

Kyowa Hakko Kirin Co., Ltd.

Consolidated Financial Summary Fiscal 2016 Interim

(January 1, 2016 – June 30, 2016)

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 information currently available to the Company and on certain assumptions deemed to be reasonable by management. As such, they do not constitute guarantees by the Company of future performance. Actual results may differ materially from these projections for a wide variety of reasons, 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 CONSOLIDATED FINANCIAL STATEMENTS (JGAAP)
for Six Months Ended June 30, 2016

July 29, 2016

Company Name: Kyowa HAKKO Kirin Co., Ltd. Listed Exchanges: 1st Section of the Tokyo Stock Exchange
 Stock Code: 4151 President: Nobuo Hanai
 Telephone: +81 3 5205 7206 Inquiries: Shigeru Morotomi
 URL: <http://www.kyowa-kirin.com/investors/index.html> Executive Officer,
 Corporate Communications Department

Scheduled date of submission of Quarterly Securities Report: August 5, 2016

Scheduled start date of dividend payment: September 1, 2016

Appendix materials to accompany the quarterly financial report: Yes

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

*(Millions of yen rounded down)***1. Consolidated Financial Results for the Six Months Ended June 30, 2016***(% changes indicate year-on-year changes.)*

(1) Consolidated operating results	Six months ended June 30, 2016	Change (%)	Six months ended June 30, 2015	Change (%)
Net sales (millions of yen)	174,056	(2.7)	178,837	10.5
Operating income (millions of yen)	15,334	(31.8)	22,469	22.0
Ordinary income (millions of yen)	13,681	(31.9)	20,079	19.1
Profit attributable to owners of parent (millions of yen)	10,763	13.0	9,523	3.7
Basic earnings per share (yen)	19.67		17.40	
Fully diluted earnings per share (yen)	19.65		17.39	

Note: Comprehensive income: Six months ended June 30, 2016: (¥13,051) million; -%
 Six months ended June 30, 2015: ¥14,243 million; 113.2%

(2) Consolidated financial position

	As of June 30, 2016	As of December 31, 2015
Total assets (millions of yen)	686,560	720,764
Net assets (millions of yen)	595,027	614,858
Equity ratio (%)	86.6	85.2

Note: Equity: As of June 30, 2016: ¥594,531 million; As of December 31, 2015: ¥614,427 million

2. Dividends

	Fiscal year ending December 31, 2016 (forecast)	Fiscal year ended December 31, 2015
First quarter dividend per share (yen)	—	—
Interim dividend per share (yen)	12.50	12.50
Third quarter dividend per share (yen)	—	—
Year-end dividend per share (yen)	12.50 (forecast)	12.50
Total dividend per share (yen)	25.00 (forecast)	25.00

Note: Revisions to the dividend forecast most recently announced: None

3. Consolidated Earnings Forecasts for the Fiscal Year Ending December 31, 2016*(% changes indicate year-on-year changes.)*

	Full year	
		Change (%)
Net sales (millions of yen)	344,000	(5.6)
Operating income (millions of yen)	32,000	(26.9)
Ordinary income (millions of yen)	26,000	(33.7)
Profit attributable to owners of parent (millions of yen)	18,000	(39.5)
Basic earnings per share (yen)	32.89	

Note: Changes to the earnings forecast most recently announced: None

Notes:

- 1) Changes to significant subsidiaries during the period**
(Changes of specified subsidiaries resulting in changes in the scope of consolidation during the period under review): No
- 2) Use of accounting procedures special to the preparation of quarterly consolidated financial statements:** Yes
 (Note) See page 7, "2. Summary Information (Other Items)."
- 3) Changes in accounting policies, accounting estimates, and restatement:**
1. Changes in accounting policies in accordance with changes in accounting standards: No
 2. Changes in accounting policies other than 1. above: No
 3. Changes in accounting estimates: No
 4. Restatement: No
- 4) Number of shares issued (ordinary shares)**
1. Number of shares issued (including treasury shares)

As of June 30, 2016	576,483,555 shares
As of December 31, 2015	576,483,555 shares
 2. Number of treasury shares

As of June 30, 2016	29,258,941 shares
As of December 31, 2015	29,256,749 shares
 3. Average number of shares during the period

Six months ended June 30, 2016	547,225,777 shares
Six months ended June 30, 2015	547,312,978 shares

Notice regarding quarterly review procedures

The Financial Instruments and Exchange Act review process for this quarterly financial report was not yet completed at the time this financial report was issued.

Notice regarding the appropriate use of the earnings forecasts and other special comments

The forward-looking statements, including earnings forecasts, contained in these materials are based on information currently available to the Company and on certain assumptions deemed to be reasonable by management. As such, they do not constitute guarantees by the Company of future performance. Actual results may differ materially from these projections for a wide variety of reasons.

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1. Operating Results and Financial Statements

(1) Summary of consolidated business performance

For the six months ended June 30, 2016 (January 1, 2016 to June 30, 2016), net sales were ¥174.0 billion (down 2.7% compared to the same period of the previous fiscal year), operating income was ¥15.3 billion (down 31.8%), ordinary income was ¥13.6 billion (down 31.9%), and profit attributable to owners of parent was ¥10.7 billion (up 13.0%). Furthermore, core operating income (operating income + amortization of goodwill + share of profit/loss of entities accounted for using equity method) listed as a management target in our FY2016 to 2020 Mid-term Business Plan totaled ¥19.7 billion (down 26.5%).

- Net sales and operating income decreased due mainly to the impact of exchange rates and an increase in research and development expenses, despite growth in sales of new products.
- Ordinary income also decreased, but profit attributable to owners of parent increased due to an increase in extraordinary income from the gain on sales of non-current assets, etc.

Performance by segment is as follows.

Pharmaceuticals business

1) Results

In the pharmaceuticals business, net sales were ¥132.2 billion (down 2.3%) and operating income was ¥11.6 billion (down 37.2%).

- Sales in Japan increased year on year due to such factors as the increase in sales of new products despite the impact of reductions in drug price standards implemented in April.
 - Sales of core products NESP[®], a long-acting erythropoiesis stimulating agent, and REGPARA[®], a treatment for secondary hyperparathyroidism, were solid, increasing on a year-on-year basis.
 - There was steady growth in sales of new products such as G-Lasta[®], a sustained-duration Granulocyte Colony-Stimulating Factor (G-CSF) product, NOURIAST[®], an antiparkinsonian agent, Onglyza[®], a treatment for type 2 diabetes, and Dovobet[®], a topical combination drug for psoriasis vulgaris.
 - Sales of long term NHI products such as ALLELOCK[®], an anti-allergy agent, CONIEL[®], a hypertension and angina pectoris drug, and GRAN[®], a G-CSF product, decreased due to the impacts of the market penetration of generics, etc.
- International sales decreased year on year due mainly to the impact of exchange rates and the decline in licensing revenue.
 - In Europe and Americas, while sales of products such as Abstral[®] and PecFent[®], which are treatments for cancer pain, increased, sales decreased year on year due mainly to the decline in licensing revenue.
 - We acquired the EU sales rights to Moventig[®], an opioid-induced constipation (OIC) treatment, from AstraZeneca, and sales started in April.
 - In Asia, despite steady sales particularly in China and South Korea, sales decreased from the same period of the previous fiscal year, due to yen appreciation in foreign exchange.

2) Research and development

Using cutting-edge biotechnology centered on antibody technology, we have made nephrology, oncology, immunology/allergy and CNS the focus of research and development, and by investing resources efficiently, we aim to further speed up the creation of new medical value and drug creation.

The development statuses of our main late-stage development products in the six months ended June 30, 2016 are as follows.

Nephrology

- In Japan, we are currently conducting phase III clinical study of calcium receptor agonist KHK7580 for secondary hyperparathyroidism patients receiving hemodialysis.

- In Japan, we are currently conducting phase II clinical study for RTA 402 targeting chronic kidney disease (CKD) with type 2 diabetes.
- In China, in February we withdrew our application for approval of indication for KRN321 (product name in Japan: NESP®), a long-acting erythropoiesis stimulating agent for the treatment of renal anemia in patients receiving dialysis. The timing for reapplication is undecided.

Oncology

- In Japan, we are currently conducting phase III clinical study evaluating c-Met inhibitor ARQ 197 for patients with c-Met diagnostic-high inoperable hepatocellular carcinoma treated with one prior sorafenib therapy.
- Anti-CCR4 humanized monoclonal antibody KW-0761 (product name in Japan: POTELIGEO®) is currently conducting phase III clinical study targeting cutaneous T-cell lymphoma in the U.S., Europe, Japan, etc., and phase II clinical study targeting adult T-cell leukemia-lymphoma in the U.S., Europe, etc.

Immunology and allergy

- In Japan, we are applying for approval of indication for the anti-IL-17 receptor A fully human antibody KHK4827, targeting psoriasis vulgaris, arthropathic psoriasis, pustular psoriasis, and psoriatic erythroderma, for which existing treatments are insufficiently effective (approval was obtained on July 4, 2016).
- As part of the multi-regional clinical study being conducted by AstraZeneca, our licensing partner for the anti-IL-5 receptor humanized monoclonal antibody KHK4563 mainly in the U.S. and Europe, we are currently carrying out a phase III clinical study of KHK4563 in Japan and South Korea, targeting asthma patients, and a phase III clinical study in Japan, targeting patients with chronic obstructive pulmonary disease.

CNS

- In North America, Europe, and other areas, we are currently conducting phase III clinical study of KW-6002 (product name in Japan: NOURIAST®) targeting Parkinson's disease.

Other

- For the human monoclonal anti-Fibroblast Growth Factor 23 antibody KRN23, we are currently carrying out a multi-regional phase III clinical study in the U.S., Canada, Europe, Japan and South Korea, targeting X-linked hypophosphatemia in adult patients, a phase II clinical study in the U.S. and Europe, targeting X-linked hypophosphatemia in pediatric patients, and a phase II clinical study in the U.S., targeting tumor induced osteomalacia and epidermal nevus syndrome. Also, we initiated a phase II clinical study in Japan and South Korea, targeting tumor induced osteomalacia and epidermal nevus syndrome in June.
- In China, we are currently conducting a phase III clinical study of thrombopoietin receptor agonist AMG531 (product name in Japan: ROMIPLATE®) targeting chronic idiopathic (immune) thrombocytopenic purpura. Also, we initiated phase III clinical study in aplastic anemia in Japan and Korea.

Bio-Chemicals business

In the Bio-Chemicals business, net sales were ¥43.1 billion (down 4.1%) and operating income was ¥3.4 billion (down 12.9%).

- Sales in Japan were broadly unchanged from the same period of the previous fiscal year.
- Sales of infusion-use amino acids and active pharmaceutical ingredients (APIs) decreased year on year due mainly to a drop in the price of some products and the effect from a concentration of shipments occurring in the same period of the previous fiscal year.

- Sales of mail-order sales were solid for Ornithine and the new product Arginine EX.
- International sales decreased compared to the same period of the previous fiscal year partly reflecting yen appreciation in foreign exchange.
- In the Americas, in addition to an increase in sales volume for Cognizin® (Citicoline), which was adopted in a U.S. nationwide health food chain's supplement series, sales of infusion-use amino acids also grew.
- In Europe, sales declined compared to the same period of the previous fiscal year due mainly to the effect of having transferred operations of raw materials for cosmetics ingredients business in May, 2015, and the impact of exchange rates.
- In Asia, sales decreased compared to the same period of the previous fiscal year due mainly to intensified competition in APIs.

(2) Summary of consolidated financial position

- Total assets as of June 30, 2016 were ¥686.5 billion, a decrease of ¥34.2 billion compared to the end of the previous fiscal year.
 - Current assets decreased by ¥12.8 billion to ¥311.5 billion, affected by decreases in inventories, notes and accounts receivable - trade and other items despite increases in short-term loans to the parent company and other items.
 - Non-current assets declined by ¥21.3 billion to ¥374.9 billion, due mainly to the impact of exchange rates and decreases in goodwill and sales right due to amortization.
 - Liabilities as of June 30, 2016 were ¥91.5 billion, a decrease of ¥14.3 billion compared to the end of the previous fiscal year due mainly to decreases in income taxes payable and accounts payable - other.
 - Net assets as of June 30, 2016 were ¥595.0 billion, a decrease of ¥19.8 billion compared to the end of the previous fiscal year, due mainly to payment of dividends as well as a decrease in foreign currency translation adjustment resulting from yen appreciation, despite the booking of profit attributable to owners of parent.
- As a result, the equity ratio as of the end of the second quarter was 86.6%, an increase of 1.4 percentage points compared to the end of the previous fiscal year.

Cash flow summary

- Cash and cash equivalents as of June 30, 2016 were ¥10.5 billion, a decrease of ¥2.2 billion compared to the balance of ¥12.7 billion as of December 31, 2015.

The main contributing factors affecting cash flow during the six months ended June 30, 2016 were as follows:

- Net cash provided by operating activities was ¥26.8 billion, a 17.2% increase compared to the same period of the previous fiscal year. The main factors included profit before income taxes of ¥18.1 billion, depreciation of ¥11.7 billion and amortization of goodwill of ¥6.4 billion, despite income taxes paid of ¥13.0 billion.
- Net cash used in investing activities was ¥20.0 billion, a 14.3% increase compared to the same period of the previous fiscal year. Major outflows included ¥9.0 billion for purchase of property, plant and equipment, ¥8.3 billion for purchase of intangible assets, and ¥4.0 billion for purchase of investment securities.
- Net cash used in financing activities was ¥7.1 billion, a 0.6% increase compared to the same period of the previous fiscal year. The main outflows included cash dividends paid of ¥6.8 billion.

(3) Summary of consolidated earnings forecasts and other forward-looking statements

No revisions have been made to the consolidated earnings forecasts announced on July 21, 2016.

2. Summary Information (Other Items)

(1) Changes to significant subsidiaries during the period

No applicable items.

(2) Use of accounting procedures special to the preparation of quarterly consolidated financial statements

Tax expenses on profit before income taxes for the six months period under review are calculated first by reasonably estimating the effective tax rate after applying tax effect accounting for the fiscal year including the second quarter under review, and next by multiplying profit before income taxes for the six months period under review by the estimated effective tax rate.

(3) Changes in accounting policies, accounting estimates, and restatement

No applicable items.

3. Consolidated Financial Statements

(1) Consolidated balance sheets

	<i>(Millions of yen)</i>	
	As of June 30, 2016	As of December 31, 2015
Assets		
Current assets		
Cash and deposits	10,907	13,236
Notes and accounts receivable - trade	100,784	106,829
Merchandise and finished goods	54,873	61,965
Work in process	11,528	12,363
Raw materials and supplies	11,888	10,476
Deferred tax assets	10,551	11,147
Short-term loans receivable	98,702	96,104
Accounts receivable - other	3,962	7,692
Other	8,635	4,818
Allowance for doubtful accounts	(235)	(202)
Total current assets	311,597	324,433
Non-current assets		
Property, plant and equipment		
Buildings and structures	136,681	141,227
Accumulated depreciation	(89,086)	(91,810)
Buildings and structures, net	47,595	49,417
Machinery, equipment and vehicles	160,269	165,623
Accumulated depreciation	(132,536)	(134,994)
Machinery, equipment and vehicles, net	27,733	30,629
Land	46,185	46,685
Construction in progress	14,912	11,339
Other	49,373	51,124
Accumulated depreciation	(40,992)	(42,152)
Other, net	8,381	8,972
Total property, plant and equipment	144,808	147,043
Intangible assets		
Goodwill	140,101	155,851
Sales right	52,005	56,233
Other	555	722
Total intangible assets	192,663	212,807
Investments and other assets		
Investment securities	13,148	14,043
Net defined benefit asset	8,391	6,964
Deferred tax assets	9,855	10,355
Other	6,251	5,311
Allowance for doubtful accounts	(155)	(194)
Total investments and other assets	37,491	36,480
Total non-current assets	374,963	396,331
Total assets	686,560	720,764

(1) Consolidated balance sheets (continued)

	<i>(Millions of yen)</i>	
	As of June 30, 2016	As of December 31, 2015
Liabilities		
Current liabilities		
Notes and accounts payable - trade	17,234	19,086
Short-term loans payable	4,808	4,840
Accounts payable - other	36,344	39,866
Income taxes payable	6,833	11,830
Provision for sales rebates	1,730	2,097
Provision for point card certificates	241	238
Provision for bonuses	323	427
Other	7,249	6,436
Total current liabilities	74,765	84,823
Non-current liabilities		
Deferred tax liabilities	9,745	12,092
Net defined benefit liability	1,769	1,883
Provision for directors' retirement benefits	101	114
Allowance for loss on plants reorganization	3,005	3,203
Asset retirement obligations	214	404
Other	1,931	3,385
Total non-current liabilities	16,768	21,082
Total liabilities	91,533	105,906
Net assets		
Shareholders' equity		
Capital stock	26,745	26,745
Capital surplus	509,128	509,127
Retained earnings	89,920	85,997
Treasury shares	(26,885)	(26,881)
Total shareholders' equity	598,908	594,989
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	1,590	2,979
Foreign currency translation adjustment	(3,862)	18,819
Remeasurements of defined benefit plans	(2,104)	(2,360)
Total accumulated other comprehensive income	(4,376)	19,438
Subscription rights to shares	496	430
Total net assets	595,027	614,858
Total liabilities and net assets	686,560	720,764

(2) Consolidated statements of income and comprehensive income**Consolidated statements of income**

	<i>(Millions of yen)</i>	
	January 1, 2016 to June 30, 2016	January 1, 2015 to June 30, 2015
Net sales	174,056	178,837
Cost of sales	70,231	69,975
Gross profit	103,824	108,861
Selling, general and administrative expenses		
Research and development expenses	27,273	24,121
Amortization of goodwill	6,490	6,694
Other	54,726	55,576
Total selling, general and administrative expenses	88,490	86,392
Operating income	15,334	22,469
Non-operating income		
Interest income	249	217
Dividend income	213	207
Gain on valuation of derivatives	1,866	1,032
Other	405	414
Total non-operating income	2,733	1,871
Non-operating expenses		
Interest expenses	22	24
Foreign exchange losses	1,780	1,328
Share of loss of entities accounted for using equity method	2,063	2,271
Loss on disposal of non-current assets	309	194
Other	210	443
Total non-operating expenses	4,386	4,261
Ordinary income	13,681	20,079
Extraordinary income		
Gain on sales of non-current assets	2,901	-
Gain on forgiveness of debts	1,334	-
Gain on sales of investment securities	256	-
Compensation income	-	619
Total extraordinary income	4,491	619
Extraordinary losses		
Impairment loss	-	3,282
Loss due to fire	-	209
Total extraordinary losses	-	3,491
Profit before income taxes	18,172	17,207
Income taxes	7,409	7,683
Profit	10,763	9,523
Profit attributable to owners of parent	10,763	9,523

Consolidated statements of comprehensive income

	<i>(Millions of yen)</i>	
	January 1, 2016 to June 30, 2016	January 1, 2015 to June 30, 2015
Profit	10,763	9,523
Other comprehensive income		
Valuation difference on available-for-sale securities	(1,389)	2,250
Foreign currency translation adjustment	(22,546)	2,310
Remeasurements of defined benefit plans	255	159
Share of other comprehensive income of entities accounted for using equity method	(135)	-
Total other comprehensive income	(23,815)	4,720
Comprehensive income	(13,051)	14,243
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(13,051)	14,243
Comprehensive income attributable to non-controlling interests	-	-

(3) Consolidated statements of cash flows

	<i>(Millions of yen)</i>	
	January 1, 2016 to June 30, 2016	January 1, 2015 to June 30, 2015
Cash flows from operating activities		
Profit before income taxes	18,172	17,207
Depreciation	11,719	11,240
Impairment loss	–	3,282
Amortization of goodwill	6,490	6,694
Increase (decrease) in net defined benefit liability	(49)	(20)
Decrease (increase) in net defined benefit asset	(999)	(685)
Interest and dividend income	(462)	(425)
Interest expenses	22	24
Share of (profit) loss of entities accounted for using equity method	2,063	2,271
Loss (gain) on sales and retirement of property, plant and equipment	(2,865)	68
Loss (gain) on sales of investment securities	(256)	(65)
Decrease (increase) in notes and accounts receivable - trade	2,293	3,801
Decrease (increase) in inventories	3,072	1,094
Increase (decrease) in notes and accounts payable - trade	747	(5,468)
Other, net	(480)	(8,089)
Subtotal	39,470	30,930
Interest and dividend income received	462	425
Interest expenses paid	(14)	(26)
Income taxes paid	(13,043)	(8,400)
Net cash provided by (used in) operating activities	26,875	22,929

(3) Consolidated statements of cash flows (continued)

(Millions of yen)

	January 1, 2016 to June 30, 2016	January 1, 2015 to June 30, 2015
Cash flows from investing activities		
Purchase of property, plant and equipment	(9,019)	(9,848)
Proceeds from sales of property, plant and equipment	3,918	45
Purchase of intangible assets	(8,315)	(47)
Purchase of investment securities	(4,000)	(5,200)
Proceeds from sales of investment securities	776	65
Payments into time deposits	(437)	(960)
Proceeds from withdrawal of time deposits	437	2,214
Net decrease (increase) in short-term loans receivable	(2,627)	(3,547)
Other, net	(764)	(249)
Net cash provided by (used in) investing activities	(20,033)	(17,526)
Cash flows from financing activities		
Net increase (decrease) in short-term loans payable	(185)	(71)
Purchase of treasury shares	(4)	(101)
Cash dividends paid	(6,840)	(6,841)
Other, net	(124)	(99)
Net cash provided by (used in) financing activities	(7,154)	(7,113)
Effect of exchange rate change on cash and cash equivalents	(1,962)	(1,501)
Net increase (decrease) in cash and cash equivalents	(2,274)	(3,213)
Cash and cash equivalents at beginning of period	12,784	17,013
Cash and cash equivalents at end of period	10,509	13,800

(4) 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)

I. Six months ended June 30, 2016 (January 1, 2016 – June 30, 2016)

Information on sales and profit or loss by reportable segment

(Millions of yen)

	Pharmaceuticals	Bio-Chemicals	Total	Adjustments	Consolidated
Net sales					
Sales to external customers	131,837	42,219	174,056	–	174,056
Inter-segment sales and transfers	455	943	1,399	(1,399)	–
Total sales	132,292	43,163	175,455	(1,399)	174,056
Segment profit	11,662	3,482	15,145	188	15,334

Notes: 1. The ¥188 million for adjustments of segment profit is due to elimination of inter-segment transactions.
2. Segment profit is adjusted for operating income as recorded in the Consolidated Statements of Income.

II. Six months ended June 30, 2015 (January 1, 2015 – June 30, 2015)

Information on sales and profit or loss by reportable segment

(Millions of yen)

	Pharmaceuticals	Bio-Chemicals	Total	Adjustments	Consolidated
Net sales					
Sales to external customers	134,911	43,925	178,837	–	178,837
Inter-segment sales and transfers	425	1,096	1,522	(1,522)	–
Total sales	135,337	45,021	180,359	(1,522)	178,837
Segment profit	18,558	3,999	22,558	(88)	22,469

Notes: 1. The negative ¥88 million for adjustments of segment profit is due to elimination of inter-segment transactions.
2. Segment profit is adjusted for operating income as recorded in the Consolidated Statements of Income.