

Kyowa Hakko Kirin Co., Ltd.

Consolidated Financial Summary Fiscal 2012, Third Quarter

(January 1, 2012 – September 30, 2012)

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, 2012

Kyowa Hakko Kirin Co., Ltd.

October 26, 2012

Stock Code: 4151	Listed exchanges: Tokyo, 1 st section
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Scheduled date of submission of Financial Report: November 9, 2012	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. Results for the nine months ended September 30, 2012

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

(1) Consolidated business performance

(Millions of yen, rounded down)

	Nine months to September 30, 2012	Change (%)	Nine months to September 30, 2011	Change (%)
Net sales	244,691	-6.7	262,358	-13.8
Operating income	37,343	-3.0	38,503	15.8
Ordinary income	32,581	-15.4	38,523	13.3
Net income	15,440	-31.9	22,672	57.3
Net income per share (¥)	28.14		39.82	
Fully diluted net income per share (¥)	28.12		39.80	

(2) Consolidated financial position

(Millions of yen, rounded down)

	As of September 30, 2012	As of December 31, 2011
Total assets	656,996	658,873
Net assets	539,682	540,023
Shareholders' equity ratio (%)	82.0	81.8

Note: Total shareholders' equity: September 30, 2012: ¥538,783 million; December 31, 2011: ¥538,869 million

2. Dividends

Dividends per share	Fiscal year ending December 31, 2012 (forecast)	Fiscal period ended December 31, 2011
First quarter per share (¥)	---	---
Interim dividend per share (¥)	10.00	10.00
Third quarter dividend per share (¥)	---	---
Year-end dividend per share (¥)	10.00 (forecast)	10.00
Total dividend per share (¥)	20.00 (forecast)	20.00

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

3. Consolidated results forecasts for the fiscal year ending December 31, 2012

(Millions of yen)

	January 1, 2012 to December 31, 2012	Change (%)
Net sales	333,000	-3.1
Operating income	52,000	11.6
Ordinary income	46,500	-0.5
Net income	23,000	-10.2
Net income per share (¥)	41.94	

Notes: 1. Percentage changes are compared to the previous fiscal year

2. Changes to the consolidated results forecast during the term: None

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

Note: For details, please refer to page 6, item 2, other information (notes)

3) **Changes in accounting methods, procedures, amendments and restatements:**

1. Changes following revisions to accounting standards: No

2. Changes to accounting policies other than 1. above: No

3. Changes to accounting procedures: No

4. Amendments and restatements: No

4) Number of shares outstanding (ordinary shares)

1. Number of shares outstanding (including treasury shares)	September 30, 2012	576,483,555 shares	December 31, 2011	576,483,555 shares
2. Number of treasury shares	September 30, 2012	29,048,152 shares	December 31, 2011	21,037,327 shares
3. Average number of shares during the nine-month period	Third quarter period ended September 30, 2012	548,757,014 shares	Third quarter period ended September 30, 2011	569,392,449 shares

Notice regarding quarterly review procedures

The Financial Products Law 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

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

During the first nine months of the fiscal year (the period from January 1, 2012 to September 30, 2012) Japan's economy was supported by reconstruction demand related to the March 2011 earthquake, but the recovery has stalled against the background of weak exports resulting from the slowing of the global economy.

The pharmaceutical business continues to experience challenging operating conditions due to increased generic usage, the aggressive stance of US and European pharmaceutical manufacturers and intensifying international competition to develop new drugs. Kyowa Hakko Kirin responded to these conditions by further strengthening domestic operations, expanding the market for core products and working for the rapid market penetration by our new products.

In bio-chemicals, our efforts were directed to expanding sales of high value-added amino acids, nucleic acids and related compounds, primarily for pharmaceutical and medical applications. In healthcare products, we strengthened the *Remake series* of mail order products, centered on brands such as *Remake Ornithine*.

Cumulative net sales to the end of the third quarter were ¥244.6 billion (down 6.7% compared to the same period of the previous fiscal year) while operating income was ¥37.3 billion (down 3.0%), ordinary income ¥32.5 billion (down 15.4%) and net income ¥15.4 billion (down 31.9%). The chemical business was excluded from the scope of consolidation at the end of March 2011, resulting in a loss of ¥33.5 billion in net sales and of ¥2.1 billion in operating income compared to the same period of last fiscal year. FUJIFILM KYOWA KIRIN BIOLOGICS Co. Ltd., a joint venture (affiliated company) established between FUJIFILM Corporation and Kyowa Hakko Kirin Co., Ltd. for the development, manufacture and sale of biosimilar products was newly included in the scope of consolidation as an equity method affiliate as of March 27.

Results by business segment were as follows:

Pharmaceuticals

Consolidated net sales of Pharmaceuticals were ¥182.4 billion (up 8.4% compared to the same period of the previous year), and operating income was ¥34.8 billion (up 5.2%).

Despite a strong performance by core products, domestic sales of pharmaceuticals were down compared to the same period of the previous year, affected by government drug price revisions implemented in April 2012. Sales of core product *NESP*[®], a treatment for renal anemia, performed favorably, and *REGPARA*[®], an agent to treat secondary hyperparathyroidism associated with dialysis, *Fentos*[®], a transdermal analgesic for persistent cancer pain, and *ASACOL*[®], for ulcerative colitis, all advanced. Furthermore, we began sales of *POTELIGEO*[®] for adult T-cell leukemia-lymphoma in May 2012, and *Apokyn*[®], a treatment for Parkinson's disease in July 2012, both of which performed well. However, revenues of *ALLELOCK*[®], an anti-allergy agent,

and *Patanol*[®] anti-allergy eye drops, both declined compared with the same period of the last fiscal year.

Revenues from pharmaceutical exports and licensing revenues increased over the same period of last fiscal year due to firm exports and the booking of licensing revenue from FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.

The ProStrakan Group plc (the parent company and its 11 subsidiaries) which was newly consolidated as of June 30, 2011, performed broadly in line with expectations, contributing net sales of ¥11.5 billion with an operating loss (after amortization of goodwill) of ¥2.5 billion.

In new drug development in oncology, in Japan we received approval in March for *POTELIGEO*[®] for adult T-cell leukemia-lymphoma (ATL) and began sales in May. Also, in March Kyowa Medex secured approval for *POTELIGEO*[®] *TEST*, an in vitro diagnostic reagent designed to identify patients most likely to respond to *POTELIGEO*[®] and began sales in May. Overseas, in Europe and the U.S. we began phase II studies in August on KW-0761 for adult T-cell leukemia-lymphoma, and in South Korea, we secured approval in May for pegfilgrastim (brand name Neulasta).

In nephrology, we began domestic phase II trials in February on RTA 402 for chronic kidney disease patients with Type 2 diabetes mellitus, but decided to suspend the trial in October following news that the overseas phase III trial being conducted by Reata Pharmaceuticals had been terminated due to safety concerns. However, we filed in September for approval of KRN321 for renal anemia in infants in Japan. Overseas, we discontinued Indian phase III trials in September on KRN321 for renal anemia in dialysis patients following a review of our portfolio in response to changes in the business environment and other factors.

In the CNS area, we obtained Japanese approval in March for *Apokyn*[®] for the treatment of Parkinson's disease and began sales in July. We filed in March for approval of KW-6002, also for Parkinson's disease. Furthermore, we began phase II trials in May on KHK6188, an agent for neuropathic pain in post-herpes zoster patients.

Bio-Chemicals

Consolidated net sales for the Bio-Chemicals business were ¥57.4 billion (down 2.5% compared to the same period of the previous year), while operating income was ¥2.2 billion (down 26.7%).

We implemented an increase in production and a review of sales prices due to continued buoyant overseas demand for pharmaceutical and industrial use raw materials, mainly amino acids, nucleic acids and related compounds, but net sales fell compared with the same period of last fiscal year due to the impact of the strong yen.

In healthcare products, mail order revenues advanced steadily helped by sales of *Remake Ornithine* and other products, but sales of raw materials for food and drinks were sluggish with the result that overall sales were below the same period of the previous year.

Sales at Daiichi Fine Chemical advanced sharply over the same period of last fiscal year as the new production facilities for tranexamic acid completed last year came fully online.

Other

In the Other segment (the distribution business and others), consolidated net sales were ¥7.7 billion (down 1.9% compared to the same period of the previous year), while operating income was ¥0.2 billion (up 1.6%).

(2) Summary of consolidated financial position

Total assets at the end of the consolidated third quarter were ¥656.9 billion, a decline of ¥1.8 billion compared to the end of the previous fiscal year. Current assets declined by ¥1.1 billion to ¥283.0 billion compared to the end of the previous fiscal year. This was due to a decrease in accounts and notes receivable, which offset increases in inventories and in short-term loans to the parent company as part of cash management. Non-current assets declined by ¥0.7 billion to ¥373.8 billion. The value of product rights increased, but there were decreases in marketable investment securities and in goodwill due to amortization. Provisions for bonuses increased, but a decline in notes and accounts payable resulted in a reduction in liabilities of ¥1.5 billion to ¥117.3 billion as compared with the end of last fiscal year.

Net assets at the end of the third quarter were ¥539.6 billion. There were increases in booked quarterly net income and in the foreign exchange adjustment account, but purchases of treasury stock, dividend payments and other factors resulted in a decline of ¥0.3 billion in net assets compared to the end of the previous fiscal year.

(3) Consolidated results forecasts

No revisions have been made to the consolidated results forecasts that were announced on **July 19, 2012**.

2. Other Information

(1) Changes to important subsidiaries during the period January-September 2012

None applicable.

(2) Use of special accounting procedures in the preparation of consolidated quarterly financial reports

The calculation of tax expenses applies an estimated effective tax rate to net income before taxes. This is based on reasonable assumptions as to the effective tax rate after applying tax effective accounting to net income before income taxes for the consolidated fiscal year, including the consolidated third quarter under review.

(3) Changes in accounting methods, procedures and amendments or restatements

None applicable

3. Consolidated financial statements

(1) Consolidated Balance Sheets

	<i>(Millions of yen)</i>	
	As of December 31, 2011	As of September 30, 2012
ASSETS		
Current assets:		
Cash and deposits	27,063	26,546
Notes and accounts receivable-trade	99,109	92,374
Merchandise and finished goods	36,840	39,833
Work in process	12,232	12,604
Raw materials and supplies	9,907	10,524
Deferred tax assets	8,629	9,030
Short-term loans receivable	82,958	84,074
Others	8,067	8,434
Allowance for doubtful accounts	(591)	(325)
Total current assets	284,217	283,097
Non-current assets:		
Property, plant and equipment		
Buildings and structures	129,190	131,553
Accumulated depreciation	(91,855)	(93,732)
Buildings and structures, net	37,334	37,820
Machinery, equipment and vehicles	139,796	139,030
Accumulated depreciation	(120,761)	(122,306)
Machinery, equipment and vehicles, net	19,034	16,723
Land	53,954	53,581
Construction in progress	6,221	11,568
Others	46,967	48,421
Accumulated depreciation	(40,569)	(41,989)
Other, net	6,398	6,431
Total property, plant and equipment	122,943	126,125
Intangible assets		
Goodwill	177,267	169,923
Product rights	29,025	34,951
Others	4,324	3,401
Total intangible assets	210,616	208,275
Investments and other assets		
Investment securities	24,818	22,593
Deferred tax assets	6,680	7,362
Others	9,958	9,909
Allowance for doubtful accounts	(361)	(367)
Total investments and other assets	41,096	39,497
Total non-current assets	374,656	373,899
Total assets:	658,873	656,996

Consolidated Balance Sheets (continued)

(Millions of yen)

	As of December 31, 2011	As of September 30, 2012
LIABILITIES		
Current liabilities:		
Notes and accounts payable-trade	27,341	24,165
Short-term loans payable	5,943	5,679
Accounts payable-other	31,009	26,694
Income taxes payable	7,821	9,605
Provision for sales rebates	667	516
Provision for point card certificates	167	208
Provision for bonuses	161	4,137
Others	5,254	6,574
Total current liabilities	78,366	77,582
Non-current liabilities:		
Long-term loans payable	98	43
Deferred tax liabilities	10,926	10,689
Provision for retirement benefits	20,654	19,807
Provision for directors' retirement benefits	94	104
Provision for environmental measures	737	539
Asset retirement obligations	654	659
Others	7,317	7,888
Total non-current liabilities	40,484	39,731
Total liabilities:	118,850	117,313
NET ASSETS		
Shareholders' equity:		
Capital stock	26,745	26,745
Capital surplus	512,348	512,329
Retained earnings	34,956	39,368
Treasury stock	(19,194)	(26,525)
Total shareholders' equity	554,856	551,917
Valuation and translation adjustments:		
Valuation difference on marketable securities	(3,144)	(2,205)
Foreign currency translation adjustment	(12,841)	(10,928)
Total valuation and translation adjustments	(15,986)	(13,134)
Subscription rights to shares:	250	178
Minority interests:	902	720
Total net assets:	540,023	539,682
Total liabilities and net assets:	658,873	656,996

(2) Consolidated Statements of Income

(Millions of yen)

	January 1, 2011 to September 30, 2011	January 1, 2012 to September 30, 2012
Net sales	262,358	244,691
Cost of sales	115,024	90,305
Gross profit	147,334	154,386
Selling, general and administrative expenses		
Research and development expenses	34,032	33,626
Amortization of goodwill	7,768	9,127
Others	67,029	74,288
Total selling, general and administrative expenses	108,830	117,043
Operating income	38,503	37,343
Non-operating income		
Interest income	343	436
Dividend income	334	477
Foreign exchange gains	---	106
Gain on revaluation of derivatives	296	---
Income from equity-method affiliates	189	---
Others	713	913
Total non-operating income	1,878	1,933
Non-operating expenses		
Interest expenses	110	150
Foreign exchange loss	570	---
Loss on revaluation of derivatives	---	134
Loss at equity-method affiliates	---	4,643
Loss on disposal of non-current assets	453	631
Others	724	1,135
Total non-operating expenses	1,858	6,694
Ordinary income	38,523	32,581
Extraordinary income		
Gain on sale of affiliates' stock	7,339	---
Reversal of allowance for doubtful accounts	104	---
Total extraordinary income	7,444	---
Extraordinary loss		
Loss on valuation of investment securities	2,011	905
Loss on sale of investment securities	---	340
Advisory fees	1,062	---
Effect of application of accounting provisions to asset retirement obligations	447	---
Loss on disaster	447	---
Impairment loss	273	---
Loss on liquidation of affiliated companies	209	---
Provision for point card certificates for prior periods	128	---
Total extraordinary loss	4,580	1,246

Consolidated Statements of Income (continued)

(Millions of yen)

	January 1, 2011 to September 30, 2011	January 1, 2012 to September 30, 2012
Income before income taxes and minority interests	41,387	31,335
Income taxes	18,640	15,847
Net income before minority interests	22,746	15,488
Minority interests	74	47
Net income	22,672	15,440

Consolidated Statements of Comprehensive Income

(Millions of yen)

	January 1, 2011 to September 30, 2011	January 1, 2012 to September 30, 2012
Net income before minority interests	22,746	15,488
Other comprehensive income		
Valuation loss on other marketable securities	(783)	934
Loss on deferred hedges	(0)	---
Foreign exchange loss account	(6,238)	1,921
Other comprehensive income	(5)	4
Total other comprehensive income	(7,027)	2,860
Comprehensive income	15,719	18,348
(of which)		
Comprehensive income attributable to parent company shareholders	15,690	18,293
Comprehensive income attributable to minority interests	28	55

(3) Items related to going concern assumption

No applicable items

(4) Notes applicable in cases of significant changes to shareholders' equity

Acquisition of own shares in accordance with the provisions of the articles of association and pursuant to Article 2, Chapter 165 of the Companies Law.

At a meeting of the board of directors convened on 25 August 2011, it was resolved to purchase treasury shares in accordance with Chapter 156 of the Companies Law, applicable in lieu as provided by Article 3, Chapter 165 of the Companies' Law. The purchase was completed on 23 February 2012. As a result, the value of treasury shares increased by ¥7,331 million during the cumulative first three quarters of the current consolidated fiscal year and stood at ¥26,525 million as of the end of the consolidated third quarter.

(5) Segment information

I Fiscal 2011 cumulative segment information to Q3 (January 1, 2011 – September 30, 2011)

1. Sales and profit (loss) by segment

(Millions of yen)

	Pharmaceuticals	Bio-Chemicals	Chemicals	Other	Total	Adjustments	Consolidated
Net sales							
(1) Sales to external customers	168,088	56,264	32,787	5,218	262,358	--	262,358
(2) Inter-segment sales and transfers	129	2,709	762	2,637	6,239	(6,239)	--
Total sales	168,218	58,973	33,550	7,856	268,598	(6,239)	262,358
Segment income	33,114	3,018	2,135	255	38,524	(20)	38,503

Notes:

1. The Other segment includes distribution and certain other businesses not included in the reported segments.
2. The adjustment item of (¥20 million) in Segment Income is due to inter-segment eliminations.
3. Segment Income has been reconciled with operating income as given in the quarterly Consolidated Statement of Income.
4. The Chemicals segment, which previously included Kyowa Hakko Chemical and its consolidated subsidiary Miyako Kagaku Co., Ltd., was eliminated from the scope of consolidation at the end of the consolidated first quarter. This was due to the transfer of all shares of Kyowa Hakko Chemical held by Kyowa Hakko Kirin as executed on March 31, 2011. The value of the assets of the Chemicals segment is now zero. Furthermore, the assets of the Pharmaceuticals segment increased by ¥36,382 million compared to the end of the previous consolidated fiscal year. This increase was primarily due to the acquisition of all outstanding shares of the ProStrakan Group plc. ProStrakan and its 10 subsidiaries (Pharmaceuticals segment) were newly included in the scope of consolidation from the end of the second quarter of the fiscal year.

II Fiscal 2012 cumulative segment information to Q3 (January 1, 2012 – September 30, 2012)

1. Sales and profit (loss) by segment

(Millions of yen)

	Pharmaceuticals	Bio-Chemicals	Other	Total	Adjustments	Consolidated
Net sales						
(1) Sales to external customers	182,272	56,193	6,225	244,691	--	244,691
(2) Inter-segment sales and transfers	133	1,295	1,477	2,906	(2,906)	--
Total sales	182,406	57,488	7,703	247,597	(2,906)	244,691
Segment income	34,837	2,213	259	37,311	31	37,343

Notes:

1. The Other segment includes distribution and certain other businesses not included in the reported segments.
2. The adjustment item of ¥31 million in Segment Income is due to inter-segment eliminations.
3. Segment Income has been reconciled with operating income as given in the quarterly consolidated statement of income.