

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

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

**Fiscal 2016 Third Quarter**

**(January 1, 2016 – September 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 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 Nine Months Ended September 30, 2016**

October 28, 2016

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Scheduled date of submission of Quarterly Securities Report: November 7, 2016

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 Nine Months Ended September 30, 2016***(% changes indicate year-on-year changes.)*

(1) Consolidated operating results	Nine months ended September 30, 2016	Change (%)	Nine months ended September 30, 2015	Change (%)
Net sales (millions of yen)	257,761	(5.6)	272,943	14.2
Operating income (millions of yen)	26,831	(34.4)	40,882	55.6
Ordinary income (millions of yen)	22,623	(38.3)	36,680	54.1
Profit attributable to owners of parent (millions of yen)	16,469	(36.8)	26,044	116.4
Basic earnings per share (yen)	30.10		47.59	
Fully diluted earnings per share (yen)	30.07		47.55	

Note: Comprehensive income: Nine months ended September 30, 2016: ¥10,357 million; -%  
 Nine months ended September 30, 2015: ¥22,219 million; 46.8%

(2) Consolidated financial position	As of September 30, 2016	As of December 31, 2015
Total assets (millions of yen)	677,211	720,764
Net assets (millions of yen)	590,912	614,858
Equity ratio (%)	87.2	85.2

Note: Equity: As of September 30, 2016: ¥590,383 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 September 30, 2016	576,483,555 shares
As of December 31, 2015	576,483,555 shares
2. Number of treasury shares
 

As of September 30, 2016	29,259,966 shares
As of December 31, 2015	29,256,749 shares
3. Average number of shares during the period
 

Nine months ended September 30, 2016	547,225,223 shares
Nine months ended September 30, 2015	547,299,121 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 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.

## Contents

<b>1. Operating Results and Financial Statements</b> .....	<b>4</b>
<b>(1) Summary of consolidated business performance</b> .....	4
<b>(2) Summary of consolidated financial position</b> .....	6
<b>(3) Summary of consolidated earnings forecasts and other forward-looking statements</b> .....	6
<b>2. Summary Information (Other Items)</b> .....	<b>7</b>
<b>(1) Changes to significant subsidiaries during the period</b> .....	7
<b>(2) Use of accounting procedures special to the preparation of quarterly consolidated financial statements</b> .....	7
<b>(3) Changes in accounting policies, accounting estimates, and restatement</b> .....	7
<b>3. Consolidated Financial Statements</b> .....	<b>8</b>
<b>(1) Consolidated balance sheets</b> .....	8
<b>(2) Consolidated statements of income and comprehensive income</b> .....	10
<b>Consolidated statements of income</b> .....	10
<b>Consolidated statements of comprehensive income</b> .....	11
<b>(3) Notes to the consolidated financial statements</b> .....	12
(Items related to going concern assumption) .....	12
(Notes on significant change in shareholders' equity) .....	12
(Segment information) .....	12

## 1. Operating Results and Financial Statements

### (1) Summary of consolidated business performance

For the nine months ended September 30, 2016 (January 1, 2016 to September 30, 2016), net sales were ¥257.7 billion (down 5.6% compared to the same period of the previous fiscal year), operating income was ¥26.8 billion (down 34.4%), ordinary income was ¥22.6 billion (down 38.3%), and profit attributable to owners of parent was ¥16.4 billion (down 36.8%). 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 ¥31.4 billion (down 33.6%).

- Net sales and operating income decreased due mainly to the effect of yen appreciation, the decline in licensing revenue and an increase in research and development expenses, despite growth in sales of new products.
- Ordinary income and profit attributable to owners of parent also decreased.

Performance by segment is as follows.

### Pharmaceuticals business

#### 1) Results

In the pharmaceuticals business, net sales were ¥196.4 billion (down 5.9%) and operating income was ¥22.0 billion (down 37.0%).

- Sales in Japan increased year on year due mainly to the growth in sales of new products, despite such factors as the impact of reductions in drug price standards implemented in April.
  - Sales of core products NESP<sup>®</sup>, a long-acting erythropoiesis stimulating agent, and REGPARA<sup>®</sup>, a treatment for secondary hyperparathyroidism, were solid.
  - 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.
  - We launched LUMICEF<sup>®</sup> for psoriasis treatment in September.
- International sales decreased year on year due mainly to the impact of yen appreciation and the decline in licensing revenue.
  - In Europe and the 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.
  - In Asia, despite steady sales particularly in China and South Korea, sales decreased from the same period of the previous fiscal year, partly reflecting the impact of yen appreciation.

#### 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 nine months ended September 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<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 obtained approval in July for LUMICEF<sup>®</sup>, the anti-IL-17 receptor A fully human antibody for indications of psoriasis vulgaris, arthropathic psoriasis, pustular psoriasis, and psoriatic erythroderma, for which existing treatments are insufficiently effective, and launched the drug in September.
- 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 bronchial asthma patients, and a phase III clinical study in Japan, targeting patients with chronic obstructive pulmonary disease.
- In Japan, in July we applied for approval of additional dosage and administration for the ulcerative colitis treatment drug ASACOL<sup>®</sup> that is being jointly developed with Zeria Pharmaceutical Co., Ltd.

### **CNS**

- In the U.S., Canada, 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**

- 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<sup>®</sup>) targeting chronic idiopathic (immune) thrombocytopenic purpura. Also, in June, we initiated phase II/III clinical study in aplastic anemia in Japan and South Korea.
- In Japan, in September we applied for approval of the 1800IU product of the recombinant antithrombin (AT) drug ACOALAN<sup>®</sup>.

### **Bio-Chemicals business**

In the Bio-Chemicals business, net sales were ¥63.6 billion (down 5.1%) and operating income was ¥4.7 billion (down 26.2%).

- Sales in Japan decreased compared to the same period of the previous fiscal year.
  - The year-on-year decline in sales reflected the price drops of some products and the effect from the same period of the previous fiscal year's concentration of shipments, etc., both in active pharmaceutical ingredients (APIs).
  - Sales of mail-order sales increased compared to the same period of the previous fiscal year with strong performances for Ornithine and the new product Arginine EX.
- International sales decreased compared to the same period of the previous fiscal year despite strong sales in the Americas and Europe, partly reflecting the impact of yen appreciation.
  - 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, although the region felt the effect of having transferred operations of the raw materials for cosmetics ingredients business in May, 2015, sales of amino acids for infusion and industrial uses were strong.
  - In Asia, sales decreased compared to the same period of the previous fiscal year due to the effect of a drop in the price of some products resulting from intensified competition.

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

- Total assets as of September 30, 2016 were ¥677.2 billion, a decrease of ¥43.5 billion compared to the end of the previous fiscal year.
  - Current assets decreased by ¥12.4 billion to ¥311.9 billion, affected by decreases in notes and accounts receivable - trade, inventories and other items despite increases in short-term loans to the parent company and other items.
  - Non-current assets declined by ¥31.0 billion to ¥365.2 billion, due to the impact of exchange rates and decreases in goodwill, sales right and others due to amortization.
- Liabilities as of September 30, 2016 were ¥86.2 billion, a decrease of ¥19.6 billion compared to the end of the previous fiscal year due to decreases in accounts payable - other and income taxes payable.
- Net assets as of September 30, 2016 were ¥590.9 billion, a decrease of ¥23.9 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 third quarter was 87.2%, an increase of 2.0 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 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 nine 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 third quarter under review, and next by multiplying profit before income taxes for the nine 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 September 30, 2016	As of December 31, 2015
<b>Assets</b>		
Current assets		
Cash and deposits	11,822	13,236
Notes and accounts receivable - trade	96,270	106,829
Merchandise and finished goods	53,966	61,965
Work in process	10,087	12,363
Raw materials and supplies	12,621	10,476
Deferred tax assets	10,380	11,147
Short-term loans receivable	107,874	96,104
Accounts receivable - other	4,253	7,692
Other	4,914	4,818
Allowance for doubtful accounts	(238)	(202)
Total current assets	311,953	324,433
Non-current assets		
Property, plant and equipment		
Buildings and structures	139,555	141,227
Accumulated depreciation	(89,275)	(91,810)
Buildings and structures, net	50,279	49,417
Machinery, equipment and vehicles	161,784	165,623
Accumulated depreciation	(133,392)	(134,994)
Machinery, equipment and vehicles, net	28,392	30,629
Land	45,916	46,685
Construction in progress	13,913	11,339
Other	49,460	51,124
Accumulated depreciation	(40,276)	(42,152)
Other, net	9,184	8,972
Total property, plant and equipment	147,686	147,043
Intangible assets		
Goodwill	135,367	155,851
Sales right	47,784	56,233
Other	554	722
Total intangible assets	183,706	212,807
Investments and other assets		
Investment securities	10,726	14,043
Net defined benefit asset	8,710	6,964
Deferred tax assets	9,310	10,355
Other	5,220	5,311
Allowance for doubtful accounts	(103)	(194)
Total investments and other assets	33,864	36,480
Total non-current assets	365,257	396,331
Total assets	677,211	720,764

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

	<i>(Millions of yen)</i>	
	As of September 30, 2016	As of December 31, 2015
<b>Liabilities</b>		
Current liabilities		
Notes and accounts payable - trade	17,764	19,086
Short-term loans payable	4,840	4,840
Accounts payable - other	29,736	39,866
Income taxes payable	5,289	11,830
Provision for sales rebates	1,480	2,097
Provision for point card certificates	246	238
Provision for bonuses	3,856	427
Other	7,115	6,436
Total current liabilities	70,328	84,823
Non-current liabilities		
Deferred tax liabilities	8,688	12,092
Net defined benefit liability	1,747	1,883
Provision for directors' retirement benefits	110	114
Allowance for loss on plants reorganization	3,005	3,203
Asset retirement obligations	501	404
Other	1,916	3,385
Total non-current liabilities	15,969	21,082
Total liabilities	86,298	105,906
<b>Net assets</b>		
Shareholders' equity		
Capital stock	26,745	26,745
Capital surplus	509,128	509,127
Retained earnings	88,787	85,997
Treasury shares	(26,887)	(26,881)
Total shareholders' equity	597,772	594,989
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	1,851	2,979
Foreign currency translation adjustment	(7,248)	18,819
Remeasurements of defined benefit plans	(1,991)	(2,360)
Total accumulated other comprehensive income	(7,389)	19,438
Subscription rights to shares	529	430
Total net assets	590,912	614,858
Total liabilities and net assets	677,211	720,764

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

	<i>(Millions of yen)</i>	
	January 1, 2016 to September 30, 2016	January 1, 2015 to September 30, 2015
Net sales	257,761	272,943
Cost of sales	101,927	102,523
Gross profit	155,834	170,420
Selling, general and administrative expenses		
Research and development expenses	38,809	36,171
Amortization of goodwill	9,583	10,092
Other	80,609	83,274
Total selling, general and administrative expenses	129,002	129,537
Operating income	26,831	40,882
Non-operating income		
Interest income	362	328
Dividend income	272	209
Foreign exchange gains	401	-
Gain on valuation of derivatives	-	1,541
Other	883	697
Total non-operating income	1,920	2,776
Non-operating expenses		
Interest expenses	32	60
Foreign exchange losses	-	2,250
Loss on valuation of derivatives	457	-
Share of loss of entities accounted for using equity method	4,937	3,600
Loss on disposal of non-current assets	483	570
Other	216	497
Total non-operating expenses	6,128	6,979
Ordinary income	22,623	36,680
Extraordinary income		
Gain on sales of non-current assets	2,901	375
Gain on forgiveness of debts	1,334	-
Gain on sales of investment securities	256	6,561
Compensation income	-	619
Total extraordinary income	4,491	7,556
Extraordinary losses		
Impairment loss	233	3,346
Loss due to fire	-	209
Total extraordinary losses	233	3,555
Profit before income taxes	26,882	40,681
Income taxes	10,412	14,636
Profit	16,469	26,044
Profit attributable to owners of parent	16,469	26,044

**Consolidated statements of comprehensive income**

	<i>(Millions of yen)</i>	
	January 1, 2016 to September 30, 2016	January 1, 2015 to September 30, 2015
Profit	16,469	26,044
Other comprehensive income		
Valuation difference on available-for-sale securities	(1,128)	(498)
Foreign currency translation adjustment	(25,961)	(3,635)
Remeasurements of defined benefit plans	368	308
Share of other comprehensive income of entities accounted for using equity method	(107)	-
Total other comprehensive income	(26,827)	(3,824)
Comprehensive income	(10,357)	22,219
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(10,357)	22,219
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. Nine months ended September 30, 2016 (January 1, 2016 – September 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	195,857	61,903	257,761	–	257,761
Inter-segment sales and transfers	582	1,765	2,347	(2,347)	–
Total sales	196,439	63,668	260,108	(2,347)	257,761
Segment profit	22,039	4,747	26,786	44	26,831

Notes: 1. The ¥44 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. Nine months ended September 30, 2015 (January 1, 2015 – September 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	208,122	64,821	272,943	–	272,943
Inter-segment sales and transfers	646	2,282	2,928	(2,928)	–
Total sales	208,768	67,103	275,871	(2,928)	272,943
Segment profit	34,956	6,431	41,388	(505)	40,882

Notes: 1. The negative ¥505 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.