

# **Kyowa Hakko Kirin Co., Ltd.**

## **FY2010-12 Medium-term Business Plan**

**January 29, 2010**

**President & CEO**

**Yuzuru Matsuda**

**Kyowa Hakko Kirin Co., Ltd**

## Notice:

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Forecasts for operating results, the status of R&D and other matters are judgments based on information currently available.

Actual results could be materially different for a wide variety of reasons including changes to foreign exchange rates and the economic environment.

This document refers to the 2009 results as those of the 12-month period from January 1, 2009 to December 31, 2009 which consists 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).

## Contents

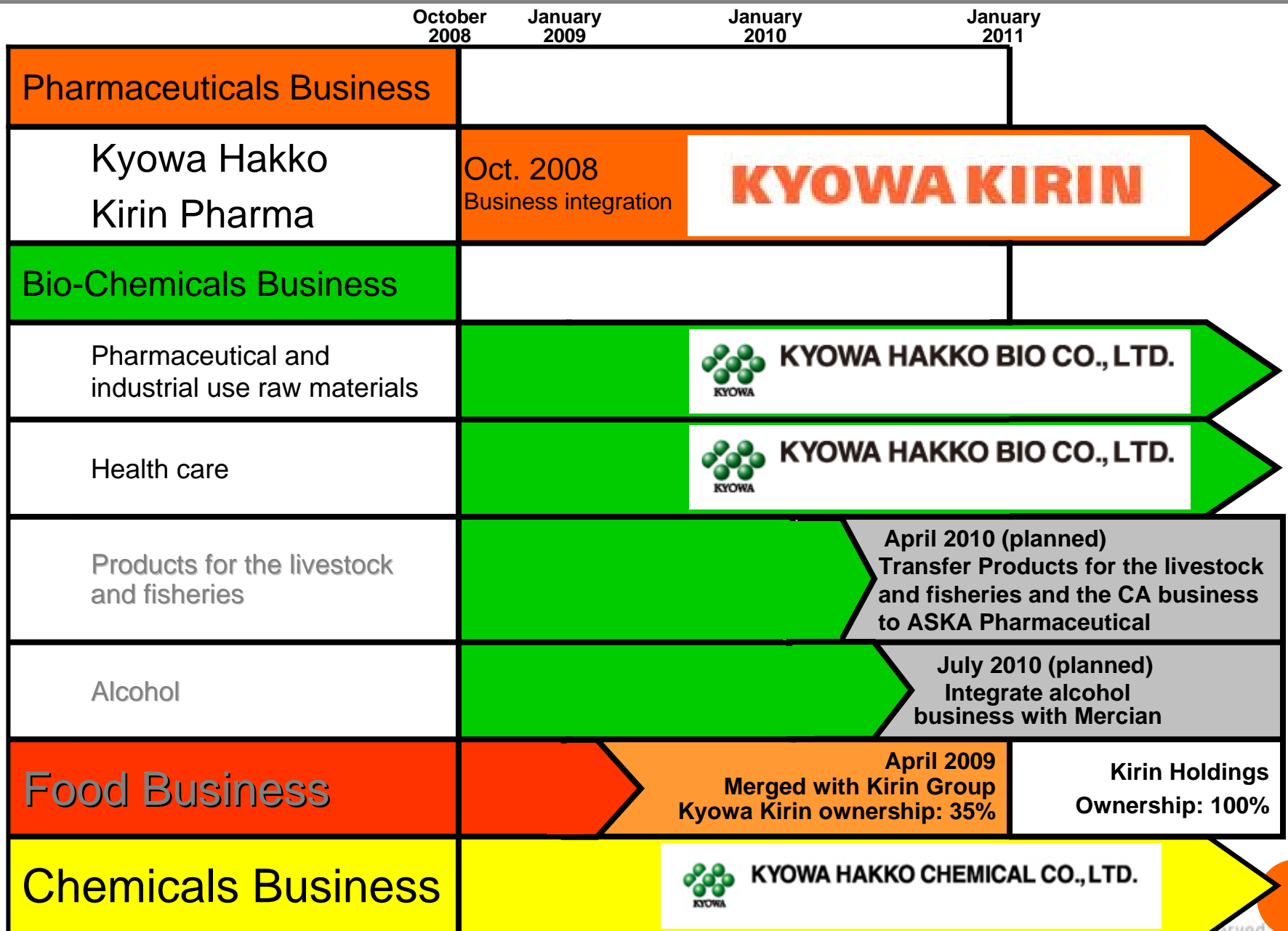
	Page
>> Business portfolio	4
>> Outline of FY2010-12 medium-term business plan	6
>> Pharmaceuticals business - Medium-term business plan	11
>> Bio-Chemicals business – Medium term business plan	25
>> Chemicals business – Medium term business plan	27
>> Shareholder returns	29

## **Efficiently use business resources to promote rapid progress in our development pipeline**

- Select and concentrate business portfolio
- Strengthen profitability by reorganizing production facility locations
- Develop our world-class therapeutic antibody business

## Business portfolio

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## Outline of the FY2010-12 medium-term business plan

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(¥bn)	2009 results	2012 targets
Net sales	407.0	454.0
Operating income (prior to amortization of goodwill)	40.3	61.0
Operating income (after amortization of goodwill)	30.9	51.7
EPS (prior to amortization of goodwill)	¥33.97	¥70.58

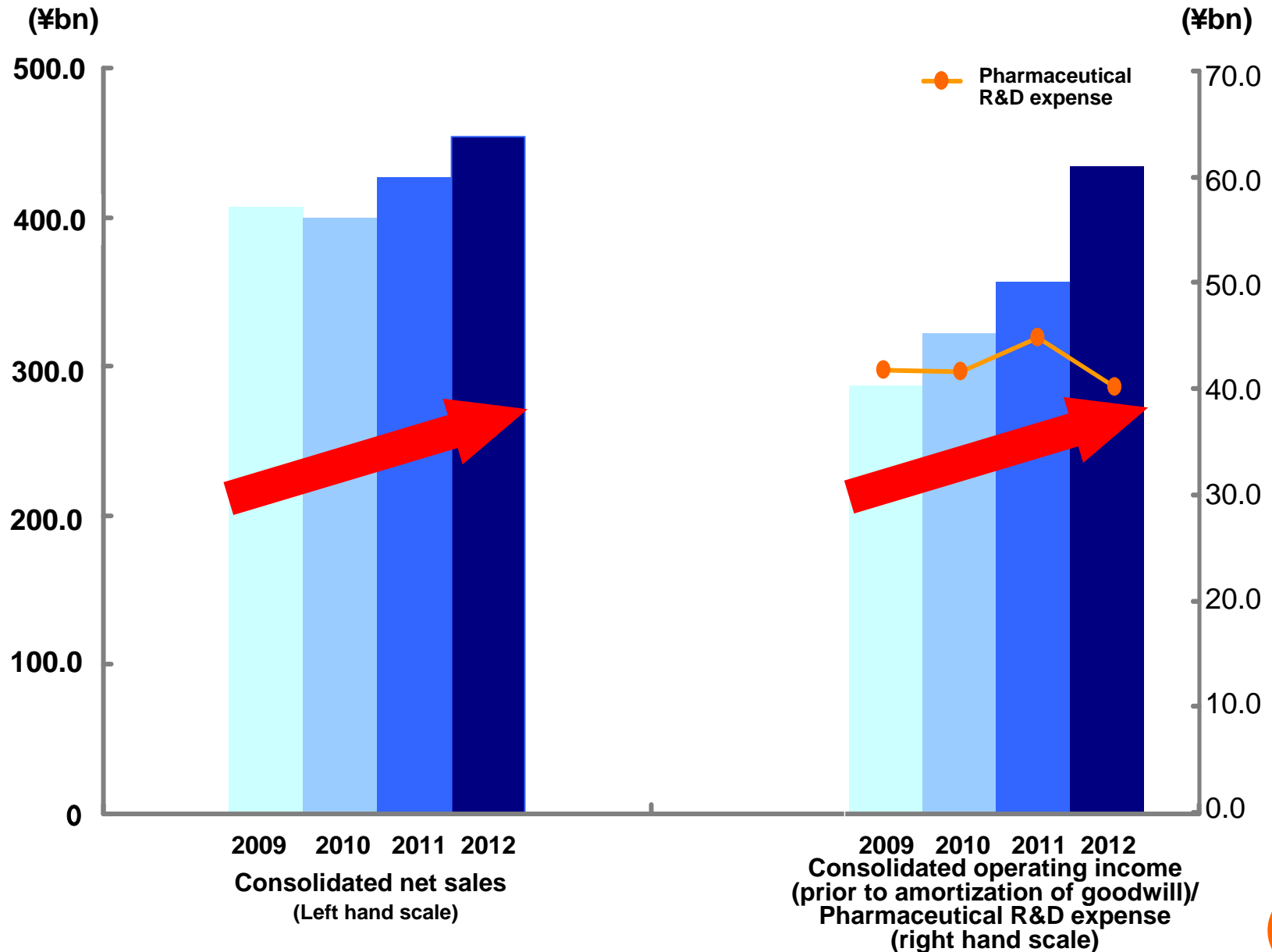
**Targeting a consolidated dividend payout ratio of at least 30% on a prior to amortization of goodwill basis**

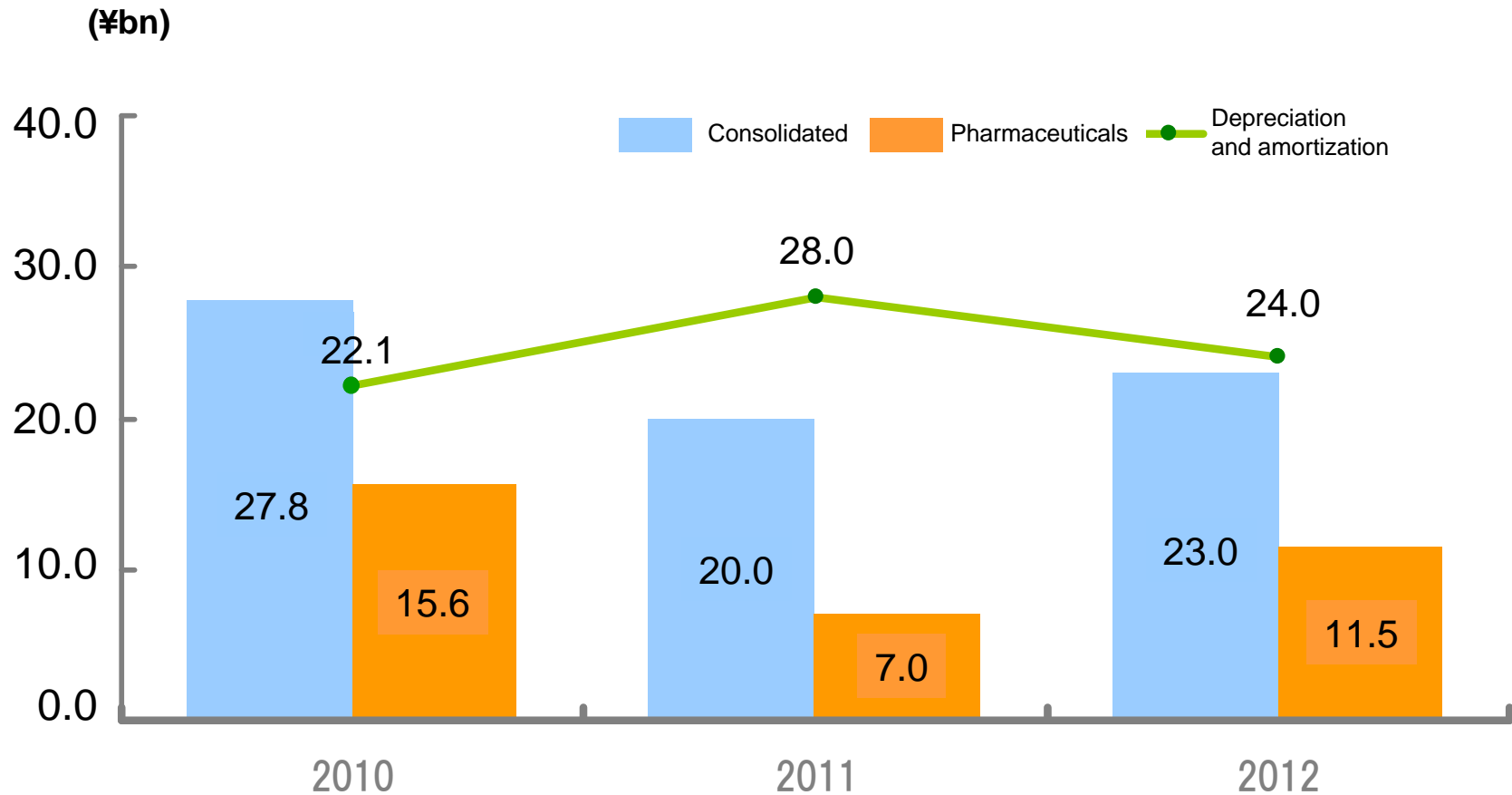
Note: Fiscal 2009 was a nine-month period due to a change in fiscal year end. The above 2009 results are for the 12 month period from January 1, 2009 to December 31, 2009 and consist of the sum of the results of the consolidated fourth quarter of fiscal 2008 (the 3-month period from January 1, 2009 to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



# ● Consolidated results forecasts by segment

	(¥bn)	FY2010 (forecasts)	FY2011 (forecasts)	FY2012 (forecasts)
Pharmaceuticals business		205.0	215.0	225.0
Bio-Chemicals business		84.0	84.0	88.0
Chemicals business		121.0	135.0	147.0
Other / eliminations		(10.0)	(7.0)	(6.0)
<b>Net sales</b>		<b>400.0</b>	<b>427.0</b>	<b>454.0</b>
Pharmaceuticals business		41.5	44.5	40.0
Businesses other than Pharmaceuticals		4.8	5.0	5.0
<b>R&amp;D expenses</b>		<b>46.4</b>	<b>49.5</b>	<b>45.0</b>
Pharmaceuticals business		37.6	39.5	45.0
Bio-Chemicals business		4.6	6.5	9.0
Chemicals business		2.7	4.0	7.0
Other / eliminations		0.3	0.0	0.0
Operating income (prior to amortization of goodwill)		<b>45.3</b>	<b>50.0</b>	<b>61.0</b>
Operating income (after amortization of goodwill)		<b>36.0</b>	<b>40.7</b>	<b>51.7</b>





## Pharmaceuticals business – Medium-term business plan

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(¥bn)	2009 results	2012 targets
Net sales	207.3	225.0
Operating income (prior to amortization of goodwill)	40.4	45.0
Operating income (after amortization of goodwill)	31.8	36.4
R&D expense	41.6	40.0

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).

## ● Research and development

- **Leverage our cutting edge bio-technologies, primarily antibody technologies, to enhance our development pipeline and promote discovery research in key areas (Oncology, Nephrology, Immunology)**
- Four products to enter development annually
- Integrate R&D facilities to enhance efficiencies, complete new facility in Tokyo Research Park in April 2010
- Leverage external networks such as the La Jolla Institute for Allergy & Immunology (USA)
- **Accelerate new drug development through effective utilization of overseas locations and strive to quickly acquire proof of concept for several products in development**
- Expand clinical trial implementation regions to include emerging nations, etc.
- Join and contribute to the global study systems in Asia
- Build a global structure for in-house development
- **Each year aim to achieve new drug applications for two or more products (including those for additional indications)**

## ● Production

- **Realize production efficiencies by reorganizing production facilities and promoting outsourcing**
- Optimize use of facilities throughout the Group
- **Begin operation of new manufacturing facilities with large-scale animal cell culture tanks for investigational therapeutic antibodies**
- March 2010 - Complete construction inside the Bio Process Research and Development Laboratories (Takasaki)

## ● Domestic sales

- Continue to expand our market share for existing core products
  - Expand market share for Erythropoiesis-stimulating agents (ESA) in hemodialysis and non-dialysis
  - Continue to grow Regpara sales
  - Maximize Allelock value
- Rapidly penetrate the market with new products
  - Rapidly penetrate markets with Asacol and HFT-290
  - Achieve smooth transfer of Permax sales
- Reorganize marketing structure to improve sales efficiencies
  - Optimize structure to improve MR productivity

## ● Overseas sales

- Expand sales in Asia by strengthening in-house sales capabilities and improving our reliability assurance system
  - Integrate locations and sales channels, and grow product line up
  - Improve our reliability assurance system
- Improve organizations in the US and Europe with a view to commencing new drug sales
  - Improve organization matched to stage in product development (includes exploring partnerships)

(¥bn)	2009	2010	2011	2012
Nesp/Espo	48.9	49.7	48.5	45.0
Coniel	23.3	21.3	20.5	19.0
Allelock	26.7	26.0	28.0	28.0
Patanol	7.4	7.9	9.0	10.0
Gran/Neu-up	17.0	15.1	14.5	13.5
Depakene	11.2	11.0	11.0	11.0
Regpara	6.8	7.3	8.0	9.0
Permax	-	2.0	2.5	2.5
New drugs	0.0	1.4	6.0	11.5
Export and technology out-licensing revenues*	18.0	22.6	22.0	24.0

\*2009 figures are on a shipments basis and figures from 2010 onwards are on an actual consumption basis

\*Fiscal 2009 was a nine-month period due to a change in fiscal year end. The above 2009 figures are for the 12-month period from January 1 to December 31, 2009

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

\*Sales of Permax will be transferred from Eli Lilly as of April 2010









## Objectives

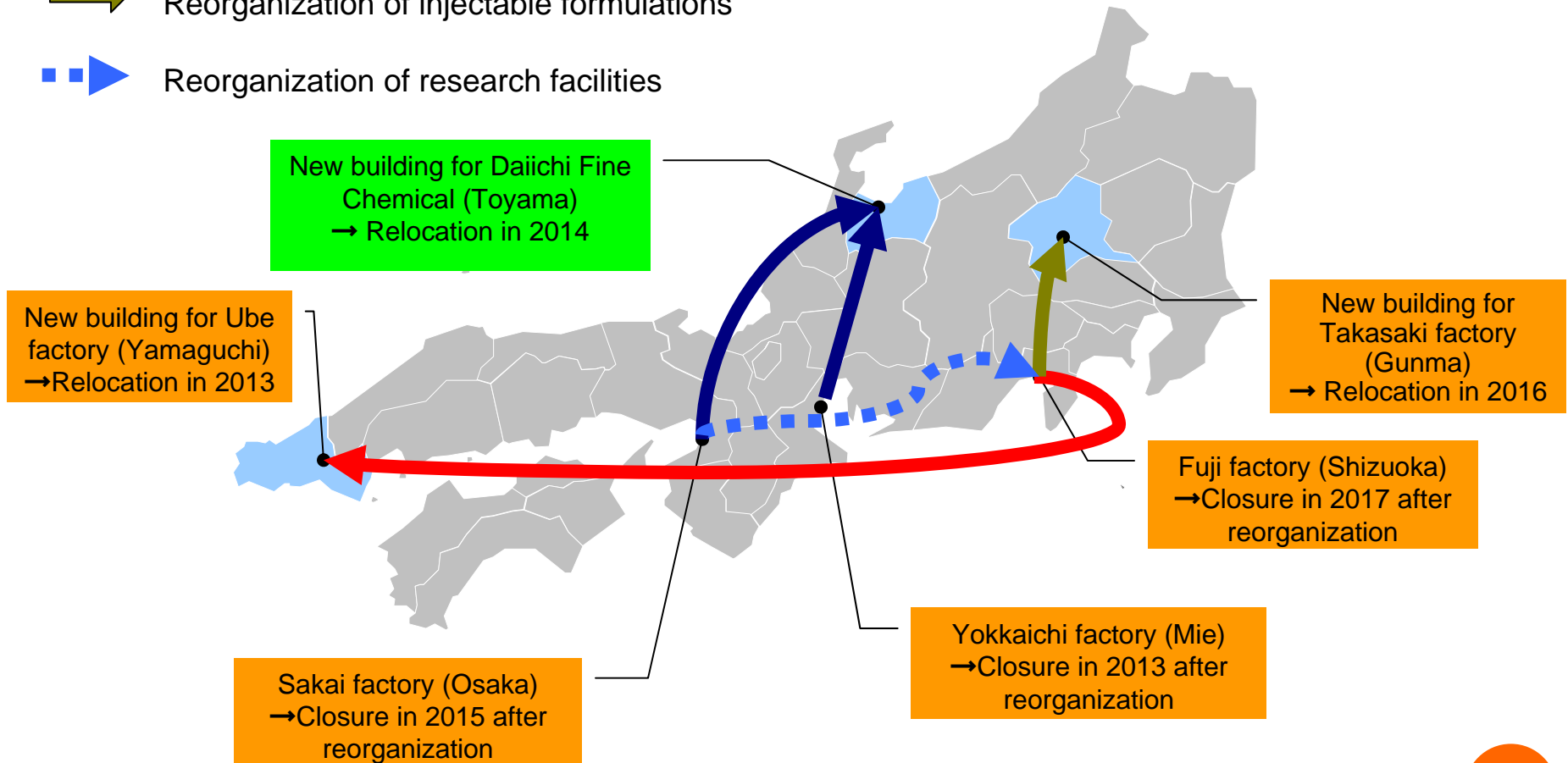
- Resolve deterioration of facilities and local issues through reorganization of production facilities
- Strengthen cost competitiveness by improving production efficiencies, including production automation, and high GMP levels

## Investment plan

- Construct new buildings as a part of the reorganization
- Planned investment of ¥10.0 billion + by 2017 when reorganization has been completed
- Recorded extraordinary loss in December 2009 for extraordinary depreciation of fixed assets due to reorganization

-  Reorganization of synthetic drug raw materials
-  Reorganization of oral formulations
-  Reorganization of injectable formulations
-  Reorganization of research facilities

-  Kyowa Hakko Kirin locations
-  Kyowa Hakko Bio locations



## Targeted diseases

CCR4-positive adult T cell leukemia-lymphoma and peripheral T-cell lymphomas

## Purpose of clinical trials

- 1) Tolerance, safety profile, recommended phase II dose, pharmacokinetics, immunogenicity
- 2) Response rate

## Dosage and administration schedule

Intravenous infusion: Weekly for 4 weeks

3 patients (Max of 6 patients) per group: 1 / 0.01 mg/kg

2 / 0.1 mg/kg

3 / 0.5 mg/kg

4 / 1.0 mg/kg + recommended dose

## Results overview

Phase I clinical trials

Safety: Maximum tolerated dose up to 1.0 mg/kg  
No production of anti-KW-0761 antibody

Response: Response rate of 31% (2CR, 3PR)

\*Journal of Clinical Oncology (Accepted Nov. 2009)

## Phase II clinical trials

In Phase II clinical trials with a set dosage of 1.0 mg/kg

## Targeted diseases

Peripheral T-cell lymphoma (PTCL) and Cutaneous T cell lymphoma (CTCL)

## Purpose of clinical trials

- 1) Tolerance, safety profile, recommended phase II dose
- 2) Response rate

## Dosage and administration schedule

Intravenous infusion: Weekly 4 times

3 patients (Max of 6 patients) per group: 1 / 0.1 mg/kg  
2 / 0.3 mg/kg  
3 / 1.0 mg/kg

## Results overview

Phase I clinical trials

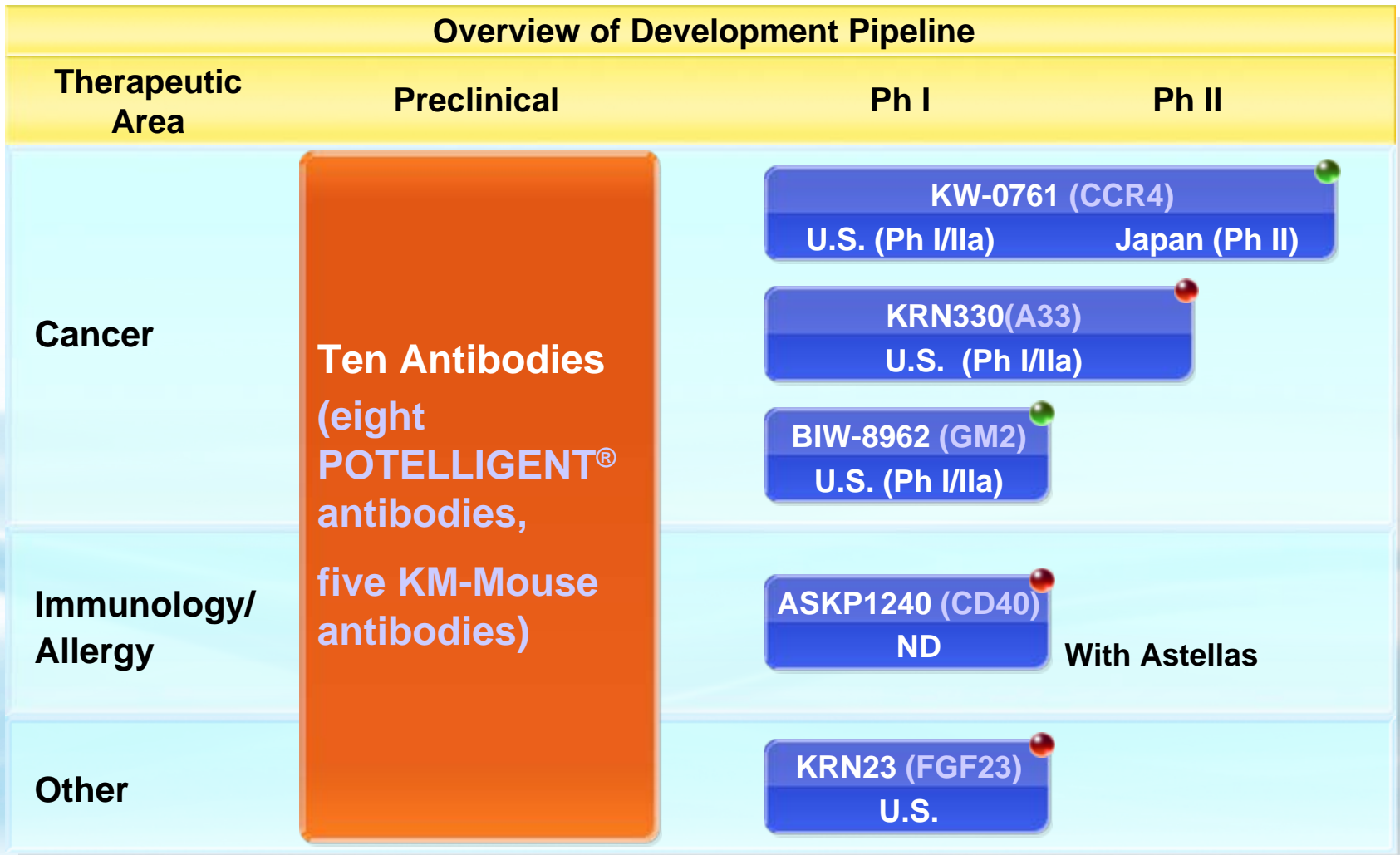
Safety: Maximum tolerated dose up to 1.0 mg/kg

Response: Confirmed effectiveness of 3 pts among 8 evaluable pts

## Phase II clinical trials

In Phase II clinical trials with a set dosage of 1.0 mg/kg

● Antibody pharmaceutical pipeline (as of January 2010)



● : POTELLIGENT® Technology

● : KM-Mouse Technology

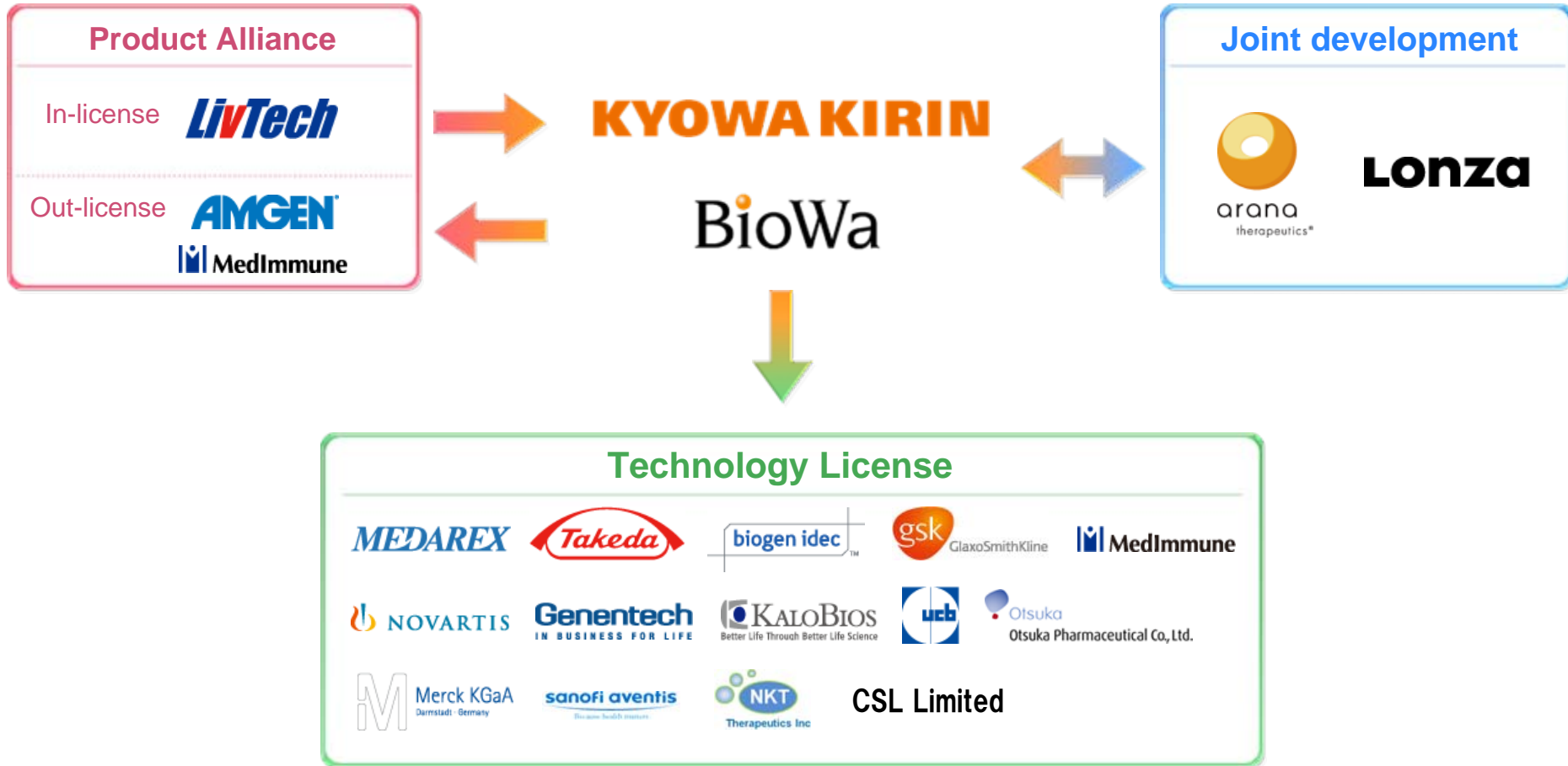
# ● Licensed-out antibody pharmaceuticals (as of January 2010)

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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

# ● POTELLIGENT<sup>®</sup> technology related alliances (as of January 2010)






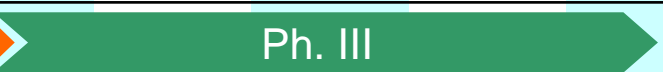







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\*Clinical trials are in progress for five out-licensed POTELLIGENT<sup>®</sup> antibodies

**● In-house antibody development and clinical trial schedule** **KYOWA KIRIN**

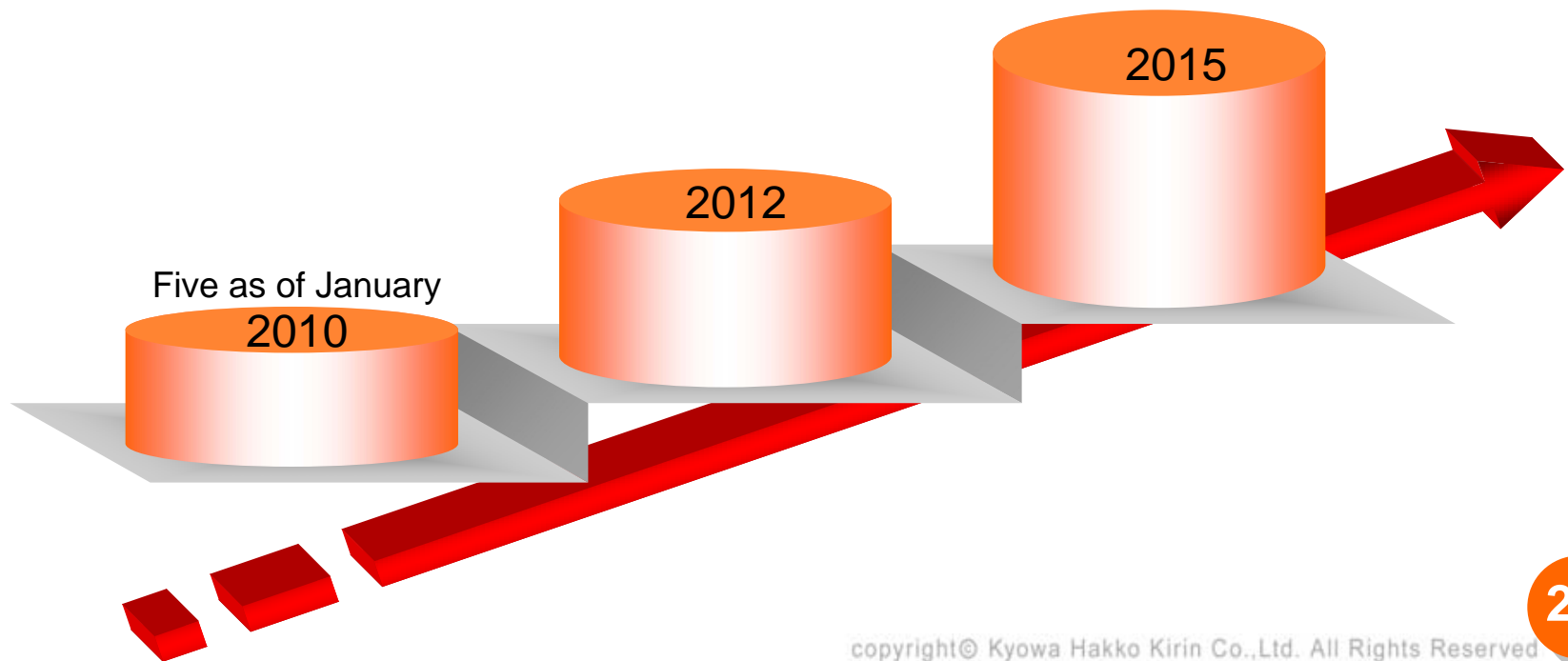
Scheduled for application  Scheduled for launch 

Area	Antibody	Region	2010	2012	2015
Cancer/ Hematology	KW-0761 (cancer)	Japan	Ph. II  		
		USA	Ph. I-II 		
	KRN330	USA	Ph. I-II 	Ph. III  	
	BIW-8962	USA	Ph. I-II 	Ph. II-III 	
Immunology / Allergy	ASKP1240		Ph. I-II-III 		
Other	KRN23	USA	Ph. I-II-III  		
	Preclinical antibodies		Two antibodies to enter clinical trials each year 		

The above forecasts are based on information available and assumptions made at the time of release of this document about a number of uncertain factors that can affect results in the future. It is possible that actual results are materially different for a wide variety of reasons.



Clinical trials for POTELLIGENT® antibody contracts will steadily increase



## Bio-Chemicals business – Medium-term business plan

(¥bn)	2009 results	2012 targets
Net sales	90.6	88.0
Operating income (prior to amortization of goodwill)	4.5	9.0
Operating income (after amortization of goodwill)	3.9	8.4
Foreign exchange	¥94/\$ ¥130/€	¥91/\$ ¥133/€

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).

● Basic strategy

- Expand sales of core products such as high value added amino acids
- Strengthen affiliations in health care areas within the Kirin Group
- Expand production infrastructure to ensure a steady supply of pharmaceutical raw materials and Fine Chemical products

● Factors to increase profits

- Cost reductions (from technology development, etc.): About ¥2.0 bn
- Profit increase from increase in amino acid sales volumes (8% annual growth): About ¥2.5 bn

## Chemicals business – Medium-term business plan

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(¥bn)	2009 results	2012 targets
Net sales	64.2	147.0
Operating income (prior to amortization of goodwill)	(5.5)	7.0
Operating income (after amortization of goodwill)	(5.5)	7.0
Naphtha	¥36,000/kl	¥52,000/kl

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).

● Basic strategy

- Strengthen business fundamentals to stabilize profits and expand sales of core products
- Expand sales of environment-friendly chemical products globally
- Maintain a safe and stable operating structure

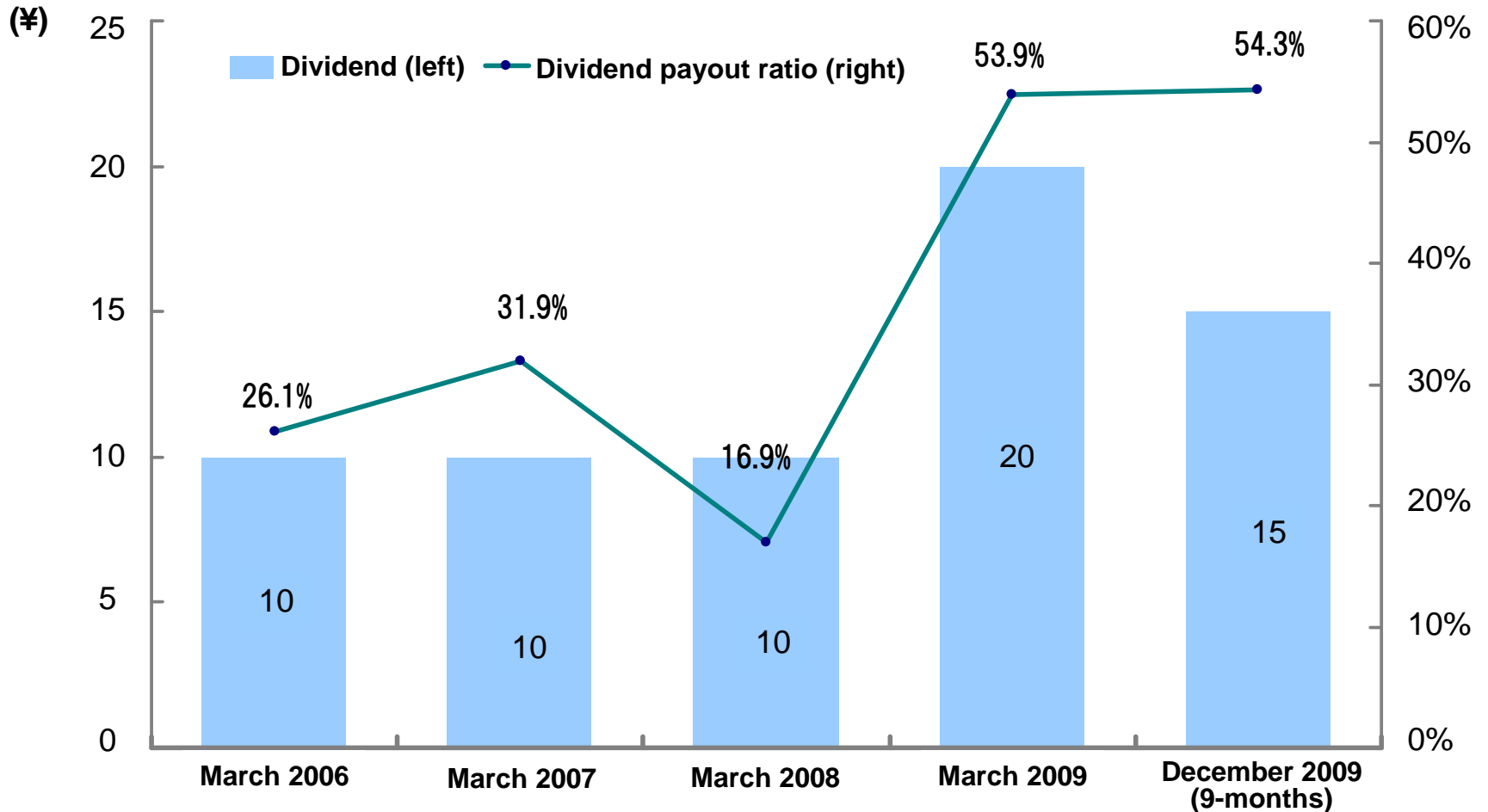
● Factors to increase revenues and profits

- Increased sales volumes from rise in demand for chemical products along with global economic recovery
- Expand sales of environment-friendly chemical products —one of our strengths
- Improved product prices from increased raw material and fuel prices
- Changes to consolidated subsidiaries segment (Other business ⇒ Chemicals business)

## Shareholder return policy

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The medium-term business plan targets a consolidated dividend payout ratio of 30% prior to amortization of goodwill



Five year trends in the dividend and consolidated dividend payout ratio (prior to amortization of goodwill)

## Key points of medium-term business plan

- Efficiently use business resources to promote rapid progress in our development pipeline
- Ensure the launch from the second half of the plan period onwards of new pharmaceuticals developed in house in the US and European markets
- Improve our sales organizations in the US and European markets in accordance with progress made on the development pipeline



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