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Kyowa Hakko Kirin Fiscal 2010 Sales up 1.7%, Operating income up 46.8%

Tokyo, January 28, 2011--- Kyowa Hakko Kirin Co., Ltd. (Kyowa Hakko Kirin; TSE 4151) today announced its consolidated financial results for the fiscal year ended December 31, 2010 (the twelve-month period ended December 31, 2010)*. In 2010 both sales and profits increased and exceeded the forecasts announced on October 28, 2010.

(As the previous fiscal period was a nine-month period, figures for the twelve-month period from January 1, 2009 to December 31, 2009 have been provided here as reference).

Compared to the previous year, consolidated net sales increased 1.7% to ¥413.7 billion, operating income increased 46.8% to ¥45.4 billion and recurring income increased 42.5% to ¥46.5 billion. Net income increased by 121.1% to ¥22.1 billion. The year-end dividend per share for fiscal 2010 is ¥10, which along with the interim dividend of ¥10 per share makes an annual dividend for fiscal 2010 of ¥20 per share.

In fiscal 2011, sales and profits are expected to be significantly affected by the planned sale of all shares held in Kyowa Hakko Chemical Co., Ltd., scheduled for March, and whose revenues and profits will only be recorded in the consolidated accounts for the first quarter of the fiscal year. Consolidated forecasts for fiscal 2011 are for consolidated net sales of ¥325.0 billion, a decrease of 21.4%, operating income of ¥37.0 billion, down 18.5%, recurring income of ¥38.0 billion, down 18.3%, net income of ¥25.5 bn, up 14.9% 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 higher sales and profits for 2010, which is the first year of our medium-term business plan. Sales and profits exceeded our forecasts despite challenging conditions in our core businesses. In fiscal 2011 results will be significantly affected by the planned sale of Kyowa Hakko Chemical in March. However this will allow Kyowa Hakko Kirin focus its resources on its ethical pharmaceutical products business, while Kyowa Hakko Chemical can flexibly implement the capital expenditure required to meet diverse market needs, independently of Kyowa Hakko Kirin. In fiscal 2011 we forecast a continued increase in sales in our Pharmaceuticals business but profits will be affected by a planned increase in R&D expenditure. Despite this we are forecasting a 14.9% increase in consolidated net income in fiscal 2011. We will also continue to promote the rapid realization of our strengths in antibody pharmaceuticals 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 2010 Results

(Amounts less than ¥0.1 billion have been ignored)

I. Operating results for the fiscal year ended December 31, 2010

	Fiscal year ended December 31, 2010	Twelve months ended December 31, 2009*	(Billions of yen) Change
Net sales	413.7	407.0	6.7
Operating income	45.4	30.9	14.4
Recurring income	46.5	32.6	13.8
Net income	22.1	10.0	12.1

Segmental results for the fiscal year ended December 31, 2010

Sales	(Billions of Yen)		
	Fiscal year ended December 31, 2010	Twelve months ended December 31, 2009*	Change
Pharmaceuticals	210.3	207.3	2.9
Bio-Chemicals	84.2	90.6	(6.4)
Chemicals	130.0	64.2	65.8
Other	10.4	63.7	(53.2)

Operating income	(Billions of Yen)		
	Fiscal year ended December 31, 2010	Twelve months ended December 31, 2009*	Change
Pharmaceuticals	35.8	31.8	4.0
Bio-Chemicals	3.2	3.9	(0.6)
Chemicals	5.6	(5.5)	11.2
Other	0.3	0.4	(0.0)

Note: As the previous fiscal period was a nine-month period, figures for the twelve-month period from January 1, 2009 to December 31, 2009 have been provided here as reference.

During the fiscal year ended December 2010 (January 1, 2010 to December 31, 2010) the domestic economy continued to gradually recover although the improvement was weak and the outlook remains uncertain due to fears that overseas economies, primarily those of the Europe and US, will underperform expectations, as well as due to changes in foreign exchange rates.

Against this background we achieved a strong start in the first year of our 2010-12 Medium-term Business Plan as we work towards our goal of becoming a world-class, R&D based life sciences company, founded on biotechnology with the pharmaceutical business at its core.

In the Pharmaceuticals business in Japan, in addition to the effects of reductions in National Health reimbursement prices in April, domestic market conditions remained challenging due to the promotion of generic pharmaceuticals, increased competition as European and American drug manufacturers and major domestic pharmaceutical companies shift their area of focus to cancer and other areas with unmet medical needs, and the growing trend towards the development of biopharmaceuticals. Against this background, Kyowa Hakko Kirin further strengthened its domestic sales operation with the aim of expanding sales of core products and achieving swift market penetration of new products.

We also sought to advance our antibody pharmaceuticals, one of our core strengths, to the next stage of clinical development in Japan and overseas, while also seeking to form new technology and product licensing agreements as well as enhancing our production facilities for investigational therapeutic antibodies. Further, we moved to strengthen our competitive position through launching a new research building in our Tokyo Research Park, while also reorganizing existing production facilities in order to enhance efficiency.

In our Bio-Chemicals business, as the yen rapidly appreciated, we strived to expand sales of high-value-added products mainly focused on amino acids for use in infusions and pharmaceutical raw materials. Further, in our health care business we strengthened our health food mail order *Remake Series*, while promoting development of the market for in-house branded amino acid materials such as ornithine.

In the Chemicals business, the worldwide economic recovery led to increased product demand. Overseas markets conditions for core products were firm, while we focused on sales of environment-friendly specialty chemicals.

Regarding our Chemicals business, Kyowa Hakko Kirin has signed a basic agreement to sell all shares owned by Kyowa Hakko Kirin in Kyowa Hakko Chemical Co., Ltd., to KJ Holdings Inc. in March 2011. As a result, Kyowa Hakko Kirin will be able to effectively focus its resources on its ethical pharmaceutical products business, while Kyowa Hakko Chemical can flexibly implement the capital expenditure required to meet diverse market needs, independently of Kyowa Hakko Kirin.

As the previous fiscal period was a nine-month period, figures for the twelve-month period from January 1, 2009 to December 31, 2009 have been provided here as reference.

Segmental performance

Pharmaceuticals

In the Pharmaceuticals business, consolidated net sales were ¥210.3 billion (up 1.4% compared to the same period of the previous year), while operating income was ¥35.8 billion (up 12.7%). Domestic sales of ethical pharmaceutical products were broadly flat despite the effects of reductions in National Health reimbursement prices in April. By product, sales of renal anemia treatments Nesp and Espo and Regpara, a treatment for secondary hyperparathyroidism during dialysis therapy increased. Also, Parkinson's disease treatment Permax, launched in April, and Fentos, a transdermal analgesic for persistent cancer pain, each performed well. However, due in part to the effects of reductions in National Health reimbursement prices in April, sales of products including Coniel, a treatment for hypertension and angina pectoris, were lower than in the previous comparable period. In the licensing-out of technologies and export of pharmaceutical products, revenues increased significantly due to an increase in one-time income from outlicensing and strong performance in export of pharmaceutical products, mainly to Asia.

Sales at subsidiary Kyowa Medex, which is responsible for the manufacture and sale of diagnostic reagents, were compared to the previous 12-month period as sales of clinical chemistry diagnostic reagents and exports both performed well.

In new drug development in Japan, in the cancer therapeutic area ARQ 197 commenced Phase II trials as a gastric cancer treatment in July. An application was filed in February for KW-2246, an analgesic for cancer pain, but the application was temporarily withdrawn in August and it was decided to conduct additional clinical trials (Phase III clinical trials). In addition, in September, KW-0761 entered late Phase II clinical trials as a joint therapy with mLSG15 for CCR4-positive Adult T-Cell Lymphoma and as a treatment for peripheral T/NK cell lymphoma.

In the renal therapeutic area in Japan, Nesp injection plastic syringe, a long-acting erythropoiesis stimulating agent, was approved and sales were launched in August. Overseas, in March approval was received in South Korea and Taiwan for Regpara.

In the areas of immunology and allergy in Japan, in July antiallergenic Allelock received additional approvals for children aged seven and above regarding effect/efficacy and dosing method and amount. Further, following receipt of approval, sales of Allelock OD Tablets, a disintegrating oral tablet developed in-house using our latest technology, began in November. In overseas markets, in June approval was received for Allelock in China.

In the central nervous system therapeutic area in Japan, in July antiepileptic drug Topina began Phase III clinical trials for pediatric indications. In November, approval for additional applications of Depakene, an antiepileptic drug, for its effectiveness and efficiency in averting the onset of migraine headaches was filed.

In other areas, in Japan, we received approval for AMG531, a treatment for idiopathic thrombocytopenic purpura.

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

Bio-Chemicals

In the Bio-Chemicals business, consolidated net sales were ¥84.2 billion (down by 7.1% compared to the previous 12-month period), while operating income was ¥3.2 billion (down 17.4%). Sales of pharmaceutical and industrial use raw materials, mainly amino acids, nucleic acids and related compounds, increased compared to the previous 12-month period despite the effects of a strong yen, primarily due to an increase in demand from Asia for pharmaceutical raw materials and amino acids for intravenous liquids and strong sales of raw materials for generic pharmaceuticals in the domestic market. In health care products, sales were much higher than in the previous year due to strong sales of materials related to Kirin Health Project *KIRIN Plus-i* that was launched in April, as well as strong growth in the number of customers of our mail order *Remake Series*.

In agrochemicals and products for the livestock and fisheries industries, sales were down significantly due to the transfer of domestic livestock and fisheries product sales to Asuka Pharmaceuticals in April, and in alcohol, sales were down due to the transfer of raw material alcohol sales to Daiichi Alcohol, the joint venture between Kyowa Hakko Bio Co., Ltd. and Mercian Corporation, in July. Daiichi Fine Chemical sales declined due to sluggish sales of bulk pharmaceuticals and intermediate products.

In R&D, in the area of amino acids, nucleic acids and related compound we focused on R&D and new product development to raise productivity of fermented products at the Bio Process Research and Development Laboratories and the Bio Process Development Center and on synthetic compounds at Daiichi Fine Chemical Co., Ltd. At the Healthcare Product Development Center, we continued the exploration and development of functions and applications of a variety of amino acids and other compounds.

Chemicals

In the Chemicals business, operating results improved significantly compared to the previous fiscal year that was significantly impacted by the global economic recession. Consolidated net sales were ¥130.0 billion, up by 102.5% compared to the same period of the previous year and operating income was ¥5.6 billion (compared to an operating loss of ¥5.5 billion in the previous year).

In the domestic market, both sales and sales volumes recorded a large increase due to recovery of demand for automobiles and household appliances, and price revisions reflecting a rise in fuel and raw material prices and higher overseas product prices. In exports, sales and sales volumes also improved due to strong sales of environment-friendly specialty chemicals and strong overseas market conditions for core products.

All product areas, including solvents, plasticizer raw materials and specialty chemicals, recorded higher sales volumes and sales revenues. Particularly strong growth was recorded by specialty chemicals such as raw materials for refrigerant oils and by high purity solvents for electronic materials.

Miyako Kagaku and Kashiwagi Corporation, which were included in the Chemicals segment from fiscal 2010, also performed strongly.

Other businesses

In the Other business segment due to changes in segmental classification net sales decreased 83.5% to ¥10.4 billion and operating income decreased 16.4% to ¥0.3 billion.

II. Forecasts for the fiscal period ending December 31, 2011

(Billions of Yen)

	FORECAST FY to December 31, 2011	Amount change compared to FY ended December 31, 2010	Percentage change compared to FY ended December 31, 2010
Net sales	325.0	(88.7)	-21.4%
Operating income	37.0	(8.4)	-18.5%
Recurring income	38.0	(8.5)	-18.3%
Net income	25.5	3.3	+14.9%

These forecasts assume average exchange rates for fiscal 2011 of ¥85/US\$ and ¥110/euro.

In the fiscal year to December 31, 2011 we expect the domestic economy to improve against a background of improving overseas economies and the effect of various policy measures. However, concerns such as volatility in the foreign exchange market, the effects of deflation and concerns about worsening employment conditions remain, and the outlook remains uncertain.

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, while more actively promoting our global development. In the Bio-Chemicals business, we will 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 in-house branded amino acid materials such as ornithine.

Our consolidated financial results forecasts for fiscal 2011 (January 1, 2011 to December 31, 2011) are for net sales of ¥325.0 billion, a decrease of 21.4%, operating income of ¥37.0 billion, down 18.5%, recurring income of ¥38.0 billion, down 18.3%, and net income of ¥25.5 bn, an increase of 14.9%.

In the Pharmaceuticals business, we forecast growth in sales due to an increase in sales volumes of core products including antiallergic agent Allelock, antiallergic ophthalmic solution Patanol and Regpara, a treatment for secondary hyperthyroidism during dialysis therapy. We are also anticipating growth from new products such as Fentos, a transdermal analgesic for persistent cancer pain and Asacol, an ulcerative colitis treatment. However, due to an expected increase in R&D spending, we expect operating income to decline.

In the Bio-Chemicals business, we expect a decrease in revenues and profits due to the effects of a strong yen and despite an expected increase in sales volumes of core amino acids and related compounds, and the mail order *Remake Series*.

In the Chemicals business, we anticipate a large decrease in revenue and profits due to the transfer of all shares held in Kyowa Hakko Chemical Co., Ltd., scheduled for March, and whose revenues and profits will only be recorded in the consolidated accounts for the first quarter of the fiscal year.

*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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