Kyowa Hakko KirinFiscal 2009 Interim Results

October 29, 2009

President & CEO

Yuzuru Matsuda

Kyowa Hakko Kirin Co., Ltd



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Summary of fiscal 2009 interim results

Summary of fiscal 2009 interim results: P&L

(¥bn)	Net sales	Operating income	Recurring income	Net income
FY2009 interim	194.3	20.7	22.2	10.8
Change	-53.3 (-21.5%)	-8.3 (-28.7%)	-8.1 (-26.9%)	+2.5 (+30.5%)
FY2008 interim	247.7	29.1	30.3	8.2

Summary

- Sales decreased, impacted by lower sales in the Chemicals business and the exclusion from consolidation of the Food segment
- Operating income decreased, effected by a sluggish Chemicals business and the effects of foreign exchange on the Bio-Chemicals business
- Pharmaceuticals: Although domestic sales of core products grew, sales decreased compared to the previous interim period when a one-off licensing payment for KW-0761 was recorded. Operating income increased, helped by integration benefits
- Bio-Chemicals: Sales and profits declined significantly affected by the strong yen, despite efforts to expand sales of amino acids for industrial and pharmaceutical raw materials (mainly for intravenous liquid and pharmaceutical use)
- >> Chemicals: Sales and profit dropped significantly due to the impact of the economic downturn that began in the autumn of the previous year

(¥bn)	FY2008 interim	FY2009 interim	Change
Net sales	108.7	103.9	-4.7
Operating income	19.6	21.3	+1.6
R&D expenses	23.0	17.5	-5.4

Reasons for changes (compared to FY2008 H1)

- Positive factors for sales and operating income included growth in sales of core products such as Nesp/Espo and Allelock, and contributions from new drugs such as Regpara. Expenses declined due to a decrease in in-licensing expenses while SG&A were reduced, mainly due to efficient management of R&D expenses
- Negative factors for sales and operating income include the effect of the one-off income recorded in the previous interim period as licensing payment for KW-0761

Sales of core pharmaceutical products



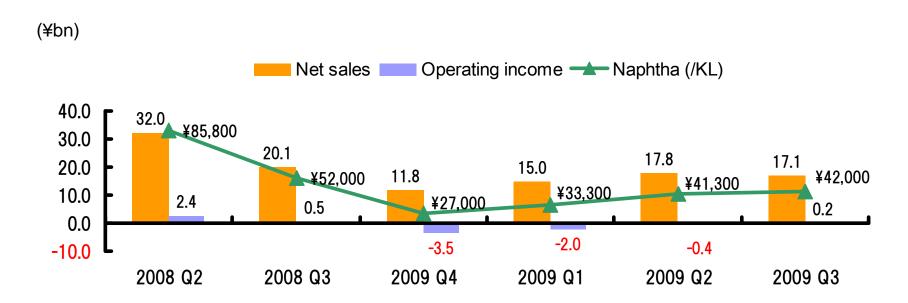
(¥bn)	FY2008 interim	FY2009 interim	Change
Nesp/Espo	21.3	25.7	21% 🕇
Coniel	11.6	11.7	1% 🕇
Allelock	9.6	10.9	14% 🕇
Patanol	1.4	1.9	36% 🕇
Gran/Neu-up*	9.1	8.9	2%↓
Depakene	5.3	5.7	8% 🕇
Coversyl	2.6	2.4	8%↓
Regpara	1.9	3.4	79% 🕇
Export and technology out-licensing revenues*	22.8	11.7	49%↓

(¥bn)	FY2008 interim	FY2009 interim	Change
Net sales	45.7	41.4	-4.2
Operating income	5.2	1.6	-3.5
Forex	¥106/\$ ¥163/€	¥96/\$ ¥133/€	-¥10/\$ -¥30/€

- Sales of amino acid for pharmaceutical and industrial raw material decreased due to the effects of the strong yen and other factors
- In healthcare products, domestic mail order sales were strong, but sales of raw materials for healthcare products were sluggish, primarily in the US, due to the effects of the global economic downturn
- Daiichi Fine Chemical's sales of vitamins declined due to weak vitamin markets

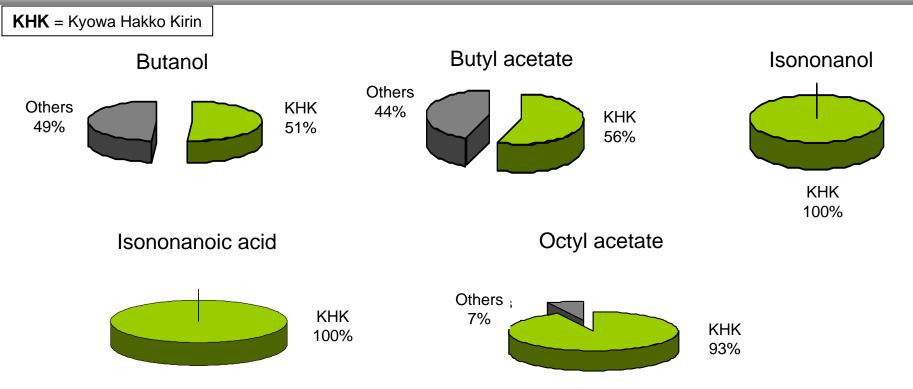
Chemicals business





- Along with the global economic slowdown since Autumn 2008, sales volumes have dropped while sales prices have been depressed due to the drop in the naphtha price, which is the index price for raw materials
- Since Spring 2009, measures to stimulate domestic demand in many countries have led to a recovery trend, particularly in China, and sales volumes have grown.
 Prices have been revised along with the rise in naphtha prices and the operating environment is improving.





- Many of Kyowa Kirin's basic chemical products have a high market share and we will continue to fulfill our responsibility to provide steady and secure supplies
- We expect expanding sales of Isononanoic acid, Octyl acetate and other environment-friendly products

Note: Environment-friendly products:

We are anticipating growth in 'people- or environment-friendly' chemical products such as synthetic fatty acids used as alternatives to fluorocarbons in raw materials for lubricant oils and raw materials for water-based plasticizers. We also have products with large market shares in these fields.



(¥bn)	Net sales	Operating income	Recurring income	Net income	Dividends (¥ per share)
2009 (AprDec.)	310.0	35.0	36.0	15.0	\/A.F
vs. 2008 (AprDec)	(-14.4%)	(-18.0%)	(-16.8%)	(+43.1%)	¥15
2008 (Apr Dec.)	362.2	42.6	43.2	10.4	_
April 08 - March 09	460.1	45.3	46.4	11.7	¥20

Nine month fiscal period, April – December 2009, resulting from change in fiscal year end.

- >> Change in fiscal year end to December results in a nine-month reporting period
- >> In Pharmaceuticals, we are aiming for increased sales and profits as the effect of a one-time licensing fee for KW-0761 recorded in the previous fiscal year is offset by growth in core pharmaceutical products and reduced expenses
- >> In Bio-Chemicals we aim to expand sales industrial and pharmaceutical raw materials (mainly amino acids for intravenous liquid and pharmaceutical use), but we expect forex and intensifying price competition in vitamins to have an effect
- >> A gradual recovery trend in the environment for the Chemicals business is expected (Oct. to Dec. forecast naphtha price: ¥42,000/kl)



(¥bn)	2008 Apr- Dec	2009 Apr-Dec	Change on adjusted figures
Net sales	161.3	162.0	+0.7
Operating income	29.6	33.5	+3.8
R&D expenses	32.5	29.0	-3.5

Apr-Dec	2008	2009
Yen /\$	¥103/\$	¥94/\$

We are forecasting an increase in revenues and profits for the Pharmaceuticals business

- >> Negative factors include the effect of a one-time licensing fee for KW-0761 in the comparable period and the impact of the strong yen on exports. We expect these to be offset by a significant increase in revenues from sales of core products such as Nesp/Espo, Allelock and Patanol, and new products such as Regpara.
- >> We are forecasting a year-on-year increase in operating income due to reduced SG&A expenses primarily from efficient R&D expense management in addition to a reduction of inlicensing fees compared to the previous period

Sales of core pharmaceutical products (9-months consolidated)

Fiscal 2009 forecasts:

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(¥bn)	2008/4-12	2009/4-12 (forecast)	Change	Forecasts at beginning of term	Forecasts at first quarter
Nesp/Espo	34.4	40.0	16% 🕇	35.1	36.9
Coniel	18.1	18.0	1%↓	17.3	17.6
Allelock	15.6	17.0	9% 🕇	16.4	17.0
Patanol	2.2	3.2	45% 🕇	3.2	3.2
Gran/Neu-up*	14.3	14.0	2%↓	13.4	13.4
Depakene	8.3	8.8	6% 🕇	8.5	8.5
Coversyl	4.0	3.6	10%↓	3.6	3.6
Regpara	3.3	5.0	52% 🕇	4.6	5.0
Export and technology out- licensing revenues*	26.3	14.7	44%↓	14.7	14.7

[★]2008 figures on a shipments basis. 2009 forecasts, on an actual consumption basis.

Fiscal 2009 forecasts:

Bio-Chemicals/ Chemicals (9-months consolidated)

(¥bn)		2008/4-12	2009/4-12	Change
Bio-	Sales	67.5	70.0	+2.5
Chemicals	Operating income	7.4	3.3	-4.1
Chemicals	Sales	77.3	50.0	-27.3
Chemicais	Operating income	3.5	-2.3	-5.8
Forex	¥/\$	¥103/\$	¥94/\$	-¥9/\$
rolex	¥/€	¥151/€	¥133/€	-¥18/€
Naphtha	¥/kl	Approx. ¥70,000/kl	Approx. ¥39,000/kl	Approx. -¥31,000/kl

Bio-Chemicals

- >> Due to change in fiscal year end, overseas subsidiaries 12-month forecasts have been consolidated
- >> Profits forecast to decline due to the impact of the strong yen and other factors and despite efforts to expand sales of industrial and pharmaceutical raw materials (mainly for intravenous liquid and pharmaceutical use) (FY08 ¥103/\$, ¥151/€ and FY09 ¥94/\$, ¥133/€)

Chemicals

>> We are forecasting a profit for the October to December period due to the steady price of raw materials and fuels since July, however the effect of the first half will be significant and we forecast a loss for the 9 month period

R&D Pipeline



Kyowa Hakko Kirin (Phase II onwards)

(As of October 29, 2009)

Category	Code name/		Stage	Indication	Formulation	In-house or licensed	Remarks
3 ,	Product name	Japan	Other countries				
	KW-0761	Phase II	Phase I in USA	Cancer (Hematologic tumor)	Injection	In-house	Humanized monoclonal antibody (The exclusive right to develop and commercialize for treatments other than cancer, and except in Japan, Korea, China and Taiwan, was out-licensed to Amgen in March 08)
	KRN321 NESP	Filed Nov/2008		★Chemotherapy induced anemia	Injection	Kirin-Amgen	Long-acting erythropoietin stimulating protein. On sales in Japan as anemia of CKD patients on dialysis since July 2007
Cancer/ Hematology	AMG531	Phase III		Immune thrombocytopenic purpura	Injection	Kirin-Amgen	Thrombopoiesis stimulating peptibody Clinical development is being conducted by Amgen 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 Canada	Renal Cell Carcinoma	Injection	Developed with Argos	Dendritic cell-based immunotherapeutic
	AGS-004		Phase II in USA and Canada	HIV	Injection	Developed with Argos	Dendritic cell-based immunotherapeutic
	PB94 PHOSBLOCK (RENAGEL)		Filed in China Jun/2008	Hyperphosphate mia	Oral	Licensed from Chugai	Launched in Japan
Kidney	KRN321	Filed Dec/2008		★Anemia (not on dialysis)	Injection	Kirin-Amgen	Long-acting erythropoietin stimulating
	NESP		Phase II in China	★Anemia (on dialysis)	injoonon	179017	protein. On sales in Japan as anemia of CKD patients on dialysis since July 2007



Updated since Apr. 28th, 2009 (Area, Stage, Filed, Approved, Launched etc.)

New indications

R&D Pipeline



Kyowa Hakko Kirin (Phase II onwards)

(As of October 29, 2009)

	0-1	Code name/ Stage		La Partira	Farmed affice	Developed in-house or	Demonto	
	Category	Product name	Japan	Other countries	Indication	Formulation	licensed	Remarks
	KW-4679 Filed in China ALLELOCK Jul/2008		Allergy	Oral	In-house	Launched in Japan		
	Immunology/Allergy	Z-206 ASACOL Phase III			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 III	Filed in USA Apr/2007	Parkinson's disease	Oral	In-house	
l	0.10	KW-6500	Phase III		Parkinson's disease	Injection	Britannia Pharma	

Kyowa Hakko Kirin (Phase I)

	Code name/	Ç	Stage			Developed in-house or licensed	
Category	Product name	Japan	Other countries	Indication	Formulation		Remarks
	KW-2450		Phase I	Cancer	Oral	In-house	
	KRN654	Phase I/II		Essential thrombocythemia	Oral	Licensed from Shire	
	KW-2449		Phase I/IIa in USA	Cancer	Oral	In-house	
Cancer/	KW-2478		Phase I in Europe	Cancer	Injection	In-house	
Hematology	ARQ197	Phase I		Cancer	Oral	ArQule	
	KRN330		Phase I/IIa in USA	Cancer	Injection	In-house	Fully human monoclonal antibody
	BIW-8962		Phase I in USA	Cancer	Injection	In-house	Humanized monoclonal antibody
	KRN951	Phase I		Cancer	Oral	In-house	

Updated since Apr. 28th, 2009 (Area, Stage, Filed, Approved, Launched etc.)

R&D Pipeline



Kyowa Hakko Kirin (Phase I)

(As of October 29, 2009)

	Code name/	,	Stage			Developed in-house or licensed	
Category	Product name	Japan	Other countries	Indication	Formulation		Remarks
NU206			Phase I in Australia	Inflammatory bowel disease	Injection	Developed with ARCA biopharma (the former Nuvelo).	
Allergy	ASKP1240		Phase I	Organ Transplant Rejection	Injection	In-house	Fully human monoclonal antibody developed with Astellas
Other	KW-3357	Phase I		Disseminated intravascular coagulation, Congenital antithrombin deficiency	Injection	In-house	Recombinant antithrombin product
Other	KRN23		Phase I in USA	Hypophosphatemic disease such as X-linked Hypophosphatemia (XLH)	Injection	In-house	Fully human monoclonal antibody

(Note)

In the Philippines, application for approval has been filed for Filgrastim (G-CSF)

In Thailand and Hong Kong, approval for Nesp (Long-acting erythropoietin stimulating protein) has been filed. In Korea and Taiwan, Nesp has been approved.

Kyowa Hakko Kirin (discontinued)

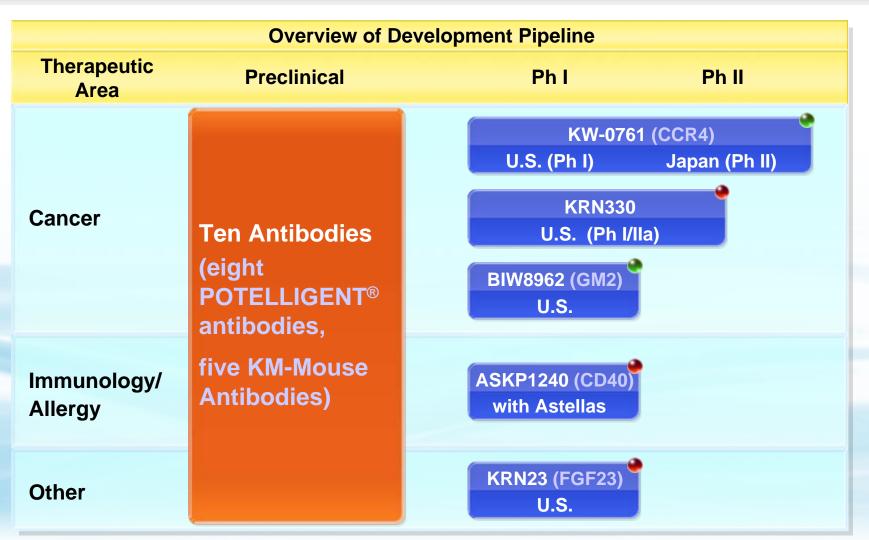
Cardiovascular KW-3902 Phase I Acute heart failure with renal impairment	Injection	In-house	Discontinued based on Phase III clinical trials results conducted by Merck overseas
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Updated since Apr. 28th, 2009 (Area, Stage, Filed, Approved, Launched etc.)

In Taiwan and Korea application for approval of Regpara(Calcimimetic agent) has been filed. In Macau and Hong Kong, Regpara has been approved.

Antibody pharmaceutical pipeline (as of October 2009)





: POTELLIGENT® Technology

: KM-Mouse Technology

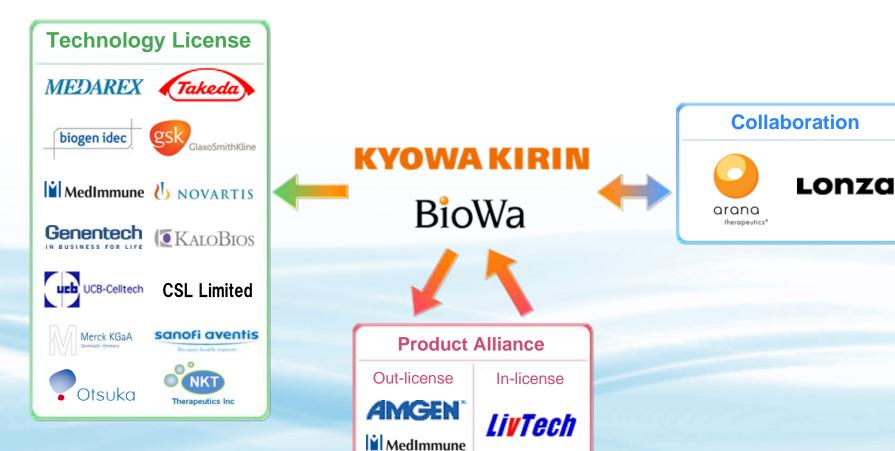
Licensing-out antibody pharmaceuticals (as of October 2009)

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Antibody	Target	Licensee	Reported Stage	Remarks
KW-0761	CCR4	Amgen (Except in Japan, Asia)	Ph I (AMG 761)	POTELLIGENT®
BIW-8405	IL-5R	AstraZeneca (MedImmune) (Except in Japan, Asia)	Ph II (MEDI-563)	POTELLIGENT®
KW-2871	GD3	Life Science Pharmaceuticals	Ph II	
Anti LIGHT antibody	LIGHT	Sanofi-aventis (Except in Japan, Asia)		KM Mouse

● POTELLIGENT® technology related alliances (as of October 2009)





*Clinical trials are in progress for five out-licensed POTELLIGENT anti-bodies

Progress in licensing-out (as of October 2009)



Name	Partner	Phase		Remarks
Hamo		II	III	. tomante
KW-3902	Merck (NovaCardia)			Terminated
CEP-701	Cephalon			Myeloproliferative disorders (FLT-3 inhibitor)
KW-2871 (Low-fucose antibody)	Life Science			Cancer (anti-GD3) (malignant melanoma)
MEDI-563 (BIW-8405:POTELLIGENT®)	AstraZeneca (MedImmune)			Allergy (Anti-IL-5R antibody)
KRN951 (AV-951)	AVEO			Cancer (VEGF receptor inhibitor)
KRN5500	DARA			Cancer pain
LY2523355	Eli Lilly			Cancer (Mitotic Kinesin Eg5 inhibitor)
AMG 761 (KW-0761:POTELLIGENT®)	Amgen			Allergy (Anti-CCR4 antibody)

Progress in licensing-in (as of October 2009)



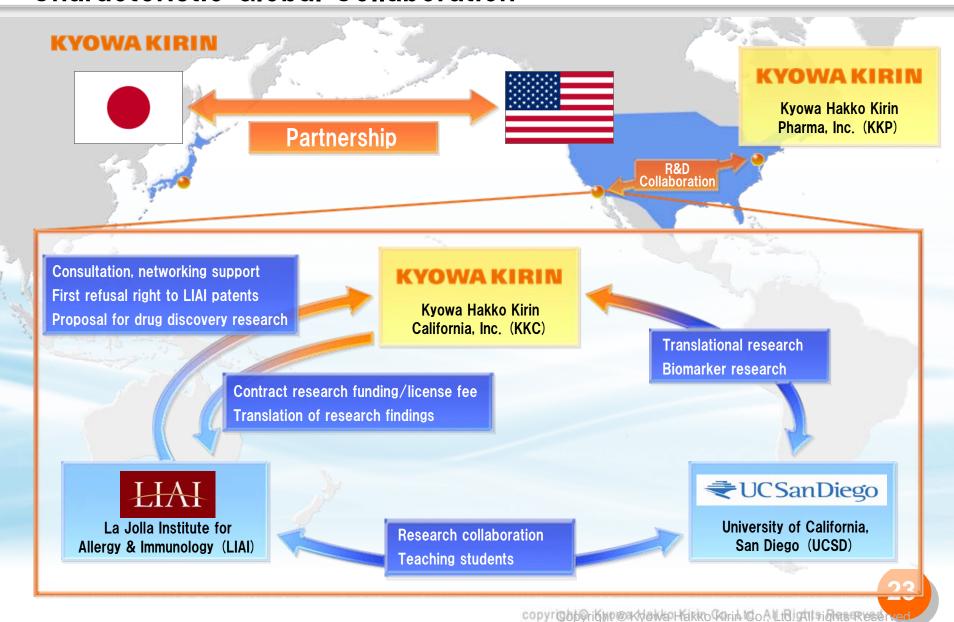
Name	Partner	Phase			Remarks
11441116	1 41 11101	I	II	III	
Asacol	Zeria Pharmaceuticals				Inflammatory bowel disease (Crohn's disease) *Application filed for ulcerative colitis
KW-6500	Britannia				Parkinson's disease (injection)
AGS-003	Argos				Renal cell carcinoma
AGS-004	Argos				HIV
ARQ197	ArQule				Cancer
HFT-290	Hisamitsu Pharmaceuticals		Filed		Cancer pain
KW-2246	Orexo	In prep	aration fo	or filing	Cancer pain





Kyowa Hakko Kirin's Characteristic Global Collaboration

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Transfer of Neu-up to Yakult Honsha



Events and schedule

December 19, 2008	Announced issue resolution measures following business integration with Kirin Group
October 15, 2009	Announced that application for manufacturing and sales of G-CSF formulation Neu-up is in progress and other items
	Agreed to a license for use and transfer to Yakult Honsha
January 1, 2010 (planned)	Begin to assign provision of information on Neu-up to Yakult Honsha
March 1, 2010 (planned)	Yakult Honsha to launch sales

^{*}Production will be handled by Kyowa Hakko Kirin for the foreseeable future

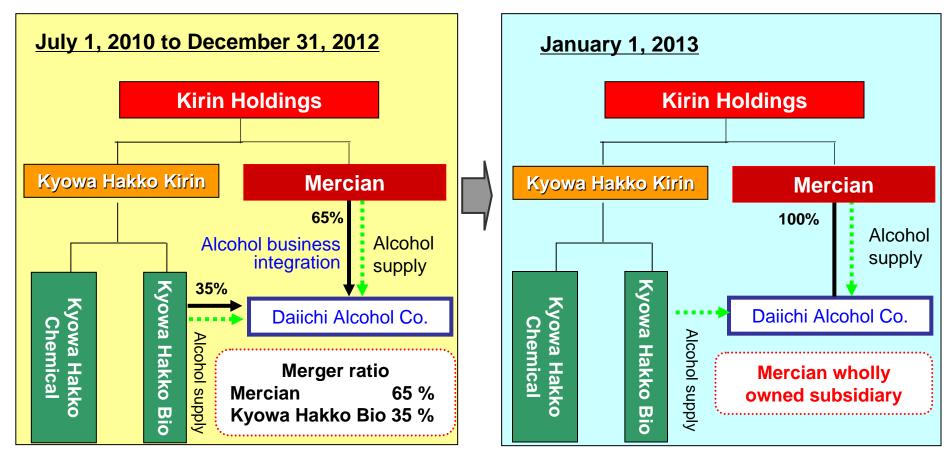
Lonza and BioWa Introduce Potent New Cell Line for Recombinant Antibody Production

Basel (CH) and **Princeton, NJ, USA**, 13 October 2009 – Lonza and BioWa, Inc today unveiled Potelligent® CHOK1SV, a new host cell line for manufacturing recombinant antibodies. The new cell line combines the power of BioWa's engineered glycosylation Potelligent® Technology with the advantages of Lonza's proprietary GS Gene Expression System™ and industry-leading cell line CHOK1SV.

Advantages of Potelligent® CHOK1SV

- ➤The Potelligent® CHOK1SV cell line retains the desirable features of a high-productivity cell line (robust, high-yielding, scalable)
- ➤ Proven bioprocess platform for CHOK1SV is repeatable in the new cell line
- ➤ Antibodies produced by the new cell line:
 - Exhibit enhanced antibody dependent cellular cytotoxicity (ADCC) even with the low-ADCC allotype of CD16, overcoming CD16 polymorphism
 - •Can exert potent cytotoxic effects when their target antigen is low
 - Work in whole blood
 - •Retain all the other desirable features of antibodies, such as Protein A binding.

Alcohol Business: Integration with Mercian



Step 1: July 1, 2010

Kyowa Hakko Bio and Mercian will form Daiichi Alcohol Co., a newly merged company, by joint investment. The alcohol business of both companies will be integrated into Daiichi Alcohol and will continue to supply alcohol. Mercian will hold 65% and Kyowa Hakko Bio will hold 35%.

Step 2: January 1, 2013

Mercian will purchase all of Kyowa Hakko Bio's holdings (35%) to make Daiichi Alcohol a wholly owned subsidiary.

Regarding medium-term business plan



	October 26, 2009	Kirin Holdings announced medium term business plan
		Kyowa Hakko Kirin's target:
		-FY ending Dec. 2012: ¥459.0 bn in net sales
•	End January 2010	Announce fiscal 2009 results, investor presentation
	(planned):	2010-2012 medium-term business plan, and investor presentation



Appendix

Pharmaceuticals: Major factors affecting results



All listed factors are on a non-consolidated basis unless stated otherwise

Fiscal 2008 H1	Net sales	Fiscal 2009 H1
¥108.7 bn	-¥4.7 bn	¥103.9 bn
Positive factors	Growth in sales of core products	
Negative factors	Negative factors One-time contract payment from Amgen Effects of foreign exchange	
	Operating income	
¥19.6bn	+¥1.6bn	¥21.3bn
Positive factors	Growth in sales of core products R&D and SG&A expense efficiencies Cost synergies from integration	
Negative factors	One-time contract payment from Amgen Effects of foreign exchange	Integration-related goodwill ¥4.31 billion

Bio-Chemicals: Major factors affecting results



All listed factors are on a non-consolidated basis unless stated otherwise

Fiscal 2008 H1	Net sales	Fiscal 2009 H1
¥45.7 bn	-¥4.2 bn	¥41.4 bn
Positive factors	Growth in mail-order sales business Growth in sales of industrial use alcohol	
Negative factors	Effects of foreign exchange	
	Operating income	
¥5.2 bn	-¥3.5 bn	¥1.6 bn
Positive factors	Growth in mail-order sales business	
Negative factors	Effects of foreign exchange	Integration-related goodwill ¥0.31 billion

Chemicals: Major factors affecting results



All listed factors are on a non-consolidated basis unless stated otherwise

Fiscal 2008 H1	Net sales	Fiscal 2009 H1
¥57.2 bn	-¥24.3 bn	¥32.8 bn
Positive factors	••	
Negative factors	Reduced demand due to economic downturn Worsening products market	
	Operating income	
¥2.9 bn	-¥5.4 bn	-¥2.4 bn
Positive factors	Cost improvements from drop in price of	
	raw materials and fuels	
Negative factors	Reduced demand due to economic downturn	Integration-related goodwill ¥0.02 billion
	Worsening products market	
	Effects of inventory	

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