KYOWA KIRIN

Unleashing the Power



Kyowa Hakko Kirin Annual Report 2010

History

Kyowa Hakko Kirin

2011	Release of Romiplate [®] , a platelet production stimulator.		
2011	Announcement of agreement to begin the process of acquiring Pr	oStraka	an Group ple
	Conclusion of agreement to transfer all shares of Kyowa Hakko Ch		
2010	Transfer of all shares of Kyowa Hakko Food Specialties Co., Ltd., to		Holdings Company, Limited.
2010	Release of Fentos [*] , a transdermal analgesic for persistent cancer	-	Romiplate*
	Completion of the new research building at the Tokyo Research Pa		
	Completion of one of Japan's leading facilities for producing inves antibodies at the Bio Process Research and Development Laborate		
2009	Release of Asacol [®] , a treatment for ulcerative colitis.		
	Introduced "Sharing Values, Aims, and Ideals; Team Kyowa Hakko	Kirin."	
2008	Formation of Kyowa Hakko Kirin through the merger of Kyowa Ha	kko and	d Kirin Pharma.
(vowa	l Hakko	Kirin I	Pharma
2008	TIAKO		Release of Regpara [®] , a drug for secondary hyperparathyroidism.
	Announcement of a strategic alliance between Kyowa Hakko	2000	
2007	Group and Kirin Group.	2007	adoption by Kirin Brewery Co., Ltd. of a pure holding company system.
2007	Release of the antiepileptic drug Topina [®] .	2007	Release of Nesp [®] , a long-acting ESA ¹¹ formulation.
2006	Release of Patanol [®] antiallergic eyedrops. Allelock [*]	2006	Nesp*
2005		2005	Acquisition of Hematech, Inc.
2003	Establishment of BioWa, Inc., in the	2003	and the second se
	United States to promote Kyowa Hakko's		and the second se
	therapeutic antibody business.		
2001	Release of Allelock [®] , an anti-allergic drug.	2001	- P
1999	Development of an innovative antibody	1999	Agreement with Medarex for human antibody-generating mice
	technology (POTELLIGENT [®]) that greatly enhances antibody activity.		(KM Mouse).
1991	Release of Coniel [®] , a remedy for hypertension and angina pectoris.	1991	Release of Gran [®] , G-CSF ² agent.
1990	Coniel®	1990	Release of Espo [®] , ESA ^{*1} formulation.
1984	Conter	1984	Establishment of Kirin-Amgen, Inc.
1982		1982	First real move into the pharmaceuticals business with a
	In State		reorganization of research and development, involving the
1001		1001	establishment of a new R&D Division in Head Office.
1981		1981	Clarification of the move toward the pharmaceuticals business with the "Long-Term Business Vision" plan.
1963	Initiation of full-scale involvement in the pharmaceutical business.	1963	
	Successful isolation and commercial mass production of the	1956	
	anticancer drug, Mitomycin C.		
	Invention of the process of L-glutamic acid production by fermentation (a world first).		
1951	Introduction of production technology for Streptomycin, an	1951	
1731	antitubercular drug, from U.S. pharmaceutical company Merck	1751	
	& Co., Inc.		
	Successful mass production of Streptomycin, contributing		
	to the wiping out of tuberculosis in Japan (beginning of involvement in pharmaceutical business operations).		
1949	Establishment of Kyowa Hakko Kogyo Co., Ltd., as a secondary	1949	
	company of Kyowa Sangyo Co., Ltd., as part of industrial		
	readjustment plans.		
1948	Initiation of Japan's first mass production of acetone butanol	1948	
	from syrup (beginning of involvement in chemical business operations).		
1907		1907	Establishment of Kirin Brewery Co., Ltd.
		1,0,	Lotaonominent of Anni Drewery Co., Etc.

Selection and Concentration in Business Portfolio

Current Business Segments

Pharmaceuticals Operations

Our Pharmaceuticals operations trace back to the introduction of production technology for Streptomycin, a treatment for tuberculosis, which was said to be incurable at the time. In 2007, Kyowa Hakko, which had strengths in anticancer and anti-allergy drugs, merged with Kirin Pharma, which had strengths in the cancer and renal disease areas. Now, Kyowa Hakko Kirin leverages the strengths of both of its predecessor companies in such areas as therapeutic antibody technologies.

Bio-Chemicals Operations

On a foundation of Kyowa Hakko's traditional fermentation technology, Bio-Chemicals operations produce a wide range of nucleic acid and amino acid products. In recent years, operations have been expanded to high-end products, such as pharmaceutical intermediates, and health food products. As a pioneer in fermentation, we have established a position as an industry leader.

Transferred Business Segments

Chemicals Operations

In Chemicals operations, we successfully commercialized the acetone butanol fermentation process, which led to the establishment of Kyowa Hakko. Chemicals operations provide basic chemical products, such as solvents and raw materials for plasticizers. In recent years, Chemicals operations have focused on the development, production, and sales of functional products/specialty chemicals, such as products in the fields of environmental conservation and leading-edge technologies. In Chemicals operations, in April 2011 we transferred all of our shares of Kyowa Hakko Chemical Co., Ltd.

Food Operations

In Food operations, representative products include seasonings and freeze-dried foods that leverage fermentation technologies. In April 2009, Kyowa Hakko Food Specialties Co., Ltd., and Kirin Food-Tech Company, Limited, were integrated to form Kirin Kyowa Foods Company, Limited. In January 2011, Kirin Kyowa Foods became a wholly owned subsidiary of Kirin Holdings.

^{*1} Erythropoiesis Stimulating Agent

^{*2} Granulocyte-Colony Stimulating Factor

Special Feature

Unleashing the Power

About Kyowa Hakko Kirin

Kyowa Hakko Kirin Co., Ltd., was inaugurated in October 2008 as an R&D-based life sciences company with special strengths in biotechnology, following the integration of Kirin Pharma Company, Limited, of the Kirin Group, and Kyowa Hakko Kogyo Co., Ltd. The Company is dedicated to the creation of new value in the life sciences, especially in its core business segments of Pharmaceuticals and Bio-Chemicals, and strives to contribute to the health and well-being of people around the world. We are seeking new heights by aggressively promoting our proprietary technologies in each business domain.

In Pharmaceuticals operations, the Company has actively engaged in the R&D, production, and sale of pharmaceuticals that address medical needs in such areas as renal anemia, cancer, allergies, and hypertension. Utilizing leading-edge biotechnologies, particularly antibody technologies, we are aiming to be a global specialty pharmaceutical company that creates innovative pharmaceuticals.

Bio-Chemicals operations are centered on Kyowa Hakko Bio Co., Ltd., which was established as a separate company at the same time as the inauguration of Kyowa Hakko Kirin and is a global leader in fermented bulk products, such as amino acids, nucleic acids, and related compounds.

Contents

1 Special Feature Unleashing the Power of Biotechnology

8 From the President

- 8 Financial Highlights
- 9 Letter to Our Shareholders and Friends
- 16 R&D
 - 16 Research and Development Activities
 - 22 Pharmaceutical Pipeline
- 26 Review of Operations
 - 26 At a Glance
 - 27 Pharmaceuticals
 - 30 Bio-Chemicals

32 Management & Organization

- 32 Intellectual Property
- 34 Corporate Social Responsibility
- 36 Corporate Governance
- 40 Management Members
- 41 Financial Section
- 81 Principal Subsidiaries and Affiliates
- 82 Overseas Network
- 84 Corporate Data
- 85 Investor Information

Note to Performance Forecasts:

Forecasts contained in Annual Report 2010 represent judgments based on information available as of March 24, 2011. It should be noted that there is a possibility that actual results could differ significantly due to a variety of factors.

Unleashing the Power of Biotechnology

FROM THE PRESIDENT

of Biotechnology

POTELLIGENT[®]—Expanding the Global Potential of Antibody Technology

For Kyowa Hakko Kirin, 2011 was truly a milestone year.

In Japan, we filed a new drug application (NDA) for KW-0761, the first therapeutic antibody that used POTELLIGENT[®], the innovative antibody technology that we developed by drawing on our leading-edge capabilities in the field of biotechnology. We expect KW-0761, a new candidate for the treatment of adult T-cell leukemia-lymphoma (ATL), to be launched in 2012. This filing marks a major step toward a new stage of growth for Kyowa Hakko Kirin.

The latent potential of Kyowa Hakko Kirin and biotechnology are being unleashed.



Unleashing the Power of Biotechnology

NDA for KW-0761

In April 2011, we reached an important milestone. We can now look ahead to the launch in 2012 of the first therapeutic antibody using our original POTELLIGENT[®] antibody-dependent cellular cytotoxicity (ADCC) enhancing technology.

KW-0761, an anti-CCR4 (chemokine (c-c motif) receptor 4) humanized monoclonal antibody, has been developed for an indication of adult T-cell leukemia-lymphoma (ATL). There have been no effective treatments for this disease, and the specific efficacy of KW-0761 has been a focus of attention for some time. Phase II clinical trials in Japan produced favorable results, and an NDA was filed. (For information about the results of the clinical trials, please see the table below.)

This is a very significant step for the future direction of Kyowa Hakko Kirin. Until now, we have taken a comparatively restrained approach to global business development, but this initiative demonstrates our commitment to independently targeting markets around the world.

In Japan, there are about 2,000 people who suffer from ATL, a fact that holds significant meaning for the KW-0761 NDA. Our commitment to responding to unmet medical needs is bearing fruit.

In addition, while POTELLIGENT[®] technology had previously been evaluated at the pre-clinical stage, with this first POTELLIGENT[®] antibody we have been able to verify the efficacy of POTELLIGENT[®] technology in humans. This achievement has expanded the potential of the therapeutic antibodies being developed by Kyowa Hakko Kirin and POTELLIGENT[®] licensees.

At the same time, we filed an NDA with the Ministry of Health, Labour and Welfare for manufacturing and marketing approval in Japan for two companion diagnostics products for KW-0761. This will make it possible to investigate the genetic and biomarker information of patients, thereby facilitating the selection of the optimal method of treatment. (For further information, please see the column on page 21.)

In a variety of ways, the progress of KW-0761 can be seen as an indicator of what the future holds for Kyowa Hakko Kirin.



Overview of Phase II Clinical Trial in Japan

Objective	To evaluate the efficacy and safety of once-weekly doses (8 administrations) of 1.0mg/kg KW-0761 in patients with relapsed CCR4-positive ATL after prior response to chemotherapy.
Target Sample Size	25 evaluable patients
Primary Endpoint	Overall response rate
Efficacy	The efficacy of this product was evaluated in 26 patients.
	Response rate: 50% (95%Cl, 30-70%) 8 patients with complete response, 5 patients with partial response
	Progression free survival (PFS) = 158 days (median value)
Safety	The safety of this product was evaluated in 27 patients.
	KW-0761 was found to be well tolerated at this dose level.



The Potential of POTELLIGENT®

POTELLIGENT[®] is drawing attention as a revolutionary technology in the development of therapeutic antibodies. Currently, Kyowa Hakko Kirin is developing seven antibodies as new drug candidates, and in addition 17 licensees have multiple antibodies under development. Moving forward, we anticipate steady progress of these candidates to later development stages.

The main feature of POTELLIGENT[®], Kyowa Hakko Kirin's original ADCC enhanced antibody technology, is its ability to remarkably increase ADCC activity by reducing the amount of fucose in the carbohydrate structure of antibodies, thus enabling the extremely

effective elimination of target cells, such as cancer cells.

There have been some reports of attempts to enhance antibody activity through research targeting sugar chains other than fucose or through amino acid substitution, but these techniques have not been shown to be more effective than POTELLIGENT[®].

In animal studies, it has been confirmed that antibodies using POTELLIGENT[®] technology are over a hundred times more effective against tumors than normal antibodies.



Moreover, therapeutic antibodies are recognized to generally have low levels of side effects, and in addition the dosage amount of POTELLIGENT[®] is extremely low. As a result, there is likely to be significant reduction in the burden on patients. Also, because antibodies specifically attack cancer cells, a high degree of efficacy can be expected.

The verification of POTELLIGENT*'s efficacy will expand the potential of therapeutic antibodies.





Unleashing the Power of Biotechnology

The Potential of Therapeutic Antibodies

Distinctive Features of Therapeutic Antibodies

Therapeutic antibodies are the focus of attention around the world as next-generation pharmaceuticals. The global market value for therapeutic antibodies was \$36.0 billion in 2009, and it is expected to surpass \$60.0 billion by 2015. Therapeutic antibodies use biotechnology to strengthen the human immune function. Because these antibodies act with pinpoint accuracy on pathogens in the human body, they are extremely effective yet have low levels of side effects. Therapeutic antibodies show great promise as pharmaceuticals that have solid potential to respond to unmet medical needs, such as infectious diseases and cancer.

In a 2008 ranking of the top-selling drugs around the world, therapeutic antibodies accounted for five of the top 15 drugs. These drugs, which had recorded double-digit, year-on-year growth, showcased the usefulness of therapeutic antibodies.

Kyowa Hakko Kirin has a range of basic technologies in the field of therapeutic antibodies, which offers tremendous potential. In addition to POTELLIGENT[®], which is mentioned above, the Company's lineup includes KM Mouse technology for the production of fully human antibodies and COMPLEGENT[®] complement-dependent cytotoxicity (CDC) technology.

Therapeutic Antibody Structure

Antibodies have the distinctive feature of only recognizing specific pathogens. Pathogens have distinctive antigens. The basic structure of antibodies is a Y-shape. The tips of the "Y," which are called the hypervariable regions, are the sites that bind to the pathogen's antigen. The tips have structures that differ by antigen, so the antibodies have the distinctive feature of binding only to a specific antigen, much like a lock and key. Therapeutic antibodies utilize these structures and properties.

For example, in the field of oncology, the anticancer agents that are traditionally used in chemotherapy limit



Therapeutic antibodies have the merit of extremely low side effects because only cancer antigen molecules are attacked. Furthermore, through genome analysis, the antigen molecule that is the target of drug discovery is specified, so the potential of therapeutic antibodies is expected to expand even further.



From the President

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

For the year ended December 31, 2010, the nine months ended December 31, 2009 and the year ended March 31, 2009

		Millions of Yen		Thousands of U.S. Dollars ¹
	2010/12	2009/12	2009/3	2010/12
For the Year:				
Net sales	¥413,739	¥309,112	¥460,184	\$5,077,175
Operating income	45,410	28,244	45,387	557,250
Net income	22,197	8,797	11,727	272,392
Capital expenditures	29,374	25,135	18,523	360,463
Depreciation and amortization	22,188	17,003	18,780	272,282
R&D expenses	44,221	34,980	48,389	542,530
At Year-End:				
Total assets	695,862	695,268	699,041	8,539,239
Interest-bearing debt	7,515	13,229	13,540	92,226
Total net assets	544,993	540,344	543,070	6,687,841
Total shareholders' equity	553,173	539,304	547,203	6,788,226
		Yen		U.S. Dollars ¹
Per Share Data:				
Net income-basic ²	¥ 39.0	¥ 15.4	¥ 20.4	\$ 0.478
Net assets	954.6	940.8	938.4	11.714
Cash dividends	20.0	15.0	20.0	0.245
Financial Ratios:				
Poture on accets $(P \cap A)$	2 10%	1 260/	1 6 2 0/	

Return on assets (ROA)	3.19%	1.26%	1.62%
Return on equity (ROE)	4.11%	1.64%	2.17%

1. U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥81.49=U.S.\$1, the approximate exchange rate at December 31, 2010.

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.





Sales Composition by **Business Segment*** (2010/12)



Sales Composition by Geographic Area



Letter to Our Shareholders and Friends



Letter to Our Shareholders and Friends

Off to a Strong Start with Medium-Term Management Plan—2010 to 2012

Management Environment and Results in Fiscal 2010 Gains in sales and profits. Record-high operating income.

Despite a challenging operating environment, I am pleased to report that Kyowa Hakko Kirin achieved gains in both sales and profits¹¹ in fiscal 2010, ended December 31, 2010. These results would not have been possible without the forward-looking initiative and dedicated efforts of all of our employees.

The domestic economy continued to gradually recover during the fiscal year under review. Nonetheless, the recovery lacked strength, and there were a number of areas of uncertainty. These included concerns about business conditions overseas, primarily in Europe and the United States, as well fluctuations in foreign exchange rates.

In this setting, Kyowa Hakko Kirin's consolidated net sales increased 1.7%, to ¥413.7 billion; operating income⁺² rose 46.8%, to ¥45.4 billion; and net income increased 121.1%, to ¥22.2 billion. Of special note was our achievement of a new record high in operating income. Fiscal 2010 was the first year of the Medium-Term Management Plan—2010 to 2012. Despite the adverse effects of the April 2010 reductions in National Health Insurance (NHI) reimbursement prices and the rapid appreciation of the yen, we were able to meet the objectives for the plan's first year.

In our Pharmaceuticals operations, sales of mainstay products increased and new products rapidly achieved market penetration. As a result, we were able to offset the reductions in reimbursement prices, which had an adverse effect of more than ¥10.0 billion, and record an increase in sales. In Bio-Chemicals operations, favorable results were recorded by health care products and by amino acids for pharmaceutical and industrial use. Consequently, we were able to minimize the adverse effect on sales stemming from the transfer of alcohol sales operations, the transfer of livestock and fisheries products operations, and the appreciation of the yen. In Chemicals operations, business was supported by a recovery in demand in China and other Asian countries. In addition, a change in the segment classification of two subsidiaries resulted in the transfer of those subsidiaries from the Other operations to the Chemicals operations. Consequently, sales increased.

^{1.} For year-on-year comparisons, the results in the year under review are compared with the corresponding period of the previous year, the 12-month period from January 1, 2009, to December 31, 2009.

^{2.} Operating income after amortization of goodwill

Medium-Term Management Plan—2010 to 2012

Notable Progress in Three Focus Areas

The Medium-Term Management Plan—2010 to 2012 has three focus areas—the implementation of the principles of selection and concentration in our business portfolio, the achievement of higher profitability through the reorganization of our production bases, and the development of our therapeutic antibody business, centered on our world-class antibody technologies. In each of these areas, we are making steady progress.

Implementing the Principles of Selection and Concentration in Our Business Portfolio

In accordance with our vision of "becoming a world-class, R&D-based life sciences company, founded on biotechnology with the pharmaceutical business at its core," we have strived to be a global specialty pharmaceutical company. To that end, we have focused our management resources on our core Pharmaceuticals operations and Bio-Chemicals operations.

In April 2009, the consolidated subsidiary that was responsible for our Food operations, Kyowa Hakko Food

Specialties Co., Ltd., was integrated with Kirin Food-Tech Company, Limited, to form Kirin Kyowa Foods Company, Limited. As initially planned, Kyowa Hakko Kirin transferred its 35% share in Kirin Kyowa Foods Company. Furthermore, in April 2010 we transferred our livestock and fisheries products operations to ASKA Pharmaceutical Co., Ltd., and in July 2010 we integrated our alcohol sales operations with Kirin Group member Mercian Corporation. In this way, we have taken steps to implement selection and concentration in our business portfolio.

Our Chemicals operations have been the focus of attention from investors for several years. Recently, we concluded an agreement to transfer to KJ Holdings Inc. all our shares of Kyowa Hakko Chemical Co., Ltd., the consolidated subsidiary that handled the Company's business in this segment. As a result, Kyowa Hakko Chemical can now implement flexible operational management that is responsive to wide-ranging market needs.

While working toward the goal of implementing the principles of selection and concentration in our business portfolio, I have very carefully considered the transfer of business operations, with employment if possible. In

Achieving Rapid Progress in Our Development Pipeline through the Efficient Use of Management Resources

- Implementing the principles of selection and concentration in our business portfolio
- Improving profitability by reorganizing production bases
- Further developing our world-class therapeutic antibody business

Pharmaceuticals Segment

Fundamental Strategies

R&D

- Leverage our leading-edge biotechnologies, primarily antibody technologies, to promote discovery research in key areas oncology, nephrology, and immunology/allergy—and enhance our development pipeline
- Accelerate new drug development through the effective utilization of overseas development bases and strive to quickly acquire Proof of Concept (POC) for several products in development
- Obtain manufacturing approval for two or more products each year (including additional indications)

Production

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

Domestic Sales

- Continue to expand the market share for existing core products
- Rapidly penetrate markets with new products
- Reorganize marketing structure to improve sales efficiency

Overseas Operations

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

Bio-Chemicals Segment

Fundamental Strategies

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

Letter to Our Shareholders and Friends

making these decisions, financial considerations were not our top priority. That is, we did not transfer a business simply because it had low profitability. Rather, we searched for the best alternative for our coworkers, with whom we have worked together closely for many years. We were fortunate in that we found superior partners within the Kirin Group for our food business and our alcohol business, and our progress in these initiatives has been comparatively smooth. In that sense, we worked closely with the company that acquired our Chemicals operations, which were facing considerable hurdles. We carefully examined all aspects of this initiative in detail and reached the point where we were confident that we could take this step. Through the transfer of all Kyowa Hakko Chemical shares, we achieved our goal of implementing selection and concentration in our business portfolio.

Bolstering Earnings Capacity through the Reorganization of Our Production Bases

The management plan also calls for the reorganization of our production bases. Through this reorganization project, we have taken steps to update old production equipment, consolidate scattered production bases, and improve production efficiency. These initiatives have made solid progress. Plans call for these production system reorganization measures to be completed by 2017 in Pharmaceuticals operations. At the A pharmaceutical raw material building, which was completed in March 2010, we produce investigational therapeutic antibodies. This building's facilities for the cultivation of recombinant animal cells and for purification are among the largest in the world, and through its operation we expect to make progress in the further development of therapeutic antibodies.

We completed the consolidation of our R&D system by May 2009. In addition, we instituted a comprehensive renewal with the completion of a new building at the Tokyo Research Park in April 2010. In April 2011, we consolidated the Innovative Drug Research Laboratories, the Antibody Research Laboratories, and the Research Planning & Administration Department at the Tokyo Research Park and established the Biopharmaceutical Research Laboratories. This center will be a mainstay research facility for the Company. Its mission will be to establish innovative drug discovery technologies that leverage leading-edge biotechnologies as well as discovery of new drug candidates. Regrettably, there were incidents of improper handling of research animals at the center. Accordingly, this area is one facet of our initiatives for strengthening governance with the objective of operating an integrated management system. Also, the Chemical Process Research and Development Laboratories (Osaka), which handles research of production processes for small-molecule drugs, has been relocated to the Fuji



Business Portfolio

Pharmaceuticals	• Ethical drugs
	Diagnostic reagents
Bio-Chemicals	• Fine chemicals
	Health care products
	• Livestock and fisheries products → Transferred to ASKA Pharmaceutical Co., Ltd., in April 2010
	• Alcohol (Sales operations) → Integrated with Mercian Corporation in July 2010
Chemicals	Transferred to KJ Holdings Inc. in April 2011
Food	Merged with Kirin Food-Tech Company, Limited, to form Kirin Kyowa Foods Company, Limited, in April 2009

Research Park, which is a base for research into smallmolecule drug discovery.

We plan to invest about ¥10.0 billion in the reorganization of these production and R&D bases, and when these initiatives are completed, we anticipate annual cost savings of several billion yen.

Development of Our World-Class Therapeutic Antibody Business

Progress in the therapeutic antibody business will be indispensable as Kyowa Hakko Kirin works to establish its presence as a global specialty pharmaceutical company. Together with the POTELLIGENT[®] and COMPLEGENT[®] enhanced antibody technologies, we also have KM Mouse, a technology for the production of fully human antibodies from mice. With these strengths, our presence in therapeutic antibodies is increasing.

To maximize the value of our therapeutic antibody business, we use three business models: (1) in-house development/joint development, (2) early stage outlicensing, and (3) antibody technology licensing.

In particular, KW-0761 will be the first therapeutic antibody using POTELLIGENT[®] technology, and we expect the NDA for KW-0761 to increase the momentum toward the creation of new drugs. Technologies similar to POTELLIGENT[®] have been developed, and there are concerns about their effect on the adoption of POTELLI-GENT[®], but POTELLIGENT[®] is an innovative technology that completely eliminates fucose. This feature marks a distinct difference between POTELLIGENT[®] and these other technologies, and accordingly, we believe that POTELLIGENT[®] technology continues to maintain a competitive advantage.

Progress toward NDA for KW-0761

The Launch of KW-0761: The Next Chapter in Our Growth Story

The launch of KW-0761, which is rapidly approaching, will be an event with tremendous significance for Kyowa Hakko Kirin. First, this will be the first therapeutic antibody that uses POTELLIGENT[®], and as a result it will be proof of the superiority of POTELLIGENT[®]. This will lead once again to increased attention on the effects of POTELLIGENT[®], and as a result, we expect the potential of therapeutic antibodies using POTELLIGENT[®] to increase substantially.

Second, this will be a turning point in the establishment of a system that will enable us to step up to the next stage by serving as a foothold for our advance into global markets on our own. In Japan, we demonstrated the effectiveness of this candidate from the results of clinical development. For this drug, Amgen previously had an option to expand its license to include the indication of cancer in its licensed territory. However, we have a good relationship with Amgen, and we were able to buy out that option. As a result, we have regained worldwide development and marketing rights in the field of oncology.

Third, KW-0761 has been designated by the Ministry of Health, Labour and Welfare as an orphan drug. It is expected to be effective in treating an intractable disease, adult T-cell leukemia-lymphoma (ATL). This is not a large market, but there are no effective methods of treating relapse and recurrence. From the perspective of responding to unmet medical needs, this is an extremely important drug for the Company.

Challenges in Pharmaceuticals Operations Growing Presence as a Global Specialty Pharmaceutical Company

In preparation for the launch of KW-0761 in the next few years, we will establish a sales network in Europe and the United States. We recently announced the start of acquisition procedures for ProStrakan Group plc, a specialty pharmaceutical company in the United Kingdom. After considering a wide range of factors, we decided that this was the best option for the Company moving forward.

POC Fast Strategy and Short- to Medium-Term Initiatives

It will be a few years until POTELLIGENT[®] antibodies begin to contribute to the Company's results, and over the intervening period Kyowa Hakko Kirin plans to implement a number of aggressive initiatives.

First, we will advance the Proof of Concept⁻³ (POC) Fast strategy in our new drug pipeline. For companies Letter to Our Shareholders and Friends

that develop and manufacture new drugs, the success of the development pipeline is indispensable for sustained growth, and we are proud that our development pipeline is comparatively robust. However, a more important point is to conduct R&D with a focus on the speed from discovery to POC. This is the POC Fast strategy. After obtaining POC for a new drug, we consider the development period and the probability of success, and then decide whether to proceed through in-house development, joint development, or out-licensing. We believe that this wide range of business choices is of vital importance. In the end, we believe that this approach will lead to quicker launches of new drugs and enable us to maximize new drug value.

In addition, through the in-licensing of new drug candidates over the short to medium term, we will further enhance our new drug pipeline. This pipeline contains many compounds that are still in the early stages of development, and consequently it is clear that we will not be able to launch new drugs in the short to medium term. To fund the in-licensing of these new drug candidates, we plan to utilize the funds that we obtained as a result of the Kyowa Hakko Chemical and Kirin Kyowa Foods share exchanges.

3. Initial verification that a drug has the desired pharmacological effect in humans.

Bio-Chemicals Operations

Vertical Diversification: Our Core Competencies

Following the transfer of alcohol sales operations and the transfer of livestock and fisheries products operations, Bio-Chemicals operations can focus its management

resources on the fields of nucleic acids and amino acids as well as health care.

In particular, amino acids comprise the core of Bio-Chemicals operations. They are not simply a representative business for the Company, they also provide indispensable technological underpinnings for Pharmaceuticals operations. The Company was the first in the world to succeed in industrial production of amino acids through fermentation. From an original focus on lysine for agricultural feed, we have shifted to high-value-added, high-purity amino acids for medical and pharmaceutical applications. In addition, we have technology for the production of a variety of amino acids, such as dipeptides. Consequently, we have been able to establish a strong presence in the high end of the market and to conduct amino acid operations that are highly price competitive.

These leading-edge amino acid technologies also foster synergies with our Pharmaceuticals operations. We provide high-purity amino acids for use as raw materials, such as for pharmaceutical intermediates and for infusions. In this way, we have a diverse business portfolio that is unique in its coverage of everything from pharmaceutical raw materials to pharmaceutical products. I call this vertical diversification, and I believe it is a key point of differentiation from other companies.

In this way, our core competencies are derived from a business portfolio that is based on original technical capabilities and has a high degree of synergy between Pharmaceuticals and Bio-Chemicals operations.



Vertical Diversification

Increasing Our Enterprise Value

Becoming a Company with a Strong Presence from the ESG Perspective

As an R&D-based life sciences company with special strengths in biotechnology, Kyowa Hakko Kirin works to create new value through the development of therapeutic antibodies and other new drugs and through the supply of raw materials for pharmaceuticals, such as amino acids. These endeavors are implemented in accordance with our corporate philosophy of "contributing to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technology." In this way, we believe that we can raise our enterprise value.

Companies are said to be instruments of society, and if they do not serve society then they have no purpose. I have always believed that activities that do not contribute to society in an environmentally friendly manner have no place whatsoever in company operations. Through our products, we not only contribute to the health of people around the world and the medical treatment of patients, but also, in the implementation of our business activities, following social norms and rules and working to implement environmental conservation are indispensable elements in the Company's sustained growth. Our Pharmaceuticals operations trace back to the introduction of production technology for Streptomycin, a treatment for tuberculosis, which was said to be incurable at the time. This is representative of our philosophy, which is also reflected in the therapeutic antibody KW-0761, which has been designated as an orphan drug.

Fermentation technologies, which are the starting point of Kyowa Hakko Kirin, are production technologies that utilize vegetable-derived sugars as raw materials. Plants absorb carbon dioxide, and the sugars derived from plants are used as raw materials for the fermentation process. The products that are manufactured through this process are used around the world, and the resulting waste products are returned to the soil or incinerated, becoming carbon dioxide that is once again absorbed by plants. This natural cycle, known as the carbon cycle, is one facet of fermentation technology. In addition, biotechnology-based manufacturing, which began with fermentation technology, has carried on the doctrine of the carbon cycle. Accordingly, I believe that biotechnology is suitable for environmental management.

In the area of corporate governance, the Company utilizes a system with a board of directors and a board of corporate auditors. The Board of Directors, which has nine members (including three outside directors), works to implement robust governance. Given the high degree of specialization of our operations, for corporate auditor positions we believe that it is best to employ individuals with a thorough knowledge of related markets and technologies. In addition to one member selected from within the Company, to maintain impartiality, we have selected four independent directors from outside the Company.

In September 2010, a Kyowa Hakko Bio facility in Hofu City, Yamaguchi, received a warning letter from the U.S. Food and Drug Administration (FDA) in regard to its quality control processes. We are taking this incident very seriously, and to rapidly rebuild the quality control system for the Group as a whole, we established the Corporate Quality Management Department. In this way, we have taken further steps to build a system for rigorous quality control.

Great East Japan Earthquake Damage from the Great East Japan Earthquake

We would like to express our heartfelt condolences to all those who have suffered as result of the Great East Japan Earthquake, which occurred on March 11, 2011.

In Pharmaceuticals operations, Kyowa Hakko Kirin sustained no significant damage to its factories. However, we have begun to manufacture certain products in-house since the factories of certain contract manufacturers were damaged and restarting production will take time. Sales at the Tohoku Office (Sendai City, Miyagi Prefecture), the Fukushima Sales Office (Koriyama City, Fukushima Prefecture), and the Mito Sales Office (Mito City, Ibaraki Prefecture) were temporarily suspended due to physical damage from the earthquake, but sales have since recommenced. In Bio-Chemicals operations, Kyowa Hakko Bio sustained no significant damage to its factories or sales offices. Letter to Our Shareholders and Friends

Shareholder Return

Providing a Return to Shareholders through Stable Dividends

Kyowa Hakko Kirin considers returns to shareholders to be one of its most important management issues. Our dividend policy balances the need to augment retained earnings as a foundation for future business growth with the desire to make stable and consistent dividend payments after giving thorough consideration of each fiscal period's consolidated business results, the dividend payout ratio, and the yield of net assets. Internal reserves, including retained earnings, are used to supplement the investments that will help us achieve our next growth stage, including R&D and capital expenditures that will contribute to future increases in corporate value. In accordance with this policy, dividends for the period under review were ¥20.0 per share, including an interim dividend of ¥10.0 per share.

Under the Medium-Term Management Plan—2010 to 2012, we will continue to target a consolidated dividend payout ratio of 30% or more, using profit before amortization of goodwill. We plan dividends of ¥20.0 per share (¥10.0 interim dividend, ¥10.0 final dividend) for fiscal 2011, ending December 31, 2011.

Outlook

Looking Forward to Exciting Developments

In fiscal 2011, we expect the domestic economy to pick up against a background of improving overseas economies and the effects of various policy measures. However, some concerns remain, such as volatility in the foreign exchange market, deflation, and worsening employment conditions, and the outlook is uncertain.

In Pharmaceuticals operations, we will further strengthen our domestic sales capabilities, aiming for early market penetration of new products and expanding sales of core products, while more actively promoting our global development. In Bio-Chemicals operations, we will aim to expand sales in the amino acid market, primarily those for pharmaceutical use in high-value-added areas, and promote the development of the market for such in-house branded amino acid materials as Ornithine.



However, we must also take into account higher R&D expenses in Pharmaceuticals operations, the influence of the appreciation of the yen on Bio-Chemicals operations, and the fact that Chemicals operations will only be consolidated for three months as a result of their transfer. Accordingly, our consolidated financial results forecasts for fiscal 2011 are for net sales of ¥325.0 billion, a decrease of 21.4%; operating income of ¥37.0 billion, down 18.5%; and net income of ¥25.5 billion, an increase of 14.9%. The effect of the Great East Japan Earthquake on the Company's results is currently being investigated, and we will make a prompt disclosure if a significant effect on results is anticipated.

Fiscal 2011 will be a challenging year in terms of our results, but we are close to completing the process of selection and concentration in our business portfolio, which we have pursued for several years, and the first POTELLIGENT[®] antibody is poised to move from NDA to approval. I believe that 2011 will be an exciting year. I would like to thank our shareholders for your support, and to ask for your continued understanding and support in the years ahead.

April 2011

hy Materia

Yuzuru Matsuda President and Chief Executive Officer

R&D

Research and Development Activities



Therapeutic antibodies are currently a focus of attention in the field of new drug development. These drugs, which utilize the ability of antibodies to recognize antigens, offer an extremely effective method of treatment with high efficacy and low side effects.

Kyowa Hakko Kirin has drawn on its leading-edge biotechnologies to develop advanced technology in the field of therapeutic antibody development. As a pioneer in this field, we are working to contribute to the health of people around the world through the development of innovative new drugs, such as therapeutic antibodies, that respond to unmet medical needs.

Pharmaceuticals R&D Strategy

In R&D, Kyowa Hakko Kirin is focusing on new therapeutic antibodies that use the Company's original antibody technologies—such as <u>POTELLIGENT</u>[®] and <u>KM Mouse</u>, which produces fully human antibodies from mice—as well as on low molecular weight pharmaceuticals. In the three key fields of oncology, nephrology, and immunology/allergy, we will take steps to enhance our development pipeline through discovery research.

Since the establishment of Kyowa Hakko Kirin, we have worked to consolidate our bases for drug discovery and research. In April 2010, we completed a new building at the Tokyo Research Park in Machida City, Tokyo, and consolidated the research bases that had previously been separately located in Gunma Prefecture and Tokyo Prefecture. As a result, we now have two research bases in Japan—Tokyo Research Park and Fuji Research Park—and two overseas—Kyowa Hakko Kirin California, Inc., and Hematech, Inc.

In addition, we are strengthening our alliances with external institutions, such as the La Jolla Institute for Allergy & Immunology (LIAI), to which we provide research support. By actively utilizing our external network, we are aiming to step up joint research initiatives and to enhance our product pipeline.

We have development bases in Japan, the United States, the United Kingdom, and China. We will work to accelerate new drug development initiatives by establishing our own global

POTELLIGENT®

In animal testing, antibodydependent cellular cytotoxicity (ADCC) enhancing technology that has been shown to increase antibody activity by 100 times to 1,000 times

KM Mouse

Technology for using mice to produce antibodies that are the same as those produced in the human body **Research and Development Activities**

development network and by participating in global joint development initiatives.

In addition, we have three laboratories that conduct research in fields related to pharmaceutical production—the Chemical Process Research and Development Laboratories, the Bio Process Research and Development Laboratories, and the Drug Formulation Research and Development Laboratories.

In the production of drugs for clinical trials, we are actively utilizing contract manufacturing organizations (CMOs) in Japan and overseas for the production of low molecular weight pharmaceuticals. For therapeutic antibodies, we now have worldwide supply capability. At the Bio Process Research and Development Laboratories in Takasaki, Gunma Prefecture—our principal antibody production base—we completed one of the world's leading antibody production facilities in March 2010.

Driving Progress in Antibodies

Therapeutic Antibody Business

Using the antigen-antibody reaction that is a natural function of the human body, therapeutic antibodies target malignant cells, such as cancer, with pinpoint accuracy. Accordingly, therapeutic antibodies are expected to have limited side effects and to show high efficacy against diseases that have been difficult to treat with traditional pharmaceuticals. However, therapeutic antibodies are produced with mammalian cell cultures, requiring sophisticated production processes and large-scale facilities. Accordingly, one of the major issues with these drugs is their high cost. In animal testing, our original ADCC enhancing technology, POTEL-LIGENT*, has been shown to increase antibody activity, such as the ability to kill cancer cells, by 100 times to 1,000 times. Consequently, this technology is highly anticipated as a means of solving the issue of high cost. The market for therapeutic antibodies has continued to grow rapidly in recent years. The global market value reached more than \$36.0 billion in 2009 and is expected to surpass \$60.0 billion by 2015.

In this growing market, the Company will leverage its world-leading antibody technologies, which include POTELLIGENT® ADCC enhancing technology, which is becoming a global





Tokyo Research Park



A Pharmaceutical Raw Material Building

standard antibody technology; <u>COMPLEGENT</u>[®] CDC technology; KM Mouse technology for the generation of fully human antibodies; and manufacturing technologies for use in the production of bio-pharmaceuticals. Centered on these technologies, we will bolster our discovery capabilities, expand our opportunities to acquire new antigens through an enhanced presence in the field of therapeutic antibody technologies, and accelerate our development of therapeutic antibodies.

Enhancing Development Models:

Three Business Models for Therapeutic Antibody Operations

Our therapeutic antibody development pipeline now includes various antibodies that utilize our POTELLIGENT[®] technology as well as antibodies that use KM Mouse technology. Current drug candidates under development are in clinical trial (including one for which an NDA has been filed) or preclinical trial stages. To maximize value, we assess each drug candidate to decide how far along the development process it should be taken in-house, whether it should be out-licensed, or whether we should complete the development process in-house. Because we utilize multiple methods of drug development, we can accelerate the commercialization of therapeutic antibodies and provide new drugs for diseases that still do not have effective methods of treatment.

Model 1: In-House Development/Joint Development

As shown in the accompanying table, our in-house pipeline has seven antibodies that are currently in clinical trials, either through in-house development or joint development. For

ASKP1240, a CD40 antigen produced with the use of KM Mouse, we have concluded a worldwide joint development and marketing agreement with Astellas Pharma Inc., and joint clinical trials are currently underway. In addition, as described below in the section on earlystage out-licensing, we are currently implementing phase I clinical trials in Japan for KHK4563, for which the licensee has already moved ahead with development overseas. For KW-0761, an anti-CCR4 antibody licensed to Amgen, Kyowa Hakko Kirin will continue clinical trials in the field of oncology. In 2010, we repurchased the development and commercialization rights in the field of oncology in Amgen's territory (worldwide except certain major Asian countries).

<u>COMPLEGENT®</u>

Complement-dependent cytotoxicity (CDC) technology that, like POTELLIGENT*, increases antibody activity

Three Business Models for Therapeutic Antibody Operations



Antibody Pharmaceuticals Pipeline

As of April 2011

			Ph	nase				
Therapeutic Area	Code Name (Antigen)	1		11		NDA Filed	Country	Remarks
ONCOLOGY	KW-0761 (CCR4)						Japan	
					Phase I/II		U.S.	
	KRN330 (A33)				Phase I/IIa		U.S.	
	BIW-8962 (GM2)				Phase I/IIa		U.S.	
	KHK2866 (HB-EGF)						U.S.	
	ASKP1240 (CD40)						U.S.	Co-developed with Astellas Pharma
ALLERGY							Japan	Co-developed with Astellas Pharma
	KHK4563 (IL-5R)						Japan	
OTHER	KRN23 (FGF23)						U.S.	

Research and Development Activities

In addition to antibodies that we have discovered, we are also moving forward with joint R&D initiatives that combine promising antigens/antibodies for cancer or inflammatory allergic treatment held by bio-venture companies with our POTELLIGENT[®] and COMPLE-GENT® technologies. We have entered into a co-development agreement with Arana Therapeutics Limited, of Australia, to develop an antibody to treat colorectal cancer, and both companies are now implementing research activities.

Model 2: Early Stage Out-Licensing

To maximize value, in certain cases we out-license during the early clinical or non-clinical stages. We licensed worldwide rights (excluding certain major Asian countries) to the anti-IL-5R antibody KHK4563, which uses POTELLIGENT®, to MedImmune, LLC, of the United States (MedImmune development code: MEDI-563). MedImmune is conducting phase II clinical trials of MEDI-563 for asthma patients.

In addition, we have licensed the anti-CCR4 antibody KW-0761, which uses POTELLIGENT* technology, to Amgen. The licensing agreement provides for milestone payments in line with progress in development and sales. After the product is launched, we will receive royalty payments from Amgen based on the amount of sales. Moreover, in 2009 we signed a research collaboration and licensing agreement under which sanofi-aventis receives worldwide rights (except for certain major Asian countries) to anti-LIGHT fully human monoclonal antibodies, which utilize KM Mouse technology.

Model 3: Antibody Technology Licensing

The Company has steadily licensed out its POTELLIGENT® technology through U.S. subsidiary BioWa, Inc. In 2007, a U.S. patent was issued covering all antibodies with fucose-free complex-type sugar chains (a type of mammalian sugar chain), irrespective of the antigen or type of production method. This means that 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 R&D of POTELLIGENT® antibodies, and we are making progress toward our goal of making POTELLIGENT® a global standard. At this point, we have granted licenses for POTELLIGENT* technology to 17 companies, including world leaders in the field of therapeutic antibodies and major pharmaceutical companies. These companies include Genentech, Inc., Biogen Idec Inc., GlaxoSmithKline plc, Novartis

Early Stage Out-Licensing	Antibody Technology Li	censing	Collaborative Alliances
 KW-0761 (Out-licensed to Amgen) KHK4563 (Out-licensed to MedImmune) 	 Agensys Biogen Idec Bristol-Myers Squibb CSL Limited Daiichi-Sankyo Genentech GlaxoSmithKline KaloBios Merck KGaA Seven POTELLIGENT* antib 	 MedImmune NKT Therapeutics Novartis Otsuka Pharmaceutical Oxford Bio Therapeutics sanofi-aventis Takeda Pharmaceutical UCB-Celltech 	• Lonza

POTELLIGENT[®] Technology Alliances

As of April 2011

AG, Takeda Pharmaceutical Co., Ltd., and sanofi-aventis. Out-licensing agreements for antibody technologies like POTELLIGENT[®] include up-front payments when the agreements comes into effect, various milestone payments along the development process, and royalty payments once the product is launched.

In addition to POTELLIGENT[®], we have also begun licensing activities for COMPLEGENT[®] technologies. We licensed COMPLEGENT[®] to Medarex, Inc. (currently Bristol-Myers Squibb), in 2008 and GlaxoSmithKline in 2010.

Further, as a result of joint research with Lonza Group Ltd., we can offer POTELLIGENT[®] CHOK1SV, a potent new cell line. POTELLIGENT[®] CHOK1SV has high productivity and is expected to become a future standard for therapeutic antibodies. We are currently moving ahead with agreements to provide this new cell technology. In 2010, we concluded non-exclusive agreements with two companies: Daiichi Sankyo Company, Limited, and KaloBios Pharmaceuticals, Inc.

KM Mouse, a technology for producing fully human antibodies, was co-developed by Kyowa Hakko Kirin and Medarex (currently Bristol-Myers Squibb). KM Mouse has been licensed to a wide range of pharmaceutical manufacturers by Kyowa Hakko Kirin and Bristol-Myers Squibb.

Licensing Activities

To enhance our development pipeline and to maximize the value of our intellectual property, we are actively engaged in both out-licensing and in-licensing activities.

Progress of Out-Licensing Compounds

As of January 2011

Code Name	Company	Stage	Remarks
KW-6002	Biovail	Out-licensed in U.S.	Parkinson's disease (adenosine A2a receptor antagonist)
KRN951	AVEO	Phase III	Malignant tumor (VEGFR inhibitor)
KW-2871	Life Science	Phase II	Malignant tumor (Anti-GD3 antibody), Low-fucose antibody
MEDI-563 (KHK4563)	MedImmune	Phase II	Allergy (Anti-IL-5R antibody), POTELLIGENT® antibody
KRN5500	DARA	Phase II	Cancer pain
LY2523355	Eli Lilly	Phase II	Malignant tumor (Mitotic kinesin Eg5 inhibitor)
AMG 761 (KW-0761)	Amgen	Phase I	Allergy (Anti-CCR4 antibody), POTELLIGENT® antibody

Progress of In-Licensing Compounds

As of January 2011

Code Name (Product Name)	Company	Stage	Remarks
HFT-290 (Fentos)	Hisamitsu	Product has been launched	Cancer pain (µ-opioid receptor agonist)
SP-01	Solasia	Preparing to be filed	Vomiting (Serotonin antagonist)
KW-2246	Orexo	Phase III	Cancer pain (μ-opioid receptor agonist)
KW-6500	Britannia	Phase III	Parkinson's disease (Dopamine agonist)
ARQ 197	ArQule	Phase II	Gastric cancer (c-met inhibitor)
Z-206 (Asacol)	Zeria	Phase I	Inflammatory bowel disease (Crohn's disease) Application filed for ulcerative colitis
RTA 402	Reata	Phase I	Diabetic nephropathy

Research and Development Activities

Out-Licensing

In the out-licensing of therapeutic antibodies, we have licensed KHK4563, KW-0761, ASKP1240, anti-LIGHT antibodies, and others.

In the out-licensing of low molecular weight pharmaceuticals, in the field of oncology we licensed KRN951, an anticancer agent with angiogenesis inhibition action, to AVEO Pharmaceuticals, Inc., of the United States. Phase III clinical trials are now underway. In 2010, Astellas Pharma purchased the development and marketing rights from AVEO. In addition, the Eg5 inhibitor that we licensed to Eli Lilly and Company is now in phase II clinical trials.

In the central nervous system field, we concluded two out-licensing agreements in 2010. In Japan, we have KW-6002 in phase III clinical trials as a treatment for Parkinson's disease, and we have licensed KW-6002 to Biovail Corporation, which has development and marketing rights in North America. For KW-6356, which targets central nervous system diseases such as Parkinson's, we licensed worldwide rights (except Japan and Asia) to H. Lundbeck A/S.

Moreover, export sales and royalties for olopatadine hydrochloride, the active ingredient in the antiallergic agent Allelock®, are making a significant contribution to our revenues. Olopatadine hydrochloride, which has been licensed to Alcon, Inc., is marketed in more than 100 countries as ophthalmic formulations under the brand names Patanol® and Pataday™. It is also available in the United States as a nasal spray.

In-Licensing

In December 2009, we entered into an exclusive license agreement for anti-amyloid-beta-peptide antibody with Immunas Pharma, Inc., of Japan. 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 January 2010, we also announced the signing of a licensing agreement for exclusive development and sales rights in Japan and Asia for RTA 402, which is in phase II clinical trials in the United States as a treatment for diabetic chronic kidney disease. In March 2010, we announced we

would license-in SP-01 (extended release transdermal granisetron patch), from Solasia Pharma K.K., in Taiwan, Hong Kong, Singapore, and Malaysia. In 2011, we announced that we had licensed from Amgen AMG-827, a fully human antibody that targets the IL-17 receptor, which has been reported to be related to a variety of autoimmune diseases. In these ways, we continue to aggressively implement activities to enhance our pipeline.

In addition to in-licensing activities for our pipeline, we are also focusing on product licensing to enhance our product lineup. We acquired the sales rights for Permax[®], for the treatment of Parkinson's disease, in Japan from Eli Lilly Japan K.K. as of April 2010. We are steadily proceeding to launch products that we have in-licensed. These include Asacol®, a treatment for ulcerative colitis for which we entered into an agreement with Zeria Pharmaceutical Co., Ltd., for co-development and co-marketing, and a transdermal, sustained-release treatment for cancer pain for which we have concluded a co-marketing agreement with Hisamitsu Pharmaceutical Co., Inc. Both of these products have been launched in Japan.

Companion Diagnostics Products for KW-0761

The Company has submitted a new drug application (NDA) to the Ministry of Health, Labour and Welfare for two in vitro diagnostic (IVD) reagents under development for companion diagnostics^{*} products for KW-0761.

These products are IVD reagents as principles of immunohistochemistry (IHC) and flow cytometry (FCM). These products are used for aiding the diagnosis for therapy of adult T-cell leukemia-lymphoma (ATL), a target disease for KW-0761.

KW-0761 exerts an effect against CCR4 (chemokine (c-c motif) receptor 4). These diagnostic products can determine the presence of CCR4 expressed by ATL cells before treatment of KW-0761. Diagnostic reagent as principle of IHC was used tissue samples such as lymph node or skin of ATL patients. Diagnostic reagent based on FCM can be applied to the blood sample, of ATL patients. The combination of diagnosis and treatment has potential to provide better treatment options for patients in today's increasingly tailored treatments.

* Identification of genes and biomarkers can allow physicians to provide highly effective treatment for each patient with fewer adverse drug reactions, and also allow patients to choose the best treatment and therapeutic agents.

Pharmaceutical Pipeline

	Die Die	-Pharmaceutica	I 🔒 Low Molecular Weight Pl	harmaceutical M Antibody Pharmaceutical	* Code nar	ne in Japan
	0	KRN654	Angrelid hydrochloride	Essential thrombocythemia	Japan	Oral
ONCOLOGY	0	KW-2449		Cancer	U.S.	Oral
Discontinued	0 1	KRN23		X-linked hypophosphatemic rickets/ osteomalacia (XLH)	U.S.	Injection
				Disseminated intravascular coagulation, Congenital antithrombin deficiency	Europe	Injection
	0	KW-3357	Antithrombin	Disseminated intravascular coagulation, Congenital antithrombin deficiency	Japan	Injection
	•	KHK6188		purpura Neuropathic pain	Japan	Oral
				purpura Ideopathic (immune) thrombocytopenic	Asia	Injection
OTHER	0	AMG531	Romiplostim	Ideopathic (immune) thrombocytopenic	Japan	Injection
SYSTEM	0	KW-6485	Topiramate	Pediatric epilepsy	Japan	Oral
NERVOUS	8	KW-65002	Apomorphine hydrochloride	Parkinson's disease	Japan	Injection
CENTRAL	00	KW-6002	Istradefylline	Parkinson's disease	Japan Japan	Oral
	0	KHK4563	Benralizumab	Organ transplant rejection Asthma	Japan	Injection Injection
	0 1	ASKP1240		Organ transplant rejection	U.S.	Injection
ALLERGY	•	Z-206	Mesalazine	Crohn's disease	Japan	Oral
IMMUNOLOGY/	8	KW-4679	Olopatadine hydrochloride	Antiallergic	China	Oral
	0	RTA 402	Bardoxolone methyl	Diabetic nephropathy	Japan	Oral
	•		enacareer nyaroemonae	Secondary hyperparathyroidism	China	Oral
	0	KRN1493*	Cinacalcet hydrochloride	Secondary hyperparathyroidism	Singapore	Oral
				Renal anemia (on dialysis)	China	Injection
				Renal anemia (on dialysis) Pediatric renal anemia	Asia Japan	Injection Injection
NEPHROLOGY	0	KRN321*	Darbepoetin Alfa	Renal anemia (For CKD patients not on dialysis)	Japan Asia	Injection
	0	KHK2866		Cancer	U.S.	Injection
	8	KW-2450		Cancer	U.S.	Oral
	0	KRN951	Tivozanib	Cancer	Japan	Oral
	0	KW-2478		Multiple myeloma	U.K./U.S./ Philippines	Injection
	•	BIW-8962		Cancer	U.S.	Injection
		KRN330		Cancer	U.S.	Injection
				Lung cancer	Japan	Oral
				Gastric cancer	South Korea	Oral
	0	ARQ 197		Gastric cancer	Japan	Oral
	0	KRN125*	regingrastiffi	Chemotherapy-induced febrile neutropenia Chemotherapy-induced febrile neutropenia	Asia Japan	Injection Injection
	_		Pegfilgrastim		·	tablet
	8	KW-2246	Fentanyl citrate	Cancer pain	Japan	Sublingual
	0	KRN321	Darbepoetin Alfa	cutaneous T-cell lymphoma (CTCL) Chemotherapy-induced anemia	Japan	Injection
				Peripheral T/NK-cell lymphoma Peripheral T-cell lymphoma (PTCL) and	Japan U.S.	Injection Injection
				Adult T-cell leukemia-lymphoma (ATL), combination therapy	Japan	Injection
		KW-0761		Adult T-cell leukemia-lymphoma (ATL)	Japan	Injection
ONCOLOGY						

SPECIAL FEATURE FROM THE PRESIDENT R&D REVIEW OF OPERATIONS MANAGEMENT & ORGANIZATION FINANCIAL SECTION	SPECIAL FEATURE	FROM THE PRESIDENT	R&D	REVIEW OF OPERATIONS	MANAGEMENT & ORGANIZATION	FINANCIAL SECTION
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Pharmaceutical Pipeline

	Phase II III	NDA Filed	Approved	Remarks
				POTELLIGENT® antibody Humanized monoclonal antibody
				Humanized monocional antibody
				-
	Phase I/II			-
	i nase ij n			
			l	Licensed from Kirin-Amgen
				Long-acting erythropoiesis stimulating agent
				Launched for anemia of CKD patients
				Licensed from Orexo
			1	Licensed from Kirin-Amgen
				Long-acting G-CSF
				Asia: South Korea, Taiwan, and Vietnam
				_ Licensed from ArQule
				_
	Phase I/IIa			Fully human monoclonal antibody
	Phase I/IIa			POTELLIGENT [®] antibody Humanized monoclonal antibody
	Phase I/II			Hamanized monocional antibody
				POTELLIGENT [®] antibody
				Humanized monoclonal antibody
				Licensed from Kirin-Amgen
				Long-acting erythropoiesis stimulating agent Asia: Singapore, Thailand, and Philippines
			1	– – – – – – – – – – – – – – – – – – –
				-
			1	Licensed from NPS
				Launched in Japan for secondary hyperparathyroidism
				Licensed from Reata Pharmaceuticals
				Launched for an antiallergic
				Jointly developed with Zeria Pharmaceutical
				Launched in Japan for ulcerative colitis
				Fully human monoclonal antibody
				Jointly developed with Astellas Pharma
				POTELLIGENT [®] antibody
				Humanized monoclonal antibody
				Licensed from Dritemais Discuss
				Licensed from Britannia Pharma
				Licensed from JANSSEN PHARMACEUTICAL
				Licensed from JANSSEN PHARMACEUTICAL Licensed from Kirin-Amgen
			1	Licensed from JANSSEN PHARMACEUTICAL
			 	Licensed from JANSSEN PHARMACEUTICAL Licensed from Kirin-Amgen Asia: South Korea, Singapore, Hong Kong, and Malaysia
				Licensed from JANSSEN PHARMACEUTICAL Licensed from Kirin-Amgen
				Licensed from JANSSEN PHARMACEUTICAL Licensed from Kirin-Amgen Asia: South Korea, Singapore, Hong Kong, and Malaysia
			1	Licensed from JANSSEN PHARMACEUTICAL Licensed from Kirin-Amgen Asia: South Korea, Singapore, Hong Kong, and Malaysia
				Licensed from JANSSEN PHARMACEUTICAL Licensed from Kirin-Amgen Asia: South Korea, Singapore, Hong Kong, and Malaysia Recombinant antithrombin product
				Licensed from JANSSEN PHARMACEUTICAL Licensed from Kirin-Amgen Asia: South Korea, Singapore, Hong Kong, and Malaysia
				Licensed from JANSSEN PHARMACEUTICAL Licensed from Kirin-Amgen Asia: South Korea, Singapore, Hong Kong, and Malaysia Recombinant antithrombin product
	Phase I/IIa			Licensed from JANSSEN PHARMACEUTICAL Licensed from Kirin-Amgen Asia: South Korea, Singapore, Hong Kong, and Malaysia Recombinant antithrombin product

ONCOLOGY

KW-0761 is a humanized monoclonal antibody against CCR4 (chemokine (c-c motif) receptor 4), which is a chemokine receptor selectively expressed on T helper type 2 (Th2), regulatory T cells, and certain types of T-cell neoplasms. The monoclonal antibody was developed using Kyowa Hakko Kirin's exclusive POTELLIGENT® technology platform, which enhances antibody-dependent cell-mediated cytotoxicity (ADCC). After conducting Phase I clinical trials in Europe as a treatment for allergic disorders, we concluded an out-licensing agreement in March 2008, granting Amgen exclusive development and commercial rights for all indications except cancer in all countries except Japan, China, South Korea, and Taiwan. In 2010, we purchased back the option rights to develop and commercialize KW-0761 for cancer treatment in territory previously granted to Amgen, so that we now have rights of KW-0761 for cancer treatment in all countries. The latest research reveals that CCR4 expresses in certain kinds of hematological cancer. Therefore, we are conducting clinical trials of KW-0761 on hematological cancer. We have conducted clinical trials in human adult T-cell leukemia-lymphoma (ATL) patients and confirmed safety and efficacy of KW-0761. In April, we filed an NDA in Japan for KW-0761 for the treatment of ATL. Also, from 3Q of 2010, we are conducting a clinical trial of KW-0761 in combination with standard chemotherapy for ATL patients (Phase IIb trial) and monotherapy of KW-0761 for peripheral T/NK-cell lymphoma patients (Phase IIb trial). In addition, a Phase I/II clinical trial for cutaneous T-cell lymphoma (CTCL) and peripheral T-cell lymphoma (PTCL) is ongoing in the United States, beginning in July 2009. Since KW-0761 is targeted for rare diseases, KW-0761 has been designated as an orphan drug in 2010 for ATL in Japan and for CTCL and PTCL in the United States.

🔂 KW-2246

KW-2246 is a fentanyl citrate tablet that was in-licensed from Orexo AB, of Sweden. With the expectation that KW-2246 would have rapid absorption and analgesic effects, it was in-licensed as a treatment for sudden pain (breakthrough cancer pain) occurring during around-theclock management of cancer pain. Subsequently, we moved ahead with clinical trials in Japan and filed an NDA in February 2010. In August 2010, the application was withdrawn. Currently, preparations for phase III clinical trials are underway.

🕐 KRN125

This is a long-acting type of the genetically modified protein G-CSF Gran[®] (generic name: Pegfilgrastim) that has been chemically modified with polyethylene glycol. Because it has a longer half-life than Gran[®], it is expected to show the same effects as Gran[®] with a reduced administration frequency. From February 2011, phase III clinical trials were commenced in Japan for febrile neutropenia in cancer chemotherapy.

🔂 ARQ 197

In the United States, ArQule, Inc. has completed phase II clinical trials for ARQ 197, an orally administered proprietary small molecule for treating malignant tumors. It selectively inhibits c-Met, a receptor tyrosine kinase, and the anticancer action comes about through molecular targeting. 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, ARQ 197 entered phase I clinical trials in February 2008, and in March 2010 combination therapy phase I clinical trials for lung cancer were commenced.

🔮 🏠 KRN330

This fully human monoclonal antibody recognizes the intestine-specific A33 antigen, which is expressed in 95% of colorectal cancers. Through ADCC and CDC activities, it shows cytotoxic effects against colorectal cancer cells, and as a result it is expected to have antitumor effects. In 2010, phase I clinical trials were completed in the United States, and currently it is in concomitant therapy phase I/IIa clinical trials for colorectral cancer.

🖤 🍞 BIW-8962

BIW-8962 is a humanized monoclonal antibody that targets the GM2, which is expressed at high levels in multiple myeloma, small cell lung cancer, and brain tumors. It utilizes POTELLIGENT* technology to increase ADCC activity and has shown promising antitumor effects by destroying GM2 positive cancer cells through ADCC activity. Phase I clinical trials in the United States for multiple myeloma began in February 2009 and are currently in progress.

🔂 KW-2478

Starting with a compound obtained through microbial screening and designed using our organic synthesis and X-ray crystallography technologies, KW-2478 possesses a new type of anticancer action. This compound inhibits the functions of heat shock protein 90 (Hsp90) client proteins and induces degradation of these proteins, which are involved in the survival, proliferation, metastasis, and other processes of cancer cells. Primary indications are for myeloma and lymphoma. Its safety was confirmed in phase I clinical trials in Europe. In Europe and the United States, combination therapy phase I/IIa clinical trials for relapsed multiple myeloma were started in May 2010.

🔂 KRN951

KRN951 is a vascular endothelial growth factor receptor (VEGFR) tyrosine kinases inhibitor. With selective inhibition of VEGFR signals, it inhibits the tumor-induced angiogenesis and decreases vascular permeability in tumors. It is expected to show wide-ranging antitumor activity against a wide range of tumors. Overseas, AVEO, of the United States, is implementing phase III clinical trials for renal cell carcinoma, and in Japan it is in phase I clinical trials.

🔂 KW-2450

This is a small molecule inhibitor of IGF-1 receptor and insulin receptor tyrosine kinases, which are said to contribute to cancer, proliferation, and resistance to anticancer drugs. In 2010, monotherapy phase I clinical trials were completed in the United States, and phase Ib/II clinical trials for concomitant treatment for breast cancer are currently underway.

NEPHROLOGY

🔮 KRN321

In April 2010, additional indications were received for initial administration in dialysis and for chronic renal disease prior to the start of dialysis. In August, we launched Nesp[®] INJECTION PLASTIC SYRINGE, in 10µg/1ml and other dosages. Currently, clinical trials are underway for renal anemia in children. In addition, we filed an application for an indication for anemia induced by cancer chemotherapy in November 2008.

Pharmaceutical Pipeline

🔂 RTA 402

This small molecule compound has the action of activating the transcription factor Nrf2, which controls the production of many of the body's antioxidant and anti-inflammatory factors. Overseas, in clinical trials with diabetic nephropathy patients conducted by Reata Pharmaceuticals, Inc., of the United States, improvement in renal function was confirmed. In Japan, plans call for moving ahead with development for an indication of diabetic nephropathy. Phase I clinical trials were commenced in Japan in September 2010.

IMMUNOLOGY/ALLERGY

O ASKP1240

This fully human monoclonal antibody is combined with CD40, which blocks the molecular interaction with CD40 ligand (CD154). By inhibiting cellularity and humoral immunity, this antibody is expected to meet needs that are not being met by existing therapeutic agents for organ transplants. In January 2007, we entered into a joint-research agreement with Astellas Pharma. In December 2009, phase I clinical trials were concluded, and in 2010 plans for phase II clinical trials were filed with the U.S. FDA.

🔂 Z-206

In January 2007, we concluded a co-development and co-marketing agreement with Zeria Pharmaceutical for Asacol[®], a treatment for inflammatory bowel disease (Crohn's disease). Clinical trials are in progress in Japan, and preparations for additional clinical trials are underway. Z-206 is an enteric product comprising mesalazine coated with a pH-dependent controlled-release substance. It is already marketed in more than 60 countries worldwide. In April 2008, Zeria Pharmaceutical filed an NDA for the additional indication of ulcerative colitis, and the application was approved in October 2009. Since December 2009, in accordance with the sales contract, it has been sold, under a single brand name, through the sales channels of both companies. For Crohn's disease, phase I clinical trials have been completed, and preparations are underway for phase II clinical trials.

🖤 🕜 KHK4563

This is a humanized antibody that binds to the IL-5 receptor, which is expressed largely on eosinophils and basophils in humans. KHK4563 uses POTELLIGENT^{*} technology. Eosinophils are believed to contribute to the pathogenesis of asthma. This antibody is expected to improve asthma symptoms by depleting eosinophils in respiratory tissues through heightened ADCC activity. In Japan, phase I clinical trials were commenced in March 2010. In 2006, we licensed development and marketing rights, excluding Japan and Asia, to MedImmune, of the United States. Currently, it is in phase II clinical trials overseas.

CENTRAL NERVOUS SYSTEM

🔂 KW-6002

This is the world's first selective adenosine A2a receptor antagonist for treating Parkinson's disease. We completed phase III clinical trials in Europe and the United States and filed an NDA in the United States in April 2007. Unfortunately, in February 2008 we received a Not Approvable Letter from the U.S. FDA. However, the results of a phase IIb study in Japan demonstrated the efficacy of KW-6002 compared with a placebo, and phase III clinical trials were started in August 2009 and are currently underway.

🔂 KW-6500

The dopamine D1 and D2 agonist Apomorphine is the active ingredient in KW-6500, which is self-administered as an injection. It improves the symptoms of patients in the final stage of Parkinson's disease and can be used when the effectiveness of existing treatments is wearing off or becoming inconsistent. In February 2006, an in-licensing agreement was completed with Britannia Pharma Limited for exclusive development and sales rights in Japan and certain countries in Asia. In Japan, phase I clinical trials were started in March 2007 and phase II clinical trials were completed in November 2008, confirming the trial outcomes. In the phase III clinical trials that were started in October 2009, effectiveness was confirmed in December 2010, and currently longterm safety trials are underway.

OTHER MG531

AMG531, which is being jointly developed with Amgen, increases platelets through stimulation of the thrombopoietin (TPO) receptor. Amgen Development (Amgen's Japan subsidiary) confirmed its efficacy and safety in phase III clinical trials in Japan, and Kyowa Hakko Kirin filed an NDA in March 2010. In January 2011, manufacturing and marketing approval was approved for an indication of chronic (immune) ideopathic thrombocytopenic purpura.

C KHK6188

KHK6188 is a cannabinoid CB2 receptor agonist (oral formulation). It is under development as a treatment for neuropathic pain. Currently, it is in phase I clinical trials in Japan.

🕐 KW-3357

KW-3357 is a recombinant human antithrombin produced from Chinese Hamster Ovary (CHO) expressions system by 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 treatment that eliminates any risk of infection. It entered phase I clinical trials in Japan in December 2007, and its safety was confirmed. Currently preparations are underway for next phase clinical trials. Further, phase I clinical trials were commenced in Europe in August 2009.

🖤 🐨 KRN23

This fully human monoclonal antibody with neutralizing activity targets the excessive production of FGF23 within blood plasma. In patients with X-linked hypophosphatemic rickets, the excessive production of FGF23 accentuates the excretion of phosphorous from the kidney. By normalizing phosphorous concentrations within blood plasma, this antibody is expected to improve such disease conditions as underdevelopment of both legs, small-stature syndrome, and osteomalasia. It is undergoing phase I clinical trials in the United States.

Review of Operations

At a Glance

As of December 31, 2010

Pharmaceuticals



The Pharmaceuticals segment conducts R&D, production, and sales of ethical drugs—principally in the fields of oncology, allergies, renal anemia, and hypertension and of diagnostic reagents. In ethical pharmaceuticals, the segment is working to expand its business in overseas markets. To this end, we are conducting clinical development of new drugs in Europe, North America, and China and are moving ahead with therapeutic antibody operations based on our original strong-acting antibody technologies.

Ethical Drugs: Nesp*/ Espo* (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) **Diagnostic Reagents:** Determiner* series (clinical chemistry diagnostic reagents)

Bio-Chemicals



In domestic and overseas markets, the Bio-Chemicals segment manufactures and markets fine chemical products, such as amino acids, nucleic acids, and related compounds. These products are used as raw materials for pharmaceuticals, health foods and dietary supplements, cosmetics, and pharmaceutical intermediates. In addition, the segment conducts mail-order sales of health care products in Japan and provides plant growth regulators to the agricultural industry in Japan and overseas.

Fine Chemical Products: Amino acids, nucleic acids, related compounds Health Care Products: Amino acids, vitamins, minerals, carotin, peptides, Remake[®] series products, Enguard[®] series products Other: Plant growth regulators

Chemicals



The Chemicals segment produces and markets basic chemicals and specialty chemicals. Basic chemicals include solvents used in paints and inks as well as raw materials for plasticizers used as additives in PVC products. Recently, the segment places particular emphasis on specialty chemicals, including environment-friendly products and products for advanced technologies. In Chemicals operations, on March 31, 2011, we transferred all shares of Kyowa Hakko Chemical Co., Ltd.

Solvents: Butyl alcohol, butyl acetate, ethyl acetate, acetone, glycol ethers, MIBK, PM, PMA

Raw Materials for Plasticizers: 2-ethylhexyl alcohol, isononyl alcohol (INA), isodecyl alcohol (IDA)

Specialty Chemicals: 2-ethyl hexanoic acid, isononanoic acid, DAAM (diacetone acrylamide), high-purity solvents (PM-P, PMA-P, etc.), Diols





Net Sales/Operating Income* Billions of Yen







Pharmaceuticals

Pharmaceuticals

Industry Trend

Japan's pharmaceutical companies continue to face a competitive operating environment that has been influenced by the government's revision of drug pricing, the accelerating use of generic drugs, and intensified competition in new drug development on a global scale. In this setting, the Company aims to contribute to the widespread utilization of evidence-based medicine (EBM) by providing high-quality medical information, thereby earning the trust of patients and health care professionals. In addition, centered on the fields of oncology, nephrology, and immunology/allergy, we will strive to rapidly and continually create innovative new drugs that meet medical needs. To that end, we will make full use of our leadingedge biotechnologies, centered on our core antibody technologies, and will reinforce our strategic alliances and partnerships.

R&D

Operational Strategy

We are striving to become a global specialty pharmaceutical company that contributes to the health and well-being of people around the world. The Medium-Term Management Plan—2010 to 2012 spells out the basic strategy for our Pharmaceuticals operations.

In R&D, we will take steps to enhance our development pipeline through discovery research in key fields. We will also strive to speed up our progress as we emphasize working effectively with external resources, such as the La Jolla Institute for Allergy & Immunology (LIAI). Also, to bolster our development in Asia, which is expected to be a promising market, we will reinforce our development system and enhance our pipeline.

In manufacturing, we will reorganize our production bases and advance our use of outside contractors in order to enhance cost competitiveness. Our facilities for producing investigational therapeutic antibodies, which were completed in March 2010, will help us to increase development speed in our antibody pipeline.

In domestic marketing, our primary objective will be ongoing expansion of the market shares of our existing mainstay products. We will also work to achieve rapid market penetration for new products and to maximize their product value. Furthermore, to increase marketing efficiency, we will reorganize our marketing system and enhance medical representative productivity.

In overseas operations, we will work to bolster our presence in Asia by increasing sales through a reinforced in-house sales system. Moreover, targeting the establishment of a system for sales of new drugs in Europe and the United States, we made ProStrakan a wholly owned subsidiary on April 21, 2011. The acquisition of ProStrakan's management resources will enable us to achieve dramatic progress in the implementation of our global strategy.

In accordance with these strategies, we will leverage advanced biotechnologies, centered on our core therapeutic antibodies, principally in the fields of oncology, nephrology, and immunology/allergy. We will strive to continually discover innovative new drugs and to implement global development and marketing activities. In this way, we will work to be a Japanbased, global specialty pharmaceutical company that contributes to the health and well-being of people around the world.

Overview

In the Pharmaceuticals business, consolidated net sales rose 1.4% from the corresponding period of the previous year, to ¥210.4 billion. Operating income increased 12.7%, to ¥35.9 billion. NHI reimbursement prices were reduced in April 2010, but in domestic ethical drug



Yuzuru Matsuda Kyowa Hakko Kirin Co., Ltd. President and Chief Executive Officer

operations, the Company's core products recorded strong performances. In addition, exports increased, centered on Asian markets, and we also recorded a valuation gain on one-time payments associated with out-licensing agreements. As a result, we recorded higher sales and profits.

Accompanying the change in the fiscal year-end, the previous fiscal period is the ninemonth period from April 1, 2009, to December 31, 2009. Accordingly, for year-on-year comparisons, the results in the year under review are compared with the corresponding period of the previous year, the 12-month period from January 1, 2009, to December 31, 2009.

Ethical Drugs

Domestic sales of ethical drugs were basically flat, as the contributions of core products and new products offset the effects of the reductions in NHI reimbursement prices that were implemented in April 2010.

Anemia treatments Nesp[®] and Espo[®] recorded a combined increase in sales of 107% from the corresponding period of the previous year, to ¥52.6 billion. Together, these drugs have the number one share of the erythropoiesis stimulating agent (ESA) market.

Since it was launched in January 2008, Regpara[®], a treatment for secondary hyperparathyroidism, has steadily penetrated the market, and sales increased substantially in the year under review, rising 140% from the corresponding period of the previous year.

New products in the year under review included Parkinson's disease treatment Permax[®], which we launched in April 2010, and Fentos[®], a transdermal analgesic for persistent cancer pain that we launched in June. Each of these drugs performed well.

On the other hand, in March 2010 we transferred manufacturing, sales, and other rights for Neu-up[®], a neutropenia agent, to Yakult Honsha Co., Ltd. Subsequently, Gran[®] was our only neutropenia treatment agent, and as a result sales of these agents declined.

Coniel[®], a treatment for hypertension and angina pectoris, registered a decline in sales due to changes in the market environment, the effects of reductions in NHI reimbursement prices, and the influence of generics.

In the licensing-out of technologies and the export of pharmaceutical products, revenues increased significantly from the corresponding period of the previous year. We received a one-time payment of ¥1.8 billion from Amgen, to which we licensed KW-0761 in March 2008, and a one-time payment of ¥0.9 billion from Canada's Biovail Laboratories International SRL, to which we licensed Parkinson's disease treatment agent KW-6002 in June 2010. In addition, exports of pharmaceuticals were favorable, centered on Asian markets.

Diagnostic Reagents

Subsidiary Kyowa Medex Co., Ltd., is responsible for the manufacture and marketing of diagnostic reagents. Sales increased from the corresponding period of the previous year due to strong sales of clinical chemistry diagnostic reagents and favorable exports.

New Drug Development

In the field of oncology, in Japan we started phase II clinical trials of ARQ 197 for gastric cancer treatment in July 2010. In February 2010, we filed an NDA for KW-2246, an analgesic for cancer pain, but we temporarily withdrew the application in August and decided to conduct additional phase III clinical trials. In addition, in September 2010 anti-CCR4 antibody KW-0761 entered late phase II clinical trials as a combination therapy with existing



Nesp®, an ESA formulation



Allelock® OD (Oral Disintegrant) Tablets, an antiallergic agent



Coniel®, an agent for hypertension and angina pectoris



Regpara®, a treatment for secondary hyperparathyroidism

Pharmaceuticals

chemotherapy agents for CCR4-positive ATL and late phase II clinical trials as a treatment for peripheral T/NK-cell lymphoma.

R&D

In the renal field, in Japan we obtained approval for Nesp[®] Injection Plastic Syringe, a longacting erythropoiesis stimulating agent, and launched it in August 2010. Overseas, in March 2010 we received approval for Regpara[®] in South Korea and Taiwan.

In immunology/allergy, in July 2010 we received approval in Japan for antiallergic agent Allelock[®] for additional effects/efficacy, dosing method, and dosages for children aged seven and above. We also received approval for Allelock[®] OD Tablets, a disintegrating tablet formulation developed in-house using original, leading-edge technology, and began sales in November.

In overseas markets, in June 2010 we received approval for Allelock® in China.

In the central nervous system field, in July 2010 we began phase III clinical trials in Japan for pediatric indications for Topina[®], an antiepileptic agent. In November, we filed for approval of additional applications of Depakene[®], an antiepileptic agent, for its effectiveness and efficiency in averting the onset of migraine headaches.

In other therapeutic areas, in March 2010 we filed an application in Japan for AMG531, a treatment for ideopathic thrombocytopenic purpura, and received approval in January 2011.



CL-JACK RK, a fully automated chemiluminescence system



HM-JACKarc, a fully automatic human hemoglobin analyzer

Indication	Billions of Yen			
	2010/12	2009/12 ²	2009/12	2009/3
ESA formulation	¥52.6	¥48.9	¥39.6	¥43.7
Antiallergic	26.8	26.7	17.3	25.0
Cardiovascular (hypertension and angina pectoris)	21.0	23.3	18.3	23.1
G-CSF	14.4	17.0	13.8	17.6
Antiepileptic	11.0	11.2	8.8	10.7
Secondary hyperparathyroidism	9.5	6.8	5.5	4.6
Antiallergic eyedrops	7.5	7.4	3.0	6.6
Gastrointestinal	5.3	5.1	3.8	5.5
Anticancer	4.8	6.4	4.9	7.4
Cardiovascular (hypertension)	4.2	4.8	3.7	5.0
Anticancer	3.1	3.7	2.9	3.6
Cardiovascular	3.0	3.5	2.7	3.7
Antiallergic	2.7	3.3	2.3	3.6
Antiepileptic	2.1	1.5	1.2	0.9
Anticancer	2.0	2.9	2.2	3.1
Parkinson's disease	2.0	_		-
Cancer pain	0.8	-	-	-
Inflammatory bowel disease	0.7	0.0	0.0	-
	24.1	18.0	15.1	29.1
	ESA formulation Antiallergic Cardiovascular (hypertension and angina pectoris) G-CSF Antiepileptic Secondary hyperparathyroidism Antiallergic eyedrops Gastrointestinal Anticancer Cardiovascular (hypertension) Anticancer Cardiovascular Antiallergic Antiepileptic Antiepileptic Anticancer Parkinson's disease Cancer pain	ESA formulation¥52.6Antiallergic26.8Cardiovascular21.0(hypertension and angina pectoris)	Indication 2010/12 2009/12² ESA formulation ¥52.6 ¥48.9 Antiallergic 26.8 26.7 Cardiovascular (hypertension and angina pectoris) 21.0 23.3 G-CSF 14.4 17.0 Antiepileptic 11.0 11.2 Secondary hyperparathyroidism 9.5 6.8 Antiallergic eyedrops 7.5 7.4 Gastrointestinal 5.3 5.1 Anticancer 4.8 6.4 Cardiovascular (hypertension) 4.2 4.8 Anticancer 3.1 3.7 Cardiovascular (hypertension) 4.2 4.8 Anticancer 3.0 3.5 Antiallergic 2.7 3.3 Antiepileptic 2.1 1.5 Antiencer 2.0 2.9 Parkinson's disease 2.0 - Cancer pain 0.8 - Inflammatory bowel disease 0.7 0.0	Indication 2010/12 2009/12 ² 2009/12 ESA formulation ¥52.6 ¥48.9 ¥39.6 Antiallergic 26.8 26.7 17.3 Cardiovascular (hypertension and angina pectoris) 21.0 23.3 18.3 G-CSF 14.4 17.0 13.8 Antiepileptic 11.0 11.2 8.8 Secondary hyperparathyroidism 9.5 6.8 5.5 Antiallergic eyedrops 7.5 7.4 3.0 Gastrointestinal 5.3 5.1 3.8 Anticancer 4.8 6.4 4.9 Cardiovascular (hypertension) 4.2 4.8 3.7 Anticancer 3.0 3.5 2.7 Anticancer 3.0 3.5 2.7 Antiepileptic 2.1 1.5 1.2 Antiegic 2.7 3.3 2.3 Antiepileptic 2.1 1.5 1.2 Antiencer 2.0 2.9 2.2 Parkinson's disease

Principal Drug Sales¹

1. Non-consolidated basis

2. Reference: Total for the 12-month period 1/09 - 12/09

3. As of March 1, 2010, manufacturing, sales, and other rights for Neu-up were transferred to Yakult Honsha. Therefore, Gran/Neu-up figures after March 2010 include only sales figures for Gran.

4. Sales of Permax began April 1, 2010.

5. Sales of Fentos began June 24, 2010.

6. Sales of Asacol began December 16, 2009.

Bio-Chemicals

Industry Trend

Our mainstay fermented bulk products, including amino acids, nucleic acids, and related compounds, are used widely in such products as pharmaceuticals, pharmaceutical intermediates, foods and dietary supplements, and cosmetics. There is strong demand for pharmaceutical- and industrial-use amino acids in the BRICs and Asia, and in the United States we are seeing marked growth in demand for fermented bulk products, such as amino acids for dietary supplements.

Conditions in the domestic market for health foods have bottomed out and turned upward, and there have been noticeable differences in demand for certain products. With interest in health maintenance and improvement steadily rising, the industry has begun to focus on products for which demand is strong, functional benefits are easy to understand, and recognition is high. In recent years, sharply rising prices for raw materials and crude oil have led to unavoidable cost increases, and the market is also paying growing attention to product safety and quality. In Bio-Chemicals operations, we are working to maximize customer value. To that end, we will take steps to increase production efficiency and to further enhance and strengthen our global quality assurance system to support the provision of safe, high-quality products.



Shuichi Ishino Kyowa Hakko Bio Co., Ltd. President and Chief Executive Officer

Operational Strategy

In Bio-Chemicals, we have three strategic objectives that guide efforts to strengthen our business base in fine chemicals, such as amino acids, and to promote growth in the pharma-ceutical raw materials and health care products markets.

First, we aim to increase amino acid sales volume in the key areas of infusions, culture media, and nutritional supplements. Our production system comprises bases in three regions— Japan, the United States, and China. By increasing productivity through production capacity increases and production process innovation, we will enhance the cost-competitiveness of our amino acids and reinforce our position in the global market. In addition, by implementing branding initiatives for our fermented products, we will work to increase value added in the field of nutritional supplements and foods and to expand new markets.

Second, we will take steps to strengthen cooperation with Daiichi Fine Chemical Co., Ltd., a consolidated subsidiary of Kyowa Hakko Bio. By combining Kyowa Hakko Bio's fermentation technologies and Daiichi Fine Chemical's synthesis technologies, we will strive to create innovative production processes for high-value-added products and to increase our business in synthetic pharmaceutical raw materials and intermediates.

Third, we will cultivate and strengthen our health care business in Japan. To that end, we are bolstering our marketing system, including consumer needs tracking, product development, and product proposal capabilities. In addition, we are taking steps to cultivate latent markets for key products, such as Ornithine and Citrulline, in mail-order, raw material, and OEM operations. Moreover, we will work to increase sales of products that meet needs in existing markets, such as glucosamine.

Overview

In Bio-Chemicals operations, compared with the corresponding period of the previous year, sales declined 7.1%, to ¥84.2 billion, while operating income decreased 17.4%, to ¥3.3 billion.

Bio-Chemicals

Fine Chemicals

In raw materials for pharmaceutical and industrial use—primarily amino acids, nucleic acids, and related compounds—domestic sales of raw materials for generic pharmaceuticals remained strong. In addition, there was an increase in demand from Asian markets for amino acids used in infusions and for pharmaceutical raw materials. As a result, sales increased year on year.

Health Care Products

In health care products, we recorded strong sales of materials related to the Kirin Health Project—KIRIN Plus-i, which was launched in April 2010—as well as favorable growth in the number of customers for our mail-order Remake[®] series. Consequently, sales increased substantially year on year.

Other

In livestock and fisheries products, in April 2010 we transferred our operations to ASKA Pharmaceutical Co., Ltd. In addition, in July 2010 our alcohol sales operations were transferred to Daiichi Alcohol Co., Ltd., a joint venture between Kyowa Hakko Bio Co., Ltd., and Mercian Corporation. As a result, sales in other operations declined significantly.

Daiichi Fine Chemical's sales declined due to sluggish sales of bulk pharmaceuticals and intermediate products.

R&D

In R&D, we worked to increase productivity through technical development and product development initiatives. At the Bio Process Research and Development Laboratories and the Bioprocess Development Center, these efforts were focused on fermentation products, such as amino acids, nucleic acids, and related compounds, while Daiichi Fine Chemical focused on synthetic compounds. At the Healthcare Products Development Center, we continued working to discover new functions and develop applications for all types of amino acids.

Sales Breakdown by Product Category¹

	Billions of Yen					
	2010/12	2009/12 ²	2009/12	2009/3		
Bio-Chemicals division total	¥54.2	¥55.4	¥42.3	¥55.2		
Pharmaceuticals/Industrial raw materials						
Amino acids	20.4	19.1	14.8	19.3		
Nucleic acids and vitamins	4.8	4.5	3.5	5.0		
Health care products	9.8	8.4	6.5	8.1		
Agrochemicals, livestock and fisheries products ³	1.8	3.2	2.1	3.6		
Alcohol ⁴	7.1	9.8	7.8	9.3		

1. Non-consolidated basis

2. Reference: Total for the 12-month period 1/09 - 12/09

3. As of April 1, 2010, livestock and fisheries product operations of Kyowa Hakko Bio Co., Ltd., have been transferred to Aska Pharmaceuticals Co., Ltd.

 On July 1, 2010, Kyowa Hakko Bio Co., Ltd.'s alcohol sales operations were transferred to Daiichi Alcohol Co. Ltd., a joint venture with Mercian Corporation.



Citrulline (left) and Ornithine, Remake[®] series of health care products



Coenzyme Q10, Remake[®] series of health care products

Management & Organization

Intellectual Property

Basic Policies Regarding Intellectual Property

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

To this end, the Company is strengthening its systems to conduct such activities as acquiring and maintaining IP rights, managing licensing, and monitoring third parties' rights from a global perspective. For example, in Pharmaceuticals operations the Company protects core technologies and prolongs the life of products through the strategic filing of relevant patents.

Functions of the Intellectual Property Department

The Intellectual Property Department is responsible for the IP-related activities of the Company's Pharmaceuticals operations. 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.

In recent years, the Company has recognized integrating business and IP strategies as an important Companywide issue. The Intellectual Property Department is strengthening its coordination with each business division, the head office of each business division, and research laboratories by holding regular meetings as well as exchanging information and consulting with research laboratories more frequently.

Moreover, we recognize the necessity of being familiar with the IP environment at each important stage of research and business decision making. Members of the Intellectual Property Department therefore participate in major projects related to development themes, existing products, licensing, and other relevant issues.

Another important function of the Intellectual Property Department is the education of employees on IP rights. The department sends IP supervisors on overseas training courses and plans to steadily introduce training programs, including programs for specific fields or groups of employees. Also, the Company has close relationships with lawyers and patent attorneys with expertise in related fields in Japan and overseas to appropriately address highly specialized issues.
Intellectual Property

MANAGEMENT & ORGANIZATION

Contributions to Licensing Activities

As it is becoming increasingly difficult to continue to independently develop new products, the Company selectively out-licenses products developed in-house and actively in-licenses to be a "Global Specialty Pharma" in its Pharmaceuticals operations, which in turn has raised the importance of the evaluation of IP issues related to in-licensed candidates.

The Company has accumulated numerous core technologies that are founded on unique and innovative research and technology. These include the proprietary POTELLIGENT[®] technology, which dramatically enhances the antibody-dependent cellular cytotoxicity (ADCC) of antibodies, COMPLEGENT[®], complement-dependent cytotoxicity (CDC) enhanced antibody technology, and KM Mouse technology, which develops and evaluates novel fully human monoclonal antibodies for cancer treatment.

While working to acquire multifaceted patent rights for these technologies, the Company is also active in out-licensing them. Moreover, the Company has multiple core technologies related to drug formulation, which are contributing to its profits under the protection of IP rights.

Policies Related to the Patent Portfolio

In principle, the Company encourages the filing of patents based on discoveries created from research. Nevertheless, the timing of overseas applications and examination requests as well as post-registration operations, management, and other activities are evaluated in terms of technology, business operations, and invention. An additional factor is cost effectiveness. The Company is working to make clear decisions to maintain only those deemed necessary. In this way, the department facilitates the Company's efforts to build a patent portfolio that is consistent with its business strategy, taking into account the position of individual patent themes under the strategy as well as the position of each theme within the project. In addition, the Company is working to ensure that it can concentrate IP-related resources on the most significant issues.

	Kyowa Hakko Kirin	Rest of the Kyowa Hakko Kirin Group	Total
Japan	189	184	373
Overseas	1,382	784	2,166

Number of Patents Owned (As of December 31, 2010)

Corporate Social Responsibility

At the Kyowa Hakko Kirin Group, we consider corporate social responsibility (CSR) activities, such as environment and safety management, quality assurance, and corporate citizenship, to be among our most important management tasks, and under the leadership of top management we are striving to carry out these tasks and fulfill our corporate social responsibilities.

Environment and Safety Management

Management Systems

To deal with its environment and safety management, the Kyowa Hakko Kirin Group has adopted the ISO 14001 standard for environmental issues and established the safety and health management system for the safety, health, and welfare of employees, focused on risk assessment. We have been pushing forward with environment and safety management initiatives by implementing the Plan, Do, Check, and Act (PDCA) cycle, and in addition to complying with environmental and safety-related laws and regulations, we have set our own even higher standards for compliance. We have also acquired ISO 14001 certification on an integrated Companywide basis, including at the head office and at production and R&D bases. Through these activities, we will strive to strengthen environmental governance and will continue working to further reduce the Group's carbon emissions by enhancing our environmental activities throughout the supply chain.

Performance

In the period under review, we worked to reduce the impact of our business activities on the environment through the Groupwide implementation of the Kyowa Hakko Kirin Eco Project, which targets energy and resource conservation and zero emissions. Thanks to our efforts in recycling industrial waste, we were able to achieve Groupwide zero emissions for the sixth consecutive year. In addition, in the period under review our emissions of greenhouse gases totaled 700 thousand tons of CO₂ equivalent emissions. This year-on-year increase of 60 thousand tons of CO₂ equivalent emissions (annualized basis) was attributable to a substantial increase in the production of chemicals. This means that we achieved a reduction of approximately 12.4% from the Kyoto Protocol base year of fiscal 1991. In addition, we are moving forward with the installation of solar power generation equipment as a renewable energy source. This equipment was in operation at the Fuji Plant throughout the fiscal year under review and was in operation at the new building at the Tokyo Research Park from September 2010. Moreover, we have decided to install this solar power generation equipment at the Ube Plant in 2011.

Furthermore, the entire Group is engaged in green office plan activities, with a focus on the promotion of a green supply chain along with saving energy and promoting recycling in administrative departments.

At Kyowa Hakko Kirin, Kyowa Hakko Bio, and Kyowa Medex, there was one accident resulting in lost work time, and at other consolidated subsidiaries, there were two accidents resulting in lost work time. Moving forward, we will continue to implement safety activities as we strive to achieve zero accidents resulting in lost work time.

Communication

The Group published the Corporate Social Responsibility Report 2010, containing information on the Group's environment and safety efforts. In addition, we are proactively carrying out responsible care (RC) activities, such as holding regular RC discussions with communities,



Solar power generation system installed at the Fuji Plant



Solar power information panel at the Tokyo Research Park



Corporate Social Responsibility

government entities, and non-governmental organizations (NGOs) in those areas where we have plants. In addition, we have joined together with local residents in Takasaki, Mishima, and Yamaguchi to carry out forest conservation activities to maintain areas surrounding headwaters.

Continuous Improvement

An important issue for any company in its corporate activities is the achievement of sustainable growth. More than 50 years ago, we developed a system that recycles liquid waste from fermentation processes into fertilizer and livestock feed. We have also constantly worked to curtail emissions of chemical substances. With this attitude, we will continue to strive to be a group that works in harmony with the environment.

Quality Assurance

In accordance with its Quality Assurance Action Policy, the Kyowa Hakko Kirin Group is working to maintain high levels of quality throughout the Group, including at overseas subsidiaries. Our goal is to provide products and services that satisfy our customers. To that end, we are striving to bolster our quality assurance system throughout the supply chain, from R&D through to procurement, production, distribution, and sales.

Further, by establishing and enhancing quality assurance systems, including GMP (good manufacturing practice) and ISO 9001, at all our plants to address new laws, such as the Pharmaceutical Affairs Law, we have been successfully implementing highly reliable production control and quality control.

Corporate Citizenship

Local Science Experiment Classrooms

The BioAdventure vehicle is a mobile classroom equipped with microscopes and other scientific equipment that is operated by the Tokyo Research Park, in Machida, Tokyo. Kyowa Hakko Kirin's researchers visit elementary, junior high, and senior high schools to demonstrate science to the students and assist them in conducting experiments. The Group also conducts various community programs in many regions, including the Children's Science Experiment Classroom for local elementary school students at the Fuji Plant in Shizuoka Prefecture and the Junior Science Classroom for elementary school and junior high school students, located at the Kyowa Hakko Bio Yamaguchi Production Center in Yamaguchi Prefecture.

Kato Memorial Bioscience Foundation

Established in 1988 in commemoration of Kyowa Hakko's founder, Dr. Benzaburo Kato, the Kato Memorial Bioscience Foundation supports creative bioscience research through the provision of research and financial assistance to young researchers.

Free Braille Calendars for Schools for the Blind Nationwide

Every year since 1994, Kyowa Hakko Kirin has created a Braille calendar for people with visual disabilities and distributed it free to schools for the blind all over Japan. Approximately 4,000 of the 2011 calendars were delivered to 70 schools.









- Fiscal 1991 figures are the reference values for numerical targets spelled out in the Kyoto Protocol, which determined emission reduction obligations for CO₂ and other greenhouse gases.
- Following the revision of the law in 2006, CO₂ equivalent units and the areas for which energy are calculated have been revised.



2011 braille calendar

Corporate Governance

Fundamental Approach

Kyowa Hakko Kirin operates its business in accordance with its corporate philosophy of "contributing to the health and well-being of people worldwide by creating new value with the pursuit of advances in life sciences and technology." Our basic goal in corporate governance is to clarify the responsibilities and duties of the management organization, to ensure the policies that we have in place are complied with, and to progress toward the realization of the Company's philosophy. We recognize the importance of increasing management transparency and reinforcing oversight functions and strive to enhance corporate governance to continually raise corporate value.

Fundamental Structure

Kyowa Hakko Kirin's management structure is based on the Board of Directors and the Board of Auditors, which together carry out the functions stipulated under the Corporation Law of Japan. To strengthen the management function and increase management efficiency, the following governance entities have been established.

Directors and Board of Directors

In principle, the Board of Directors meets once a month. The Board of Directors had nine members, including three outside directors, as of March 24, 2011. The Board of Directors performs critical Groupwide management functions, including strategic planning, decision making, and the monitoring of operational execution. The Company has not adopted a company-with-committees governance system, but the Company has established the Remuneration Consultative Committee and the Nomination Consultative Committee as advisory bodies to the Board of Directors. These committees are made up of four directors each, including outside directors. In regard to compensation and nomination issues regarding the Board of Directors and the corporate auditors, these committees provide objective, impartial advice.

Corporate Governance Structure





Corporate Governance

MANAGEMENT & ORGANIZATION

The Board of Directors met 16 times during the fiscal year ended December 31, 2010. The Board of Directors made decisions about management policies and other important matters and conducted oversight of the directors' performance of their duties. 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 regarding the Board of Directors and the company auditors.

Company Auditors and the Board of Auditors

The Company has adopted the company auditor corporate governance system. The Board of Auditors comprised five members, including four outside auditors, as of March 24, 2011. Based on the audit policies established by the Board, company auditors attend important meetings, including those of the Board of Directors, inspect operations and assets, and audit the work of directors. In performing these duties, the Board of Auditors met 15 times during the fiscal year ended December 31, 2010. There are no conflicts of interest in terms of personal, capital, business, or other relationships between the Company and its outside directors and outside company auditors.

Executive Committee and Executive Officers' Meeting

The Executive Officers' Meeting has been established as a decision-making body to make accurate and effective management decisions from a strategic viewpoint. It met 22 times during the fiscal year ended December 31, 2010, to deliberate and decide on overall important issues related to management.

In addition, an executive officer system has been introduced to facilitate rapid decision making and strengthen operational execution.

Account Auditing and Legal Compliance

The Company's financial statements are prepared in conformity with generally accepted accounting principles and practices prevailing in Japan. In order to ensure that the presentation, etc., is appropriate, audits are conducted by independent auditors. With regard to problems that arise in the course of operational execution, the Company gives the highest priority to legal compliance, and when necessary the Company receives appropriate advice from third parties, such as attorneys.

Risk Management System and Various In-House Committees

To address the variety of risks inherent in management issues, a number of in-house committees have been established to strengthen risk management and enhance corporate governance. These committees regularly report on their activities to the Board of Directors. These in-house committees are the CSR Committee, the Group Risk Management Committee, the Crisis Management Committee, the Group Environmental Safety Committee, the Group Quality Assurance Committee, the Information Disclosure Committee, and the Financial Management Committee. For details of identified risks, please refer to "Risk Factors" on pages 50 to 51.

Internal Auditing

The Company has established the Audit Department, which audits and reports on the status of the Group's operational execution from the perspectives of compliance with laws,

regulations, and the articles of incorporation and of efficient management. In addition, the department provides advice and proposals regarding improvements and increased efficiency.

Corporate Ethics

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

Internal Control System

At a meeting on April 22, 2009, the Company's Board of Directors resolved to revise the internal control system as described below. The Company is moving ahead with the establishment of a system based on the content of that resolution.

- Systems for ensuring that the execution of duties by directors and employees is in compliance with laws, regulations, and the articles of incorporation
- Systems for the storage and control of information related to the execution of duties by directors
- Regulations and systems regarding the risk of losses
- Systems for ensuring the efficiency of the execution of duties by directors
- Systems for ensuring that the actions of the corporate group, comprising the Company, its parent companies, and subsidiaries, are appropriate
- Systems related to the handling of requests from company auditors for support staff and matters related to the independence from directors of those support staff
- Systems for reporting by directors or employees to the Board of Auditors or to company auditors and other systems for reporting to company auditors
- Other systems for ensuring the effectiveness of audits by company auditors

Independent Auditor

The Company's independent audit is carried out by two certified public accountants, each of whom is an employee of Ernst & Young ShinNihon LLC. Also, a further five certified public accountants and 12 other staff provide support for the execution of the independent audit.

Compensation to Directors and Company Auditors

Executive compensation to directors, company auditors, and outside directors and company auditors during the fiscal year ended December 31, 2010, totaled ¥422 million, of which ¥298 million was compensation for directors (excluding compensation paid to outside directors), ¥24 million for company auditors (excluding outside company auditors), and ¥100 million for outside directors and outside company auditors. The compensation for directors includes ¥35 million in stock options. For directors, the Company has introduced systems for performance-linked compensation and for stock options as stock-based compensation.

The system for performance-linked compensation is an annual salary system that reflects company performance and individual performance in the determination of annual compensation. The system for stock options as stock-based compensation has the objective of enhancing motivation to increase enterprise value through aligning the interests of directors with

Corporate Governance

MANAGEMENT & ORGANIZATION

those of shareholders in regard to changes in the Company's stock price. To ensure the operation of the management supervision function, outside directors and outside company auditors receive only fixed compensation. In addition, ¥134 million in audit fees were paid to the independent auditor, including ¥124 million for audit-certification duties.

Resolutions Regarding the Number of Directors and the Election of Directors

The articles of incorporation stipulate that the Company shall have no more than 10 directors. The articles of incorporation stipulate that the adoption of resolutions at a general meeting of shareholders regarding the election of directors shall require a majority of the voting rights of the shareholders present at a general meeting of shareholders attended by shareholders representing one-third or more of the voting rights of the shareholders who are entitled to vote.

Matters that Can be Decided by Resolution of the Board of Directors Instead of Resolution of the General Meeting of Shareholders

To facilitate flexibility in the acquisition of treasury stock and to provide a stable return of profits to shareholders in the form of interim dividends, the articles of incorporation stipulate that these matters can be decided by resolution of the Board of Directors instead of resolution of the general meeting of shareholders.

Requirements for Special Resolutions of the General Meeting of Shareholders

With the objective of ensuring the smooth administration of general meetings of shareholders, the articles of incorporation stipulate that special resolutions of the general meeting of shareholders can be adopted with two-thirds or more of the voting rights of the shareholders present at a general meeting of shareholders attended by shareholders representing onethird or more of the voting rights of the shareholders who are entitled to vote.

Management Members

As of April 1, 2011

























Members of the Board

Directors Yuzuru Matsuda^{1*} President

Ken Yamazumi^{2*}

Nobuo Hanai³

Kazuyoshi Tachibana⁴

Hiroyuki Kawai⁵

Yoshiki Tsunekane⁶

Mutsuyoshi Nishimura^{7**} Motoaki Kitayama^{8**}

Lawyer

Yoshinori Isozaki9**

Company Auditors Akira Taniguchi^{10***} Tomojiro Sato^{11***} Hiroaki Nagai^{12***} Manabu Suzuki¹³ Hiroyuki Takahashi^{14***}

Managing Officers President and Chief Executive Officer Yuzuru Matsuda

Executive Vice President Ken Yamazumi

Senior Executive Managing Officer

Nobuo Hanai Vice President Head Development Division

Executive Managing Officers

Kazuyoshi Tachibana

Hiroyuki Kawai Vice President Head Production Division

Yoshiki Tsunekane Director Human Resources Department

Managing Officers

Fumihiro Nishino Vice President Head Sales & Marketing Division

Akira Karasawa Director External Relations Department

Shigeru Morotomi Director Corporate Communications Department

Toshifumi Mikayama Director Corporate Planning Department

Nobuhisa Yamazaki Director Legal Department

Yoichi Sato Vice President Head Pharmacovigilance and Quality Assurance Division

Etsuo Ohshima Vice President Head Research Division

Toshiro Kawano Director Osaka Branch

Hiroshi Sugitani Director Sales Department

Masafumi Inoue Director Tokyo Branch

Shiro Akinaga Global Development Development Division

Hiroshi Okazaki Director Overseas Business Department

Kazuyoshi Adachi Director Takasaki Plant

Kenya Shitara Director Intellectual Property Department

* Representative Director

** Outside Director

*** Outside Company Auditor

Financial Section

- 42 Eleven-Year Selected Financial Data
- 44 Management's Discussion and Analysis
- 50 Risk Factors
- 52 Consolidated Balance Sheets
- 54 Consolidated Statements of Income
- 55 Consolidated Statements of Changes in Net Assets
- 56 Consolidated Statements of Cash Flows
- 57 Notes to the Consolidated Financial Statements
- 80 Report of Independent Auditors

Eleven-Year Selected Financial Data

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

For the year ended December 31, 2010, the nine months ended December 31, 2009 and the year ended March 31, 2009

	2010/12	2009/12	2009/3	2008/3	
For the Year:	2010/12	2003/12	2007/3	2000/0	
Net sales	¥413,739	¥309,112	¥460,184	¥392,120	
Gross profit	190,979	139,740	200,298	144,918	
Selling, general and administrative expenses	145,569	111,496	154,911	105,528	
Operating income	45,410	28,244	45,387	39,390	
Net income	22,197	8,797	11,727	23,477	
Capital expenditures	29,374	25,135	18,523	14,796	
Depreciation and amortization	22,188	17,003	18,780	14,347	
R&D expenses	44,221	34,980	48,389	34,110	
Cash Flavor					
Cash Flows:	(4.100	24.204	41.000	20.714	
Net cash provided by operating activities	64,189 (32,374)	24,204	41,069 (3,981)	30,714	
Net cash (used in) provided by investing activities Net cash used in financing activities	(14,447)	(13,247) (16,906)	(20,978)	(9,492) (13,500)	
Cash and cash equivalents at the end of the period	79,883	63,745	69,287	44,119	
	79,005	03,745	09,207	44,119	
At Year-End:					
Total current assets	288,853	276,588	279,476	232,661	
Total assets	695,862	695,268	699,041	394,081	
Total current liabilities	102,483	110,081	108,522	111,744	
Interest-bearing debt	7,515	13,229	13,540	12,790	
Total net assets	544,993	540,344	543,070	256,758	
Total shareholders' equity ²	553,173	539,304	547,203	239,329	
Number of employees	7,484	7,436	7,256	6,073	
Per Share Data:					
Net income-basic ³	¥ 39.0	¥ 15.4	¥ 20.4	¥ 59.0	
Net assets	954.6	940.8	938.4	639.7	
Cash dividends	20.0	15.0	20.0	10.0	
				· ·	
Common Stock Price Range (Per share):					
High	1,040	1,178	1,235	1,430	
Low	773	793	586	933	
Stock Information (Thousands of shares):					
Number of common stock issued	576,484	576,484	576,484	399,244	
Weighted average number of common stock issued	569,711	570,936	574,083	397,717	
Financial Ratios:					
Return on assets (ROA)	3.19	1.26	1.62	6.07	
Operating return on assets	6.53	4.05	6.26	10.19	
Return on equity (ROE)	4.11	1.64	2.17	9.47	
Equity ratio	78.16	77.07	77.04	64.53	
Debt/equity ratio	1.38	2.47	2.51	5.03	

1. U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥81.49=U.S.\$1, the approximate exchange rate at December 31, 2010.

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.

Thousands o U.S. Dollars ¹						Millions of Yen	
2010/12	2001/3	2002/3	2003/3	2004/3	2005/3	2006/3	2007/3
\$5,077,175	¥375,610	¥378,668	¥359,285	¥348,838	¥358,963	¥353,440	¥354,274
2,343,590	123.945	128,744	126,328	129,507	132,113	126,983	131,425
				·		·	·
1,786,340	106,233	108,387	110,239	102,671	98,606	101,448	100,726
557,250	17,712	20,357	16,089	26,836	33,507	25,535	30,699
272,392	9,395	5,535	8,485	10,017	17,932	16,273	12,694
360,463	17,092	11,454	11,791	9,041	7,647	10,859	14,498
272,282	18,502	17,819	14,768	11,358	10,565	9,789	10,006
542,530	28,921	29,294	31,438	29,206	28,762	32,876	33,342
787,694	28,789	16,955	18,193	34,264	30,104	14,303	23,381
(397,27	(1,991)	8,377	2,586	10,477	(8,104)	(1,796)	(8,494)
(177,283	(20,871)	(16,843)	(38,748)	(44,226)	(9,116)	(5,139)	(24,417)
980,274	32,600	41,908	24,588	24,911	37,818	45,820	36,614
3,544,63	237,852	244,410	195,878	194,062	210,341	212,985	214,352
8,539,23	431,410	430,113	368,772	361,096	374,493	384,381	378,871
1,257,620	169,821	162,508	95,046	98,914	103,489	94,148	106,566
92,226	87,624	74,354	51,969	13,358	12,193	12,216	13,137
6,687,84						257,491	244,082
6,788,226	194,692	211,652	219,047	225,042	235,439	232,621	220,427
	7,766	7,299	6,749	6,294	5,960	5,800	5,756
U.S. Dollars						Yen	
\$ 0.47	¥ 21.6	¥ 12.7	¥ 19.4	¥ 23.0	¥ 41.7	¥ 38.4	¥ 31.3
11.71	448.3	487.5	505.4	522.6	556.3	604.9	607.5
0.24	7.5	7.5	7.5	7.5	10.0	10.0	10.0
12.76	1,225	899	780	719	864	946	1,154
9.48	701	587	411	495	661	656	722
	434,244	434,244	434,244	434,244	434,244	434,244	399,244
	434,244	434,244	433,748	431,497	427,636	422,920	405,270
						%	
	2.17	1.28	2.12	2.74	4.88	4.29	3.33
	4.09	4.73	4.03	7.35	9.11	6.73	8.04
	4.82	2.72	3.94	4.51	7.79	6.63	5.10
	45.13	49.21	59.40	62.32	62.87	66.55	63.80
	45.01	35.13	23.73	5.94	5.18	4.78	5.43

Management's Discussion and Analysis

Change of Fiscal Year-End

Effective from the previous fiscal year, the Company has changed its fiscal year-end from March 31 to December 31. Accompanying this change, in this annual report the previous fiscal period is the nine-month period from April 1, 2009, to December 31, 2009. Accordingly, for year-on-year comparisons, the results in the year under review are compared with the corresponding period of the previous year, the 12-month period from January 1, 2009, to December 31, 2009.

Profit and Loss

Sales

Consolidated net sales in the fiscal year ended December 31, 2010, increased 1.7% from the corresponding period of the previous year, to ¥413.7 billion. This increase was attributable to higher sales in the core Pharmaceuticals segment as well as in the Chemicals segment. Sales in the Chemicals segment were boosted by improved market conditions. On the other hand, in the Bio-Chemicals segment, sales declined due to the influence of the appreciation of the yen, to the transfer of alcohol sales operations, and to the transfer of livestock and fisheries products operations.

Cost of Sales and SG&A Expenses

Cost of sales was down 1.8%, to ¥222.8 billion. Gross profit registered a 6.0% increase, to ¥191.0 billion. As a result, the gross margin was up 1.9 percentage points, from 44.3% to 46.2%. Selling, general and administrative (SG&A) expenses were down 2.5%, to ¥145.6 billion. This total includes ¥9.7 billion in amortization of goodwill that resulted primarily from the business integration with Kirin Pharma Company, Limited. The ratio of SG&A expenses to net sales decreased 1.5 percentage points, from 36.7% to 35.2%.

Operating Income

Operating income increased 46.8%, to ¥45.4 billion, and the operating income margin was up 3.4 percentage points, from 7.6% to 11.0%. The operating income margin before amortization of goodwill was 13.2%.

Other Revenue (Expenses)

Net other expenses declined substantially, from ¥8.7 billion in the corresponding period of the previous year to ¥3.1 billion. Foreign exchange losses were ¥1.3 billion, and loss on revision of retirement benefit plan was ¥1.8 billion. However, these factors were offset by gain on sales of investment securities of ¥1.8 billion, gain on negative goodwill of ¥0.9 billion, a decline of ¥5.1 billion in impairment loss, and a decline of ¥2.1 billion in non-recurring depreciation on noncurrent assets.

Consequently, income before income taxes and minority interests was up 89.8%, to ¥42.3 billion.

Income Taxes

Income taxes in the fiscal period under review totaled ¥20.0 billion, an increase of 64.1%. As a percentage of pretax income, the effective tax rate was 47.4%, down from 54.8% in the corresponding period of the previous year.

Net Income

Consequently, net income rose 121.1%, to \pm 22.2 billion, and the net margin increased substantially, from 2.5% to 5.4%.







Performance by Business Segment

Sales and operating income (loss) by business segment are shown in the table below. Segment performance figures include intersegment transactions.

Pharmaceuticals

Sales in this segment, Kyowa Hakko Kirin's core business, were up 1.4%, to ¥210.4 billion, contributing 48.3% of total sales. Operating expenses declined 0.6%, to ¥174.5 billion, and operating income was up 12.7%, to ¥35.9 billion. NHI drug price standards were reduced in April 2010, but strong performances were recorded by the Company's core products—Nesp®/Espo® and Regpara®. In addition, bulk export and licensing sales increased substantially, and the Company achieved a reduction in operating expenses. Overall, the Pharmaceuticals segment recorded gains in sales and profits.

Bio-Chemicals

In the Bio-Chemicals segment, sales decreased 7.1%, to \pm 84.2 billion, accounting for 19.4% of total sales. Operating expenses decreased 6.6%, to \pm 81.0 billion, and operating income was down 17.4%, to \pm 3.3 billion.

Domestic sales of health care products were favorable. In addition, we recorded solid sales of amino acids for pharmaceutical- and industrial-use raw materials. However, sales were adversely affected by the transfer of alcohol sales operations and the transfer of livestock and fisheries products operations. Also, overseas sales declined due to the appreciation of the yen. Overall, the segment recorded lower sales and lower profits.

Chemicals

Sales in the Chemicals segment were up 102.5%, to ¥130.0 billion, accounting for 29.9% of total sales. Operating expenses, at ¥124.3 billion, were held to a rise of 78.2%. Consequently, operating results improved significantly, from an operating loss of ¥5.6 billion in the corresponding period of the previous year to operating income of ¥5.7 billion. In addition to overall improvement in chemical market conditions, a change in segment classification resulted in a transfer of Miyako Kagaku Co., Ltd., and Kashiwagi Corporation from the Other segment to the Chemicals segment.

Kyowa Hakko Chemical Co., Ltd., a consolidated subsidiary that handled the Company's business in this segment, was sold to KJ Holdings Inc. in March 2011.

Other

In the Other segment, sales were down 83.5%, to ¥10.5 billion, with the segment accounting for 2.4% of total sales. Operating expenses decreased 84.0%, to ¥10.1 billion, and operating income fell 16.4%, to ¥0.4 billion. The Other segment includes wholesale and transportation operations at subsidiaries. Accompanying the change in segment classification, two subsidiaries—Miyako Kagaku Co., Ltd., and Kashiwagi Corporation—were transferred to the Chemicals segment.

			Millions	s of Yen			Thousands of U.S. Dollars ¹
	2010/12	2009/12	2009/3	2008/3	2007/3	2006/3	2010/12
Sales by Business Segment:							
Pharmaceuticals	¥210,363	¥158,274	¥210,449	¥138,377	¥131,526	¥148,939	\$2,581,453
Bio-Chemicals	84,237	69,752	88,465	86,820	67,120	63,241	1,033,709
Chemicals	130,018	52,326	89,204	108,007	98,650	85,835	1,595,511
Food ²	_		42,469	43,324	42,589	42,440	-
Other	10,499	49,500	68,733	49,000	48,480	45,950	128,839
Corporate, elimination and other	(21,378)	(20,740)	(39,136)	(33,408)	(34,091)	(32,965)	(262,337)
Total	¥413,739	¥309,112	¥460,184	¥392,120	¥354,274	¥353,440	\$5,077,175
Operating Income (Loss) by Busines	s Segment:						
Pharmaceuticals	¥35,858	¥26,658	¥34,832	¥19,962	¥15,746	¥14,268	\$440,022
Bio-Chemicals	3,276	3,049	8,342	9,688	4,112	4,341	40,199
Chemicals	5,678	(1,985)	(47)	7,169	7,974	4,501	69,684
Food ²	_		1,087	1,577	1,832	1,602	-
Other	363	400	1,094	839	968	711	4,458
Corporate, elimination and other	235	122	79	155	67	112	2,887
Total	¥45,410	¥28,244	¥45,387	¥39,390	¥30,699	¥25,535	\$557,250

1. U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥81.49=U.S.\$1, the approximate exchange rate at December 31, 2010.

2. Due to the reclassification of the Other segment effective from fiscal 2007, segment information for the Pharmaceuticals, Bio-Chemicals, and Other segments for fiscal 2006 has been restated. However, segment information for years prior to fiscal 2006 has not been restated.

Performance by Geographic Segment Japan

In Japan, net sales increased 3.5%, to ¥399.3 billion, accounting for 88.9% of total sales. Operating expenses declined 1.0%, to ¥357.4 billion, and operating income was up 67.5%, to ¥42.0 billion. The primary factor in this performance was improved market conditions in chemicals.

Other Regions

Net sales in other regions declined 2.2%, to ¥49.9 billion, accounting for 11.1% of total sales. Operating expenses increased 0.8%, to ¥46.0 billion, and operating income decreased 27.4%, to ¥3.9 billion. This was principally due to a decrease in revenues from technologies at overseas subsidiaries and to the influence of the strong yen on the conversion of overseas results to a yen basis.

Cash Flows

Cash and cash equivalents as of December 31, 2010, were \$79.9 billion, an increase of \$16.1 billion compared to the balance of \$63.7 billion as of December 31, 2009. Cash flows during the period under review were as follows.

Net cash provided by operating activities was ¥64.2 billion. Inflows included income before income taxes and minority interests of ¥42.3 billion, depreciation and amortization of ¥22.2 billion, and amortization of goodwill of ¥9.9 billion. Major outflows included income taxes paid of ¥13.6 billion.

Net cash used in investing activities was ¥32.4 billion. The main outflows included purchase of property, plant and equipment of ¥28.0 billion and purchase of intangible assets of ¥7.5 billion. The main inflows included proceeds from sales and redemption of investment securities of ¥6.4 billion.

Net cash used in financing activities was \$14.4\$ billion. This was primarily due to cash dividends paid of <math>\$8.6\$ billion and decrease in short-term loans payable of <math>\$5.4\$ billion.

Quarterly Information by Business Segment

				l	Millions of Yen	I					
	2009/3		200	9/12		2010/12					
	4th Quarter	1st Quarter	2nd Quarter	3rd Quarter	12-Months	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	12-Months	
Segment Sales:											
Pharmaceuticals	¥ 49,111	¥ 52,211	¥ 51,757	¥ 54,306	¥207,385	¥ 49,674	¥ 53,801	¥ 50,617	¥ 56,271	¥210,363	
Bio-Chemicals	20,919	21,145	20,272	28,335	90,671	22,213	21,973	19,782	20,269	84,237	
Chemicals	11,882	15,034	17,820	19,472	64,208	30,281	31,008	33,372	35,357	130,018	
Food	9,634	_	_	_	9,634	_	_	_	_	-	
Other	14,231	14,195	14,732	20,573	63,731	2,494	2,590	2,624	2,791	10,499	
Total	105,777	102,585	104,581	122,686	435,629	104,662	109,372	106,395	114,688	435,117	
Eliminations	(7,871)	(5,770)	(7,002)	(7,968)	(28,611)	(5,406)	(5,162)	(5,408)	(5,402)	(21,378)	
Consolidated	¥ 97,905	¥ 96,816	¥ 97,579	¥114,717	¥407,017	¥ 99,256	¥104,210	¥100,987	¥109,286	¥413,739	
Operating Income (Loss)):										
Pharmaceuticals	¥ 5,170	¥ 11,570	¥ 9,793	¥ 5,295	¥ 31,828	¥ 9,678	¥ 8,315	¥ 8,472	¥ 9,393	¥ 35,858	
Bio-Chemicals	917	1,277	388	1,384	3,966	1010	843	993	430	3,276	
Chemicals	(3,579)	(2,073)	(413)	501	(5,564)	674	915	1,968	2,121	5,678	
Food	87	_	_	_	87	_	_	_	_	-	
Other	34	184	(14)	230	434	84	68	102	109	363	
Total	2,629	10,958	9,754	7,410	30,751	11,446	10,141	11,535	12,053	45,175	
Eliminations	63	81	(14)	55	185	81	24	15	115	235	
Consolidated	¥ 2,691	¥ 11,041	¥ 9,738	¥ 7,465	¥ 30,935	¥ 11,527	¥ 10,165	¥ 11,550	¥ 12,168	¥ 45,410	

Financial Position

Assets

Total assets as of December 31, 2010, were up 0.1%, or \pm 0.6 billion, from December 31, 2009, to \pm 695.9 billion.

Total current assets were up 4.4%, or ¥12.3 billion, to ¥288.9 billion. Inventories were down 3.2%, to ¥61.8 billion, but cash and deposits increased 9.8%, to ¥33.1 billion, and short-term loans receivable rose 32.6%, to ¥53.5 billion, resulting in the increase in total current assets. Short-term loans receivable includes short-term loans of ¥53.2 billion under the cash management system provided by the Company's parent company, Kirin Holdings, for companies in the group.

Total property, plant and equipment, net, declined 1.7%, or ¥2.8 billion, to ¥159.7 billion. The Company's continued investment in production and research facilities was offset by depreciation and amortization, non-recurring depreciation on noncurrent assets, and an impairment loss, leading to the decline.

Total investments and other assets (including intangible fixed assets) fell 3.5%, or ¥8.8 billion, to ¥247.3 billion. This decline was primarily due to sales of investment securities and amortization of goodwill, which offset the acquisition of other intangible noncurrent assets and an increase in deferred tax assets.

Liabilities

Total Assets

Total liabilities were down 2.6%, or ¥4.1 billion, from the end of the previous fiscal year, to ¥150.9 billion. Total current liabilities declined 6.9%, to ¥102.5 billion. An increase in income taxes payable was offset by major declines in short-term loans payable, construction and purchase of properties, and other current liabilities.

Total long-term liabilities were up 7.9%, or ¥3.5 billion, to ¥48.4 billion. Principal factors were increases in deferred tax

liabilities and other long-term liabilities¹. Interest-bearing debt at the end of the period was down 43.2%, to ¥7.5 billion, while cash and bank deposits remained considerably higher than borrowings.

Net Assets

Total net assets at the end of the period under review were ¥545.0 billion, an increase of 0.9%, or ¥4.6 billion, from the end of the previous fiscal year. Total shareholders' equity was ¥553.2 billion at the end of the period, an increase of 2.6%, or ¥13.9 billion. Cash dividends paid declined because the preceding fiscal year was a nine-month period, but the increase in retained earnings made a substantial contribution to shareholders' equity.

As a result, the equity ratio² rose 1.1 percentage points, to 78.2%. A high level of stability was maintained, with the debt/ equity ratio³ at 1.4%.

- 1. Includes long-term payables and allowance for environmental countermeasures
- Equity ratio = (Total shareholders' equity + Total valuation and translation adjustments) / Total assets x 100
- Debt/equity ratio = Interest-bearing debt (Short-term borrowings + Current portion of long-term debt + Long-term debt) / (Total shareholders' equity + Total valuation and translation adjustments) x 100







ROE and ROA



Management Indexes

Both return on equity (ROE) and return on assets (ROA) improved substantially from the end of previous fiscal year, from 1.64% to 4.11% and from 1.26% to 3.19%, respectively. This was primarily due to the increase in net income. Operating return on assets also improved, from 4.05% to 6.53%.

Because the business integration generated goodwill, the calculations were made with operating income before the amortization of goodwill and with noncurrent assets excluding goodwill. Earnings before income tax, interest, depreciation, and amortization (EBITDA)⁴ for the period increased 46.9%, to \pm 64.7 billion.

4. EBITDA = Income before income taxes and minority interests + Interest expenses + Depreciation and amortization

Capital Expenditures

Capital expenditures declined 4.5%, to ¥29.4 billion. These funds were primarily used in Pharmaceuticals operations for the construction of new facilities at the Tokyo Research Park and to expand production facilities for therapeutic antibodies used in clinical trials. Depreciation and amortization increased 3.6%, to ¥22.2 billion. Capital expenditures were greater than depreciation and amortization but were covered by net cash provided by operating activities.

Our policy for capital expenditures is to invest strategically with consideration for the balance between capital expenditures and depreciation and amortization. However, we have positioned our investment during the period under review as aggressive investment for future growth that was implemented in consideration of the reorganization of production bases, increasing operational efficiency, and expanding leading-edge facilities.

The breakdown of capital expenditures and depreciation and amortization are shown in the following table.

	Millions of Yen								
	Cap	oital Expenditu	res	Depreci	ation and Amo	ortization			
	2010/12	2009/12	2009/3	2010/12	2009/12	2009/3			
Pharmaceuticals	¥19,251	¥16,508	¥ 9,641	¥10,733	¥ 9,212	¥ 8,394			
Bio-Chemicals	7,604	5,000	5,376	6,733	4,322	5,027			
Chemicals	2,505	3,583	4,359	4,652	3,358	4,218			
Food	_	_	566	_	_	998			
Other	15	45	103	73	113	150			
Corporate, elimination and other	(1)	(1)	(1,522)	(3)	(2)	(7)			
Consolidated Total	¥29,374	¥25,135	¥18,523	¥22,188	¥17,003	¥18,780			

EBITDA

Billions of Yen



Capital Expenditures





Depreciation and Amortization

Billions of Yen



R&D Expenses

R&D expenses, which are accounted for under production expenses and SG&A expenses, declined 8.1%, to \pm 44.2 billion. This represented 10.7% of consolidated net sales, a decrease of 0.6 percentage point from the level of 11.3% in the corresponding period of the previous year.

R&D expenses in Pharmaceuticals operations were ¥40.0 billion, accounting for 90.5% of total R&D expenses. This represented 19.0% of Pharmaceuticals operations sales, a decline of 1.1 percentage points. Future plans for R&D expenses in Pharmaceuticals operations call for 20% of Pharmaceuticals operations sales to be invested in the development of new drugs.

Per Share Data

Net income per share-basic was ¥38.96, compared with ¥17.58 in the corresponding period of the previous year. Net income per share before the amortization of goodwill was ¥55.29. Net assets per share at the end of the period grew to ¥954.58 from ¥940.79 at the end of the corresponding period of the previous year.

Distribution of Profits

Kyowa Hakko Kirin considers returns to shareholders to be one of its most important management principles. Its dividend policy balances the need to augment retained earnings as a foundation for future business growth with the desire to make stable and consistent dividend payments after giving thorough consideration of each fiscal period's consolidated business results, the dividend payout ratio, and the yield of net assets. Internal reserves, including retained earnings, are used to supplement the investments that will help us achieve our next growth stage, including R&D and capital expenditures that will contribute to future increases in corporate value. In accordance with this policy, dividends for the period under review were ¥20.0 per share, which was in line with our plans.

Under the Medium-Term Management Plan—2010 to 2012, we will continue to target a consolidated dividend payout ratio of over 30% (calculated on the basis of net income before the amortization of goodwill). Currently, we plan dividends of ¥20.0 per share (¥10.0 interim dividend, ¥10.0 final dividend) for the year ending December 31, 2011.

Goodwill

Accompanying the business combination with Kirin Pharma, a share exchange was implemented on April 1, 2008. In that exchange, the acquisition cost of the Company, which was the acquiree, exceeded the market value of the Company's net assets at the time of the business combination, and consequently the excess amount was recognized as goodwill.

- Total goodwill generated: ¥191.9 billion
- Amortization method: Straight-line method
- Amortization period: 20 years (from March 2009 period)

Amortization of goodwill in the year under review, including amortization of goodwill from the business integration with Kirin Pharma Company, Limited, was ¥9.7 billion, compared with ¥7.0 billion in the 9-month period ended December 31, 2009.



R&D Expenses

Net Income per Share-Basic Yen



Net Assets per Share



Risk Factors

In the analysis of Kyowa Hakko Kirin's future business performance and financial position, the major risks that could have a significant influence on the judgment of investors include those outlined below. The Group recognizes that these risk events may occur and uses a risk management system to prevent the occurrence of risk events that it is able to control. At the same time, the Company will do its utmost to respond to risk events if and when they were to occur. Matters in this section dealing with future events represent the judgment of the Kyowa Hakko Kirin Group as of December 31, 2010, the end of the fiscal period under review.

Risks Inherent in the Domestic Pharmaceutical Industry's Operating Environment

The Company's mainstay Pharmaceuticals operations face periodic reductions to the official prices of the majority of ethical drugs under the domestic public drug pricing system. As a result, the Company is unable to avoid reductions in the selling prices of drugs that are not awarded premiums for the development of new drugs or the elimination of off-label drug use.

Risks of Non-Recovery of Substantial R&D Investments

The Company makes substantial R&D investments in the course of its development of new products and technologies, the improvement of existing products, and the development of new applications for existing products. However, there is no guarantee that all these investments will successfully bear fruit. For example, the development of new ethical drugs requires long periods of time and substantial R&D expenditures. Therefore, there may be instances in which the Company is unable to recover R&D investments for reasons including the cancellation of development if the expected efficacy is not recognized, lackluster sales after a product is launched, or the termination of sales because of the appearance of serious side effects.

Risks Related to Intellectual Property Rights

In the event that legal proceedings are instituted against the Company alleging that the Company's products or technologies infringe upon the intellectual property rights of another party, the Company could be forced to suspend product sales or pay compensation or settlement fees, which could adversely affect its business activities, business performance, and financial position.

Conversely, if the Company's intellectual property rights are infringed upon by products that compete with the products that are either produced by the Company or out-licensed by the Company, the Company's product sales or technology licensing fees could decrease faster than anticipated, which could also adversely affect the Company's business performance and financial position.

Risks Related to Side Effects

Before pharmaceuticals are approved, they undergo rigorous safety evaluation at the development stage and are screened by

the related authorities. Nonetheless, there are some cases in which side effects are newly discovered as a result of the accumulation of usage results after drugs are marketed. In the event of the emergence of unforeseen side effects after a drug is marketed, there could be a major impact on the Company's business performance and financial position.

Legal Risks

In the course of carrying out operations in Japan and overseas, statutory regulations must be observed. To ensure that it does not violate relevant statutory regulations in the course of its operations, the Company emphasizes compliance and works to bolster internal control functions through programs that include administrative oversight. However, the possibility that the Company could inadvertently fail to comply with relevant statutory regulations cannot be entirely eliminated, and the failure to comply with such statutory regulations could lead to a loss of public trust in the Company.

Risks Related to Defective Products

Kyowa Hakko Kirin manufactures a variety of products at plants in the countries in which it operates, in compliance with locally recognized quality control and other standards. Furthermore, the Company requires that the products it purchases for sale conform to the same quality and standards required of Kyowa Hakko Kirin products. However, there is no guarantee that all products will be free of defects. Therefore, the possibility of product defects leading to large-scale product recalls or product liability claims cannot be ruled out.

Risks Related to Disasters and Accidents

To minimize the negative effects of interruptions in manufacturing line activities, the Company conducts regular disaster prevention tests and inspections of all its production facilities. Nevertheless, there is no guarantee that the Company will be able to completely prevent risk events at its production facilities that interrupt production, including accidents, such as earthquakes and fires, electrical outages, and boiler stoppages. Furthermore, at its headquarters, sales bases, and distribution bases, in the event of an accident that exceeds expectations, operating activities could be affected. In addition, the Company handles substances that are subject to an array of statutory regulations and guidelines. The handling of these materials is strictly controlled, but if a fire, natural disaster, or some other risk event were to occur, for any reason, surrounding areas could suffer damage. Moreover, in the event of the emergence of social disorder due to the spread of an infectious disease, such as H1N1 influenza, in the regions or countries where the Group conducts business, the Group's operating activities could be restricted. These types of accidents or disasters could not only result in large payments for damages but also adversely affect the public's trust in the Group.

Risks Related to the Strengthening of Environmental Regulations on Production Activities

The Company processes and disposes of waste fluid generated from its fermentation production processes in accordance with the environmental regulations of the countries in which its plants are situated. Furthermore, the Company is endeavoring to shift to raw materials that minimize the toll on the environment and improve its waste fluid treatment technology. However, given the trend of environmental regulations becoming more stringent each year, it is possible that regulatory changes could lead to restrictions on the Company's production activities or increased production costs.

Risks Inherent in Overseas Business Activities

The Company operates in the United States and various countries throughout Europe and Asia. The development of operations in overseas markets entails a number of potential risks, which are outlined below.

- Unforeseeable laws and regulations or disadvantageous changes in tax systems
- The occurrence of disadvantageous political or economic factors
- Difficulty in recruiting and maintaining personnel
- Social unrest resulting from terrorism, war, or other factors The occurrence of one or more of these potential risk events

could prevent the Company from operating effectively in the affected country.

Risks of Drops in Product Prices from Fluctuations in the Supply-Demand Balance

Market prices for some of the Company's products, including solvents and raw materials for plasticizers in its Chemicals operations, fluctuate significantly in response to the worldwide balance of supply and demand. It is therefore possible that a situation of excess supply could result in substantial declines in sales prices for these products.

Risks of Declines in Profitability from Major Fluctuations in Crude Oil Prices

The primary raw materials for the products of the Company's Chemicals operations include ethylene and propylene, which are made from naphtha, refined from crude oil. The prices of these raw materials are significantly affected by fluctuations in the price of crude oil, which can be triggered by a variety of unpredictable factors, including the worldwide balance of supply and demand, weather conditions, war, and terrorism. In some cases, the Company may not be able to factor fluctuations in raw materials prices into product prices, or offset fluctuations through cost reductions, in a timely manner.

Risks Related to Fluctuations in Currency Exchange Rates

The Company conducts transactions denominated in foreign currencies, such as product sales and income received from

overseas companies for out-licensed technology, or the purchase of raw materials from international suppliers. Rapid fluctuations in currency exchange rates may have a significantly adverse effect on the Company's financial position or management performance. In addition, as the Company sells its products in the same markets as its overseas competitors, fluctuations in currency exchange rates may impact the relative price competitiveness of the Company's products. Further, in order to prepare consolidated financial statements in Japan, the financial statements of overseas subsidiaries denominated in local currencies are converted into Japanese yen. Consequently, currency exchange rates when the conversions are made may impact values when converted to yen.

Risks Related to Fluctuations in the Price of Shares and Other Marketable Securities

The Company owns marketable securities with market value. A major decline in the market value of shares may result in the Company having to record a valuation loss on the marketable securities it owns. This may have a material impact on the Company's financial position and management performance. Also, some of the assets the Company manages for its corporate pension are marketable securities with market value. Therefore, fluctuations in the market value may change actuarial calculations carried out within accounting for retirement benefits. This may have an adverse impact on the Company's financial position or management performance.

Risks Related to the Impairment of Fixed Assets

Regarding fixed assets owned by the Company, in the event there is a significant deterioration in its operating environment that results in a fall in profits, or if there is a major decline in the market value of the fixed assets, then, in accordance with the principles of accounting for the impairment of fixed assets, the Company may have to record a loss on impairment. This may have an adverse impact on the Company's financial position or management performance.

Risks Related to the Procurement of Raw Materials

For some of the raw materials it procures, the Company may encounter difficulties if it is required to switch suppliers, to find replacement raw materials, or to procure raw materials from a limited number of specified suppliers. The Company implements measures to secure sufficient levels of those raw materials that are particularly important to manufacturing to ensure there are no interruptions in production, including maintaining stock at certain levels across a designated period. However, if unforeseeable events occur and the Company is unable to procure important raw materials that cannot be replaced with an alternative, then product manufacturing may have to be suspended. This could have a major impact on the Company's management performance.

Consolidated Balance Sheets

Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries As at December 31, 2010 and 2009

			Thousands of U.S. Dollars	
	Millior	ns of Yen	(Note 3)	
ASSETS	2010/12	2009/12	2010/12	
Current Assets:				
Cash and deposits (Note 12)	¥ 33,128	¥ 30,160	\$ 406,533	
Notes and accounts receivable (Note 12):				
Trade	115,190	114,578	1,413,539	
Unconsolidated subsidiaries and affiliates	8,693	7,297	106,678	
Other	4,221	3,108	51,802	
	128,104	124,983	1,572,019	
Inventories (Note 6)	61,762	63,805	757,904	
Deferred tax assets (Note 9)	8,369	9,250	102,697	
Short-term loans receivable (Note 12):				
Parent company	53,199	40,178	652,833	
Other	285	165	3,492	
	53,484	40,343	656,325	
Other current assets	4,155	8,200	50,993	
Less: Allowance for doubtful accounts	(149)	(153)	(1,834)	
Total Current Assets	288,853	276,588	3,544,637	

Property, Plant and Equipment, at Cost (Note 16):			
Land (Note 17)	70,697	71,993	867,555
Buildings and structures	153,136	146,097	1,879,195
Machinery and equipment	211,317	204,829	2,593,169
Other	51,585	51,413	633,022
Construction in progress	10,578	17,589	129,808
	497,313	491,921	6,102,749
Less: Accumulated depreciation	(337,575)	(329,361)	(4,142,529)
Total Property, Plant and Equipment, Net	159,738	162,560	1,960,220

Investments and Other Assets:			
Investments and other Assets.	36,770	48,315	451,223
Investments in unconsolidated subsidiaries and affiliates (Notes 12 and 13)	18,579	18,167	227,988
Goodwill	162,659	170,055	1,996,066
Deferred tax assets (Note 9)	9,954	4,263	122,154
Other assets	20,785	16,771	255,066
Less: Allowance for doubtful accounts	(1,476)	(1,451)	(18,115)
Total Investments and Other Assets	247,271	256,120	3,034,382
Total Assets	¥ 695,862	¥ 695,268	\$ 8,539,239

	Million	is of Yen	Thousands of U.S. Dollars (Note 3)
LIABILITIES AND NET ASSETS	2010/12	2009/12	2010/12
Current Liabilities:			
Short-term loans payable (Notes 7 and 12)	¥ 7,253	¥ 12,691	\$ 89,010
Current portion of long-term loans payable (Notes 7 and 12)	162	243	1,994
Notes and accounts payable (Note 12):			
Trade (Note 17)	42,049	43,615	515,999
Unconsolidated subsidiaries and affiliates	5,632	5,568	69,113
Construction and purchase of properties	6,347	10,572	77,886
Other	20,338	21,596	249,581
	74,366	81,351	912,579
Income taxes payable	15,380	7,313	188,729
Accrued bonuses	100	1,225	1,231
Other current liabilities	5,222	7,258	64,077
Total Current Liabilities	102,483	110,081	1,257,620
Noncurrent Liabilities:			
Long-term loans payable (Note 7)	100	295	1,222
Deferred tax liabilities (Note 9)	16,379	14,647	200,996
Provision for retirement benefits:		·	·
Employees (Note 11)	24,110	27,268	295,863
Directors and corporate auditors	135	107	1,652
Other long-term liabilities	7,662	2,526	94,045
Total Long-Term Liabilities	48,386	44,843	593,778
Total Liabilities	150,869	154,924	1,851,398
Commitments and Contingent Liabilities (Note 18) Net Assets: Characteristic (Note 10)			
Shareholders' equity (Note 19)			
Capital stock:			
Authorized: 987,900,000 shares at December 31, 2010 and 2009			
Issued: 576,483,555 shares at December 31, 2010 and 2009	26,745	26,745	328,200
Additional paid-in capital	512,359	512,398	6,287,387
Retained earnings	20,745	7,093	254,565
Treasury stock, at cost:			
6,691,427 shares at December 31, 2010 and		((000)	(24, 224)
6,935,900 shares at December 31, 2009	(6,676)	(6,932)	(81,926)
Total Shareholders' Equity	553,173	539,304	6,788,226
Valuation and Translation Adjustments:			(24.007)
Net unrealized holding gain (loss) on other securities (Note 13)	(2,195)	475	(26,937)
Net deferred gain on hedges (Note 14)	0	4	3
Foreign currency translation adjustments	(7,063)	(3,957)	(86,676)
Total Valuation and Translation Adjustments	(9,258)	(3,478)	(113,610)
Subscription rights to shares (Note 10)	208	197	2,551
Minority interests	870	4,321	10,674
Total Net Assets	544,993	540,344	6,687,841
Total Liabilities and Net Assets	¥695,862	¥695,268	\$8,539,239

Consolidated Statements of Income

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

For the year ended December 31, 2010, the nine months ended December 31, 2009 and the year ended March 31, 2009

		222,760 169,372 259,886 190,979 139,740 200,298 145,569 111,496 154,911 45,410 28,244 45,381		
	2010/12	2009/12	2009/3	2010/12
Net Sales (Note 21)	¥413,739	¥309,112	¥460,184	\$5,077,175
Cost of Sales (Note 11)	222,760	169,372	259,886	2,733,585
Gross Profit	190,979	139,740	200,298	2,343,590
Selling, General and Administrative Expenses (Notes 11 and 15)	145,569	111,496	154,911	1,786,340
Operating Income (Note 21)	45,410	28,244	45,387	557,250
Other Revenue (Expenses):				
Interest and dividend income	1,207	1,358	3,083	14,815
Interest expense	(199)	(245)	(523)	(2,448)
Foreign exchange gains (losses)	(1,280)	(112)	136	(15,713)
Equity in earnings of affiliates	1,074	1,559	1,212	13,181
Loss on sale and disposal of fixed assets	(1,634)	(289)	(1,000)	(20,049)
Impairment loss (Note 16)	(1,375)	(2,671)	(5,725)	(16,868)
Gain on negative goodwill	854			10,480
Loss on valuation of investment securities	(1,473)	(537)	(6,634)	(18,078)
Non-recurring depreciation on noncurrent assets	(1,225)	(3,300)		(15,037)
Loss on revision of retirement benefit plan (Note 11)	(1,772)			(21,741)
Provision for environmental measures	(888)			(10,892)
Gain on sales of investment securities (Note 13)	1,828		_	22,437
Loss on sales of investment securities (Note 13)	(101)	(991)		(1,245)
Loss on dilution of equity interest in subsidiary	_	(1,380)		_
Gain on sale of investments in subsidiaries and affiliates	_	_	5,835	_
Expenses related to business integration under the Strategic Alliance with the Kirin Group	_	_	(5,514)	_
Compensation for damages	_	_	(1,937)	-
Other, net	1,873	(1,007)	(3,382)	22,983
	(3,111)	(7,615)	(14,449)	(38,175)
Income before Income Taxes and Minority Interests	42,299	20,629	30,938	519,075
Income Taxes (Note 9):				
Current	(21,364)	(16,451)	(20,799)	(262,167)
Deferred	1,323	4,819	1,865	16,236
	(20,041)	(11,632)	(18,934)	(245,931)
Income before Minority Interests	22,258	8,997	12,004	273,144
Minority Interests	(61)	(200)	(277)	(752)
Net Income	¥ 22,197	¥ 8,797	¥ 11,727	\$ 272,392

Consolidated Statements of Changes in Net Assets Kyowa Hakko Kirin Co., Ltd. and its consolidated subsidiaries

For the year ended December 31, 2010, the nine months ended December 31, 2009 and the year ended March 31, 2009

							Millions	s of Yen					
			Shareholde	rs' equity			Valu	uation and trans	lation adjustme	nts			
	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 valuation and translation adjustments		Minority interests	Total net assets
Balance at March 31, 2008	399,243,555	¥ 26,745	¥ 43,180	¥170,948	¥(1,544)	¥ 239,329	¥ 15,349	¥(9)	¥ (379)	¥14,961	¥ 156	¥2,312	¥ 256,758
Balance of acquiree at March 31, 2008		(26,745)	(43,180)	(170,948)	1,544	(239,329)	(15,349)	9	379	(14,961)	(156)	(2,312)	(256,758)
Balance of acquirer at March 31, 2008		3,000	56,814	4,444		64,258	(163)		(868)	(1,031)		1,452	64,679
Increase due to share exchange	177,240,000	23,745	455,618		(1,544)	477,819							477,819
Net income for the year ended March 31, 2009				11,727		11,727							11,727
Cash dividends				(5,739)		(5,739)							(5,739)
Purchases of treasury stock					(1,001)	(1,001)							(1,001)
Disposal of treasury stock			(14)		153	139							139
Net changes during the year							(4,570)	5	(3,052)	(7,617)	189	2,874	(4,554)
Balance at March 31, 2009	576,483,555	26,745	512,418	10,432	(2,392)	547,203	(4,733)	5	(3,920)	(8,648)	189	4,326	543,070
Net income for the nine month ended December 31, 2009	_			8,797		8,797							8,797
Cash dividends				(11,435)		(11,435)							(11,435)
Purchases of treasury stock					(4,638)	(4,638)							(4,638)
Disposal of treasury stock			(20)		98	78							78
Decrease due to initial consolidation of subsidiaries				(878)		(878)							(878)
Increase due to exclusion of consolidated subsidiaries				68		68							68
Increase due to merger				109		109							109
Net changes during the nine month period						_	5,208	(1)	(37)	5,170	8	(5)	5,173
Balance at December 31, 2009	576,483,555	26,745	512,398	7,093	(6,932)	539,304	475	4	(3,957)	(3,478)	197	4,321	540,344
Net income for the year ended December 31, 2010				22,197		22,197							22,197
Cash dividends				(8,545)		(8,545)							(8,545)
Purchases of treasury stock					(113)	(113)							(113)
Disposal of treasury stock			(39)		369	330							330
Net changes during the year							(2,670)	(4)	(3,106)	(5,780)	11	(3,451)	(9,220)
Balance at December 31, 2010	576,483,555	¥26,745	¥512,359	¥ 20,745	¥(6,676)	¥ 553,173	¥ (2,195)	¥ 0	¥(7,063)	¥ (9,258)	¥ 208	¥ 870	¥ 544,993

					Thousa	nds of U.S. Dollars	(Note 3)					
		Sha	reholders' equ	uity		Valu	ation and trans	lation adjustme	nts			
	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 valuation and translation adjustments	Subscription rights to shares	Minority interests	Total net assets
Balance at December 31, 2009	\$328,200	\$6,287,867	\$ 87,048	\$(85,070)	\$6,618,045	\$ 5,830	\$ 42	\$(48,556)	\$ (42,684)	\$2,412	\$ 53,026	\$6,630,799
Net income for the year ended December 31, 2010			272,392		272,392							272,392
Cash dividends			(104,875)		(104,875)							(104,875)
Purchases of treasury stock				(1,389)	(1,389)							(1,389)
Disposal of treasury stock		(480)		4,533	4,053							4,053
Net changes during the year						(32,767)	(39)	(38,120)	(70,926)	139	(42,352)	(113,139)
Balance at December 31, 2010	\$328,200	\$6,287,387	\$254,565	\$(81,926)	\$6,788,226	\$(26,937)	\$ 3	\$(86,676)	\$(113,610)	\$2,551	\$ 10,674	\$6,687,841

Consolidated Statements of Cash Flows

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

For the year ended December 31, 2010, the nine months ended December 31, 2009 and the year ended March 31, 2009

		Millions of Yon		Thousands of U.S. Dollars
	2010/12	Millions of Yen 2009/12	2009/3	(Note 3) 2010/12
Cash Flows from Operating Activities:				
Income before income taxes and minority interests	¥ 42,299	¥ 20,629	¥30,938	\$ 519,075
Adjustments to reconcile income before income taxes and minority interests to net cash provided by operating activities:				
Depreciation and amortization	22,188	17,003	18,780	272,282
Impairment loss	1,375	2,671	5,725	16,868
Amortization of goodwill	9,929	7,182	9,860	121,840
Increase (decrease) in provision for retirement benefits	(3,138)	576	214	(38,502)
(Increase) decrease in prepaid pension costs	(252)	824	(3,670)	(3,087)
Increase (decrease) in provision for bonuses	(1,122)	(2,891)	(114)	(13,770)
Increase (decrease) in allowance for doubtful accounts		501	(549)	
Interest and dividends income	(1,207)	(1,358)	(3,083)	(14,815)
Interest expenses	199	245	523	2,448
Equity in earnings of affiliates	(1,074)	(1,559)	(1,212)	(13,181)
(Gain) loss on sales and retirement of property, plant and equipment	625	278	1,000	7,667
Loss (gain) on sales of investment securities	(1,727)	982	(17)	(21,192)
Gain on sale of investments in subsidiaries and affiliates			(5,835)	
Loss on valuation of investment securities	1,473	537	6,634	18,078
Increase (decrease) in notes and accounts receivable	(2,627)	(9,814)	14,457	(32,242)
(Increase) decrease in inventories	477	4,588	(5,148)	5,850
Increase (decrease) in notes and accounts payable	1,955	6,187	(10,856)	23,991
Other	6,517	(1,969)	(95)	79,971
	75,890	44,612	57,552	931,281
Interest and dividends income received	2,114	1,535	4,051	25,946
Interest expenses paid	(205)	(259)	(496)	(2,514)
Income taxes paid	(13,610)	(21,684)	(20,038)	(167,019)
Net Cash Provided by Operating Activities	64,189	24,204	41,069	787,694
Cash Flows from Investing Activities:				
Purchase of property, plant and equipment	(28,002)	(19,778)	(18,231)	(343,623)
Proceeds from sales of property, plant and equipment	1,148	2,283	338	14,092
Purchase of intangible assets	(7,471)	(1,085)		(91,681)
Purchase of investment securities	(65)	(2,159)	(150)	(797)
Proceeds from sales and redemption of investment securities	6,363	4,024	87	78,084
Purchase of investments in capital of subsidiaries resulting in change in scope of consolidation	(3,880)	(59)		(47,615)
Proceeds from sale of investment in consolidated subsidiaries resulting in change in scope of consolidation			16,908	-
Payments into time deposits	(7,013)	(4,135)	(7,040)	(86,056)
Proceeds from withdrawal of time deposits	6,290	3,213	3,078	77,190
Other	256	4,449	1,029	3,131
Net Cash Used in Investing Activities	(32,374)	(13,247)	(3,981)	(397,275)
Cash Flows from Financing Activities:				
Decrease in short-term loans payable	(5,381)	(384)	(7)	(66,030)
Proceeds from long-term loans payable	_		492	_
Repayment of long-term loans payable		(202)	(12,573)	(3,053)
Purchase of treasury stock	(113)	(4,638)	(1,001)	(1,389)
Cash dividends paid	(8,569)	(11,373)	(7,687)	(105,149)
Cash dividends paid to minority shareholders	(55)	(205)	(190)	(672)
Other	(329)	(104)	(12)	(988)
Net Cash Used in Financing Activities	(14,447)	(16,906)	(20,978)	(177,281)
Effect of Exchange Rate Change on Cash and Cash Equivalents	(1,230)	(40)	(1,028)	(15,108)
Net Increase (Decrease) in Cash and Cash Equivalents	16,138	(5,989)	15,082	198,030
Cash and Cash Equivalents at the Beginning of the Period	63,745	69,287	44,119	782,244
Cash and Cash Equivalents of Acquiree at the Beginning of the Period			(44,119)	-
Cash and Cash Equivalents of Acquirer at the Beginning of the Period			10,440	_
Increase in Cash and Cash Equivalents from Newly Consolidated Subsidiaries	_	393	43,742	
Decrease in Cash and Cash Equivalents Resulting from Exclusion of Subsidiaries from Consolidation		(215)		-
Increase in Cash and Cash Equivalents Resulting from Merger		269	23	
Cash and Cash Equivalents at the End of the Period	¥ 79,883	¥ 63,745	¥ 69,287	\$ 980,274
Reconciliation between cash and cash equivalents at year-end and the accounts booked in the consolidated balance sheets				
Cash and deposits	¥ 33,128	¥ 30,160	¥ 32,979	\$ 406,533
Time deposits whose maturity periods exceed 3 months	(6,444)	(6,593)	(5,734)	(79,092)
Short-term loans receivable from parent company	53,199	40,178	42,042	652,833
Cash and Cash Equivalents	¥ 79,883	¥ 63,745	¥ 69,287	\$ 980,274

Notes to the Consolidated Financial Statements

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

NOTE 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 has adopted the "Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for Consolidated Financial Statements" (Practical Issues Task Force No. 18 (hereinafter "PITF No. 18"), issued by the Accounting Standards Board of Japan (hereinafter "ASBJ")). In accordance with the new accounting standard, the accompanying consolidated financial statements for the year ended December 31, 2010, 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.

NOTE 2

Summary of Significant Accounting Policies (1) Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and significant companies which it controls directly or indirectly. As of December 31, 2010, the numbers of consolidated subsidiaries and affiliates accounted for by the equity method were 31 and 8, respectively (29 and 9 as of December 31, 2009). All significant intercompany balances and transactions are eliminated in consolidation.

Investments in subsidiaries and affiliates which 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.

(2) Cash and Cash Equivalents

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

(3) Securities

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

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

(4) Inventories

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

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

Depreciation is computed mainly by the declining-balance method. The Company and its domestic consolidated subsidiaries compute depreciation expense for buildings (other than related

equipment and leasehold improvements) acquired on or after April 1, 1998, by the straight-line method.

The range of useful lives is principally as follows: Buildings and structures 15 - 50 years Machinery and equipment 4 - 15 years

(6) Goodwill

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

(7) Intangible Assets (Except for leased assets)

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

(8) Leases

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

(9) Allowance for Doubtful Accounts

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

(10) Accrued Bonuses

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

(11) Provision for Retirement Benefits

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

Unrecognized prior service costs are amortized by the straight-line method mainly over 5 years from the year they occur.

Unrecognized actuarial differences are amortized by the straight-line method mainly over 10 years from a year after they occur.

A provision for retirement benefits to directors and corporate auditors is provided in accordance with each company's internal rules.

(12) Foreign Currency Translation

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

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

(13) Derivative Financial Instruments

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

(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 inhabitants' 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 years ended December 31, 2009 and March 31, 2009 have been reclassified to conform to the current period presentation.

(19) Accounting Changes

Effective January 1, 2010, the Company and its domestic consolidated subsidiaries have adopted ASBJ Statement No. 21, "Accounting Standard for Business Combinations," No. 22 "Accounting Standard for Consolidated Financial Statements," No. 23 "Partial amendments to Accounting Standard for Research and Development Costs," No. 7 "Accounting Standard for Business Divestitures," No. 16 "Accounting Standard for Equity Method of Accounting for Investments" and ASBJ Guidance No. 10 "Guidance on Accounting Standard for Business Combinations and Accounting Standard for Business Divestitures." Effective April 1, 2009, the Company and its domestic consolidated subsidiaries have adopted ASBJ Statement No. 19, "Partial amendments to Accounting Standard for Retirement Benefits (Part 3)." This adoption had no impact on the consolidated statements of income.

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

NOTE 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

NOTE 4

Change in End of Fiscal Year

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

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

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

increased ¥41 million in the period compared to the amounts which would have been recorded under the previous method.

(20) Additional Information

Effective January 1, 2010, the Company and its domestic consolidated subsidiaries have adopted ASBJ Statement No. 10, "Accounting Standard for Financial Instruments and its Implementation Guidance," and No. 19, "Guidance on Disclosures about Fair Value of Financial Instruments."

Due to an increase in the estimated amount of environmental expenditures, the Company recognize "Provision for environmental measures" of ¥888 million (\$10,892 thousand) for the year ended December 31, 2010. As a result, income before income taxes and minority interests declined by the same amount. And the same amount is including other long-term liabilities of consolidated balance sheet.

Following its decision to reorganize plants, etc., the Company revised the useful lives of property, plant and equipment and declared the difference between the book value before the change and after the change amounting to ¥1,225 million (\$15,037 thousand) in the form of Non-recurring depreciation on noncurrent assets for the year ended December 31, 2010 and ¥3,300 million for the nine months ended December 31, 2009. As a result, income before income taxes and minority interests declined by the same amount in each fiscal year.

of ¥81.49=U.S.\$1, the approximate exchange rate at December 31, 2010. 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 ¥81.49=U.S.\$1 or at any other rate.

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

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

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

BioWa, Inc., Kyowa Hakko Kirin America, Inc., Kyowa Hakko Kirin Pharma, Inc., Kyowa Hakko Bio U.S. Holdings, Inc., BioKyowa Inc., Kyowa Hakko Europe GmbH, Kyowa Italiana Farmaceutici S.r.I., Shanghai Kyowa Amino Acid Co., Ltd.,

NOTE 5

Business Combinations

(1) Share Exchange

The Company entered into a "Share Exchange Agreement" making it a parent of Kirin Pharma Company, Limited (hereinafter "Kirin Pharma") and Kirin Pharma its wholly owned subsidiary following the resolution passed at the meeting of the Board of Directors held on October 22, 2007, and executed the exchange of shares with the approval obtained at the extraordinary General Shareholders' Meeting convened on February 29, 2008. The effective date of the business combination was April 1, 2008.

Through the share exchange under this agreement, the Company acquired all outstanding shares of Kirin Pharma. However, because the Company issued 177,240,000 new common shares to Kirin Pharma's parent Kirin Holdings, Kirin Holdings holds 50.1% of the total number of outstanding shares of the Company and has thus become the parent of the Company. Therefore, the share exchange corresponds to a "Reverse Acquisition" whereby Kirin Pharma became the acquirer and the Company the acguiree in accordance with ASBJ Statement No. 21, "Accounting Standard for Business Combinations," and ASBJ Guidance No. 10, "Guidance on Accounting Standard for Business Combinations and Accounting Standard for Business Divestitures," and the purchase method has been applied as the accounting procedure for such share exchange. For this reason, Kirin Pharma's acquisition of 100% of the Company's voting rights has been accounted for in the consolidated financial statements.

Given that the acquisition cost of the Company as acquiree exceeded the market valuation of the Company's net assets as of the date of the business combination, the excess amount of \$191,930 million was recognized as "goodwill," to be amortized over the next 20 years by the straight-line method.

(2) Merger

At the meeting of the Board of Directors held on April 28, 2008, the Board passed a resolution to undertake an absorption and merger whereby the Company would become the surviving company and its wholly owned subsidiary Kirin Pharma the extinguished entity effective October 1, 2008, and the Company entered into a "Merger Agreement" with Kirin Pharma on the said date of the Board meeting. Subsequently, the merger was approved at the ordinary General Shareholders' Meeting held on June 24, 2008, and came into effect on October 1, 2008. In conjunction with this, the Company's trade name "KYOWA Kyowa Hakko U.S.A., Inc., Kyowa Hakko (H.K.) Co., Ltd., Kashiwagi Corporation.

As a result, net sales increased ¥11,986 million, operating income ¥158 million, ordinary income ¥147 million and income before income taxes and minority interests ¥23 million.

HAKKO KOGYO CO., LTD." was changed to "Kyowa Hakko Kirin Co., Ltd." on October 1, 2008.

The share exchange and the merger were executed as part of the strategic alliance between the Kyowa Hakko Group and the Kirin Group. Antibody drug technology-centered biotechnology is the strength of both the Company and Kirin Pharma. Through the integration of antibody technologies, both companies aim to improve drug development capabilities, expand opportunities to acquire novel antigens through an improved presence in the antibody drug sector and increase development speed and proactive overseas business development of antibody drugs through the mutual exploitation of antibody technologies. Furthermore, through the integration, the Company and Kirin Pharma expect an increase in the scale of research and development and marketing, the establishment of effective business operations systems and the further strengthening of the profitability and competitiveness of their pharmaceutical business, all of which is believed to result in a strengthening of the operational base.

(3) Divestiture of a Business

At the meeting of the Board of Directors held on April 28, 2008, the Board passed a resolution to divest the Company's Bio-Chemicals Division effective October 1, 2008, and to transfer the division to a newly established company named Kyowa Hakko Bio Co., Ltd. (hereinafter "Kyowa Hakko Bio"). The divestiture of the business was subsequently approved at the ordinary General Shareholders' Meeting held on June 24, 2008, and through its execution on October 1, 2008, Kyowa Hakko Bio was newly established.

As the business model for the Bio-Chemicals Division in particular with a focus on materials differs from the business model for the Pharmaceuticals Division, the Company took advantage of its merger with Kirin Pharma as an opportunity to spin off the Bio-Chemicals Division and thereby develop a management system unique to the bio-chemicals business. The spin-off facilitates faster decision making and enables flexible and proactive business development, and seeks to achieve a more competitive edge and growth on a self-sustaining basis as a significant business entity of the Kyowa Hakko Kirin Group.

(4) Business Combination of a Subsidiary

At the meeting of the Board of Directors held on October 21, 2008, the Board passed a resolution to conclude an "Agreement to Integrate Food Products Businesses" aimed at integrating the food products businesses of the Company's wholly owned subsidiary Kyowa Hakko Food Specialties Co., Ltd. (hereinafter "Kyowa Hakko Foods,") and Kirin Holdings' wholly owned subsidiary Kirin Food-Tech Company, Limited (hereinafter "Kirin Food-Tech"), and the Company entered into the agreement on the said date of the Board meeting. Under the agreement, the Company sold 526 shares out of a total of 1,000 shares of Kyowa Hakko Foods to Kirin Holdings at ¥17,095 million on March 31, 2009.

As a result of the above-mentioned sale of shares, Kyowa Hakko Foods and its wholly-owned subsidiaries Kyowa F.D. Foods Co., Ltd., Ohland Foods Co., Ltd. and Kyowa HiFoods Co., Ltd. changed from consolidated subsidiaries of the Company to affiliated companies accounted for by the equity method effective March 31, 2009.

Kyowa Hakko Foods and Kirin Food-Tech subsequently merged on April 1, 2009. The new company's trade name was changed to Kirin Kyowa Foods Company, Limited.

As a result of the merger, the Company recorded a ¥1,380 million loss on dilution of equity interest in a subsidiary.

(5) Additional Information: Sale of Shares of an Affiliate

Under the above-mentioned "Agreement to Integrate the Food Products Businesses," the Company sold all of the remaining 474 shares of Kirin Kyowa Foods Company, Limited to Kirin Holdings on January 1, 2011.

NOTE 6

Inventories

Inventories as of December 31, 2010 and 2009 are as follows:

	Million	ns of Yen	Thousands of U.S. Dollars
	2010/12	2009/12	2010/12
Merchandise and finished goods	¥40,803	¥43,864	\$500,716
Work in process	10,629	8,970	130,427
Raw materials and supplies	10,330	10,971	126,761
	¥61,762	¥63,805	\$757,904

NOTE 7

Short-Term Borrowings and Long-Term Debt

(1) Short-term borrowings at December 31, 2010 and 2009 consisted of the following:

	Million	ns of Yen	Thousands of U.S. Dollars
	2010/12	2009/12	2010/12
Unsecured loans, principally from banks, with a weighted average interest rate of 1.3%			
at December 31, 2010 and 2009	¥7,253	¥12,691	\$89,010

(2) Long-term debt at December 31, 2010 and 2009 consisted of the following:

	Million	Millions of Yen	
	2010/12	2009/12	2010/12
Secured loans, principally from banks and other financial institutions, due 2011 to 2012 at December 31, 2010 and due 2010 to 2012 at December 31, 2009 with interest ranging			
from 5.8% to 6.0% per annum in 2010 and from 1.9% to 6.2% per annum in 2009	¥ 262	¥ 538	\$ 3,216
Less: Current portion of long-term debt	(162)	(243)	(1,994)
	100	¥ 295	\$ 1,222

(3) The aggregate annual maturities of long-term debt subsequent to December 31, 2010 are as follows:

December 31	Millions of Yen	Thousands of U.S. Dollars
2011	¥162	\$1,994
2012	100	1,222
2013	_	
2014	_	_
2015	_	_
	¥262	\$3,216

NOTE 8

Leases

(1) Finance Leases

The Companies hold certain machinery, equipment and other fixed assets under finance leases that do not transfer ownership of the leased assets to the lessee. Lease transactions entered into on or before March 31, 2008 are not capitalized, but are accounted for as operating leases. If these leases had been capitalized, the purchase cost, accumulated depreciation and net book value of such leased assets at December 31, 2010 and 2009 would have been as follows:

		Millions of Yen			Thousands of U.S. Dollars	
	Machinery and			Machinery and		
December 31, 2010	equipment	Other	Total	equipment	Other	Total
Purchase cost	¥ —	¥671	¥671	\$ —	\$8,236	\$8,236
Accumulated depreciation	_	541	541		6,638	6,638
Net book value	¥ —	¥130	¥130	\$ —	\$1,598	\$1,598

	Millions of Yen				
December 31, 2009	Machinery and equipment	Other	Total		
Purchase cost	¥28	¥991	¥1,019		
Accumulated depreciation	25	702	727		
Net book value	¥З	¥289	¥ 292		

Lease payments relating to finance leases accounted for as operating leases amounted to ¥162 million (\$1,991 thousand), which were equal to the depreciation expense of the leased assets computed by the straight-line method over the lease terms, for the year ended December 31, 2010.

Future minimum lease payments subsequent to December 31, 2010 on finance leases accounted for as operating leases are summarized as follows:

	Millions of Yen	Thousands of U.S. Dollars
2011	¥ 94	\$1,156
Thereafter	36	442
	¥130	1,598

(2) Operating Leases

Future minimum lease payments subsequent to December 31, 2010 on non-cancelable operating leases are summarized as follows:

	Millions of Yen	Thousands of U.S. Dollars
2011	¥ 194	\$ 2,377
Thereafter	2,802	34,383
	¥2,996	\$36,760

NOTE 9

Income Taxes

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

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

	2010/12	2009/12	2009/3
Statutory tax rate	40.7%	40.7%	40.7%
(Reconciliation)			
Undistributed profit of affiliates scheduled to be sold	8.5	—	19.9
Amortization of goodwill	9.4	13.8	12.6
Permanently non-deductible expenses, such as entertainment expenses	4.0	6.2	6.8
Future deductible temporary differences deemed not to be realized	(2.4)	15.3	(1.3)
Permanently non-taxable income, such as dividend income	(1.2)	(2.8)	(1.1)
Equity in earnings of affiliates	(1.0)	(3.0)	(1.6)
Difference in statutory tax rate of subsidiaries	(1.5)	(2.0)	(1.9)
Special corporate tax credit	(9.6)	(13.4)	(11.5)
Loss on dilution of equity interest in a subsidiary	_	2.7	_
Other	0.5	(1.1)	(1.4)
Effective tax rates	47.4%	56.4%	61.2%

(2) The significant components of deferred tax assets and liabilities as of December 31, 2010 and 2009 are as follows:

	Millior	Millions of Yen	
	2010/12	2009/12	2010/12
Deferred tax assets:			
Non-deductible portion of provision for retirement benefits to employees	¥ 9,844	¥ 11,699	\$ 120,800
Non-deductible portion of depreciation of property, plant and equipment	12,028	11,323	147,597
Prepaid expenses for tax purposes	4,546	3,951	55,790
Investments in affiliates	-	2,572	_
Gain on sale of investments in affiliates	3,270	1,617	40,130
Tax loss carried forward	_	1,636	_
Other	14,758	11,360	181,105
Sub-total	44,446	44,158	545,422
Valuation allowance	(9,460)	(10,199)	(116,095)
Total deferred tax assets	¥ 34,986	¥ 33,959	\$ 429,327
Deferred tax liabilities:			
Valuation of assets and liabilities of the former Kyowa Hakko			
Group at the fair market value related to reverse acquisition	¥(22,785)	¥(23,265)	\$(279,608)
Undistributed gain on affiliates scheduled to be sold	(3,042)		(37,331)
Unrealized gains on marketable other securities	(2,692)	(6,738)	(33,031)
Deferred gain, mainly related to expropriation of fixed assets	(1,958)	(2,154)	(24,024)
Prepaid pension expenses	(1,576)	(2,061)	(19,338)
Other	(989)	(875)	(12,141)
Total deferred tax liabilities	(33,042)	(35,093)	(405,473)
Deferred tax assets (liabilities), net	¥ 1,944	¥ (1,134)	\$ 23,854

NOTE 10

Stock Option Plans

(1) The following table summarizes the information on stock options as of December 31, 2010:

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

(2) The following table summarizes the changes in stock options for the year ended December 31, 2010:

	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, 2009	_	_	_	_	_	_
Granted during the period	85,000	_	_	_		_
Forfeited during the period	_	_	_	_		_
Vested during the period	85,000	_	_	_		_
Stock options outstanding at December 31, 2010	_	_	_	_	_	_
Vested (number of shares): Stock options outstanding at December 31, 2009		93,000	53,000	37,000	39,000	40,000
Vested during the period	85,000					
Exercised during the period		27,000	22,000	14,000	7,000	8,000
Forfeited during the period						
Stock options outstanding at December 31, 2010	85,000	66,000	31,000	23,000	32,000	32,000

(3) The following table summarizes the price information of stock options as of December 31, 2010:

	2010/12 Plan	2009/12 Plan	2009/3 Plan	2008/3 Plan	2007/3 Plan	2006/3 Plan
Exercise price	¥ 1	¥ 1	¥ 1	¥ 1	¥ 1	¥ 1
Weighted average market price per stock at the time of exercise		957	957	957	957	957
Fair value per stock at the date of grant	940	1,014	1,038	1,140	705	

(4) Method of estimating the fair value of stock options

1. Valuation method used: Black-Scholes model

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

	2010/12 Plan	2009/12 Plan	2009/3 Plan
Share price volatility*1	10.2%	8.8%	5.8%
Expected remaining period $^{\star 2}$	2 years	3 years	2 years
Expected dividends*3	¥20/per share	¥20/per share	¥20/per share
Risk-free interest rate*4	0.69%	0.52%	0.42%

*1. Calculated based on share price results over 2 years (from March 2008 to February 2010).

*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 2010/12.

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

(5) Method of estimating the number of stock options vested

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

NOTE 11

Provision for Retirement Benefits to Employees

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

(1) Details on the provision for retirement benefits to employees as of December 31, 2010 and 2009 are as follows:

	Million	ns of Yen	Thousands of U.S. Dollars
	2010/12	2009/12	2010/12
Retirement benefit obligations*	¥(74,749)	¥(78,009)	\$(917,282)
Plan assets at fair value	42,809	46,091	525,326
Unfunded retirement benefit obligations	(31,940)	(31,918)	(391,956)
Unrecognized actuarial differences	11,006	8,030	135,057
Unrecognized prior service costs	430	(27)	5,274
Prepaid pension expenses	(3,606)	(3,353)	(44,238)
Provision for retirement benefits to employees	¥(24,110)	¥(27,268)	\$(295,863)

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

* Effects on the transition of a part of the Company's pension plans from defined benefit plan to defined contribution plan are as follows

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

Plan assets of ¥3,761 million will be transferred to defined contribution plan over four years.

Plan assets of ¥2,784 million which have not yet been transferred as of December 31, 2010 is presented as other long-term liabilities.

(2) The retirement benefit expenses for the year ended December 31, 2010 the nine months ended December 31, 2009 and the year ended March 31, 2009 are as follows:

		Millions of Yen		Thousands of U.S. Dollars
	2010/12	2009/12	2009/3	2010/12
Service cost*1	¥ 3,510	¥2,669	¥3,552	\$ 43,069
Interest cost	1,855	1,437	1,976	22,769
Expected return on plan assets	(1,014)	(902)	(1,427)	(12,440)
Amortization of unrecognized actuarial differences	1,656	1,239	278	20,322
Amortization of unrecognized prior service costs	111	1	(2)	1,367
Contribution to defined contirbution pension plan	755	_	_	9,265
Special severance payment	_	22	3	_
Other	26 * ³	182*2	212*2	309 * ³
Retirement benefit expenses	¥ 6,899	¥4,648	¥ 4,592	\$ 84,661
Loss on revision of retirement benefit plan	1,772*4	—	_	21,741*4
Total	¥8,671	¥4,648	¥4,592	\$106,402

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

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

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

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

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

	2010/12	2009/12	2009/3
Discount rate	2.5% (mainly)	2.5%	2.5%
Expected rate of return on plan assets	2.5% (mainly)	3.0% (mainly)	3.0% (mainly)
Amortization period for prior service costs	5 years (mainly)	5 years (mainly)	5 years (mainly)
	(Straight-line method)	(Straight-line method)	(Straight-line method)
Amortization period for actuarial differences	10 years (mainly)	10 years (mainly)	10 years (mainly)
	(Straight-line method)	(Straight-line method)	(Straight-line method)

NOTE 12

Financial Instruments

1. Qualitative information on financial instruments

(1) Policies for financial instruments

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

(2) Details of financial instruments and risks

Notes and accounts receivable are exposed to credit risks associated with customers. Receivables denominated in foreign currencies generated through business operations conducted globally are exposed to the risk of fluctuations in exchange rates. Investment securities, consisting mainly of the stocks of business partners are exposed to the risk of fluctuations in stock prices. Notes and accounts payable that are due within one year, and denominated in foreign currencies are generated through the 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 recognize risks of incurrence of uncollectible accounts promptly. The Companies enter into derivative trading contracts with only highly rated financial institutions in order to minimize credit risk.

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

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

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

The Company manages liquidity risk by making future cash flow plans in the accounting and finance section based on the 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 sheet at December 31, 2010 are described as follows. The table below excludes those financial instruments whose fair value estimation is extremely difficult and these are separately described below.

	Millions of Yen			Thousands of U.S. Dollars		
	Book value	Fair value	Difference	Book value	Fair value	Difference
(i) Cash and deposits	¥ 33,128	¥ 33,128	¥ —	\$ 406,533	\$ 406,533	\$—
(ii) Notes and accounts receivable	128,104	128,104	_	1,572,019	1,572,019	—
(iii) Short-term loans receivable	53,484	53,484	_	656,325	656,325	_
(iv) Investment securities	25,070	25,070	_	307,648	307,648	_
(v) Notes and accounts payable*1	(74,366)	(74,366)	_	(912,579)	(912,579)	_
(vi) Derivative financial instruments*2	189	189	_	2,314	2,314	_

*1. Liabilities are stated in parenthesis.

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

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

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

The book value approximates fair value because of the short-term maturity of these instruments. (iv) Investment securities

- (IV) Investment securities
- The fair value of securities is based on year-end quoted market prices. See Note 13.
- (v) Notes and accounts payable
- The book value approximates fair value because of the short-term maturity of these instruments.
- (vi) Derivative financial instruments

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

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

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

	Millions of Yen	Thousands of U.S. Dollars
Unlisted stocks	¥30,144	\$369,908
Other	135	1,655

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

	Millions of Yen				
	Within one year	Between one and five years	Between five and ten years	Total	
Cash and deposits	¥ 33,128	¥ —	¥ —	¥ 33,128	
Notes and accounts receivable	128,104	_	_	128,104	
Short-term loans receivable	53,484	_	_	53,484	
Total	¥214,716	_	_	¥214,716	

	Thousands of U.S. Dollars			
	Within one year	Between one and five years	Between five and ten years	Total
Cash and deposits	\$ 406,533	\$—	\$—	\$ 406,533
Notes and accounts receivable	1,572,019	_	_	1,572,019
Short-term loans receivable	656,325	_	_	656,325
Total	\$2,634,877	_	_	\$2,634,877

NOTE 13

Securities

(1) Marketable other securities as of December 31, 2010 and 2009 are as follows:

	2010/12 Millions of Yen		
	Purchase cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their purchase cost:			
Stocks	¥ 4,225	¥ 5,122	¥ 897
Securities whose purchase cost exceeds their carrying value:			
Stocks	24,501	19,948	(4,553)

	2010/12			
	Thousands of U.S. Dollars			
	Purchase cost	Carrying value	Unrealized gain (loss)	
Securities whose carrying value exceeds their purchase cost:				
Stocks	\$ 51,853	\$ 62,862	\$ 11,009	
Securities whose purchase cost exceeds their carrying value:				
Stocks	300,668	244,787	(55,881)	
		2009/12		
--	-----------------	----------------	---------------------------	--
	Millions of Yen			
	Purchase cost	Carrying value	Unrealized gain (loss)	
Securities whose carrying value exceeds their purchase cost:				
Stocks	¥18,309	¥23,176	¥4,867	
Securities whose purchase cost exceeds their carrying value:				
Stocks	16,308	12,220	(4,088)	

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

(2) Sales of other securities for the year ended December 31, 2010 and the nine months ended December 31, 2009 are as below.

	Millions of Yen		Tho	usands of U.S. Dol	lars	
	Sales amount	Gain	Loss	Sales amount	Gain	Loss
Year ended December 31, 2010	¥6,363	¥1,828	¥(101)	\$78,085	\$22,437	\$(1,245)

		Millions of Yen	
	Sales amount	Gain	Loss
Nine months ended December 31, 2009	¥2,024	¥10	¥(991)

(3) Impairment losses on valuation of investment securities

The Companies recognized ¥1,473 million (\$18,078 thousand) and ¥537 million in Loss on valuation of investment securities for the year ended December 31, 2010, and the nine months ended December 31, 2009, respectively.

NOTE 14

Derivatives transactions

(1) Hedge accounting not applied to derivative financial instruments

Year ended December 31, 2010		Millions of Yen			Thousands of U.S. Dollars		
Type of transaction	Contract amount	Fair value	Unrealized gain (loss)	Contract amount	Fair value	Unrealized gain (loss)	
Foreign exchange forward contracts							
Selling U.S. dollar	¥3,229	¥ 61	¥ 61	\$ 39,628	\$ 746	\$ 746	
Selling Euro	2,156	59	59	26,453	720	720	
Currency swaps							
Receiving							
Japanese yen,							
Paying U.S. dollar	3,007	75	75	36,897	917	917	
	¥8,392	¥195	¥195	\$102,978	\$2,383	\$2,383	

Nine months ended December 31, 2009		Millions of Yen	
Type of transaction	Contract amount	Fair value	Unrealized gain (loss)
Foreign exchange forward contracts			
Selling U.S. dollar	¥3,273	¥3,337	¥ (64)
Selling Euro	1,919	1,912	6
Currency swaps			
Receiving			
Japanese yen,			
Paying U.S. dollar	3,992	(151)	(151)
	¥9,184	¥5,098	¥(209)

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

(2) Hedge accounting applied to derivative financial instruments

Year ended December 31, 2010		Millions of Yen		Thousands of U.S. Dollars		
Type of transaction	Contract amount	Fair value	Unrealized gain (loss)	Contract amount	Fair value	Unrealized gain (loss)
Foreign exchange forward contracts						
(principle method)						
Selling U.S. dollar	¥ 61	¥ 60	¥(1)	\$ 745	\$ 731	\$ (14)
Selling Euro	28	27	(1)	349	346	(3)
Buying U.S. dollar	252	245	(7)	3,089	3,003	(86)
	¥341	¥332	¥(9)	\$4,183	\$4,080	\$(103)

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

Year ended December 31, 2010		Millions of Yen		Thousands of U.S. Dollars		
Type of transaction	Contract amount	Fair value	Unrealized gain (loss)	Contract amount	Fair value	Unrealized gain (loss)
Foreign exchange forward contracts (exceptional method)						
Selling U.S. dollar	¥1,008	_	*	\$12,366	_	*
Selling Euro	78	_	*	962	_	*
	¥1,086	_	*	\$13,328		*

* The amounts of fair value of gain (loss) on foreign exchange forward contracts (exceptional method) are included in the fair value of accounts receivable.

NOTE 15

Research and Development Expenses

Research and development expenses, all of which were included in selling, general and administrative expenses for the year ended December 31, 2010, the nine months ended December 31, 2009, and the year ended March 31, 2009, totaled ¥44,221 million (\$542,530 thousand), ¥34,980 million and ¥48,389 million, respectively.

NOTE 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, 2010 Location	Description	Classification	Millions of Yen	Thousands of U.S. Dollars
Osaka City, Osaka Prefecture	Lease assets	Land and Equipment, other	¥581	\$7,130
Takaoka City, Toyama Prefecture	Idle assets	Buildings and Equipment, other	559	6,859
Maebashi City, Gunma Prefecture	Idle assets	Land	223	2,737
Osaka City, Osaka Prefecture	Idle assets	Buildings	12	142
Nine months ended December 31, 2009 Location	Description	Classification	Millions of Yen	
Takasaki City, Gunma Prefecture	Idle assets	Buildings and Structures, other	¥2,559	
Hofu City, Yamaguchi Prefecture	Idle assets	Equipment, other	112	

Year ended March 31, 2009 Location	Description	Classification	Millions of Yen
Itabashi-ku, Tokyo	Idle assets	Land	¥3,506
Maebashi City, Gunma Prefecture	Idle assets	Buildings and Structures, other	1,366
Ube City, Yamaguchi Prefecture	Idle assets	Buildings and Equipment, other	386
Takasaki City, Gunma Prefecture	Idle assets	Buildings and Equipment, other	288
Hofu City, Yamaguchi Prefecture	Idle assets	Other	179

NOTE 17

Pledged Assets

(1) The following assets were pledged as collateral for debts and other liabilities at December 31, 2010 and 2009:

	Millio	ns of Yen	Thousands of U.S. Dollars
	2010/12	2009/12	2010/12
Land	¥ 270	¥ 257	\$ 3,308
Investment securities	1,151	1,104	14,123
Other	69	83	857
	¥1,490	¥1,444	\$18,288

(2) Such collateral secured the following obligations:

	Millio	ns of Yen	Thousands of U.S. Dollars
	2010/12	2009/12	2010/12
Notes and accounts payable – trade	¥1,584	¥1,747	\$19,434
Other	100	133	1,227
	¥1,684	¥1,880	\$20,661

NOTE 18

Contingent Liabilities

The Companies had contingent liabilities arising from notes discounted by banks in the amount of ¥30 million (\$371 thousand) at December 31, 2010.

NOTE 19

Supplementary Information for Consolidated Statements of Changes in Net Assets

(1) Type and Number of Outstanding Shares

Type of shares		Year ended December 31, 2010					
	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			
lssued stock:							
Common stock	576,483,555	_	_	576,483,555			
Total	576,483,555	_	_	576,483,555			
Treasury stock:							
Common stock* ^{1, 2}	6,935,900	125,137	369,610	6,691,427			
Total	6,935,900	125,137	369,610	6,691,427			

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

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

		Nine months ended December 31, 2009							
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:									
Common stock	576,483,555	_	_	576,483,555					
Total	576,483,555	_	_	576,483,555					
Treasury stock:									
Common stock* ^{1, 2}	2,589,766	4,446,929	100,795	6,935,900					
Total	2,589,766	4,446,929	100,795	6,935,900					

*1. Treasury stock increased 4,446,929 shares due to the repurchase in response to the shareholders' request under paragraph 1, Article 797 of The Companies Act of Japan, 4,333,000 shares, and the repurchase of shares less than one unit, 113,929 shares.

*2. Treasury stock decreased 100,795 shares due to the stock options exercised, 93,000 shares, and the sale of shares less than one unit, 7,795 shares.

(2) Dividends

The Companies Act of Japan provides that an amount equal to 10% of cash appropriations of retained earnings shall be set aside as additional paid-in capital or legal earnings reserve until the total of such reserve and additional paid-in capital equals 25% of the stated capital. The maximum amount that the Company can distribute as dividends is calculated based on the non-consolidated financial statements of the Company in accordance with Japanese laws and regulations.

1. Dividends paid to shareholders

				Amount				
	Resolution	Type of	Amount	(Thousands of	Per share	Per share		
Date of approval	approved by	shares	(Millions of Yen)	U.S. Dollars)	(Yen)	(U.S. Dollars)	Record date	Effective date
March 24, 2010	Annual general meeting of shareholders	Common stock	¥2,847	\$34,946	¥10	\$0.123	December 31, 2009	March 25, 2010
		Common						
July 28, 2010	Board of directors	stock	5,698	69,929	10	0.123	June 30, 2010	September 1, 2010

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

		Amount								
	Resolution	Resource of	Type of	Amount	(Thousands of	Per share	Per share			
Date of approval	approved by	dividends	shares	(Millions of Yen)	U.S. Dollars)	(Yen)	(U.S. Dollars)	Record date	Effective date	
March 24, 2011	Annual general meeting	Retained	Common	¥5,698	\$69,922	¥10	\$0.123	December 31,	March 25, 2011	
	of shareholders	earnings	stock					2010		

NOTE 20

Related Party Transactions

Significant transactions and balances with related parties as of and for the year ended December 31, 2010, and the nine months ended December 31, 2009 were as follows:

(1) Parent Company

Year ended December 31, 2010									
	Capital	Ratio of		Amo	ounts		Amo	ounts	
		voting rights owning			Thousands of			Thousands of	
Name	Millions of Yen	(owned)	Transactions	Millions of Yen	U.S. Dollars	Closing balances	Millions of Yen	U.S. Dollars	
Kirin Holdings	¥102,045	directly	Loan of funds*1	¥41,287	\$506,653	Short-term	¥53,199	\$652,833	
Company, Limited		(51.1%)				loans receivable			

			Nine months er	nded December 31, 2009		
	Capital	Ratio of		Amounts		Amounts
		voting rights				
		owning			Closing	
Name	Millions of Yen	(owned)	Transactions	Millions of Yen	balances	Millions of Yen
Kirin Holdings	¥102,045	directly	Loan of funds*1	¥48,252	Short-term	¥40,178
Company, Limited		(51.2%)			loans receivable	č

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

(2) Fellow Subsidiaries

Not applicable for the year ended December 31, 2010.

Nine months ended December 31, 2009										
	Capital	Ratio of		Amounts		Amounts				
Name	Millions of Yen	voting rights owning (owned)	Transactions	Millions of Yen	Closing balances	Millions of Yen				
Kirin Engineering Company, Limited	¥1,000	_	Purchase, construction and maintenance operation of equipment	¥7,346 on	Notes and account payable	¥2,644				

(3) Directors of the Companies

Year ended December 31, 2010									
	Ratio of		Amounts						
Name and position	voting right owning (owned)	Transactions	Millions of Yen	Thousands of U.S. Dollars					
Yoshiki Tsunekane Director	directly 0.0%	Disposal of treasury stocks by exercise of stock options*	¥14	\$172					
Manabu Suzuki Corporate auditor	directly 0.0%	Disposal of treasury stocks by exercise of stock options*	¥15	\$184					

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

Not applicable for the nine months ended December 31, 2009.

NOTE 21

Segment Information

(1) Business Segment Information

The Companies operate principally in the following 4 business segments:

Business segments	Major products
Pharmaceuticals Division	Ethical drugs and diagnostic reagents
Bio-Chemicals Division	Pharmaceutical- and industrial-use raw materials, healthcare products, agrochemicals, products for livestock and fisheries industries and alcohol
Chemicals Division	Solvents, raw materials of plasticizers and specialty chemicals
Other Division	Transportation and facilities

		Millions of Yen								
		Bu	usiness segment							
Year ended December 31, 2010	Pharmaceuticals	Bio-Chemicals	Chemicals	Other	Total	Corporate, elimination and other	Consolidated total			
I. Sales and Operating Income:										
Sales to outside customers	¥210,157	¥ 75,578	¥124,361	¥ 3,643	¥413,739	¥ —	¥413,739			
Intersegment sales and transfers	206	8,659	5,657	6,856	21,378	(21,378)	_			
Net sales	210,363	84,237	130,018	10,499	435,117	(21,378)	413,739			
Operating expenses	174,505	80,961	124,340	10,136	389,942	(21,613)	368,329			
Operating income	¥ 35,858	¥ 3,276	¥ 5,678	¥ 363	¥ 45,175	¥ 235	¥ 45,410			
II. Total Assets, Depreciation and Amortization, Impairment Loss and Capital Expenditures:										
Total assets	¥381,350	¥135,338	¥102,313	¥17,660	¥636,661	¥ 59,201	¥695,862			
Depreciation and amortization	10,733	6,733	4,652	73	22,191	(3)	22,188			
Impairment loss	804	559	12	_	1,375	_	1,375			

2,505

15

29,375

(1)

29,374

7,604

			Tho	ousands of U.S. E	Oollars		
		В	usiness segment				
Year ended December 31, 2010	Pharmaceuticals	Bio-Chemicals	Chemicals	Other	Total	Corporate, elimination and other	Consolidated total
I. Sales and Operating Income:							
Sales to outside customers	\$2,578,931	\$ 927,453	\$1,526,084	\$ 44,707	\$5,077,175	\$ —	\$5,077,175
Intersegment sales and transfers	2,522	106,256	69,427	84,132	262,337	(262,337)	_
Net sales	2,581,453	1,033,709	1,595,511	128,839	5,339,512	(262,337)	5,077,175
Operating expenses	2,141,431	993,510	1,525,827	124,381	4,785,149	(265,224)	4,519,925
Operating income	\$ 440,022	\$ 40,199	\$ 69,684	\$ 4,458	\$ 554,363	\$ 2,887	\$ 557,250
II. Total Assets, Depreciation and Amortization, Impairment Loss and Capital Expenditures:							
Total assets	\$4,679,710	\$1,660,788	\$1,255,533	\$216,713	\$7,812,744	\$ 726,495	\$8,539,239
Depreciation and amortization	131,714	82,611	57,090	896	272,311	(29)	272,282
Impairment loss	9,867	6,859	142	_	16,868	_	16,868
Capital expenditures	236,243	93,309	30,739	185	360,476	(13)	360,463

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

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

If the reclassification is reflected in the previous nine months ended December 31, 2009, it becomes as shown on the following page:

19,251

Capital expenditures

				Millions of Yen			
Nine months ended December 31, 2009	Pharmaceuticals	Bio-Chemicals	Chemicals	Other	Total	Corporate, elimination and other	Consolidated total
I. Sales and Operating Income:							
Sales to outside customers	¥157,932	¥63,251	¥85,246	¥2,683	¥309,112	¥ —	¥309,112
Intersegment sales and transfers	342	6,501	3,434	5,114	15,391	(15,391)	
Net sales	158,274	69,752	88,680	7,797	324,503	(15,391)	309,112
Operating expenses	131,616	66,703	90,515	7,548	296,382	(15,514)	280,868
Operating income (loss)	¥ 26,658	¥ 3,049	¥ (1,835)	¥ 249	¥ 28,121	¥ 123	¥ 28,244

Amortization, Impairment Loss

and Capital Expenditures:

Total assets	¥381,819	¥140,916	¥103,448	¥17,043	¥643,226	¥ 52,042	¥695,268
Depreciation and amortization	9,212	4,322	3,413	58	17,005	(2)	17,003
Impairment loss	2,559	112	_		2,671	_	2,671
Capital expenditures	16,508	5,000	3,609	19	25,136	(1)	25,135

Before the reclassification, the previous nine months ended December 31, 2009 is as follows:

				Millions of Yen			
		Bu	isiness segment				
Nine months ended December 31, 2009	Pharmaceuticals	Bio-Chemicals	Chemicals	Other	Total	Corporate, elimination and other	Consolidated total
I. Sales and Operating Income:							
Sales to outside customers	¥157,932	¥ 63,251	¥45,562	¥42,367	¥309,112	¥ —	¥309,112
Intersegment sales and transfers	342	6,501	6,764	7,133	20,740	(20,740)	_
Net sales	158,274	69,752	52,326	49,500	329,852	(20,740)	309,112
Operating expenses	131,616	66,703	54,311	49,100	301,730	(20,862)	280,868
Operating income (loss)	¥ 26,658	¥ 3,049	¥ (1,985)	¥ 400	¥ 28,122	¥ 122	¥ 28,244
II. Total Assets, Depreciation and Amortization, Impairment Loss							

and Capital Expenditures

und capital Experiataics.							
Total assets	¥381,819	¥140,916	¥80,464	¥42,394	¥645,593	¥ 49,675	¥695,268
Depreciation and amortization	9,212	4,322	3,358	113	17,005	(2)	17,003
Impairment loss	2,559	112		_	2,671	_	2,671
Capital expenditures	16,508	5,000	3,583	45	25,136	(1)	25,135

* The Food Division was excluded from segment information. This is due to the abolition of the Food Division in the period, following the sale of shares of a consolidated subsidiary on March 31, 2009, that operated the foods business in the previous fiscal period.

** In conjunction with the change in the closing date of accounts on a consolidated basis for this fiscal period, preparation of the consolidated financial statements for the nine months ended December 31, 2009, involved using financial statements for the twelve month accounting period from January 1, 2009, to December 31, 2009, with respect to 11 consolidated subsidiaries whose financial statements as at their respective closing dates had been used due to their accounts conventionally being closed on December 31 that was within three months before March 31.

As a result, net sales increased ¥357 million in the Pharmaceuticals Division, ¥7,173 million in the Bio-Chemicals Division and ¥4,458 million in the Other Division, while operating income declined ¥60 million in the Pharmaceuticals Division, and increased ¥196 million in the Bio-Chemicals Division and ¥21 million in the Other Division.

				Millions	of Yen			
			Business segr	nent			Corporate, elimination	Consolidated
Year ended March 31, 2009	Pharmaceuticals	Bio-Chemicals	Chemicals	Food	Other	Total	and other	total
I. Sales and Operating Income:								
Sales to outside customers	¥209,760	¥ 77,876	¥77,686	¥38,358	¥56,504	¥460,184	¥ —	¥460,184
Intersegment sales and transfers	689	10,589	11,518	4,111	12,229	39,136	(39,136)	
Net sales	210,449	88,465	89,204	42,469	68,733	499,320	(39,136)	460,184
Operating expenses	175,617	80,123	89,251	41,382	67,639	454,012	(39,215)	414,797
Operating income (loss)	¥ 34,832	¥ 8,342	¥ (47)	¥ 1,087	¥ 1,094	¥ 45,308	¥ 79	¥ 45,387
II. Total Assets, Depreciation and Amortization, Impairment Loss and Capital Expenditures:								
Total assets	¥383,934	¥140,256	¥75,762	¥15,949	¥26,940	¥642,841	¥56,200	¥699,041
Depreciation and amortization	8,394	5,027	4,218	998	150	18,787	(7)	18,780
Impairment loss	3,484	179	_	2,062	_	5,725		5,725
Capital expenditures	9,641	5,376	4,359	566	103	20,045	(1,522)	18,523

* Kyowa Hakko Foods—which belonged to the Food Division—as well as its subsidiaries Kyowa F.D. Foods Co., Ltd., Ohland Foods Co., Ltd. and Kyowa HiFoods Co., Ltd., have been transformed into affiliates accounted for by the equity method in conjunction with the sale of some Kyowa Hakko Foods shares held by the Company on March 31, 2009. However, as such transformation came into effect at the end of the fiscal year, only the statements of income have been prepared on a consolidated basis for the fiscal year. The amount of Total assets of the Food Division for the fiscal year is stated in the amount of investments in such affiliates accounted for by the equity method, etc.

(2) Geographic Segment Information

The classification of geographic segments is as follows:

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

	Millions of Yen						
	(Geographic segment		Corporate,			
Year ended December 31, 2010	Japan	Other	Total	elimination and other	Consolidated total		
I. Sales and Operating Income:							
Sales to outside customers	¥374,383	¥39,356	¥413,739	¥ —	¥413,739		
Intersegment sales and transfers	24,952	10,544	35,496	(35,496)	_		
Net sales	399,335	49,900	449,235	(35,496)	413,739		
Operating expenses	357,351	45,967	403,318	(34,989)	368,329		
Operating income	¥ 41,984	¥ 3,933	¥ 45,917	¥ (507)	¥ 45,410		
II. Total Assets	¥611,240	¥44,896	¥656,136	¥39,726	¥695,862		

	Thousands of U.S. Dollars							
		Geographic segmen	t	Corporate,				
Year ended December 31, 2010	Japan	Other	Total	elimination and other	Consolidated total			
I. Sales and Operating Income:								
Sales to outside customers	\$4,594,214	\$482,961	\$5,077,175	\$ —	\$5,077,175			
Intersegment sales and transfers	306,200	129,379	435,579	(435,579)	_			
Net sales	4,900,414	612,340	5,512,754	(435,579)	5,077,175			
Operating expenses	4,385,208	564,086	4,949,294	(429,369)	4,519,925			
Operating income	\$ 515,206	\$ 48,254	\$ 563,460	\$ (6,210)	\$ 557,250			
II. Total Assets	\$7,500,803	\$550,935	\$8,051,738	\$487,501	\$8,539,239			

	Millions of Yen						
	(Geographic segment		Corporate, elimination	Consolidated		
Nine months ended December 31, 2009	Japan	Other	Total	and other	total		
I. Sales and Operating Income:							
Sales to outside customers	¥275,917	¥33,195	¥309,112	¥ —	¥309,112		
Intersegment sales and transfers	15,792	7,408	23,200	(23,200)	_		
Net sales	291,709	40,603	332,312	(23,200)	309,112		
Operating expenses	267,259	37,244	304,503	(23,635)	280,868		
Operating income	¥ 24,450	¥ 3,359	¥ 27,809	¥ 435	¥ 28,244		
II. Total Assets	¥611,492	¥46,085	¥657,577	¥ 37,691	¥695,268		

* In conjunction with the change in the closing date of accounts on a consolidated basis, preparation of the consolidated financial statements for the nine months ended December 31, 2009 involved using financial statements for the twelve month accounting period from January 1, 2009, to December 31, 2009, with respect to consolidated subsidiaries whose financial statements as at their respective closing dates had been used due to their accounts conventionally being closed on December 31 or within three months of the consolidated closing date.

As a result, net sales increased ¥4,458 million in the Japan Segment and ¥7,528 million in the Other Segment, while operating income increased ¥21 million in the Japan Segment and ¥136 million in the Other Segment.

		Millions of Yen							
	(Geographic segment	Corporate, elimination	Consolidated					
Year ended March 31, 2009	Japan	Other	Total	and other	total				
I. Sales and Operating Income:									
Sales to outside customers	¥423,132	¥37,052	¥460,184	¥ —	¥460,184				
Intersegment sales and transfers	21,021	10,737	31,758	(31,758)	_				
Net sales	444,153	47,789	491,942	(31,758)	460,184				
Operating expenses	404,590	41,326	445,916	(31,119)	414,797				
Operating income	¥ 39,563	¥ 6,463	¥ 46,026	¥ (639)	¥ 45,387				
II. Total Assets	¥615,653	¥43,964	¥659,617	¥ 39,424	¥699,041				

(3) Overseas 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					
Year ended December 31, 2010	America	Europe	Asia	Other areas	Total	
I. Overseas sales	¥23,468	¥21,477	¥39,690	¥507	¥ 85,142	
II. Consolidated net sales					413,739	
III. Ratio of overseas sales to consolidated net sales	5.7%	5.2%	9.6%	0.1%	20.6%	

	Thousands of U.S. Dollars					
Year ended December 31, 2010	America	Europe	Asia	Other areas	Total	
I. Overseas sales	\$287,981	\$263,554	\$487,051	\$6,229	\$1,044,815	
II. Consolidated net sales					5,077,175	
III. Ratio of overseas sales to consolidated net sales	5.7%	5.2%	9.6 %	0.1%	20.6%	

		Millions of Yen				
Nine months ended December 31, 2009	America	Europe	Asia	Other areas	Total	
I. Overseas sales	¥16,850	¥18,524	¥27,416	¥578	¥ 63,368	
II. Consolidated net sales					309,112	
III. Ratio of overseas sales to consolidated net sales	5.5%	6.0%	8.9%	0.2%	20.5%	

	Millions of Yen				
Year ended March 31, 2009	America	Europe	Asia	Other areas	Total
I. Overseas sales	¥31,023	¥22,632	¥34,255	¥860	¥ 88,770
II. Consolidated net sales					460,184
III. Ratio of overseas sales to consolidated net sales	6.8%	4.9%	7.4%	0.2%	19.3%

* In conjunction with the change in the closing date of accounts on a consolidated basis, preparation of the consolidated financial statements for the nine months ended December 31, 2009, involved using financial statements for the twelve month accounting period from January 1, 2009, to December 31, 2009, with respect to 11 consolidated subsidiaries whose financial statements as at their respective closing dates had been used due to their accounts conventionally being closed on December 31 that was within three months before March 31.

As a result, net sales increased ¥1,812 million in America, ¥3,124 million in Europe and ¥1,279 million in Asia.

NOTE 22 Per Share Data

		Yen		U.S. Dollars
	2010/12	2009/12	2009/3	2010/12
Net assets	¥954.6	¥940.8	¥938.4	\$11.714
Net income-basic	39.0	15.4	20.4	0.478
Net income-diluted	38.9	15.4	20.4	0.478

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

NOTE 23

Subsequent Events

(1) Sale of shares of consolidated subsidiary

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

In accordance with the Group's Medium-term Business Plan for the period 2010 to 2012, against a background of intense competition in the market for pharmaceutical products, Kyowa Hakko Kirin aims to rapidly develop its product pipeline through efficient utilization of the operating resources, while selecting and concentrating its business portfolio to create a business platform capable of achieving sustained growth. of common stock outstanding each year after giving effect to the dilutive potential of shares of common stock to be issued upon the exercise of share subscription rights.

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

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

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

Overview of sale of shares of consolidated subsidiary

Subsidiary sold	Kyowa Hakko Chemical Co., Ltd.
Transferee	KJ Holdings Inc.
Transfer date	In late March, 2011
Number on shares	22,264,000 shares
Investment ratio after selling shares	-%
Proceeds	¥60,000 million of appraised business value of Kyowa Hakko Chemical plus the total amount of cash and deposits of both companies; Kyowa Hakko Chemical and its subsidiary Miyako Kagaku Co., Ltd. at the date of selling shares, minus the total amount of debt of those two companies at the same date and considering other adjustments.
Business segment of the subsidiary	Chemicals segment

(2) Sale of shares of an affiliate

At the meeting of the Board of Directors held on October 21, 2008, the Board passed a resolution to conclude an "Agreement to Integrate Food Products Businesses" aimed at integrating the food products businesses of the Company's wholly owned subsidiary Kyowa Hakko Foods and Kirin Holdings' wholly owned subsidiary Kirin Food-Tech and the Company entered into the agreement on the said date of the Board meeting.

Kyowa Hakko Foods and Kirin Food-Tech subsequently merged on April 1, 2009. The new company's trade name was changed to Kirin Kyowa Foods Company, Limited.

Under the above-mentioned "Agreement to Integrate the Food Products Businesses," the Company sold all of the remaining 474 shares of Kirin Kyowa Foods Company, Limited to Kirin Holdings for ¥14,987 million (\$183,912 thousand) on January 1, 2011. As a result, the Company will recognize a gain on sales of investment in subsidiaries and affiliates' stocks of ¥4,700 million (\$57,676 thousand) for the year ending December 31, 2011.

(3) Agreement of starting procedure purchasing shares of ProStrakan Group plc

On February 21, 2011, the Company and ProStrakan Group plc ("ProStrakan") announced that they have reached agreement on the terms of the recommended cash acquisition by the Company of the entire issued and to be issued share capital of ProStrakan (the "Acquisition"). Under the terms of the Acquisition, ProStrakan shareholders will be entitled to receive 130 pence in cash for each ProStrakan share, valuing the entire issued and to be issued ordinary share capital of ProStrakan at approximately \pounds 292 million.

Based in Galashiels, UK, ProStrakan is a fast-growing specialty pharmaceutical company engaged in the development and commercialization of prescription medicines for the treatment of unmet therapeutic needs in major markets.

The Company believes that the Acquisition would represent a key strategic milestone in our development and could provide the Company with an established European and US marketing and sales platform, together with a portfolio of proprietary products.

It is intended that the Acquisition will be implemented by way of a court sanctioned scheme of arrangement.

As for this matter, it is scheduled to be completed in the second quarter of the year ending December 31, 2011.

Name of the company	ProStrakan Group plc
Business of the company	Sales, marketing and development of pharmaceuticals
Location of offices	Galashiels, United Kingdom
Stock listing	Main Market of the London Stock Exchange
Capital stock	£10.1 million as at December 31, 2009
Number of fully diluted outstanding shares	224,332,026 fully diluted ProStrakan shares as at February 18, 2011
Consolidated revenues	£79.0 million for the year ended December 31, 2009
Consolidated total assets	£78.1 million as at December 31, 2009

Overview of ProStrakan

Report of Independent Auditors

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

Report of Independent Auditors

The Board of Directors Kyowa Hakko Kirin Co., Ltd.

We have audited the accompanying consolidated balance sheets of Kyowa Hakko Kirin Co., Ltd. and consolidated subsidiaries as of December 31, 2010 and 2009, and the related consolidated statements of income, changes in net assets, and cash flows for the year ended December 31, 2010, the nine months ended December 31, 2009 and the year ended March 31, 2009, all expressed in yen. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in Japan. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Kyowa Hakko Kirin Co., Ltd. and consolidated subsidiaries at December 31, 2010 and 2009, and the consolidated results of their operations and their cash flows for the year ended December 31, 2010, the nine months ended December 31, 2009 and the year ended March 31, 2009, in conformity with accounting principles generally accepted in Japan.

Supplemental Information

As described in NOTE 23 (1) to the consolidated financial statements, at the meeting of the Board of Directors held on January 28, 2011, the Board passed a resolution to conclude the transfer of the entire shares of Kyowa Hakko Chemical Co., Ltd. to KJ Holdings Inc., a special purpose company established and managed by Japan Industrial Partners, Inc. and other investors. On the same day, the Company signed an assignment agreement for selling all these shares with KJ Holdings Inc. and Japan Industrial Partners, Inc.

As described in NOTE 23 (2) to the consolidated financial statements, the Company sold all shares of Kirin Kyowa Foods Company, Limited to Kirin Holdings on January 1, 2011.

The U.S. dollar amounts in the accompanying consolidated financial statements with respect to the year ended December 31, 2010 are presented solely for convenience. Our audit also included the translation of yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made on the basis described in Note 3.

Ernst & young Shin Nikon LLC

March 16, 2011

Principal Subsidiaries and Affiliates As of December 31, 2010

Name of Company	Percentage Owned Directly or Indirectly by the Company	Capital Stock (Millions)	Principal Business	
PHARMACEUTICALS				
Kyowa Medex Co., Ltd. ¹	100.0%	¥450	Manufacture and sale of diagnostic reagents	
Kirin Kunpeng (China) Bio-Pharmaceutical Co., Ltd.¹	100.0%	CNY 247	Manufacture and sale of pharmaceuticals	
Kyowa Medical Promotion Co., Ltd. ¹	100.0%	¥50	Sales promotion of pharmaceuticals	
Kyowa Hakko Kirin America, Inc.	100.0%	\$76	Holding company for managing subsidiaries in the United States	
BioWa, Inc. ¹	100.0%	\$10	Licensing of antibody technology	
Kyowa Hakko Kirin Pharma, Inc. ¹	100.0%	\$0.1	Development of pharmaceuticals	
Kyowa Hakko Kirin California, Inc. ¹	100.0%	\$0.1	Discovery of new drug candidates	
Hematech, Inc. ¹	100.0%		Research of base technology for production of therapeutic antibodies	
Hematech-GAC Venture, LLC ¹	51.0%	—	Research of base technology for production of therapeutic antibodies	
Jeil-Kirin Pharmaceutical Inc. ¹	90.0%	KRW 2,200	Sale of pharmaceuticals	
Kyowa Hakko Kirin (Taiwan) Co., Ltd. ¹	100.0%	NT\$12	Sale of pharmaceuticals	
Kyowa Hakko Kirin (Hong Kong) Co., Ltd. ¹	100.0%	HK\$6	Sale of pharmaceuticals	
Kyowa Hakko Kirin (Singapore) Pte. Ltd. ¹	100.0%	\$1	Sale of pharmaceuticals	
Kyowa Hakko Kirin Italia S.r.l.	100.0%	€0.7	Sale of pharmaceuticals	
	·			
BIO-CHEMICALS Kyowa Hakko Bio Co., Ltd. ¹	100.0%	¥10,000	Manufacture and sale of raw materials for pharmaceuticals and industrial use and health care products	
Daiichi Fine Chemical Co., Ltd.	100.0%	¥6,276	Manufacture and sale of bulk pharmaceuticals and intermediates	
Biokyowa Inc. ¹	100.0%	\$20	Manufacture and sale of amino acids	
Shanghai Kyowa Amino Acid Co., Ltd. ¹	70.0%	CNY 156	Manufacture and sale of amino acids	
Kyowa Hakko U.S.A., Inc. ¹	100.0%	\$1	Import, export, and sale of amino acids and fine chemicals	
Kyowa Hakko Europe GmbH ¹	100.0%	€1	Import, export, and sale of amino acids and fine chemicals	
Kyowa Hakko Bio Italia S.r.l. ¹	100.0%	€0.7	Import, export, and sale of amino acids and fine chemicals	
Kyowa Hakko Bio Singapore Pte. Ltd.	100.0%	\$4	Import, export, and sale of amino acids and fine chemicals	
Kyowa Hakko (H.K.) Co., Ltd. ¹	100.0%	HK\$1	Import, export, and sale of amino acids and fine chemicals	
Kyowa Hakko Bio U.S. Holdings, Inc. ¹	100.0%	\$0.001	Holding company for managing subsidiaries in the United States	
Kyowa Wellness Co., Ltd. ¹	100.0%	¥30	Sale of health care products	
Shinwa Pharmaceutical Co., Ltd. ¹	100.0%	¥95	Manufacture and sale of herbal medicines and health foods	
Kyowa Engineering Co., Ltd. ¹	100.0%	¥70	Design and installation of equipment and facilities	
CHEMICALS ³				
Kyowa Hakko Chemical Co., Ltd. ¹	100.0%	¥5,320	Manufacture and sale of petrochemicals	
J-PLUS Co., Ltd. ²	50.0%	¥480	Manufacture and sale of plasticizers	
Kurogane Kasei Co., Ltd. ²	40.0%	¥90	Manufacture and sale of plasticizers and fine chemicals	
Miyako Kagaku Co., Ltd. ^{1,4}	100.0%	¥111	Wholesale of pharmaceuticals, chemicals, and foods	
Kashiwagi Corporation ^{1,4}	100.0%	¥90	Wholesale of pharmaceuticals and chemicals	
OTHER				
Chiyoda Kaihatsu Co., Ltd. ¹	100.0%	¥113	Transportation, insurance, and wholesale of foods	
Japan Synthetic Alcohol Co., Ltd. ²	33.3%	¥480	Manufacture and sale of industrial-use alcohol	
Kirin Kyowa Foods Company, Limited ²	35.0%	¥3,000	Manufacture and sale of industrial-use alconor Manufacture and sale of seasonings and bakery products and ingredients	
Kirin Kyowa FD Co., Ltd. ²	35.0%	¥100	Manufacture and sale of freeze-dried foods	
Kirin Ohland Foods Co., Ltd. ²	35.0%	¥50	Manufacture and sale of foods	
Aji Nihon Co., Ltd. ²	16.2%	¥95	Manufacture and sale of foods and seasonings	
Zenmi Foods Inc. ²	17.5%	¥190	Manufacture and sale of seasonings	

Consolidated subsidiary
Affiliate accounted for by the equity method

3. In April 2011, Chemicals operations were transferred to KJ Holdings Inc.

4. Transferred to the Chemicals segment from the Other segment, effective January 1, 2010

Overseas Network

16 24

(11)

10 25 26 32

(17)28(13)27

(15)

14 31

Pharmaceuticals

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

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

BioWa, Inc. (3)

212 Carnegie Center, Suite 101, Princeton, NJ 08540, U.S.A. TEL: 1-609-580-7500 FAX: 1-609-580-7534

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

Hematech, Inc. 05

4401 South Technology Drive, Sioux Falls, SD 57106, U.S.A. TEL: 1-605-361-6793 FAX: 1-605-361-9702

Hematech-GAC Venture, LLC 66

3483 US 75 Avenue, Hull, IA 51239, U.S.A. TEL: 1-712-722-4130 FAX: 1-712-722-4965 Kirin-Amgen, Inc. (7) 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

0923

Kyowa Hakko Kirin UK Ltd. (8) 258 Bath Road, Slough,

Berkshire SL1 4DX, United Kingdom TEL: 44-1753-566000 FAX: 44-1753-566010

Kyowa Hakko Kirin Italia S.r.l. 🛞

Viale Piero e Alberto Pirelli, 6, 20126 Milan, Italy TEL: 39-02-644-704-1 FAX: 39-02-644-704-33

Kirin Kunpeng (China) Bio-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

Jeil-Kirin Pharmaceutical Inc. (1)

5F, Poonglim B/D, 823 Yeoksam-Dong, Kangnam-Ku, Seoul 135-080, Republic of Korea TEL: 82-2-3471-4321 FAX: 82-2-3471-4322 Kyowa Hakko Kirin (Taiwan) Co., Ltd. (2) 9F, No.44, Sec 2, Chung Shan N. Road, Taipei 10448, Taiwan TEL: 886-2-2564-2800 FAX: 886-2-2560-1667

Kyowa Hakko Kirin

(Hong Kong) Co., Ltd. (3) 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

Kyowa Hakko Kirin

(Singapore) Pte. Ltd. (2) 260 Orchard Road, #07-06, The Heeren, 238855 Singapore TEL: 65-6836-3991 FAX: 65-6836-3928

Kyowa Hakko Kirin

(Thailand) Co. Ltd. (19) 323 United Center Building, 20th Floor, Room 2003B Silom Road, Silom, Bangrak, Bankok 10500, Thailand TEL: 66-2631-2126 FAX: 66-2631-2125 Bio-Pharmaceutical Co., Ltd. (i) Beijing Representative Office Room 702, Beijing Fortune Bldg., No. 5, Dong San Huan Bei Lu, Chao Yang District Beijing 1000

Kirin Kunpeng (China)

Chao Yang District, Beijing 100004, People's Republic of China TEL: 86-10-6410-7070 FAX: 86-10-6590-9640

Kirin Kunpeng (China)

Bio-Pharmaceutical Co., Ltd. (17) Guangzhou Branch Room 1806, The Centrepoin, 374-2 Beijing road, Guangzhou, 510030 People's Republic of China (18) (01)(02)(03) (20)(21)

Bio-Chemicals

Kyowa Hakko U.S.A., Inc. (18) 767 Third Avenue, 19th Floor, New York, NY 10017, U.S.A. TEL: 1-212-319-5353 FAX: 1-212-421-1283

Kyowa Hakko U.S.A., Inc. West Coast Office (19) 85 Enterprise, Suite 430, Aliso Viejo, CA 92656, U.S.A. TEL: 1-949-425-0707 FAX: 1-949-425-0708

Kyowa Hakko Bio U.S. Holdings, Inc. @ 5469 Nash Road, P.O. Box 1550, Cape Girardeau, MO 63702-1550, U.S.A. TEL: 1-573-335-4849 FAX: 1-573-335-1466

Biokyowa Inc. 2) Head Office & Plant 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

Kyowa Hakko Europe GmbH (2) Am Wehrhahn 50, D-40211 Düsseldorf, Germany

TEL: 49-211-17545-0

FAX: 49-211-17545-441

Kyowa Hakko Bio Italia S.r.l. 🗵

Viale Piero e Alberto Pirelli, 6, 20126, Milan, Italy TEL: 39-02-367-069-01 FAX: 39-02-644-704-44

Kyowa Hakko Bio Co., Ltd. Beijing Representative Office Kyowa Hakko Bio (Shanghai) Trading Co., Ltd. (24)

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

Kyowa Hakko Bio Co., Ltd. Shanghai Representative Office Kyowa Hakko Bio (Shanghai)

Trading Co., Ltd. (2) Shanghai Representative Office Room 1501-1502, Metro Plaza, No. 555 Lou Shan Guan Road Chang Ning District, Shanghai, 200051, People's Republic of China TEL: 021-6233-1919 FAX: 021-6233-6067

Shanghai Kyowa

Amino Acid Co., Ltd. (3) No. 158, Xintuan Road, Qingpu Industrial Zone, Shanghai 201700, People's Republic of China TEL: 86-21-5970-1998 FAX: 86-21-5970-1135 Kyowa Hakko (H.K.) Co., Ltd. ② Room 1501, 68 Yee Wo Street, Causeway Bay, Hong Kong, People's Republic of China TEL: 852-2895-6795 FAX: 852-2576-6142

Kyowa Hakk<mark>o Bio (Shanghai)</mark>

Trading Co., Ltd. (28) 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

Kyowa Hakko Bio India Pvt., Ltd. Kyowa Hakko Bio Co., Ltd. (29)

Mumbai Liaison Office 65, 3 North Avenue, Maker Maxity, Bandra Kurla Complex, Bandra (East), Mumbai 400051, India TEL: 91-22-6725-3457 FAX: 91-22-6725-3458

Kyowa Hakko Bio

Singapore Pte Ltd ⁽³⁾ 47 Scotts Road, #12-05, Goldbell Towers, 228233 Singapore TEL: 65-6732-7889 FAX: 65-6732-7989

Chemicals Kyowa Hakko Industry (S)

Pte Ltd. ③ 260 Orchard Road, #12-04, The Heeren, 238855 Singapore TEL: 65-6733-4948 FAX: 65-6733-0819

Kyowa Hakko Chemical Co., Ltd. 32

Shanghai Representative Office Room 908, MaxDo Bldg., No. 8 Xingyi Road, Changning District, Shanghai 200336, People's Republic of China TEL: 86-21-5208-0009 FAX: 86-21-5208-0130

Corporate Data

As of December 31, 2010

Kyowa Hakko Kirin Co., Ltd. Head Office

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

Number of Employees 7,484 (Parent Company: 4,303)

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)

<mark>Chemicals</mark> Yokkaichi, Chiba

Overseas

Pharmaceuticals Kirin Kunpeng (China) Bio-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

- Antibody Research Laboratories
- Innovative Drug Research Laboratories
- Fuji Research Park
 - Drug Discovery Research Laboratories
 - Pharmacological Research Laboratories
 - Medicinal Chemistry Research Laboratories
 - Pharmacokinetic Research Laboratories
 - Toxicological Research Laboratories

Bio Process Research and Development Laboratories Chemical Process Research and Development Laboratories Drug Formulation Research and Development Laboratories Kyowa Medex Co., Ltd. Research Laboratories

Bio-Chemicals Technical Research Laboratories Tsukuba Development Center

Chemicals Yokkaichi Research Laboratories

Overseas

Pharmaceuticals Kyowa Hakko Kirin Pharma, Inc. (U.S.A.) Hematech, Inc. (U.S.A.) Kyowa Hakko Kirin California, Inc. (U.S.A.) Kyowa Hakko Kirin UK Ltd. (U.K.) Kirin Kunpeng (China) Bio-Pharmaceutial Co., Ltd. (China) Jeil-Kirin Pharmaceutical Inc. (South Korea) Kyowa Hakko Kirin (Taiwan) Co., Ltd. (Taiwan)

Investor Information

As of December 31, 2010

Stock Listing

Tokyo

Securities Code Number 4151

Transfer Agent of Common Stock

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

Number of Shares of Common Stock

Authorized: 987,900,000 576,483,555 Issued:

Number of Shareholders

44,509

Principal Shareholders

	Number of Shares Held (Thousands)	Percentage of Total Shares Issued
Kirin Holdings Company, Limited	288,819	50.10
The Master Trust Bank of Japan, Ltd. (Trust account)	22,839	3.96
Japan Trustee Services Bank, Ltd. (Trust account)	18,165	3.15
The Norinchukin Bank	10,706	1.86
Mizuho Trust & Banking Co., Ltd. (Retirement Benefit Trust for Mizuho Bank, Ltd.) 1	4,781	0.83
The Nomura Trust and Banking Co., Ltd.	4,512	0.78
JPMorgan Securities Japan Co., Ltd.	4,184	0.73
State Street Bank and Trust Company	4,029	0.70
Japan Trustee Services Bank, Ltd. (Trust account 7)	4,027	0.70
Juniper	3,787	0.66

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 6,691 thousand shares (1.16%) held by the Company as treasury stock are excluded from above because treasury stock has no voting rights.



Stock Price

Kyowa Hakko Kirin Co., Ltd.

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





