

Kyowa Hakko Kirin Co., Ltd.

Consolidated Financial Summary Fiscal 2013 Interim

(January 1, 2013 – June 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 Interim Period of the Year Ending December 31, 2013

Kyowa Hakko Kirin Co., Ltd.

July 26, 2013

Stock Code: 4151 Listed exchanges:

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Scheduled start of dividend payment: Scheduled date of submission of Financial Report: August 7, 2013

September 2, 2013

Tokyo, 1st section

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 six months ended June 30, 2013

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

(1) Consolidated husiness performance

(1) Consolidated business performance			(Millions of yen, ro	ounded down)
	Six months to	Change	Six months to	Change
	June 30, 2013	(%)	June 30, 2012	(%)
Net sales	169,707	2.1	166,290	(10.8)
Operating income	27,176	6.2	25,585	(14.5)
Ordinary income	26,523	14.8	23,094	(23.6)
Net income	17,678	53.4	11,523	(35.0)
Net income per share (¥)	32.29		20.98	
Fully diluted net income per share (¥)	32.27		20.97	

Note: Comprehensive income: June 30, 2013: ¥28,944 million (116.7%); June 30, 2012: ¥13,356 million (-20.2%)

(2) Consolidated financial position

(2) Consolidated infancial position (willions of yen, rounde		
	As of	As of
	June 30, 2013	December 31, 2012
Total assets	691,403	679,342
Net assets	579,370	555,898
Shareholders' equity ratio	83.6%	81.7 %

Note: Total shareholders' equity: June 30, 2013: ¥578,114 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 (forecast)	¥10.00
Total dividend per share (¥)	¥25.00 (forecast)	¥20.00

Note: Changes compared to the most recent published dividend forecast: None.

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

(Millions of yen)

		o.
	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. % changes are compared to the same period of the previous fiscal year

2. Changes compared to the most recent published forecast: Yes

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 8, 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 standards other than (1) above: None
- 3. Changes in accounting methods, procedures and presentation: Yes
- 4. Restatement of revisions: None

See Page 8, Section 2. Summary information (Other items)

4) Number of shares outstanding (ordinary shares)

Number of shares outstanding (including treasury shares)	Interim period ended June 30, 2013	576,483,555 shares	December 31, 2012	576,483,555 shares
Number of treasury shares	Interim period ended June 30, 2013	29,089,014 shares	December 31, 2012	29,062,630 shares
Average number of shares during the interim period	Interim period ended June 30, 2013:	547,412,193 shares	Interim period ended June 30, 2012:	549,320,986 shares

Notice regarding quarterly review procedures

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

Notice regarding the appropriate use of the financial forecasts

- 1. This document contains revisions to the forecast of consolidated results as announced on January 31, 2013
- 2. 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

Net sales for the first half were ¥169.7 billion (up 2.1% compared to the first half of the previous fiscal year), operating income was ¥27.1 billion (up 6.2%) and ordinary income was ¥26.5 billion (up 14.8%). Net income for the half year was ¥17.6 billion (up 53.4%).

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

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 15, Section 6.)

Pharmaceuticals business

1. Results

In the Pharmaceuticals business, net sales were ¥129.9 billion (up 1.8%) and operating income was ¥24.1 billion (up 2.5%).

- 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*, 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* anti-allergy eye drops grew significantly due to the effects of higher amounts of airborne pollen and other factors. However, due in part to the impact of generics, sales of *Allelock*, an anti-allergy agent, remained unchanged, and sales of *Coniel*, a hypertension and angina pectoris drug, declined.
- 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 strongly.
- In May, we launched *Nouriast*, the world's first antiparkinsonian agent of an adenosine A_{2A} receptor antagonist.
- In May, we took over the manufacturing and sales rights for *Onglyza*, a treatment for type-two diabetes, from Otsuka Pharmaceutical Co., Ltd. (Sales began in July).
- 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 ¥10.7 billion (up 39.6%), with strong growth in Abstral a treatment for cancer pain, and other core products. Operating loss (after amortization of goodwill, etc.) was ¥0.3 billion (down 83.1%).

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.
- 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*, a treatment for secondary hyperparathyroidism during dialysis therapy.
- We are currently seeking approval of KW-2246 (overseas name: Abstral), for the treatment of cancer pain.
 (Application filed in November 2012.)

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 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 for KRN321 (product name in Japan: *NESP*) 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* 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 *Nouriast* for the treatment of Parkinson's disease and began sales in May.
- 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 increased by 2.8% to ¥41.2 billion, while operating income increased 52.1% to ¥3.1 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 first half 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 U.S., sales of some amino acids for supplements declined due to intensifying competition, but overall net sales increased from the first half of the previous year.
- In Europe and Asia, infusion-use amino acids remained strong.

(2) Summary of consolidated financial position

- Total assets as of June 30, 2013 were ¥691.4 billion, an increase of ¥12.0 billion compared to the end of the previous fiscal year.
- Current assets increased by ¥2.5 billion to ¥306.5 billion due to an increase in cash and deposits and inventory assets and despite a decrease in notes and accounts receivable and short-term loans receivable.
- Non-current assets increased by ¥9.5 billion to ¥384.8 billion due to an increase in tangible assets and sales rights.
- Liabilities were ¥112.0 billion, a decrease of ¥11.4 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 ¥579.3 billion, an increase of ¥23.4 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 second period was 83.6%, an increase of 1.9 percentage points compared to the end of the previous fiscal year.

Cash flow summary

• Cash and cash equivalents at the end of the interim period were ¥32.5 billion, a decrease of ¥17.8 billion compared to the end of the previous fiscal period, impacted by an increase of ¥16 billion in short-term loans to the parent company in excess of three months, which are not included within the scope of cash and cash equivalents. These loans were made as a part of our asset resource management.

The main cash flows and factors affecting them during the interim period were as follows:

- Net cash provided by operating activities was ¥20.6 billion (a 35.3% decrease compared to the same period of the previous fiscal year). The primary factors affecting cash inflows were net income before income taxes of ¥30.8 billion, depreciation expenses of ¥9.9 billion, and amortization of goodwill of ¥5.7 billion. The main cash outflow was the corporation tax payment of ¥16.5 billion.
- Net cash used by investing activities was ¥34.2 billion (a 118.5% increase compared to the same period of the previous fiscal year). The primary factors affecting cash outflows included a net increase in short-term loans of ¥15.9 billion, ¥12.7 billion for the acquisition of intangible assets, and ¥10.7 billion for the acquisition of property, plant and equipment. The major inflows were ¥3.7 billion from the sale and redemption of investment securities and ¥3.2 billion from sale of shares in affiliate companies.
- Net cash used in financing activities was ¥5.3 billion (a 60.2% decrease compared to the same period of the previous fiscal year). The main outflow was ¥5.4 billion for payment of dividends.

(3)Consolidated results forecasts

Consolidated results for the first half of fiscal year 2013 were positively impacted by a weaker than anticipated yen but sales of core product *NESP* were below initial forecast in reaction to shipments made at the end of 2012. Also, certain licensing revenues included in our initial forecasts are now expected to be booked next fiscal year. In light of these factors we have revised our full-year consolidated earnings forecast.

Revision to consolidated full-year forecast announced January 31, 2013

	Net Sales	Operating Income	Ordinary income	Net income	Net income per share
	Million yen	Million yen	Million yen	Million yen	Yen
Previous Forecast (A)	338,000	55,000	49,000	30,000	54.80
Revised forecast (B)	339,000	51,000	48,000	28,000	51.15
Change (B-A)	1,000	(4,000)	(1,000)	(2,000)	-
Rate of change (%)	0.3	(7.3)	(2.0)	(6.7)	-
Fiscal 2012 results	333,158	52,905	49,001	24,199	44.12

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 six-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 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	
• •	As of	As of
	June 30, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and deposits	24,890	21,577
Notes and accounts receivable - trade	98,515	101,556
Merchandise and finished goods	45,754	40,334
Work in process	14,349	12,176
Raw materials and supplies	10,808	10,931
Deferred tax assets	10,656	10,369
Short-term loans receivable	94,144	98,194
Other	7,811	9,228
Allowance for doubtful accounts	(426)	(381)
Total current assets	306,504	303,988
Non-current assets:		
Property, plant and equipment		
Buildings and structures	130,038	134,875
Accumulated depreciation	(89,547)	(94,114)
Buildings and structures, net	40,490	40,760
Machinery, equipment and vehicles	147,459	143,595
Accumulated depreciation	(127,624)	(124,200)
Machinery, equipment and vehicles, net	19,835	19,395
Land	54,802	53,386
Work in progress	8,789	7,360
Other	47,233	48,166
Accumulated depreciation	(40,887)	(42,196)
Other, net	6,346	5,969
Total property, plant and equipment	130,264	126,872
Intangible assets	<u> </u>	
Goodwill	165,245	168,850
Marketing rights	45,539	36,214
Other	2,125	2,442
Total intangible assets	212,910	207,506
Investments and other assets	<u>-</u>	·
Investment securities	24,786	23,654
Deferred tax assets	6,309	7,724
Other	10,881	9,871
Allowance for doubtful accounts	(253)	(276)
Total investments and other assets	41,723	40,974
Total non-current assets	384,898	375,353
Total assets:	691,403	679,342

Consolidated Balance Sheets (continued)	Millions of yen	
	As of	As of
	June 30, 2013	December 31, 2012
LIABILITIES		
Current liabilities:		
Notes and accounts payable - trade	23,411	26,303
Short-term loans payable	5,814	5,699
Accounts payable - other	26,567	29,009
Income taxes payable	12,829	15,777
Provision for sales rebates	822	771
Provision for point card certificates	225	187
Provision for bonuses	214	241
Other	7,492	7,784
Total current liabilities	77,379	85,774
Non-current liabilities:		
Deferred tax liabilities	11,578	11,262
Provision for retirement benefits	19,185	19,503
Provision for directors' retirement benefits	114	114
Provision for environmental measures	321	331
Asset retirement obligations	383	383
Other	3,069	6,074
Total non-current liabilities	34,653	37,668
Total liabilities:	112,032	123,443
NET ASSETS		<u> </u>
Shareholders' equity:		
Capital stock	26,745	26,745
Capital surplus	512,328	512,329
Retained earnings	60,331	48,127
Treasury stock	(26,573)	(26,538)
Total shareholders' equity	572,830	560,663
Other accumulated comprehensive income adjustments	,	,
Valuation difference on other marketable securities	995	(2,264)
Foreign currency translation adjustment	4,288	(3,528)
Total accumulated comprehensive income adjustments	5,283	(5,792)
Subscription rights to shares:	241	203
Minority interests:	1,014	823
Total net assets:	579,370	555,898
Total liabilities and net assets:	691,403	679,342

(2) Consolidated Statements of Income		Millions of yen
	January 1, 2013 to	January 1, 2012 to
	June 30, 2013	June 30, 2012
Net sales	169,707	166,290
Cost of sales	64,547	61,968
Gross profit	105,159	104,321
Selling, general and administrative expenses		
Research and development expenses	20,988	22,122
Amortization of goodwill	5,749	6,070
Other	51,244	50,542
Total selling, general and administrative expenses	77,982	78,736
Operating income	27,176	25,585
Non-operating income		·
Interest income	375	285
Dividend income	529	442
Foreign exchange gains	433	
Gain on revaluation of derivatives	668	16
Other	396	675
Total non-operating income	2,402	1,419
Non-operating expenses		.,
Interest expenses	144	81
Foreign exchange loss		45
Loss on disposal of non-current assets	217	414
Investment losses in affiliated companies	2,075	2,549
Other	618	818
Total non-operating expenses	3,055	3,909
Ordinary income	26,523	23,094
Extraordinary income		
Gain on sale of shares in affiliate companies	2,758	
Gain on sale of non-current assets	1,033	
Gain on sale of investment securities	662	<u></u>
Total extraordinary income	4,455	
Extraordinary loss		
Loss on valuation of shares in affiliate companies	121	<u></u>
Loss on sale of investment securities		324
Total extraordinary loss	121	324
Income before income taxes and minority interests	30,856	22,769
Income taxes	13,134	11,212
Income before minority interests	17,722	11,556
Minority interests in income	44	32
Net income	17,678	11,523
	17,070	11,020

interests

Consolidated Statements of Comprehensive Income Millions of yen January 1, 2013 to January 1, 2012 to June 30, 2013 June 30, 2012 Net income before minority interests 17,722 11,556 Other comprehensive income Valuation difference on other marketable securities 3,259 294 Foreign currency translation adjustment 7,963 1,504 Share of other comprehensive income of (0)equity-method affiliates Total other comprehensive income 11,222 1,799 Comprehensive income 28,944 13,356 (Breakdown) Comprehensive income attributable to parent company shareholders 28,754 13,306 Comprehensive income attributable to minority

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(3) Consolidated Statements of Cash Flows

		Millions of Yen
_	January 1, 2013 to	January 1, 2012 to
	June 30, 2013	June 30, 2012
Net cash provided by (used in) operating activities		
Income before income taxes and minority interests	30,856	22,769
Depreciation and amortization	9,984	9,652
Amortization of goodwill	5,749	6,070
Increase (decrease) in provision for retirement benefits	(331)	(643)
Decrease (increase) in prepaid pension costs	(558)	(212)
Interest and dividend income	(904)	(727)
Interest expenses	144	81
Equity in (earnings) losses of affiliates	2,075	2,549
Loss (gain) on sale and retirement of property, plant and	(937)	77
Loss (gain) on sale of investment securities	(662)	316
Loss (gain) on sale of stocks of subsidiaries and affiliates	(2,755)	(0)
Decrease (increase) in notes and accounts	4,552	5,441
Decrease (increase) in inventories	(5,671)	(2,706)
Increase (decrease) in notes and accounts payable-trade	(4,398)	(4,265)
Other, net	(708)	517
Subtotal	36,434	38,921
Interest and dividend income received	1,024	792
Interest expenses paid	(188)	(76)
Income taxes paid	(16,594)	(7,670)
Net cash provided by (used in) operating activities	20,675	31,966

Consolidated Statements of Cash Flows (continued)

, ,		Millions of Yen
	January 1, 2013 to	January 1, 2012 to
	June 30, 2013	June 30, 2012
Net cash provided by (used in) investing activities		
Purchase of property, plant and equipment	(10,794)	(7,321)
Proceeds from sale of property, plant and equipment	1,651	343
Purchase of intangible assets	(12,755)	(7,131)
Purchase of investment securities	(1,950)	(3,508)
Proceeds from sale of investment securities	3,766	2,247
Proceeds from sale of stocks of subsidiaries and affiliates	3,247	0
Purchase of investments in subsidiaries resulting in change in		
scope of consolidation		(111)
Payments into time deposits	(3,687)	(1,617)
Proceeds from withdrawal of time deposits	2,965	1,917
Net decrease (increase) in short-term loans	(15,999)	(11)
Other, net	(660)	(470)
Net cash provided by (used in) investing activities	(34,218)	(15,663)
Net cash provided by (used in) financing activities		
Net increase (decrease) in short-term loans payable	307	(155)
Repayment of long-term loans payable		(56)
Cash used to purchase own shares	(66)	(7,482)
Cash dividends paid	(5,475)	(5,557)
Cash dividends paid to minority shareholders		(25)
Other, net	(75)	(60)
Net cash provided by (used in) financing activities	(5,309)	(13,339)
Effect of exchange rate change on cash and cash equivalents	1,031	152
Net increase (decrease) in cash and cash equivalents	(17,821)	3,115
Cash and cash equivalents at beginning of period	50,334	107,555
Cash and cash equivalents at end of period	32,512	110,671

(4) Items related to going concern assumption

No applicable items

(5) Notes on significant change in shareholders' equity

No applicable items

(6) Segment information

Fiscal 2012 segment information cumulative to Q2 by business type (January 1, 2012 – June 30, 2012) is as shown below in section 2. Changes in reported segment information

Fiscal 2013 segment information cumulative to Q2 (January 1, 2013 – June 30, 2013)

1. Sales and profit (loss) by segment

(Millions of yen)

	Pharmaceuticals	Bio-Chemicals	Total	Adjustments	Consolidated
Net sales					
Sales to external					
customers	129,206	40,501	169,707		169,707
Inter-segment sales					
and transfers	743	706	1,450	(1,450)	
Total sales	129,950	41,207	171,157	(1,450)	169,707
Segment income	24,125	3,103	27,228	(51)	27,176

Notes: 1. The minus ¥51 million for adjustments of segment Income is due to intersegment eliminations.

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 interim 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	126,950	39,340	166,290		166,290
Inter-segment sales					
and transfers	643	742	1,385	(1,385)	
Total sales	127,593	40,082	167,675	(1,385)	166,290
Segment income	23,527	2,040	25,567	17	25,585

Notes: 1. The ¥17 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.} In segment income, operating income from the Consolidated Statements of Income, has been adjusted.