# Kyowa Hakko Kirin Fiscal 2009 Results

(Nine-month period April-December 2009)

January 29, 2010

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Statements on results, forecasts and R&D status contained in this presentation represent judgments based on information available at the current time. Actual results may differ significantly due to a variety of factors such as economic conditions and exchange rate fluctuations.

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Summary of fiscal 2009 results

#### Summary of fiscal 2009 results: P&L

## **KYOWA KIRIN**

	(¥bn)	Net sales	Operating income	Recurring income	Net income
FY2009 (AprDec.)		309.1	28.2	29.4	8.7
Change		-53.1 (-14.7%)	-14.4 (-33.8%)	-13.7 (-31.9%)	-1.6 (-16.1%)
FY2008 (AprDec.)		362.2	42.6	43.2	10.4

#### Summary

Sales and profits decreased due to the exclusion of the Food business from consolidation, sluggish sales in the Chemicals business due to the economic downturn, and the effects of foreign exchange

- >> Pharmaceuticals: Despite growth in domestic sales of core products, sales and profits declined due to the considerable effect in the previous year of a one-off licensing payment for KW-0761
- >> **Bio-Chemicals:** Sales increased but profits declined due to a worsening vitamins market and the effects of foreign exchange, and despite growth in health care products and consolidation of the January to December results of overseas subsidiaries following the change to fiscal year end
- Chemicals: Despite an operating profit in the October to December period, sales and profits fell due to the considerable effect of first half results
- Extraordinary losses: Losses included an impairment loss from the integration of R&D facilities, and extraordinary depreciation of fixed assets following the decision to reorganize pharmaceutical production facilities

#### Summary of fiscal 2009 results: Pharmaceuticals business

#### **KYOWA KIRIN**

(¥bn)	FY2008 (AprDec.)	FY2009 (AprDec.)	CI	Change		
Net sales	161.3	158.2		-3.0		
Operating income	29.6	26.6		-3.0		
R&D expenses	32.5	31.6		-0.9		
			Apr. to Dec.	2008	2009	
			Forex	¥103/\$	¥94/\$	

# Excluding the one-time effects of the out-licensing income received in the previous period both sales and profits increased

 Sales decreased despite growth in domestic sales of core products such as Nesp/Espo, Regpara, Allelock and Patanol, due to the effects of the one-time ¥9.8 bn licensing payment for KW-0761 recorded in the previous year and the effect of foreign exchange on exports

 Operating income decreased due to the effects of foreign exchange and the one-time ¥9.8 bn licensing payment for KW-0761 recorded in the previous year and despite more efficient use of SG&A and R&D expenses

#### Sales of core pharmaceutical products – non-consolidated

#### **KYOWA KIRIN**

(¥bn)	FY2008 (AprDec.)	FY2009 (AprDec.)	Change
Nesp/Espo	34.4	39.6	15% 🕇
Coniel	18.1	18.3	1% 🕇
Allelock	15.6	17.3	11% 🕇
Patanol	2.2	3.0	36% 🕇
Gran/Neu-up	14.3	13.8	3%↓
Depakene	8.3	8.8	6% 🕇
Coversyl	4.0	3.7	8%↓
Regpara	3.3	5.5	67% 🕇
Export and technology out-licensing revenues	26.3	15.1	43%↓

#### Summary of fiscal 2009 results:

Bio-Chemicals and Chemicals businesses

## **KYOWA KIRIN**

	(¥bn)	FY2008 (AprDec.)	FY2009 (AprDec.)	Change
Bio-Chemicals	Net sales	67.5	69.7	+2.2
BIO-Chemicais	Operating income	7.4	3.0	-4.3
Chemicals	Net sales	77.3	52.3	-24.9
Chemicals	Operating income	3.5	-1.9	-5.5
Forey	¥/\$	¥103/\$	¥94\$	-¥9/\$
Forex	¥/€	¥151/€	¥133/€	-¥18/€
Naphtha	¥/KI	Approx. ¥70,000/kl	Approx. ¥39,000/kl	Approx. ¥31,000/kl

#### **Bio-Chemicals**

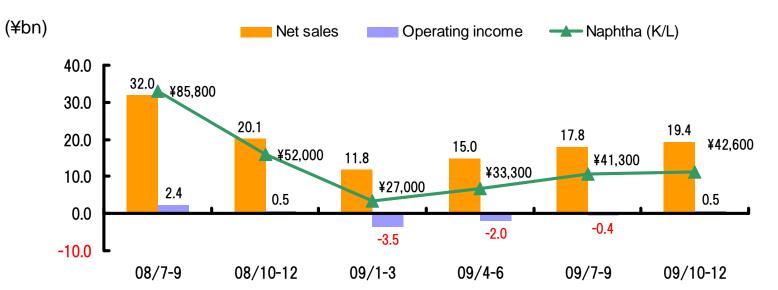
- Source Consolidated the January to December results of overseas subsidiaries following the change to fiscal year end
- Profits decreased due to the effect of foreign exchange and despite efforts to expand sales of industrial and pharmaceuticals raw materials (primarily for intravenous and medical use) (2008 ¥103/\$, ¥151/€ compared to 2009 ¥94/\$, ¥133/€)
- Sales of vitamins by Daiichi Fine Chemicals declined, impacted by an ongoing slump in the vitamin market

#### Chemicals

>> Sales and profits for the 9-month period decreased due to the considerable effect of first half results and despite returning to an operating profit in the October to December period

#### Chemicals business

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# The price of naphtha (the index price for raw materials) is steadily rising, and sales volumes are recovering

- Focused on expanding sales of basic chemical products in growth markets such as China
- Steadily recovery of demand for environmentally friendly products in both domestic and overseas markets

Due to the above factors we achieved an operating profit in the October to December period

### **KYOWA KIRIN**

Pipeline



#### **KYOWA KIRIN**

#### Phase II, Phase III

(As of January 2010)

Category	Code name/ Product name		Stage Other	Indication	Formulation	In-house or licensed	Remarks
<u> </u>	Product name	Japan	countries				
	KW-0761	Phase II	Phase <b>I</b> / <b>II</b> a 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).
Cancer/	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.
Hematology	AMG531	Phase III		Immune thrombocytopenic Injection Kirin-Amgen purpura		Kirin-Amgen	Thrombopoiesis stimulating peptibody. The 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
	PB94 PHOSBLOCK (RENAGEL)		Filed in China Jun/2008	Hyperphosphatemia	Oral	Licensed from Chugai.	Launched in Japan
Kidney	KRN321	Filed Dec/2008		★Anemia (not on dialysis)	Injection	Kirin-Amgen	Long-acting erythropoietin stimulating protein. On sales in Japan as anemia of CKD patients on dialysis
	NESP		Phase II in China	★Anemia (on dialysis)	njeelen		since July 2007.
	KW-4679 ALLELOCK		Filed in China 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.

★ New indications

#### Phase II, Phase III

(As of January 2010)

	Code name/		Stage		<b>F</b> 1.4		
Category	Product name	Japan	Other countries	Indication	Formulation	In-house or licensed	Remarks
CNS	KW-6002	Phase III	Filed in USA Apr/2007	Parkinson's disease	Oral	In-house	
CINS	KW-6500	Phase III		Parkinson's disease	Injection	Licensed from Britannia Pharma.	

#### Phase I

	Code name/	:	Stage				
Category	Product name	Japan	Other countries	Indication	Indication Formulation I		Remarks
	KW-2450		Phase I in USA	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	ARQ 197	Phase I		Cancer	Oral	Licensed from ArQule.	
	KRN330		Phase I/IIa in USA	Cancer	Injection	In-house	Fully human monoclonal antibody
	BIW-8962		Phase I/IIa in USA	Cancer	Injection	In-house	Humanized monoclonal antibody
	KRN951	Phase I		Cancer	Oral	In-house	

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#### • R&D Pipeline (continued)

## **KYOWA KIRIN**

Phase I							(As of January 2010)	
	Code name/	Stage						
Category	Product name	Japan	Other countries	Indication	Formulation	In-house or licensed	Remarks	
Immunology/ Allergy	ASKP1240		Phase I	Organ Transplant Rejection	Injection	In-house	Fully human monoclonal antibody Developed with Astellas.	
Other	KW-3357	Phase I	Phase I in Europe	Disseminated intravascular coagulation, Congenital antithrombin deficiency	Injection	In-house	Recombinant antithrombin product	
	KRN23		Phase I in USA	X-linked Hypophosphatemic rickets/osteomalacia (XLH)	Injection	In-house	Fully human monoclonal antibody	

(Note)

In the Philippines, an NDA of Filgrastim (G-CSF) has been filed for neutropenia.

In Thailand, Singapore, Malaysia and the Philippines, NESP (Long-acting erythropoietin stimulating protein) has been filed. In Korea, Taiwan, and Hong Kong, NESP was approved. In Korea and Taiwan REGPARA (Calcimimetic agent) has been filed. In Hong Kong (Macau), REGPARA was approved.



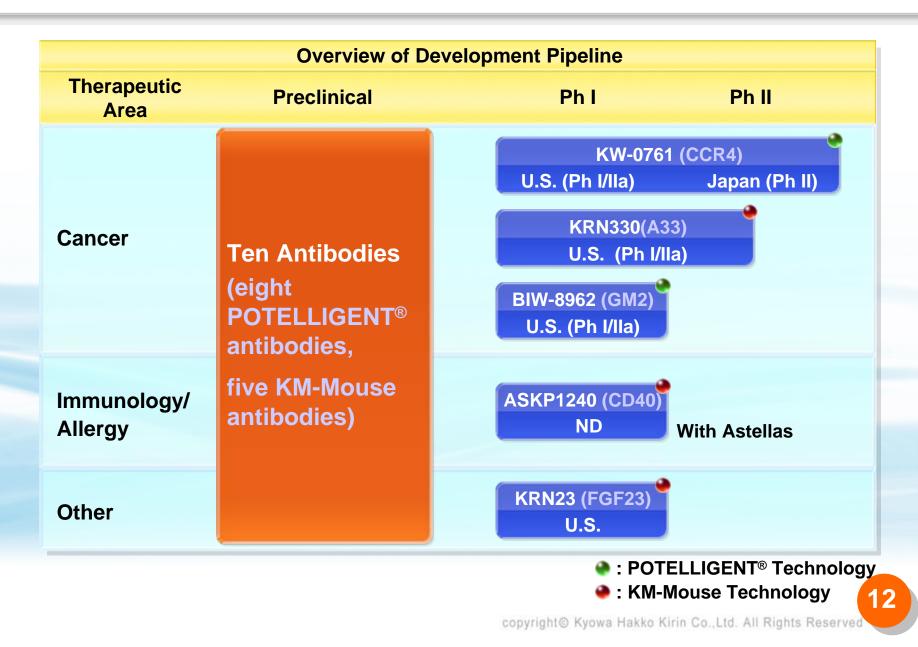
New indications

#### **Discontinued**

	Code name/	:	Stage					
Category	ory Product name Japan Other Indication		Formulation	In-house or licensed	Remarks			
Immunology/ Allergy	NU206		Phase I in Australia	Inflammatory bowel disease	Injection	Developed with ARCA biopharma. (the former Nuvelo).	Portfolio review	
Cancer/	AGS-003		Phase II in USA and Canada	Renal Cell Carcinoma	Injection	Developed with Argos.	Portfolio review	
Hematology	AGS-004		Phase II in USA and Canada	HIV	Injection	Developed with Argos.	Portfolio review	

Antibody pharmaceutical pipeline (as of January 2010)

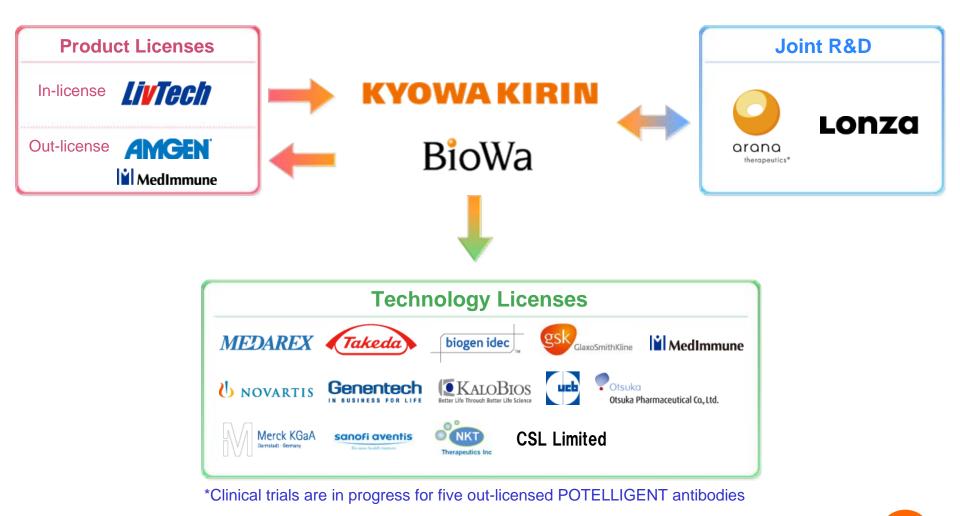
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Antibody	Target	Licensee	Reported Stage	Remarks
KW-0761	CCR4	Amgen (Except in JP, CN, KR,TW)	Ph I (AMG 761)	POTELLIGENT®
BIW-8405	IL-5R	MedImmune (Except in Japan, Asia)	Ph II (MEDI-563)	POTELLIGENT®
KW-2871	GD3	Life Science Pharmaceuticals	Ph II	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





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Name	Partner	Phase	Remarks
		II	
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®)	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)

Name	Partner		Phase		Remarks
			=		
Asacol	Zeria Pharmaceutical				Inflammatory bowel disease (Crohn's disease) *Application filed for ulcerative colitis
KW-6500	Britannia				Parkinson's disease (injection)
ARQ197	ArQule				Cancer
HFT-290	Hisamitsu Pharmaceuticals	Filed			Cancer pain
KW-2246	Orexo	In preparation for filing		or filing	Cancer pain

#### Update on licensing-in contracts

**KYOWA KIRIN** 

Dec. 24, 2009	Immunas Pharma, Inc. (Japan)		
	Acquisition of exclusive implementation rights to ANTIAMYLOID & PEPTIDE ANTIBOD		
January 4, 2010	Dicerna Pharmaceuticals, Inc. (USA) Joint research on DDS technology for nucleic acid pharmaceuticals and acquisition of commercialization rights		
	One time licensing payment: \$4 million		
	Development / Sales Milestones, etc. Max. \$120 million		
January 8,	Reata Pharmaceuticals, Inc. (USA)		
2010	Acquired exclusive sales rights in Japan and Asia for Bardoxolone methyl, a treatment for chronic kidney disease		
	One-time contract payment: \$35 million		
	Development milestones: Max. \$97 million		
	Sales milestone: Max. \$140 million		
	Royalty Double-digit royalties		
January 29, 2010	Eli Lilly and Company Acquisition of sales rights (in Japan) for Permax a treatment for Parkinson's disease		

Dates are those of the public announcements

# Reata Pharmaceuticals, Inc. <a href="http://www.reatapharma.com/">http://www.reatapharma.com/</a>

Established: 2002

- Location: Irving, Texas, USA
- CEO: Warren Huff
- Business: Development of anti-inflammatory drugs



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#### **Bardoxolone methyl**

A low molecular weight pharmaceutical targeting diabetic patients with chronic kidney disease currently in phase II in the USA

Estimated glomerular filtration rate (eGFR) improved for more than 90% of clinical test participants

Promising improvements were also observed for other kidney functions, and indicators of blood sugar and cardio-vascular disorders

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Fiscal 2010 forecasts

#### Fiscal 2010 full year forecasts

## **KYOWA KIRIN**

(¥bn)	Net sales	Operating income	Recurring income	Net income
2010 (JanDec.)	400.0	36.0	37.5	20.0
vs. 2009 (JanDec.)	(-1.7%)	(+16.4%)	(+14.9%)	(+99.2%)
2009 (JanDec.)	407.0	30.9	32.6	10.0

Note: Fiscal 2009 was a nine-month period due to a change in fiscal year end. The above 2009 results are for the 12 month period from January 1, 2009 to December 31, 2009 and consist of the sum of the results of the consolidated fourth quarter of fiscal 2008 (the 3-month period from January 1, 2009 to March 31, 2009) and consolidated fiscal 2009 (the 9-month period from April 1, 2009 to December 31, 2009).

# Forecasting increased profits for the full year despite reduced revenues from the effects of price reductions in Pharmaceuticals segment

- In Pharmaceuticals we expect increased sales of core products Nesp/Espo, Regpara and Patanol, and contributions from new products and milestone payments but sales and profits expected to decline due to the effects of price reductions
- >> In Bio-Chemicals we aim to expand sales of industrial and pharmaceutical raw materials, however the reorganization of the alcohol and agro businesses will lead to reduced sales and operating income is expected to remain largely unchanged from the previous year
- >> In Chemicals, we are forecasting increased sales volumes due to improvement in the operating environment. We are also expecting a significant rise in sales and profits from product price revisions due to an increase in naphtha prices, and changes to segment classification of consolidated subsidiaries

(¥bn)	<b>2009</b> (JanDec.)	<b>2010</b> (JanDec.)	Change
Net sales	207.3	205.0	-2.3
Operating income	31.8	29.0	-2.8
R&D expenses	41.6	41.5	-0.1

#### >> Net sales

- Although price revisions are expected to result in a decline in sales, sales of core products are expected to increase due to increased volume sales of core products Nesp/Espo, Regpara and Patanol

- In new products, Permax, Asacol and HFT-290 are expected to contribute to sales

- Forecasts for technology licensing income include an increase in milestone payments

#### >> R&D expenses

- Despite the absence of one-time in-licensing expenses recorded in the previous year, R&D expenses are forecast to remain largely inline with those of the previous year due to an increase in depreciation expenses following the opening of a new research building in Tokyo Research Park and new antibody and other pharmaceutical manufacturing facilities

Expenses other than R&D

>> - Expenses other than R&D will remain largely inline with those of the previous year. Cost control measures will be pursued but depreciation of sales rights for in-licensed products will increase

• Fiscal 2010 full year forecasts: Sales of core pharmaceutical products (non consolidated)

# **KYOWA KIRIN**

(¥bn)	<b>2009</b> (JanDec.)	<b>2010</b> (JanDec.)	% change
Nesp/Espo	48.9	49.7	2% 🕇
Coniel	23.3	21.3	9%↓
Allelock	26.7	26.0	3%↓
Patanol	7.4	7.9	7% 🕇
Gran/Neu-up*	17.0	15.1	11%↓
Depakene	11.2	11.0	2% ↓
Coversyl	4.8	4.4	8%↓
Regpara	6.8	7.3	7% 🕇
Permax		2.0	
Export and technology out-licensing revenues*	18.0	22.6	26% 🕇

\*2009 figures on a shipments basis. 2010 forecasts, on an actual consumption basis.

\*Sales of Neu-up are planned to be transferred to Yakult Honsha as of March 2010

\*Sales of Permax are planned to be transferred from Eli Lilly as of April 2010

#### Fiscal 2010 forecasts: Bio-Chemicals/ Chemicals

## **KYOWA KIRIN**

	(¥bn)	<b>2009</b> (JanDec.)	<b>2010</b> (JanDec.)	Change
Bio-	Sales	90.6	84.0	-6.6
Chemicals	Operating income	3.9	4.0	+0
Chemicals	Sales	64.2	121.0	+56.7
	Operating income	(5.5)	2.7	+8.2
Forex	¥/\$	¥94/\$	¥91/\$	-¥3/\$
FUIEX	¥/€	¥130/€	¥133/€	+¥3/€
Naphtha	¥/kl	Approx. ¥36,000/kl	Approx. ¥45,000/kl	Approx. +¥9,000/kl

## **Bio-Chemicals**

- >> We are forecasting year-on-year increases in sales and sales volumes from the amino acid business but the effects of price competition will continue
- >> There will be a negative impact from the reorganization of the domestic alcohol and livestock and fisheries businesses

#### Chemicals

>> We are forecasting a significant increase in sales and profits from increased sales volumes in all areas including raw materials for solvents, plasticizers and functional products, improvements in product markets from the increased price of raw materials and fuels, and from changes to consolidated subsidiaries segment

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## **KYOWA KIRIN**

Appendix

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

Fiscal 2008 (Apr Dec.)	Net sales	Fiscal 2009 (Apr Dec.)
¥161.3 bn	-¥3.0 bn	¥158.2 bn
Positive factors	Growth in sales of core products	
Negative factors	One-time contract payment from Amgen Effects of foreign exchange	
	Operating income	
¥29.6 bn	-¥3.0 bn	¥26.6 bn
Positive factors	Growth in sales of core products R&D and SG&A expense efficiencies	
Negative factors	One-time contract payment from Amgen Effects of foreign exchange	Integration-related goodwill ¥6.47 billion

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

Fiscal 2008 (Apr Dec.)	Net sales	Fiscal 2009 (Apr Dec.)
¥67.5 bn	+¥2.2 bn	¥69.7 bn
Positive factors	Consolidation of 12-month results of overseas subsidiaries following changes to fiscal year end	
	Growth in sales of healthcare products	
Negative factors	Effects of foreign exchange Sluggish vitamin market	
	<b>Operating income</b>	
¥7.4 bn	-¥4.3 bn	¥3.0 bn
Positive factors	Growth in sales of healthcare products	
Negative factors	Effects of foreign exchange Sluggish vitamin market	Integration-related goodwill ¥0.46 billion

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

Fiscal 2008 (Apr Dec.)	Net sales	Fiscal 2009 (Apr Dec.)
¥77.3 bn	-¥24.9 bn	¥52.3 bn
Positive factors	Expanded sales of functional products	
Negative factors	Reduced demand due to economic downturn Worsening price of products	
	Operating income	
¥3.5 bn	-¥5.5 bn	-¥1.9 bn
Positive factors	Cost improvements from drop in price of raw materials and fuels	
Negative factors	Reduced demand due to economic downturn Worsening price of products Inventory effects	Integration-related goodwill ¥0.03 billion

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