

# Kyowa Hakko Kirin Co., Ltd.

# Consolidated Financial Summary (JGAAP) Fiscal 2017 Interim (January 1, 2017 – June 30, 2017)

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 the 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, 2017

July 28, 2017

Company Name: Kyowa Hakko Kirin Co., Ltd.

Listed
Exchanges: 1st Section of the Tokyo Stock Exchange

Stock Code:4151President:Nobuo HanaiTelephone:+81 3 5205 7206Inquiries:Niro SakamotoURLhttp://www.kyowa-kirin.com/investors/index.htmlExecutive Officer,

Corporate Communications Department

Scheduled date of submission of Quarterly Securities Report: August 7, 2017

Scheduled start date of dividend payment: September 1, 2017 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, 2017

(% changes indicate year-on-year changes.)

(1) Consolidated operating results	Six months ended June 30, 2017	Change (%)	Six months ended June 30, 2016	Change (%)
Net sales (millions of yen)	175,685	0.9	174,056	(2.7)
Operating income (millions of yen)	24,127	57.3	15,334	(31.8)
Ordinary income (millions of yen)	22,044	61.1	13,681	(31.9)
Profit attributable to owners of parent (millions of yen)	13,670	27.0	10,763	13.0
Basic earnings per share (yen)	24.98		19.67	
Fully diluted earnings per share (yen)	24.95		19.65	

Note: Comprehensive income: Six months ended June 30, 2017: ¥14,763 million; -% Six months ended June 30, 2016: (¥13,051) million; -%

(2) Consolidated financial position	As of June 30, 2017	As of December 31, 2016
Total assets (millions of yen)	697,488	697,167
Net assets (millions of yen)	608,769	600,745
Equity ratio (%)	87.2	86.1

Note: Equity: As of June 30, 2017: ¥608,200 million; As of December 31, 2016: ¥600,182 million

#### 2. Dividends

	Fiscal year ending December 31, 2017 (forecast)	Fiscal year ended December 31, 2016
First quarter dividend per share (yen)		_
Interim dividend per share (yen)	12.50	12.50
Third quarter dividend per share (yen)	<del></del>	_
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, 2017

(% changes indicate year-on-year changes.)

	Full year		
		Change (%)	
Net sales (millions of yen)	347,000	1.2	
Operating income (millions of yen)	39,000	23.3	
Ordinary income (millions of yen)	35,000	32.6	
Profit attributable to owners of parent (millions of yen)	21,000	12.5	
Basic earnings per share (yen)	38.37		

Note: Changes to the earnings forecast most recently announced: Yes

#### 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 14, "2. Consolidated Financial Statements and Significant Notes Thereto (4) Notes to the consolidated financial statements (Use of accounting procedures special to the preparation of quarterly consolidated financial statements)."

#### 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, 2017 576,483,555 shares As of December 31, 2016 576,483,555 shares

2. Number of treasury shares

As of June 30, 2017 29,172,664 shares As of December 31, 2016 29,261,490 shares

3. Average number of shares during the period

Six months ended June 30, 2017 547,273,428 shares Six months ended June 30, 2016 547,225,777 shares

Quarterly financial reports are not required to be subjected to quarterly reviews.

#### 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 the 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, 2017 (January 1, 2017 to June 30, 2017), net sales were ¥175.6 billion (up 0.9% compared to the same period of the previous fiscal year), operating income was ¥24.1 billion (up 57.3%), ordinary income was ¥22.0 billion (up 61.1%), and profit attributable to owners of parent was ¥13.6 billion (up 27.0%). 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 ¥27.9 billion (up 41.2%).

- Net sales and operating income increased due mainly to the increase in licensing revenue and a decline in research and development expenses.
- Ordinary income and profit attributable to owners of parent also increased.

Performance by segment is as follows.

#### **Pharmaceuticals business**

#### 1) Results

In the pharmaceuticals business, net sales were ¥135.7 billion (up 2.6%) and operating income was ¥20.7 billion (up 77.7%).

- Sales in Japan decreased year on year due mainly to the impacts of the market penetration of generics in conjunction with measures to reduce medical costs and reductions in drug price standards implemented in April 2016.
- · Sales of core product NESP®, a renal anemia treatment drug, decreased compared to the same period of the previous fiscal year, due to the impact of reductions in drug price standards and other factors.
- · Sales of long term NHI products such as ALLELOCK®, an anti-allergy agent, CONIEL®, a hypertension and angina pectoris drug, Depakene®, an anti-epileptic drug, and GRAN®, a neutropenia treatment drug, decreased due to the impacts of the market penetration of generics, etc.
- · Sales of G-Lasta®, an agent for decreasing the incidence of febrile neutropenia, NOURIAST®, an antiparkinsonian agent, Onglyza®, a treatment for type 2 diabetes, and other products showed solid growth.
- International sales increased year on year due mainly to the increase in licensing revenue.
- · In Europe and the Americas, products such as Abstral® and PecFent®, which are treatments for cancer pain, and Moventig®, an opioid-induced constipation (OIC) treatment, saw an increase in sales, while sales increased compared to the same period of the previous fiscal year due to lump-sum agreement and milestone revenue related to Benralizumab from AstraZeneca and other factors.
- · In Asia, sales increased compared to the same period of the previous fiscal year, reflecting steady sales particularly in Taiwan and South Korea.

#### 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, 2017 are as follows.

#### **Nephrology**

· In Japan, in April we applied for approval of indication of calcium receptor agonist KHK7580 for the treatment of secondary hyperparathyroidism in maintenance dialysis patients.

- · In Japan, we are currently conducting phase II clinical study for RTA 402 targeting chronic kidney disease (CKD) with type 2 diabetes.
- · In China, we are currently preparing to reapply 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.

#### 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.
- · We are currently preparing for approval of indication of Anti-CCR4 humanized monoclonal antibody KW-0761 (product name in Japan: POTELIGEO®) for the treatment of hematological cancer in the U.S., Europe, etc.

#### Immunology and allergy

- · AstraZeneca, our licensing partner for the anti-IL-5 receptor humanized monoclonal antibody KHK4563, applied for approval of indication in treatment of bronchial asthma for KHK4563 in Japan, in February. Also, as part of the multi-regional clinical study being conducted by said company, we are currently conducting a phase III clinical study in Japan and South Korea, targeting bronchial asthma patients, and a phase III clinical study in Japan, targeting patients with chronic obstructive pulmonary disease.
- · In April we started a phase III clinical study targeting axial spondyloarthritis in Japan, South Korea, etc. for the anti-IL-17 receptor A fully human antibody KHK4827 (product name in Japan: LUMICEF®). We are also currently conducting a phase III clinical study for psoriasis in South Korea.
- · In Japan, in May we obtained approval of additional dosage and administration for the ulcerative colitis treatment drug ASACOL® that is being jointly developed with Zeria Pharmaceutical Co., Ltd.

#### **CNS**

- · We are currently studying the potential for reapplication of adenosine A<sub>2A</sub> receptor antagonist KW-6002 (product name in Japan: NOURIAST®) targeting Parkinson's disease in the U.S.
- · In Japan, we started a phase III clinical study targeting HTLV-1 associated myelopathy in June for the anti-CCR4 humanized monoclonal antibody KW-0761 (product name in Japan: POTELIGEO®).

#### Other

- · For the human monoclonal anti-Fibroblast Growth Factor 23 antibody KRN23, we are currently applying for approval of indication in treatment of X-linked hypophosphatemia in Europe (application accepted in December 2016). Also, we are currently conducting 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 multi-regional phase III clinical study in the U.S., Canada, Europe, Australia, Japan and South Korea, targeting X-linked hypophosphatemia in pediatric patients. In addition, we are currently conducting a phase II clinical study in the U.S., Japan and South Korea, targeting tumor induced osteomalacia and epidermal nevus syndrome.
- · 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 are currently conducting a phase II/III clinical study in aplastic anemia in Japan and South Korea.

#### **Bio-Chemicals business**

In the Bio-Chemicals business, net sales were ¥41.7 billion (down 3.3%) and operating income was ¥3.3 billion (down 5.0%).

- Sales in Japan were broadly unchanged from the same period of the previous fiscal year.
- · Sales of active pharmaceutical and health food ingredients were solid, increasing on a year-on-year basis.
- · In the mail-order business, sales grew for Arginine EX, which was released last year.
- International sales decreased compared to the same period of the previous fiscal year.
- · In the Americas, sales declined compared to the same period of the previous fiscal year, when there were concentrated shipments of raw materials for supplements.
- · In Europe, sales were broadly unchanged from the same period of the previous fiscal year, excluding currency effects.
- · In Asia, sales decreased compared to the same period of the previous fiscal year due to the effect of intensified competition of some products.

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

- Total assets as of June 30, 2017 were ¥697.4 billion, an increase of ¥0.3 billion compared to the end of the previous fiscal year.
- · Current assets increased by ¥12.9 billion to ¥339.3 billion, due mainly to an increase in short-term loans to the parent company as fund management, despite decreases in notes and accounts receivable trade and other items.
- · Non-current assets declined by ¥12.5 billion to ¥358.1 billion, due to decreases in goodwill and sales right due to amortization and others.
- Liabilities as of June 30, 2017 were ¥88.7 billion, a decrease of ¥7.7 billion compared to the end of the previous fiscal year due to decreases in accounts payable - other and other items.
- Net assets as of June 30, 2017 were ¥608.7 billion, an increase of ¥8.0 billion compared to the end
  of the previous fiscal year, due to the booking of profit attributable to owners of parent and others,
  despite a decrease due to payment of dividends.
  - As a result, the equity ratio as of the end of the second quarter was 87.2%, an increase of 1.1 percentage points compared to the end of the previous fiscal year.

#### Cash flow summary

● Cash and cash equivalents as of June 30, 2017 were ¥15.8 billion, an increase of ¥2.7 billion compared to the balance of ¥13.0 billion as of December 31, 2016.

The main contributing factors affecting cash flow during the six months ended June 30, 2017 were as follows:

- · Net cash provided by operating activities was ¥31.1 billion, a 16.0% increase compared to the same period of the previous fiscal year. The main factors included profit before income taxes of ¥22.6 billion, depreciation of ¥10.7 billion and amortization of goodwill of ¥6.2 billion, despite income taxes paid of ¥8.7 billion.
- Net cash used in investing activities was ¥22.3 billion, an 11.6% increase compared to the same period of the previous fiscal year. Major outflows included a net increase of ¥13.3 billion in short-term loans receivable, ¥8.0 billion for purchase of property, plant and equipment, and ¥2.0 billion for purchase of investment securities.
- · Net cash used in financing activities was ¥6.8 billion, a 4.5% decrease compared to the same period of the previous fiscal year. The main outflows included cash dividends paid of ¥6.8 billion.

#### (3) Qualitative information of consolidated earnings forecasts

In regard to the consolidated results for the first six months of fiscal year 2017, net sales for the pharmaceuticals business were strong and higher than initial expectations, and predictions include a decrease in research and development expenses. In light of these factors, we have revised our consolidated earnings forecast.

The differences from the consolidated earnings forecasts for the fiscal year ending December 31, 2017 announced January 31, 2017 are as follows.

(Full year)

(i dii youi)					
	Net Sales	Operating Income	Ordinary income	Profit attributable to owners of parent	Basic earnings per share
Previous forecast (A)	(Millions of yen) 344,000	(Millions of yen) 35,000	(Millions of yen) 30,000	(Millions of yen)	(Yen) 34.72
Revised forecast (B)	344,000	39,000	35,000	21,000	34.72
Change (B-A)	3,000	4,000	5,000	2,000	-
Rate of change (%)	0.9	11.4	16.7	10.5	_
Fiscal 2016 results	343,019	31,638	26,397	18,669	34.12

# 2. Consolidated Financial Statements and Significant Notes Thereto

# (1) Consolidated balance sheets

		(Millions of yen)
	As of June 30, 2017	As of December 31, 2016
Assets		
Current assets		
Cash and deposits	15,825	13,066
Notes and accounts receivable - trade	98,754	100,999
Merchandise and finished goods	50,811	51,349
Work in process	13,303	12,934
Raw materials and supplies	11,642	11,945
Deferred tax assets	10,999	10,824
Short-term loans receivable	128,197	114,866
Accounts receivable - other	5,148	5,900
Other	4,985	4,848
Allowance for doubtful accounts	(282)	(265)
Total current assets	339,385	326,469
Non-current assets		
Property, plant and equipment		
Buildings and structures	141,405	141,432
Accumulated depreciation	(91,139)	(89,967)
Buildings and structures, net	50,265	51,464
Machinery, equipment and vehicles	167,191	162,747
Accumulated depreciation	(135,615)	(133,539)
Machinery, equipment and vehicles, net	31,575	29,207
Land	44,445	45,685
Construction in progress	12,034	15,339
Other	50,232	49,935
Accumulated depreciation	(40,335)	(40,585)
Other, net	9,896	9,350
Total property, plant and equipment	148,218	151,047
Intangible assets		
Goodwill	129,230	134,910
Sales right	45,123	49,402
Other	784	708
Total intangible assets	175,138	185,021
Investments and other assets		
Investment securities	11,001	11,412
Net defined benefit asset	7,231	6,563
Deferred tax assets	11,248	11,496
Other	5,364	5,257
Allowance for doubtful accounts	(100)	(100)
Total investments and other assets	34,745	34,629
Total non-current assets	358,102	370,698
Total assets	697,488	697,167

## (1) Consolidated balance sheets (continued)

(1) Consolidated balance sheets (continued)		(Millions of yen)
	As of	As of
	June 30, 2017	December 31, 2016
Liabilities		
Current liabilities		
Notes and accounts payable - trade	17,861	18,230
Short-term loans payable	5,511	5,360
Accounts payable - other	29,154	37,608
Income taxes payable	8,689	8,183
Provision for sales rebates	2,097	1,677
Provision for point card certificates	260	249
Provision for bonuses	464	422
Other	7,732	7,684
Total current liabilities	71,772	79,416
Non-current liabilities		
Deferred tax liabilities	8,988	9,144
Net defined benefit liability	2,045	2,358
Allowance for loss on plants reorganization	2,988	2,988
Asset retirement obligations	480	502
Other	2,443	2,012
Total non-current liabilities	16,946	17,006
Total liabilities	88,719	96,422
Net assets		
Shareholders' equity		
Capital stock	26,745	26,745
Capital surplus	509,145	509,128
Retained earnings	97,816	90,986
Treasury shares	(26,812)	(26,889)
Total shareholders' equity	606,894	599,970
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	2,547	2,037
Foreign currency translation adjustment	2,568	2,385
Remeasurements of defined benefit plans	(3,809)	(4,210)
Total accumulated other comprehensive income	1,305	212
Subscription rights to shares	568	562
Total net assets	608,769	600,745
Total liabilities and net assets	697,488	697,167

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

#### Consolidated statements of income

		(Millions of yen)
	January 1, 2017 to June 30, 2017	January 1, 2016 to June 30, 2016
Net sales	175,685	174,056
Cost of sales	66,512	70,231
Gross profit	109,173	103,824
Selling, general and administrative expenses		
Research and development expenses	24,619	27,273
Amortization of goodwill	6,231	6,490
Other	54,195	54,726
Total selling, general and administrative expenses	85,046	88,490
Operating income	24,127	15,334
Non-operating income		
Interest income	227	249
Dividend income	91	213
Gain on valuation of derivatives	_	1,866
Other	736	405
Total non-operating income	1,055	2,733
Non-operating expenses		
Interest expenses	25	22
Foreign exchange losses	39	1,780
Loss on valuation of derivatives	225	_
Share of loss of entities accounted for using equity method	2,446	2,063
Loss on disposal of non-current assets	164	309
Other	236	210
Total non-operating expenses	3,138	4,386
Ordinary income	22,044	13,681
Extraordinary income		
Gain on sales of non-current assets	603	2,901
Gain on forgiveness of debts	_	1,334
Gain on sales of investment securities	_	256
Total extraordinary income	603	4,491
Profit before income taxes	22,647	18,172
Income taxes	8,977	7,409
Profit	13,670	10,763
Profit attributable to owners of parent	13,670	10,763

# Consolidated statements of comprehensive income

_		(Millions of yen)
	January 1, 2017 to	January 1, 2016 to
	June 30, 2017	June 30, 2016
Profit	13,670	10,763
Other comprehensive income		
Valuation difference on available-for-sale securities	510	(1,389)
Foreign currency translation adjustment	192	(22,546)
Remeasurements of defined benefit plans	400	255
Share of other comprehensive income of entities accounted for using equity method	(9)	(135)
Total other comprehensive income	1,093	(23,815)
Comprehensive income	14,763	(13,051)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	14,763	(13,051)

#### (3) Consolidated statements of cash flows

(Millions of yen) January 1, 2017 to January 1, 2016 to June 30, 2016 June 30, 2017 Cash flows from operating activities Profit before income taxes 18,172 22,647 Depreciation 10,734 11,719 6,490 Amortization of goodwill 6,231 Increase (decrease) in net defined benefit liability (173)(49)Decrease (increase) in net defined benefit asset (999)(323)Interest and dividend income (319)(462)Interest expenses 25 22 Share of (profit) loss of entities accounted for using 2,446 2,063 equity method Loss (gain) on sales and retirement of property, plant (543)(2,865)and equipment Loss (gain) on sales of investment securities (13)(256)Decrease (increase) in notes and accounts 2,411 2,293 receivable - trade 3,072 Decrease (increase) in inventories 380 Increase (decrease) in notes and accounts payable -747 (333)trade Other, net (3,529)(480)Subtotal 39,641 39,470 Interest and dividend income received 462 319 Interest expenses paid (20)(14)Income taxes paid (13,043)(8,777)Net cash provided by (used in) operating activities 26,875 31,162

#### (3) Consolidated statements of cash flows (continued)

(Millions of yen) January 1, 2017 to January 1, 2016 to June 30, 2017 June 30, 2016 **Cash flows from investing activities** Purchase of property, plant and equipment (9,019)(8,028)Proceeds from sales of property, plant and equipment 1,851 3,918 Purchase of intangible assets (1,579)(8,315)Purchase of investment securities (2,000)(4,000)Proceeds from sales of investment securities 452 776 Net decrease (increase) in short-term loans (13,329)(2,627)receivable Other, net 283 (764)Net cash provided by (used in) investing activities (22,349)(20,033)Cash flows from financing activities (185)Net increase (decrease) in short-term loans payable 139 Purchase of treasury shares (7) (4) Cash dividends paid (6,840)(6,840)Other, net (123)(124)Net cash provided by (used in) financing activities (6,831)(7,154)Effect of exchange rate change on cash and cash 779 (1,962)equivalents Net increase (decrease) in cash and cash equivalents 2,760 (2,274)Cash and cash equivalents at beginning of period 13,075 12,784 Cash and cash equivalents at end of period 15,836 10,509

#### (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.

(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.

#### (Segment information)

I. Six months ended June 30, 2017 (January 1, 2017 – June 30, 2017)
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 Inter-segment sales and transfers	135,247 474	40,437 1,298	175,685 1,773	– (1,773)	175,685 -
Total sales	135,722	41,736	177,458	(1,773)	175,685
Segment profit	20,728	3,308	24,036	90	24,127

Notes: 1. The ¥90 million for adjustments of segment profit is due to elimination of inter-segment transactions.

II. 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 Inter-segment	131,837	42,219	174,056	_	174,056
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.

<sup>2.</sup> Segment profit is adjusted for operating income as recorded in the Consolidated Statements of Income.