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## Kyowa Hakko Kirin Fiscal 2012 Results: Record operating income for third consecutive year

**Tokyo, January 31, 2013---** Kyowa Hakko Kirin Co., Ltd. (Kyowa Hakko Kirin; TSE 4151) today announced its consolidated financial results for the fiscal year ended December 31, 2012, a year in which we achieved a record high in operating income, despite a challenging operating environment.

Compared to the previous year, consolidated net sales decreased ¥10.5 billion to ¥333.1 billion, partly due to the exclusion from consolidation of the Chemicals business as of March 31, 2011. Operating income increased ¥6.2 billion to ¥52.9 billion, ordinary income increased ¥2.2 billion to ¥49.0 billion, and net income decreased ¥1.4 billion to ¥24.1 billion.

Our consolidated financial results forecasts for fiscal 2013 (January 1, 2013 to December 31, 2013) are for net sales of ¥338.0 billion, an increase of 1.5% compared to the previous fiscal year, operating income of ¥55.0 billion, up 4.0%, ordinary income of ¥49.0 billion (unchanged), and net income of ¥30.0 billion, an increase of 24.0%.

Commenting on the results, Nobuo Hanai, President and CEO of Kyowa Hakko Kirin said, *"I am pleased to report that in 2012 we reported our highest-ever operating income and exceeded our sales and profit forecasts for the year, despite challenging conditions in Japan and overseas. Performance was driven by strong growth of sales and profits in our Pharmaceuticals business, and looking ahead we will pursue our strategy to develop globally. In fiscal 2013, we are forecasting further growth in sales and profits, and 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 2012 Results

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

#### 1) Operating results for the fiscal year ended December 31, 2012

	Fiscal year ended December 31, 2012	Fiscal year ended December 31, 2011	Change
Net sales	333.1	343.7	(10.5)
Operating income	52.9	46.6	6.2
Ordinary income	49.0	46.7	2.2
Net income	24.1	25.6	(1.4)

- In the Pharmaceuticals business, the operating environment remained challenging, impacted by a decline in both domestic and international success rates of new drug generation and stricter screening, progress with measures to reduce medical treatment costs, and increased market share of generic pharmaceuticals. Against this background, Kyowa Hakko Kirin made progress with new drug development in Europe, America and Asia, while pursuing expanded sales of core products and swift penetration of the market with new products, mainly in Japan.

To prepare our business platform for global growth we further strengthened collaboration with the ProStrakan Group plc (ProStrakan), the UK company which we acquired in the previous year, and launched a biosimilar products business through a joint venture (affiliated company) established between FUJIFILM Corporation and Kyowa Hakko Kirin Co. Ltd.

- In the Bio-Chemicals business, despite being heavily affected by the strength of the yen due to our comparatively large volume of overseas activities, we worked to expand sales and revise prices of high value-added products such as amino acids, nucleic acids and related compounds which are seeing buoyant demand. In healthcare products, we carried out initiatives to strengthen mail-order sales, mainly using our own brand materials such as Ornithine.
- Consolidated net sales for the fiscal year were down compared with the previous year, impacted by the removal of the Chemicals business (previous year sales of ¥33.5 billion, operating income ¥2.1 billion) from the scope of consolidation. However, due to strong sales of core products in the Pharmaceuticals business, operating income rose to a new high for the third year in a row.
- Although ordinary income rose, net income declined compared to the previous year when a gain on sales of affiliates' stock was recorded.

### Pharmaceuticals business

	(Billions of yen)		
	Fiscal year ended December 31, 2012	Fiscal year ended December 31, 2011	Change
Net sales	249.8	229.3	20.5
Operating income	50.3	41.3	9.0

- Domestic sales of pharmaceutical products were robust but were affected by a reduction in standard drug prices in Japan and other factors.
- Domestic sales of core pharmaceutical products such as *Nesp*, a treatment for renal anemia, and *Allelock*, an antiallergic agent, trended strongly. Meanwhile, sales of *Coniel*, a treatment for hypertension and angina pectoris declined, impacted by generic pharmaceuticals.
- Sales of *Regpara*, a treatment for secondary hyperparathyroidism during dialysis therapy, *Fentos*, a transdermal analgesic for persistent cancer pain, *Asacol*, an ulcerative colitis treatment, and *Romiplate*, a treatment for chronic idiopathic thrombocytopenic purpura, also grew steadily.
- We began sales of *POTELIGEO*<sup>®</sup> for adult T-cell leukemia-lymphoma (ATL) in May and *Apokyn*<sup>®</sup> for the treatment of Parkinson's disease in July, and sales performed well.
- In the licensing-out of technologies and export of pharmaceutical products, sales increased due to strong exports combined with the booking of licensing revenue from FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. for the development of biosimilars.
- Sales of 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 which was newly consolidated as of June 30, 2011, performed broadly in line with expectations, contributing net

sales of ¥16.2 billion with an operating loss (after amortization of goodwill) of ¥2.5 billion. R&D activities in the Pharmaceuticals business were as follows:

## **Oncology**

(Domestic)

- We received approval in March for *POTELIGEO*<sup>®</sup> for relapsed or refractory CCR4-positive adult T-cell leukemia-lymphoma (ATL) and began sales in May. Also, in March Kyowa Medex Co., Ltd. secured approval for *POTELIGEO*<sup>®</sup> *TEST*, an in vitro diagnostic reagent designed to help identify patients most likely to respond to *POTELIGEO*<sup>®</sup>, and began sales in May.
- In November, we submitted an application for approval of KW-2246 a treatment for cancer pain (overseas brand name *Abstra*).
- In October, we resolved to discontinue international Phase III trials in Japan, Korea and Taiwan of ARQ 197 in combination with *Erlotinib* for patients with advanced or metastatic non-small cell lung cancer, after a recommendation by the Safety Review Committee concerning side effects in interstitial lung disease patients.

(Overseas)

- In South Korea, we secured approval in May for neutropenia treatment, *Neulasta*.
- In Taiwan, we received approval in October for *Sancuso* (common name: *Granisetron*), a treatment for nausea and vomiting induced by chemotherapy.
- In the U.S., we began phase III studies in December on KW-0761 (domestic brand name *POTELIGEO*<sup>®</sup>) for relapsed or refractory cutaneous T-cell lymphoma.
- In Europe and the U.S., we began phase II trials in August on KW-0761 for relapsed or refractory adult T-cell leukemia-lymphoma.
- In Europe, ProStrakan received approval in April for *Sancuso*, a treatment for nausea and vomiting induced by chemotherapy.

## **Nephrology**

(Domestic)

- In September we filed for additional approval of *Nesp* for renal anemia in infants.
- We began Phase II trials in February on RTA 402 for chronic kidney disease patients with Type 2 diabetes mellitus, but decided to suspend the trials in October following news that the overseas phase III trial being conducted by Reata Pharmaceuticals had been terminated due to safety concerns.

(Overseas)

- In India, in September we discontinued phase III trials on KRN321 for renal anemia in dialysis patients following a review of our portfolio in response to changes in the business environment and other factors.

## **Immunology and allergy**

(Domestic)

- We began Phase II trials in December on KHK4827 for psoriasis.

## **CNS**

(Domestic)

- We obtained approval in March for *Apokyn*<sup>®</sup> for the treatment of Parkinson's disease and began sales in July.
- We filed in March for approval of KW-6002, also for Parkinson's disease.
- In December we filed for additional approval of anti-epileptic drug *Topina* for use in infants and for a new formulation (granules)
- We began phase II trials in May on KHK6188, an agent for neuropathic pain in post-herpes zoster patients.

## Other

(Overseas)

- We obtained approval in October for *Nplate* (domestic brand name *Romiplate*) for the treatment of chronic idiopathic thrombocytopenic purpura.

## Bio-Chemicals business

	Fiscal year ended December 31, 2012	Fiscal year ended December 31, 2011	(Billions of yen) Change
Net sales	76.9	77.5	(0.5)
Operating income	2.1	2.8	(0.7)

### Domestic business

- Sales in the pharmaceutical and medical treatment fields increased compared to the previous fiscal year.
  - In the pharmaceutical and medical fields pharmaceutical-use amino acids, nucleic acids such as ATP, and other pharmaceutical raw materials each performed steadily.
  - Tranexamic acid sales volumes grew strongly following completion of production facilities in the previous year.
- Sales in the healthcare field were broadly unchanged on the previous fiscal year.
  - In healthcare, we achieved strong growth in mail-order sales, primarily those of *Ornithine*.
  - As an ingredient in Kirin Health Project *KIRIN Plus-i* brands, *Ornithine* is blended in beverages, yoghurt and rice porridge. While awareness has greatly increased due to the synergistic effect of mail-order sales advertising, sales as a raw material have also increased.
  - However, sales of materials other than food and beverage raw materials were subdued.

### Overseas business

- Sales in overseas business were in line with the previous year.
  - In the US, sales of amino acids for supplements performed steadily.
  - In Europe and Asia, amino acids and nucleic acids including infusion-use amino acids, and pharmaceutical raw material-use citicoline continued to perform strongly.
  - High capacity utilization at each factory continued and we responded to this buoyant demand by revising sales prices.
  - However, overseas sales were flat overall due to the significant impact of the strong yen.
- In R&D, we are actively developing manufacturing methods for new raw materials using high technological capabilities and developing new markets while continuing to focus on research to improve efficiency in the fermentation production process for core products such as amino acids, nucleic acids and related compounds.
- Through the combination of fermentation technology and organic synthesis technology we are developing new manufacturing methods for high value-added pharmaceuticals and intermediate products.
- In the healthcare field, based on functional data obtained through joint research with Japanese and overseas universities and research institutes we are actively making new product proposals and application developments that can contribute to health maintenance.

## Other

(Billions of yen)

	Fiscal year ended December 31, 2012	Fiscal year ended December 31, 2011	Change
Net sales	10.4	10.6	(0.2)
Operating income	0.3	0.3	(0.0)

Net sales in the Other segment, principally distribution, were ¥10.4 billion (down by 2.2% compared to the previous fiscal year), while operating income was ¥0.3 billion (down 5.9%).

## 2) Outlook for Fiscal 2013

(Billions of yen)

	FORECAST* FY to December 31, 2013	Change compared to FY ended December 31, 2012	% Change compared to FY ended December 31, 2012
Net sales	338.0	4.8	1.5%
Operating income	55.0	2.0	4.0%
Ordinary income	49.0	(0.0)	0.0%
Net income	30.0	5.8	24.0%

These forecasts assume average exchange rates for fiscal 2013 of ¥85/US\$, ¥115/euro and ¥140/British pound.

- In the Pharmaceuticals business, we forecast an increase in sales compared to the previous fiscal year due to growth in domestic sales volumes of products such as *Nesp*, a treatment for renal anemia, *Patanol* antiallergic eye drops, *Fentos*, a transdermal analgesic for persistent cancer pain, *Asacol*, an ulcerative colitis treatment, and *Regpara*, a treatment for secondary hyperthyroidism during dialysis therapy, as well as growth in overseas sales at ProStrakan. However, segmental operating income is expected to decline due to lower licensing revenue and other factors.
- In the Bio-Chemicals business, we are forecasting higher sales and profits due to an increase in sales volumes of core amino acids, nucleic acids and Ornithine and other factors, and in addition to making progress with the restructuring of Daiichi Fine Chemical Co., Ltd., we also expect the yen to weaken compared to fiscal 2012.
- Ordinary income is forecast to be at the same level as last fiscal year due to factors including an increase in losses from investment in equity method and other factors. However, net income is expected to increase due to a decline in extraordinary losses and the recording of extraordinary gains on the sales of affiliates' stocks and other factors.

\*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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