

# Kyowa Hakko Kirin Co., Ltd.

## Consolidated Financial Summary Fiscal 2014 First Quarter

(January 1, 2014 – March 31, 2014)

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 First Quarter of the Year Ending December 31, 2014

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

**April 24, 2014**

Stock Code: 4151	Listed exchanges: 1st Section of the Tokyo Stock Exchange
URL: <a href="http://www.kyowa-kirin.com">http://www.kyowa-kirin.com</a>	Inquiries: Shigeru Morotomi, Executive Officer
President: Nobuo Hanai	Corporate Communications Department
	Telephone: 81-3-3282-0009

Scheduled date of submission of Financial Report: May 8, 2014

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. Consolidated Financial Results for the three months ended March 31, 2014

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

#### (1) Consolidated business performance

(Millions of yen, rounded down)

	Three months to March 31, 2014	Change (%)	Three months to March 31, 2013	Change (%)
Net sales	86,079	(0.7)	86,669	(0.5)
Operating income	12,447	(14.0)	14,465	(19.8)
Ordinary income	12,063	(18.7)	14,836	(10.5)
Net income	6,332	(39.6)	10,489	23.2
Net income per share (¥)	11.57		19.16	
Fully diluted net income per share (¥)	11.56		19.15	

Note: Comprehensive income: Three months to March 31, 2014: ¥3,833 million (-77.2%); Three months to March 31, 2013: ¥16,802 million (+12.0%)

#### (2) Consolidated financial position

(Millions of yen, rounded down)

	As of March 31, 2014	As of December 31, 2013
Total assets	689,961	719,257
Net assets	591,481	595,415
Shareholders' equity ratio (%)	85.7	82.6

Note: Total shareholders' equity: March 31, 2014: ¥591,203 million; December 31, 2013: ¥593,957 million

### 2. Dividends

Dividends per share	Fiscal year ending December 31, 2014 (forecast)	Fiscal period ended December 31, 2013
First quarter per share (¥)	---	---
Interim dividend per share (¥)	12.50	12.50
Third quarter dividend per share (¥)	---	---
Year-end dividend per share (¥)	12.50	12.50
Total dividend per share (¥)	25.00	25.00

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

### 3. Consolidated results forecasts for the fiscal year ending December 31, 2014

(Millions of yen)

	January 1, 2014 to June 30, 2014	Change (%)	January 1, 2014 to December 31, 2014	Change (%)
Net sales	163,000	(4.0)	337,000	(1.1)
Operating income	16,000	(41.1)	41,000	(20.8)
Ordinary income	--	--	35,000	(29.3)
Net income	--	--	20,000	(33.5)
Net income per share	--	--	36.54	

Notes: 1. Changes to the consolidated results forecast during the term: None

2. Kyowa Hakko Kirin calculates forecasts for ordinary income and net income for the full year only therefore interim period forecasts for only net sales and operating income are shown.

#### 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 6, Section 2. Summary information (Other items)
- 3) **Changes to accounting policies, accounting estimates, and restatement of revisions:**
  1. Changes following revisions to accounting standards: No
  2. Changes to accounting policies other than 1. above: No
  3. Changes to accounting estimates: No
  4. Restatement of revisions: No

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

1. Number of shares outstanding (including treasury shares)	March 31, 2014	576,483,555 shares	December 31, 2013	576,483,555 shares
2. Number of treasury shares	March 31, 2014	29,100,123 shares	December 31, 2013	29,143,513 shares
3. Average number of shares during the three-month period	Quarter ended March 31, 2014	547,345,502 shares	Quarter ended March 31, 2013	547,417,916 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.

## Contents

### 1. Operating Results and Financial Statements

(1) Summary of consolidated business performance.....	4
(2) Summary of consolidated financial position.....	6
(3) Consolidated results forecasts.....	6

### 2. Summary Information (Other items)

(1) Changes to significant subsidiaries during the period.....	6
(2) Use of special accounting procedures in the preparation of this report.....	6
(3) Changes to accounting policies, accounting estimates, and restatement of revisions.....	6

### 3. Consolidated financial statements

(1) Consolidated balance sheets.....	7
(2) Consolidated statements of income and comprehensive income	
Consolidated statements of income.....	9
Consolidated Statements of comprehensive income.....	10
(3) Notes to the consolidated financial statements.....	11
(Items related to going concern assumption).....	11
(Notes applicable in cases of significant changes to shareholders' equity).....	11
(Segment information).....	11

## 1. Operating Results and Financial Statements

### (1) Summary of business performance

Net sales for the first three months of the fiscal year (January 1, 2014 to March 31, 2014) were ¥86.0 billion (down 0.7% compared to the first three months of the previous fiscal year), operating income was ¥12.4 billion (down 14.0%) and ordinary income was ¥12.0 billion (down 18.7%). Net income for the three-month period was ¥6.3 billion (down 39.6%).

- Net sales and operating income decreased due to a decline in licensing revenue and a decline in sales of anti-allergy agents and anti-allergy eye drops as a result of lower amounts of airborne pollen.
- The decline in ordinary income was a result of the decrease in operating income, the booking of foreign exchange losses and other factors while the decline in net income was due to recording gain on sales of subsidiaries and affiliates' stocks and other factors in the previous fiscal year.

### Performance by segment

#### Pharmaceuticals business

##### 1. Results

In the Pharmaceuticals business, net sales were ¥63.1 billion (down 6.3%) and operating income was ¥9.4 billion (down 27.7%).

- Domestic sales of ethical pharmaceutical products declined compared to the same period of the previous fiscal year.
  - Sales of core product NESP<sup>®</sup>, a treatment for renal anemia, were steady and sales increased over the same period in the previous fiscal year, in which sales declined due to lower shipments following the launch of a unified dosage product in December 2012. Sales of ALLELOCK<sup>®</sup>, an anti-allergy agent, and Patanol<sup>®</sup> anti-allergy eye drops declined year on year due to the effects of lower amounts of airborne pollen. Sales of ALLELOCK<sup>®</sup> were also impacted by the market penetration of generics.
  - Sales of REGPARA<sup>®</sup>, a treatment for secondary hyperparathyroidism during dialysis therapy, ASACOL<sup>®</sup>, an ulcerative colitis treatment, NOURIAST<sup>®</sup>, an antiparkinsonian agent, Abstral<sup>®</sup>, a treatment for cancer pain, Fentos<sup>®</sup>, a transdermal analgesic for persistent cancer pain, and Romiplate<sup>®</sup>, a treatment for chronic idiopathic thrombocytopenic purpura, all advanced steadily.
- In the licensing-out of technologies and export of pharmaceutical products, exports were steady but sales declined significantly due to a decline in licensing revenue and other factors.
- ProStrakan net sales were ¥6.5 billion (up 30.3%), operating income (after amortization of goodwill, etc.) was ¥0.1 billion (compared to an operating loss of ¥0.2 billion in the same period in the previous fiscal year). Sales of Abstral<sup>®</sup> a treatment for cancer pain, and other core products, grew strongly.

##### 2. Research and development

#### **Nephrology**

##### (Domestic)

- In March we applied for approval for calcium receptor agonist REGPARA<sup>®</sup> 12.5mg.

##### (Overseas)

- In China, we are currently seeking approval of Cinacalcet Hydrochloride (product name in Japan: REGPARA<sup>®</sup>), a calcium receptor agonist. (Application filed in October 2011.)

## **Oncology**

(Domestic)

- In February we received approval 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 following surgery, and for dosage and administration for REGPARA<sup>®</sup>.
- In March we received approval for additional indications for relapsed or refractory CCR4-positive peripheral T-cell lymphoma (PTCL) and cutaneous T-cell lymphoma (CTCL) and for dosage and administration for anti-CCR4 humanized antibody POTELIGEO<sup>®</sup>.
- In March we applied for approval for additional indication of NESP<sup>®</sup>, a treatment for renal anemia, for anemia with myelodysplastic syndrome.
- In February, we temporarily withdrew our application for approval for additional indication for untreated CCR4-positive adult T-cell leukemia-lymphoma (ATL) for POTELIGEO<sup>®</sup>.
- We are currently seeking approval for sustained-duration G-CSF product KRN125 for the treatment of chemotherapy induced febrile neutropenia (application filed in June 2013).
- In February, we initiated a phase III clinical study evaluating ARQ 197 patients with c-Met diagnostic-high inoperable hepatocellular carcinoma treated with one prior sorafenib therapy.

## **Immunology and allergy**

(Domestic)

- We are currently preparing for the inclusion of anti-IL-5 receptor humanized antibody, KHK4563 in a global phase III trial targeting asthma patients, which began in October 2013 and is being conducted by our licensing partner, AstraZeneca.

## **CNS**

(Domestic)

- In January, we received approval for a new formulation (granules) for anti-epileptic drug TOPINA<sup>®</sup>.

## **Bio-Chemicals business**

In the Bio-Chemicals business, net sales were ¥23.5 billion (up 18.0%) and operating income was ¥3.0 billion (up 106.1%).

### Domestic business

- Sales in the pharmaceutical and medical treatment fields increased compared to the first quarter of previous fiscal year.
- In the pharmaceutical and medical treatment fields, sales of active pharmaceutical ingredients (APIs) for generic pharmaceuticals grew.
- In the healthcare field, year-on-year mail-order sales, such as those of Ornithine, increased, but sales of food and beverage raw materials remained steady.

### Overseas business

- Sales from overseas businesses were higher than the previous year due in part to a weaker yen.
- In the U.S., sales increased from the same period in the previous year despite intensifying competition in some amino acids for supplements.
- In Europe, sales volumes of some products, such as infusion-use amino acids, declined due to the impact of customer production schedules, but sales increased overall due in part to yen depreciation.

- In Asia, sales increased significantly due to early shipments of some amino acids and nucleic acids and related compounds for the China market.

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

- Total assets as of March 31, 2014 were ¥689.9 billion, a decrease of ¥29.2 billion compared to the end of the previous fiscal year.
- Current assets decreased by ¥28.4 billion to ¥300.8 billion due to a decrease in short-term loans receivable to the parent company as part of cash management, and despite an increase in notes and accounts receivable-trade and an increase in inventories.
- Non-current assets decreased by ¥0.8 billion to ¥389.0 billion due to a decrease in goodwill as a result of amortization, a decrease in marketing rights, and other factors and despite an increase in property, plant and equipment and investments and other assets.
- Liabilities were ¥98.4 billion, a decrease of ¥25.3 billion compared to the end of the previous fiscal year, due to declines in accounts payable-other and income taxes payable, as well as a significant decrease in provision for retirement benefits due to a cash payment of ¥19.0 billion to retirement benefit trusts.
- Net assets were ¥591.4 billion, a decrease of ¥3.9 billion from the end of the previous fiscal year due to dividend payments, a decline in the foreign currency translation adjustment, and other factors, and despite the addition of net income for the period.

As a result, the shareholders' equity ratio as of the end of the first quarter was 85.7%, an increase of 3.1 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 on January 31, 2014.

## **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 three-month period under review.

### **(3) Changes to accounting policies, accounting estimates, and restatement of revisions**

No applicable items.

## 3. Consolidated financial statements

### (1) Consolidated Balance Sheets

	<i>Millions of yen</i>	
	As of March 31, 2014	As of December 31, 2013
<b>ASSETS</b>		
Current assets:		
Cash and deposits	17,236	20,190
Notes and accounts receivable - trade	102,987	98,602
Merchandise and finished goods	52,136	50,863
Work in process	15,111	13,465
Raw materials and supplies	11,730	11,371
Deferred tax assets	10,208	10,409
Short-term loans receivable	85,159	113,133
Other	6,737	11,780
Allowance for doubtful accounts	(409)	(497)
Total current assets	300,898	329,320
Noncurrent assets:		
Property, plant and equipment		
Buildings and structures	132,807	132,861
Accumulated depreciation	(91,454)	(90,637)
Buildings and structures, net	41,353	42,223
Machinery, equipment and vehicles	148,271	146,935
Accumulated depreciation	(126,701)	(125,860)
Machinery, equipment and vehicles, net	21,569	21,075
Land	54,580	54,620
Construction in progress	14,992	13,501
Other	48,389	47,795
Accumulated depreciation	(41,456)	(41,297)
Other, net	6,933	6,498
Total property, plant and equipment	139,428	137,919
Intangible assets		
Goodwill	161,688	163,713
Marketing rights	44,354	46,519
Other	1,616	1,841
Total intangible assets	207,659	212,073
Investments and other assets		
Investment securities	23,445	24,602
Deferred tax assets	3,938	3,893
Other	14,773	11,638
Allowance for doubtful accounts	(182)	(191)
Total investments and other assets	41,974	39,942
Total non-current assets	389,063	389,936
Total assets:	689,961	719,257

## Consolidated Balance Sheets (continued)

Millions of yen

	As of March 31, 2014	As of December 31, 2013
<b>LIABILITIES</b>		
Current liabilities:		
Notes and accounts payable - trade	26,037	22,589
Short-term loans payable	4,835	6,207
Accounts payable - other	27,364	36,519
Income taxes payable	5,476	10,483
Provision for sales rebates	1,276	1,217
Provision for point card certificates	265	254
Provision for bonuses	3,973	342
Other	7,531	7,462
Total current liabilities	76,760	85,076
Noncurrent liabilities:		
Deferred tax liabilities	11,367	11,807
Provision for retirement benefits	2,660	19,196
Provision for directors' retirement benefits	126	134
Provision for environmental measures	224	266
Allowance for loss on plants reorganization	3,390	3,390
Asset retirement obligations	355	374
Other	3,595	3,597
Total noncurrent liabilities	21,720	38,765
Total liabilities:	98,480	123,841
<b>NET ASSETS</b>		
Shareholders' equity:		
Capital stock	26,745	26,745
Capital surplus	512,326	512,328
Retained earnings	65,379	65,888
Treasury stock	(26,596)	(26,632)
Total shareholders' equity	577,854	578,329
Other accumulated comprehensive income adjustments		
Valuation difference on available-for-sale securities	1,206	1,414
Foreign currency translation adjustment	12,141	14,214
Total other accumulated comprehensive income adjustments	13,348	15,628
Subscription rights to shares:	277	306
Minority interests:	--	1,150
Total net assets:	591,481	595,415
Total liabilities and net assets:	689,961	719,257

## (2) Consolidated Statements of Income

Millions of yen

	January 1, 2014 to March 31, 2014	January 1, 2013 to March 31, 2013
Net sales	86,079	86,669
Cost of sales	34,787	34,309
Gross profit	51,292	52,360
Selling, general and administrative expenses		
Research and development expenses	10,353	10,629
Amortization of goodwill	3,050	2,858
Other	25,442	24,406
Total selling, general and administrative expenses	38,845	37,895
Operating income	12,447	14,465
Non-operating income		
Interest income	198	180
Dividend income	91	65
Foreign exchange gains	--	222
Gain on valuation of derivatives	511	396
Other	204	180
Total non-operating income	1,006	1,043
Non-operating expenses		
Interest expenses	59	64
Foreign exchange losses	734	--
Equities in losses in affiliates	437	301
Loss on disposal of noncurrent assets	66	86
Other	91	219
Total non-operating expenses	1,390	672
Ordinary income	12,063	14,836
Extraordinary income		
Insurance Income	308	--
Gain on sales of subsidiaries and affiliates' stocks	--	2,758
Gain on sales of investment securities	--	660
Gain on sales of noncurrent assets	--	400
Total extraordinary income	308	3,819
Income before income taxes and minority interests	12,371	18,656
Income taxes	6,038	8,158
Income before minority interests	6,332	10,498
Minority interests in income	--	8
Net income	6,332	10,489

## Consolidated Statements of Comprehensive Income

(Millions of yen)

	January 1, 2014 to March 31, 2014	January 1, 2013 to March 31, 2013
Income before minority interests	6,332	10,498
Other comprehensive income		
Valuation difference on available-for-sale securities	(207)	2,240
Foreign currency translation adjustment	(2,291)	4,064
Total other comprehensive income	(2,498)	6,304
Comprehensive income	3,833	16,802
(Comprehensive attributable to)		
Comprehensive income attributable to owners of the parent	3,833	16,707
Comprehensive income attributable to minority interests	--	94

## (3) Notes to the consolidated financial statements

(Items related to going concern assumption)

No applicable items

(Notes on significant change in shareholders' equity)

No applicable items

(Segment information)

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

Fiscal 2014 segment information by business type (January 1, 2014 – March 31, 2014)

(Millions of yen)

	Pharmaceuticals	Bio-Chemicals	Total	Adjustments	Consolidated
Net sales					
Sales to external customers	62,885	23,193	86,079	--	86,079
Inter-segment sales and transfers	296	395	692	(692)	--
Total sales	63,182	23,589	86,771	(692)	86,079
Segment income	9,437	3,052	12,490	(43)	12,447

Notes: 1. The minus ¥43 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. Sales and profit (loss) by segment

Fiscal 2013 segment information by business type (January 1, 2013 – March 31, 2013)

(Millions of yen)

	Pharmaceuticals	Bio-Chemicals	Total	Adjustments	Consolidated
Net sales					
Sales to external customers	67,070	19,599	86,669	--	86,669
Inter-segment sales and transfers	352	398	750	(750)	--
Total sales	67,422	19,997	87,420	(750)	86,669
Segment income	13,061	1,480	14,541	(76)	14,465

Notes: 1. The minus ¥76 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.