KYOWA KIRIN

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Kyowa Hakko Kirin Fiscal 2013 Results: Strong domestic pharmaceutical sales, forex, and extraordinary gains offset challenging operating environment

Tokyo, January 31, 2014--- Kyowa Hakko Kirin Co., Ltd. (Kyowa Hakko Kirin; TSE 4151) today announced its consolidated financial results for the fiscal year ended December 31, 2013, a year in which our U.K. subsidiary, ProStrakan Group plc, recorded its first operating profit.

Compared to the previous year, consolidated net sales increased ¥7.4 billion to ¥340.6 billion. Operating income decreased ¥1.1 billion to ¥51.7 billion, ordinary income increased ¥0.5 billion to ¥49.5 billion, and net income increased ¥5.8 billion to ¥30.0 billion.

Our consolidated financial results forecasts for fiscal 2014 (January 1, 2014 to December 31, 2014) are for net sales of ¥337.0 billion, a decrease of 1.1% compared to the previous fiscal year, operating income of ¥41.0 billion, down 20.8%, ordinary income of ¥35.0 billion, down 29.3%, and net income of ¥20.0 billion, a decrease of 33.5%.

Commenting on the results, Nobuo Hanai, President and CEO of Kyowa Hakko Kirin said, *"Net sales exceeded forecasts in 2013, reflecting strong sales of pharmaceutical products in Japan and continued growth of ProStrakan, as well as yen weakness. While sales volumes are expected to remain strong in 2014, we are forecasting a decline in net sales and operating income, reflecting the significant impact expected from drug price revisions and investment in late-stage development products. Looking ahead, we will pursue our strategy to develop globally 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 2013 Results

(Amounts less than ¥0.1 billion have been ignored)

1) Operating results for the fiscal year ended December 31, 2013

(Billions of yen)

	Fiscal year ended December 31, 2013	Fiscal year ended December 31, 2012	Change
Net sales	340.6	333.1	7.4
Operating income	51.7	52.9	(1.1)
Ordinary income	49.5	49.0	0.5
Net income	30.0	24.1	5.8

- In the Pharmaceuticals business, the operating environment remained challenging, impacted by a decline in both domestic and international success rates of new drug generation, stricter screening, and progress with measures to reduce medical treatment costs.
  Against this background, Kyowa Hakko Kirin launched NOURIAST®, an antiparkinsonian agent which uses a globally unique new mechanism, Onglyza®, a treatment for type-two diabetes, and Abstral® a treatment for cancer pain, and pursued swift penetration of the market with these new products and expanded sales of core products. In overseas markets,

ProStrakan Group plc and its 11 subsidiaries (ProStrakan), achieved an important milestone, recording an operating profit (after amortization of goodwill, etc.). We also continue to actively pursue clinical development in the Europe and the U.S.

- In the Bio-Chemicals business, sales increased from the previous fiscal year as a result of steps to strengthen mail-order sales of health food materials such as Ornithine, and due to expanded sales of amino acids, nucleic acids and related compounds with a focus on pharmaceutical and medical applications. Profits increased significantly due to in part to the effect of yen weakness, which was pronounced because overseas sales account for a comparatively large share of the overall business.
- Consolidated net sales for the fiscal year increased due to strong sales of pharmaceutical products in Japan and continued growth of U.K. subsidiary ProStrakan, as well as benefits from the weaker yen. Operating income however declined due to a decline in technology licensing income and other factors.
- We achieved a record high in both ordinary income and net income. Ordinary income increased due to the booking of forex related gains and a decline in losses at equity-accounted affiliates, and net income increased due to the recording of extraordinary gains on the sale of affiliates' stock and other factors.

Pharmaceuticals business

(Billions of yen)

	Fiscal year ended December 31, 2013	Fiscal year ended December 31, 2012	Change
Net sales	261.0	259.3	1.6
Operating income	46.1	50.7	(4.6)

- Domestic sales of ethical pharmaceutical products were up compared to the previous fiscal year.
  - Sales of core product NESP®, a treatment for renal anemia, declined year on year due to lower shipments following the launch of a unified dosage product in December 2012. Sales of Patanol® anti-allergy eye drops grew significantly due to the effects of higher amounts of airborne pollen. However, due in part to the impact of generics, sales of ALLELOCK®, an anti-allergy agent, and sales of CONIEL®, a hypertension and angina pectoris drug, declined from the previous fiscal year.
  - Sales of REGPARA®, a treatment for secondary hyperparathyroidism during dialysis therapy, ASACOL®, an ulcerative colitis treatment, Romiplate®, a treatment for chronic idiopathic thrombocytopenic purpura, and Fentos®, a transdermal analgesic for persistent cancer pain, all advanced steadily.
  - In May, we launched NOURIAST®, the world's first antiparkinsonian agent of an adenosine A_{2A} receptor antagonist. We launched Onglyza®, a treatment for type-two diabetes, in July and Abstral®, a treatment for cancer pain, in December.
- In the licensing-out of technologies and export of pharmaceutical products, exports were steady but a decline in licensing revenue for the development of biosimilars from FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd., and other factors, resulted in a decline in sales.
- ProStrakan net sales were ¥23.3 billion (up 43.4%), driven by strong growth of Abstral® a treatment for cancer pain, and other core products. Operating income (after amortization of goodwill, etc.) was ¥0.2 billion (compared to an operating loss of ¥2.5 billion in the previous fiscal year).

R&D activities in the Pharmaceuticals business:

Nephrology

(Domestic)

- Approvals for additional pediatric indications for NESP®, a treatment for renal anemia, and for the 5μg Plastic Syringe were received in September.
- In November we suspended phase II trials of RTA 402, targeting patients with chronic kidney disease (CKD) with type 2 diabetes. Although this trial has been suspended, we continue to assess new development programs for RTA 402 in CKD patients with type 2 diabetes.

(Overseas)

- In China, we are currently seeking approval of Cinacalcet Hydrochloride (product name in Japan: REGPARA®), a treatment for secondary hyperparathyroidism. (Application filed in October 2011.)
- In China we began phase III trials in April for KRN321 (product name in Japan: NESP®) for the treatment of renal anemia in patients receiving dialysis.

Oncology

(Domestic)

- We received approval in February for additional indications for intramuscular administration and dosage of Leunase®, an anti-cancer drug.
- In March we received approval for additional indication of Pheochronocytoma for anti-cancer drug Dacarbazine®.
- In June we filed an application for marketing approval for sustained-duration G-CSF product KRN125 for the treatment of chemotherapy induced febrile neutropenia.
- In June we applied for additional indications of hypercalcemia in patients with parathyroid carcinoma, and hypercalcemia in patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy or who experience recurrent primary hyperparathyroidism for REGPARA®, a treatment for secondary hyperparathyroidism during dialysis therapy.
- In July we applied for approval for additional indications for untreated CCR4-positive adult T-cell leukemia-lymphoma (ATL), relapsed CCR4-positive peripheral T-cell lymphoma (PTCL) and cutaneous T-cell lymphoma (CTCL) and for dosage and administration for anti-CCR4 humanized antibody POTELIGEO®.
- Application for Abstral®, a treatment of cancer pain, was approved in September and sales began in December.
- In December, we received approval for additional indications for unresectable pancreatic cancer and dosage and administration of injectable 5-FU.
- We are currently preparing to start phase III trials of ARQ 197 targeting hepatocellular cancer.

(Overseas)

- KW-0761 (product name in Japan: POTELIGEO®) is currently undergoing phase III trials targeting cutaneous T-cell lymphoma in the U.S. and Europe, phase II trials targeting peripheral T-cell lymphoma in Europe, and phase II trials targeting adult T-cell leukemia/ lymphoma in the U.S. and Europe.

Immunology and allergy

(Domestic)

- We began phase III trials in March on KHK4827 for psoriasis.
- In October, we completed a phase II trial of KHK4563, an anti-IL-5 receptor humanized antibody, in asthma patients. We are currently preparing for participation in a global phase III program, which began in October and is being conducted by our licensing partner, AstraZeneca.

CNS

(Domestic)

- In February we obtained approval for a time-window extension of thrombolytic agent ACTIVACIN® for administration within 4.5 hours after the onset of symptoms of ischemic cerebrovascular disease (up from 3 hours).
- We acquired approval for NOURIAST® for the treatment of Parkinson's disease in March, and launched the drug in May.
- In November we acquired additional approval of anti-epileptic drug TOPINA® for use in infants
- We are currently seeking approval for a new formulation (granules) for anti-epileptic drug TOPINA®. (Application filed December 2012.)

(Overseas)

- A global phase III trial for KW-6002 (product name in Japan: NOURIAST®) began in November targeting Parkinson's disease.

Other

(Domestic)

- In February we received approval for an additional indication of Pasetocin®, a synthesized penicillin drug (as part of triple therapy including proton pump inhibitors and either clarithromycin or metronidazole) for the eradication of Helicobacter pylori in Helicobacter pylori gastritis infection.
- We are currently analyzing results of phase III trials of recombinant antithrombin (AT) preparation KW-3357 for disseminated intravascular coagulation (DIC) accompanied by a decrease in AT.

(Overseas)

- Anti-FGF23 fully human antibody KRN23, is currently undergoing phase I/II trials in North America for X-linked hypophosphatemia (XLH).

Bio-Chemicals business

(Billions of yen)

	Fiscal year ended December 31, 2013	Fiscal year ended December 31, 2012	Change
Net sales	82.9	76.9	5.9
Operating income	5.6	2.1	3.5

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 and other active pharmaceutical ingredients (APIs) each performed steadily.
  - *Tranexamic acid* sales declined from the previous year, during which there was a concentration of shipments.
- Sales in the healthcare field declined from the previous year.
  - In healthcare, we achieved strong growth in mail-order sales, primarily those of Ornithine.
  - As an ingredient in healthy *KIRIN Plus-i* brand products, Ornithine is used in beverages and other products and its increased recognition has contributed to mail-order sales.
  - Food and beverage raw materials sales declined year on year.

Overseas business

- Sales from overseas businesses were higher than the previous year due in part to a weaker yen.

- In the U.S., sales of some amino acids for supplements declined due to intensifying competition, but overall net sales increased from the previous year.
- Sales in Europe increased compared to the previous year due to an increase in sales volumes of APIs.
- In Asia, although the tough competitive environment remained, sales increased due to an increase in sales of infusion-use amino acids in China.

R&D activities in the Bio-Chemicals business:

- We are actively developing manufacturing methods for raw materials such as oligosaccharides 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 APIs and intermediate products.
- In the healthcare field, based on functionality and safety 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. We are also working on the development of dosage forms that are easy to use.

2) Outlook for Fiscal 2014

(Billions of yen)

	FORECAST* FY to December 31, 2014	Change compared to FY ended December 31, 2013	% Change compared to FY ended December 31, 2013
Net sales	337.0	(3.6)	(1.1%)
Operating income	41.0	(10.7)	(20.8%)
Ordinary income	35.0	(14.5)	(29.3%)
Net income	20.0	(10.0)	(33.5%)

These forecasts assume average exchange rates of ¥100/US$, ¥130/euro and ¥155/British pound.

- In the Pharmaceuticals business, we forecast an increase in sales volumes compared to the previous fiscal year due to growth in domestic sales volumes of core product NESP®, a treatment for renal anemia, and new products such as NOURIAST® an antiparkinsonian agent and Onglyza®, a treatment for type-two diabetes. In overseas markets we expect sales at ProStrakan to increase. However, we expect to be significantly affected by drug price revisions that are expected to be implemented in April 2014 and therefore consolidated net sales for fiscal 2014 are forecast to decline. In addition, as we expect to incur expenses for development of late-stage development products, operating income is expected to decline.
- 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.
- Ordinary income is forecast to decline due to the expected decline in operating income as well as an increase in losses from equity-accounted affiliates and other factors. Net income is also expected to decline due to a decline in extraordinary gains.

*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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