). In calculating diluted earnings per share, for stock options given with the right to exercise options after a specified service period, the fair value of the services expected to be provided to the Company in the future is added to the proceeds assumed to be received when the options are exercised. This change had no impact on the earnings per share information for the year ended December 31, 2012.

(20) Additional Information

(a) Adoption of "Accounting Standard for Accounting Changes and Error Corrections"

Effective January 1, 2012, the Company and its domestic consolidated subsidiaries have adopted the "Accounting Standard for Accounting Changes and Error Corrections" (ASBJ Statement No. 24, issued on December 4, 2009) and the "Guidance on Accounting Standard for Accounting Changes and Error Corrections" (ASBJ Guidance No. 24, issued on December 4, 2009).

(b) 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. On March 27, 2012, the joint venture was established.

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, manufacturing and sales of biosimilars
Location of offices	Chiyoda-ku, Tokyo
Capital stock	¥100 million ($1,155 thousand)
Start of establishment and business operations	March 27, 2012
Capitalization ratio	Kyowa Hakko Kirin Co., Ltd.: 50%
	FUJIFILM Co., Ltd.: 50%

Overview of accounting treatment

Equity in losses of affiliates of ¥4,933 million ($56,983 thousand) is recorded as other expenses for the year ended December 31, 2012.

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 ¥86.58=U.S.$1, the approximate exchange rate at December 31, 2012. 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 ¥86.58=U.S.$1 or at any other rate.

4 Other Comprehensive Income

Reclassification adjustments and tax effects for each component of other comprehensive income for the year ended December 31, 2012 are as follows:

	Millions of yen	Thousands of U.S. dollars
Unrealized holding gain on other securities:		
Arising during the year	¥ 12	$ 147
Reclassification adjustment	1,339	15,469
Sub-total, before tax	1,352	15,616
Tax effects	(477)	(5,517)
Sub-total, net of tax	874	10,099
Foreign currency translation adjustments:		
Arising during the year	9,413	108,727
Share of other comprehensive income of associates accounted for using the equity method:		
Arising during the year	0	2
Reclassification adjustment	6	72
Sub-total, net of tax	6	75
Total other comprehensive income	¥10,294	$118,902

5 Inventories

Inventories as of December 31, 2012 and 2011 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2012	2011	2012
Merchandise and finished goods	¥40,334	¥36,840	$465,869
Work in process	12,176	12,232	140,638
Raw materials and supplies	10,931	9,907	126,255
	¥63,442	¥58,981	$732,763

6 Short-Term Borrowings and Long-Term Debt

(1) Short-term borrowings at December 31, 2012 and 2011 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2012	2011	2012
Unsecured loans, principally from banks, with weighted average interest rates of 1.9% and 2.1% at December 31, 2012 and 2011, respectively	¥5,699	¥5,943	$65,830

(2) Long-term debt at December 31, 2012 and 2011 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2012	2011	2012
No relevant items at December 31, 2012.			
Secured loans, principally from banks and other financial institutions, during 2012 at December 31, 2011 with interest ranging from 6.0% to 6.9% per annum	¥ —	¥ 98	$ —
Less: Current portion of long-term debt	—	(98)	—
	¥ —	¥ —	$ —

7 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, 2012 and 2011 would have been as follows:

	Millions of yen		Thousands of U.S. dollars	
December 31, 2012	Other (tools, furniture and fixtures)	Total	Other (tools, furniture and fixtures)	Total
Purchase cost	¥31	¥31	$363	$363
Accumulated depreciation	30	30	347	347
Net book value	¥ 1	¥ 1	$ 16	$ 16

	Millions of yen	
December 31, 2011	Other (tools, furniture and fixtures)	Total
Purchase cost	¥361	¥361
Accumulated depreciation	328	328
Net book value	¥ 32	¥ 32

Lease payments relating to finance leases accounted for as operating leases amounted to ¥32 million ($371 thousand) and ¥95 million, and the depreciation expense of the leased assets computed by the straight-line method over the lease terms amounted to ¥31 million ($360 thousand) and ¥90 million for the years ended December 31, 2012 and 2011, respectively.

Future minimum lease payments subsequent to December 31, 2012 and 2011 on finance leases accounted for as operating leases are summarized as follows:

	Millions of yen		Thousands of U.S. dollars
	2012	2011	2012
Due within one year	¥ 1	¥31	$16
Due after one year	—	1	—
Total	¥ 1	¥32	$16

(2) Operating Leases

Future minimum lease payments subsequent to December 31, 2012 and 2011 on non-cancelable operating leases are summarized as follows:

	Millions of yen		Thousands of U.S. dollars
(Lessee)	2012	2011	2012
Due within one year	¥ 367	¥ 301	$ 4,244
Due after one year	3,218	2,973	37,176
Total	¥3,586	¥3,274	$41,421

	Millions of yen		Thousands of U.S. dollars
(Lessor)	2012	2011	2012
Due within one year	¥ 221	¥ 202	$ 2,563
Due after one year	2,776	2,687	32,066
Total	¥2,998	¥2,890	$34,629

8 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, 2012 and 2011. 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, 2012 and 2011 differ from the statutory tax rate for the following reasons:

	2012	2011
Statutory tax rate	40.7%	40.7%
(Reconciliation)		
Amortization of goodwill	10.0	8.9
Equity in losses (earnings) of affiliates	4.4	(0.2)
Permanently non-deductible expenses, such as entertainment expenses	2.7	3.2
Permanently non-taxable income, such as dividend income	(1.3)	(0.2)
Future deductible temporary differences deemed not to be realized	(2.8)	2.2
Special corporate tax credit	(8.2)	(9.4)
Other	0.3	(0.9)
Effective tax rates	45.8%	44.4%

(2) The significant components of deferred tax assets and liabilities as of December 31, 2012 and 2011 are as follows:

	Millions of yen		Thousands of U.S. dollars
Deferred tax assets:	2012	2011	2012
Non-deductible portion of depreciation of property, plant and equipment	¥ 10,454	¥ 10,291	$ 120,750
Tax loss carried forward	9,034	7,960	104,350
Non-deductible portion of provision for retirement benefits to employees	6,811	7,179	78,667
Prepaid expenses for tax purposes	4,391	4,286	50,721
Investments in affiliates	1,939	1,828	22,404
Other	14,240	13,112	164,477
Sub-total	46,871	44,658	541,371
Valuation allowance	(15,965)	(15,994)	(184,405)
Total deferred tax assets	¥ 30,906	¥ 28,664	$ 356,966
Deferred tax liabilities:			
Valuation of land of the former Kyowa Hakko Group at the fair market value related to reverse acquisition	¥(14,183)	¥(14,304)	$(163,817)
Valuation of intangible assets related to business combinations	(4,881)	(4,190)	(56,377)
Prepaid pension expenses	(2,075)	(1,432)	(23,969)
Valuation of investment securities of the former Kyowa Hakko Group at the fair market value related to reverse acquisition	(1,458)	(1,562)	(16,840)
Deferred gain, mainly related to expropriation of fixed assets	(1,385)	(1,583)	(16,006)
Other	(106)	(1,207)	(1,235)
Total deferred tax liabilities	¥(24,090)	¥(24,280)	$(278,247)
Deferred tax assets (liabilities), net	¥ 6,815	¥ 4,383	$ 78,718

(Note) Deferred tax assets (liabilities), net corresponds to the following items on the consolidated balance sheet as of December 31, 2012:

	Millions of yen	Thousands of U.S. dollars
Current Assets — Deferred tax assets	¥ 10,369	$ 119,770
Current Liabilities — Other current liabilities	(16)	(188)
Noncurrent Assets — Deferred tax assets	7,724	89,217
Noncurrent Liabilities — Deferred tax liabilities	(11,262)	(130,079)

9 Stock Option Plans

Stock option expenses included in selling, general and administrative expenses for the years ended December 31, 2012 and 2011 were ¥96 million ($1,112 thousand) and ¥86 million, respectively.

1. The stock options outstanding as of December 31, 2012 are as follows:

	2012/12 Plan	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	Directors and executive officers
Number of grantees	22	20	17	14	20	18	18	19
Type of stock	Common stock	Common stock	Common stock	Common stock	Common stock	Common stock	Common stock	Common stock
Date of grant	April 27, 2012	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	No provisions
Applicable period of service	No provisions	No provisions	No provisions	No provisions	No provisions	No provisions	No provisions	No provisions
Exercisable period	April 28, 2012 – March 22, 2032	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. The changes in stock options for the year ended December 31, 2012 are as follows:

	2012/12 Plan	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, 2011	–	–	–	–	–	–	–	–
Granted during the period	126,000	–	–	–	–	–	–	–
Forfeited during the period	–	–	–	–	–	–	–	–
Vested during the period	126,000	–	–	–	–	–	–	–
Stock options outstanding at December 31, 2012	–	–	–	–	–	–	–	–
Vested (number of shares):								
Stock options outstanding at December 31, 2011	–	119,000	75,000	52,000	22,000	18,000	26,000	25,000
Vested during the period	126,000	–	–	–	–	–	–	–
Exercised during the period	–	39,000	31,000	28,000	22,000	18,000	21,000	19,000
Forfeited during the period	–	–	–	–	–	–	–	–
Stock options outstanding at December 31, 2012	126,000	80,000	44,000	24,000	–	–	5,000	6,000

3. The price information of stock options outstanding as of December 31, 2012 is as follows:

	2012/12 Plan	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	¥ 1
Weighted average market price per stock at the time of exercise	–	882	882	882	882	882	882	882
Fair value per stock at the date of grant	786	741	940	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 principal assumptions used in estimating the fair value of stock options issued during the year ended December 31, 2012 are as follows:

	2012/12 Plan
Share price volatility*1	6.0%
Expected remaining period*2	3 years
Expected dividends*3	¥20 per share
Risk-free interest rate*4	0.56%

*1. Calculated based on share price results over 3 years (from April 2009 to March 2012).
*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 December 2012.
*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 difficult to estimate reasonably the number of shares forfeited in the future.

10 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.

(1) Details of the provision for retirement benefits to employees as of December 31, 2012 and 2011 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2012	2011	2012
Retirement benefit obligations*	¥(81,635)	¥(78,296)	$(942,889)
Plan assets at fair value	49,170	42,009	567,922
Unfunded retirement benefit obligations	(32,464)	(36,287)	(374,967)
Unrecognized actuarial differences	17,703	19,813	204,474
Unrecognized prior service costs	208	319	2,403
Prepaid pension expenses	4,949	4,499	57,171
Provision for retirement benefits to employees	¥(19,503)	¥(20,654)	$(225,260)

* Certain subsidiaries calculate retirement benefit obligations by the simplified method permitted under the accounting standards generally accepted in Japan.

(2) Retirement benefit expenses for the years ended December 31, 2012 and 2011 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2012	2011	2012
Service cost*1	¥ 3,558	¥ 3,192	$ 41,103
Interest cost	1,311	1,737	15,145
Expected return on plan assets	(1,023)	(1,022)	(11,825)
Amortization of unrecognized actuarial differences	2,328	1,123	26,891
Amortization of unrecognized prior service costs	110	111	1,274
Contribution to defined contribution pension plan	1,019	948	11,776
Other*2	2	2	27
Retirement benefit expenses	¥ 7,306	¥ 6,093	$ 84,393

*1. Includes retirement benefit expenses incurred by the subsidiaries that apply the simplified method.
*2. Prepaid retirement benefits under prepaid pension plan.

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

	2012	2011
Discount rate	1.7%	1.7%
Expected rate of return on plan assets	2.5% (mainly)	2.5% (mainly)
Amortization period for prior service costs	5 years (mainly) (Straight-line method)	5 years (mainly) (Straight-line method)
Amortization period for actuarial differences	10 years (mainly) (Straight-line method)	10 years (mainly) (Straight-line method)

11 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 using 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 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 currency 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, 2012 and 2011 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			Thousands of U.S. dollars		
2012	Book value	Fair value	Difference	Book value	Fair value	Difference
(i) Cash and deposits	¥ 21,577	¥ 21,577	¥ —	$ 249,225	$ 249,225	$ —
(ii) Notes and accounts receivable	106,093	106,093	—	1,225,376	1,225,376	—
(iii) Short-term loans receivable	98,194	98,194	—	1,134,144	1,134,144	—
(iv) Derivative financial instruments*	(629)	(629)	—	(7,273)	(7,273)	—

	Millions of yen		
2011	Book value	Fair value	Difference
(i) Cash and deposits	¥ 27,063	¥ 27,063	¥ —
(ii) Notes and accounts receivable	104,448	104,448	—
(iii) Short-term loans receivable	82,958	82,958	—
(iv) Derivative financial instruments*	92	92	—

* 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) Derivative financial instruments

The fair value of derivative financial instruments is based on the quotes provided by financial institutions. See Note 13.

(2) Redemption schedule for financial instruments and debt securities by contractual maturities at December 31, 2012 and 2011 is as follows:

	Millions of yen			
2012	Within one year	Between one and five years	Between five and ten years	Total
Cash and deposits	¥ 21,577	¥ —	¥ —	¥ 21,577
Notes and accounts receivable	106,093	—	—	106,093
Short-term loans receivable	98,194	—	—	98,194
Total	¥225,864	¥ —	¥ —	¥225,864

	Thousands of U.S. dollars			
2012	Within one year	Between one and five years	Between five and ten years	Total
Cash and deposits	$ 249,225	$ —	$ —	$ 249,225
Notes and accounts receivable	1,225,376	—	—	1,225,376
Short-term loans receivable	1,134,144	—	—	1,134,144
Total	$2,608,745	$ —	$ —	$2,608,745

	Millions 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	—	—	104,448
Short-term loans receivable	82,958	—	—	82,958
Total	¥214,470	¥ —	¥ —	¥214,470

12 Securities

(1) Marketable other securities as of December 31, 2012 and 2011 are as follows:

	2012		
	Millions of yen		
	Purchase cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their purchase cost:			
Stocks	¥ 1,839	¥ 2,529	¥ 690
Securities whose purchase cost exceeds their carrying value:			
Stocks	14,412	10,176	(4,236)

	2012		
	Thousands of U.S. dollars		
	Purchase cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their purchase cost:			
Stocks	$ 21,241	$ 29,215	$ 7,973
Securities whose purchase cost exceeds their carrying value:			
Stocks	166,467	117,535	(48,932)

	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)

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. The book value of the unlisted stocks is ¥7,109 million ($82,111 thousand) and ¥7,049 million for the years ended December 31, 2012 and 2011, respectively.

(2) Information on sales of other securities for the years ended December 31, 2012 and 2011 is presented below:

	Millions of yen			Thousands of U.S. dollars		
	Sales amount	Gain	Loss	Sales amount	Gain	Loss
Year ended December 31, 2012	¥2,466	¥67	¥(344)	$28,486	$783	$(3,973)

	Millions of yen		
	Sales amount	Gain	Loss
Year ended December 31, 2011	¥2,258	¥16	¥(692)

(3) Impairment losses on valuation of investment securities

The Companies recognized ¥1,007 million ($11,636 thousand) and ¥2,374 million in loss on valuation of investment securities for the years ended December 31, 2012 and 2011, respectively.

13 Derivative Transactions

(1) Hedge accounting not applied to derivative financial instruments

Year ended December 31, 2012	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	¥ 3,296	¥(287)	¥(287)	$ 38,074	$(3,322)	$(3,322)
Selling Euro	1,597	(177)	(177)	18,449	(2,051)	(2,051)
Currency swaps						
Receiving Japanese yen, Paying GBP	8,907	(164)	(164)	102,882	(1,899)	(1,899)
	¥13,801	¥(629)	¥(629)	$159,406	$(7,273)	$(7,273)

Year ended December 31, 2011	Millions of yen		
Type of transaction	Notional amount	Fair value	Unrealized gain (loss)
Foreign exchange forward contracts			
Selling U.S. dollar	¥ 2,727	¥ (2)	¥ (2)
Selling Euro	1,416	51	51
Currency swaps			
Receiving Japanese yen, Paying GBP	7,129	43	43
	¥11,273	¥92	¥92

(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 years ended December 31, 2012 and 2011.

14 Cost of Sales

The Companies recognized ¥491 million ($5,676 thousand) and ¥156 million in valuation loss on inventories in cost of sales for the years ended December 31, 2012 and 2011, respectively.

15 Research and Development Expenses

Research and development expenses, all of which were included in selling, general and administrative expenses and production cost for the years ended December 31, 2012 and 2011, totaled ¥44,808 million ($517,544 thousand) and ¥47,961 million, respectively.

16 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, 2012 Location	Description	Classification	Millions of yen	Thousands of U.S. dollars
China	Other	Goodwill	¥896	$10,352
UK	Idle assets	Sales rights	218	2,520
Maebashi City, Gunma Prefecture	Idle assets	Land	201	2,327
Takaoka City, Toyama Prefecture	Idle assets	Equipment, other	25	298

Year ended December 31, 2011 Location	Description	Classification	Millions of yen
Takaoka City, Toyama Prefecture	Idle assets	Equipment, other	¥346
Ube City, Yamaguchi Prefecture	Idle assets	Land	173
Sakai City, Osaka Prefecture	Idle assets	Land and buildings	151
Hofu City, Yamaguchi Prefecture	Idle assets	Buildings and equipment, other	72
Bando City, Ibaraki Prefecture	Potential disposal assets	Land	24

17 Loss on Transfer of Assets

The Company transferred the business of Hematech, Inc. (a consolidated subsidiary). The breakdown of the loss associated with the transfer was ¥294 million ($3,397 thousand) as asset transfers of Hematech and ¥741 million ($8,560 thousand) as intangible fixed asset transfers of the Company.

18 Contingent Liabilities

The Companies had contingent liabilities arising from notes discounted by banks in the amount of ¥37 million ($430 thousand) and ¥83 million at December 31, 2012 and 2011, respectively.

19 Supplementary Information for Consolidated Statements of Changes in Net Assets

(1) Type and number of outstanding shares

Year ended December 31, 2012

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
Treasury stock:				
Capital stock*1, 2	21,037,327	8,208,314	183,011	29,062,630
Total	21,037,327	8,208,314	183,011	29,062,630

*1. Treasury stock increased by 8,208,314 shares due to the acquisition of treasury stock (8,152,000 shares) and the repurchase of shares of less than one unit (56,314 shares).
*2. Treasury stock decreased by 183,011 shares due to the stock options exercised (178,000 shares) and the sale of shares of less than one unit (5,011 shares).

Year ended December 31, 2011

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	6,691,427	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).

(2) Stock subscription rights

Year ended December 31, 2012

Company	Description	Millions of yen	Thousands of U.S. dollars
The Company	Share subscription rights as stock options	¥203	$2,350

(3) 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 22, 2012	Annual general meeting of shareholders	Common stock	¥5,554	$64,154	¥10	$0.115	December 31, 2011	March 23, 2012
July 27, 2012	Board of directors	Common stock	5,474	63,230	10	0.115	June 30, 2012	September 3, 2012

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, 2013	Annual general meeting of shareholders	Retained earnings	Common stock	¥5,474	$63,227	¥10	$0.115	December 31, 2012	March 25, 2013

20 Related Party Transactions

Significant transactions and balances with related parties as of and for the years ended December 31, 2012 and 2011 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, 2012

Name	Capital	Ratio of voting rights owning (owned)	Transactions	Amounts		Closing balances	Amounts	
	Millions of yen			Millions of yen	Thousands of U.S. dollars		Millions of yen	Thousands of U.S. dollars
Kirin Holdings Company, Limited	**¥102,045**	**Directly (53.2%)**	**Loan of funds*1**	**¥85,004**	**$981,800**	**Short-term loans receivable**	**¥98,189**	**$1,134,095**

Year ended December 31, 2011

Name	Capital	Ratio of voting rights owning (owned)	Transactions	Amounts	Closing balances	Amounts
	Millions of yen			Millions of yen		Millions of yen
Kirin Holdings Company, Limited	¥102,045	Directly (52.4%)	Loan of funds*1	¥65,612	Short-term loans receivable	¥82,473
			Sales price of subsidiary's shares*2	14,987		
			Gain on sales of subsidiary's shares*2	4,712		

*1. Related to "Cash Management System" offered by Kirin Holdings. The amount of the transactions is calculated based on 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

Year ended December 31, 2012

Name and position	Ratio of voting rights owned	Transactions	Amounts
			Millions of yen
Fumihiro Nishino Director	Directly (0.0%)	Disposal of treasury stocks by exercise of stock options*	¥21

* The amount of the transactions is calculated based on the book value of treasury stocks at the time of disposal.

No relevant items for the year ended December 31, 2011

(3) Financial summary of a significant affiliate

FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. is a significant affiliate. The financial summary for the year ended December 31, 2012 is as follows:

	Millions of yen	Thousands of U.S. dollars
Current assets	¥ 3,334	$ 38,518
Noncurrent assets	1,166	13,473
Current liabilities	1,368	15,809
Noncurrent liabilities	12,900	148,995
Net assets	(9,767)	(112,812)
Sales	—	—
Loss before income taxes	(9,866)	(113,963)
Net loss	(9,867)	(113,967)

21 Segment Information

Segment information for the year ended December 31, 2012

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

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

1. Information on sales and income, identifiable assets and other items by reportable segment

The accounting method for reportable segments is based on the accounting method and information provided in "Summary of Significant Accounting Policies".

Segment income is based on operating income.

Intersegment sales are mainly based on transaction prices with third parties.

Millions of yen

	Reportable segment				Adjustments*2	Consolidated total
	Pharmaceuticals	Bio-Chemicals	Other*1	Total		
Sales						
Sales to outside customers	¥249,691	¥ 75,133	¥ 8,334	¥333,158	¥ —	¥333,158
Intersegment sales and transfers	199	1,833	2,095	4,127	(4,127)	—
Net sales	249,891	76,966	10,429	337,286	(4,127)	333,158
Segment income	50,392	2,127	338	52,859	46	52,905
Segment assets	435,369	141,864	7,218	584,452	94,889	679,342
Other items						
Depreciation and amortization	¥ 14,573	¥ 6,280	¥ 52	¥ 20,906	¥ (1)	¥ 20,904
Amortization of goodwill	11,400	625	—	12,026	—	12,026
Investment to equity method affiliates	1,566	—	1,239	2,805	—	2,805
Increase of property, plant and equipment and intangible assets	18,333	9,454	24	27,812	(3)	27,808

Thousands of U.S. dollars

	Reportable segment				Adjustments*2	Consolidated total
	Pharmaceuticals	Bio-Chemicals	Other*1	Total		
Sales						
Sales to outside customers	$2,883,938	$ 867,790	$ 96,258	$3,847,987	$ —	$3,847,987
Intersegment sales and transfers	2,306	21,171	24,198	47,676	(47,676)	—
Net sales	2,886,245	888,962	120,457	3,895,664	(47,676)	3,847,987
Segment income	582,033	24,573	3,915	610,522	533	611,055
Segment assets	5,028,520	1,638,536	83,378	6,750,435	1,095,974	7,846,409
Other items						
Depreciation and amortization	$ 168,320	$ 72,544	$ 605	$ 241,470	$ (21)	$ 241,449
Amortization of goodwill	131,678	7,226	—	138,905	—	138,905
Investment to equity method affiliates	18,091	—	14,317	32,409	—	32,409
Increase of property, plant and equipment and intangible assets	211,756	109,194	277	321,229	(40)	321,188

*1. The Other segment is a business segment that is 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: ¥ (11,245) million
Corporate assets: ¥ 106,135 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
¥260,524	¥21,207	¥30,997	¥19,880	¥548	¥333,158

Thousands of U.S. dollars

Japan	America	Europe	Asia	Other areas	Total
$3,009,064	$244,944	$358,018	$229,625	$6,334	$3,847,987

(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% of the balances of property, plant and equipment recognized in the consolidated balance sheet at December 31, 2012, information on property, plant and equipment at December 31, 2012 was omitted.

3. Information by major customer

Millions of yen

Customer name	Net sales	Related segment name
Alfresa Corporation	¥45,741	Pharmaceuticals

Thousands of U.S. dollars

Customer name	Net sales	Related segment name
Alfresa Corporation	$528,320	Pharmaceuticals

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

Millions of yen

	Pharmaceuticals	Bio-Chemicals	Other	Total	Adjustments	Consolidated total
Impairment losses	¥1,316	¥25	¥ —	¥1,341	¥ —	¥1,341

Thousands of U.S. dollars

	Pharmaceuticals	Bio-Chemicals	Other	Total	Adjustments	Consolidated total
Impairment losses	$15,200	$298	$ —	$15,499	$ —	$15,499

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

	Millions of yen					
	Pharmaceuticals	Bio-Chemicals	Other	Total	Adjustments	Consolidated total
Amortization of goodwill	¥ 11,400	¥ 625	¥ —	¥ 12,026	¥ —	¥ 12,026
Unamortized balance	159,309	9,541	—	168,850	—	168,850

	Thousands of U.S. dollars					
	Pharmaceuticals	Bio-Chemicals	Other	Total	Adjustments	Consolidated total
Amortization of goodwill	$ 131,678	$ 7,226	$ —	$ 138,905	$ —	$ 138,905
Unamortized balance	1,840,022	110,201	—	1,950,224	—	1,950,224

6. Information regarding gain on recognition of negative goodwill by reportable segment

No relevant items.

Segment information for the year ended December 31, 2011

1. Information on sales and income, identifiable assets and other items by reportable segment

Reportable segment information for the year ended December 31, 2011 was as follows:

	Millions of yen						
	Reportable segment					Adjustments*3	Consolidated total
	Pharmaceuticals	Bio-Chemicals	Chemicals*1	Other*2	Total		
Sales							
Sales to outside customers	¥229,159	¥ 74,370	¥32,787	¥ 7,405	¥343,722	¥ —	¥343,722
Intersegment sales and transfers	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

*1. The Company sold all shares of Kyowa Hakko Chemicals on March 31, 2011. As a result, the "Chemicals division" was discontinued on March 31, 2011.
*2. The Other segment is a business segment that is not included in the reportable segments. It includes logistics operations, etc.
*3. (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 are not allocated to each reportable segment.
The amounts were as follows.
Elimination of the intersegment transactions: ¥ (10,544) million
Corporate assets: ¥ 98,593 million

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

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

(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% of 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

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

Millions of yen

	Pharmaceuticals	Bio-Chemicals	Chemicals	Other	Total	Adjustments	Consolidated total
Impairment losses	¥151	¥617	¥ —	¥ —	¥769	¥ —	¥769

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

Millions of yen

	Pharmaceuticals	Bio-Chemicals	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

6. Information regarding gain on recognition of negative goodwill by reportable segment

No relevant items.

22 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 life of approximately 14 years with a discount rate of 1.59%.

(3) Changes in the asset retirement obligations in the fiscal years ended December 31, 2012 and 2011

	Millions of yen		Thousands of U.S. dollars
	2012	2011	2012
Balance at beginning of year*1	¥ 654	¥674	$ 7,561
Accretion adjustment with the passing of time	5	6	58
Decrease due to fulfillment of obligations	—	(0)	—
Decrease due to change in the estimate*2	(276)	—	(3,194)
Other	—	(25)	—
Balance at end of year	¥ 383	¥654	$ 4,424

*1. The balance of the asset retirement obligations at the beginning of 2011 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).

*2. The Company changed the estimate of the asset retirement obligations based on a decline in the corresponding costs.

23 Per Share Data

	Yen		U.S. dollars
	2012	2011	2012
Net assets	¥1,013.6	¥970.2	$11.707
Net income–basic	44.1	45.2	0.509
Net income–diluted	44.1	45.1	0.509

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 taking into account 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, 2012 and 2011 in the above table is as follows:

	Millions of yen		Thousands of U.S. dollars
	2012	2011	2012
Net income–basic			
Net income used in the calculation of net income per share	¥24,199	¥25,608	$279,505
Weighted average number of shares of common stock outstanding (Number of shares)	548,449,701	567,029,639	—
Net income–diluted			
Increasing number of common stock attributable to: (Number of shares)	288,656	324,056	—
Stock subscription rights (Number of shares)	288,656	324,056	—

The financial data used in the computation of net assets per share at December 31, 2012 and 2011 in the above table is as follows:

	Millions of yen		Thousands of U.S. dollars
	2012	2011	2012
Total net assets	¥555,898	¥540,023	$6,420,630
Amounts deducted from total net assets attributable to	1,027	1,153	11,865
Stock subscription rights	203	250	2,350
Minority interests	823	902	9,515
Net assets used in the calculation of net assets per share	¥554,870	¥538,869	$6,408,765
Number of shares used in the calculation of net assets per share (Number of shares)	547,420,925	555,446,228	—

24 Subsequent Event

No relevant items.

Independent Auditor's Report

ERNST & YOUNG

Ernst & Young ShinNihon LLC
Hibiya Kokusai Bldg.
2-2-3 Uchisaiwai-cho
Chiyoda-ku, Tokyo, Japan 100-0011

Tel : +81 3 3503 1100
Fax: +81 3 3503 1197

Independent Auditor's Report

The Board of Directors
KYOWA HAKKO KIRIN Co., Ltd.

We have audited the accompanying consolidated financial statements of KYOWA HAKKO KIRIN Co., Ltd. and its consolidated subsidiaries, which comprise the consolidated balance sheet as at December 31, 2012, and the consolidated statements of income, comprehensive income, changes in net assets, and cash flows for the year then ended and a summary of significant accounting policies and other explanatory information, all expressed in Japanese yen.

Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in Japan, and for designing and operating such internal control as management determines is necessary to enable the preparation and fair presentation of the consolidated financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit 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 consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. The purpose of an audit of the consolidated financial statements is not to express an opinion on the effectiveness of the entity's internal control, but in making these risk assessments the auditor considers internal controls relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of KYOWA HAKKO KIRIN Co., Ltd. and its consolidated subsidiaries as at December 31, 2012, and their consolidated financial performance and cash flows for the year then ended in conformity with accounting principles generally accepted in Japan.

Convenience Translation

We have reviewed the translation of these consolidated financial statements into U.S. dollars, presented for the convenience of readers, and, in our opinion, the accompanying consolidated financial statements have been properly translated on the basis described in Note 3.

Ernst & Young ShinNihon LLC

March 15, 2013
Tokyo, Japan

Principal Subsidiaries and Affiliates

(As of December 31, 2012)

Name of Company	Percentage Owned Directly or Indirectly by the Company	Capital[2] (Thousand)	Principal Business
PHARMACEUTICALS			
Kyowa Medex Co., Ltd.	100.0%	¥450,000	Manufacture and sale of diagnostic reagents
Kyowa Medical Promotion Co., Ltd.	100.0%	¥50,000	Promotion and sales of pharmaceuticals
Kyowa Hakko Kirin America, Inc.	100.0%	$76,300	Holding company for administration and management of subsidiaries (U.S.A.)
BioWa, Inc.	100.0%	$10,000	Out-licensing of anti-body technology (U.S.A.)
Kyowa Hakko Kirin Pharma, Inc.	100.0%	$100	Development of outsourced pharmaceutical products (U.S.A.)
Kyowa Hakko Kirin California, Inc.	100.0%	$100	Generate new candidate substances and develop pharmaceuticals (U.S.A.)
Hematech, Inc.[3]	100.0%	$1	Technology research for manufacture of therapeutic antibody (U.S.A.)
ProStrakan Inc.	100.0%	$235	Sales of pharmaceuticals (U.S.A.)
ProStrakan Group plc	100.0%	£10,771	Supervision and management of special companies (UK)
Strakan International S.a r.l.	100.0%	$112,826	Sales, licensing-in and licensing-out of pharmaceuticals (UK)
Strakan Pharmaceuticals Limited	100.0%	£501	Development of pharmaceuticals (UK)
ProStrakan Limited	100.0%	£6,951	Sales of pharmaceuticals (UK)
ProStrakan Pharma S.A.S	100.0%	€1,139	Sales of pharmaceuticals (France)
ProStrakan Farmaceutica SLU	100.0%	€216	Sales of pharmaceuticals (Spain)
ProStrakan Pharma GmbH	100.0%	€51.2	Sales of pharmaceuticals (Germany)
ProStrakan Holdings B.V.	100.0%	€110.771	Holding company for special companies (Netherlands)
ProStrakan Pharma B.V.	100.0%	€18	Sales of pharmaceuticals (Netherlands)
ProStrakan S.r.l.	100.0%	€10.4	Sales of pharmaceuticals (Italy)
ProStrakan AB	100.0%	SEK 200	Sales of pharmaceuticals (Sweden)
Kyowa Hakko Kirin China Pharmaceutical Co., Ltd.	100.0%	CNY 246,794	Manufacture and sale of pharmaceuticals (China)
Kyowa Hakko Kirin Korea Co., Ltd.	100.0%	KRW 2,200,000	Sales of pharmaceuticals (Korea)
Kyowa Hakko Kirin (Taiwan) Co., Ltd.	100.0%	NT $12,450	Sales of pharmaceuticals (Taiwan)
Kyowa Hakko Kirin (Hong Kong) Co., Ltd.	100.0%	HK $6,000	Sales of pharmaceuticals (Hong Kong)
Kyowa Hakko Kirin (Singapore) Pte. Ltd.	100.0%	S $1,000	Sales of pharmaceuticals (Singapore)
FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.[1]	50.0%	¥100,000	Development, manufacture and sale of biosimilar pharmaceuticals
BIO-CHEMICALS			
Kyowa Hakko Bio Co., Ltd.	100.0%	¥10,000,000	Manufacture and sale of pharmaceutical and industrial raw materials, and health care products
Daiichi Fine Chemical Co., Ltd.	100.0%	¥6,276,000	Manufacture and sale of active pharmaceutical ingredients and pharmaceutical intermediates
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 plant facilities and equipment
BioKyowa Inc.	100.0%	$20,000	Manufacture and sale of amino acids (U.S.A.)
Kyowa Hakko U.S.A., Inc.	100.0%	$1,000	Sale and import/export of fine chemicals including amino acids (U.S.A.)
Kyowa Hakko Bio U.S. Holdings, Inc.	100.0%	$1	Holding company for administration and management of US special companies (U.S.A.)
Kyowa Hakko Europe GmbH	100.0%	€1,030	Sale and import/export of fine chemicals including amino acids (Germany)
Kyowa Hakko Bio Italia S.r.l.	100.0%	€700	Sale and import/export of fine chemicals including amino acids (Italy)
Shanghai Kyowa Amino Acid Co., Ltd.	70.0%	CNY 156,436	Manufacture and sale of amino acids (China)
Thai Kyowa Biotechnologies Co., Ltd.	100.0%	THB 500,000	Manufacture and sale of amino acids (Thailand)
Kyowa Hakko (H.K.) Co., Ltd.	100.0%	HK $1,200	Sale and import/export of fine chemicals including amino acids (Hong Kong)
Kyowa Hakko Bio Singapore Pte. Ltd.	100.0%	$4,000	Sale and import/export of fine chemicals including amino acids (Singapore)
OTHER			
Chiyoda Kaihatsu CO., LTD.	100.0%	¥112,000	Distribution, insurance, wholesale and retail
Japan Synthetic Alcohol Co., Ltd.[1]	33.3%	¥480,000	Manufacture and sale of industrial use alcohol

1. All of the companies listed are consolidated subsidiaries except FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. and Japan Synthetic Alcohol Co., Ltd., which are equity-method affiliates.
2. The unit for capital for all companies listed is thousands regardless of currency, except for Hematech, Inc., for which capital is $1, and ProStrakan Inc., for which capital is $235.
3. The business of producing fully humanized antibodies using cows that Hematech, Inc. developed was sold to non-profit organization Sanford Applied Biosciences, LLC on December 31, 2012.

Development Summary

(As of January 24, 2013)

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 breakthrough cancer pain. We filed an application for manufacturing and marketing approval in Japan in November 2012, which is under review.

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®. Both KRN125 and GRAN® stimulate the growth of neutrophils, a type of white blood cell. KRN125 has a much longer half-life than GRAN®. In Japan, we completed phase III clinical trials for chemotherapy-induced febrile neutropenia and are now preparing to submit an application for manufacturing and marketing approval.

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. In Japan, we are conducting a phase II clinical trial for non-small cell lung cancer with EGF receptor mutation and a phase I clinical trial for hepatocellular cancer.

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® in the United States, the United Kingdom and the Philippines.

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 have completed 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. has submitted an NDA to the U.S. FDA for advanced renal cell carcinoma.

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. 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. We suspended phase II clinical trials in Japan for CKD patients with Type 2 diabetes after Realta Pharmaceuticals of the United States terminated an overseas phase III clinical study due to safety concerns.

KHK7580
This next-generation calcium receptor agonist targets reduction of the digestive system side effects of REGPARA®, which is marketed as a treatment for secondary hyperparathyroidism during dialysis. We are conducting a phase I clinical trial in Japan covering healthy adults.

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 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 joint 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 II clinical trial in Japan covering psoriasis patients.

KHK4083
This fully human monoclonal antibody targets the antigens reported to play a key role in the pathogenesis of various autoimmune diseases. We are now conducting a phase I clinical trial in Canada.

KHK4577
This oral anti-inflammatory agent has a novel mechanisms of action. We are now conducting a phase I clinical trial in Japan.

Central Nervous System

KW-6002
KW-6002 is the world's first selective adenosine A_{2a} receptor antagonist for treating Parkinson's disease. Clinical trials in Japan demonstrated improvement in patients with Parkinson's disease under treatment with levodopa tablets and confirmed efficacy and tolerability. The new drug application in Japan was filed in March 2012, and approval was received in March 2013.

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.

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 hypophosphatemic rickets/osteomalacia in the United States and Canada.

Glossary

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

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, 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 trials involving humans that enhance data reliability and comply with pharmaceutical laws and regulations.

Good Distribution Practice (GDP)

Multifaceted standards for the pharmaceutical distribution process to ensure pharmaceutical quality and identity.

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.

Overseas Network

(As of December 31, 2012)

Pharmaceuticals

① Kyowa Hakko Kirin America, Inc.
212 Carnegie Center, Suite 101,
Princeton, NJ 08540, U.S.A.
Tel: 1-609-580-7400
Fax: 1-609-919-1111

② Kyowa Hakko Kirin Pharma, Inc.
212 Carnegie Center, Suite 101,
Princeton, NJ 08540, U.S.A.
Tel: 1-609-919-1100
Fax: 1-609-919-1111

③ BioWa, Inc.[1]
9420 Athena Circle,
La Jolla, CA 92037, U.S.A.
Tel: 1-858-952-7200
Fax: 1-858-952-7001

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.[2]
4401 South Technology Drive,
Sioux Falls, SD 57106, U.S.A.
Tel: 1-605-361-6793
Fax: 1-605-361-9702

⑥ Kirin-Amgen, Inc.
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

⑦ ProStrakan Group plc
Galabank Business Park, Galashiels TD1
1QH, United Kingdom
Tel: 44-1896-664000
Fax: 44-1896-664001

⑧ Kyowa Hakko Kirin China Pharmaceutical Co., Ltd.
970 Long Dong Road,
Z. J. High-Tech Park,
Pudong New Area,
Shanghai 201203,
People's Republic of China
Tel: 86-21-5080-0909
Fax: 86-21-5080-0026

⑨ 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

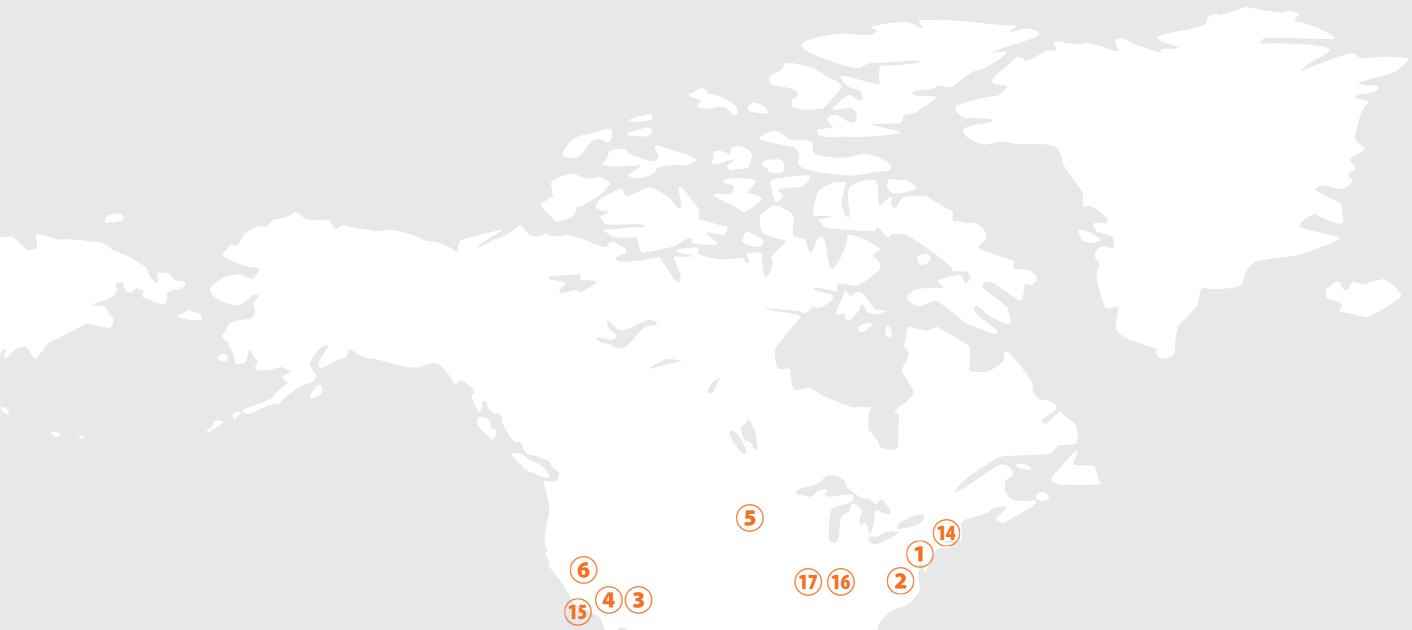
⑩ Kyowa Hakko Kirin (Taiwan) Co., Ltd.
9F, No. 44, Sec 2,
Chung Shan N. Road,
Taipei 10448, Taiwan
Tel: 886-2-2564-2800
Fax: 886-2-2560-1667

⑪ 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

⑫ Kyowa Hakko Kirin (Singapore) Pte. Ltd.
260, Orchard Road, #07-06,
The Heeren, 238855, Singapore
Tel: 65-6836-3991
Fax: 65-6836-3928

⑬ Kyowa Hakko Kirin (Thailand) Co., Ltd.
20F, United Center Bldg., 323
Silom Road, Bangrak,
Bangkok 10500, Thailand
Tel: 66-2631-2126
Fax: 66-2631-2125

1. Relocated office on March 18, 2013
2. Sold to non-profit organization Sanford Applied Biosciences, LLC on December 31, 2012



Bio-Chemicals

⑭ **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

⑮ **Kyowa 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

⑯ **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

⑰ **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

⑱ **Kyowa Hakko Europe GmbH**
Am Wehrhahn 50,
D-40211 Düsseldorf, Germany
Tel: 49-211-175-45-0
Fax: 49-211-175-45-441

⑲ **Kyowa Hakko Bio Italia S.r.l.**
Viale Piero e Alberto Pirelli, no. 6,
Milan, 20126, Italy
Tel: 39-02-367-069-01
Fax: 39-02-367-069-25

⑳ **Kyowa 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
Fax: 86-10-6590-8517

㉑ **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

㉒ **Shanghai Kyowa**
Amino Acid Co., Ltd.
No. 158, Xintuan Road,
Qingpu Industrial Zone,
Shanghai 201707,
People's Republic of China
Tel: 86-21-5970-1998
Fax: 86-21-5970-1135

㉓ **Kyowa 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

㉔ **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

㉕ **Kyowa Hakko Bio India**
Private Limited
65, 3 North Avenue, Maker Maxity,
Bandra Kurla Complex, Bandra (East),
Mumbai 400051, India
Tel: 91-22-6725-3457
Fax: 91-22-6725-3458

㉖ **Kyowa Hakko Bio**
Singapore Pte. Ltd.
47 Scotts Road, #12-05,
Goldbell Towers, Singapore 228233
Tel: 65-6732-7889
Fax: 65-6732-7989

㉗ **Thai Kyowa**
Biotechnologies Co., Ltd.
388 Exchange Tower, 29th Floor,
Room 2940, Sukhumvit Road, Khwaeng
Klongtoey, Khet Klogtoey,
Bangkok 10110, Thailand
Tel: 66-2-104-9150
Fax: 66-2-104-9101

Corporate Data

(As of December 31, 2012)

Kyowa Hakko Kirin Co., Ltd.

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

Number of Employees
4,197 (Consolidated: 7,243)

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)

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
- Tsukuba Development Center
- Technical Research Laboratories

Overseas

Pharmaceuticals
- Kyowa Hakko Kirin Pharma, Inc. (U.S.A.)
- Kyowa Hakko Kirin California, Inc. (U.S.A.)
- ProStrakan Group Plc (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 April 1, 2013)

Board Members

Executive Director of the Board, President and Chief Executive Officer
Nobuo Hanai[1]

Executive Director of the Board, Executive Vice President
Yoshiharu Furumoto[1]

Directors of the Board
Hiroyuki Kawai
Kazuyoshi Tachibana
Fumihiro Nishino
Mutsuyoshi Nishimura[2]
Motoaki Kitayama[2]
Hajime Nakajima[2]

Company Auditors
Hiroaki Nagai[3]
Manabu Suzuki
Takahiro Kobayashi[3]
Hiroyuki Takahashi[3]
Kazuyoshi Suzusyo[3]

Managing Officers

President and Chief Executive Officer
Nobuo Hanai

Executive Vice President
Yoshiharu Furumoto

Senior Executive Managing Officer
Hiroyuki Kawai
Vice President Head
Production Division

Executive Managing Officers
Kazuyoshi Tachibana

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

Hiroshi Sugitani
Director
Strategic Product Portfolio Department

Masafumi Inoue
Director
Tokyo Branch
Sales & Marketing Division

Hiroshi Okazaki
Vice President Head
Research Division
Head
Fuji Research Park

Kazuyoshi Adachi
Vice President Head
Pharmacovigilance and Quality Assurance Division

Kenya Shitara
Director
Intellectual Property Department

Masashi Miyamoto
Director
Regulatory Affairs Department
Pharmacovigilance and Quality Assurance Division

Takashi Oishi
Director
Sales Department
Sales & Marketing Division

Satoshi Nakanishi
Head
Tokyo Research Park
Research Division

Niro Sakamoto
Director
Corporate Strategy & Planning Department

Tamao Watanabe
Director
Business Development Department

Yutaka Osawa
Director
Production Planning Department
Production Division

Wataru Murata
Director
General Affairs & External Relations Department

1. Representative director
2. Outside director
3. Outside company auditor

Investor Information

(As of December 31, 2012)

Stock Listing
Tokyo

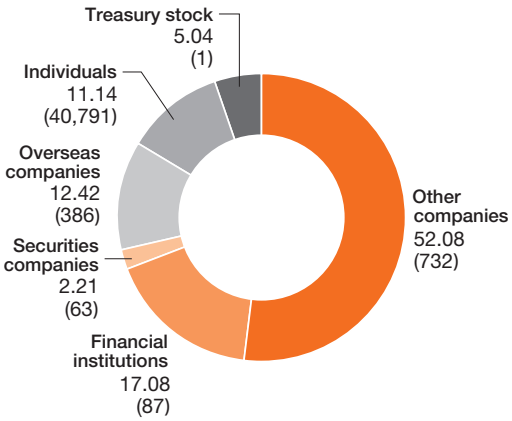
Securities Code
4151

Transfer Agent of Common Stock
Sumitomo Mitsui Trust Bank, Limited
1-4-1 Marunouchi, Chiyoda-ku, Tokyo
100-8233, Japan

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

Number of Shareholders
42,060

Shareholding by Type of Investor (%)

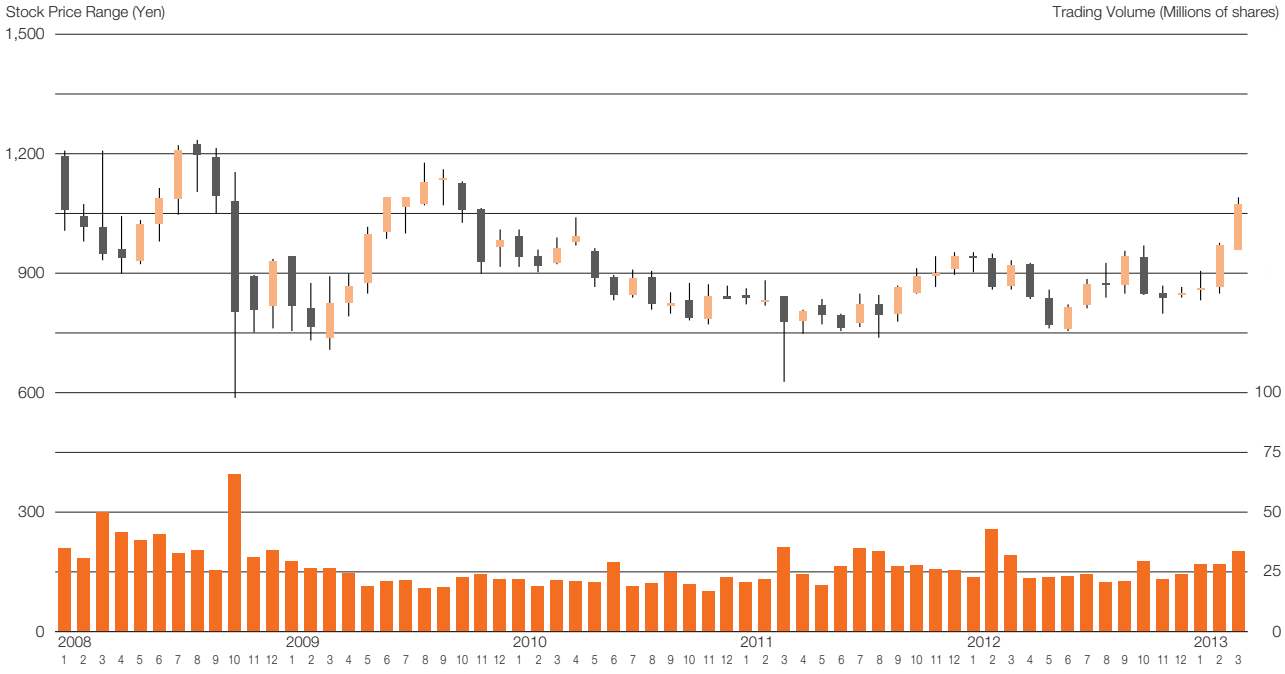


Principal Shareholders

	Number of Shares Held (Thousands)	Percentage of Total Shares Issued (%)
Kirin Holdings Company, Limited	288,819	52.75
The Master Trust Bank of Japan, Ltd. (Trust Account)	22,003	4.01
Japan Trustee Services Bank, Ltd. (Trust Account)	14,196	2.59
The Norinchukin Bank	10,706	1.95
Mizuho Trust & Banking Co., Ltd. (Retirement Benefit Trust for Mizuho Bank, Ltd.) [1]	4,781	0.87
The Nomura Trust and Banking Co., Ltd. (Trust Account)	3,905	0.71
Juniper	3,384	0.61
Kyowa Hakko Kirin Employees' Stock Holding Association	3,275	0.59
BBH493025BlackRock Global Allocation Fund, Inc.	3,175	0.57
The Dai-ichi Life Insurance Company, Limited	2,920	0.53

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 29,062 thousand shares (5.04%) held by the Company as treasury stock are excluded from the above because treasury stock has no voting rights.

Stock Price and Trading Volume



Kyowa Hakko Kirin Co., Ltd.

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

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