

# **Kyowa Hakko Kirin**

## **Fiscal 2011 Interim Results**

(January 1- June 30, 2011)

**President & CEO**  
**Yuzuru Matsuda**  
August 2, 2011

**Kyowa Hakko Kirin Co., Ltd**

*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 interim results

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● Summary of fiscal 2011 interim results: P&L

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(¥bn)	Net sales	Operating income	Ordinary income	Net income
<b>FY 2011 interim</b>	<b>186.3</b>	<b>29.9</b>	<b>30.2</b>	<b>17.7</b>
<b>Change</b>	<b>-17.0 (-8.4%)</b>	<b>+8.2 (+38.0%)</b>	<b>+7.8 (+35.3%)</b>	<b>+7.8 (+78.9%)</b>
<b>FY 2010 interim</b>	<b>203.4</b>	<b>21.6</b>	<b>22.3</b>	<b>9.9</b>

\*ProStrakan results for the first half of fiscal 2011 are not included in the above figures.

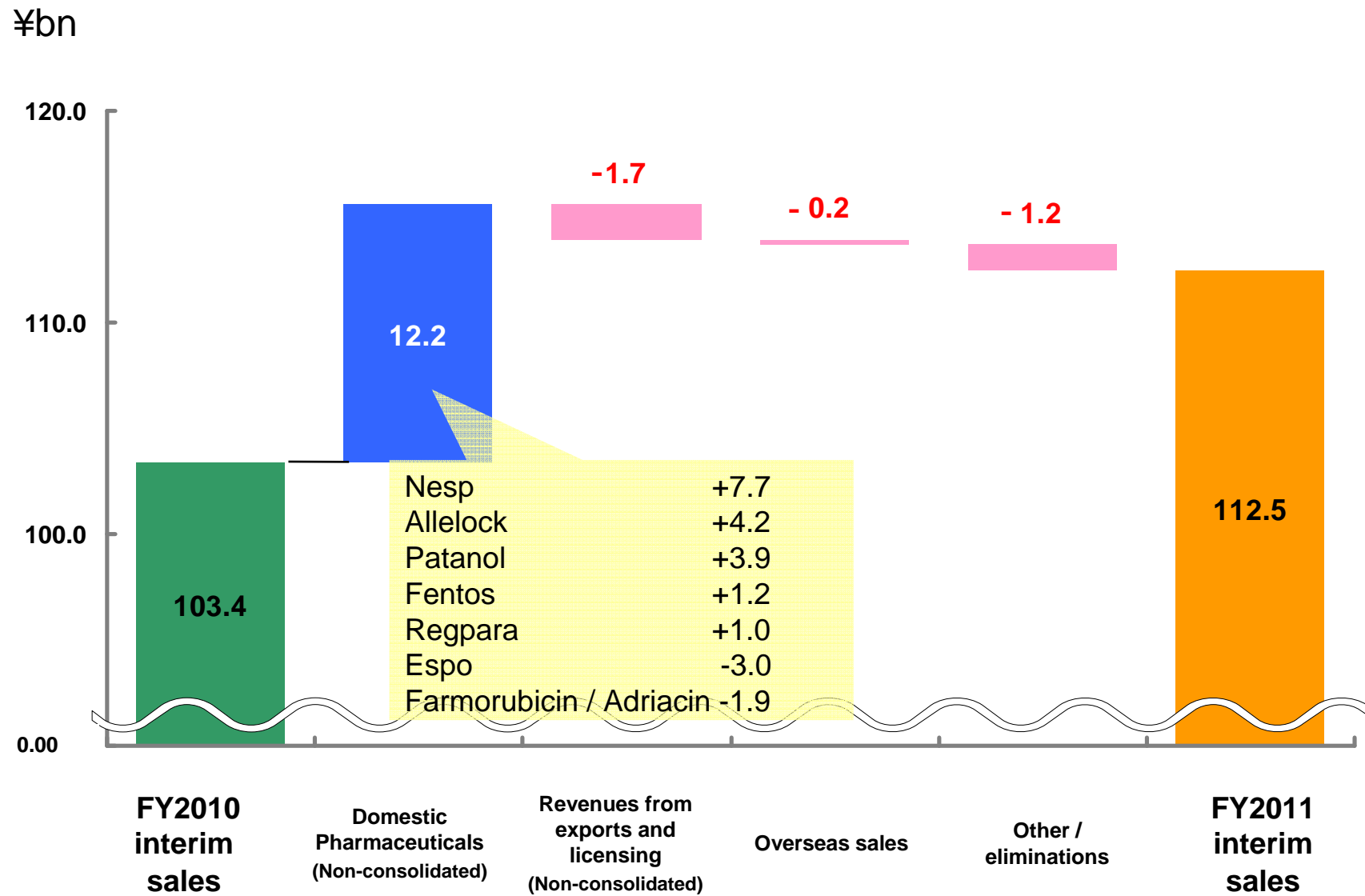
## ● Pharmaceuticals business

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(¥bn)	FY2010 interim	FY2011 interim	Change
Net sales	103.4	112.5	+9.0
Operating income	17.9	25.1	+7.1
R&D expenses	19.3	20.4	+1.1

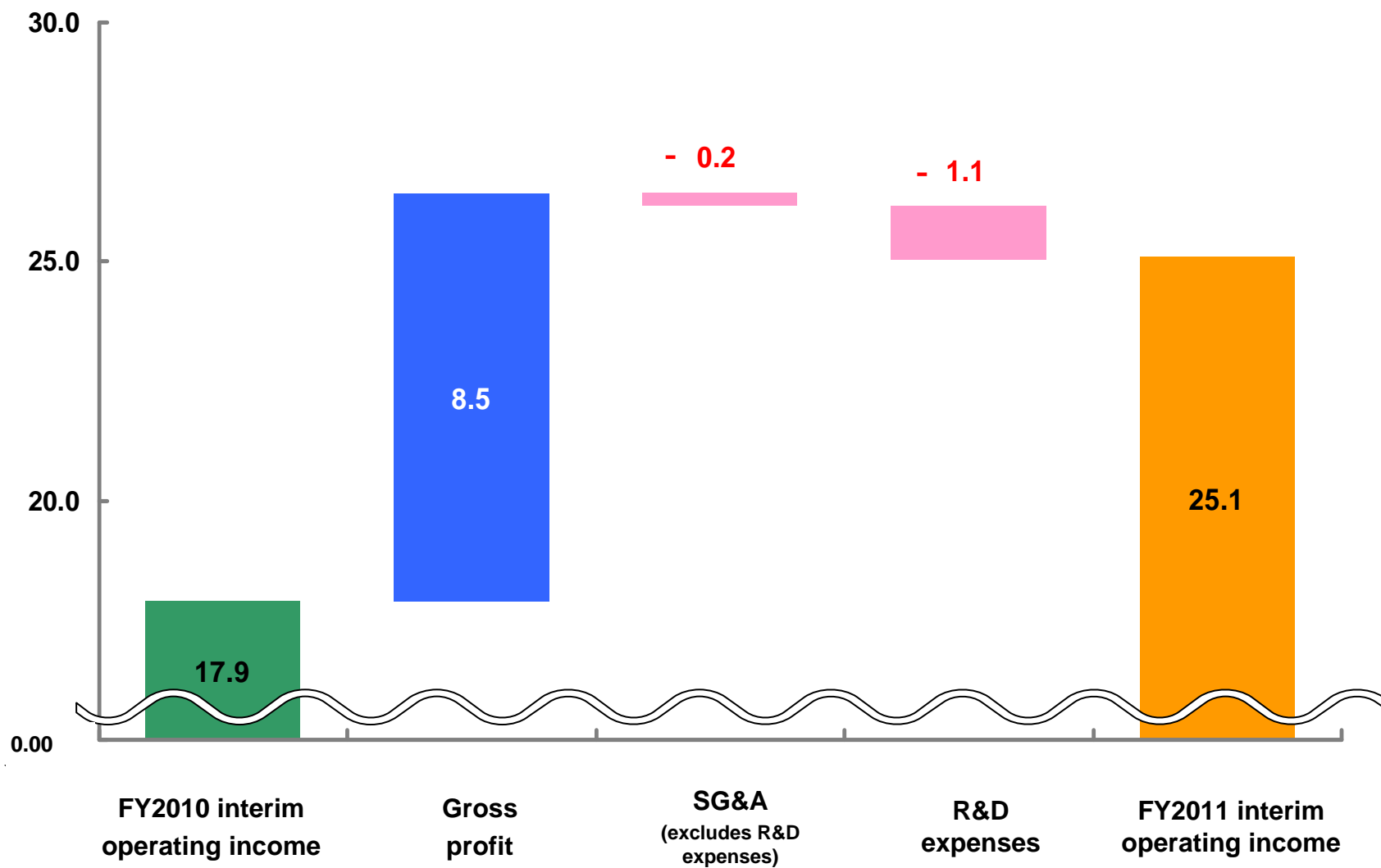
\*ProStrakan results for the first half of fiscal 2011 are not included in the above figures.

● Pharmaceuticals business: Change in net sales



# ● Pharmaceuticals business: Change in operating income **KYOWA KIRIN**

¥bn



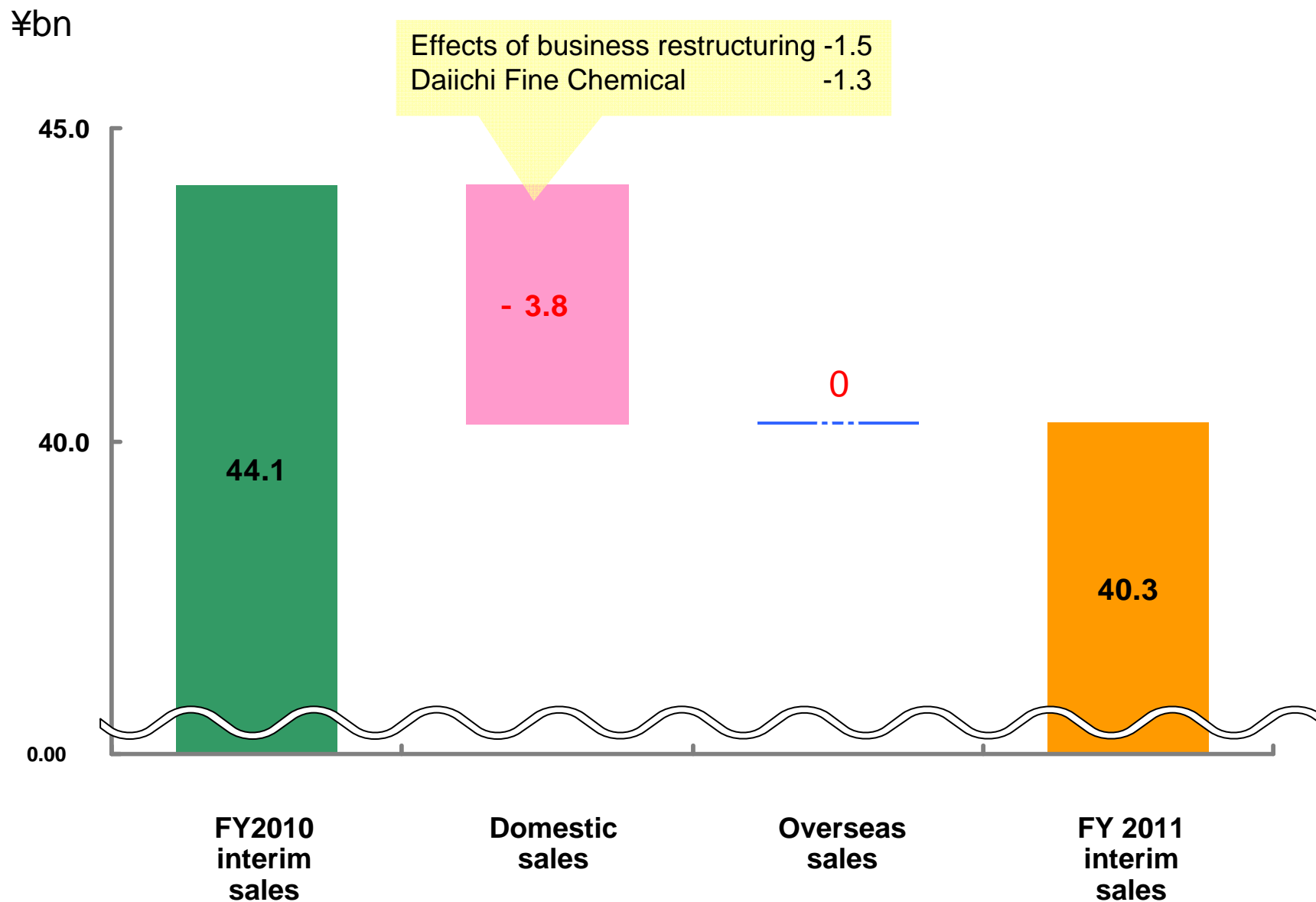
# ● Bio-Chemicals and Chemicals businesses

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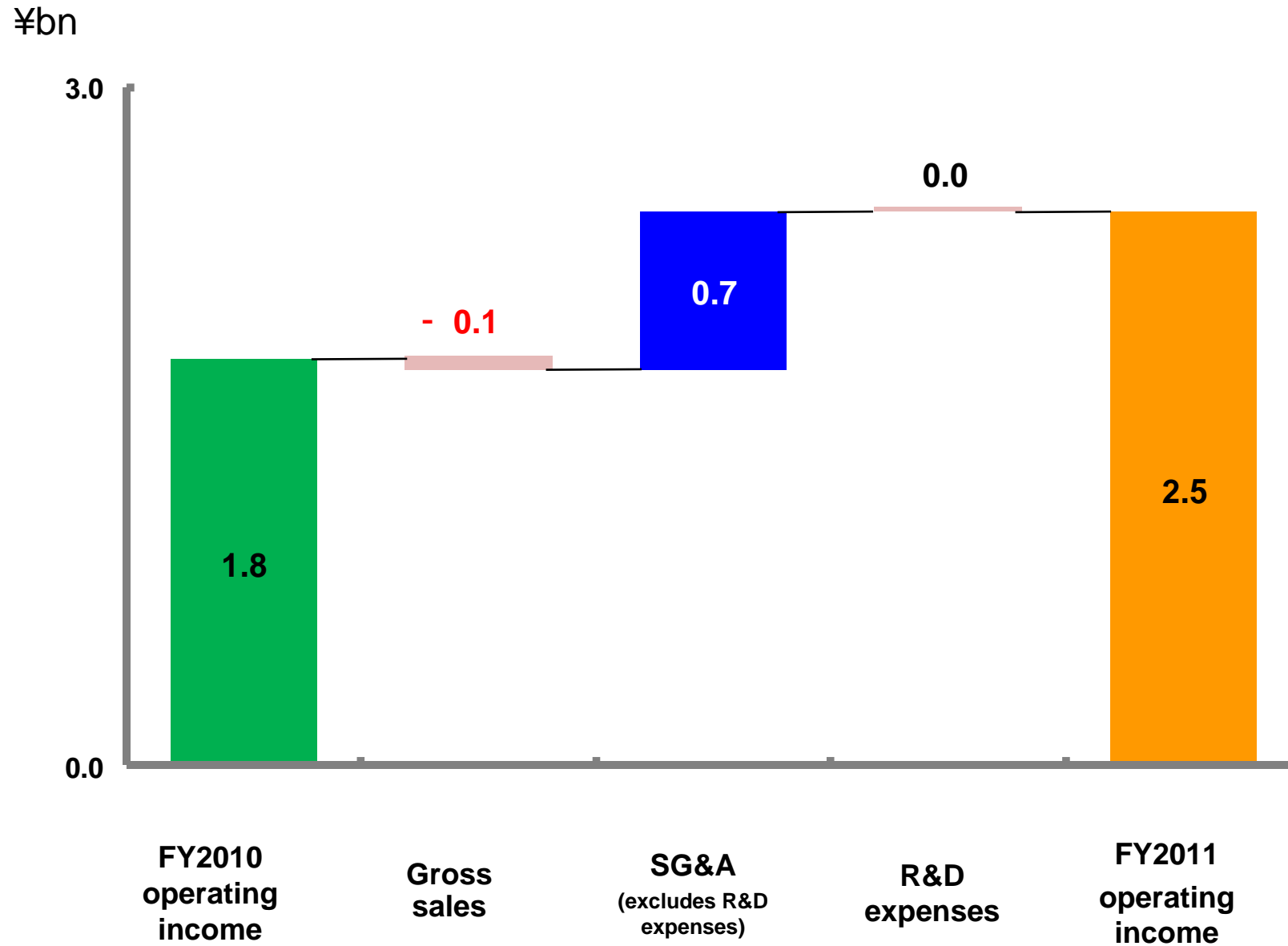
(¥bn)		FY 2010 interim	FY2011 interim	Change
<b>Bio-Chemicals</b>	<b>Net sales</b>	<b>44.1</b>	<b>40.3</b>	<b>-3.8</b>
	<b>Operating income</b>	<b>1.8</b>	<b>2.5</b>	<b>+0.6</b>
<b>Chemicals*</b>	<b>Net sales</b>	<b>61.2</b>	<b>33.5</b>	<b>-27.7</b>
	<b>Operating income</b>	<b>1.5</b>	<b>2.1</b>	<b>+0.5</b>
<b>Forex rates vs. ¥</b>	<b>/ \$</b>	<b>¥91/\$</b>	<b>¥82/\$</b>	<b>-¥9/\$</b>
	<b>/ €</b>	<b>¥121/€</b>	<b>¥115/€</b>	<b>-¥6/€</b>
* The Chemicals segment is included in consolidation for the January-March period of fiscal 2011 and excluded from April 2011.				



# Bio-Chemicals business: Change in net sales



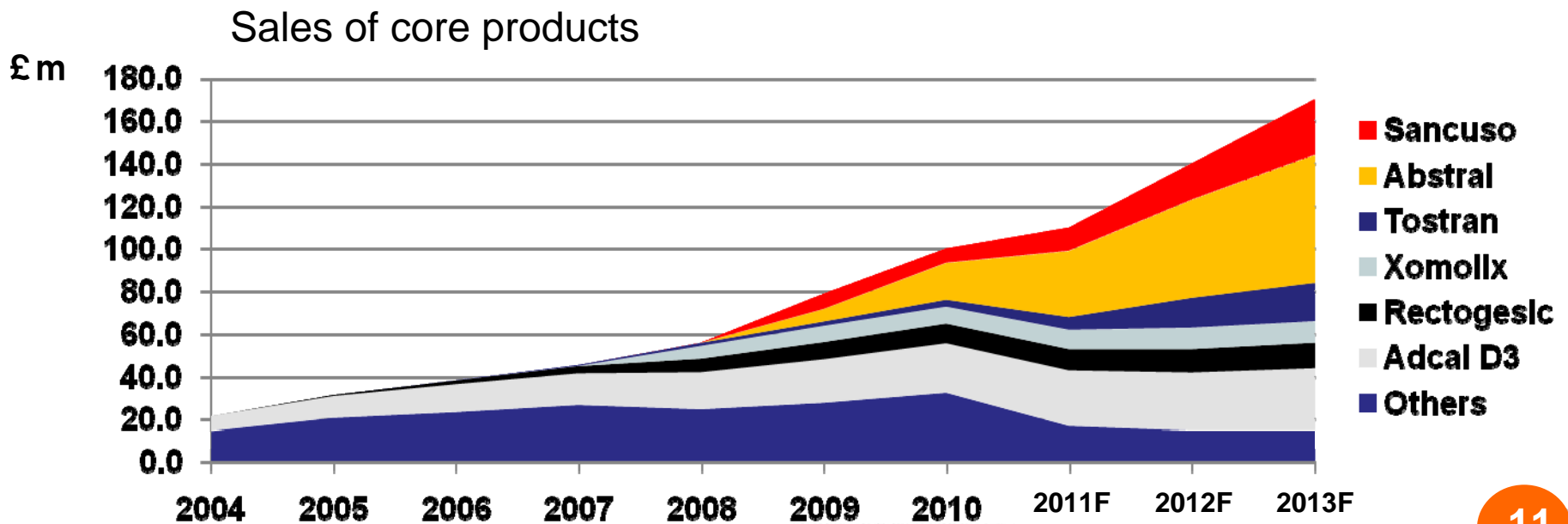
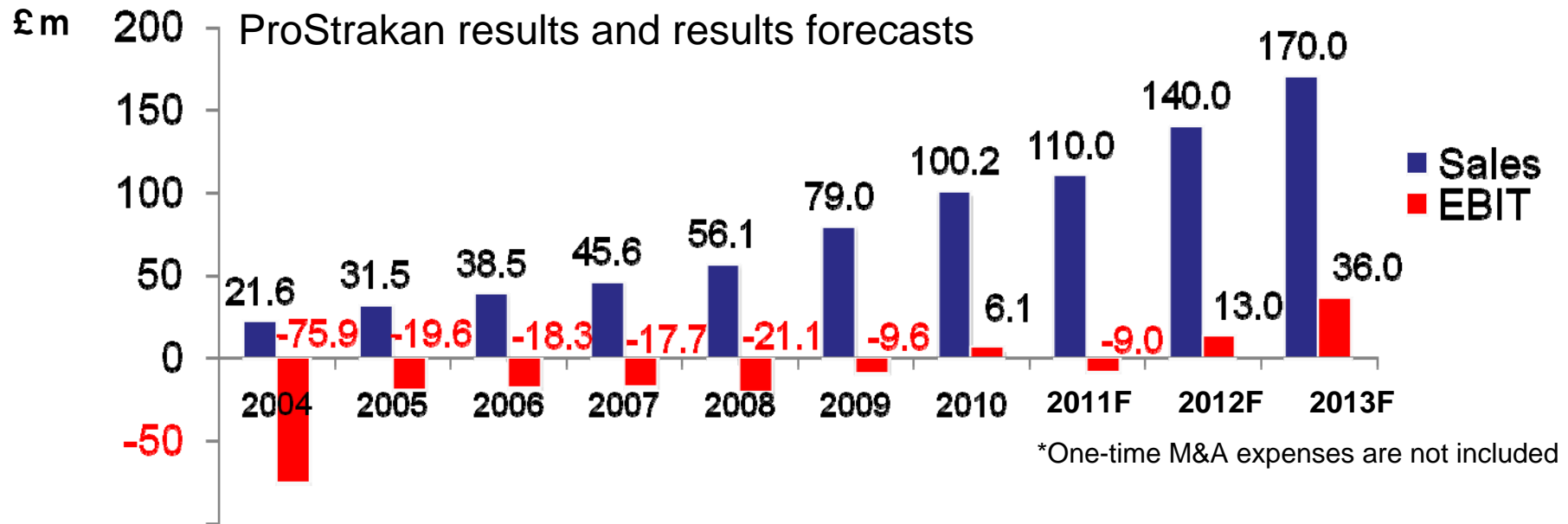
● Bio-Chemicals business: Change in operating income



## Outline of ProStrakan, accounting treatment

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● Outline of ProStrakan



## ● ProStrakan: Management policy and strategy

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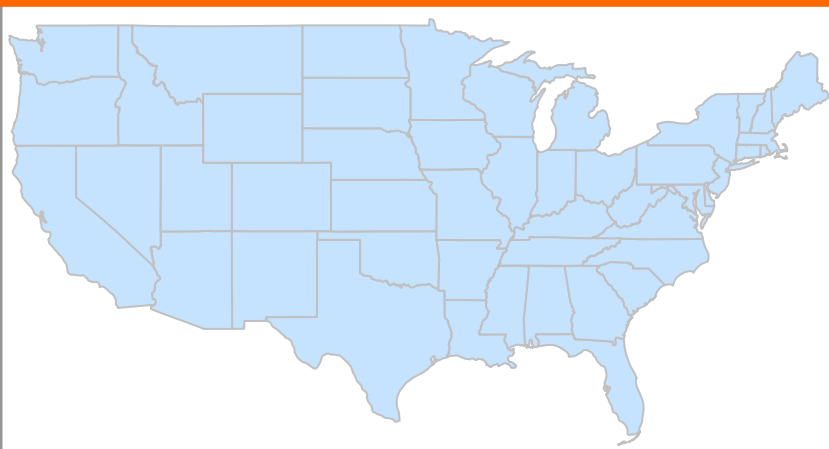
### Europe sales force

KHK approx. 15

ProStrakan approx. 150



### U.S. sales force of approx. 50



#### ➤ Governance

- 2 KHK executives will join the ProStrakan board
- 2 KHK executives based in the UK will join the ProStrakan Executive Committee

#### ➤ Europe strategy

- Organically combine the European sales infrastructure of ProStrakan and KHK
- Assess cross-selling opportunities for KHK's core European anticancer treatment Mitomycin-C and pursue other synergies

#### ➤ U.S. strategy

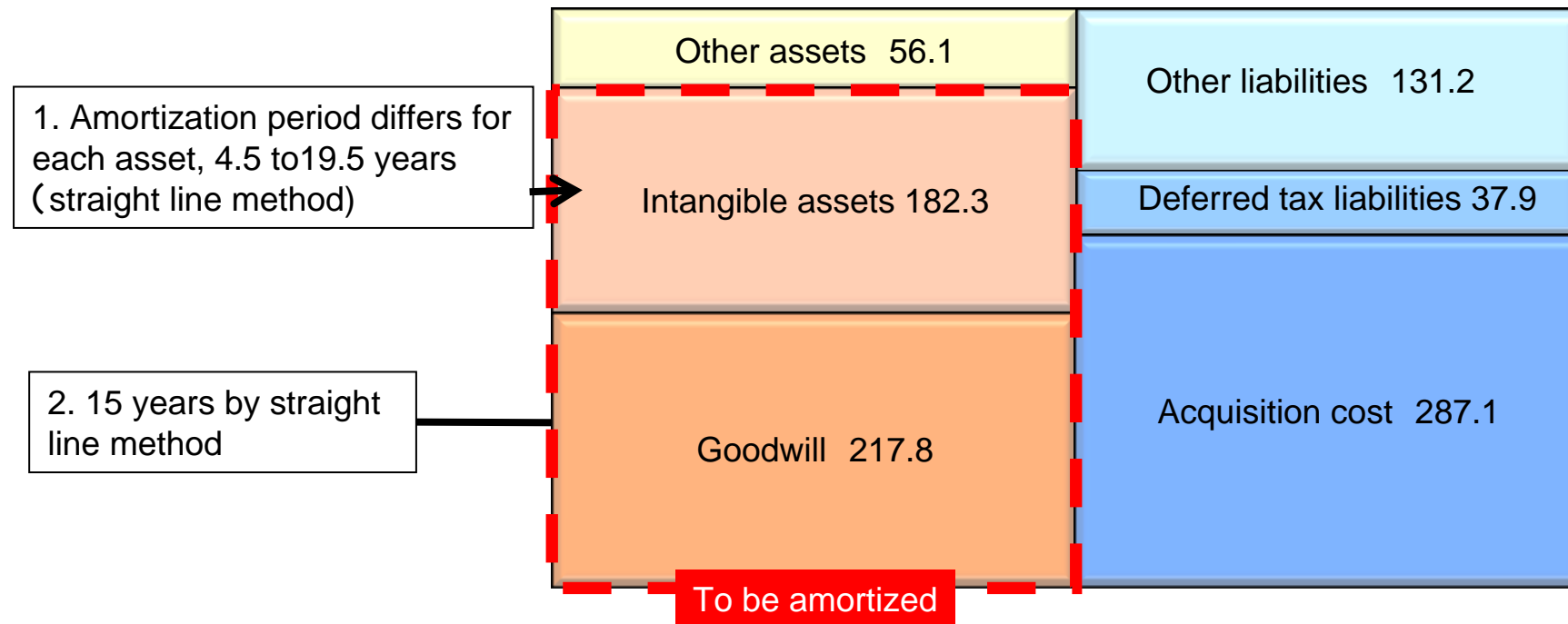
- Focus on establishing the presence of Sancuso and Abstral in the U.S. market
- Sales of KW-0761 and other new products

## ● ProStrakan: Corporate merger accounting treatment

Initial balance sheet (provisional accounting treatment as of the assumed acquisition date  
June 30, 2011)

Balance sheet after valuation of intangible assets by Purchase Price Allocation method

(Unit: GBP million)



### Expected effects on profits from corporate merger accounting treatment:

1. Intangible assets amortization:	2011 H2 GBP9.0m (Ref: 2012 full year GBP18.1m)
2. Goodwill amortization:	2011 H2 GBP7.3m (Ref: 2012 full year GBP14.5m)
<b>Total amortization:</b>	<b>2011 H2 GBP16.3m (Ref: 2012 full year GBP32.6m)</b>

## 2011 forecasts

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## ● 2011 forecasts (including ProStrakan)

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(¥ bn)	Net sales	Operating income	Ordinary income	Net income
<b>Fiscal 2011 forecast</b> (vs. Jan 28 2011 forecast)	<b>342.0</b> (+5.2%)	<b>43.5</b> (+17.6%)	<b>44.5</b> (+17.1%)	<b>25.5</b> (--)
<b>Previous fiscal 2011 forecast</b> (announced Jan 28 2011)	<b>325.0</b>	<b>37.0</b>	<b>38.0</b>	<b>25.5</b>
<b>Fiscal 2010 results</b>	<b>413.7</b>	<b>45.4</b>	<b>46.5</b>	<b>22.1</b>

\*ProStrakan figures consolidated based on an assumed acquisition date of June 30, 2011.



● Pharmaceuticals business 2011 forecasts (including ProStrakan) **KYOWA KIRIN**

¥bn	FY2010 results (1)	Revised 2011 forecast (2)	YonY change (2)-(1)	Initial 2011 forecast (3)	Difference between initial and revised forecasts (2)-(3)	Effects of ProStrakan acquisition
Net sales	210.3	225.0	+14.6	212.0	+13.0	+7.4
Operating income	35.8	37.5	+1.6	32.0	+5.5	<p><b>Total effect = -2.6</b>                      Inventory revaluation: -0.6                      Intangibles amortization: -1.2                      Goodwill amortization: -0.9</p> <p>Note: Forecast FY2011 H2 operating income for ProStrakan alone = - ¥0bn</p>
R&D expenses	40.0	45.0	+5.0	46.5	-1.5	+0.6

● 2011 forecast sales of core pharmaceutical products

¥bn	Fiscal 2010	Fiscal 2011 forecast	YonY change	Initial forecast
Nesp	41.7	50.8	22% ↑	46.9
Espo	10.8	5.3	51% ↓	4.0
Nesp/Espo	52.6	56.1	7% ↑	50.9
Regpara	9.5	11.1	17% ↑	11.1
Allelock	26.8	29.0	8% ↑	29.8
Patanol	7.5	11.6	55% ↑	10.2
Gran/Neu-up	14.4	14.5	1% ↑	14.5
Fentos	0.8	2.6	225% ↑	2.4
Coniel	21.0	19.7	6% ↓	19.9
Coversyl	4.2	3.9	7% ↓	3.9
Depakene	11.0	11.1	1% ↑	11.0
Permax	2.0	2.3	15% ↑	2.3
Asacol	0.7	2.8	300% ↑	2.6
Exports and technology out-licensing revenues	24.1	22.4	7% ↓	23.9

\*Sales of Neu-up were transferred to Yakult Honsha as of March 2010

\*Sales of Fentos began in June 2010

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

● 2011 forecasts (Bio-Chemicals)

¥bn		Fiscal 2010	Fiscal 2011	Change
<b>Bio-Chemicals</b>	<b>Sales</b>	84.2	80.0	-4.2
	<b>Operating Income</b>	3.2	3.5	+0.2
<b>Forex rates vs ¥</b>	<b>/ \$</b>	¥88/\$	¥82/\$	-¥6/\$
	<b>/ €</b>	¥116/€	¥118/€	+¥2/€

## Pipeline

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## ● Pipeline (as of August 2, 2011)

### ( Filed/Approved)

Category	Code name/ Product name	Stage		Indication	Formulation	In-house or licensed	Remarks
		Japan	Other countries				
Oncology	KW-0761	Filed April 2011		(Adult T-cell leukemia/lymphoma)	Injection	In-house	POTELLIGENT antibody*
	KRN321 Darbepoetin Alfa	Filed Nov/2008		Chemotherapy induced anemia	Injection	Kirin-Amgen	Launched for anemia of CKD patients
	Pegfilgrastim		Filed in Asia	Neutropenia	Injection	Kirin-Amgen	Asia: Korea, Taiwan and Vietnam
Nephrology	Cinacalcet Hydrochloride		Filed in Singapore	Secondary hyperparathyroidism	Oral	NPS	Launched in Japan for secondary hyperparathyroidism
	Darbepoetin Alfa		Approved in Asia	Anemia (on dialysis)	injection	Kirin-Amgen	Approved in Thailand on May 25 (Asia: Filed in Singapore and the Philippines)
CNS	KW-6500 Apomorphine Hydrochloride	Filed July 2011		Parkinson's disease	Injection	Licensed from Britannia Pharma.	
Other	AMG531 Romiplostim	Launched April 2011	Approved in Asia	Immune thrombocytopenic purpura	Injection	Kirin-Amgen	Approved in Korea on June 1 (Asia: Filed in Singapore, Hong Kong, Malaysia and Taiwan)

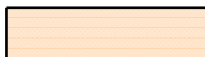
\*KW-0761 was outlicensed to Amgen Inc. in March, 2008, with an exclusive right to develop and commercialize KW-0761 worldwide, except in Japan, Korea, China and Taiwan. However, in 2010, Kyowa Hakko Kirin repurchased the development and commercialization rights held by Amgen for overseas markets in cancer-related areas. Kyowa Hakko Kirin now holds the development and commercialization rights worldwide for cancer-related areas.

Updated since January 28, 2011 ( Area, Stage, Filed, Approved, Launched etc.)

● Pipeline (as of August 2, 2011)

(Phase II, Phase III)

Category	Code name/ Product name	Stage		Indication	Formulation	In-house or licensed	Remarks
		Japan	Other countries				
Oncology	KW-0761		Phase I/II in USA	(Peripheral T-cell lymphoma and cutaneous T-cell lymphoma)	Injection	In-house	POTELLIGENT® antibody KW-0761 was outlicensed to Amgen Inc. in March, 2008, with an exclusive right to develop and commercialize KW-0761 worldwide, except in Japan, Korea, China and Taiwan. However, in 2010, Kyowa Hakko Kirin repurchased the development and commercialization rights held by Amgen for overseas markets in cancer-related areas. Kyowa Hakko Kirin now holds the development and commercialization rights worldwide for cancer-related areas.
		Phase II		Adult T-cell leukemia/lymphoma, Add-on therapy			
		Phase II		(Peripheral T/NK-cell Lymphoma)			
	KW-2246 Fentanyl citrate	Phase III		Cancer pain	Sublingual tablet	Licensed from Orexo	
	KRN125 Pegfilgrastim	Phase III		Neutropenia	Injection	Kirin-Amgen	
	ARQ 197	Phase II	Phase II in Korea	Cancer (Gastric cancer)	Oral	Licensed from ArQule.	
		Phase I		Lung cancer			
KW-2478		Phase I/II In UK, USA, Philippines	Multiple myeloma	Injection	In-house		



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# ● Pipeline (as of August 2, 2011)

## (Phase II, Phase III) continued

Category	Code name/ Product name	Stage		Indication	Formulation	In-house or licensed	Remarks
		Japan	Other countries				
Nephrology	KRN321 Darbepoetin Alfa	Phase III		★ Pediatric Renal Anemia	Injection	Kirin-Amgen	Launched in Japan for anemia of CKD patients
			Phase II in China	Anemia (on dialysis)			
	Cinacalcet Hydrochloride		Phase III in China	Secondary hyperparathyroidism	Oral	Licensed from NPS	Japan: Already launched
Immunology/ Allergy	ASKP1240	Phase I	Phase II in USA	Organ Transplant Rejection	Injection	In-house	Developed with Astellas
	Z-206 Mesalazine	Phase II		★ Crohn's disease	Oral (pH dependent controlled- release formulation)	Licensed from Zeria Pharma.	Jointly developed with Zeria Pharma Already launched in Japan for ulcerative colitis
CNS	KW-6002 Istradefylline	Phase III		Parkinson's disease	Oral	In-house	North America rights outlicensed to Valeant Pharmaceuticals International have been restored to Kyowa Kirin
	KW-6485 Topiramate	Phase III		★ Pediatric epilepsy	Oral	Licensed from Janssen Pharmaceuticals KK	Launched as an epilepsy treatment in Japan
Other	KW-3357 Antithrombin	Phase III	Phase I in Europe	Disseminated intravascular coagulation, Congenital antithrombin deficiency	Injection	In-house	



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Expanded application

# ● Pipeline (as of August 2, 2011)

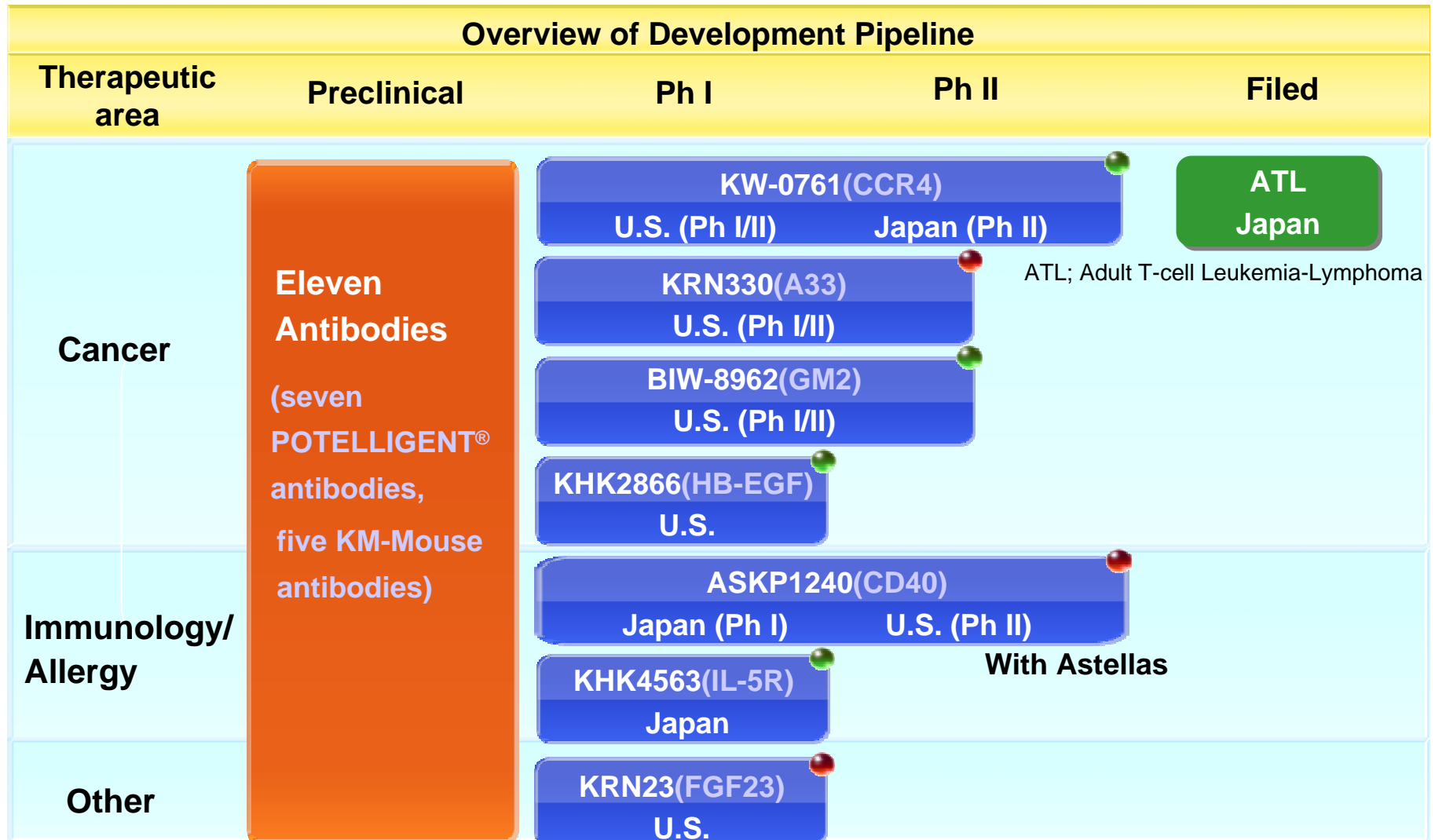
## (Phase I)

Category	Code name/ Product name	Stage		Indication	Formulation	Developed in- house or licensed	Remarks
		Japan	Other countries				
Oncology	KW-2450		Phase I/II in USA	Cancer	Oral	In-house	
	KRN330		Phase I/IIa in USA	Cancer	Injection	In-house	
	BIW-8962		Phase I/IIa in USA	Cancer	Injection	In-house	POTELLIGENT <sup>®</sup> antibody
	KRN951 Tivozanib	Phase I		Cancer	Oral	In-house	
	KHK2866		Phase I in USA	Cancer	Injection	In-house	POTELLIGENT <sup>®</sup> antibody
	LY2523355 Litrnesib	Phase I		Cancer	Injection	In-house	Being developed by Eli Lilly outside Japan
Nephrology	RTA402 Bardoxolone Methyl	Phase I		Diabetic nephropathy	Oral	Licensed from Reata	
Immunology/ Allergy	KHK4563 Benralizumab	Phase I		Asthma	Injection	In-house	Potelligent antibody Being developed by MedImmune as MEDI-563 worldwide except in Japan and other Asian countries
Other	KHK6188	Phase I		Neuropathy	Oral	In-house	
	KRN23		Phase I in USA	Hypophosphatemic rickets	Injection	In-house	

Updated since January 28, 2011 ( Area, Stage, Filed, Approved, Launched etc.)



● Antibody pharmaceutical pipeline (as of August 2, 2011)



● : POTELLIGENT® Technology    ● : KM-Mouse Technology

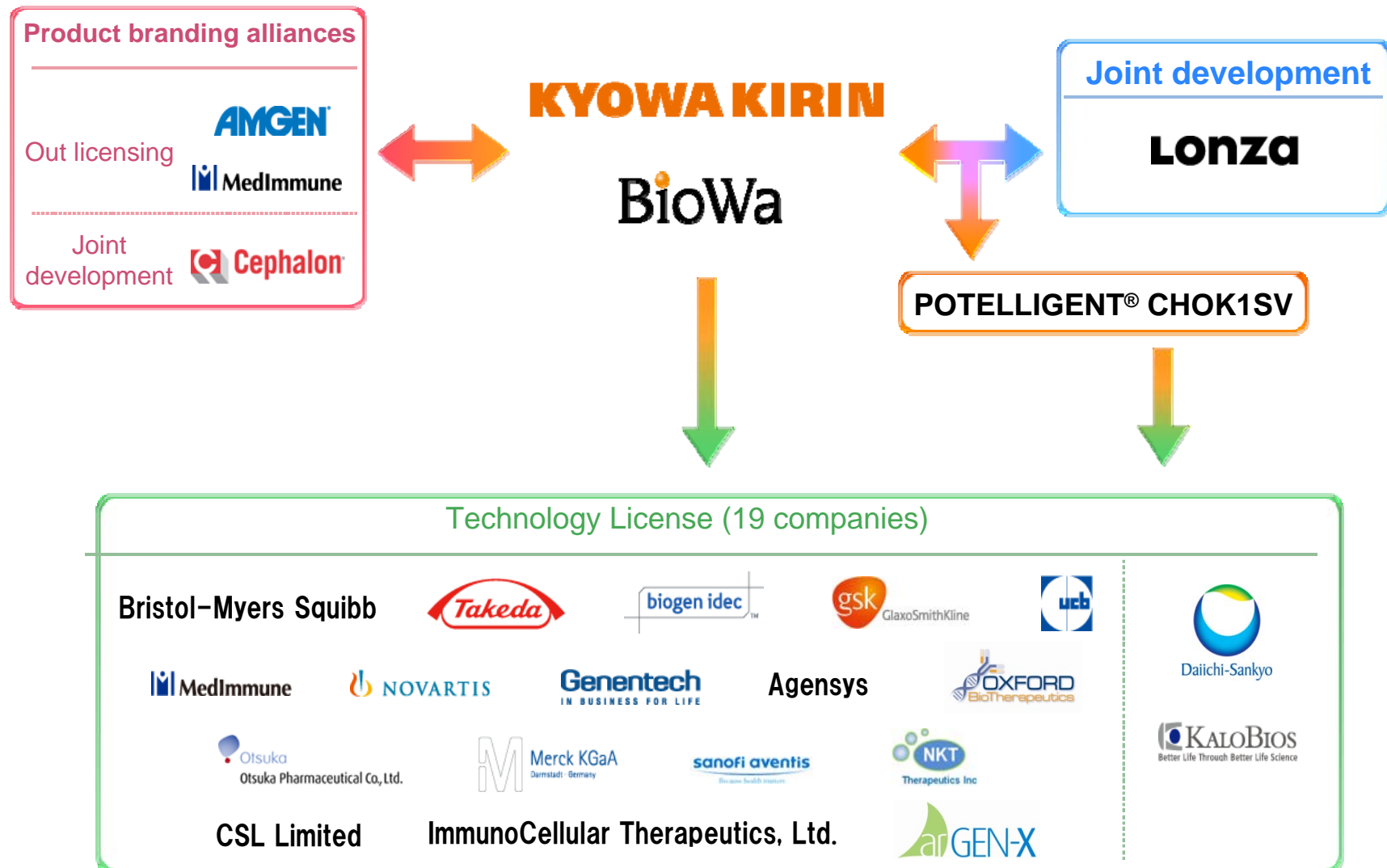
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● Licensing-out antibody pharmaceuticals (as of August 2, 2011)

Antibody	Target	Licensee	Reported Stage	Remarks
KW-0761	CCR4	Amgen (Except in JP, CN, KR, TW)	Ph I (AMG 761)	POTELLIGENT®
KHK4563	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 (Except in Japan, Asia)	Research	KM-Mouse

● POTELLIGENT® technology-related alliances (as of August 2, 2011)

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\*To date seven out-licensed POTELLIGENT® antibodies have entered clinical trials, including those by Bristol-Myers Squibb and Genentech.

● Progress with outlicensed compounds (as of August 2, 2011)

Name	Partner	Phase			Remarks
		I	II	III	
Tivozanib (KRN951)	AVEO Astellas				Cancer (VEGF receptor inhibitor)
KW-2871 (Low-fucose antibody)	Life Science				Cancer (Anti-GD3 antibody)
MEDI-563 (KHK4563:POTELLIGENT®)	MedImmune				Allergy (Anti-IL-5R antibody)
KRN5500	DARA				Peripheral neuropathy
LY2523355	Eli Lilly				Cancer (Mitotic kinesin Eg5 inhibitor)
AMG 761 (KW-0761:POTELLIGENT®)	Amgen				Allergy (Anti-CCR4 antibody)
RGI2001	REGiMMUNE				Immunosuppressive

● Progress with inlicensed compounds (as of August 2, 2011)

Name	Partner	Phase			Remarks
		I	II	III	
KW-6500	Britannia	Filed			Parkinson's disease (Dopamine agonist)
SP-01	Solasia	Preparing to file			Emesis (Serotonin antagonist)
KW-2246	Orexo				Cancer pain (m-opioid receptor agonist)
ARQ 197	ArQule				Gastric cancer (c-met inhibitor)
Asacol	Zeria				Crohn's disease *as a treatment for ulcerative colitis
RTA 402	Reata				Diabetic neuropathy

### KW-0761

- An anti-CCR4 antibody using enhanced antibody manufacturing technology POTELLIGENT<sup>®</sup> developed in-house

### Hematological cancer: Development update

- Japan: ATL (Adult T-cell leukemia/lymphoma)
  - Ph I: Published in Journal of Clinical Oncology 28:1591-1598
  - Ph II: Clinical trial results announced at ASH, Dec. 2010
  - Application: Also in conjunction with companion diagnostics, Apr. 26, 2011
  - Launch: 2012 (planned)
- Japan: Other clinical trials
  - ATL add-on therapy (for untreated patients): In Ph II clinical trials
  - Peripheral T/NK-cell lymphoma: In Ph II clinical trials
- USA: PTCL, CTCL development (In Ph I/II clinical trials)
  - Ph I: Interim report: T Cell Lymphoma Forum (Jan. 28-30, 2010)
  - Ph I/II: Clinical trial results announced at ASH, Dec. 2010

### Main items January –July 2011

- 1/20 KW-6500 (Parkinson's disease treatment) released results of Phase III trials in Japan
- 3/11 KRN125 (treatment for neutropenia during chemotherapy) released start of Phase III trials in Japan
- 4/13 Launch of ROMIPLATE® [250 mcg] for subcutaneous injection
- 4/21 Announced completion of ProStrakan acquisition
- 4/26 Filed in Japan for manufacturing and sales of KW-0761 as treatment for ATL  
Filed in Japan for manufacturing and sales of KW-0761 companion diagnostics
- 5/10 KW-6002 (Parkinson's disease treatment) released initial results of Phase III trials in Japan
- 5/24 Won Patanol® US patent infringement lawsuit against Apotex (released by Novartis)
- 6/2 POTELLIGENT® 18<sup>th</sup> outlicensing contract (to ImmunoCellular Therapeutics)
- 6/3 KW-6002: Termination of North America licensing agreement
- 6/29 KW-3357: Announced start of Phase III trials in Japan
- 7/26 KW-6500: Filed in Japan for manufacturing and sales
- 7/26 POTELLIGENT® 19<sup>th</sup> outlicensing contract (to arGEN-X)

# **KYOWA KIRIN**

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