

# **Kyowa Hakko Kirin Co., Ltd.**

## **Consolidated Financial Summary Fiscal 2013, Third Quarter**

(January 1, 2013 – September 30, 2013)

This document is an English translation of parts of the Japanese-language original. All financial information has been prepared in accordance with generally accepted accounting principles in Japan. It contains forward-looking statements based on a number of assumptions and beliefs made by management in light of information currently available. Actual financial results may differ 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.

## Summary of Financial Statements for the Third Quarter of the Year Ending December 31, 2013

**Kyowa Hakko Kirin Co., Ltd.**

**October 25, 2013**

Stock Code: 4151	Listed exchanges: Tokyo, 1 <sup>st</sup> section
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Scheduled date of submission of Financial Report: November 8, 2013	Scheduled start date of dividend payment: ---

Appendix materials prepared to accompany the quarterly financial report: Yes

Quarterly results presentation meeting: Yes (For institutional investors and securities analysts)

### 1. Results for the nine months ended September 30, 2013

(%changes are compared to the same period of the previous fiscal year)

#### (1) Consolidated business performance

(Millions of yen, rounded down)

	Nine months to September 30, 2013	Change (%)	Nine months to September 30, 2012	Change (%)
Net sales	252,103	3.0	244,691	(6.7)
Operating income	41,409	10.9	37,343	(3.0)
Ordinary income	39,203	20.3	32,581	(15.4)
Net income	23,323	51.1	15,440	(31.9)
Net income per share (¥)	42.61		28.14	
Fully diluted net income per share (¥)	42.58		28.12	

Note: Comprehensive income: FY to September 30, 2013: ¥36,768 million (100.4%); FY to September 30, 2012: ¥18,348 million (16.7%)

#### (2) Consolidated financial position

(Millions of yen, rounded down)

	As of September 30, 2013	As of December 31, 2012
Total assets	691,278	679,342
Net assets	580,362	555,898
Shareholders' equity ratio (%)	83.8	81.7

Note: Total shareholders' equity: September 30, 2013: ¥579,057 million; December 31, 2012: ¥554,870 million

### 2. Dividends

Dividends per share	Fiscal year ending December 31, 2013 (forecast)	Fiscal period ended December 31, 2012
First quarter per share (¥)	--	---
Interim dividend per share (¥)	12.50	10.00
Third quarter dividend per share (¥)	--	---
Year-end dividend per share (¥)	12.50 (forecast)	10.00
Total dividend per share (¥)	25.00 (forecast)	20.00

Note: Changes to the dividend forecast during the term: None.

### 3. Consolidated results forecasts for the fiscal year ending December 31, 2013

(Millions of yen)

	January 1, 2013 to December 31, 2013	Change (%)
Net sales	339,000	1.8
Operating income	51,000	(3.6)
Ordinary income	48,000	(2.0)
Net income	28,000	15.7
Net income per share (¥)	51.15	

Notes: 1. Percentage changes are compared to the previous fiscal year  
2. Changes compared to the most recent published forecast: None

#### Notes:

- 1) **Transfer of important subsidiaries during the period (transfers of specified subsidiaries resulting in changes in the scope of consolidation during the period under review):** No
- 2) **Use of special accounting procedures in the preparation of quarterly consolidated financial statements:** Yes  
See Page 7, Section 2. Summary information (Other items)
- 3) **Changes to accounting policies, accounting estimates, and restatement of revisions:**
  1. Changes following revisions to accounting standards: Yes
  2. Changes to accounting policies other than 1. above: No
  3. Changes to accounting estimates: Yes
  4. Restatement of revisions: No
 See Page 7, Section 2. Summary information (Other items)

#### 4) Number of shares outstanding (ordinary shares)

1. Number of shares outstanding (including treasury shares)	September 30, 2013	576,483,555 shares	December 31, 2012	576,483,555 shares
2. Number of treasury shares	September 30, 2013	29,109,689 shares	December 31, 2012	29,062,630 shares
3. Average number of shares during the nine-month period	Third quarter period ended September 30, 2013	547,402,840 shares	Third quarter period ended September 30, 2012	548,757,014 shares

#### Notice regarding quarterly review procedures

The Financial Products Law review process for this quarterly financial report was not yet complete at the time this financial report was issued.

#### Notice regarding the appropriate use of the financial forecasts and other special comments

Forecasts of results and other forward-looking statements contained in this document are based on information available to and on assumptions deemed reasonable by the company at the time of release of this document. Actual results may be affected by a range of factors and may differ materially.

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## 1. Operating Results and Financial Statements

### (1) Summary of business performance

Net sales for the first nine-months of the fiscal year (January 1, 2013 to September 30, 2013) were ¥252.1 billion (up 3.0% compared to the first nine-months of the previous fiscal year), operating income was ¥41.4 billion (up 10.9%) and ordinary income was ¥39.2 billion (up 20.3%). Net income for the nine-month period was ¥23.3 billion (up 51.1%).

- Growth in net sales and operating income was driven by a strong performance from ethical pharmaceutical products in Japan, continued strong growth from ProStrakan, along with some benefits from a further decline in the yen.
- Ordinary income also grew, driven by the increase in operating income in addition to the booking of foreign exchange gains and a decline in losses from equity-accounted affiliates. Net income for the period also increased due to the booking of extraordinary profit from the gain on sale of shares in an affiliated company and other factors.

### Performance by segment

*Note: As of the first quarter of the current fiscal year there has been a revision to the way segments are classified. Year-on-year comparisons shown below are with adjusted figures for the first half of last year reflecting these revisions. (For details please see page 12, (5.) Segment information.*

### Pharmaceuticals business

#### 1. Results

In the Pharmaceuticals business, net sales were ¥192.7 billion (up 1.7%) and operating income was ¥36.9 billion (up 5.3%).

- Domestic sales of ethical pharmaceutical products were up from the same period in the previous fiscal year despite the impact of drug price revisions, which were implemented in April 2012.
  - Sales of core product NESP<sup>®</sup>, a treatment for renal anemia, declined year on year due to lower shipments following the launch of unified dosage product which launched in December 2012. Sales of Patanol<sup>®</sup> 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<sup>®</sup>, an anti-allergy agent, and sales of CONIEL<sup>®</sup>, a hypertension and angina pectoris drug, declined from the same period in the previous fiscal year.
  - Sales of REGPARA<sup>®</sup>, a treatment for secondary hyperparathyroidism during dialysis therapy, ASACOL<sup>®</sup>, an ulcerative colitis treatment, Romiplate<sup>®</sup>, a treatment for chronic idiopathic thrombocytopenic purpura, and Fentos<sup>®</sup>, a transdermal analgesic for persistent cancer pain, all advanced steadily.
  - In May, we launched NOURIAST<sup>®</sup>, the world's first antiparkinsonian agent of an adenosine A<sub>2A</sub> receptor antagonist.
  - In July, we launched Onglyza<sup>®</sup>, a treatment for type-two diabetes.
- In the licensing-out of technologies and export of pharmaceutical products, exports were steady but licensing revenue for the development of biosimilars from FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. declined significantly.
- ProStrakan net sales were ¥16.7 billion (up 44.6%), with strong growth in Abstral<sup>®</sup> a treatment for cancer pain, and other core products. Operating income (after amortization of goodwill, etc.) was ¥0.1 billion (compared to an operating loss of ¥2.5 billion in the comparable nine-month period of the previous fiscal year).

## 2. Research and development

### **Oncology**

#### (Domestic)

- We received approval in February for additional indications for intramuscular administration and dosage of Leunase<sup>®</sup>, an anti-cancer drug.
- In March we received approval for additional indication of Pheochromocytoma for anti-cancer agent Dacarbazine<sup>®</sup>.
- In May we applied for approval for additional indications for pancreatic cancer and dosage and administration of injectable 5-FU.
- 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<sup>®</sup>, 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 POTELIGEO<sup>®</sup>, a humanized anti-CCR4 monoclonal antibody.
- Application for Abstral<sup>®</sup>, a treatment of cancer pain, was approved in September.

### **Nephrology**

#### (Domestic)

- Approvals for additional pediatric indications for NESP<sup>®</sup>, a treatment for renal anemia, and for the 5µg Plastic Syringe were received in September.

#### (Overseas)

- In China, we are currently seeking approval of Cinacalcet Hydrochloride (product name in Japan: REGPARA<sup>®</sup>), 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<sup>®</sup>) for the treatment of renal anemia in patients receiving dialysis.

### **Immunology and allergy**

#### (Domestic)

- We began Phase III trials in March for KHK4827 for psoriasis.

### **CNS**

#### (Domestic)

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

### **Other**

#### (Domestic)

- In February, we received approval for an additional indication of Pasetocin<sup>®</sup>, 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.

## **Bio-Chemicals business**

Sales in the Bio-Chemicals business increased by 7.1% to ¥61.5 billion, while operating income increased 103.7% to ¥4.5 billion.

### Domestic business

- Sales in the pharmaceutical and medical treatment fields increased compared to the previous fiscal year.
  - In the pharmaceutical and medical treatment fields, pharmaceutical-use amino acids, nucleic acids and related compounds, and other pharmaceutical raw materials performed steadily.
  - Tranexamic acid sales declined from the same period of the previous year, during which there was a concentration of shipments.
- In the healthcare field, year-on-year mail-order sales, such as those of ornithine, increased, but sales of food and beverage raw materials 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 same period in the previous year.
  - In Europe and Asia, some products such as industrial-use amino acids declined from the same period of the previous year due to intensifying competition, but overall net sales increased year on year due to the continued strong performance of infusion-use amino acids.

## **(2) Summary of consolidated financial position**

- Total assets as of September 30, 2013 were ¥691.2 billion, an increase of ¥11.9 billion compared to the end of the previous fiscal year.
  - Current assets increased by ¥1.5 billion to ¥305.5 billion due to a decrease in notes and accounts receivable and an increase in inventory assets and short-term loans receivable
  - Non-current assets increased by ¥10.4 billion to ¥385.7 billion due to an increase in tangible assets and sales rights.
- Liabilities were ¥110.9 billion, a decrease of ¥12.5 billion compared to the end of the previous fiscal year, due to declines in notes and accounts payable and income taxes payable.
- Net assets at the end of the fiscal year were ¥580.3 billion, an increase of ¥24.4 billion due to addition of net income for the period, as well as increases in the valuation difference on the available-for-sale securities account and the foreign exchange adjustment account.

As a result, the shareholders' equity ratio as of the end of the nine-month period was 83.8%, an increase of 2.1 percentage points compared to the end of the previous fiscal year.

### **(3) Consolidated results forecasts**

There have been no changes made to the consolidated fiscal results forecast announced July 26, 2013.

## **2. Summary Information (Other items)**

### **(1) Changes to significant subsidiaries during the period**

No applicable items.

### **(2) Use of special accounting procedures in the preparation of this report**

Calculations for tax expenses use an estimated effective tax rate for net income before taxes based on reasonable assumptions of an effective tax rate after the application of tax effect accounting for net income before income taxes for the consolidated fiscal year, including net income before income taxes of the nine-month period under review.

### **(3) Changes to accounting policies and changes or revisions to accounting estimates**

(Changes to accounting policies in cases where it is difficult to distinguish between a change in an accounting policy and a change in an accounting estimate)

From the first quarter fiscal period, in respect of tangible non-current assets acquired since January 1, 2013, Kyowa Hakko Kirin and its domestic consolidated subsidiaries have changed the method of calculation of depreciation based on the revised Corporate Tax Law.

The effects of this change on the third quarter figures for operating income, ordinary income and net income before income taxes are minimal.

## 3. Consolidated financial statements

### (1) Consolidated Balance Sheets

	<i>Millions of yen</i>	
	As of September 30, 2013	As of December 31, 2012
<b>ASSETS</b>		
Current assets:		
Cash and deposits	21,435	21,577
Notes and accounts receivable - trade	92,007	101,556
Merchandise and finished goods	49,637	40,334
Work in process	12,723	12,176
Raw materials and supplies	10,465	10,931
Deferred tax assets	10,701	10,369
Short-term loans receivable	101,134	98,194
Other	7,842	9,228
Allowance for doubtful accounts	(440)	(381)
Total current assets	305,506	303,988
Noncurrent assets:		
Property, plant and equipment		
Buildings and structures	130,788	134,875
Accumulated depreciation	(90,362)	(94,114)
Buildings and structures, net	40,426	40,760
Machinery, equipment and vehicles	145,888	143,595
Accumulated depreciation	(126,303)	(124,200)
Machinery, equipment and vehicles, net	19,584	19,395
Land	54,674	53,386
Construction in progress	12,498	7,360
Other	47,371	48,166
Accumulated depreciation	(41,095)	(42,196)
Other, net	6,275	5,969
Total property, plant and equipment	133,459	126,872
Intangible assets		
Goodwill	163,761	168,850
Marketing rights	45,221	36,214
Other	1,929	2,442
Total intangible assets	210,912	207,506
Investments and other assets		
Investment securities	24,012	23,654
Deferred tax assets	6,434	7,724
Other	11,170	9,871
Allowance for doubtful accounts	(218)	(276)
Total investments and other assets	41,399	40,974
Total non-current assets	385,771	375,353
Total assets:	691,278	679,342

## Consolidated Balance Sheets (continued)

Millions of yen

	As of September 30, 2013	As of December 31, 2012
<b>LIABILITIES</b>		
Current liabilities:		
Notes and accounts payable - trade	17,905	26,303
Short-term loans payable	5,552	5,699
Accounts payable - other	26,472	29,009
Income taxes payable	11,235	15,777
Provision for sales rebates	897	771
Provision for point card certificates	246	187
Provision for bonuses	4,057	241
Other	6,751	7,784
Total current liabilities	73,116	85,774
Noncurrent liabilities:		
Deferred tax liabilities	11,461	11,262
Provision for retirement benefits	19,095	19,503
Provision for directors' retirement benefits	124	114
Provision for environmental measures	321	331
Allowance for loss on plants reorganization	3,390	--
Asset retirement obligations	383	383
Other	3,022	6,074
Total noncurrent liabilities	37,799	37,668
Total liabilities:	110,915	123,443
<b>NET ASSETS</b>		
Shareholders' equity:		
Capital stock	26,745	26,745
Capital surplus	512,328	512,329
Retained earnings	59,134	48,127
Treasury stock	(26,595)	(26,538)
Total shareholders' equity	571,612	560,663
Other accumulated comprehensive income adjustments		
Valuation difference on available-for-sale securities	1,097	(2,264)
Foreign currency translation adjustment	6,347	(3,528)
Total other accumulated comprehensive income adjustments	7,445	(5,792)
Subscription rights to shares:	274	203
Minority interests:	1,030	823
Total net assets:	580,362	555,898
Total liabilities and net assets:	691,278	679,342

## (2) Consolidated Statements of Income

Millions of yen

	January 1, 2013 to September 30, 2013	January 1, 2012 to September 30, 2012
Net sales	252,103	244,691
Cost of sales	94,839	90,305
Gross profit	157,264	154,386
Selling, general and administrative expenses		
Research and development expenses	30,723	33,626
Amortization of goodwill	8,648	9,127
Other	76,482	74,288
Total selling, general and administrative expenses	115,854	117,043
Operating income	41,409	37,343
Non-operating income		
Interest income	574	436
Dividend income	534	477
Foreign exchange gains	654	106
Gain on valuation of derivatives	568	--
Other	661	913
Total non-operating income	2,994	1,933
Non-operating expenses		
Interest expenses	205	150
Loss on valuation of derivatives	--	134
Equities in losses in affiliates	3,590	4,643
Loss on disposal of noncurrent assets	502	631
Other	900	1,135
Total non-operating expenses	5,199	6,694
Ordinary income	39,203	32,581
Extraordinary income		
Gain on sales of subsidiaries and affiliates' stocks	3,217	--
Gain on sales of noncurrent assets	1,065	--
Gain on sales of investment securities	673	--
Total extraordinary income	4,956	--
Extraordinary loss		
Provision for loss on plants reorganization	3,390	--
Loss on valuation of shares in affiliate companies	140	--
Loss on sales of investment securities	131	340
Loss on valuation of investment securities	--	905
Total extraordinary loss	3,661	1,246
Income before income taxes and minority interests	40,498	31,335
Income taxes	17,107	15,847
Income before minority interests	23,391	15,488
Minority interests in income	67	47
Net income	23,323	15,440

## Consolidated Statements of Comprehensive Income

(Millions of yen)

	January 1, 2013 to September 30, 2013	January 1, 2012 to September 30, 2012
Income before minority interests	23,391	15,488
Other comprehensive income		
Valuation difference on available-for-sale securities	3,361	934
Foreign currency translation adjustment	10,015	1,921
Share of other comprehensive income of associates accounted for using equity method	--	4
Total other comprehensive income	13,377	2,860
Comprehensive income	36,768	18,348
(Comprehensive attributable to)		
Comprehensive income attributable to owners of the parent	36,561	18,293
Comprehensive income attributable to minority interests	207	55

### (3) Items related to going concern assumption

No applicable items

### (4) Notes on significant change in shareholders' equity

No applicable items

### (5) Segment information

Fiscal 2012 segment information cumulative to Q3 by business type (January 1, 2012 – September 30, 2012) is as shown below in section 2. Changes in reported segment information

Fiscal 2013 segment information cumulative to Q3 (January 1, 2013 – September 30, 2013)

#### 1. Sales and profit (loss) by segment

(Millions of yen)

	Pharmaceuticals	Bio-Chemicals	Total	Adjustments	Consolidated
Net sales					
Sales to external customers	191,718	60,385	252,103	--	252,103
Inter-segment sales and transfers	1,063	1,200	2,264	(2,264)	--
Total sales	192,781	61,585	254,367	(2,264)	252,103
Segment income	36,963	4,509	41,472	(63)	41,409

Notes: 1. The minus ¥63 million for adjustments of segment Income is due to intersegment eliminations.  
2. In segment income, operating income from the Consolidated Statements of Income has been adjusted.

#### 2. Changes in reported segment information

From this first quarter accounting period the classification of Kyowa Hakko Kirin Group affiliated companies has been reviewed and as a result affiliated companies previously included in the Other segment have been included in the Pharmaceuticals segment and the Other segment has been discontinued.

Segment information for sales and profit (loss) for the nine-month period of the previous fiscal year reflecting this change is as follows:

(Millions of yen)

	Pharmaceuticals	Bio-Chemicals	Total	Adjustments	Consolidated
Net sales					
Sales to external customers	188,498	56,193	244,691	--	244,691
Inter-segment sales and transfers	990	1,295	2,285	(2,285)	--
Total sales	189,489	57,488	246,977	(2,285)	244,691
Segment income	35,109	2,213	37,323	19	37,343

Notes: 1. The ¥19 million for adjustments of segment Income is due to intersegment eliminations.  
2. In segment income, operating income from the Consolidated Statements of Income, has been adjusted.