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## Kyowa Hakko Kirin Fiscal 2011 Results: Record operating income and ordinary income

**Tokyo, January 31, 2012---** Kyowa Hakko Kirin Co., Ltd. (Kyowa Hakko Kirin; TSE 4151) today announced its consolidated financial results for the fiscal year ended December 31, 2011, a year in which we achieved record highs in operating income and ordinary income, despite a challenging operating environment.

Compared to the previous year, consolidated net sales decreased ¥70.0 billion to ¥343.7 billion, partly due to the exclusion from consolidation of the Chemicals business as of March 31, 2011. Operating income increased ¥1.2 billion to ¥46.6 billion, ordinary income increased ¥0.2 billion to ¥46.7 billion, and net income increased ¥3.4 billion to ¥25.6 billion.

In fiscal 2012, operating income is expected to rise due to factors including increased sales and profits from the Pharmaceuticals business, revenue contributions from ProStrakan, acquired in April 2011, and despite the impact of the planned National Health reimbursement price reductions scheduled for April 2012. Consolidated forecasts for fiscal 2012 are for net sales of ¥326.0 billion, a decrease of 5.2%, operating income of ¥48.0 billion, up 3.0%, ordinary income of ¥42.5 billion, down 9.1%, net income of ¥20.0 billion, down 21.9%, and an annual dividend of ¥20 per share.

Commenting on the results, Yuzuru Matsuda, President and CEO of Kyowa Hakko Kirin said, *"I am pleased to report that we achieved record operating income and ordinary income for 2011, driven by strong growth in our core Pharmaceuticals business and despite extremely challenging conditions in Japan and overseas. We also achieved significant progress in our strategy to develop globally and focus resources on our ethical pharmaceutical products business through the sale of our Chemicals business in March and the acquisition of ProStrakan in the UK. In fiscal 2012, the final year of our three-year business plan, we forecast a further increase in operating income but our results will be affected by a continued strong yen and challenges in the operating environment. We will continue to promote the rapid realization of our strengths in therapeutic antibodies with the aim of becoming a world-class, R&D based life sciences company, founded on biotechnology with the pharmaceutical business at its core."*

### Fiscal 2011 Results

*(Amounts less than ¥0.1 billion have been ignored)*

#### 1) Operating results for the fiscal year ended December 31, 2011

	Fiscal year ended December 31, 2011	Fiscal year ended December 31, 2010	Change
Net sales	343.7	413.7	(70.0)
Operating income	46.6	45.4	1.2
Ordinary income	46.7	46.5	0.2
Net income	25.6	22.1	3.4

During the fiscal year ended December 2011 (January 1, 2011 to December 31, 2011) the domestic economy continued to be affected by the Great East Japan Earthquake that occurred on March 11, 2011, while the outlook remained uncertain due to the continued strong yen and a slowdown in overseas economies as well as the financial crisis in Europe.

In the Pharmaceuticals business, domestic market conditions remained challenging due to the promotion of generic pharmaceuticals, the increasing presence of European and American drug manufacturers and major specialist pharmaceutical companies, and increasing global competition in new drug development. Against this background, Kyowa Hakko Kirin further strengthened its domestic sales operation with the aim of expanding sales of core products and of rapidly penetrating the market with new products. Aiming for further progress in overseas development, in April we acquired all outstanding shares of ProStrakan Group plc (ProStrakan), a UK specialty pharmaceutical company, making it our wholly owned subsidiary and securing its management resources.

In the Bio-Chemicals business, we worked to expand sales of high value-added products such as amino acids, nucleic acids and related compounds, primarily pharmaceutical and industrial use raw materials, despite being heavily affected by the rapid appreciation of the yen. In healthcare products, we carried out initiatives to strengthen mail-order sales of our *Remake Series*, mainly using our own brand materials such as Ornithine.

In the Chemicals business, we sold all shares of Kyowa Hakko Chemical Co., Ltd. in March with the aim of effectively focusing our operational resources in the pharmaceutical products and pharmaceuticals materials businesses.

Partly due to the removal of the Chemicals business from the scope of consolidation, consolidated net sales for the fiscal year totaled ¥343.7 billion (down 16.9% compared with the previous year). However, we achieved record highs in profits despite a challenging operating environment as operating income rose 2.7% to ¥46.6 billion, ordinary income rose 0.5% to ¥46.7 billion, and net income rose 15.4% to ¥25.6 billion.

Although the plants of some of our suppliers were affected by the Great East Japan Earthquake, Kyowa Hakko Kirin Group did not suffer significant damage.

### **Segmental performance**

*Note: As of the current fiscal year, the Accounting Standards for Disclosure about Segments of an Enterprise and Related Information (ASBJ statement No. 17, March 27, 2009) and the Guidance on Accounting Standard for Disclosures about Segments of an Enterprise and Related Information (ASBJ Guidance No. 20, March 21, 2008) have been applied. Year-on-year comparisons are provided since the segmental classification following application of these accounting standards is the same as that previously used.*

## **Pharmaceuticals business**

	<i>(Billions of yen)</i>		
	Fiscal year ended December 31, 2011	Fiscal year ended December 31, 2010	Change
Net sales	229.3	210.3	18.9
Operating income	41.3	35.8	5.4

In the Pharmaceuticals business, consolidated net sales increased 9.0% to ¥229.3 billion and operating income increased 15.2% to ¥41.3 billion. Domestic sales of core ethical pharmaceutical products such as Nesp, a treatment for renal anemia, were robust while sales of Allelock, an antiallergic agent, and Patanol antiallergic eye drops, were significantly higher than the previous fiscal year due to the effects of higher amounts of airborne pollen and other factors. In addition, sales of Fentos, a transdermal analgesic for persistent cancer pain, Asacol, an ulcerative colitis treatment, Regpara, a treatment for secondary hyperparathyroidism during dialysis therapy, and sales of Romiplate, a treatment for chronic idiopathic thrombocytopenic purpura, launched in April, also grew steadily. In the licensing-out of technologies and export of pharmaceutical products, revenues from licensing-out of technologies were lower than in the same period of the previous consolidated fiscal year while exports, primarily those to Asia, performed strongly.

Sales at subsidiary Kyowa Medex, which manufactures and sells diagnostic reagents, were up compared to the previous consolidated fiscal year as sales of immunological reagents and exports both performed well.

ProStrakan Group plc, a UK-based specialty pharmaceuticals company, was acquired on April 21, 2011. ProStrakan has an established development and marketing capability for cancer-related and other drugs in Europe and the US. Looking ahead, we can dramatically advance our global strategy through a mutually beneficial partnership accelerating development and expanding sales of new global drugs in core areas. As regards consolidated accounting treatment following the acquisition of ProStrakan, June 30, 2011 is the deemed acquisition date therefore our consolidated results for the fiscal 2011 include the results of ProStrakan and its ten subsidiaries for the six-month period from July 1, 2011 to December 31, 2011 (net sales of ¥6.9 billion).

In new drug development in Japan, in the cancer therapeutic area, KRN125 began Phase III clinical trials in February targeting chemotherapy induced febril neutropenia. In April, we submitted an NDA for anti-CCR4 antibody KW-0761 that targets adult T-cell leukemia-lymphoma, a type of hematological cancer. In Asia, ARQ 197, in conjunction with Erlotinib, began comparative international Phase III trials in August in Japan, South Korea and Taiwan for patients diagnosed with advanced or metastatic non-small cell lung cancer. In December, KRN321 (product name in Japan: Nesp) began Phase II trials in Japan and South Korea targeting anemia caused by myelodysplastic syndrome. In addition, Pegfilgrastim (product name Neulasta) was approved in Taiwan in September.

In the renal therapeutic area in Japan, Phase III clinical trials commenced in January 2011 for KRN321 targeting renal anemia in infants. In Asia, Phase III trials for KRN321 that targets renal anemia in patients on dialysis commenced in India in September. In October, approval was filed in China for KRN1493 (product name in Japan: Regpara) that is being developed as a treatment for

secondary hyperparathyroidism.

In the areas of immunology and allergy in Japan, in July approval was received for anti-allergenic Allelock granules, and sales commenced in November. In Asia, in August, anti-IL5R humanized monoclonal antibody KHK4563 began Phase II trials targeting bronchial asthma in South Korea and Japan.

In the central nervous system therapeutic area in Japan, in June, approval was gained for additional applications of Depakene, an antiepileptic drug, for usage and volumes and its effectiveness and efficiency in averting the onset of migraine headaches. In July, an NDA was filed for KW-6500, a drug being developed to treat hyperakinesia caused by Parkinsons' disease-related motor complications.

In other areas, in Japan, we received approval for Romiplate, a treatment for chronic idiopathic thrombocytopenic purpura, and commenced sales in April. Phase III clinical trials for KW-3357 which targets diffuse intravascular coagulation syndrome following a reduction of antithrombin (an anticoagulant component) began in June. Further, in July, approval was received for Nauzelin OD tablets, used to treat diseases of the gastrointestinal tract, and sales commenced in December. Overseas, in South Korea, approval was received for Nplate (product name in Japan: Romiplate), a treatment for chronic idiopathic thrombocytopenic purpura, in June. ProStrakan, which became a consolidated subsidiary in April, received approval in the U.S. for Rectiv<sup>TM</sup>, a treatment for pain associated with chronic anal fissures, in June.

In therapeutic antibody research and development, while strengthening our in-house development pipeline of therapeutic antibodies we also developed the global outlicensing of our POTELLIGENT® and COMPLEGENT® technologies via our U.S. subsidiary BioWa, Inc. To date, we have licensing agreements with nineteen companies for these technologies and we are actively pursuing our strategy of promoting the fastest possible development of therapeutic antibodies that utilize our original technology.

### **Bio-Chemicals business**

	<i>(Billions of yen)</i>		
	Fiscal year ended December 31, 2011	Fiscal year ended December 31, 2010	Change
Net sales	77.5	84.2	(6.6)
Operating income	2.8	3.2	(0.3)

In the Bio-Chemicals business, consolidated net sales were ¥77.5 billion (down by 7.9%), while operating income was ¥2.8 billion (down 11.6%). Sales declined due to the significant impact of the strong yen although sales volumes of pharmaceutical and industrial use raw materials, mainly amino acids, nucleic acids and related compounds showed steady growth as a result of active efforts to expand sales to meet increased overseas demand.

In healthcare products, we achieved steady growth in mail-order sales, primarily those of own brand materials such as Ornithine. However sales were lower than in the previous year due to the delay of the planned April renewal of Kirin Health Project *KIRIN Plus-i* related products resulting from the earthquake disaster.

Sales at Daiichi Fine Chemical declined due to a drop in sales volumes and sales prices of certain bulk pharmaceuticals and intermediate products.

In R&D, we are actively developing new products and new applications based on functional data while continuing to focus on researching to improve efficiency in the fermentation production process for core products such as amino acids, nucleic acids and related compounds. In healthcare-related products, we plan to strengthen product development, improve efficiencies in R&D, manufacturing, marketing, and our training and sales support operations, and strengthen integrated operations. We will develop enhanced high value-added pharmaceuticals and intermediate products leveraging the fermentation and enzyme technology of Dai-Ichi Fine Chemical, such as its highly functional organic synthesis technology.

### **Chemicals business**

	<i>(Billions of yen)</i>		
	January 1 to March 31, 2011 First quarter of the fiscal year ended December 31, 2011*	Fiscal year ended December 31, 2010	Change
Net sales	33.5	130.0	(96.4)
Operating income	2.1	5.6	(3.5)

*The Chemicals segment results includes only the consolidated results of the first quarter of the consolidated fiscal year (January 1, 2011 to March 31, 2011) due to the sale of all outstanding shares of Kyowa Hakko Chemical on March 31, 2011 by Kyowa Hakko Kirin.*

In the Chemicals business, consolidated net sales were ¥33.5 billion (up by 10.8% compared to the first quarter of the previous year), and operating income was ¥2.1 billion (up 216.6%). In the previous fiscal year (the 12-month period from January 1, 2010 to December 31, 2010), net sales in the Chemicals business were ¥130.0 billion and operating income was ¥5.6 billion

Domestic and overseas sales revenues and sales volumes increased over the first quarter of the previous fiscal year supported by factors including increased demand and firm markets in Asia, and a recovery in domestic demand.

All areas including solvents, plasticizer raw materials and specialty chemicals, recorded higher sales volumes and sales revenues than the first quarter of the previous fiscal year. Particularly strong growth was recorded by specialty chemicals in which raw materials for refrigerant oils performed steadily.

### **Other**

	<i>(Billions of yen)</i>		
	Fiscal year ended December 31, 2011	Fiscal year ended December 31, 2010	Change
Net sales	10.6	10.4	0.1
Operating income	0.3	0.3	(0.0)

In the Other segment, consolidated net sales were ¥10.6 billion (up by 1.5% compared to the previous fiscal year), while operating income was ¥0.3 billion (down 0.8%).

## 2) Outlook for Fiscal 2012

*(Billions of yen)*

	FORECAST FY to December 31, 2012	Amount change compared to FY ended December 31, 2011	Percentage change compared to FY ended December 31, 2011
Net sales	326.0	(17.7)	(5.2)%
Operating income	48.0	1.3	3.0%
Ordinary income	42.5	(4.2)	(9.1)%
Net income	20.0	(5.6)	(21.9)%

These forecasts assume average exchange rates for fiscal 2012 of ¥77/US\$, ¥98/euro and ¥119/British pound

In the fiscal year to December 31, 2012 in the domestic economy, we expect the trend towards gradual improvement to continue. However, the outlook remains uncertain and due to factors such as a further worsening of fiscal and financial problems in Europe, overseas economies could underperform expectations thereby increasing the risk of downward pressure on the domestic economy.

In this environment, in the Pharmaceuticals business, we will further strengthen our domestic sales capabilities aiming for early market penetration of new products and expanding sales of core products. We will also more actively promote global expansion of our development and sales capabilities. In the Bio-Chemicals business, we will develop global sales of amino acids, nucleic acids and related compounds, primarily in high value-added areas for use in pharmaceutical products, medical treatment and healthcare. In domestic healthcare, we will promote the development of the market for in-house branded amino acid materials such as Ornithine.

Our consolidated financial results forecasts for fiscal 2012 (January 1, 2012 to December 31, 2012) are for net sales of ¥326.0 billion, a decrease of 5.2% compared to the previous fiscal year, operating income of ¥48.0 billion, up 3.0%, ordinary income of ¥42.5 billion, down 9.1%, and net income of ¥20.0 billion, a decrease of 21.9%.

In the Pharmaceuticals business, we expect to be heavily affected by the reduction in National Health reimbursement prices scheduled for April 2012, however we anticipate an increase in sales and profits compared to the previous fiscal year due to factors including expected growth in sales of products such as Fentos, a transdermal analgesic for persistent cancer pain, Regpara, a treatment for secondary hyperthyroidism during dialysis therapy, Asacol, an ulcerative colitis treatment and Romiplate, a treatment for chronic idiopathic thrombocytopenic purpura, as well as in-licensing revenues from the biosimilar joint venture with FUJIFILM Corporation planned to be established in the spring, and full year consolidated contributions from ProStrakan.

In the Bio-Chemicals business, we are aiming for an increase in sales over the previous consolidated fiscal year due to an increase in sales volumes of core amino acids, nucleic acids and related compounds and mail-order Remake Series, despite the effects of a strong yen. In regards to operating income, we expect a decrease in revenues due to anticipated increases in depreciation and amortization following large-scale capital expenditure at DAIICHI Fine Chemical Co., Ltd.

In the Chemicals business, net sales and operating income will not be recorded due to the elimination of the Chemicals segment at the end of March 2011 following the transfer of all shares held in Kyowa Hakko Chemical Co., Ltd. In the first quarter period of the fiscal year ended December 2011, consolidated net sales in the Chemicals business were ¥33.5 billion and operating income was ¥2.1 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.

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For further information please access: <http://www.kyowa-kirin.co.jp/english/index.html>

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· accordance with generally accepted accounting principles in Japan. It contains forward-looking statements based on a number of ·  
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· materially depending on a number of factors, including fluctuations in exchange rates, changing economic conditions, legislative ·  
· and regulatory developments, delays in new product launches, and pricing and product initiatives of competitors. ·  
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