

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

## **Consolidated Financial Summary**

**First Quarter of the Fiscal Year to December 31, 2013**

**(January 1, 2013 – March 31, 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 First Quarter of the Year Ending December 31, 2013

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

**April 24, 2013**

Stock Code: 4151      Listed exchanges: Tokyo, 1<sup>st</sup> section  
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Scheduled date of submission of Financial Report: May 10, 2013

Scheduled start date of dividend payment: --

Appendix materials prepared to accompany the quarterly financial report: Yes

FY2013 Q1 earnings presentation meeting: Yes. (for institutional investors and analysts)

### 1. Results for the three months ended March 31, 2013

(%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, 2013	Change (%)	Three months to March 31, 2012	Change (%)
Net sales	86,669	(0.5)	87,111	(24.2)
Operating income	14,465	(19.8)	18,039	(17.7)
Ordinary income	14,836	(10.5)	16,575	(25.5)
Net income	10,489	23.2	8,514	(42.4)
Net income per share (¥)	19.16		15.46	
Fully diluted net income per share (¥)	19.15		15.45	

Comprehensive income: Three months to March 31, 2013: ¥16,802 million (+12.0%)

Three months to March 31, 2012: ¥15,003 million (-2.7%)

#### (2) Consolidated financial position

(Millions of yen, rounded down)

	As of March 31, 2013	As of December 31, 2012
Total assets	694,165	679,342
Net assets	567,244	555,898
Shareholders' equity ratio (%)	81.6%	81.7%

Note: Total shareholders' equity: March 31, 2013: ¥566,104 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
Interim dividend per share (¥)	12.50	10.00
Year-end dividend per share (¥)	12.50	10.00
Total dividend per share (¥)	25.00	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 June 30, 2013	Change (%)	January 1, 2013 to December 31, 2013	Change (%)
Net sales	169,000	1.6	338,000	1.5
Operating income	29,000	13.3	55,000	4.0
Ordinary income	--	--	49,000	(0.0)
Net income	--	--	30,000	24.0
Net income per share	--	--	54.80	

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.

## 4. Other

### 1) Changes to significant subsidiaries during the period: None

(Indicates transfers of specified subsidiaries resulting in changes in the scope of consolidation)

### 2) Use of special accounting procedures in the preparation of this report: Yes

See Page 6, Section 2. Summary information (Other items)

### 3) Changes to accounting policies and change or revisions to accounting estimates:

1. Changes following revisions to accounting standards: Yes

2. Other changes: None

3. Changes in accounting estimates: Yes

4. Restatements: None

See Page 6, Section 2. Summary information (Other items)

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

1. Number of shares outstanding (including treasury shares)	March 31, 2013	576,483,555 shares	December 31, 2012	576,483,555 shares
2. Number of treasury shares	March 31, 2013	29,061,291 shares	December 31, 2012	29,062,630 shares
3. Average number of shares during the period	Quarter ended March 31, 2013:	547,417,916 shares	Quarter ended March 31, 2012:	550,721,704 shares

### Notice regarding quarterly review procedures

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

### Notice regarding the appropriate use of the financial forecasts

The above forecasts are based on the information available and assumptions made at the time of release of this document about a number of uncertain factors that may affect results in the future.

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## 1. Operating Results and Financial Statements

### (1) Summary of business performance

In the first quarter of the fiscal year ending December 2013 (the three-month period from January 1, 2013 to March 31, 2013), net sales for were ¥86.6 billion (down 0.5% compared to the first quarter of the previous fiscal year), operating income was ¥14.4 billion (down 19.8%) and ordinary income was ¥14.8 billion (down 10.5%). Net income for the quarter was ¥10.4 billion (up 23.2%).

- Core products in the Pharmaceuticals business performed well but due to a decline in licensing income, net sales and operating income declined.
- Ordinary income also declined, but net income for the quarter 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 quarter of last year reflecting these revisions. (For details please see page 12, Section 5.)*

### Pharmaceuticals business

#### 1. Results

In the Pharmaceuticals business, net sales were ¥67.4 billion (up 0.3%) and operating income was ¥13.0 billion (down 22.0%).

- Domestic sales of ethical pharmaceutical products were impacted by a reduction in standard drug prices in Japan, which came into effect in April last year, but core products performed strongly.
  - Sales of *Allelock*, an anti-allergy agent, and *Patanol* anti-allergy eye drops were robust, due to the effects of higher amounts of airborne pollen and other factors. Sales of *NESP*, a treatment for renal anemia declined.
  - Sales of *Regpara*, a treatment for secondary hyperparathyroidism during dialysis therapy, *Asacol*, an ulcerative colitis treatment, *Fentos*, a transdermal analgesic for persistent cancer pain, and *Romiplate*, a treatment for chronic idiopathic thrombocytopenic purpura, all advanced strongly.
  - We are currently in the process of taking over the marketing rights for *Onglyza*, a treatment for type-two diabetes, from Otsuka Pharmaceutical Co., Ltd., which obtained approval for the drug in March.
- In the licensing-out of technologies and export of pharmaceutical products, exports were strong but net sales declined significantly from the first quarter of the previous fiscal year in which we booked licensing revenue from FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. for the development of biosimilars.
- ProStrakan net sales were ¥5.0 billion (up 41.6%), with strong growth in *Abstral*, a treatment for cancer pain, and other core products. Operating loss (after amortization of goodwill, etc.) was ¥0.2 billion (down 75.2%).

#### 2. Research and development

##### **Oncology**

(Domestic)

- We received approval in February for additional indications for intramuscular administration and dosage of *Leunase*, an anti-cancer drug.
- In March we secured approval for the additional indication of pheochromocytoma for anti-cancer drug *Dacarbazine*.

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- In November 2012, we filed for marketing approval of KW-2246 (overseas name *Abstra*) for cancer pain treatment.

## **Nephrology**

(Domestic)

- We are currently seeking approval for additional pediatric indication for *NESP*, a treatment for renal anemia. (Application filed in September 2012.)

(Overseas)

- In Asia, we are currently seeking approval for Cinacalcet Hydrochloride (product name in Japan: *Regpara*), a treatment for secondary hyperparathyroidism. (Application filed in China in October 2011.)

## **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* for administration within 4.5 hours after the onset of symptoms of ischemic cerebrovascular disease (up from 3 hours).
- In March we acquired approval for *Nourias* for the treatment of Parkinson's disease.
- We are currently seeking approval for two additional indications for anti-epileptic drug *Topina* 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*, 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 decreased 2.9% to ¥19.9 billion while operating income increased 13.6% to ¥1.4 billion.

Domestic business

- Sales in the pharmaceutical and medical treatment fields decreased compared to the previous fiscal year.
  - In the pharmaceutical and medical fields, pharmaceutical-use amino acids, nucleic acids and related compounds, and other pharmaceutical raw materials performed steadily.
  - *Tranexamic acid* sales were down from the first quarter 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*, were broadly unchanged, 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 US, sales of amino acids for supplements were somewhat weak due to consumer demand trends and intensifying competition.

- In Europe and Asia, demand remained strong for amino acids and nucleic acids including infusion-use amino acids, pharmaceutical raw material-use *Citicoline* and raw materials for amino acids.

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

- Total assets as of March 31, 2013 were ¥694.1 billion, an increase of ¥14.8 billion compared to the end of the previous fiscal year.
- Current assets increased by ¥6.0 billion to ¥310.0 billion due to an increase in notes and accounts receivable and inventories.
- Non-current assets increased by ¥8.7 billion to ¥384.0 billion due to an increase in tangible assets and sales rights.
- Liabilities were ¥126.9 billion, an increase of ¥3.4 billion compared to the end of the previous fiscal year due to increases in notes and accounts payable and reserve for bonuses, despite a decline in income taxes payable.
- Net assets at the end of the fiscal year were ¥567.2 billion, an increase of ¥11.3 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 fiscal period was 81.6%, a decrease of 0.1 percentage points compared to the end of the previous fiscal year.

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

- No revisions have been made to the forecasts of consolidated results as announced on January 31, 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 three-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 this 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

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calculation of depreciation based on the revised Corporate Tax Law.

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



## 3. Consolidated financial statements

### (1) Consolidated Balance Sheets

(Millions of yen)

	As of March 31, 2013	As of December 31, 2012
<b>ASSETS</b>		
Current assets:		
Cash and deposits	23,257	21,577
Notes and accounts receivable-trade	103,518	101,556
Merchandise and finished goods	44,615	40,334
Work in process	13,371	12,176
Raw materials and supplies	10,788	10,931
Deferred tax assets	10,690	10,369
Short-term loans receivable	97,323	98,194
Other	6,924	9,228
Allowance for doubtful accounts	(423)	(381)
Total current assets	310,065	303,988
Noncurrent assets:		
Property, plant and equipment		
Buildings and structures	129,498	134,875
Accumulated depreciation	(88,929)	(94,114)
Buildings and structures, net	40,569	40,760
Machinery, equipment and vehicles	145,897	143,595
Accumulated depreciation	(126,799)	(124,200)
Machinery, equipment and vehicles, net	19,098	19,395
Land	55,223	53,386
Construction in progress	8,739	7,360
Other	46,773	48,166
Accumulated depreciation	(40,732)	(42,196)
Other, net	6,040	5,969
Total property, plant and equipment	129,671	126,872
Intangible assets		
Goodwill	166,700	168,850
Sales rights	45,529	36,214
Other	2,284	2,442
Total intangible assets	214,515	207,506
Investments and other assets		
Investment securities	22,912	23,654
Deferred tax assets	6,735	7,724
Other	10,525	9,871
Allowance for doubtful accounts	(260)	(276)
Total investments and other assets	39,912	40,974
Total noncurrent assets	384,099	375,353
Total assets:	694,165	679,342

## (1) Consolidated balance sheets (continued)

(Millions of yen)

	As of March 31, 2013	As of December 31, 2012
<b>LIABILITIES</b>		
Current liabilities:		
Notes and accounts payable-trade	30,533	26,303
Short-term loans payable	5,761	5,699
Accounts payable-other	32,529	29,009
Income taxes payable	8,051	15,777
Provision for sales rebates	832	771
Provision for point card certificates	208	187
Provision for bonuses	4,142	241
Other	7,897	7,784
Total current liabilities	89,957	85,774
Non-current liabilities:		
Deferred tax liabilities	11,326	11,262
Provision for retirement benefits	19,102	19,503
Provision for directors' retirement benefits	110	114
Provision for environmental measures	328	331
Asset retirement obligations	383	383
Other	5,711	6,074
Total non-current liabilities	36,963	37,668
Total liabilities:	126,920	123,443
<b>NET ASSETS</b>		
Shareholders' equity:		
Capital stock	26,745	26,745
Capital surplus	512,329	512,329
Retained earnings	53,142	48,127
Treasury stock	(26,537)	(26,538)
Total shareholders' equity	565,678	560,663
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(23)	(2,264)
Foreign currency translation adjustment	449	(3,528)
Total accumulated other comprehensive income	425	(5,792)
Subscription rights to shares:	221	203
Minority interests:	918	823
Total net assets:	567,244	555,898
Total liabilities and net assets:	694,165	679,342

## (2) Consolidated Statements of Income

(Millions of yen)

	January 1, 2013 to March 31, 2013	January 1, 2012 to March 31, 2012
Net sales	86,669	87,111
Cost of sales	34,309	32,094
Gross profit	52,360	55,016
Selling, general and administrative expenses		
Research and development expenses	10,629	11,022
Amortization of goodwill	2,858	3,076
Other	24,406	22,878
Total selling, general and administrative expenses	37,895	36,976
Operating income	14,465	18,039
Non-operating income		
Interest income	180	142
Dividends income	65	318
Foreign exchange gain	222	926
Unrealized gain on derivatives	396	--
Other	180	273
Total non-operating income	1,043	1,660
Non-operating expenses		
Interest expenses	64	32
Derivatives valuation loss	--	292
Loss from equity method investments	301	2,465
Loss on disposal of noncurrent assets	86	115
Other	219	218
Total non-operating expenses	672	3,125
Ordinary income	14,836	16,575
Extraordinary income		
Gain on sale of shares in affiliate companies	2,758	--
Gain on sale of investment securities	660	--
Gain on sale of non-current assets	400	--
Total extraordinary income	3,819	--
Extraordinary losses		
Loss on sale of investment securities	--	324
Total extraordinary losses	--	324
Income before income taxes and minority interests	18,656	16,250
Total income taxes	8,158	7,719
Income before minority interests	10,498	8,531
Gain (loss) on minority interest	8	16
Net income	10,489	8,514

## Consolidated Statements of Income (Comprehensive)

(Millions of yen)

	January 1, 2013 to March 31, 2013	January 1, 2012 to March 31, 2012
Income before minority interests	10,498	8,531
Other comprehensive income		
Valuation difference on available-for-sale securities	2,240	1,193
Foreign currency translation adjustment	4,064	5,279
Share of other comprehensive income of associates accounted for using equity method	--	(0)
Total other comprehensive income	6,304	6,471
Comprehensive income	16,802	15,003
Breakdown		
Comprehensive income attributable to owners of the parent	16,707	14,924
Comprehensive income attributable to minority interests	94	78

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

No applicable items

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

No applicable items

### (5) Segment information

Fiscal 2012 Q1 segment information by business type (January 1, 2012 – March 31, 2012) is as shown below in section 2. Changes in reported segment information

Fiscal 2013 Q1 segment information (January 1, 2013 – March 31, 2013)

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

(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.

#### 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 net sales and income for the first quarter 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	66,932	20,178	87,111	--	87,111
Inter-segment sales and transfers	287	410	697	(697)	--
Total sales	67,220	20,589	87,809	(697)	87,111
Segment income	16,735	1,303	18,039	0	18,039

Notes: 1. The ¥0 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.