

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

## **Consolidated Financial Summary**

**Fiscal 2016, First Quarter**

**(January 1, 2016 – March 31, 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 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 CONSOLIDATED FINANCIAL STATEMENTS (JGAAP)**  
**for Three Months Ended March 31, 2016**

April 27, 2016

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Scheduled date of submission of Quarterly Securities Report: May 9, 2016

Scheduled start date of dividend payment: -

Appendix materials to accompany the annual 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, 2016***(% changes indicate year-on-year changes.)*

(1) Consolidated operating results	Three months ended March 31, 2016	Change (%)	Three months ended March 31, 2015	Change (%)
Net sales (millions of yen)	88,469	(1.3)	89,598	4.1
Operating income (millions of yen)	8,522	(8.8)	9,340	(25.0)
Ordinary income (millions of yen)	7,841	(3.0)	8,079	(33.0)
Profit attributable to owners of parent (millions of yen)	7,399	60.6	4,607	(27.2)
Basic earnings per share (yen)	13.52		8.42	
Fully diluted earnings per share (yen)	13.51		8.41	

Note: Comprehensive income: Three months ended March 31, 2016: (¥2,482) million; -%  
 Three months ended March 31, 2015: ¥3,006 million; (21.6%)

**(2) Consolidated financial position**

	As of March 31, 2016	As of December 31, 2015
Total assets (millions of yen)	702,584	720,764
Net assets (millions of yen)	605,565	614,858
Equity ratio (%)	86.1	85.2

Note: Equity: As of March 31, 2016: ¥605,102 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 (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, 2016***(% changes indicate year-on-year changes.)*

	Six months ending June 30, 2016		Full year	
		Change (%)		Change (%)
Net sales (millions of yen)	171,000	(4.4)	351,000	(3.7)
Operating income (millions of yen)	9,000	(59.9)	30,000	(31.5)
Ordinary income (millions of yen)	—	—	25,000	(36.2)
Profit attributable to owners of parent (millions of yen)	—	—	16,000	(46.3)
Basic earnings per share (yen)	—		29.24	

Notes: 1. Changes to the earnings forecast most recently announced: None

2. Because ordinary income and profit attributable to owners of parent forecasts are only included for full-year forecasts, forecasts for six months ending June 30, 2016 are provided only for net sales and operating income.

**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 March 31, 2016	576,483,555 shares
As of December 31, 2015	576,483,555 shares
2. Number of treasury shares
 

As of March 31, 2016	29,257,697 shares
As of December 31, 2015	29,256,749 shares
3. Average number of shares during the period
 

Three months ended March 31, 2016	547,226,349 shares
Three months ended March 31, 2015	547,324,783 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. 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, 2016 (January 1, 2016 to March 31, 2016), net sales were ¥88.4 billion (down 1.3% compared to the same period of the previous fiscal year), operating income was ¥8.5 billion (down 8.8%), ordinary income was ¥7.8 billion (down 3.0%), and profit attributable to owners of parent was ¥7.3 billion (up 60.6%). 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 ¥10.7 billion (down 7.0%).

- 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 ¥68.0 billion (down 0.1%) and operating income was ¥5.9 billion (down 24.2%).

- Sales in Japan increased year on year due to such factors as the growth in sales of new products.
  - Sales of core product NESP<sup>®</sup>, a long-acting erythropoiesis stimulating agent, were solid, increasing on a year-on-year basis.
  - There was steady growth in sales of new products such as G-Lasta<sup>®</sup>, a sustained-duration Granulocyte Colony-Stimulating Factor (G-CSF) product, NOURIAST<sup>®</sup>, an antiparkinsonian agent, Onglyza<sup>®</sup>, a treatment for type 2 diabetes, and Dovobet<sup>®</sup>, a topical combination drug for psoriasis vulgaris.
  - 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 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<sup>®</sup> and PecFent<sup>®</sup>, 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<sup>®</sup>, an opioid-induced constipation (OIC) treatment, from AstraZeneca, in February.
  - In Asia, despite steady sales particularly in South Korea, sales were broadly unchanged 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 three months ended March 31, 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<sup>®</sup>), 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<sup>®</sup>) 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 fully human anti-IL-17 receptor antibody KHK4827 targeting psoriasis (applied for in July 2015).
- We are currently conducting phase III clinical study of anti-IL-5 receptor humanized monoclonal antibody KHK4563 in Japan and South Korea, targeting asthma patients, as part of the multi-regional clinical study being conducted by our licensing partner, AstraZeneca. Also, we are currently conducting a phase III clinical study in Japan for patients with chronic obstructive pulmonary disease, as part of the multi-regional clinical study being conducted by AstraZeneca.

### **CNS**

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

### **Other**

- We are currently conducting multi-regional phase III clinical study of the human monoclonal anti-Fibroblast Growth Factor 23 antibody KRN23 in adult patients with X-linked hypophosphatemia in North America, Europe, Japan, and South Korea. We are currently conducting phase II clinical study of KRN23 in pediatric X-linked hypophosphatemia in the U.S. and Europe.
- In China, we are currently conducting a phase III clinical study of thrombopoietin receptor agonist AMG531 (product name in Japan: ROMIPLATE<sup>®</sup>) targeting chronic idiopathic (immune) thrombocytopenic purpura.

### **Bio-Chemicals business**

In the Bio-Chemicals business, net sales were ¥21.2 billion (down 4.1%) and operating income was ¥2.3 billion (up 58.8%).

- 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) increased year on year.
  - Mail-order sales, primarily those of Ornithine, were solid.
- 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<sup>®</sup> (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 to the effect of having transferred operations of raw materials for cosmetics ingredients business in May, 2015.

- In Asia, sales decreased compared to the same period of the previous fiscal year due mainly to the effect of adjustments of production carried out by customers of amino acids for industrial use.

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

- Total assets as of March 31, 2016 were ¥702.5 billion, a decrease of ¥18.1 billion compared to the end of the previous fiscal year.
- Current assets decreased by ¥14.1 billion to ¥310.3 billion due to a decrease in short-term loans to the parent company as fund management, and other items.
- Non-current assets declined by ¥4.0 billion to ¥392.2 billion, affected by a decrease in goodwill due to amortization and other items despite an increase in sales right.
- Liabilities as of March 31, 2016 were ¥97.0 billion, a decrease of ¥8.8 billion compared to the end of the previous fiscal year due to decreases in accounts payable - other, income taxes payable, and other items although notes and accounts payable - trade increased.
- Net assets as of March 31, 2016 were ¥605.5 billion, a decrease of ¥9.2 billion compared to the end of the previous fiscal year, due mainly to payment of dividends, a decrease in foreign currency translation adjustment, and other items 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 86.1%, an increase of 0.9 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 29, 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 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.

### **(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 March 31, 2016	As of December 31, 2015
<b>Assets</b>		
Current assets		
Cash and deposits	13,237	13,236
Notes and accounts receivable - trade	106,950	106,829
Merchandise and finished goods	59,589	61,965
Work in process	11,691	12,363
Raw materials and supplies	12,155	10,476
Deferred tax assets	10,796	11,147
Short-term loans receivable	87,302	96,104
Accounts receivable - other	4,343	7,692
Other	4,489	4,818
Allowance for doubtful accounts	(243)	(202)
Total current assets	310,312	324,433
Non-current assets		
Property, plant and equipment		
Buildings and structures	136,842	141,227
Accumulated depreciation	(88,235)	(91,810)
Buildings and structures, net	48,607	49,417
Machinery, equipment and vehicles	162,495	165,623
Accumulated depreciation	(132,712)	(134,994)
Machinery, equipment and vehicles, net	29,782	30,629
Land	46,363	46,685
Construction in progress	12,515	11,339
Other	50,238	51,124
Accumulated depreciation	(41,622)	(42,152)
Other, net	8,616	8,972
Total property, plant and equipment	145,885	147,043
Intangible assets		
Goodwill	148,647	155,851
Sales right	61,422	56,233
Other	642	722
Total intangible assets	210,713	212,807
Investments and other assets		
Investment securities	12,544	14,043
Net defined benefit asset	7,578	6,964
Deferred tax assets	10,334	10,355
Other	5,370	5,311
Allowance for doubtful accounts	(155)	(194)
Total investments and other assets	35,673	36,480
Total non-current assets	392,272	396,331
Total assets	702,584	720,764

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

	<i>(Millions of yen)</i>	
	As of March 31, 2016	As of December 31, 2015
<b>Liabilities</b>		
Current liabilities		
Notes and accounts payable - trade	23,298	19,086
Short-term loans payable	4,834	4,840
Accounts payable - other	33,399	39,866
Income taxes payable	4,595	11,830
Provision for sales rebates	1,836	2,097
Provision for point card certificates	237	238
Provision for bonuses	3,640	427
Other	7,183	6,436
Total current liabilities	79,027	84,823
Non-current liabilities		
Deferred tax liabilities	10,768	12,092
Net defined benefit liability	1,781	1,883
Provision for directors' retirement benefits	109	114
Allowance for loss on plants reorganization	3,200	3,203
Asset retirement obligations	199	404
Other	1,932	3,385
Total non-current liabilities	17,991	21,082
Total liabilities	97,018	105,906
<b>Net assets</b>		
Shareholders' equity		
Capital stock	26,745	26,745
Capital surplus	509,128	509,127
Retained earnings	86,557	85,997
Treasury shares	(26,883)	(26,881)
Total shareholders' equity	595,547	594,989
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	2,100	2,979
Foreign currency translation adjustment	9,712	18,819
Remeasurements of defined benefit plans	(2,257)	(2,360)
Total accumulated other comprehensive income	9,555	19,438
Subscription rights to shares	462	430
Total net assets	605,565	614,858
Total liabilities and net assets	702,584	720,764

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

	<i>(Millions of yen)</i>	
	January 1, 2016 to March 31, 2016	January 1, 2015 to March 31, 2015
Net sales	88,469	89,598
Cost of sales	36,746	37,677
Gross profit	51,723	51,921
Selling, general and administrative expenses		
Research and development expenses	13,706	12,128
Amortization of goodwill	3,268	3,347
Other	26,225	27,104
Total selling, general and administrative expenses	43,200	42,580
Operating income	8,522	9,340
Non-operating income		
Interest income	131	113
Dividend income	174	31
Foreign exchange gains	466	-
Gain on valuation of derivatives	-	744
Other	204	271
Total non-operating income	975	1,160
Non-operating expenses		
Interest expenses	12	15
Foreign exchange losses	-	970
Loss on valuation of derivatives	324	-
Share of loss of entities accounted for using equity method	1,041	1,124
Loss on disposal of non-current assets	238	87
Other	40	222
Total non-operating expenses	1,657	2,421
Ordinary income	7,841	8,079
Extraordinary income		
Gain on sales of non-current assets	2,719	-
Gain on forgiveness of debts	1,334	-
Gain on sales of investment securities	256	-
Compensation income	-	619
Total extraordinary income	4,310	619
Extraordinary losses		
Loss due to fire	-	209
Impairment loss	-	205
Total extraordinary losses	-	415
Profit before income taxes	12,151	8,284
Income taxes	4,752	3,676
Profit	7,399	4,607
Profit attributable to owners of parent	7,399	4,607

**Consolidated statements of comprehensive income**

	<i>(Millions of yen)</i>	
	January 1, 2016 to March 31, 2016	January 1, 2015 to March 31, 2015
Profit	7,399	4,607
Other comprehensive income		
Valuation difference on available-for-sale securities	(878)	2,409
Foreign currency translation adjustment	(9,043)	(4,020)
Remeasurements of defined benefit plans, net of tax	102	10
Share of other comprehensive income of entities accounted for using equity method	(63)	-
Total other comprehensive income	(9,882)	(1,601)
Comprehensive income	(2,482)	3,006
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(2,482)	3,006
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.

(Segment information)

## I. 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.

## II. Three months ended March 31, 2015 (January 1, 2015 – March 31, 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	67,851	21,747	89,598	–	89,598
Inter-segment sales and transfers	210	394	604	(604)	–
Total sales	68,061	22,142	90,203	(604)	89,598
Segment profit	7,787	1,460	9,247	93	9,340

Notes: 1. The ¥93 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.