

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

## **Consolidated Financial Summary (JGAAP)**

### **Fiscal 2017 First Quarter**

**(January 1, 2017 – March 31, 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 Three Months Ended March 31, 2017**

April 27, 2017

Company Name:	Kyowa Hakko Kirin Co., Ltd.	Listed Exchanges:	1st Section of the Tokyo Stock Exchange
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Scheduled date of submission of Quarterly Securities Report: May 10, 2017

Scheduled start date of dividend payment: -

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 Three Months Ended March 31, 2017***(% changes indicate year-on-year changes.)*

(1) Consolidated operating results	Three months ended March 31, 2017	Change (%)	Three months ended March 31, 2016	Change (%)
Net sales (millions of yen)	90,935	2.8	88,469	(1.3)
Operating income (millions of yen)	14,704	72.5	8,522	(8.8)
Ordinary income (millions of yen)	13,688	74.6	7,841	(3.0)
Profit attributable to owners of parent (millions of yen)	8,484	14.7	7,399	60.6
Basic earnings per share (yen)	15.50		13.52	
Fully diluted earnings per share (yen)	15.49		13.51	

Note: Comprehensive income: Three months ended March 31, 2017: ¥6,416 million; -%  
Three months ended March 31, 2016: (¥2,482) million; -%

(2) Consolidated financial position	As of March 31, 2017	As of December 31, 2016
Total assets (millions of yen)	691,788	697,167
Net assets (millions of yen)	600,362	600,745
Equity ratio (%)	86.7	86.1

Note: Equity: As of March 31, 2017: ¥599,858 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 (forecast)	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, 2017***(% changes indicate year-on-year changes.)*

	Full year	
		Change (%)
Net sales (millions of yen)	344,000	0.3
Operating income (millions of yen)	35,000	10.6
Ordinary income (millions of yen)	30,000	13.6
Profit attributable to owners of parent (millions of yen)	19,000	1.8
Basic earnings per share (yen)	34.72	

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 11, "2. Consolidated Financial Statements and Significant Notes Thereto (3) 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 March 31, 2017	576,483,555 shares
As of December 31, 2016	576,483,555 shares
2. Number of treasury shares
 

As of March 31, 2017	29,169,967 shares
As of December 31, 2016	29,261,490 shares
3. Average number of shares during the period
 

Three months ended March 31, 2017	547,244,693 shares
Three months ended March 31, 2016	547,226,349 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 three months ended March 31, 2017 (January 1, 2017 to March 31, 2017), net sales were ¥90.9 billion (up 2.8% compared to the same period of the previous fiscal year), operating income was ¥14.7 billion (up 72.5%), ordinary income was ¥13.6 billion (up 74.6%), and profit attributable to owners of parent was ¥8.4 billion (up 14.7%). 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 ¥16.5 billion (up 53.7%).

- Net sales and operating income increased due mainly to the increase in licensing revenue and a decline in research and development expenses, despite the impact of reductions in drug price standards implemented in April 2016.
- 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 ¥71.5 billion (up 5.1%) and operating income was ¥12.9 billion (up 119.2%).

- 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.
  - Sales of core product NESP<sup>®</sup>, a long-acting erythropoiesis stimulating agent, 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<sup>®</sup>, an anti-allergy agent, CONIEL<sup>®</sup>, a hypertension and angina pectoris drug, and GRAN<sup>®</sup>, a Granulocyte Colony-Stimulating Factor (G-CSF) product, decreased due to the impacts of the market penetration of generics, etc.
  - Sales of NOURIAST<sup>®</sup>, an antiparkinsonian agent, Onglyza<sup>®</sup>, a treatment for type 2 diabetes, REGPARA<sup>®</sup>, a treatment for secondary hyperparathyroidism, G-Lasta<sup>®</sup>, a sustained-duration G-CSF product, 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<sup>®</sup> and PecFent<sup>®</sup>, which are treatments for cancer pain, saw an increase in sales, while sales increased compared to the same period of the previous fiscal year due to lump-sum agreement revenue 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 three months ended March 31, 2017 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, 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.
- Anti-CCR4 humanized monoclonal antibody KW-0761 (product name in Japan: POTELIGEO®) is currently undergoing 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**

- 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. 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 South Korea, we started a phase III clinical study targeting psoriasis in January for the anti-IL-17 receptor A fully human antibody KHK4827 (product name in Japan: LUMICEF®).
- In Japan, we are currently applying for approval of additional dosage and administration for the ulcerative colitis treatment drug ASACOL® that is being jointly developed with Zeria Pharmaceutical Co., Ltd. (application filed in July 2016).

### **CNS**

- We are currently studying the potential for reapplication of KW-6002 (product name in Japan: NOURIAST®) targeting Parkinson's disease in the U.S.

### **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 ¥20.3 billion (down 4.0%) and operating income was ¥1.7 billion (down 26.7%).

- Sales in Japan decreased compared to the same period of the previous fiscal year.
  - Although sales of some active pharmaceutical ingredients (APIs) declined year on year, infusion-use amino acids and others rose compared to the same period of the previous fiscal year.
  - 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 and Asia, sales were broadly unchanged from the same period of the previous fiscal year.

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

- Total assets as of March 31, 2017 were ¥691.7 billion, a decrease of ¥5.3 billion compared to the end of the previous fiscal year.
  - Current assets increased by ¥4.3 billion to ¥330.8 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 ¥9.7 billion to ¥360.9 billion, due to the impact of yen appreciation, decreases in goodwill and sales right due to amortization, and others.
- Liabilities as of March 31, 2017 were ¥91.4 billion, a decrease of ¥4.9 billion compared to the end of the previous fiscal year due to decreases in accounts payable - other and other items.
- Net assets as of March 31, 2017 were ¥600.3 billion, a decrease of ¥0.3 billion compared to the end of the previous fiscal year, due mainly to payment of dividends and a decrease in foreign currency translation adjustment, despite the booking of profit attributable to owners of parent.
 

As a result, the equity ratio as of the end of the first quarter was 86.7%, an increase of 0.6 percentage points compared to the end of the previous fiscal year.

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

No revisions have been made to the consolidated earnings forecasts announced on January 31, 2017.

## 2. Consolidated Financial Statements and Significant Notes Thereto

### (1) Consolidated balance sheets

	<i>(Millions of yen)</i>	
	As of March 31, 2017	As of December 31, 2016
<b>Assets</b>		
Current assets		
Cash and deposits	16,286	13,066
Notes and accounts receivable - trade	96,869	100,999
Merchandise and finished goods	52,134	51,349
Work in process	11,624	12,934
Raw materials and supplies	11,954	11,945
Deferred tax assets	11,052	10,824
Short-term loans receivable	120,241	114,866
Accounts receivable - other	6,161	5,900
Other	4,744	4,848
Allowance for doubtful accounts	(265)	(265)
Total current assets	330,803	326,469
Non-current assets		
Property, plant and equipment		
Buildings and structures	140,772	141,432
Accumulated depreciation	(90,179)	(89,967)
Buildings and structures, net	50,593	51,464
Machinery, equipment and vehicles	162,893	162,747
Accumulated depreciation	(134,485)	(133,539)
Machinery, equipment and vehicles, net	28,407	29,207
Land	44,421	45,685
Construction in progress	15,360	15,339
Other	50,117	49,935
Accumulated depreciation	(40,739)	(40,585)
Other, net	9,378	9,350
Total property, plant and equipment	148,161	151,047
Intangible assets		
Goodwill	131,143	134,910
Sales right	46,617	49,402
Other	696	708
Total intangible assets	178,456	185,021
Investments and other assets		
Investment securities	10,902	11,412
Net defined benefit asset	7,031	6,563
Deferred tax assets	11,337	11,496
Other	5,197	5,257
Allowance for doubtful accounts	(102)	(100)
Total investments and other assets	34,366	34,629
Total non-current assets	360,984	370,698
Total assets	691,788	697,167

**(1) Consolidated balance sheets (continued)**

	<i>(Millions of yen)</i>	
	As of March 31, 2017	As of December 31, 2016
<b>Liabilities</b>		
Current liabilities		
Notes and accounts payable - trade	21,584	18,230
Short-term loans payable	5,575	5,360
Accounts payable - other	28,552	37,608
Income taxes payable	6,166	8,183
Provision for sales rebates	1,966	1,677
Provision for point card certificates	254	249
Provision for bonuses	3,554	422
Other	7,663	7,684
Total current liabilities	75,317	79,416
Non-current liabilities		
Deferred tax liabilities	8,869	9,144
Net defined benefit liability	2,166	2,358
Allowance for loss on plants reorganization	2,988	2,988
Asset retirement obligations	504	502
Other	1,579	2,012
Total non-current liabilities	16,108	17,006
Total liabilities	91,425	96,422
<b>Net assets</b>		
Shareholders' equity		
Capital stock	26,745	26,745
Capital surplus	509,145	509,128
Retained earnings	92,630	90,986
Treasury shares	(26,806)	(26,889)
Total shareholders' equity	601,714	599,970
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	2,120	2,037
Foreign currency translation adjustment	32	2,385
Remeasurements of defined benefit plans	(4,008)	(4,210)
Total accumulated other comprehensive income	(1,855)	212
Subscription rights to shares	504	562
Total net assets	600,362	600,745
Total liabilities and net assets	691,788	697,167

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

	<i>(Millions of yen)</i>	
	Three months ended March 31, 2017	Three months ended March 31, 2016
Net sales	90,935	88,469
Cost of sales	35,069	36,746
Gross profit	55,866	51,723
Selling, general and administrative expenses		
Research and development expenses	11,769	13,706
Amortization of goodwill	3,121	3,268
Other	26,270	26,225
Total selling, general and administrative expenses	41,161	43,200
Operating income	14,704	8,522
Non-operating income		
Interest income	110	131
Dividend income	6	174
Foreign exchange gains	-	466
Gain on valuation of derivatives	537	-
Other	414	204
Total non-operating income	1,068	975
Non-operating expenses		
Interest expenses	11	12
Foreign exchange losses	638	-
Loss on valuation of derivatives	-	324
Share of loss of entities accounted for using equity method	1,307	1,041
Loss on disposal of non-current assets	82	238
Other	44	40
Total non-operating expenses	2,084	1,657
Ordinary income	13,688	7,841
Extraordinary income		
Gain on sales of non-current assets	603	2,719
Gain on forgiveness of debts	-	1,334
Gain on sales of investment securities	-	256
Total extraordinary income	603	4,310
Profit before income taxes	14,292	12,151
Income taxes	5,807	4,752
Profit	8,484	7,399
Profit attributable to owners of parent	8,484	7,399

**Consolidated statements of comprehensive income**

	<i>(Millions of yen)</i>	
	Three months ended March 31, 2017	Three months ended March 31, 2016
Profit	8,484	7,399
Other comprehensive income		
Valuation difference on available-for-sale securities	83	(878)
Foreign currency translation adjustment	(2,340)	(9,043)
Remeasurements of defined benefit plans	202	102
Share of other comprehensive income of entities accounted for using equity method	(13)	(63)
Total other comprehensive income	(2,068)	(9,882)
Comprehensive income	6,416	(2,482)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	6,416	(2,482)
Comprehensive income attributable to non-controlling interests	-	-

**(3) Notes to the consolidated financial statements**

(Items related to going concern assumption)

No applicable items.

(Notes on significant change in shareholders' equity)

No applicable items.

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

Tax expenses on profit before income taxes for the three 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 first quarter under review, and next by multiplying profit before income taxes for the three months period under review by the estimated effective tax rate.

(Segment information)

## I. Three months ended March 31, 2017 (January 1, 2017 – March 31, 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	71,306	19,629	90,935	–	90,935
Inter-segment sales and transfers	203	753	956	(956)	–
Total sales	71,509	20,382	91,892	(956)	90,935
Segment profit	12,931	1,700	14,632	72	14,704

Notes: 1. The ¥72 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. Three months ended March 31, 2016 (January 1, 2016 – March 31, 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	67,803	20,666	88,469	–	88,469
Inter-segment sales and transfers	208	558	767	(767)	–
Total sales	68,011	21,224	89,236	(767)	88,469
Segment profit	5,900	2,318	8,219	303	8,522

Notes: 1. The ¥303 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.