

Kyowa Hakko Kirin Co., Ltd.**Appendix to the Fiscal 2010 Third Quarter Consolidated Financial Statements**

(January 1, 2010 - September 30, 2010)

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This document was made as a supplement to the Kessan Tanshin (financial report) for the third quarter of the fiscal year ending December 31, 2010. 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

	(Ref: 2009) January 1 to September 30 results (A)	April 1, 2009 to December 31, 2009		(Ref: 2009) January 1 to December 31 results	January 1, 2010 to December 31, 2010			
		April 1 to September 30 results	April 1 to December 31 results		January 1 to September 30 results (B)	Change on January to September 2009		January to December forecast
						Amount (B-A)	%	
Net sales	292,301	194,395	309,111	407,017	304,453	12,151	104%	408,000
Gross Profit	130,271	89,844	139,739	180,167	139,828	9,556	107%	-
Selling, general and administrative expenses	106,800	69,064	111,496	149,232	106,585	(215)	100%	-
Operating income (prior to amortization of goodwill)	30,521	25,431	35,221	40,311	40,220	9,698	132%	50,803
Operating income	23,470	20,779	28,243	30,934	33,242	9,771	142%	41,500
Other income	5,507	3,372	4,012	6,147	3,758	(1,748)		-
Other expenses	3,629	1,950	2,776	4,455	2,994	(634)		-
Non-operating income	25,348	22,201	29,479	32,626	34,006	8,657	134%	43,000
Extraordinary income	6,075	-	27	6,102	1,091	(4,983)		-
Extraordinary expenses	9,369	1,801	8,878	16,447	6,121	(3,248)		-
Income before income taxes	22,054	20,400	20,628	22,282	28,976	6,922	131%	37,000
Income taxes	10,002	9,423	11,631	12,210	14,513	4,511		-
Minority interests income	(3)	165	199	31	47	51		-
Net income	12,055	10,811	8,797	10,040	14,414	2,359	120%	19,000
EPS before goodwill amortization (¥/share)	33.38	27.05	27.63	33.97	37.55			49.68

*As a result of the change in fiscal year end, the figures used for comparison the above 2009 January 1 to September 30 results are the sum of the figures from the three month period from January 1 to March 31, 2009, obtained by subtracting figures for the nine month period (April 1, 2009 to December 31, 2009) from the figures for the twelve month period to March 2009, and the figures from the interim period of the fiscal year ending December 31, 2009. Also please note that figures for the Food segment are included in the reference figures for January 1 to March 31, 2009.

2. Trends in results by segment

(1) Results by operating segment

Millions of yen, rounded down

	(Ref: 2009) January 1 to September 30 results (A)	April 1, 2009 to December 31, 2009		(Ref: 2009) January 1 to December 31 results	January 1, 2010 to December 31, 2010			
		April 1 to September 30 results	April 1 to December 31 results		January 1 to September 30 results (B)	Change on January to September 2009		January to December forecast
						Amount (B-A)	%	
Net sales	292,301	194,395	309,111	407,017	304,453	12,151	104%	408,000
Pharmaceuticals	153,080	103,968	158,273	207,384	154,092	1,012	101%	207,000
Bio-Chemicals	62,336	41,417	69,751	90,670	63,968	1,632	103%	84,000
Chemicals	44,736	32,854	52,326	64,208	94,661	49,925	212%	128,000
Food	9,633	-	-	9,633	-	(9,633)	-%	-
Other	43,159	28,927	49,500	63,731	7,706	(35,452)	18%	10,000
Total	312,945	207,168	329,851	435,628	320,429	7,484	102%	429,000
Eliminations	(20,643)	(12,772)	(20,740)	(28,611)	(15,975)	4,667	77%	(21,000)
Operating income	23,470	20,779	28,243	30,934	33,242	9,771	142%	41,500
<i>*Before amortization of goodwill</i>	30,521	25,431	35,221	40,311	40,220	9,698	132%	50,803
Pharmaceuticals	26,532	21,363	26,657	31,826	26,465	(66)	100%	32,000
	33,003	25,677	33,129	40,455	32,937	(66)	100%	40,628
Bio-Chemicals	2,582	1,665	3,048	3,965	2,846	264	110%	4,000
	3,051	1,978	3,517	4,590	3,316	264	109%	4,625
Chemicals	(6,066)	(2,486)	(1,984)	(5,564)	3,557	9,623	(59%)	5,000
	(6,029)	(2,462)	(1,947)	(5,514)	3,594	9,623	(60%)	5,049
Food	87	-	-	87	-	(87)	-%	-
	161	-	-	161	-	(161)	-%	-
Other	204	170	400	434	252	48	124%	500
	204	170	400	434	252	48	124%	500
Total	23,340	20,712	28,122	30,750	33,122	9,781	142%	41,500
	30,391	25,363	35,100	40,127	40,099	9,708	132%	50,803
Eliminations	130	67	121	184	120	(10)	92%	-

Notes: 1. Figures representing amounts before amortization of goodwill have been italicized.

2. Results of subsidiaries Miyako Kagaku Co., Ltd., and Kashiwagi Corporation, are reported under the Chemicals segment rather than the Other segment as of the January 1, 2010 to December 31, 2010 period.

(2) Overseas sales

Millions of yen, rounded down

	(Ref: 2009)		April 1, 2009 to December 31, 2009				(Ref: 2009)		January 1, 2010 to December 31, 2010	
	January 1 to September 30 results	Percentage of consolidated sales	April 1 to September 30 results	Percentage of consolidated sales	April 1 to December 31 results	Percentage of consolidated sales	January 1 to December 31 results	Percentage of consolidated sales	January 1 to September 30 results	Percentage of consolidated sales
Overseas sales	53,567	18.3%	39,725	20.4%	63,367	20.5%	77,209	19.0%	63,641	20.9%
America	14,509	5.0%	10,688	5.5%	16,849	5.5%	20,670	5.1%	19,770	6.5%
Europe	15,823	5.4%	11,309	5.8%	18,524	6.0%	23,038	5.7%	16,085	5.3%
Asia	22,714	7.8%	17,420	9.0%	27,415	8.9%	32,709	8.0%	27,346	9.0%
Other regions	519	0.2%	306	0.2%	578	0.2%	790	0.2%	439	0.1%
Total consolidated net sales	292,301	100.0%	194,395	100.0%	309,111	100.0%	407,017	100.0%	304,453	100.0%

3. Trends in Other Income

Millions of yen, rounded down

	(Ref: 2009) January 1 to September 30 results	April 1, 2009 to December 31, 2009		(Ref: 2009) January 1, 2009 to December 31, 2009 results	January 1 to December 31, 2010
		April 1 to September 30 results	April 1 to December 31 results		January 1 to September 30 results
Non-operating income	5,507	3,372	4,012	6,147	3,758
Interest income	403	249	443	597	298
Dividends income	2,544	1,125	914	2,333	557
Foreign exchange gain	135	-	-	135	-
Equity in earnings of affiliates	1,160	945	1,558	1,774	1,150
Other	1,262	1,051	1,095	1,306	1,753
Other expenses	3,629	1,950	2,776	4,455	2,994
Interest expenses	262	153	244	354	172
Foreign exchange losses	(52)	503	112	(443)	1,051
Loss from disposal of noncurrent assets	2,121	843	1,163	2,441	1,121
Other	1,297	449	1,255	2,103	648

4. Trends in Extraordinary Income / Losses

Millions of yen, rounded down

	(Ref: 2009) January 1 to September 30 results	April 1, 2009 to December 31, 2009		(Ref: 2009) January 1, 2009 to December 31, 2009 results	January 1 to December 31, 2010
		April 1 to September 30 results	April 1 to December 31 results		January 1 to September 30 results
Extraordinary income	6,075	-	27	6,102	1,091
Gain on negative goodwill	-	-	-	-	854
Gain on sales of investment securities	-	-	-	-	120
Reversal of allowance for doubtful accounts	-	-	-	-	117
Gain on sale of noncurrent assets	-	-	27	27	-
Gain on sale of shares in affiliates	4,721	-	-	4,721	-
Gain of sale of investments in affiliates	1,354	-	-	1,354	-
Extraordinary losses	9,369	1,801	8,878	16,447	6,121
Loss on valuation of investment securities	1,789	421	537	1,905	2,833
Loss on revision to retirement benefit plan	-	-	-	-	1,771
Non-recurring depreciation on noncurrent assets	-	-	3,299	3,299	1,225
Loss on sale of noncurrent assets	-	-	-	-	189
Loss on sales of investment securities	-	-	991	991	101
Impairment loss	3,793	-	2,671	6,464	-
Loss from change in equity	1,379	1,379	1,379	1,379	-
Integration-related expenses	1,429	-	-	1,429	-
Other	977	-	-	977	-

5. Trends in R&D Expenses

Billions of yen, rounded down

	(Ref: 2009) January 1 to September 30 results	April 1, 2009 to December 31, 2009		(Ref: 2009) January 1, 2009 to December 31, 2009 results	January 1 to December 31, 2010	
		April 1 to September 30 results	April 1 to December 31 results		January 1 to September 30 results	January 1 to December 31 forecast
R&D (Consolidated)	31.2	19.7	34.9	46.4	32.3	47.0
R&D to net sales ratio	10.7%	10.2%	11.3%	11.4%	10.6%	11.6%
Pharmaceuticals	27.6	17.5	31.6	41.6	29.2	42.1
(R&D to net sales ratio)	18.1%	16.9%	20.0%	20.1%	19.0%	20.6%
Bio-Chemicals	2.5	1.6	2.5	3.4	2.3	3.7
Chemicals	0.7	0.5	0.7	1.0	0.7	1.0
Food	0.2	-	-	0.2	-	-
Other	-	-	-	-	-	-

6. Trends in Capital Expenditure (Tangible fixed assets)

Billions of yen, rounded down

	(Ref: 2009) January 1 to September 30 results	April 1, 2009 to December 31, 2009		(Ref: 2009) January 1, 2009 to December 31, 2009 results	January 1 to December 31, 2010	
		April 1 to September 30 results	April 1 to December 31 results		January 1 to September 30 results	January 1 to December 31 forecast
Capital expenditure (Consolidated)	20.9	15.3	24.0	29.6	17.1	26.5
Pharmaceuticals	13.5	9.4	15.4	19.5	9.1	13.5
Bio-Chemicals	4.8	3.3	4.9	6.4	5.8	9.8
Chemicals	3.8	2.5	3.5	4.9	2.2	3.1
Food	0.0	-	-	0.0	-	-
Other	0.0	0.0	0.0	0.0	0.0	0.0
Eliminations	(1.5)	(0.0)	(0.0)	(1.5)	(0.0)	-

7. Trends in Depreciation Expenses

Billions of yen, rounded down

	(Ref: 2009) January 1 to September 30 results	April 1, 2009 to December 31, 2009		(Ref: 2009) January 1, 2009 to December 31, 2009 results	January 1 to December 31, 2010	
		April 1 to September 30 results	April 1 to December 31 results		January 1 to September 30 results	January 1 to December 31 forecast
Depreciation expenses (Consolidated)	13.0	8.6	17.0	21.4	16.2	22.9
Pharmaceuticals	5.5	3.8	9.2	10.9	7.3	11.5
Bio-Chemicals	3.8	2.6	4.3	5.5	5.4	6.6
Chemicals	3.2	2.1	3.3	4.4	3.4	4.7
Food	0.2	-	-	0.2	-	-
Other	0.1	0.0	0.1	0.1	0.0	0.0
Eliminations	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	-

8. Trends in Key Indicators

(1) Exchange rate

	(Ref: 2009) January 1 to September 30 results	April 1, 2009 to December 31, 2009		(Ref: 2009) January 1, 2009 to December 31, 2009 results	January 1 to December 31, 2010	
		April 1 to September 30 results	April 1 to December 31 results		January 1 to September 30 results	January 1 to December 31 forecast
US Dollar (¥/US\$)	95	96	94	94	90	88
Euro (¥/Euro)	129	133	133	130	118	115

(2) Operating indicators (Consolidated)

	April 1, 2009 to December 31, 2009		January 1 to December 31, 2010
	April 1 to September 30 results	April 1 to December 31 results	January 1 to September 30
(prior to amortization of goodwill)	27.05	27.63	37.55
Net income per share (yen)	18.91	15.41	25.30
Operating income to sales ratio (%)	10.7%	9.1%	10.9%
Total assets (million yen)	716,199	695,268	673,094
Net assets (million yen)	547,942	540,343	538,064
Equity ratio (%)	75.9	77.1	79.8
Net assets per share (yen)	953.91	940.79	942.38
Number of staff at end of term	7,443	7,436	7,499

II. Consolidated Subsidiaries and Affiliates

(As of September 30, 2010)

Segment	Type	Company name	Percentage owned (direct and indirect)	Principal business
Pharmaceuticals	Consolidated subsidiary	Kyowa Medex Co., Ltd.	100.0%	Manufacture and sale of diagnostic reagents
		Kirin Kunpeng (China) Bio-Pharmaceutical Co., Ltd.	100.0%	Manufacture and sale of pharmaceuticals (China)
		Kyowa Medical Promotion Co., Ltd.	100.0%	Sales promotion of pharmaceuticals
		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
		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)
		Kyowa Hakko Kirin Italia S.r.l.	100.0%	Sale of pharmaceuticals (Italy)
		Jeil-Kirin Pharm. Inc.	90.0%	Sale of pharmaceuticals (Korea)
		Kyowa Hakko Kirin (Taiwan) Co., Ltd.	100.0%	Sale of pharmaceuticals (Taiwan)
		Kyowa Hakko Kirin (Hong Kong) Co., Ltd.	100.0%	Sale of pharmaceuticals (Hong Kong)
Kyowa Hakko Kirin (Singapore) Pte. Ltd.	100.0%	Sale of pharmaceuticals (Singapore)		
Bio-Chemicals	Consolidated subsidiary	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
		BioKyowa Inc.	100.0%	Manufacture and sale of amino acids (US)
		Shanghai Kyowa Amino Acid Co., Ltd.	70.0%	Manufacture and sale of amino acids (China)
		Kyowa Hakko U.S.A., Inc.	100.0%	Sale and import/export of fine chemicals including amino acids (US)
		Kyowa Hakko Europe GmbH	100.0%	Sale and import/export of fine chemicals including amino acids (Germany)
		Kyowa Hakko Bio Italia S.r.l. (*1)	100.0%	Sale and import/export of fine chemicals including amino acids (Italy)
		Kyowa Hakko (Hong Kong) Co., Ltd.	100.0%	Sale and import/export of fine chemicals including amino acids (Hong Kong)
		Kyowa Hakko Bio Singapore Pte. Ltd. (*1)	100.0%	Sale and import/export of fine chemicals including amino acids (Singapore)
		Kyowa Hakko Bio U.S. Holdings, Inc.	100.0%	Holding company for administration and management of US subsidiaries (US)
		Kyowa Wellness Co., Ltd.	100.0%	Sale of healthcare products
Chemicals	Consolidated subsidiary	Kyowa Hakko Chemical Co., Ltd.	100.0%	Manufacture and sale of chemicals
		Miyako Kagaku Co., Ltd. (*2)	100.0%	Wholesale of pharmaceutical raw materials, chemicals, foods, etc.
		Kashiwagi Corporation (*2)	100.0%	Wholesale of chemicals, food, etc.
	Affiliate accounted for by the equity method	J-Plus Co., Ltd.	50.0%	Manufacture and sale of plasticizers
		Kurogane Kasei Co., Ltd.	40.0%	Manufacture and sale of plasticizers, fine chemicals, etc.
Other	Consolidated subsidiary	Chiyoda Kaihatsu Co., Ltd.	100.0%	Transportation, insurance, wholesale of food, etc.
		Japan Synthetic Alcohol Co., Ltd.	33.3%	Manufacture and sale of industrial use alcohol
	Affiliate accounted for by the equity method	Kirin Kyowa Foods Company, Limited	35.0%	Manufacture and sale of seasonings, confectionery and bread products
		Kirin Kyowa FD Co., Ltd.	35.0%	Manufacture and sale of freeze-dried foods
		Kirin Ohland Foods Co., Ltd.	35.0%	Manufacture and sale of bakery products, etc.
		AjiNihon Co., Ltd.	16.2%	Manufacture and sale of foods and seasonings, etc.
Zenmi Foods Inc.	17.5%	Manufacture and sale of seasonings		

Notes: 1. Changes to the scope of consolidation

Newly consolidated: Two companies: Kyowa Hakko Bio Italia S.r.l. and Kyowa Hakko Bio Singapore Pte. Ltd.

2. As of the January 1, 2010 to December 31, 2010 period Miyako Kagaku Co., Ltd., and Kashiwagi Corporation are reported under the Chemicals segment rather than the Other segment.

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

1. Kyowa Hakko Kirin

Billions of yen, rounded down

Pharmaceuticals division (non-consolidated)	(Ref: 2009) January 1 to September 30 results	April 1, 2009 to December 31, 2009		(Ref: 2009) January 1, 2009 to December 31, 2009 results	January 1 to December 31, 2010	
		April 1 to September 30 results	April 1 to December 31 results		January 1 to September 30 results	January 1 to December 31 forecast
Pharmaceutical division total	138.6	94.9	143.9	187.6	140.7	190.6
Central nervous system agents						
<i>Depakene</i>	8.1	5.7	8.8	11.2	7.9	11.0
<i>Topina</i>	1.0	0.8	1.2	1.5	1.5	1.9
Sensory organ agents						
<i>Patanol</i>	6.3	1.9	3.0	7.4	6.0	7.5
Circulatory organ agents						
<i>Coniel</i>	16.8	11.7	18.3	23.3	15.3	20.8
<i>Inovan / Pre Dopa</i>	2.5	1.7	2.7	3.5	2.2	3.3
<i>Coversyl</i>	3.5	2.4	3.7	4.8	3.0	4.4
Digestive organ agents						
<i>Nauzelin</i>	3.7	2.4	3.8	5.1	3.6	5.3
Other agent affecting metabolism						
<i>Nesp/Espo</i>	35.0	25.7	39.6	48.9	36.8	50.0
<i>Regpara</i>	4.7	3.4	5.5	6.8	6.7	9.1
Agents relating to blood and body fluids						
<i>Gran/Neu-up*2</i>	12.1	8.9	13.8	17.0	11.1	15.1
Anticancer agents						
<i>Farmorubicin / Adriacin</i>	4.8	3.3	4.9	6.4	3.6	4.8
<i>5 – FU (all types)</i>	2.7	1.9	2.9	3.7	2.3	2.7
<i>Navelbine</i>	2.2	1.5	2.2	2.9	1.5	2.1
Antiallergic agents						
<i>Allelock</i>	20.3	10.9	17.3	26.7	19.1	25.5
<i>Celtect</i>	2.5	1.5	2.3	3.3	2.0	2.7
Exports and Technology Out-Licensing	14.5	11.7	15.1	18.0	19.9	24.6

Notes 1: Results based on settlement price on a shipment basis. Forecasts are based on an actual consumption basis.

2: As of March 1, 2010, manufacturing, sales and other rights for Neu-up will be transferred to Yakult Honsha. Therefore, Gran/Neu-up figures after March 31, 2010 include only sales figures for Gran.

2. Kyowa Hakko Bio

Billions of yen, rounded down

Bio-Chemicals division (non-consolidated)	(Ref: 2009) January 1 to September 30 results	April 1, 2009 to December 31, 2009		(Ref: 2009) January 1, 2009 to December 31, 2009 results	January 1 to December 31, 2010	
		April 1 to September 30 results	April 1 to December 31 results		January 1 to September 30 results	January 1 to December 31 forecast
Bio-Chemical division total	40.1	27.0	42.3	55.4	41.1	52.2
Pharmaceuticals / Industrial raw materials						
Amino acids	13.8	9.4	14.8	19.1	15.3	19.5
Nucleic acids and vitamins	3.1	2.1	3.5	4.5	3.7	4.9
Health care products	6.2	4.2	6.5	8.4	7.4	9.0
Agrochemicals, livestock and fisheries products*1	2.5	1.5	2.1	3.2	1.5	1.9
Alcohol*2	6.9	4.8	7.8	9.8	5.5	7.6

Notes 1. As of April 1, 2010 the domestic livestock and fisheries industry product sales operations of Kyowa Hakko Bio Co., Ltd. have been transferred to Aska Pharmaceuticals Co., Ltd.

2. On July 1, 2010, the Kyowa Hakko Bio Co., Ltd. alcohol business is scheduled to be transferred to Daiichi Alcohol Co. Ltd., a joint venture with Mercian Corporation (planned investment ratio: 35%).

3. Kyowa Hakko Chemical

Billions of yen, rounded down

Chemicals division (non-consolidated)	(Ref: 2009) January 1 to September 30 results	April 1, 2009 to December 31, 2009		(Ref: 2009) January 1, 2009 to December 31, 2009 results	January 1 to December 31, 2010	
		April 1 to September 30 results	April 1 to December 31 results		January 1 to September 30 results	January 1 to December 31 forecast
Chemicals division total	44.7	32.8	52.3	64.2	61.9	84.9
Solvents	19.2	14.5	22.6	27.2	24.4	34.5
Raw materials for plasticizers	13.4	9.9	16.3	19.8	19.9	27.4
Specialty chemicals	10.0	6.8	11.3	14.5	15.2	20.0

R&D PIPELINES

Phase II, Phase III

Oct 28th 2010

Category	Code Name Product Name	Generic Name	Stage		Indication	Formulation	In-house or Licensed	Remarks
			Japan	Other countries				
Cancer/Hematology	KW-0761		Phase II		Cancer (Adult T-cell leukemia/lymphoma)	Injection	Developed In-house	Humanized monoclonal antibody (※)
				Phase I / II a in USA	Cancer (Peripheral T-cell lymphoma and cutaneous T-cell lymphoma)			
			Phase II		Cancer (Adult T-cell leukemia/lymphoma, Add-on therapy)			
			Phase II		Cancer (Peripheral T/NK-cell Lymphoma)			
	KRN321 NESP	Darbepoetin Alfa	Filed Nov/2008		☆ Chemotherapy induced anemia	Injection	Kirin-Angen	Long-acting erythropoiesis stimulating protein Launched in Japan for anemia of CKD patients on dialysis from July 2007.
	AMG531	Romiplostim	Filed Mar/2010		Immune thrombocytopenic purpura	Injection	Kirin-Angen	Thrombopoiesis stimulating protein
	KW-2246	Fentanyl citrate	Phase III		Cancer pain	Sublingual tablet	Licensed from Orexo	
KRN125	Pegfilgrastim	Phase II		Neutropenia	Injection	Kirin-Angen	Long-acting G-CSF	
ARQ197		Phase II		Cancer (Gastric cancer)	Oral	Licensed from ArQule.		
Kidney	KRN321 NESP	Darbepoetin Alfa	Approved Apr/2010		☆ Anemia (not on dialysis)	Injection	Kirin-Angen	Long-acting erythropoiesis stimulating protein Launched in Japan for anemia of CKD patients on dialysis
				Phase II in China	Anemia (on dialysis)			
	KRN1493 REGPARA	Cinacalcet Hydrochloride		Phase III in China	secondary hyperparathyroidism	Oral	Licensed from NPS	Japan: Already launched
Immunology/Allergy	KW-4679 ALLELOCK	Olopatadine Hydrochloride		Approved in China Jul/2010	Allergy	Oral	Developed In-house	Japan: Already launched
CNS	KW-6002	Istradefylline	Phase III	Licensed-out Jun/2010	Parkinson's disease	Oral	Developed In-house	Entered into a license agreement with Biovail Laboratories International SRL
	KW-6500	Apomorphine Hydrochloride	Phase III		Parkinson's disease	Injection	Licensed from Britannia Pharma.	

Phase I

Category	Code Name Product Name	Generic Name	Stage		Indication	Formulation	In-house or Licensed	Remarks
			Japan	Other countries				
Cancer/Hematology	KW-2450			Phase I in USA	Cancer	Oral	Developed In-house	
	KW-2478			Phase I / II a in EU/US	Cancer	Injection	Developed In-house	
	KRN330			Phase I / II a in USA	Cancer	Injection	Developed In-house	Fully human monoclonal antibody
	BIW8962			Phase I / II a in USA	Cancer	Injection	Developed In-house	Humanized monoclonal antibody
	KRN951		Phase I		Cancer	Oral	Developed In-house	
	ARQ197		Phase I		Cancer	Oral	Licensed from ArQule.	
Kidney	RTA402	Bardoxolone methyl	Phase I		diabetic nephropathy	Oral	Licensed from Reata	
Immunology/Allergy	KHK4563		Phase I		Asthma	Injection	Developed In-house	Humanized monoclonal antibody Being developed by MedImmune as MEDI-563 worldwide except in Japan and other Asian countries
	Z-206 ASACOL	Mesalazine	Phase I		☆ Crohn's disease	Oral <small>(SIF dependent controlled-release formulation)</small>	Licensed from Zeria Pharma.	Jointly developed with Zeria Pharma Launched in Japan for ulcerative colitis from December, 2009.
	ASKP1240		Phase I	Phase I in USA	Organ Transplant Rejection	Injection	Developed with Astellas.	Fully human monoclonal antibody
Other	KHK6188		Phase I		Neuropathic pain	Oral	Developed In-house	
	KW-3357	Antithrombin	Phase I	Phase I in Europe	Disseminated intravascular coagulation, Congenital antithrombin deficiency	Injection	Developed In-house	Recombinant antithrombin product
	KRN23		Phase I	Phase I in USA	X-linked Hypophosphatemic rickets/osteomalacia (XLH)	Injection	Developed In-house	Fully human monoclonal antibody

(※) 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 these countries. (Amgen has initially acquired the rights in all non-oncology indications, and Kyowa Hakko Kirin will continue its development activities in oncology until the completion of Phase II a. At that time, Amgen may elect to reimburse Kyowa Hakko Kirin for its oncology-related development costs, expand its license to include oncology and assume the development and commercialization of KW-0761 in oncology settings.

(Note)

In Philippines, an NDA of Filgrastim(G-CSF) has been filed for neutropenia. In Vietnam, an NDA of Pegfilgrastim(peg-G-CSF) has been filed.
In Korea, Taiwan and Hong Kong(Macau), NESP(long-acting erythropoiesis stimulating protein) was approved. In Thailand, Singapore, Malaysia and Philippines, an NDA of NESP has been filed. In India, NESP is currently in phase 3 clinical trial.
In Korea, Taiwan and Hong Kong(Macau), REGPARA(regulator of parathyroid gland) was approved. In Singapore, an NDA of REGPARA has been filed.
In Hong Kong, Taiwan, Malaysia, Singapore, an NDA of Nplate has been filed. In Taiwan and Korea, an NDA of Neulasta has been filed.

Updated since July 28th, 2010 (Area, Stage, Filed, Approved, Launched etc.)

★ New indication