

Kyowa Hakko Kirin Co., Ltd.

Consolidated Financial Summary Fiscal 2014, Third Quarter

(January 1, 2014 – September 30, 2014)

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 Financial Statements for the Third Quarter of the Year Ending December 31, 2014

Kyowa Hakko Kirin Co., Ltd.

October 28, 2014

Stock Code: 4151	Listed exchanges: 1st Section of the Tokyo Stock Exchange
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Scheduled date of submission of Quarterly Securities Report: November 7, 2014
 Scheduled start date of dividend payment: -

Appendix materials prepared to accompany the quarterly financial report: Yes

Quarterly results presentation meeting: Yes
 (For institutional investors and securities analysts)

1. Consolidated Financial Results for the nine months ended September 30, 2014

(% changes are compared to the same period of the previous fiscal year)

(1) Consolidated business performance

(Millions of yen, rounded down)

	Nine months ended September 30, 2014	Change (%)	Nine months ended September 30, 2013	Change (%)
Net sales	238,936	(5.2)	252,103	3.0
Operating income	26,277	(36.5)	41,409	10.9
Ordinary income	23,800	(39.3)	39,203	20.3
Net income	12,036	(48.4)	23,323	51.1
Net income per share (¥)	21.99		42.61	
Fully diluted net income per share (¥)	21.97		42.58	

Note: Comprehensive income: Nine months ended September, 2014: ¥15,137 million (-58.8%); Nine months ended September, 2013: ¥36,768 million (100.4%)

(2) Consolidated financial position

(Millions of yen, rounded down)

	As of September 30, 2014	As of December 31, 2013
Total assets	730,396	719,257
Net assets	595,921	595,415
Shareholders' equity ratio (%)	81.5	82.6

Note: Total shareholders' equity: As of September 30, 2014: ¥595,610 million; As of December 31, 2013: ¥593,957 million

2. Dividends

Dividends per share	Fiscal year ending December 31, 2014 (forecast)	Fiscal year ended December 31, 2013
First quarter per share (¥)	---	---
Interim dividend per share (¥)	12.50	12.50
Third quarter dividend per share (¥)	---	---
Year-end dividend per share (¥)	12.50 (forecast)	12.50
Total dividend per share (¥)	25.00 (forecast)	25.00

Note: Changes to the dividend forecast during the term: None.

3. Consolidated results forecasts for the fiscal year ending December 31, 2014

(Millions of yen)

	January 1, 2014 to December 31, 2014	Change (%)
Net sales	336,000	(1.4)
Operating income	43,000	(16.9)
Ordinary income	35,000	(29.3)
Net income	18,000	(40.2)
Net income per share (¥)	32.89	

Notes: Changes to the consolidated results forecast during the term: Yes

Notes:

- 1) **Transfer of important subsidiaries during the period (transfers of specified subsidiaries resulting in changes in the scope of consolidation during the period under review):** No
- 2) **Use of special accounting procedures in the preparation of quarterly consolidated financial statements:** Yes
See Page 7, Section 2. Summary information (Other items)
- 3) **Changes to accounting policies, accounting estimates, and restatement of revisions:**
 1. Changes following revisions to accounting standards: No
 2. Changes to accounting policies other than 1. above: No
 3. Changes to accounting estimates: No
 4. Restatement of revisions: No

4) Number of shares issued (ordinary shares)

1. Number of shares issued (including treasury shares)	As of September 30, 2014	576,483,555 shares	As of December 31, 2013	576,483,555 shares
2. Number of treasury shares	As of September 30, 2014	29,138,501 shares	As of December 31, 2013	29,143,513 shares
3. Average number of shares during the period	Nine months ended September 30, 2014	547,352,905 shares	Nine months ended September 30, 2013	547,402,840 shares

Notice regarding quarterly review procedures

The Financial Instruments and Exchange Act review process for this quarterly financial report was not yet complete at the time this financial report was issued.

Notice regarding the appropriate use of the financial forecasts and other special comments

1. Changes to the forecasts announced on July 30, 2014 are reflected in this document.
2. Forecasts of results and other forward-looking statements contained in this document are based on information available to and on assumptions deemed reasonable by the Company at the time of release of this document. Actual results may be affected by a range of factors and may differ materially.

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1. Operating Results and Financial Statements

(1) Summary of consolidated business performance

Net sales for the first nine months of the fiscal year (January 1, 2014 to September 30, 2014) were ¥238.9 billion (down 5.2% compared to the first nine months of the previous fiscal year), operating income was ¥26.2 billion (down 36.5%) and ordinary income was ¥23.8 billion (down 39.3%). Net income for the nine-month period was ¥12.0 billion (down 48.4%).

- Net sales and operating income decreased due to the impact of the drug price revision in April and a decline in licensing revenue
- Ordinary income also declined, while the decline in net income also reflected the absence of a gain on sales of subsidiaries and affiliates' stocks and other factors recorded in the previous fiscal year.

Performance by segment

Pharmaceuticals business

1. Results

In the pharmaceuticals business, net sales were ¥178.6 billion (down 7.3%) and operating income was ¥20.6 billion (down 44.2%).

- Domestic sales of ethical pharmaceutical products declined compared to the same period of the previous fiscal year, impacted by the drug price revision in April and other factors.
 - Sales of core product NESP[®], a treatment for renal anemia, were steady and sales increased over the same period in the previous fiscal year, in which sales declined due to lower shipments following the launch of a unified dosage product in December 2012. Sales of ALLELOCK[®], an anti-allergy agent, and Patanol[®] anti-allergy eye drops declined year on year due to the effects of lower amounts of airborne pollen. Sales of ALLELOCK[®] were also impacted by the drug price revision and the market penetration of generics.
 - Sales of NOURIAST[®], an antiparkinsonian agent, REGPARA[®], a treatment for secondary hyperparathyroidism during dialysis therapy, Abstral[®], a treatment for cancer pain, Fentos[®], a transdermal analgesic for persistent pain, ASACOL[®], an ulcerative colitis treatment, and other products advanced steadily.
 - In September in collaboration with Leo Pharma K.K. we launched Dovobet[®], a topical combination drug for psoriasis vulgaris.
- In the licensing-out of technologies and export of pharmaceutical products, exports were steady but sales declined due to a decline in licensing revenue.
- Regarding Prostrakan, sales of Abstral[®], a treatment for cancer pain, and other core products, grew strongly. In addition, due the acquisition of Archimedes on August 5, third quarter consolidated results include results from this company and its 12 subsidiaries for the period from August 5 to September 30. As a result, following consolidation of Archimedes, ProStrakan net sales were ¥21.4 billion (up 28.1%) and operating income (after amortization of goodwill and marketing rights) was ¥0.4 billion (up 230.7%).

2. Research and development

Nephrology

(Domestic)

- In March we applied for approval for calcium receptor agonist REGPARA[®] 12.5mg.
- In August we initiated late-stage phase II clinical trials of calcium receptor agonist KHK7580 for

secondary hyperparathyroidism.

- In July we decided the future development direction for RTA 402 targeting CKD with type 2 diabetes, and have decided to initiate new phase II clinical trials in the future.

(Overseas)

- In China, we received approval in June of Cinacalcet Hydrochloride (product name in Japan: REGPARA[®]), a calcium receptor agonist.

Oncology

(Domestic)

- In February we received approval for additional indications of hypercalcemia in patients with parathyroid carcinoma, and hypercalcemia in patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy or who experience recurrent primary hyperparathyroidism following surgery, and for dosage and administration for REGPARA[®].
- In March we received approval for additional indications for relapsed or refractory CCR4-positive peripheral T-cell lymphoma (PTCL) and cutaneous T-cell lymphoma (CTCL) and for dosage and administration for anti-CCR4 humanized antibody POTELIGEO[®].
- In September we received approval for sustained-duration G-CSF product G-Lasta[®] for febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy.
- In March we applied for approval for additional indication of NESP[®], a treatment for renal anemia, for anemia with myelodysplastic syndrome.
- In February we temporarily withdrew our application for approval for additional indications and for dosage and administration for untreated CCR4-positive adult T-cell leukemia-lymphoma (ATL) for POTELIGEO[®]. We re-filed the application in June.
- In February we initiated a phase III clinical study evaluating ARQ 197 patients with c-Met diagnostic-high inoperable hepatocellular carcinoma treated with one prior sorafenib therapy.
- In April we added Japan as a site for an ongoing phase III clinical trial in the United States and Europe to evaluate the efficacy and safety of KW-0761 (product name: POTELIGEO[®]), targeting relapsed or refractory cutaneous T-Cell Lymphoma.

Immunology and allergy

(Domestic)

- In April we initiated trials of anti-IL-5 receptor humanized antibody KHK4563 in Japan and South Korea, targeting asthma patients, as part of the global phase III trials being conducted by our licensing partner, AstraZeneca.

CNS

(Domestic)

- In January we received approval for a new formulation (granules) for anti-epileptic drug TOPINA[®], and launched in May.

Other

(Domestic)

- In July we submitted an application for approval of recombinant human antithrombin drug KW-3357.

(Overseas)

- In July we initiated a phase II clinical trial of the human monoclonal anti-Fibroblast Growth Factor 23 antibody KRN23 for pediatric X-linked hypophosphatemic rickets in the U.S. and EU.

Bio-Chemicals business

In the Bio-Chemicals business, net sales were ¥62.7 billion (up 1.9%) and operating income was ¥5.6 billion (up 25.6%).

Domestic business

- Sales in the pharmaceutical and medical treatment fields increased compared to the same period of the previous fiscal year.
 - In the pharmaceutical and medical treatment fields, sales of active pharmaceutical ingredients (APIs) for generic pharmaceuticals grew.
- In the healthcare field, year-on-year mail-order sales, such as those of Ornithine, increased but sales of amino acids for use in food and beverages declined slightly due in part to unseasonable weather during the summertime.

Overseas business

- Sales from overseas businesses were higher than the same period of the previous year due in part to a weaker yen.
 - In the U.S., year-on-year sales increased due to growth in sales of amino acids for supplements and a weaker yen.
 - In Europe, sales volumes of some products, such as infusion-use amino acids, declined due to the impact of customer production schedules, but sales increased overall due in part to a weaker yen.
 - In Asia, sales were broadly unchanged from the same period of the previous fiscal year due in part to a weaker yen, despite a temporary decline in demand for amino acids for infusions in China due to customers responding to new drug regulations.

(2) Summary of consolidated financial position

- Total assets as of September 30, 2014 were ¥730.3 billion, an increase of ¥11.1 billion compared to the end of the previous fiscal year.
 - Current assets decreased by ¥33.5 billion to ¥295.7 billion due to a decrease in notes and accounts receivable-trade and short-term loans receivable by the parent company and other factors, and despite an increase in inventories.
 - Non-current assets increased by ¥44.6 billion to ¥434.6 billion due to an increase in property, plant and equipment as well as an increase in intangible assets including goodwill, marketing rights and other factors resulting from the acquisition of Archimedes Pharma Limited.
- Liabilities were ¥134.4 billion; an increase of ¥10.6 billion compared to the end of the previous fiscal year, due to an increase in commercial paper of ¥30.0 billion, which was partly offset by declines in accounts payable-other and income taxes payable, as well as a decrease in provision for retirement benefits due to a cash payment of ¥19.0 billion to retirement benefit trusts.
- Net assets were ¥595.9 billion, an increase of ¥0.5 billion from the end of the previous fiscal year as factors causing a decrease such as dividend payments were offset by the addition of net income for the period and an increase in the foreign currency translation adjustment, and other factors.

As a result, the shareholders' equity ratio as of the end of the third quarter was 81.5%, a decrease of 1.1 percentage points compared to the end of the previous fiscal year.

Reference: Archimedes acquisition: Business Combination Accounting Treatment

An outline of the provisional accounting treatment as a business combination of the assets etc. of Archimedes and its 12 subsidiaries according to Purchase Price Allocation (PPA) as of August 5, 2014.

	Allocation of assets, etc. according to PPA	Amortization method and period
Intangible assets (marketing rights etc.)	GBP152.3million	Straight line amortization according to the individually assigned amortization period (4.7 to 17.4 years)
Inventories (upwardly appraised portion)	GBP4.2 million	Book value GBP5.1 million →Market value GBP9.4 million
Loans payable	GBP(129.2million)	
Other assets and liabilities (net amount)	GBP(2.3 million)	
Goodwill	GBP72.9 million	Straight line amortization over 12 years
Acquisition cost (total)	GBP98.1million	

Note: As PPA has not been completed at this time, provisional accounting treatment has been applied based on available reasonable information.

(3) Consolidated results forecasts

Full-year consolidated results forecasts have been revised to reflect the effects of the acquisition of Archimedes, and other factors.

Revision to consolidated full-year forecasts announced July 30, 2014

	Net Sales	Operating Income	Ordinary income	Net income	Net income per share
	Million yen	Million yen	Million yen	Million yen	Yen
Previous Forecast (A)	337,000	45,000	37,000	20,000	36.54
Revised forecast (B)	336,000	43,000	35,000	18,000	32.89
Change (B-A)	(1,000)	(2,000)	(2,000)	(2,000)	—
Rate of change (%)	(0.3)	(4.4)	(5.4)	(10.0)	—
Fiscal 2013 results	340,611	51,773	49,502	30,078	54.95

2.Summary Information (Other items)

(1) Changes to significant subsidiaries during the period

No applicable items.

While it is not deemed a change in a specified subsidiary, as all shares of Archimedes Pharma Limited were acquired during the period under review, it and its 12 subsidiaries have been included in the scope of consolidation.

(2) Use of special accounting procedures in the preparation of this report

Calculations for tax expenses use an estimated effective tax rate for income before income taxes based on reasonable assumptions of an effective tax rate after the application of tax effect accounting for net income before income taxes for the consolidated fiscal year, including income before income taxes of the nine-month period under review.

(3) Changes to accounting policies, accounting estimates, and restatement of revisions

No applicable items.

3. Consolidated financial statements

(1) Consolidated Balance Sheets

	<i>Millions of yen</i>	
	As of September 30, 2014	As of December 31, 2013
ASSETS		
Current assets:		
Cash and deposits	17,353	20,190
Notes and accounts receivable - trade	91,250	98,602
Merchandise and finished goods	64,787	50,863
Work in process	14,461	13,465
Raw materials and supplies	11,143	11,371
Deferred tax assets	10,698	10,409
Short-term loans receivable	77,756	113,133
Other	8,746	11,780
Allowance for doubtful accounts	(417)	(497)
Total current assets	295,778	329,320
Non-current assets:		
Property, plant and equipment		
Buildings and structures	131,715	132,861
Accumulated depreciation	(89,771)	(90,637)
Buildings and structures, net	41,944	42,223
Machinery, equipment and vehicles	150,870	146,935
Accumulated depreciation	(128,809)	(125,860)
Machinery, equipment and vehicles, net	22,060	21,075
Land	54,281	54,620
Construction in progress	22,785	13,501
Other	50,109	47,795
Accumulated depreciation	(42,915)	(41,297)
Other, net	7,193	6,498
Total property, plant and equipment	148,266	137,919
Intangible assets		
Goodwill	169,581	163,713
Marketing rights	70,494	46,519
Other	1,452	1,841
Total intangible assets	241,528	212,073
Investments and other assets		
Investment securities	24,426	24,602
Deferred tax assets	5,571	3,893
Other	15,013	11,638
Allowance for doubtful accounts	(188)	(191)
Total investments and other assets	44,823	39,942
Total non-current assets	434,618	389,936
Total assets:	730,396	719,257

Consolidated Balance Sheets (continued)

Millions of yen

	As of September 30, 2014	As of December 31, 2013
LIABILITIES		
Current liabilities:		
Notes and accounts payable - trade	21,671	22,589
Short-term loans payable	4,857	6,207
Commercial papers	30,000	--
Accounts payable - other	31,858	36,519
Income taxes payable	5,905	10,483
Provision for sales rebates	1,391	1,217
Provision for point card certificates	307	254
Provision for bonuses	4,187	342
Other	8,200	7,462
Total current liabilities	108,380	85,076
Non-current liabilities:		
Deferred tax liabilities	15,803	11,807
Provision for retirement benefits	2,847	19,196
Provision for directors' retirement benefits	140	134
Provision for environmental measures	102	266
Allowance for loss on plants reorganization	3,310	3,390
Asset retirement obligations	314	374
Other	3,576	3,597
Total noncurrent liabilities	26,094	38,765
Total liabilities:	134,475	123,841
NET ASSETS		
Shareholders' equity:		
Capital stock	26,745	26,745
Capital surplus	512,326	512,328
Retained earnings	64,241	65,888
Treasury shares	(26,652)	(26,632)
Total shareholders' equity	576,661	578,329
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	2,235	1,414
Foreign currency translation adjustment	16,712	14,214
Total accumulated other comprehensive income	18,948	15,628
Subscription rights to shares:	310	306
Minority interests:	--	1,150
Total net assets:	595,921	595,415
Total liabilities and net assets:	730,396	719,257

(2) Consolidated Statements of Income

Millions of yen

	January 1, 2014 to September 30, 2014	January 1, 2013 to September 30, 2013
Net sales	238,936	252,103
Cost of sales	92,349	94,839
Gross profit	146,587	157,264
Selling, general and administrative expenses		
Research and development expenses	32,495	30,723
Amortization of goodwill	9,318	8,648
Other	78,495	76,482
Total selling, general and administrative expenses	120,309	115,854
Operating income	26,277	41,409
Non-operating income		
Interest income	541	574
Dividend income	262	534
Foreign exchange gains	75	654
Gain on valuation of derivatives	--	568
Other	671	661
Total non-operating income	1,551	2,994
Non-operating expenses		
Interest expenses	144	205
Loss on valuation of derivatives	654	--
Share of loss of entities accounted for using equity method	1,600	3,590
Loss on share of disposal of non-current assets	587	502
Other	1,043	900
Total non-operating expenses	4,029	5,199
Ordinary income	23,800	39,203
Extraordinary income		
Insurance Income	308	--
Gain on sales of shares of subsidiaries and associates	--	3,217
Gain on sales of non-current assets	--	1,065
Gain on sales of investment securities	--	673
Total extraordinary income	308	4,956
Extraordinary losses		
Impairment loss	863	--
Loss due to fire	254	--
Loss on sales of shares of subsidiaries and associates	233	--
Business structure improvement expenses	170	--
Provision for loss on plants reorganization	--	3,390
Loss on valuation of shares of subsidiaries and associates	--	140
Loss on sales of investment securities	--	131
Total extraordinary loss	1,521	3,661

(2) Consolidated Statements of Income (continued)

Millions of yen

	January 1, 2014 to September 30, 2014	January 1, 2013 to September 30, 2013
Income before income taxes and minority interests	22,586	40,498
Income taxes	10,550	17,107
Income before minority interests	12,036	23,391
Minority interests in income	--	67
Net income	12,036	23,323

Consolidated Statements of Comprehensive Income

Millions of yen

	January 1, 2014 to September 30, 2014	January 1, 2013 to September 30, 2013
Income before minority interests	12,036	23,391
Other comprehensive income		
Valuation difference on available-for-sale securities	821	3,361
Foreign currency translation adjustment	2,279	10,015
Total other comprehensive income	3,101	13,377
Comprehensive income	15,137	36,768
(Comprehensive income attributable to)		
Comprehensive income attributable to owners of parent	15,137	36,561
Comprehensive income attributable to minority interests	--	207

(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. Sales and profit (loss) by segment

1. Fiscal 2014 segment information by business type (January 1, 2014 – September 30, 2014)

(Millions of yen)

	Pharmaceuticals	Bio-Chemicals	Total	Adjustments	Consolidated
Net sales					
Sales to external customers	177,795	61,140	238,936	--	238,936
Inter-segment sales and transfers	877	1,620	2,498	(2,498)	--
Total sales	178,673	62,761	241,434	(2,498)	238,936
Segment income	20,613	5,665	26,279	(1)	26,277

Notes: 1. The minus ¥1 million for adjustments of segment income is due to intersegment eliminations.
 2. In segment income, operating income from the Consolidated Statements of Income has been adjusted.
 3. Pharmaceuticals segment assets increased by ¥47,036 million compared to the end of the previous fiscal year, mainly due to the inclusion in the scope of consolidation of Archimedes Pharma Limited and its 12 subsidiaries (in the pharmaceutical segment) from the period under review following the acquisition of all shares of Archimedes.

2. Impairment of noncurrent assets, goodwill, etc. by segment

(Significant changes in amount of goodwill)

Due to the acquisition of all shares of Archimedes Pharma Limited on August 5, 2014, there were significant changes in the amount of goodwill in the pharmaceuticals segment. The increase of goodwill during the consolidated period under review resulting from this event was ¥12,635 million.

* As PPA has not been completed, provisional accounting treatment has been applied based on available reasonable information.

II. Sales and profit (loss) by segment

Fiscal 2013 segment information by business type (January 1, 2013 – September 30, 2013)

(Millions of yen)

	Pharmaceuticals	Bio-Chemicals	Total	Adjustments	Consolidated
Net sales					
Sales to external customers	191,718	60,385	252,103	--	252,103
Inter-segment sales and transfers	1,063	1,200	2,264	(2,264)	--
Total sales	192,781	61,585	254,367	(2,264)	252,103
Segment income	36,963	4,509	41,472	(63)	41,409

Notes: 1. The minus ¥63 million for adjustments of segment income is due to intersegment eliminations.
 2. In segment income, operating income from the Consolidated Statements of Income has been adjusted.