

Kyowa Hakko Kirin Co., Ltd.**Appendix to the Fiscal 2011 Third Quarter Consolidated Financial Statements**

Third quarter results for Fiscal 2011
(January 1, 2011 - September 30, 2011)

Index	Page
I. Consolidated Financial Results	
1. Income	1
2. Results by segment	1
3. Non-operating income/expenses	2
4. Extraordinary income/loss	2
5. R&D expenses	2
6. Capital expenditure	3
7. Depreciation expenses	3
8. Employee numbers	3
9. Exchange rates	3
II. Consolidated Subsidiaries and Affiliates	4
III. Non-Consolidated Net Sales by Division	5
1. Kyowa Hakko Kirin	5
2. ProStrakan	6
3. Kyowa Hakko Bio	6
4. Kyowa Hakko Chemical	6
R&D Pipeline	7

This document was made as a supplement to the Kessan Tanshin (financial report) for the third quarter period of the fiscal year ending December 31, 2011. This document contains forward-looking statements based on a number of assumptions and beliefs made by management in light of information currently available. For a variety of reasons, actual financial results may differ materially from the forecasts presented here.

I. Consolidated Financial Results

1. Trends in income

Millions of yen, rounded down

	January 1, 2010 to December 31, 2010 results			FY 2011 results				FY 2011 forecasts
	January 1 to June 30	January 1 to September 30 (A)	January 1 to December 31	January 1 to June 30	January 1 to September 30 (B)	Change on January to September 2010		January to December
						Amount (B-A)	%	
Net sales	203,466	304,453	413,738	186,367	262,358	(42,094)	86%	342,000
Gross Profit	92,763	139,828	190,979	100,234	147,334	7,506	105%	--
Selling, general and administrative expenses	71,071	106,585	145,568	70,297	108,830	2,244	102%	--
Operating income (prior to amortization of goodwill)	26,344	40,220	54,713	34,576	45,456	5,236	113%	52,767
Operating income	21,692	33,242	45,410	29,936	38,503	5,261	116%	43,500
Non-operating income	3,120	3,758	5,201	1,316	1,878	(1,880)		--
Non-operating expenses	2,478	2,994	4,111	1,040	1,858	(1,136)		--
Ordinary income	22,334	34,006	46,500	30,212	38,523	4,516	113%	44,500
Extraordinary income	1,082	1,091	2,822	8,421	7,444	6,353		--
Extraordinary loss	5,775	6,121	7,023	5,363	4,580	(1,540)		--
Net income before income taxes	17,641	28,976	42,299	33,270	41,387	12,410	143%	46,500
Corporate, local and enterprise taxes	7,718	14,513	20,040	15,507	18,640	4,126		--
Income from minority interests	21	47	61	44	74	26		--
Net income	9,901	14,414	22,197	17,718	22,672	8,257	157%	25,500
EPS before goodwill amortization (¥/share)	25.55	37.55	55.29	39.24	52.03			61.02

Notes:

1. On April 21, 2011, Kyowa Hakko Kirin acquired all outstanding shares of ProStrakan Group plc and as a result ProStrakan Group, and its ten subsidiaries were newly included in the scope of consolidation. In terms of accounting treatment, June 30, 2011 will be considered as the date that the acquisition was completed and therefore results from ProStrakan have not been included in the consolidated financial results for the first half of the current fiscal year. Financial results from ProStrakan as of July have been included in the FY2011 Forecast.

2. Figures for FY2011 Forecast are those as announced July 20, 2011.

2. Trends in results by segment

(1) Results by operating segment

Millions of yen, rounded down

	January 1, 2010 to December 31, 2010 results			FY 2011 results				FY 2011 forecasts
	January 1 to June 30	January 1 to September 30 (A)	January 1 to December 31	January 1 to June 30	January 1 to September 30 (B)	Change on January to September 2010		January to December
						Amount (B-A)	%	
Net sales	203,466	304,453	413,738	186,367	262,358	(42,094)	86%	342,000
Pharmaceuticals	103,475	154,092	210,362	112,534	168,218	14,125	109%	225,000
Bio-Chemicals	44,186	63,968	84,236	40,360	58,973	(4,995)	92%	80,000
Chemicals	61,289	94,661	130,018	33,550	33,550	(61,111)	--	33,550
Other	5,082	7,706	10,499	5,306	7,856	150	102%	11,000
Total	214,034	320,429	435,116	191,752	268,598	(51,831)	84%	349,550
Eliminations	(10,567)	(15,975)	(21,377)	(5,384)	(6,239)	9,736	--	(7,550)
Operating income	21,692	33,242	45,410	29,936	38,503	5,261	116%	43,500
<i>*Before goodwill amortization</i>	26,344	40,220	54,713	34,576	45,456	5,236	113%	52,767
Pharmaceuticals	17,993	26,465	35,857	25,145	33,114	6,648	125%	37,500
	22,307	32,937	44,485	29,459	39,585	6,648	120%	46,129
Bio-Chemicals	1,853	2,846	3,275	2,519	3,018	171	106%	3,500
	2,166	3,316	3,901	2,832	3,487	171	105%	4,126
Chemicals	1,589	3,557	5,678	2,135	2,135	(1,421)	--	2,135
	1,614	3,594	5,728	2,147	2,147	(1,446)	(--)	2,147
Other	150	252	363	148	255	3	101%	365
	150	252	363	148	255	3	101%	365
Total	21,587	33,122	45,175	29,948	38,524	5,402	116%	43,500
	26,239	40,099	54,478	34,588	45,477	5,377	113%	52,767
Eliminations	105	120	235	(12)	(20)	(140)	--	--

Notes:

1. Figures representing amounts before goodwill amortization have been italicized.

2. As of the period under review, Kyowa Hakko Kirin has adopted "Accounting Standards Related to the Disclosure of Segment Information". Since the segment classification methods used to classify business by segment are the same as those used previously, we are able to make comparisons with the previous year.

3. The Chemicals Business was discontinued at the end of the first quarter following the transfer of all shares of Kyowa Hakko Chemical on March 31, 2011. As a result, income from Chemicals was consolidated on the Statements of Income only until March 31, 2011.

(2) Regional sales

Millions of yen, rounded down

	January 1, 2010 to December 31, 2010 results						FY 2011 results			
	January 1 to June 30	Percentage of consolidated sales	January 1 to September 30	Percentage of consolidated sales	January 1 to December 31	Percentage of consolidated sales	January 1 to June 30	Percentage of consolidated sales	January 1 to September 30	Percentage of consolidated sales
Japan sales	161,229	79.2%	240,812	79.1%	328,596	79.4%	148,987	79.9%	208,194	79.4%
Overseas sales	42,236	20.8%	63,641	20.9%	85,141	20.6%	37,379	20.1%	54,163	20.6%
America	12,977	6.4%	19,770	6.5%	23,467	5.7%	10,456	5.6%	16,083	6.1%
Europe	10,779	5.3%	16,085	5.3%	21,477	5.2%	10,919	5.9%	18,449	7.0%
Asia	18,114	8.9%	27,346	9.0%	39,689	9.6%	15,772	8.5%	19,256	7.3%
Other regions	364	0.2%	439	0.1%	507	0.1%	231	0.1%	374	0.1%
Total consolidated net sales	203,466	100.0%	304,453	100.0%	413,738	100.0%	186,367	100.0%	262,358	100.0%

3. Trends in non-operating income/expenses

Millions of yen, rounded down

	January 1, 2010 to December 31, 2010 results			FY 2011 results	
	January 1 to June 30	January 1 to September 30	January 1 to December 31	January 1 to June 30	January 1 to September 30
Non-operating income	3,120	3,758	5,201	1,316	1,878
Interest income	221	298	362	193	343
Dividends income	485	557	844	303	334
Foreign exchange gains	--	--	--	112	--
Gain on revaluation of derivatives	685	251	414	--	296
Equity in earnings of affiliates	626	1,150	1,074	141	189
Other	1,102	1,501	2,505	565	713
Non-operating expenses	2,478	2,994	4,111	1,040	1,858
Interest expenses	122	172	199	77	110
Foreign exchange loss	1,143	1,051	1,280	--	570
Loss on revaluation of derivatives	--	--	--	32	--
Loss on disposal of non-current assets	608	1,121	1,493	313	453
Other	604	648	1,138	617	724

4. Trends in extraordinary income / loss

Millions of yen, rounded down

	January 1, 2010 to December 31, 2010 results			FY 2011 results	
	January 1 to June 30	January 1 to September 30	January 1 to December 31	January 1 to June 30	January 1 to September 30
Extraordinary income	1,082	1,091	2,822	8,421	7,444
Gain on sales of subsidiaries and affiliates' stocks	--	--	--	8,320	7,339
Reversal of allowance for doubtful accounts	107	117	139	100	104
Gain on sale of investment securities	120	120	1,828	--	--
Gain on negative goodwill	854	854	854	--	--
Extraordinary loss	5,775	6,121	7,023	5,363	4,580
Loss on valuation of investment securities	2,588	2,833	1,473	3,043	2,011
Advisory fee	--	--	--	1,030	1,062
Loss on adjustment for changes of accounting standard for asset retirement	--	--	--	447	447
Loss on disaster	--	--	--	302	447
Impairment loss	--	--	1,374	200	273
Loss on liquidation of subsidiaries and affiliates	--	--	--	209	209
Provision for point card certificates for prior periods	--	--	--	128	128
Loss on revision of retirement benefit plan	1,771	1,771	1,771	--	--
Non-recurring depreciation on non-current assets	1,225	1,225	1,225	--	--
Provision for environmental measures	--	--	887	--	--
Other	189	290	290	--	--

5. Trends in R&D expenses

Billions of yen, rounded down

	January 1, 2010 to December 31, 2010 results			FY 2011 results		FY 2011 forecasts
	January 1 to June 30	January 1 to September 30	January 1 to December 31	January 1 to June 30	January 1 to September 30	January to December
R&D (Consolidated)	21.4	32.3	44.2	22.2	34.0	48.5
R&D to net sales ratio	10.5%	10.6%	10.7%	11.9%	13.0%	14.2%
Pharmaceuticals	19.3	29.2	40.0	20.4	31.5	45.0
(R&D to net sales ratio)	18.7%	19.0%	19.0%	18.2%	18.8%	20.0%
Bio-Chemicals	1.5	2.3	3.2	1.5	2.2	3.3
Chemicals	0.4	0.7	1.0	0.2	0.2	0.2
Other	--	--	--	--	--	--

6. Trends in capital expenditure (Tangible fixed assets)

Billions of yen, rounded down

	January 1, 2010 to December 31, 2010 results			FY 2011 results		FY 2011 forecasts
	January 1 to June 30	January 1 to September 30	January 1 to December 31	January 1 to June 30	January 1 to September 30	January to December
Capital expenditure (Consolidated)	12.2	17.1	21.9	5.9	10.4	18.3
Pharmaceuticals	7.0	9.1	11.7	2.8	5.1	8.4
Bio-Chemicals	3.7	5.8	7.5	2.7	4.9	9.6
Chemicals	1.3	2.2	2.5	0.3	0.3	0.3
Other	0.0	0.0	0.0	0.0	0.0	0.0

7. Trends in depreciation expenses

Billions of yen, rounded down

	January 1, 2010 to December 31, 2010 results			FY 2011 results		FY 2011 forecasts
	January 1 to June 30	January 1 to September 30	January 1 to December 31	January 1 to June 30	January 1 to September 30	January to December
Depreciation expenses (Consolidated)	10.5	16.2	22.1	10.4	16.2	23.0
Pharmaceuticals	4.5	7.3	10.7	6.8	11.0	15.7
Bio-Chemicals	3.8	5.4	6.7	2.6	4.2	6.2
Chemicals	2.1	3.4	4.6	0.9	0.9	0.9
Other	0.0	0.0	0.0	0.0	0.0	0.0

8. Employee numbers

	January 1, 2010 to December 31, 2010 results			FY 2011 results	
	As of June 30	As of September 30	As of December 31	As of June 30	As of September 30
Employee numbers (Consolidated)	7,554	7,499	7,484	7,305	7,298
Pharmaceuticals			5,041		
Bio-Chemicals			1,581		
Chemicals			652		
Other			210		

9. Exchange rates

	January 1, 2010 to December 31, 2010 results			FY2011 results		FY 2011 forecasts
	January 1 to June 30	January 1 to September 30	January 1 to December 31	January 1 to June 30	January 1 to September 30	January 1 to December 31
US Dollar (¥/US\$)	91	90	88	82	81	80
Euro (¥/Euro)	121	118	116	115	113	111
Pound (¥/Pound)	139	137	136	133	130	127

II. Consolidated Subsidiaries and Affiliates

(As of September 30, 2011)

Segment	Type	Region	Company name	Percentage owned (direct and indirect)	Principal business
Pharmaceuticals	Consolidated subsidiary	Japan	Kyowa Medex Co., Ltd.	100.0%	Manufacture and sale of diagnostic reagents
			Kyowa Medical Promotion Co., Ltd.	100.0%	Promotion and sales of pharmaceuticals
		The Americas	Kyowa Hakko Kirin America, Inc.	100.0%	Holding company for administration and management of US subsidiaries (US)
			BioWa, Inc.	100.0%	Out-licensing and promotion of anti-body technology (US)
			Kyowa Hakko Kirin Pharma, Inc.	100.0%	Development of outsourced pharmaceutical products (US)
			Kyowa Hakko Kirin California, Inc.	100.0%	Generate new candidate substances and develop pharmaceuticals (US)
			Hematech, Inc.	100.0%	Technology research for manufacture of therapeutic antibody (US)
			Hematech-GAC Venture, LLC	51.0%	Technology research for manufacture of therapeutic antibody (US)
			ProStrakan Inc.	100.0%	Sales of pharmaceuticals (US)
		Europe	ProStrakan Group plc	100.0%	Supervision and management of subsidiaries (UK)
			Strakan International S.a r.l.	100.0%	Sales, licensing-in and licensing-out of pharmaceuticals (UK)
			Strakan Pharmaceuticals Limited	100.0%	Development of pharmaceuticals (UK)
			ProStrakan Limited	100.0%	Sales of pharmaceuticals (UK)
			ProStrakan Pharma S.A.S	100.0%	Sales of pharmaceuticals (France)
			ProStrakan Farmaceutica SLU	100.0%	Sales of pharmaceuticals (Spain)
			ProStrakan Pharma GmbH	100.0%	Sales of pharmaceuticals (Germany)
			ProStrakan Holdings B.V.	100.0%	Holding company for special companies (Netherlands)
			ProStrakan Pharma B.V.	100.0%	Sales of pharmaceuticals (Netherlands)
			ProStrakan S.r.l.	100.0%	Sales of pharmaceuticals (Italy)
		Kyowa Hakko Kirin Italia S.r.l.	100.0%	Sales of pharmaceuticals (Italy)	
	Asia	Kirin Kunpeng (China) Bio- Pharmaceutical Co., Ltd.	100.0%	Manufacture and sale of pharmaceuticals (China)	
		Jeil-Kirin Pharmaceutical Inc.	90.0%	Sales of pharmaceuticals (Korea)	
		Kyowa Kirin Pharmaceuticals (Taiwan) Co., Ltd.	100.0%	Sales of pharmaceuticals (Taiwan)	
Kyowa Hakko Kirin (Hong Kong) Co., Ltd.		100.0%	Sales of pharmaceuticals (Hong Kong)		
Kyowa Hakko Kirin (Singapore) Pte. Ltd.		100.0%	Sales of pharmaceuticals (Singapore)		
Affiliate accounted for by the equity method	Europe	ProStrakan AB	50.0%	Sales of pharmaceuticals (Sweden)	
Bio-Chemicals	Consolidated subsidiary	Japan	Kyowa Hakko Bio Co., Ltd.	100.0%	Manufacture and sale of pharmaceutical and industrial raw materials, and health care products
			Daiichi Fine Chemical Co., Ltd.	100.0%	Manufacture and sale of active pharmaceutical ingredients and pharmaceutical intermediates
			Kyowa Wellness Co., Ltd.	100.0%	Sale of healthcare products
			Kyowa Engineering Co., Ltd.	100.0%	Design and installation of plant facilities and equipment
		The Americas	Biokyowa Inc.	100.0%	Manufacture and sale of amino acids (US)
			Kyowa Hakko U.S.A., Inc.	100.0%	Sale and import/export of fine chemicals including amino acids (US)
			Kyowa Hakko Bio U.S. Holdings, Inc.	100.0%	Holding company for administration and management of US subsidiaries (US)
		Europe	Kyowa Hakko Europe GmbH	100.0%	Sale and import/export of fine chemicals including amino acids (Germany)
			Kyowa Hakko Bio Italia S.r.l.	100.0%	Sale and import/export of fine chemicals including amino acids (Italy)
		Asia	Shanghai Kyowa Amino Acid Co., Ltd.	70.0%	Manufacture and sale of amino acids (China)
	Kyowa Hakko (H.K.) Co., Ltd.		100.0%	Sale and import/export of fine chemicals including amino acids (Hong Kong)	
Kyowa Hakko Bio Singapore Pte. Ltd.	100.0%		Sale and import/export of fine chemicals including amino acids (Singapore)		
Other	Consolidated subsidiary	Japan	Chiyoda Kaihatsu Co., Ltd.	100.0%	Transportation, insurance, wholesale sales of food, etc.
	Affiliate accounted for by the equity method		Japan Synthetic Alcohol Co., Ltd.	33.3%	Manufacture and sale of industrial use alcohol

Notes: Changes to the scope of consolidation (January 1, 2011 to September 30, 2011)

Newly consolidated: 11 companies: ProStrakan Group plc and 10 subsidiaries (*1)

Removed: 4 companies: Kashiwagi Corporation (*2), Kyowa Hakko Chemical Co., Ltd., Miyako Kagaku Co., Ltd. (*3), Shinwa Pharmaceutical Co., Ltd. (*4)

*1 On April 21, 2011, Kyowa Hakko Kirin acquired all outstanding shares of ProStrakan Group plc and as a result ProStrakan Group, and its 10 subsidiaries were newly included in the scope of consolidation.

*2 As of January 1, 2011, Kashiwagi Corporation was merged with Miyako Kagaku Co., Ltd. and eliminated.

*3 Kyowa Hakko Chemical Co., Ltd. and its subsidiary Miyako Kagaku Co., Ltd. were removed from the scope of consolidation at the end of the first quarter of the current period following the transfer of all shares of Kyowa Hakko Chemical Co., Ltd. to KJ Holdings Inc. on March 31, 2011.

*4 Shinwa Pharmaceutical Co., Ltd. was removed from the scope of consolidation as of the second quarter of the current period and all shares in the company were transferred on April 1, 2011.

III. Non-Consolidated Net Sales by Division (Items and main products)

1. Kyowa Hakko Kirin

Billions of yen, rounded down

Pharmaceuticals division (non-consolidated)	January 1, 2010 to December 31, 2010 results			FY2011 results			FY 2011 forecasts
	January 1 to June 30	January 1 to September 30 (A)	January 1 to December 31	January 1 to June 30	January 1 to September 30 (B)	Change on January 1 to September 30, 2010 (B/A)	January 1 to December 31
Pharmaceuticals division total	94.1	140.7	192.9	104.6	152.3	108%	201.2
Indication / Product							
<i>ESA formulation</i>							
Nesp	17.7	28.1	41.7	25.4	40.4	143%	50.8
<i>ESA formulation</i>							
Espo	5.7	8.7	10.8	2.7	4.0	47%	5.3
Nesp/Espo	23.4	36.8	52.6	28.2	44.4	121%	56.1
<i>Secondary hyperparathyroidism</i>							
Regpara	4.3	6.7	9.5	5.3	8.2	122%	11.1
<i>Antiallergenic</i>							
Allelock	13.9	19.1	26.8	18.1	22.2	116%	29.0
<i>Antiallergenic</i>							
Cellect	1.4	2.0	2.7	1.3	1.9	94%	2.3
<i>Antiallergic eyedrops</i>							
Patanol	4.7	6.0	7.5	8.6	9.8	164%	11.6
<i>G-CSF</i>							
Gran/Neu-up*1	7.3	11.1	14.4	6.7	10.5	94%	14.5
<i>Cancer pain</i>							
Fentos*2	0.0	0.3	0.8	1.2	2.0	615%	2.6
<i>Anticancer</i>							
Farmorubicin*3 / Adriacin	2.4	3.6	4.8	0.5	0.8	22%	
<i>Anticancer</i>							
5 – FU	1.5	2.3	3.1	1.5	2.3	100%	2.9
<i>Anticancer</i>							
Navelbine	1.0	1.5	2.0	0.8	1.3	85%	1.6
<i>Cardiovascular</i>							
Coniel	10.3	15.3	21.0	9.6	14.3	93%	19.7
<i>Cardiovascular (Hypertension)</i>							
Coversyl	2.0	3.0	4.2	1.9	2.8	93%	3.9
<i>Cardiovascular</i>							
Inovan / Pre Dopa	1.5	2.2	3.0	1.3	2.0	93%	2.9
<i>Antiepileptic</i>							
Depakene	5.2	7.9	11.0	5.3	8.1	102%	11.1
<i>Parkinson's disease</i>							
Permax*4	0.7	1.3	2.0	1.1	1.6	119%	2.3
<i>Gastrointestinal</i>							
Nauzelin	2.6	3.6	5.3	2.3	3.3	91%	4.9
<i>Inflammatory bowel disease</i>							
Asacol	0.2	0.4	0.7	1.1	1.9	444%	2.8
Exports and Technology Out-Licensing	13.1	19.9	24.1	11.4	17.7	89%	22.4

Notes 1: As of March 1, 2010, manufacturing, sales and other rights for Neu-up were transferred to Yakult Honsha.

Therefore, Gran/Neu-up figures after March 31, 2010 include only sales figures for Gran.

2: Sales of Fentos began June 24, 2010.

3: Sales of Farmorubicin ended December 31, 2010 following completion of our contract with Pfizer.

Therefore, as of January 2011, only amounts for Adriacin have been included in Farmorubicin/Adriacin.

4: Sales of Permax began April 1, 2010.

2. ProStrakan

Millions of GBP, rounded down

Pharmaceuticals division (non-consolidated)	January 1, 2010 to December 31, 2010 results				FY2011 results			FY 2011 forecasts
	January 1 to March 31	January 1 to June 30	July 1 to September 30	July 1 to December 31	January 1 to March 31	January 1 to June 30	July 1 to September 30	July 1 to December 31
Net sales	22	45	22	54	23	48	30	57
Sancuso	1	4	1	2	2	4	2	5
Abstral	3	7	4	9	5	12	7	17
Tostran	0	1	0	1	0	2	1	3
Xomolix	2	4	1	3	2	4	1	4
Rectogesic	2	4	2	4	2	4	2	5
Adcal-D3	5	10	5	12	5	11	6	13
Others	5	12	5	20	4	8	8	6
Gross profit	14	29	14	37	15	29	20	37
Selling, general and administrative expenses	15	30	14	31	18	40	18	37
Operating income (prior to amortization of goodwill)	(0)	(0)	(0)	6	(3)	(11)	2	(0)
(Ref.) Amortization of goodwill	-	-	-	-	-	-	8	16

*Amortization of goodwill is the amortization of the goodwill and noncurrent intangible assets (sales rights, etc.) resulting from the acquisition of all outstanding shares in ProStrakan Group plc.

*Sales ratio by region

(January 1 to September 30, 2011)

UK	Europe (excluding UK)	USA	Other	Total
34.7%	46.6%	17.5%	1.2%	100.0%

3. Kyowa Hakko Bio

Billions of yen, rounded down

Bio-Chemicals division (non-consolidated)	January 1, 2010 to December 31, 2010 results			FY2011 results			FY 2011 forecasts
	January 1 to June 30	January 1 to September 30 (A)	January 1 to December 31	January 1 to June 30	January 1 to September 30 (B)	Change on January 1 to September 30, 2010 (B/A)	January 1 to December 31
Bio-Chemical division total	28.7	41.1	54.2	25.9	38.0	92%	50.9
Pharmaceuticals / Industrial raw materials							
Amino acids	10.8	15.3	20.4	10.1	14.9	97%	19.7
Nucleic acids and vitamins	2.5	3.7	4.8	2.7	4.0	107%	5.2
Other	3.9	5.8	8.0	3.8	5.4	93%	7.2
Health care products	4.9	7.4	9.8	4.7	7.0	95%	9.3

4. Kyowa Hakko Chemical

Billions of yen, rounded down

Chemicals division (non-consolidated)	January 1, 2010 to December 31, 2010 results			FY2011 results
	January 1 to June 30	January 1 to September 30	January 1 to December 31	January 1 to March 31
Chemicals division total	39.7	61.9	85.7	22.9
Solvents	15.9	24.4	33.4	8.4
Raw materials for plasticizers	12.2	19.9	27.7	7.7
Specialty chemicals	9.9	15.2	21.2	5.9

Note: The Chemicals Business was discontinued at the end of the first quarter following the transfer of all shares of Kyowa Hakko Chemical on March 31, 2011. As a result, income from Chemicals are until the first quarter ended March 31, 2011.

R&D PIPELINES

Filed · Approved

Oct 20th 2011

Therapeutic area	Code Name Generic Name	Mechanism of action	Stage		Indication	Formulation	In-house or Licensed	Remarks
			Japan	Other countries				
Oncology	KW-0761 Mogamulizumab	Anti-CCR4 humanized antibody	Filed Apr/2011		Adult T-cell leukemia/lymphoma	Injection	In-house	(※) POTELLIGENT®
	KRN321 Darbepoetin Alfa	Long-Acting Erythropoiesis Stimulating Agent	Filed Nov/2008		☆ Chemotherapy induced anemia	Injection	Kirin-Amgen	Launched for anemia of CKD patients
	Pegfilgrastim	Long-acting Granulocyte colony stimulating factor		Filed in Asia	Chemotherapy induced febrile neutropenia	Injection	Kirin-Amgen	Asia: Taiwan and Vietnam (Approved in Korea on September 8)
Nephrology	Cinacalcet Hydrochloride	Calcium receptor agonist		Filed in Asia	Secondary hyperparathyroidism	Oral	Licensed from NPS	Asia: Philippine, Malaysia and China (Approved in Singapore on August 2)
	Darbepoetin Alfa	Long-Acting Erythropoiesis Stimulating Agent		Filed in Asia	Renal Anemia (on dialysis)	Injection	Kirin-Amgen	Asia: Singapore (Approved in Philippines on June 23)
CNS	KW-6500 Apomorphine Hydrochloride	Dopamine receptor agonist	Filed Jul/2011		Parkinson's disease	Injection	Licensed from Britannia Pharmaceuticals Limited	
	KW-6002 Istradefylline	Adenosine A2a receptor antagonist		Filed in USA	Parkinson's disease	Oral	In-house	Reimbursement of license from Valeant International SFL for the development and commercialization of KW-6002 in the US and Canada.
Other	AMG531 Romiplostim	Thrombopoietin receptor agonist		Filed in Asia	Idiopathic (Immune) thrombocytopenic purpura	Injection	Kirin-Amgen	Asia: Singapore, Malaysia and Taiwan (Approved in Hong Kong on July 22)

Phase II, Phase III

Therapeutic area	Code Name Generic Name	Mechanism of action	Stage		Indication	Formulation	In-house or Licensed	Remarks	
			Japan	Other countries					
Oncology	KW-0761 Mogamulizumab	Anti-CCR4 humanized antibody		Phase I / II in USA	Peripheral T-cell lymphoma and cutaneous T-cell lymphoma	Injection	In-house	(※) POTELLIGENT®	
			Phase II		Adult T-cell leukemia/lymphoma, Add-on therapy (for untreated patients)				
			Phase II		Peripheral T/NK-cell Lymphoma				
	KW-2246 Fentanyl citrate	μ-opioid receptor agonist		Phase III		Cancer pain	Sublingual tablet	Licensed from Orexo	
	KRN125 Pegfilgrastim	Long-acting Granulocyte colony stimulating factor		Phase III		Chemotherapy induced febrile neutropenia	Injection	Kirin-Amgen	
	ARQ 197 tvantinib	c-Met inhibitor		Phase II in Japan and Korea		Gastric cancer	Oral	Licensed from ArQule	
			Phase III in Japan, Korea and Taiwan		Lung cancer				
Nephrology	KRN321 Darbepoetin Alfa	Long-Acting Erythropoiesis Stimulating Agent		Phase I / II in UK/US/PH	Multiple Myeloma	Injection	In-house		
			Phase III		☆ Paediatric Renal Anemia	Injection	Kirin-Amgen	Launched in Japan for anemia of CKD patients	
Immunology/Allergy	ASKP 1240	Anti-CD40 fully human antibody	Phase I	Phase II in USA	Organ transplant rejection	Injection	In-house	Jointly developed with Astellas	
	KHK4563 Benralizumab	Anti-IL-5 receptor humanized antibody	Phase II in Japan and Korea		Asthma	Injection	In-house	Being developed by Medimmune as MEDI-563 worldwide except in Japan and other Asian countries POTELLIGENT®	
	Z-206 Mesalazine	pH dependent controlled release tablet	Phase II		☆ Crohn's disease	Oral	Licensed from Zeria Pharma.	Jointly developed with Zeria Pharma Launched in Japan for ulcerative colitis.	
CNS	KW-6002 Istradefylline	Adenosine A2a receptor antagonist	Phase III		Parkinson's disease	Oral	In-house		
	KW-6485 Topiramate	Antiepileptic drugs	Phase III		☆ Pediatric epilepsy	Oral	Licensed from Janssen Pharmaceutical K.K.	Launched in Japan for use as an epileptic drug	
Other	KW-3357 Antithrombin	Recombinant human antithrombin	Phase III	Phase I in Europe	Disseminated intravascular coagulation, Congenital antithrombin deficiency	Injection	In-house		

Phase I

Therapeutic area	Code Name Generic Name	Mechanism of action	Stage		Indication	Formulation	In-house or Licensed	Remarks
			Japan	Other countries				
Oncology	KW-2450	IGF-1 receptor signal inhibitor		Phase I / II in USA	Cancer	Oral	In-house	
	KRN330	Anti-A33 fully human antibody		Phase I / IIa in USA	Cancer	Injection	In-house	
	BIW-8962	Anti-GM2 humanized antibody		Phase I / IIa in USA	Cancer	Injection	In-house	POTELLIGENT®
	KRN951 Tivozanib	VEGF receptor inhibitor	Phase I		Cancer	Oral	In-house	
	KHK2866	Anti-HB-EGF humanized antibody		Phase I in USA	Cancer	Injection	In-house	POTELLIGENT®
	LY2523355 Litroneisb	M phase kinesin Eg5 inhibitor	Phase I		Cancer	Injection	In-house	World wide outlicensed to Eli Lilly for the development and commercialization of LY2523355 except Japan
Nephrology	RTA 402 Bardoxolone Methyl	Antioxidant Inflammation Modulator	Phase I		Diabetic nephropathy	Oral	Licensed from Reata	
Other	KHK6188	Cannabinoid CB2 receptor agonist	Phase I		Neuropathic pain	Oral	In-house	
	KRN23	Anti-FGF23 fully human antibody		Phase I in USA	X-linked hypophosphatemic rickets/osteomalacia (XLH)	Injection	In-house	

(※) KW-0761 is outlicensed to Amgen Inc. on March 6th, 2008, with an exclusive right to develop and commercialize KW-0761 worldwide, except in Japan, Korea, China and Taiwan. Kyowa Hakko Kirin has retained the development and commercialization rights in th

Updated since Aug 2nd, 2011 (Area, Stage, Filed, Approved, Launched etc.)
★ New indication