

## 1. Operating Results and Financial Position

### I. Summary of Operating Results

#### 1) Operating results for the fiscal year ended March 31, 2009

	<i>Billions of yen</i>		
	Consolidated results for the period ended March 31, 2009	Consolidated results for the period ended March 31, 2008	Change
Net sales	460.1	392.1	68.0
Operating income	45.3	39.3	5.9
Recurring income	46.4	37.9	8.4
Net income	11.7	23.4	(11.7)

During the consolidated fiscal year under review, the worldwide recession, caused by the deepening financial crisis that stemmed from the sub-prime problem in the US, spread to the domestic economy. Corporate profits revenues came under pressure from a strong yen and sagging share prices, while worsening employment conditions resulted in a sharp deterioration in Japan's economy.

In the Group's operating environment, conditions in the Pharmaceuticals business remained severe as competition from foreign pharmaceutical companies and from the development of new pharmaceutical products intensified on a global scale. Further, in addition to a price reduction averaging 5.2% implemented in April, control of medical treatment costs strengthened as the promotion and diffusion of generic drugs and other measures were further developed. The Bio-Chemicals business was impacted by the steep rise in price of raw material sugars resulting from activation of bio-ethanol production and the rapid appreciation of the yen. In the Chemicals business, the product market significantly worsened as demand rapidly decreased due to the global economic downturn amidst volatile swings in the prices of oil and naphtha. In the Food business, further emphasis was placed on initiatives to ensure food safety and security, and difficulties in the earnings environment became increasingly severe due to the steep rise in the price of raw materials and sluggish consumer spending.

Against this background we strived to implement our action plan aimed towards quickly achieving Group synergies. Based on our three-year medium-term business plan we will seek to realize the Kyowa Hako Kirin Group vision of becoming a world-class R&D-based life sciences group, based on biotechnology and with pharmaceuticals as our core business.

In the fiscal year ended March 31, 2009 consolidated net sales increased 17.4% to ¥460.1 billion affected by the consolidation of Kirin Pharma. Operating income was ¥45.3 billion, an increase of 15.2%; recurring income was ¥46.4 billion, an increase of 22.2%; and net income was ¥11.7 billion, a decrease of 50.0% due to recording an extraordinary loss of ¥21.5 billion in evaluation of marketable securities, impairment losses and other items.

## 2) Segmental Review

### Pharmaceuticals

	<i>Billions of yen</i>		
	Consolidated results for the period ended March 31, 2009	Consolidated results for the period ended March 31, 2008	Change
Net sales	210.4	138.3	72.0
Operating income	34.8	19.9	14.8

In the Pharmaceuticals business, consolidated net sales increased 52.1% to ¥210.4 billion and operating income increased 74.5% to ¥34.8 billion. Sales of pharmaceutical products in Japan were significantly higher compared to the previous fiscal year due to the consolidation of Kirin Pharma from April 2008 and despite the effect of reductions in National Health reimbursement prices.

As regards products, despite a decline in sales of Durotep, an analgesic for persistent cancer pain, due to the ending of a joint sales contract, strong sales were maintained by Allelock, an antiallergic agent, Depakene, an anti-epileptic agent, and Patanol, an antiallergic ophthalmic solution, while sales of Coversyl, an ACE inhibitor for treatment of hypertension, that commenced in April, 2008, also performed well and contributed to growth in sales. In addition, the combined market share of Kirin Pharma's two core anemia products, NESP and ESPO, increased steadily following our integration with Kirin Pharma in October 2008. Meanwhile, REGPARA Tablets, a treatment for secondary hyperthyroidism during dialysis therapy, are achieving steady market penetration.

In the licensing-out of technologies and export of pharmaceutical products a large one-off contract payment for the outlicensing to Amgen of anti-CCR4 humanized monoclonal antibody KW-0761 was recorded, resulting in a large increase in sales. At subsidiary Kyowa Medex, which is responsible for the manufacture and sale of diagnostic reagents, sales of both clinical chemistry reagents and immunological reagents increased, and its sales grew compared to the previous fiscal year.

In new drug development in Japan, applications in respect of anemia treatment NESP were made for additional indications for anemia for cancer chemotherapy in November 2008 and for additional indications for pre-dialysis renal anemia in December 2008. Phase III clinical trials are progressing for KW-2246, an analgesic for cancer pain and Phase II clinical trials are being carried out on KRN125 a treatment for neutropenia, KW-6002, an anti-Parkinson's disease treatment, KW-6500, also an anti-Parkinson's disease treatment, and KW-7158, a candidate treatment for irritable bowel syndrome. KW-0761, a blood cancer treatment (an antibody pharmaceutical), KW-3357, an agent for inhibiting blood coagulation, and ARQ 197, an anticancer agent, are in Phase I clinical trials.

Overseas, in the U.S. Phase I trials are progressing for anticancer agents KRN330 (an antibody pharmaceutical) and KW-2449, while Phase I trials for hypophosphatemic treatment KRN-23 (an antibody pharmaceutical), organ transplant immunological rejection depression treatment ASKP 1240 (an antibody pharmaceutical) and anticancer agent BIW-8962 (an antibody pharmaceutical) have begun. In Europe, Phase I trials are progressing for anticancer agent KW-2478. In Australia, joint Phase I trials with ARCA biopharma, Inc. (formerly Nuvelo, Inc.) of the U.S., for inflammatory bowel disease treatment NU-206 have begun, while in China we received approval in September 2008 for the additional indication of angina pectoris for Coniel, and filed applications for approval of hyperphosphatemia treatment Phosblock in June 2008, and for Allelock, an antiallergic agent, in July 2008.

## Bio-Chemicals

	<i>Billions of yen</i>		
	Consolidated results for the period ended March 31, 2009	Consolidated results for the period ended March 31, 2008	Change
Net sales	88.4	86.8	1.6
Operating income	8.3	9.6	(1.3)

In the Bio-Chemicals business, net sales increased 1.9% to ¥88.4 billion, while operating income decreased 13.9% to ¥8.3 billion due to the rapid appreciation of the yen. Sales volumes of pharmaceutical and industrial use raw materials, particularly amino acids, nucleic acids and related compounds continued to grow steadily, but sales declined slightly due to the stronger yen in the second half of the fiscal year.

In healthcare products, revenues increased over the previous consolidated fiscal year due to firm growth of sales of dietary supplement amino acids overseas and steady growth in mail-order sales of the Remake series. In agrochemicals and products for the livestock and fisheries industry, sales decreased due to intensifying competition in agrochemicals in overseas markets and sluggish sales in the livestock and fisheries industries due to a rapid appreciation of the price of feed and raw materials and fuel. In alcohol, revenues were lower than in the previous year despite efforts to expand sales primarily in industrial use alcohol.

In R&D, we focused on new products and continued to improve the efficiencies of fermentation production aimed at reducing the production cost of amino acids, nucleic acids and related compounds. Further, we continued to focus on synthesis process research at Daiichi Fine Chemical, and on the discovery of functionalities and the development of applications for a wide-range of amino acids and other compounds at the Healthcare Products Development Center.

## Chemicals

	<i>Billions of yen</i>		
	Consolidated results for the period ended March 31, 2009	Consolidated results for the period ended March 31, 2008	Change
Net sales	89.2	108.0	(18.8)
Operating income	(0)	7.1	(7.2)

In the Chemicals business, net sales decreased 17.4% to ¥89.2 billion, while operating income was ¥0.0 billion (operating income for the previous fiscal year was ¥7.1 billion). In the first half of the year product prices were adjusted in response to higher raw materials and fuel prices and there was steady growth in functional environmental products such as refrigerant oil raw materials and high-purity solvents for electronic materials. In the second half of the fiscal year, both domestic and overseas sales volumes decreased significantly as demand rapidly dropped against a backdrop of global recession stemming from the financial crisis in the U.S. In addition, a sharp drop in sales resulting from a major downturn in the product market due to a rapid fall in the price of raw materials and fuel, including naphtha and crude oil, caused an extremely severe operating environment.

## Food

	<i>Billions of yen</i>		
	Consolidated results for the period ended March 31, 2009	Consolidated results for the period ended March 31, 2008	Change
Net sales	42.4	43.3	(0.8)
Operating income	1.0	1.5	(0.4)

In the Food business, sales decreased 2.0% to ¥42.4 billion, while operating income decreased 31.1% to ¥1.0 billion. In seasonings, sales of natural seasonings declined due to a rise in the price of raw materials and sluggish consumer spending, but growth in sales of *Umami* seasonings led to an increase in sales. In bakery products and ingredients, sales were lower than in the previous year as a result of factors such as the suspension of product sales due to high raw material prices for processed dairy foods and others, and despite growth in sales of core products including yeast and flavor enhancers. In processed foods, sales were lower than the previous year due to a decrease in instant noodle ingredients and others.

## Other

	<i>Billions of yen</i>		
	Consolidated results for the period ended March 31, 2009	Consolidated results for the period ended March 31, 2008	Change
Net sales	68.7	48.9	19.7
Operating income	1.0	0.8	0.2

In the Other business segment, due partly to the new consolidation of Kashiwagi Corporation, sales increased 40.3% to ¥68.7 billion, while operating income increased 30.5% to ¥1.0 billion.

### 3) Outlook for Fiscal 2009

	<i>Billions of yen</i>		%
	FORECAST	Change compared to the	Change compared to the
	Fiscal period ending December 31, 2009	previous fiscal period (Amount)	previous fiscal period (%)
Net sales	300.0	(62.2)	(17.2%)
Operating income	27.0	(15.6)	(36.8%)
Recurring income	27.5	(15.7)	(36.4%)
Net income	13.0	2.5	24.0%

(These figures assume an average exchange rate of ¥90 to the U.S. dollar and ¥120 to the Euro)  
Kyowa Hakko Kirin plans to change its fiscal year-end from March 31 to December 31. As a result, the consolidated forecast is for the nine-month fiscal period from April 1, 2009 to December 31, 2009 that will result from this change. The figures for the financial results of the nine-month period from the previous fiscal year (April 1, 2008 to December 31, 2008) have been provided for comparative reference.

In the nine-month period of fiscal 2009 we expect the domestic economy to continue to worsen. Furthermore, concerns that the global financial crisis may worsen and the global economy may perform below current expectations, as well as the effects of volatility on the equity and foreign exchange markets, etc., mean that there remains the risk of further downward pressure on the economy, and the outlook remains very uncertain.

In this environment, the Kyowa Hakko Kirin Group will undertake business reform initiatives to enhance competitiveness and strengthen operations, enhance R&D efficiencies while proactively investing business resources in our core Pharmaceuticals and Bio-Chemicals businesses and aiming for further growth to strengthen revenues.

Our consolidated financial results forecasts for the next term (the nine-month period from April 1, 2009 to December 31, 2009) are for net sales of ¥300.0 billion, a decrease of 17.2%, operating income of ¥27.0 billion, a decrease of 36.8% and recurring income of ¥27.5 billion, a decrease of 36.4%. As extraordinary losses are expected to decline significantly, net income is forecast to increase 24.0% to ¥13.0 billion.

In the Pharmaceuticals business, we forecast a decrease in both sales and profits compared to the previous fiscal period. We forecast an increase in sales of domestic pharmaceutical products over the previous year due to growth of core products such as anemia products *NESP* and *ESPO*, *REGPARA* Tablets, a treatment for secondary hyperthyroidism during dialysis therapy, *Allelock*, an antiallergic agent, and *Patanol*, an antiallergic ophthalmic solution. However, regarding the export of pharmaceutical products and licensing out of technology, the absence of a large one-off contract payment from a licensing contract with Amgen that was recorded under sales in the previous fiscal period, will have a significant impact, as will the expected decrease in revenues from the effects of a strong yen.

In the Bio-Chemicals business, we are forecasting growth in domestic and overseas sales volumes of core amino acids, nucleic acids and related compounds, however due to expected downward pressure on revenues from a strong yen and other factors, we expect revenues to be higher but profits to be lower than in the previous period. In addition, following the planned change of the Kyowa Hakko Kirin fiscal year end, there will no longer be a three-month disparity in consolidation of overseas subsidiaries with a December year end. As a result, financial results of the corresponding overseas subsidiaries for the 12-month period (January 1, 2009 to December 31, 2009) will be consolidated in the fiscal period ending December 2009.

In the Chemicals business we are forecasting a continued difficult operating environment, as demand remains depressed due to the global economic downturn. As regards product prices, compared to the previous period when price revisions were implemented following a steep rise of crude oil and naphtha prices, we expect lower price levels, so we are forecasting a significant decrease in sales and operating income compared to the previous nine-month period.

In the Food business, following the sale of a portion of the shares held by Kyowa Hakko Kirin in Kyowa Hakko Foods on March 31, 2009, Kyowa Hakko Foods and three of its consolidated subsidiaries are no longer consolidated subsidiaries of Kyowa Hakko Kirin and are now affiliated companies accounted for using the equity method. As a result, net sales and operating income for the Food business will not be reported for the nine-month period ending December 31, 2009. For the nine-month period ended December 31, 2008 net sales for the Food business was ¥32.8 billion and operating income was ¥0.9 billion.

\*The above forecasts are based on information available and assumptions made at the time of release of this document about a number of uncertain factors that can affect results in the future. It is possible that actual results are materially different for a wide variety of reasons.

## **II. Summary of Financial Position**

### **1) Assets, Liabilities, and Net Assets**

Total assets as of March 31, 2009 were ¥699.0 billion, an increase of ¥304.9 billion compared to the end of the previous fiscal year, largely due to the share exchange with Kirin Pharma on April 1, 2008. Since the business integration with Kirin Pharma was deemed a reverse acquisition upon exchange of shares, this reflects changes during the fiscal year, including ¥96.8 billion in consolidated total assets of Kirin Pharma as of the beginning of fiscal 2008 and Kyowa Hakko's consolidated total assets at market value.

Current assets increased by ¥46.8 billion compared to the end of the previous consolidated fiscal year to

¥279.4 billion as a result of increases in parent company short-term loans, cash and time deposits and others items. Fixed assets increased by ¥258.1 billion to ¥419.5 billion. Following the reverse acquisition ¥191.9 billion of goodwill was recorded and of this amount, ¥9.5 billion was amortized during the fiscal year. Market valuation appraisal differences arising from the reverse acquisition of ¥67.4 billion in respect of land and investments in marketable securities were also recorded.

Liabilities increased ¥18.6 billion to ¥155.9 billion. As a result of the market valuation of land and other items following the reverse acquisition, deferred tax liabilities increased as did retirement benefit allowance and other items. Net assets at the end of the period were ¥543.0 billion, up ¥286.3 billion. This was due to the inclusion of Kirin Pharma's consolidated net assets (¥64.6 billion) and the market value of Kyowa Hakko's consolidated net assets (the acquisition cost of Kyowa Hakko as the surviving company), as of the beginning of fiscal 2008, and reflects in changes during the fiscal year. As a result, the shareholders' equity ratio as of the end of the fiscal year was 77.0%, an increase of 12.5 percentage points compared to the end of the previous fiscal year.

## 2) Cash Flow Summary

	<i>Billions of yen</i>		
	Fiscal year ended March 31, 2009	Fiscal year ended March 31, 2008	Change
Cash flows from operating activities	41.0	30.7	10.3
Cash flows from investing activities	(3.9)	(9.4)	5.5
Cash flows from financing activities	(20.9)	(13.4)	(7.4)
Cash and cash equivalents at end of period	69.2	44.1	25.1

Cash and cash equivalents as of March 31, 2009 were ¥69.2 billion. Accounting regulations for business integration deem the April 1, 2008 share exchange a reverse acquisition and therefore this includes the balance of cash and cash equivalents of Kirin Pharma as of the beginning of the consolidated fiscal year (¥10.4 billion) and the increase in cash and cash equivalents following consolidation of ¥43.7 billion (including Kyowa Hakko's balance of ¥44.1 billion of cash and cash equivalents as of the end of the previous consolidated fiscal year) and reflects changes during the consolidated fiscal year.

As a result, cash and cash equivalents increased ¥15.0 billion during the fiscal year (Note: Compared to the balance of cash and cash equivalents at March 31, 2008 of ¥44.1 billion, this represents an increase of ¥25.1 billion. The main contributing factors affecting cash flow during the fiscal year were as follows:

Net cash provided by operating activities increased 33.7% compared to the previous fiscal year to ¥41.0 billion. The main inflows included net income before income taxes of ¥30.9 billion, depreciation of ¥18.7 billion, and goodwill amortization of ¥9.8 billion. The main outflows included corporate etc. tax payments of ¥20.0 billion.

Net cash used in investing activities decreased 58.1% compared to the previous fiscal year to ¥3.9 billion. The main outflows included payments of ¥18.2 billion for the acquisition of tangible fixed assets and ¥7.0 billion for deposits in fixed-term deposits. The main inflows included ¥16.9 billion from the sale of shares in subsidiaries following changes to the scope of consolidation (the sale of a portion of shares in Kyowa Hakko Food Specialties Co., Ltd.) and ¥3.0 billion from repayments from fixed-term deposits.

Net cash used in financing activities increased 55.4% compared to the previous fiscal year to ¥20.9 billion. The main outflows included payments of ¥12.5 billion for repayment of long-term bank loans and ¥7.6 billion for payment of dividends.

## Key Shareholders' Equity and Cash Flow Indicators

	Fiscal 2004	Fiscal 2005	Fiscal 2006	Fiscal 2007	Fiscal 2008
Shareholders' equity ratio (%)	62.9%	66.6%	63.8%	64.5%	77.0%
Shareholders' equity (market price base) ratio (%)	92.7%	94.6%	114.5%	96.0%	67.9%
Cash flow / Interest bearing debt ratio (years)	0.4	0.9	0.6	0.4	0.3
Interest coverage ratio (times)	124.4	84.8	106.3	100.3	82.9

Notes:

Shareholders' equity ratio = Shareholders' equity / Total assets

Shareholders' equity (market price base) ratio = Market capitalization / Total assets

Cash flow/ Interest bearing debt ratio = Operating cash flow/ Interest-bearing debt

Interest coverage ratio = Operating cash flow / Interest payments

\*All ratios based on consolidated figures.

\*Market capitalization is based on the number of shares issued and outstanding at the end of the period (excluding treasury stock).

\*Operating cash flow is the figure for cash flows from operating activities in the consolidated statements of cash flows.

\*Of the liabilities on the consolidated balance sheet, interest-bearing debt includes short-term, corporate bonds and long-term borrowings.

\*For interest payments, the Interest payments figure in the consolidated statements of cash flows is used.

### 3) Fiscal 2009 Outlook for Financial Position

Cash flows from operating activities: Operating cash flows are expected to decrease compared to fiscal 2008 since we expect a decrease in net income before income taxes and increases in corporate, etc., tax payments.

Cash flows from investing activities: cash used in investing activities is expected to increase compared to fiscal 2008 due to an expected increase in payments for the acquisition of tangible fixed assets and the absence of inflows from the sale of subsidiaries.

Cash flows from financing activities: The amount of dividend paid is expected to increase over the fiscal 2008. As regards financing, such as fund procurement and loan repayment, we will remain flexible and act in consideration of the economic and funding environment.

As a result of the above, cash and cash equivalents as of the end of fiscal 2009 are expected to be at a lower level than at the end of fiscal 2008.

Note: The above financial position outlook is based on information available to management at the time of writing. The actual financial position may differ significantly from projections.

### III. Basic Policy on Profit Distribution: Fiscal 2008 and Fiscal 2009 Dividends

Kyowa Hakko Kirin regards the return of profits to its shareholders as one of its key priorities. Regarding dividends, we consider the delivery of stable and sustainable dividends to be the basis of our policy, while maintaining fully adequate internal reserves, and considering factors such as our consolidated results, the dividend payout ratio and the dividend return on shareholders' equity. Kyowa Hakko Kirin aims to retain sufficient reserves to make the investments in facilities and research and development that are required to fund new growth.

In accordance with this basic policy, for fiscal 2008 we expect to pay a year-end dividend of ¥10 per share. As a result, in addition to the interim dividend payment of ¥10 per share, the annual dividend per share for fiscal 2008 is expected to be ¥20 per share, ¥10 per share higher than in the previous fiscal year.

In accordance with the Kyowa Hakko Kirin Group 2008-2010 medium-term business plan, we are targeting dividend payout ratio of at least 30% (based on profits before goodwill amortization). For the fiscal year ending December 31, 2009, and based on a 9-month reporting period as a result of our change to our

fiscal year end, we expect to pay a dividend of ¥15 per share, consisting of an interim dividend of ¥10 per share, and a year-end dividend of ¥5 per share.

#### **IV. Business Risks and Other Risks**

With respect to Kyowa Hakko Kirin Group's business performance and financial position, the major risks that may significantly affect investors' judgments include, but are not limited to, those described below. The Group recognizes that these risk events may occur, and the Group uses a risk management system to prevent the occurrence of those risk events that can be controlled by the Group. At the same time, the Group will do its utmost to respond in the event of the occurrence of a risk event. Items in this section dealing with future events reflect the judgment of the Group as of the end of fiscal year to March 31, 2009.

##### **Risks associated with the operating environment in the domestic pharmaceutical industry**

In the Group's core Pharmaceuticals operations, under the domestic public pharmaceutical price system, the official prices for the majority of ethical pharmaceuticals are periodically reduced. As a result, the Group is unable to avoid reductions in selling prices of its existing drugs. Since a large portion of our ethical pharmaceuticals selling prices will fall, in cases where a price reduction cannot be compensated for by an increase in volumes, the Group's business performance and financial position could be adversely affected.

In addition, the Kyowa Hakko Kirin Group's business performance and financial position could also be affected by factors including future trends in the reform of Japan's system of medical treatment aimed at controlling the costs of medical treatment, and intensified competition resulting from the entry of foreign pharmaceutical companies into the Japanese market.

##### **Risks that substantial R&D investment will not be recovered.**

Kyowa Hakko Kirin Group invests significantly in the development of new products, technologies, improving existing products and developing applications, etc. For example, in the Group's main Pharmaceutical business, the importance of future growth being based upon the success of ground-breaking new drugs cannot be exaggerated. In ethical drug operations, the development of new drugs requires long periods of time and substantial R&D expenditures. The process of development and sales of new pharmaceuticals is inherently complicated and uncertain. In the long-term development of new drugs, there may be cases where the expected efficacy is not confirmed and R&D will be halted, or cases where successfully launched products may not result in the expected level of sales. There may also be cases where serious unpredicted side effects result in sales being suspended after the product is launched. As a result of various factors such as these, it may not be possible for the Group to recover its investment in R&D.

In addition, in non-pharmaceutical operations, the Group invests R&D resources in the development of new products and new technologies that are expected to differentiate the Group from its competitors by making use of key technologies, such as its core fermentation technologies and biotechnologies. There is no guarantee these investments will produce results. As stated above, in cases where expected R&D results are not realized, the Group's future growth and profitability may decline and our business performance and financial position may also be adversely affected.

##### **Risks related to Intellectual Property Assets**

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

revenues from technology could decline earlier than forecast and similarly, the Group's business performance and financial position could be adversely affected.

### **Legal regulation risk**

In the course of carrying out its operations in Japan and overseas, the Group must strictly comply with legal regulations. For example, in the Pharmaceuticals business, in Japan and overseas the Group is subject to pharmaceutical-related regulations in all countries at each stage, from new drug development to drug manufacturing, importing and exporting, sales, distribution, and use. The Group must comply with a large number of laws and business practices, and in addition there are a variety of approval and permission systems as well as monitoring systems. The Group emphasizes compliance to try to ensure that it does not violate the laws to which it is subject, and the Group is working to bolster internal control functions through such means as administrative oversight. However, there is no guarantee that the Group will be able to completely eliminate the possibility of committing a violation of these legal regulations. If, because we are unable to observe these legal regulations, new product development is delayed or stopped, or manufacturing or sales activities are restricted, the Group's credibility could be damaged.

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

### **Risk of defective products**

The Group manufactures a variety of products at plants in countries where it operates in line with locally recognized quality control and other standards. The Group also requires that companies whose merchandize we purchase and sell conform to the necessary quality and standards applied to the products. However, this is not a guarantee that all products will be free of defects, and the possibility of product recalls cannot be ruled out. The Group has taken out product liability insurance, but there is no guarantee this will provide enough coverage against liability claims that the Group may be forced to bear. It should also be pointed out that the Group may not be able to maintain insurance coverage at conditions acceptable to us. For example, in instances of large-scale product recalls or product defects that lead to claims, including severe side effects in ethical pharmaceuticals and drug induced diseases, that could heavily impact the Group's social credibility resulting in large expenses or losses or declines in sales that may adversely affect the Group's business performance and financial position.

### **Disaster-related and accident-related risks**

To minimize the negative effects of halting manufacturing line activities, the Group conducts periodic disaster prevention tests and facility maintenance for all of its production line facilities. However, there is no guarantee that the Group will be able to completely prevent events that interrupt production, such as accidents, electricity outages, and boiler stoppages. For example, in Shizuoka Prefecture a major earthquake or other incident could halt production in Kyowa Hakko Kirin's Fuji Plant, which produces ethical pharmaceutical products. In preparation for such an event the production system at our Ube plant in Yamaguchi is capable of substitute production of certain products. However, depending upon the extent of the damage to the Fuji plant, our production capacity for ethical pharmaceutical products could be severely reduced.

Also, the petrochemical products and alcohol manufactured by the Group are dangerous materials that are extremely flammable. In regard to these products, the Group pays particular attention to safety in its daily production activities; however, in the event of an accident caused by any of a variety of reasons, damage could be caused not only to production facilities but also to the surrounding region.

In addition to the Group handles substances that are subject to various legal regulations and guidelines. Despite the fact that these substances in the factories and research facilities are strictly managed in accordance with specifications, as a result of natural disasters etc. these substances could enter the external environment and cause damage to the surrounding area.

Should an event or accident as described above occur it might result in significant damage and negatively impact the Group's position of trust in society. Additionally, the Group's business performance and financial position could be adversely affected.

#### **Impact on production activities as a result of a tightening in environmental restrictions**

The Group engages in the manufacture of amino acid products using fermentation technology. Sugars, and other nutrient sources are also used in the fermentation production process, which generates waste fluid. This fermentation waste is processed and disposed of in accordance with the environmental regulations of the countries in which the Group engages in manufacturing activities, but both domestically and overseas there is a trend for these environmental regulations to be made more severe each year. The Group is making efforts to utilize materials with low environmental burdens as raw materials and improve our wastewater treatment technology, but in the future it is possible that our manufacturing activities will be limited as a result of alterations in the contents of environmental restrictions, leading to increased manufacturing costs, which as a result may adversely impact the Group's business performance and financial position.

The Chemicals business is currently facing issues such as restrictions on volatile organic compounds (VOC) and is moving to meet these issues with appropriate responses, but the Group's business performance and financial position could be adversely affected by the future content of environmental safety restrictions.

#### **Potential risks for overseas business activities**

The Group maintains business activities in the North America, Europe and Asia. Business development into overseas markets encapsulates a number of risks, examples of which are outlined below:

1. Unanticipated laws, restrictions and tax systems that exert an adverse impact on the company.
2. Adverse political and/or economic factors.
3. Issues regarding hiring and maintaining personnel.
4. Social unrest as a result of acts of terror, wars or other factors.

In instances where the Group is unable to effectively develop its business overseas as a result of such potential risks manifesting themselves, there is the possibility that the Group's business performance and financial position could be adversely affected.

#### **Risk of declines in product sales prices as a result of fluctuations in the supply/demand balance**

Products in the Chemicals business include those likely to be impacted by global supply/demand balances and where the underlying markets experience major fluctuations, including solvents and raw materials for plasticizers. Our competitors may strengthen their production capabilities or demand could rapidly decline for these products, both in Japan and overseas, sales prices may fall drastically in cases of over-supply, and the Group's business performance and financial position could be adversely impacted in instances where we are unable to offset this by expanding sales volumes.

#### **Risk of crude oil price fluctuations on profit margin**

In the Chemicals business the main raw materials of its products are derived from refined crude oil products such as naphtha-derived ethylene and propylene that are highly sensitive to crude oil price fluctuations. Global demand and supply and unpredictable factors such as changes in weather conditions, war and

terrorism have caused large fluctuations in the price of crude oil and should be expected to do so in the future. In the Bio-Chemicals business, the increase in the price of raw materials has become a significant issue caused by an increase in the price of fuel, the increased demand from developing countries, the expanding demand of ethanol and a poor agricultural harvest due to unseasonable weather. If the rise of raw materials prices cannot be reflected in the selling price of products in a timely manner, or cannot be absorbed through cost reduction measures, the Group's business performance and financial position could be adversely affected.

#### **Risk of changes to foreign exchange rate**

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

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

#### **Risk of changes to share prices**

The Group owns marketable securities of its business partners, financial institutions and others and in cases where market valuations drop significantly an appraisal loss on our holdings would be incurred and the Group's business performance and financial position could be adversely affected. Further, a portion of the Company's corporate pension assets comprise marketable securities and actuarial accounting differences in retirement benefit accounting could result from changes to the market value of these and the Group's business performance and financial position could be adversely affected.

#### **Risk of impairment of fixed assets**

As regards the Group's fixed assets, in cases where there is a decline in business profitability due to a marked deterioration of the operating environment, or a significant drop in market prices, the application of fixed asset impairment accounting could result in an impairment loss and the Group's business performance and financial position could be adversely affected.

#### **Risk concerning procurement of necessary raw materials**

For certain raw materials procured by the Group, changing suppliers and substituting raw materials can be very difficult and they may only be available through a small number of specialized suppliers. Although we have taken measures to store enough a sufficient supply of important raw materials to ensure production for a certain period of time, we cannot rule out the unexpected. Therefore, if procuring important resources for which there is no substitute becomes extremely difficult, product manufacturing may be suspended and the Group's business performance and financial position could be adversely affected.