

Kyowa Hakko Kirin Co., Ltd.

Consolidated Financial Summary (JGAAP)

Fiscal 2017 Third Quarter

(January 1, 2017 – September 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 Nine Months Ended September 30, 2017**

October 26, 2017

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Scheduled date of submission of Quarterly Securities Report: November 7, 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 Nine Months Ended September 30, 2017***(% changes indicate year-on-year changes.)*

(1) Consolidated operating results	Nine months ended September 30, 2017	Change (%)	Nine months ended September 30, 2016	Change (%)
Net sales (millions of yen)	258,439	0.3	257,761	(5.6)
Operating income (millions of yen)	34,399	28.2	26,831	(34.4)
Ordinary income (millions of yen)	31,430	38.9	22,623	(38.3)
Profit attributable to owners of parent (millions of yen)	19,749	19.9	16,469	(36.8)
Basic earnings per share (yen)	36.09		30.10	
Fully diluted earnings per share (yen)	36.05		30.07	

Note: Comprehensive income: Nine months ended September 30, 2017: ¥23,552 million; -%
 Nine months ended September 30, 2016: (¥10,357) million; -%

(2) Consolidated financial position	As of September 30, 2017	As of December 31, 2016
Total assets (millions of yen)	697,127	697,167
Net assets (millions of yen)	610,778	600,745
Equity ratio (%)	87.5	86.1

Note: Equity: As of September 30, 2017: ¥610,144 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)	—	—
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: 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 September 30, 2017	576,483,555 shares
As of December 31, 2016	576,483,555 shares
2. Number of treasury shares

As of September 30, 2017	29,174,125 shares
As of December 31, 2016	29,261,490 shares
3. Average number of shares during the period

Nine months ended September 30, 2017	547,284,381 shares
Nine months ended September 30, 2016	547,225,223 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 nine months ended September 30, 2017 (January 1, 2017 to September 30, 2017), net sales were ¥258.4 billion (up 0.3% compared to the same period of the previous fiscal year), operating income was ¥34.3 billion (up 28.2%), ordinary income was ¥31.4 billion (up 38.9%), and profit attributable to owners of parent was ¥19.7 billion (up 19.9%). 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 ¥40.5 billion (up 28.7%).

- 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 ¥199.0 billion (up 1.3%) and operating income was ¥29.1 billion (up 32.1%).

- 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, GRAN[®], a neutropenia treatment drug, and Depakene[®], an anti-epileptic 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 nine months ended September 30, 2017 are as follows.

Nephrology

- In Japan, in April we applied for approval of indication of calcium receptor agonist KHK7580 (generic name: evocalcet) for the treatment of secondary hyperparathyroidism in maintenance

dialysis patients.

- In Japan, we are currently conducting phase II clinical study for RTA 402 (generic name: bardoxolone methyl) 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 (generic name: tivantinib) 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 (generic name: benralizumab), 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 addition, LUMICEF[®] was also applied as a formulation for at-home self-injection in Japan, in September.
- 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_{2A} 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 (generic name: burosumab), we are currently applying for approval of indication in treatment of X-linked hypophosphatemia in pediatric patients in Europe (application accepted in December 2016). Furthermore, 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.

- In Japan, in September we obtained manufacturing and marketing approval for the new formulation strength “ACOALAN® Injection 1800” of the recombinant antithrombin (AT) drug (product name in Japan: ACOALAN®).

Bio-Chemicals business

In the Bio-Chemicals business, net sales were ¥61.8 billion (down 2.9%) and operating income was ¥5.0 billion (up 5.6%).

- Sales in Japan decreased compared to 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.
 - Sales of Kyowa Engineering Co., Ltd. decreased compared to the same period of the previous fiscal 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.
 - 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 September 30, 2017 were ¥697.1 billion, which was approximately the same amount compared to the end of the previous fiscal year.
 - Current assets increased by ¥13.0 billion to ¥339.5 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 ¥13.0 billion to ¥357.6 billion, due to decreases in goodwill and sales right due to amortization and others.
- Liabilities as of September 30, 2017 were ¥86.3 billion, a decrease of ¥10.0 billion compared to the end of the previous fiscal year due to decreases in accounts payable - other and other items.
- Net assets as of September 30, 2017 were ¥610.7 billion, an increase of ¥10.0 billion compared to the end of the previous fiscal year, due to the booking of profit attributable to owners of parent, an increase in foreign currency translation adjustment and others, despite a decrease due to payment of dividends.

As a result, the equity ratio as of the end of the third quarter was 87.5%, an increase of 1.4 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 28, 2017.

2. Consolidated Financial Statements and Significant Notes Thereto

(1) Consolidated balance sheets

	<i>(Millions of yen)</i>	
	As of September 30, 2017	As of December 31, 2016
Assets		
Current assets		
Cash and deposits	14,391	13,066
Notes and accounts receivable - trade	95,279	100,999
Merchandise and finished goods	48,930	51,349
Work in process	14,701	12,934
Raw materials and supplies	11,608	11,945
Deferred tax assets	11,006	10,824
Short-term loans receivable	135,335	114,866
Accounts receivable - other	4,264	5,900
Other	4,298	4,848
Allowance for doubtful accounts	(301)	(265)
Total current assets	339,514	326,469
Non-current assets		
Property, plant and equipment		
Buildings and structures	142,222	141,432
Accumulated depreciation	(92,202)	(89,967)
Buildings and structures, net	50,019	51,464
Machinery, equipment and vehicles	167,747	162,747
Accumulated depreciation	(137,113)	(133,539)
Machinery, equipment and vehicles, net	30,633	29,207
Land	44,497	45,685
Construction in progress	13,261	15,339
Other	51,035	49,935
Accumulated depreciation	(41,178)	(40,585)
Other, net	9,856	9,350
Total property, plant and equipment	148,269	151,047
Intangible assets		
Goodwill	127,188	134,910
Sales right	45,852	49,402
Other	839	708
Total intangible assets	173,880	185,021
Investments and other assets		
Investment securities	11,245	11,412
Net defined benefit asset	7,311	6,563
Deferred tax assets	11,384	11,496
Other	5,622	5,257
Allowance for doubtful accounts	(100)	(100)
Total investments and other assets	35,462	34,629
Total non-current assets	357,612	370,698
Total assets	697,127	697,167

(1) Consolidated balance sheets (continued)

	<i>(Millions of yen)</i>	
	As of September 30, 2017	As of December 31, 2016
Liabilities		
Current liabilities		
Notes and accounts payable - trade	15,823	18,230
Short-term loans payable	5,545	5,360
Accounts payable - other	27,904	37,608
Income taxes payable	6,645	8,183
Provision for sales rebates	1,965	1,677
Provision for point card certificates	267	249
Provision for bonuses	4,133	422
Other	7,146	7,684
Total current liabilities	69,433	79,416
Non-current liabilities		
Deferred tax liabilities	8,821	9,144
Net defined benefit liability	2,237	2,358
Allowance for loss on plants reorganization	2,988	2,988
Asset retirement obligations	472	502
Other	2,395	2,012
Total non-current liabilities	16,915	17,006
Total liabilities	86,348	96,422
Net assets		
Shareholders' equity		
Capital stock	26,745	26,745
Capital surplus	509,145	509,128
Retained earnings	97,054	90,986
Treasury shares	(26,814)	(26,889)
Total shareholders' equity	606,129	599,970
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	2,249	2,037
Foreign currency translation adjustment	5,377	2,385
Remeasurements of defined benefit plans	(3,611)	(4,210)
Total accumulated other comprehensive income	4,015	212
Subscription rights to shares	633	562
Total net assets	610,778	600,745
Total liabilities and net assets	697,127	697,167

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

	<i>(Millions of yen)</i>	
	January 1, 2017 to September 30, 2017	January 1, 2016 to September 30, 2016
Net sales	258,439	257,761
Cost of sales	97,134	101,927
Gross profit	161,304	155,834
Selling, general and administrative expenses		
Research and development expenses	36,163	38,809
Amortization of goodwill	9,346	9,583
Other	81,395	80,609
Total selling, general and administrative expenses	126,905	129,002
Operating income	34,399	26,831
Non-operating income		
Interest income	359	362
Dividend income	251	272
Foreign exchange gains	–	401
Gain on valuation of derivatives	418	–
Other	706	883
Total non-operating income	1,737	1,920
Non-operating expenses		
Interest expenses	65	32
Foreign exchange losses	681	–
Loss on valuation of derivatives	–	457
Share of loss of entities accounted for using equity method	3,235	4,937
Loss on disposal of non-current assets	263	483
Other	460	216
Total non-operating expenses	4,706	6,128
Ordinary income	31,430	22,623
Extraordinary income		
Gain on sales of non-current assets	603	2,901
Gain on sales of investment securities	588	256
Gain on forgiveness of debts	–	1,334
Total extraordinary income	1,191	4,491
Extraordinary losses		
Impairment loss	–	233
Total extraordinary losses	–	233
Profit before income taxes	32,621	26,882
Income taxes	12,872	10,412
Profit	19,749	16,469
Profit attributable to owners of parent	19,749	16,469

Consolidated statements of comprehensive income

	<i>(Millions of yen)</i>	
	January 1, 2017 to September 30, 2017	January 1, 2016 to September 30, 2016
Profit	19,749	16,469
Other comprehensive income		
Valuation difference on available-for-sale securities	212	(1,128)
Foreign currency translation adjustment	3,002	(25,961)
Remeasurements of defined benefit plans	598	368
Share of other comprehensive income of entities accounted for using equity method	(11)	(107)
Total other comprehensive income	3,802	(26,827)
Comprehensive income	23,552	(10,357)
Comprehensive income attributable to Comprehensive income attributable to owners of parent	23,552	(10,357)

(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 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.

(Segment information)

I. Nine months ended September 30, 2017 (January 1, 2017 – September 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	198,277	60,161	258,439	–	258,439
Inter-segment sales and transfers	742	1,687	2,430	(2,430)	–
Total sales	199,020	61,849	260,869	(2,430)	258,439
Segment profit	29,114	5,013	34,127	271	34,399

Notes: 1. The ¥271 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, 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.