

## Kyowa Hakko Kirin Co., Ltd.

## **Appendix to the Consolidated Financial Statements**

First quarter results for Fiscal 2009

(April 1, 2009 - June 30, 2009)

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This document was made as a supplement to the Kessan Tanshin (financial report) for the first quarter of the fiscal nine-month period 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.

#### 1. Trends in Consolidated Financial Results

1. Trends in income Millions of yen, rounded down

1. Treflus in income									
		April 1, 2					April 1, 2009 1		
		March 3	1, 2009		December 31, 2009				
	Apr. 2008 to	•	Apr. 2008	,	Apr. 2009 to		quarter arison	Apr. 2009 to	Apr. 2009 to
	Jun. 2008 (A)	to Sep. 2008	to Dec. 2008	results	Jun. 2009 (B)	Amount change (B-A)	Percentage amount	Sep. 2009 forecast	Dec. 2009 forecast
Net sales	125,435	247,769	362,278	460,183	96,816	(28,619)	77%	190,000	305,000
Gross Profit	58,843	109,345	159,870	200,297	44,517	(14,325)	76%	-	
Selling, general and administrative expenses	41,770	80,180	117,174	154,910	33,476	(8,294)	80%		-
Operating income (prior to amortization of									
goodwill)	19,471	33,962	49,893	54,983	13,367	(6,104)	69%	22,151	36,977
Operating income	17,072	29,164	42,696	45,387	11,041	(6,031)	65%	17,500	30,000
Other income	2,772	3,093	3,736	5,871	2,457	(314)		-	
Other expenses	1,049	1,899	3,166	4,846	952	(97)		-	
Recurring income	18,795	30,357	43,265	46,412	12,546	(6,248)	67%	19,000	31,500
Extraordinary income		-		6,075				-	
Extraordinary losses	1,523	4,769	13,981	21,550	1,734	211			
Net income before income taxes	17,272	25,588	29,284	30,937	10,812	(6,459)	63%	17,000	28,000
Total corporate taxes	7,515	16,948	18,355	18,934	4,983	(2,532)			
Income (loss) in minority interests	167	353	445	276	129	(38)			
Net income	9,588	8,285	10,483	11,726	5,699	(3,889)	59%	8,000	14,000
EPS before goodwill amortization (¥/share)	¥20.87	¥22.79	¥30.80	¥37.14	¥14.00			¥22.13	¥36.72

The Kyowa Hakko Kirin fiscal year end has changed from March 31 to December 31. As a result, the fiscal period to December 31, 2009 is a nine-month fiscal period.

#### 2. Trends in results by segment

(1) Results by operating segment

Millions of yen, rounded down

			April 1, 2 March 3			April 1, 2009 to December 31, 2009				
		Apr. 2008 to	Apr. 2008	Apr. 2008	Full year	Apr. 2009 to		luarter arison	Apr. 2009 to	Apr. 2009 to
		Jun. 2008 (A)	to Sep. 2008	to Dec. 2008	results	Jun. 2009 (B)	Amount change (B-A)	Percentage amount	Sep. 2009 forecast	Dec. 2009 forecast
Net sa	les	125,435	247,769	362,278	460,183	96,816	(28,619)	77%	190,000	305,000
	Pharmaceuticals	59,190	108,719	161,337	210,448	52,211	(6,979)	88%	101,000	157,000
	Bio-Chemicals	22,944	45,711	67,545	88,464	21,145	(1,799)	92%	42,000	70,000
	Chemicals	25,135	57,204	77,322	89,204	15,034	(10,101)	60%	31,000	50,000
	Food	10,393	20,804	32,834	42,468		(10,393)	-%		
	Other	17,892	36,572	54,502	68,733	14,195	(3,696)	79%	28,000	48,000
	Total	135,555	269,011	393,542	499,319	102,586	(32,969)	76%	202,000	325,000
	Eliminations	(10,120)	(21,241)	(31,264)	(39,135)	(5,770)	4,349	57%	(12,000)	(20,000)
Opera	ting income	17,072	29,164	42,696	45,387	11,041	(6,031)	65%	17,500	30,000
	(Before goodwill amortization)	(19,471)	(33,962)	(49,893)	(54,983)	(13,367)	(6,104)	(69%)	(22,151)	(36,977)
	Pharmaceuticals	12,851	19,699	29,662	34,832	11,570	(1,280)	90%	17,000	26,500
		(15,008)	(24,013)	(36,134)	(43,460)	(13,727)	(1,280)	(91%)	(21,314)	(32,971)
	Bio-Chemicals	2,972	5,216	7,425	8,342	1,277	(1,694)	43%	2,000	3,800
		(3,128)	(5,529)	(7,894)	(8,967)	(1,434)	(1,694)	(46%)	(2,313)	(4,269)
	Chemicals	509	2,960	3,532	(47)	(2,073)	(2,582)	%	(1,900)	(1,000)
		(521)	(2,984)	3,569	(2)	(2,060)	(2,582)	(%)	(1,876)	(963)
	Food	396	565	999	1,086		(396)	%		
		(469)	(711)	(1,218)	(1,379)	()	(469)	(%)	()	()
	Other	273	687	1,060	1,094	184	(89)	67%	400	700
		(273)	(687)	(1,060)	(1,094)	(184)	(89)	(67%)	(400)	(700)
	Total	17,002	29,128	42,680	45,308	10,960	(6,042)	64%	17,500	30,000
		(19,401)	33,926	49,877	(54,904)	(13,285)	(6,116)	(68%)	(22,151)	(36,977)
	Eliminations	69	35	15	78	81	11	116%	-	I

The Food business segment has been excluded as of the period ending December 31, 2009. This is due to the sale of shares of the consolidated food subsidiary businesses at the end of the previous fiscal year.

(2) Overseas sales Millions of yen, rounded down

		April 1, 2008 to March 31, 2009								l 1, 2009 to nber 31, 2009
	Apr. 2008 to Jun. 2008	Percentage of consolidated sales	Apr. 2008 to Sep. 2008	Percentage of consolidated sales	Apr. 2008 to Dec. 2008	Percentage of consolidated sales	Full year results	Percentage of consolidated sales	2009 to	Percentage of consolidated sales
Overseas sales	31,711	25.3%	59,032	23.8%	74,928	20.7%	88,700	19.3%	18,444	19.1%
America	15,859	12.6%	23,635	9.5%	27,202	7.5%	31,023	6.7%	4,738	4.9%
Europe	6,720	5.4%	12,792	5.2%	18,117	5.0%	22,631	4.9%	5,996	6.2%
Asia	8,981	7.2%	22,290	9.0%	28,960	8.0%	34,254	7.4%	7,627	7.9%
Other regions	149	0.1%	314	0.1%	647	0.2%	860	0.2%	82	0.1%
Total consolidated net sales	125,435	100%	247,769	100.0%	362,278	100.0%	460,183	100.0%	96,816	100.0%

#### 3. Trends in other income

Millions of yen, rounded down

3. Trends in other income Millions of yen, rounded do								
			2008 to 31, 2009		April 1, 2009 to December 31, 2009			
	Apr. 2008 to Jun. 2008	Apr. 2008 to Sep. 2008	Apr. 2008 to Dec. 2008	Full year results	Apr. 2009 to Jun. 2009			
Other income	2,772	3,093	3,736	5,871	2,457			
Interest income	185	351	534	688	158			
Dividend income	574	668	975	2,394	1,042			
Foreign exchange gain	1,388	442		135				
Income from equity method investments	303	694	995	1,211	743			
Other	319	936	1,230	1,441	513			
Other expenses	1,049	1,899	3,166	4,846	952			
Interest expense	190	300	413	523	83			
Foreign exchange loss			555		206			
Loss on disposal of fixed assets		856	1,205	2,483	296			
Other	859	742	991	1,839	365			

#### 4. Trends in extraordinary income / losses

Millions of yen, rounded down

4. ITCHUS III CALIGOTUINALY					yon, rounded down
			2008 to 31, 2009		April 1, 2009 to December 31, 2009
	Apr. 2008 to Jun. 2008	Apr. 2008 to Sep. 2008	Apr. 2008 to Dec. 2008	Full year results	Apr. 2009 to Jun. 2009
Extraordinary income	-	-		6,075	
Gain on sale of shares in affiliates				4,721	
Gain of sale of assets of affiliates				1,354	
Extraordinary losses	1,523	4,769	13,981	21,550	1,734
Loss from change in equity affiliates	-	-	-	1	1,379
Loss from revaluation of investment securities		180	5,266	6,634	354
Asset impairment losses	1,308	1,931	1,931	5,724	
Integration-related expenses	214	1,895	4,084	5,514	
Compensation payment			1,937	1,937	
Extraordinary depreciation of fixed assets		762	762	762	
Other				977	

Loss from change in equity affiliates resulted from the change in holdnigs of equity in affiliates following the April 1, 2009 merger of Kirin Food-Tech by Kyowa Hakko Food Specialties (now Kirin Kyowa Foods). an equity affiliate accounted for by the equity method

5. Trends in R&D expenses

Billions of yen, rounded down

5	5. Trends in R&D expenses Billions of yen, rounded down									
			•	2008 to 31, 2009		April 1, 2009 to December 31, 2009				
		Apr. 2008 to Jun. 2008	Apr. 2008 to Sep. 2008	Apr. 2008 to Dec. 2008	Full year results	Apr. 2009 to Jun. 2009	Apr. 2009 to Sep. 2009 forecast	Apr. 2009 to Dec. 2009 forecast		
R	&D (Consolidated)	14.3	25.9	36.9	48.3	9.3	22.6	35.5		
R	&D to net sales ratio (%)	11.4%	10.5%	10.2%	10.5%	9.7%	(11.9%)	11.6%		
	Pharmaceuticals	12.8	23.0	32.5	42.6	8.2	20.0	31.5		
	(R&D to net sales ratio) (%)	21.7%	21.2%	20.2%	20.3%	15.8%	(19.8%)	20.1%		
	Bio-Chemicals	0.9	1.8	2.7	3.6	0.8	2.0	3.0		
	Chemicals	0.3	0.5	0.8	1.1	0.2	0.6	0.9		
	Food	0.2	0.4	0.6	0.9					
	Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0		

# 6. Trends in capital expenditure

Billions of yen, rounded down

				, 2008 to 31, 2009	April 1, 2009 to December 31, 2009			
		Apr. 2008 to Jun. 2008	Apr. 2008 to Sep. 2008	Apr. 2008 to Dec. 2008	Full year results	Apr. 2009 to Jun. 2009	Apr. 2009 to Sep. 2009 forecasts	Apr. 2009 to Dec. 2009 forecast
Capital expenditure (Consolidated)		3.8	8.5	12.9	18.4	8.4	19.8	28.3
	Pharmaceuticals	1.4	3.6	5.5	9.6	5.3	11.8	17.5
	Bio-Chemicals	0.8	2.0	3.8	5.3	1.7	3.4	5.6
	Chemicals	1.4	2.4	2.9	4.3	1.4	4.4	5.0
	Food	0.0	0.3	0.4	0.5			
	Other	0.0	0.0	0.0	0.1	0.0	0.0	0.0
	Eliminations		(0)	(0)	(15)			

### 7. Trends in depreciation expenses

Billions of yen, rounded down

		April 1, 2008 to March 31, 2009				April 1, 2009 to December 31, 2009			
	Apr. 2008 to Jun. 2008	Apr. 2008 to Sep. 2008	Apr. 2008 to Dec. 2008	Full year results	Apr. 2009 to Jun. 2009	Apr. 2009 to Sep. 2009 forecasts	Apr. 2009 to Dec. 2009 forecast		
Depreciation expenses (Consolidated)	4.3	9.6	14.3	18.7	4.0	8.8	14.0		
Pharmaceuticals	1.9	4.6	6.6	8.3	1.7	3.8	5.9		
Bio-Chemicals	1.1	2.4	3.7	5.0	1.2	2.6	4.3		
Chemicals	0.9	2.0	3.0	4.2	0.9	2.2	3.5		
Food	0.2	0.4	0.7	0.9					
Other	0.0	0.0	0.0	0.1	0.0	0.0	0.1		
Eliminations	(0)	(0)	(0)	(0)	(0)				

## 8. Trends in key indicators

## (1) Exchange rate

(1) Exchange rate								
	April 1, 2008 to March 31, 2009				April 1, 2009 to December 31, 2009			
	Apr. 2008 to Jun. 2008	Apr. 2008 to Sep. 2008	Apr. 2008 to Dec. 2008	Full year results	Anr 2000 to	Apr. 2009 to Sep. 2009 forecasts	Apr. 2009 to Dec. 2009 forecast	
US Dollar (¥/US\$)	105	106	103	101	97	94	92	
Euro (¥/Euro)	164	163	151	143	133	126	124	

## (2) Operating indicators (Consolidated)

		April 1, March		April 1, 2009 to December 31, 2009	
	Apr. 2008 to Jun. 2008 Sep. 2008 Dec. 2008 Full y		Full year results	Apr. 2009 to Jun. 2009	
(prior to amortization of goodwill) Net income per share (yen)	(20.87) 16.69	(22.79) 14.43	(30.80) 18.26	(37.14) 20.43	(14.00) 9.94
Operating income to sales ratio (%)	13.6%	11.8%	11.8%	9.9%	11.4%
Total assets (million yen)	744,591	748,454	725,893	699,041	708,477
Net assets (million yen)	556,749	551,817	544,037	543,070	543,439
Equity ratio (%)	74.1%	73.1%	74.3%	77.0%	76.1%
Net assets per share (yen)	961.41	952.77	939.72	938.42	944.8
ROIC (Return on invested capital)*	4.7%	8.2%	12.1%	14.5%	3.5%
Number of staff at end of term	7,917.0	7,866.0	7,856.0	7,256.0	7,494

\* ROIC (%) =  $\frac{\text{Operating income}}{\text{(Fixed assets+Working capital)}}$  x100
Calculations for operating income are prior to amortization of goodwill and calculations for fixed assets do not include goodwill

				(As of June 30, 2009)																				
Segment	Туре	Company name	Percentage owned (direct and indirect)	Principal business																				
		Kyowa Medex Co., Ltd.	100.0%	Manufacture and sale of diagnostic reagents																				
		Kirin Kunpeng (China) Bio-Pharmaceutical Co., Ltd.	70.0%	Manufacture and sale and 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 and development of therapeutic antibodies (US)																				
	Consolidated	Kyowa Hakko Kirin Pharma, Inc.	100.0%	Development of outsourced pharmaceutical products																				
Pharmaceuticals	subsidiary	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)																				
		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)																				
		Kyowa Hakko Bio Co., Ltd.	100.0%	Manufacture and sale of pharmaceutical and industrial raw																				
		Daiichi Fine Chemical Co., Ltd.	100.0%	materials, and health care products  Manufacture and sale of active pharmaceutical ingredients and pharmaceutical intermediates																				
		Biokyowa Inc.	100.0%	Manufacture and sale of amino acids (US Company)																				
		Shanghai Kyowa Amino Acid Co., Ltd.	70.0%	Manufacture and sale of amino acids (China Company)																				
	Consolidated	Kyowa Hakko U.S.A., Inc.	100.0%	Sale and import/export of fine chemicals including amino acids (US Company)																				
Bio-Chemicals		Kyowa Hakko Europe GMBH	100.0%	Sale and import/export of fine chemicals including amino acids (Germany Company)																				
Die Grieffindare	subsidiary	Kyowa Italiana Farmaceutici S.R.L.	100.0%	Sale and import/export of fine chemicals including amino acids (Italy Company)																				
		Kyowa Hakko (H.K.) Co., Ltd.	100.0%	Sale and import/export of fine chemicals including amino acids (Hong Kong Company)																				
									•								-		<u></u>	-		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																				
		Shinwa Pharmaceutical Co., Ltd.	100.0%	Sale of herbal medicines and health foods																				
		Kyowa Engineering Co., Ltd.	100.0%	Design and installation of plant facilities and equipment																				
	Consolidated subsidiary	Kyowa Hakko Chemical Co., Ltd.	100.0%	Manufacture and sale of chemicals																				
Chamiasla	Affiliate	J-PLUS Co., Ltd.	50.0%	Manufacture and sale of plasticizers																				
Chemicals	accounted for by the equity method	Kurogane Kasei Co., Ltd.	40.0%	Manufacture and sale of plasticizers, fine chemicals, etc.																				
		Miyako Kagaku Co., Ltd.	52.9%	Wholesale sales of pharmaceuticals, chemicals, foods, etc.																				
	Consolidated subsidiary	Chiyoda Kaihatsu Co., Ltd.	100.0%	Transportation, insurance, sale of food, etc.																				
		Kashiwagi Corporation	62.9%	Wholesale sales of chemicals, pharmaceutical products, construction materials, etc.																				
		Japan Synthetic Alcohol Co., Ltd.	33.3%	Manufacture and sale of industrial use alcohol																				
Other		Kirin Kyowa Foods Company, Limited	35.0%	Manufacture and sale of seasonings, confectionery and bread products																				
Julei	Affiliate	Kyowa F.D. Foods Co., Ltd.	35.0%	Manufacture and sale of freeze-dried foods																				
	accounted for by the equity	Ohland Foods Co., Ltd.	35.0%	Manufacture and sale of bakery products, etc.																				
	method	Kyowa HiFoods Co. Ltd.	35.0%	Import and sale of foods, etc.																				
		Aji-Nihon Co., Ltd.	16.2%	Manufacture and sale of foods and seasonings, etc.																				
		Zenmi Foods Inc.	17.5%	Manufacture and sale of seasonings																				

Changes to the scope of consolidation

Newly consolidated: One company: Kyowa Hakko Kirin Pharma, Inc.
Eliminated: One company: Kyowa Hakko Kirin (Thailand) Co., Ltd.

# III. Net sales by division (items and main products presented on a non-consolidated basis)

Kyowa Hakko Kirin Co., Ltd.

Billions of yen, rounded down

21			, 2008 to 31, 2009		April 1, 2009 to December 31, 2009			
Pharmaceuticals division (Non-Consolidated)	Apr. 2008 to Jun. 2008 (A)	Apr. 2008 to Sep. 2008	Apr. 2008 to Dec. 2008	Full year results	Apr. 2009 to Jun. 2009 (B)	Change (B-A)	Apr. 2009 to Sep. 2009 forecasts	Apr. 2009 to Dec. 2009 forecast
Pharmaceutical division total	54.2	99.2	147.5	191.3	47.8	(6.4)	92.7	143.2
Central nervous system agents								
Depakene	2.7	5.3	8.3	10.7	2.8	0.1	5.4	8.5
Topina	0.1	0.3	0.6	0.9	0.3	0.2	0.7	1.1
Sensory organ agents								
Patanol	0.6	1.4	2.2	6.6	0.8	0.2	2.1	3.2
Circulatory organ agents								
Coniel	6.0	11.6	18.1	23.1	6.0	0.0	11.5	17.6
Inovan + Pre Dopa	0.9	1.8	2.9	3.7	0.9	0.0	1.7	2.7
Coversyl	1.4	2.6	4.0	5.0	1.2	(0.2)	2.3	3.6
Digestive organ agents								
Nauzelin	1.3	2.4	4.2	5.5	1.2	(0.1)	2.5	4.2
Other agents affecting metabolism								
Nesp/Espo	10.2	21.3	34.4	43.7	12.8	2.6	23.8	36.9
Regpara	0.8	1.9	3.3	4.6	1.6	0.8	3.1	5.0
Agents relating to blood and body	fluids							
Gran/Neu-up	4.5	9.1	14.3	17.6	4.4	(0.1)	8.7	13.4
Anticancer agents								
Farmorubicin + Adriacin	1.9	3.8	5.9	7.4	1.7	(0.2)	3.4	5.1
5-FU	0.9	1.8	2.8	3.6	0.9	0.0	1.8	2.8
Navelbine	0.8	1.5	2.4	3.1	0.8	0.0	1.5	2.3
Antiallergic agents								
Allelock	5.1	9.6	15.6	25.0	5.8	0.7	11.2	17.0
Celtect	0.9	1.7	2.6	3.6	0.8	(0.1)	1.4	2.2
Exports and technology out-licensing	15.3	22.8	26.3	29.1	5.5	(9.8)	10.8	14.7

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

Bio-Chemicals division	April 1, 2008 to March 31, 2009				April 1, 2009 to December 31, 2009			
(Non-consolidated)	Apr. 2008 to Jun. 2008 (A)	Apr. 2008 to Sep. 2008	Apr. 2008 to Dec. 2008	Full year results	Apr. 2009 to Jun. 2009 (B)	Change (B-A)	Apr. 2009 to Sep. 2009 forecasts	Apr. 2009 to Dec. 2009 forecast
Bio-Chemicals division total	14.9	28.4	42.1	55.2	13.6	(1.3)	26.5	40.3
Pharmaceuticals / Industrial raw materials								
Amino acids	5.3	10.2	14.9	19.3	4.9	(0.4)	9.4	14.1
Nucleic acids and vitamins	1.6	2.9	4.0	5.0	0.9	(0.7)	2.0	3.0
Health care products	2.1	4.2	6.2	8.1	2.1	0.0	4.3	6.3
Agrochemicals, livestock and fisheries products	0.8	1.6	2.5	3.6	0.8	0.0	1.6	2.4
Alcohol	2.4	4.6	7.2	9.3	2.4	0.0	4.2	6.8

Note 1: Figures until the second half of the fiscal year ending March 31, 2009 are those of the Bio-chemical division of Kyowa Hakko Kogyo Co., Ltd.

Kyowa Hakko Chemical non-consolidated

Billions of yen, rounded down

Chemicals division (Non-consolidated)	Apr	April 1, 2008 to March 31, 2009				April 1, 2009 to December 31, 2009			
	Apr. 2008 to Jun. 2008 (A)	Apr. 2008 to Sep. 2008	Apr. 2008 to Dec. 2008	Full year results	Apr. 2009 to Jun. 2009 (B)	Change (B-A)	Apr. 2009 to Sep. 2009 forecasts	Apr. 2009 to Dec. 2009 forecast	
Chemical division total (Kyowa Hakko Chemical non- consolidated)	25.1	57.1	77.3	89.2	14.9	(10.2)	31.0	50.0	
oonoonuutou,	25.1	57.1	11.3	09.2	14.9	(10.2)	31.0	50.0	
Solvents	11.9	25.5	35.0	39.7	4.1	(7.8)	14.1	22.0	
Raw materials for plasticizers	7.4	19.7	25.9	29.4	6.8	(0.6)	10.0	16.5	
Specialty chemicals	4.8	9.7	13.2	16.4	3.1	(1.7)	6.7	11.0	

### **R&D PIPELINES**

Kyowa Hakko Kirin (Phase Ⅱ, Phase Ⅲ)

July 29th 2009

Category	Code Name	Stage		Indication	Formulation	In-house or	Remarks
Category	Product Name	Japan	Other countries	Indication	Formulation	licensed	Remarks
Cancer/Hematology	KW-0761	Phase Ⅱ	Phase I in USA	Cancer (Hematologic tumor)	Injection	Developed In-house	Humanized monoclonal antibody
	KRN321 Nesp	Filed Nov/2008		☆ Chemotherapy induced anemia	Injection	Kirin-Amgen	Long-acting erythropoiesis stimulating protein An approval has been given in Japan for anemia o CKD patients on dialysis.
	AMG531	Phase ∭		Immune thrombocytopenic purpura	Injection	Kirin-Amgen	Thrombopoiesis stimulating peptibody The clinical development is being conducted by Ame Development KK as per agreement
	KW-2246	Phase Ⅲ		Cancer pain	Sublingual tablet	Licensed from Orexo.	
	KRN125	Phase Ⅱ		Neutropenia	Injection	Kirin-Amgen	Long-acting G-CSF
	AGS-003		Phase Ⅱ in USA and	Renal Cell Carcinoma	Injection	Developed with Argos.	Dendritic cell-based immunotherapeutics
	AGS-004		Phase Ⅱ in Canada	HIV	Injection	Developed with Argos.	Dendritic cell-based immunotherapeutics
	PB94 PHOSBLOCK		Filed in China Jun/2008	Hyperphosphatemia	Oral	Licensed from Chugai.	Launched in Japan
Kidney	KRN321 Nesp	Filed Dec/2008	Phase Ⅱ	☆ Anemia (not on dialysis)	Injection	Kirin-Amgen	Long-acting erythropoiesis stimulating protein An approval has been given in Japan for anemia of
			in China	☆ Anemia (on dialysis)			CKD patients on dialysis
Immunology/Allergy	KW-4679 ALLELOCK		Filed in China Jul/2008	Allergy	Oral	Developed In-house	Launched in Japan
	Z-206 ASACOL	Phase <u>II</u>		Inflammatory bowel disease (Crohn's disease)	Oral (pH depend controlled-release formulation)	Licensed from Zeria Pharma.	Jointly developed with Zeria Pharma
CNS	KW-6002	Phase Ⅱ b	Filed in USA Apr/2007	Parkinson's disease	Oral	Developed In-house	☆ Clinical trials for Mono-Therapy: Phase
	KW-6500	Phase Ⅱ		Parkinson's disease	Injection	Licensed from Britannia Pharma.	

Kyowa Hakko Kirin (Phase I)

Category	Code Name	Stage		Indication	Formulation	In-house or	Remarks
	Product Name	Japan	Other countries			licensed	
	KW-2450		Phase I	Cancer	Oral	Developed In-house	
	KRN654	Phase I / II		Essential thrombocythemia	Oral	Licensed from Shire.	
	KW-2449		Phase I / II a in USA	Cancer	Oral	Developed In-house	
Cancer/Hematology	KW-2478		Phase I in Europe	Cancer	Injection	Developed In-house	
	ARQ 197	Phase I		Cancer	Oral	Licensed from ArQule.	
	KRN330		Phase I / II a in USA	Cancer	Injection	Developed In-house	Fully human monoclonal antibody
	BIW-8962		Phase I in USA	Cancer	Injection	Developed In-house	Humanized monoclonal antibody
Immnology/Allergy	NU206		Phase I in Australia	Inflammatory bowel disease	Injection	Developed with ARCA biopharma (the former Nuvelo)	
	ASKP1240		Phase I in USA	Organ Transplant Rejection	Injection	Developed with Astellas.	Fully human monoclonal antibody Jointly developed with Astellas Pharma Inc.
Cardiovascular	KW-3902	Phase I		Acute heart failure with renal impairment	Injection	Developed In-house	
	KW-3357	Phase I		Disseminated intravascular coagulation, Congenital antithrombin deficiency	Injection	Developed In-house	Recombinant antithrombin product
Other	KRN23		Phase I in USA	Hypophosphatemic disease such as X-linked Hypophosphatemia (XLH)	Injection	Developed In-house	Fully human monoclonal antibody

(Note)
In the Philippines, an NDA of Filgrastim(G-CSF) has been filed for neutropenia.
In Korea, Hong Kong, Thailand, NespiLong-acting erythropoiesis stimulating protein) has been filed. In Taiwan, Nesp was approved.
In Korea and Taiwan, Regpara (Calcimimetic agent) has been filed. In Macau and Hong Kong, Regpara was approved.

**Kyowa Hakko Kirin (discontinued)** 

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	Category	Code Name	Stage		Indication	Formulation	In-house or	Reason	
		Product Name	Japan	Other countries			licensed		
ĺ	Other	KW-7158	Phase ∏a		Bowel disease (Irritable bowel syndrome)	Oral	Developed in-house	The profile of this product did not meet the criteria to support continuation of further development.	

Updated since Apr 30th, 2009 (Area, Stage, Filed, Approved, Launched etc.)
★ New indication