
Kyowa Hakko Kirin

Fiscal 2011 Results

(Fiscal year to December 31, 2011)

January 31, 2012

President & CEO
Yuzuru Matsuda

Kyowa Hakko Kirin Co., Ltd

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Summary of fiscal 2011 results

● Summary of fiscal 2011 results: P&L

(¥bn)	Net sales	Operating income	Ordinary income	Net income
FY2011	343.7	46.6	46.7	25.6
Change	-70.0 (-16.9%)	+1.2 (+2.7%)	+0.2 (+0.5%)	+3.4 (+15.4%)
FY2010	413.7	45.4	46.5	22.1

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

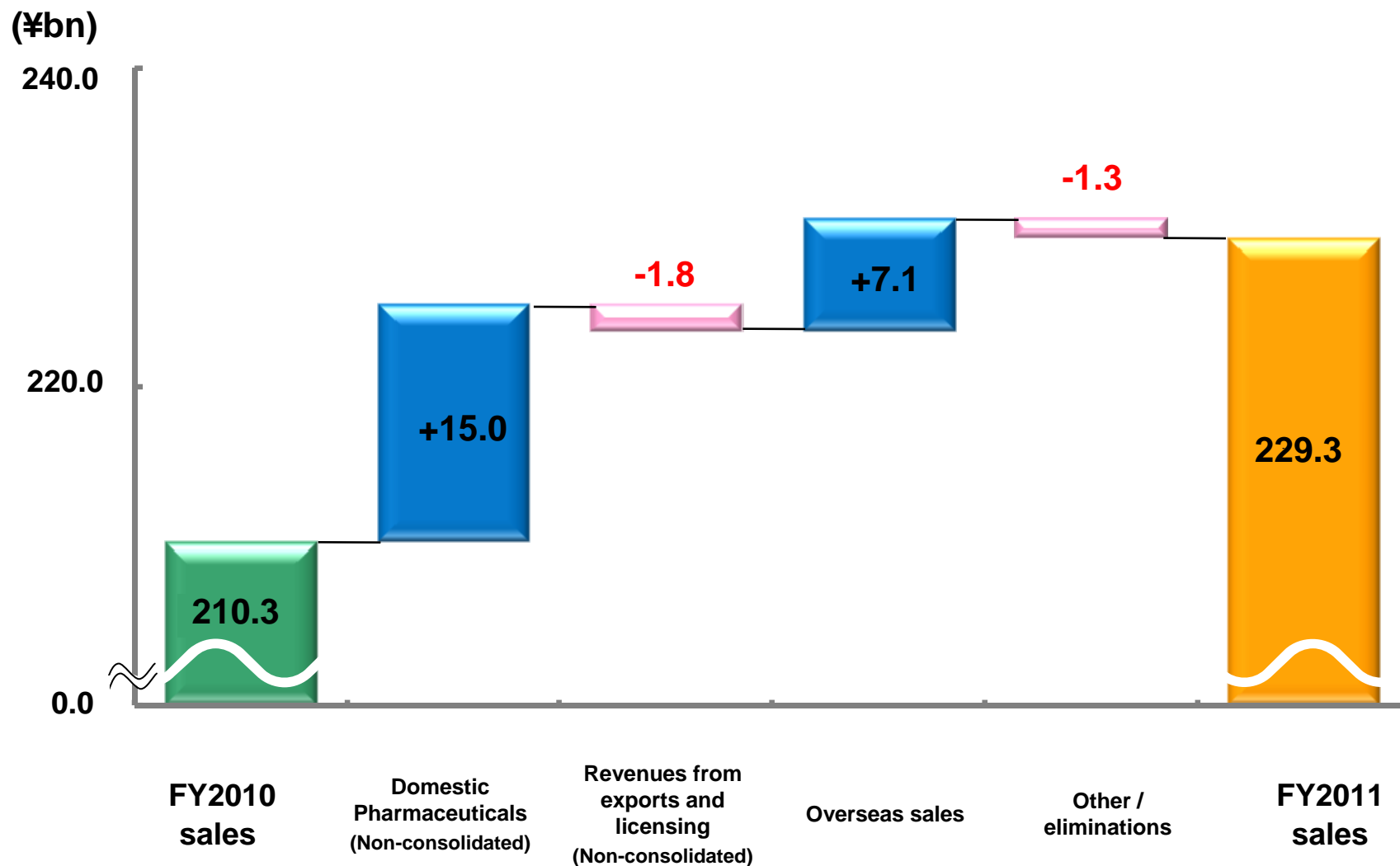
* The Chemicals segment is included in consolidation for the whole of fiscal 2010 and January-March period of fiscal 2011 and excluded from April 2011.

● Summary of fiscal 2011 results: Pharmaceuticals business **KYOWA KIRIN**

(¥bn)	FY2010	FY2011	Change
Net sales	210.3	229.3	+18.9
Operating income	35.8	41.3	+5.4
R&D expenses	40.0	44.5	+4.5

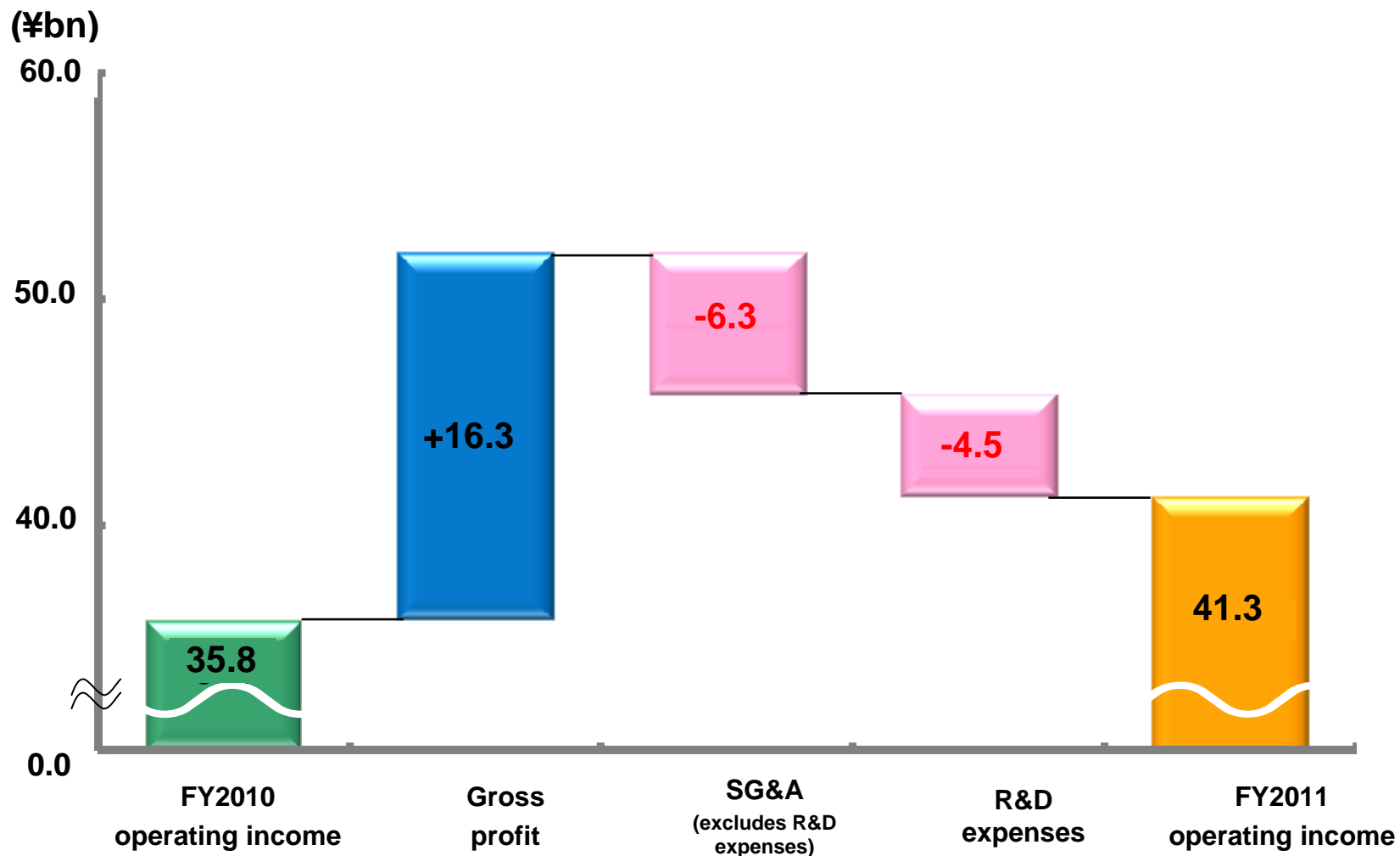
*ProStrakan results for the first half of fiscal 2011 are not included in the above figures.

● Pharmaceuticals business: Change in net sales



● Pharmaceuticals business: Change in operating income

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● Summary of fiscal 2011 results: **Bio-Chemicals and Chemicals businesses**

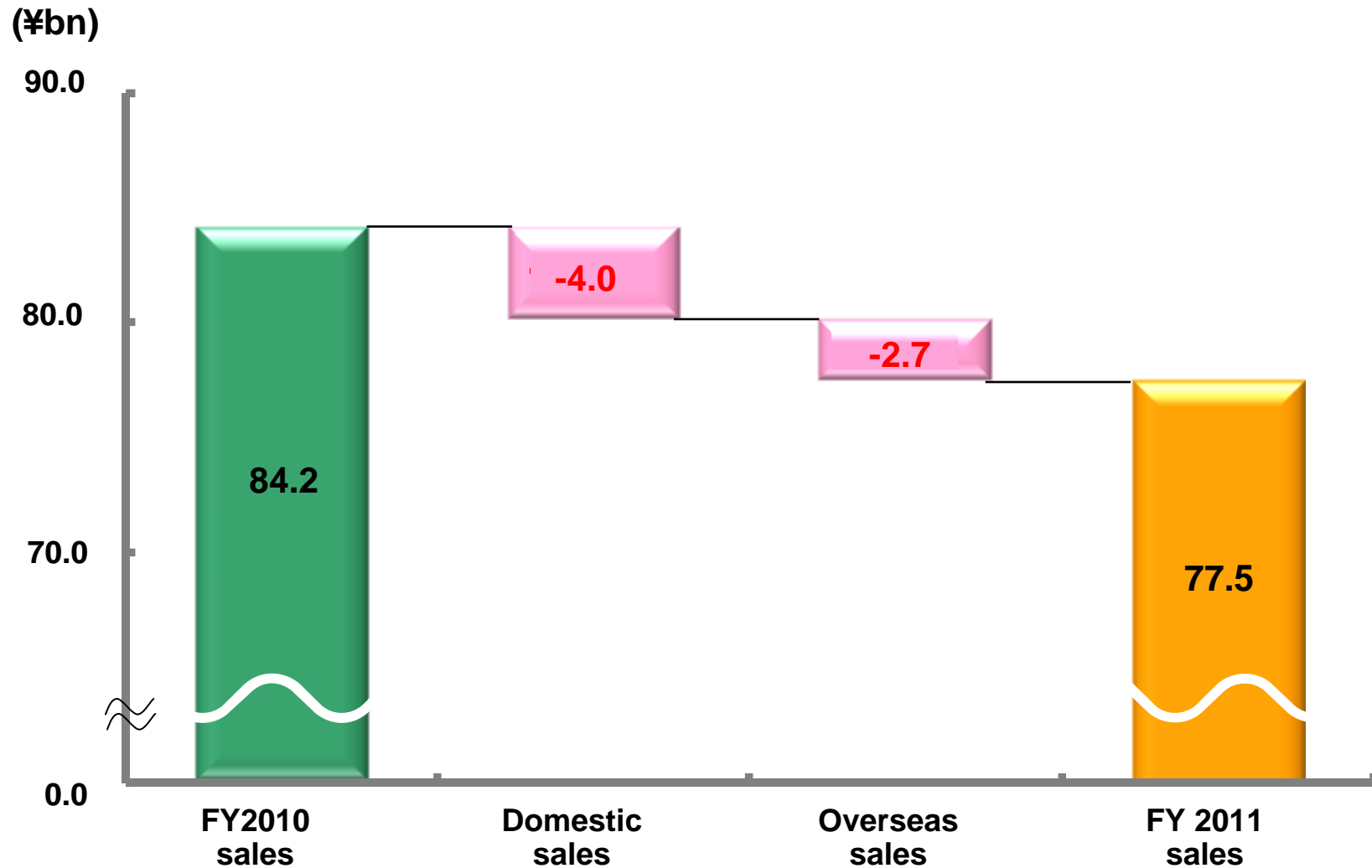
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	(¥bn)	FY 2010	FY 2011	Change
Bio-Chemicals	Net sales	84.2	77.5	-6.6
	Operating income	3.2	2.8	-0.3
Chemicals*	Net sales	130.0	33.5	-96.4
	Operating income	5.6	2.1	-3.5
Forex	¥/\$	¥88/\$	¥80/\$	-¥8/\$
	¥/€	¥116/€	¥111/€	-¥5/€

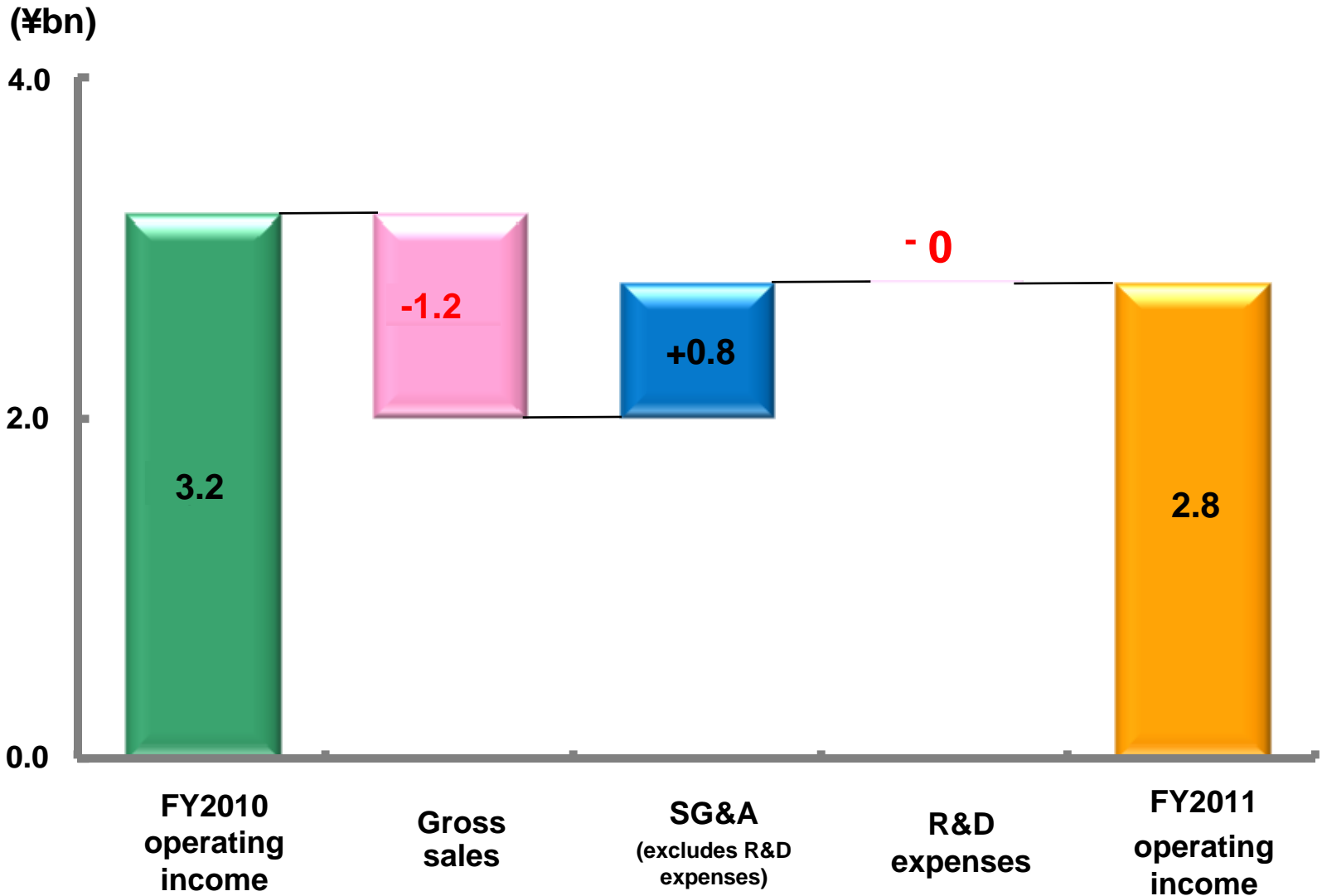
* The Chemicals segment is included in consolidation for the January-March period of fiscal 2011 and excluded from April 2011.

● Bio-Chemicals business: Change in net sales

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● Bio-Chemicals business: Change in operating income



2012 forecasts

● 2012 forecasts

(¥ bn)	Net sales	Operating income	Ordinary income	Net income
Fiscal 2012 forecast	326.0	48.0	42.5	20.0
Change	(-5.2%)	(+3.0%)	(-9.1%)	(-21.9%)
Fiscal 2011 results	343.7	46.6	46.7	25.6

* The Chemicals segment was included in consolidation for the January-March period of fiscal 2011 and excluded from April 2011.

● Fiscal 2012 full year forecasts: Pharmaceuticals

(¥bn)	FY 2011	FY 2012	Change
Net sales	229.3	242.0	+12.7
Operating income	41.3	45.7	+4.4
R&D expenses	44.5	42.9	-1.6

● Fiscal 2012 full year forecasts: Sales of core pharmaceutical products **KYOWA KIRIN**

(¥bn)	FY 2011	FY 2012	Change
<i>Nesp</i>	56.4	50.5	10.5% ↓
<i>Espo</i>	5.3	4.0	24.5% ↓
<i>Nesp/Espo</i>	61.8	54.5	11.8% ↓
<i>Regpara</i>	11.5	13.1	13.9% ↑
<i>Allelock</i>	29.1	29.7	2.1% ↑
<i>Patanol</i>	11.4	11.3	0.9% ↓
<i>Gran</i>	14.8	13.3	10.1% ↓
<i>Fentos</i>	3.1	4.9	58.1% ↑
<i>Coniel</i>	19.7	17.3	12.2% ↓
<i>Coversyl</i>	3.9	3.4	12.8% ↓
<i>Depakene</i>	11.2	10.7	4.5% ↓
<i>Permax</i>	2.1	2.0	4.8% ↓
<i>Asacol</i>	2.8	4.1	46.4% ↑
Exports and technology out-licensing revenues	22.3	33.3	49.3% ↑

● Fiscal 2012 full year forecasts: Bio-Chemicals business

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		(¥bn)	FY 2011	FY 2012	Change
Bio-Chemicals	Net sales		77.5	78.0	+0.4
	Operating income		2.8	2.0	-0.9
Forex	/ \$		¥80/\$	¥77/\$	-¥3/\$
	/ €		¥111/€	¥98/€	-¥13/€

● Fiscal 2012 full year forecasts: Relative to medium-term plan

FY2012		(¥bn)	Medium-term plan	Current forecast	Difference
Pharmaceuticals	Sales		225.0	242.0	+17.0
	OP		36.4	45.7	+9.3
	R&D expense		40.0	42.9	+2.9
Bio-Chemicals	Sales		88.0	78.0	-10.0
	OP		8.4	2.0	-6.4
Chemicals	Sales		147.0	—	-147.0
	OP		7.0	—	-7.0
Other / Eliminations	Sales		-6.0	6.0	+12.0
	OP		0.0	0.3	+0.3
Total	Sales		454.0	326.0	-128.0
	OP		51.7	48.0	-3.7

- Pharmaceuticals: Negative factors include the effects of the National Health reimbursement prices while positive factors include the effects of the biosimilar JV. The acquisition of ProStrakan has a positive effect on sales and a negative effect on operating income from the amortization of goodwill, etc.
- Bio-Chemicals: Expecting amino acid sales volumes to be higher than forecast in the medium-term business plan but revenues and profits to be lower due to sluggish sales of core products at Daiichi Fine Chemical and the effects of a strong yen (Exchange rates employed: Medium-term plan ¥91/\$, ¥133/€, FY2012 ¥77/\$, ¥98/€)
- Chemicals: The Chemicals segment has been eliminated

Pipeline

● Pipeline (as of January 24, 2012)

Filed/Approved

Category	Code name/ Product name	Stage		Indication	Formulation	In-house or licensed	Remarks
		Japan	Other countries				
Oncology	KW-0761 Mogamulizumab	Filed April 2011		Adult T-cell leukemia/lymphoma	Injection	In-house	POTELLIGENT® antibody*
	Pegfilgrastim		Filed in Asia	Chemotherapy induced febrile neutropenia	Injection	Kirin-Amgen	Asia: Korea and Vietnam
Nephrology	Cinacalcet Hydrochloride		Filed in Asia	Secondary hyperparathyroidism	Oral	Licensed from NPS	Asia: The Philippines, Malaysia, Thailand and China
	Darbepoetin Alfa		Approved in Singapore January 2012	Renal anemia (on dialysis)	injection	Kirin-Amgen	
CNS	KW-6500 Apomorphine Hydrochloride	Filed July 2011		Parkinson's disease	Injection	Licensed from Britannia Pharma.	
	KW-6002 Istradefylline		Filed in USA	Parkinson's disease	Oral	In-house	Reimbursement of License from Valeant International SRL for the Development and Commercialization of KW-6002 in the US and Canada.
Other	AMG531 Romiplostim		Filed in Asia	Idiopathic (Immune) Thrombocytopenic purpura	Injection	Kirin-Amgen	Asia: Singapore and Taiwan (Approved in Malaysia on December 2)

*:KW-0761 is outlicensed to Amgen Inc. on March 6th,2008, with an exclusive right to develop and commercialize KW-0761 worldwide, except in Japan, Korea, China and Taiwan. Kyowa Hakko Kirin has retained the development and commercialization rights in these countries. In 2010, KHK paid Amgen US\$20M for the buy-out of Amgen's option to assume the development and commercialization of KW-0761 in oncology setting in Amgen's licensed territory, which was granted under the License Agreement.

Updated since August 2, 2011 (Area, Stage, Filed, Approved, Launched etc.)

● Pipeline (as of January 24, 2012)

Phase II, Phase III

Category	Code name/ Product name	Stage		Indication	Formulation	In-house or licensed	Remarks
		Japan	Other countries				
Oncology	KW-0761 Mogamulizumab		Phase I/II in USA	Peripheral T-cell lymphoma and cutaneous T-cell lymphoma	Injection	In-house	POTELLIGENT® antibody*
		Phase II		Adult T-cell leukemia/Lymphoma, Add- on therapy (for untreated patients)			
		Phase II		Peripheral T/NK-cell Lymphoma			
	KW-2246 Fentanyl citrate	Phase III		Cancer pain	Sublingual tablet	Licensed from Orexo	
	KRN125 Pegfilgrastim	Phase III		Chemotherapy induced febrile neutropenia	Injection	Kirin-Amgen	
	ARQ 197	Phase II in Japan and Korea		Gastric cancer	Oral	Licensed from ArQule.	
		Phase III in Japan, Korea and Taiwan		Lung cancer			
	KW-2478		Phase I/II In UK, USA, Philippines	Multiple myeloma	Injection	In-house	
	KRN321 Darbepoetin Alfa	Phase II in Japan and Korea		☆Myelodysplastic syndrome related anemia	Injection	Kirin-Amgen	Launched in Japan for anemia of CKD patients
KRN1493 Cinacalcet Hydrochloride	Phase III		☆HyperCalcemia with parathyroid carcinoma or intractable primary hyperparathyroidism	Oral	Licensed from NPS	Launched in Japan for Secondary Hyperparathyroidism	

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Updated since August 2, 2011 (Area, Stage, Filed, Approved, Launched etc.)

☆:New indication

● Pipeline (as of January 24, 2012)

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	Renal anemia (on dialysis)			
			Phase III in India				
Immunology/ Allergy	ASKP1240	Phase I	Phase II in USA	Organ Transplant Rejection	Injection	In-house	Jointly developed with Astellas
	KHK4563 Benralizumab	Phase II in Japan and Korea		Asthma	Injection	In-House	Being developed by MedImmune as MEDI-563 Worldwide except in Japan and other Asian Countries POTELLIGENT® antibody
	Z-206 Mesalazine	Phase II		☆Crohn's disease	Oral	Licensed from Zeria Pharma.	Jointly developed with Zeria Pharma launched in Japan for ulcerative colitis
CNS	KW-6002 Istradefylline	Phase III		Parkinson's disease	Oral	In-house	
	KW-6485 Topiramate	Phase III		☆Pediatric epilepsy	Oral	Licensed from Janssen Pharmaceutical K.K.	Launched in Japan for use as an epileptic drug
Other	KW-3357 Antithrombin	Phase III	Phase I in Europe	Disseminated intravascular coagulation, Congenital antithrombin deficiency	Injection	Developed In-house	

☆:New indication



Updated since August 2, 2011 (Area, Stage, Filed, Approved, Launched etc.)

● Pipeline (as of January 24, 2012)

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® antibody
	KRN951 Tivozanib	Phase I		Cancer	Oral	In-house	
	KHK2866		Phase I in USA	Cancer	Injection	In-house	POTELLIGENT® antibody
	LY2523355 Litronesib	Phase I		Cancer	Injection	In-house	Worldwide Outlicensed to Eli Lilly for the Development and Commercialization of LY2523355 except Japan
	CEP-37250/ KHK2804		Phase I in USA	Cancer	Injection	Cephalon	Jointly developed with Cephalon POTELLIGENT® antibody
	KHK2898		Phase I in Singapore	Cancer	Injection	In-House	POTELLIGENT® antibody

Updated since August 2, 2011 (Area, Stage, Filed, Approved, Launched etc.)

● Pipeline (as of January 24, 2012)
Phase I (continued)

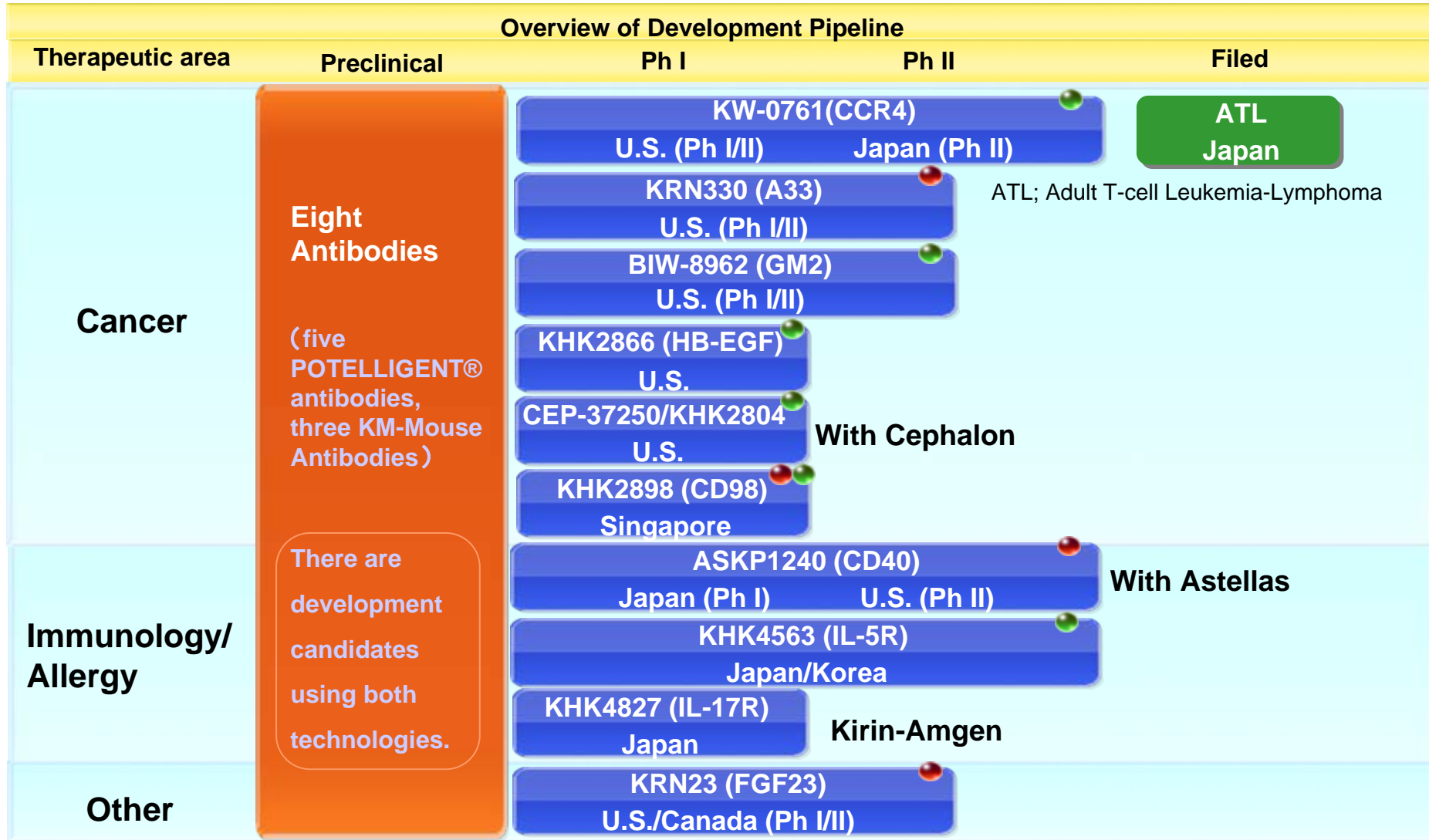
Category	Code name/ Product name	Stage		Indication	Formulation	Developed in-house or licensed	Remarks
		Japan	Other countries				
Nephrology	RTA402 Bardoxolone Methyl	Phase I		Diabetic nephropathy	Oral	Licensed from Reata	
Immunology/ Allergy	KHK4827	Phase I		Psoriasis	Injection	Kirin-Amgen	
Other	KHK6188	Phase I		Neuropathic pain	Oral	In-house	
	KRN23		Phase I /II in USA and Canada	X-linked hypophosphatemic rickets/Osteomalacia (XLH)	Injection	In-house	

Updated since August 2, 2011 (Area, Stage, Filed, Approved, Launched etc.)

Withdrawal of Application

Category	Code name/ Product name	Stage		Indication	Formulation	Developed in-house or licensed	Remarks
		Japan	Other countries				
Oncology	KRN321 Darbepoetin Alfa	Filed Nov/2008		Chemotherapy induced Anemia	Injection	Kirin-Amgen	The withdrawal of application was made because currently submitted data is insufficient to establish an evidence that is necessary to attain the approval, as a result of discussion with Pharmaceuticals and Medical Devices Agency.

● Antibody pharmaceutical pipeline (as of January 24, 2012)



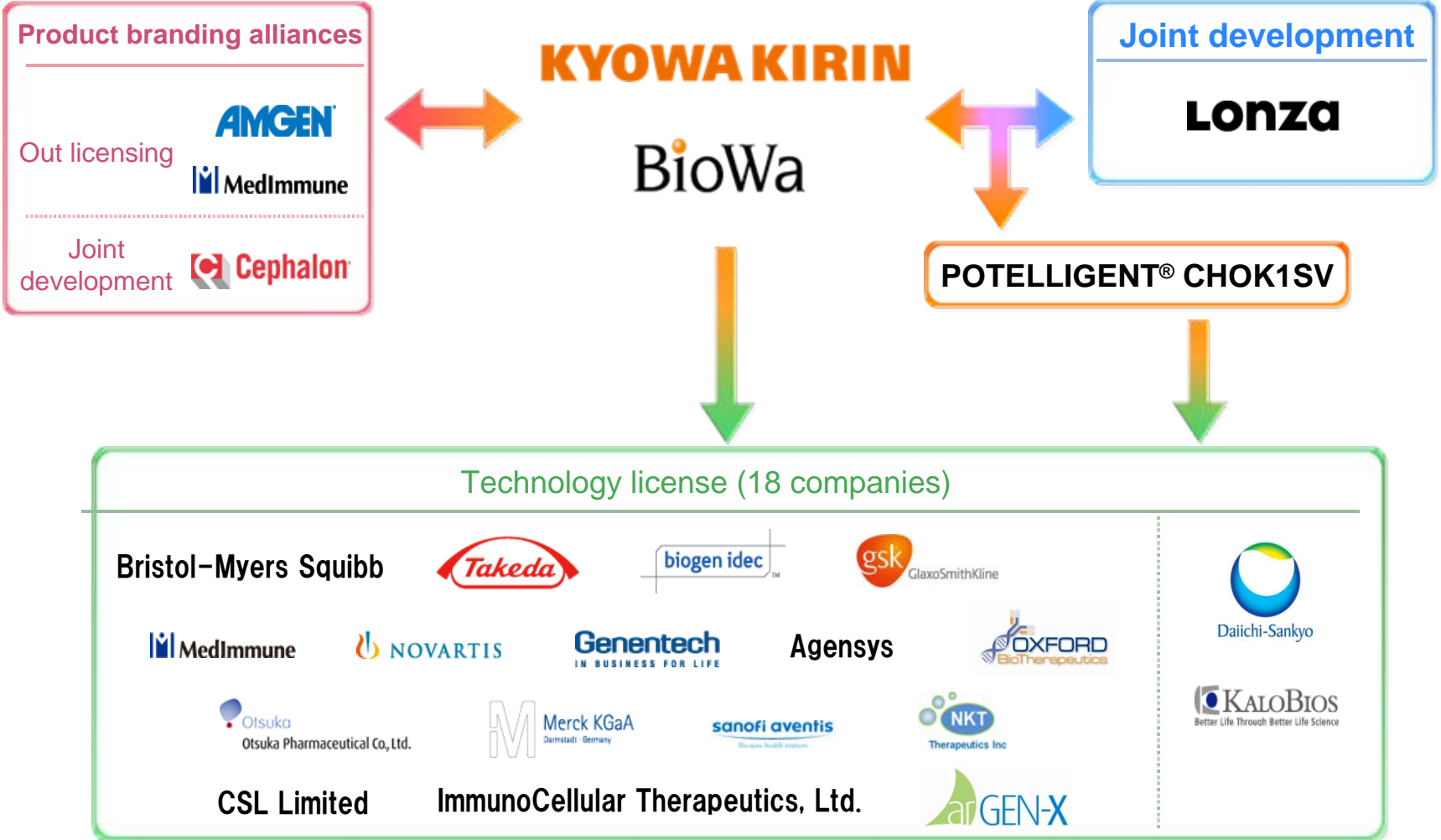
● : POTELLIGENT® technology ● : KM-Mouse technology

● **Licensing-out antibody pharmaceuticals** (as of January 24, 2012) **KYOWA KIRIN**

Antibody	Target	Licensee	Reported Stage	Remarks
KW-0761	CCR4	Amgen (Allergy) (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	Research	KM-Mouse

● POTELLIGENT® technology-related alliances (as of January 24, 2012)

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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 January 24, 2012)

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				Asthma (Anti-IL-5R antibody)
KRN5500	DARA				Peripheral neuropathy
LY2523355	Eli Lilly				Cancer (Mitotic kinesin Eg5 inhibitor)
AMG 761 (KW-0761:POTELLIGENT®)	Amgen				Asthma (Anti-CCR4 antibody)
RGI2001	REGiMMUNE				Immunosuppressive

● Progress with inlicensed compounds (as of January 24, 2012)

Name	Partner	Phase			Remarks
		I	II	III	
KW-6500	Britannia	Filed			Parkinson's disease (Dopamine agonist)
SP-01	Solasia	Filed			Emesis (Serotonin antagonist)
KW-2246	Orexo				Cancer pain (m-opioid receptor agonist)
ARQ 197	ArQule				Lung cancer (c-met inhibitor)
					Gastric cancer (c-met inhibitor)
Asacol	Zeria				Crohn's disease *as a treatment for ulcerative colitis
RTA 402	Reata				Diabetic neuropathy
KHK2804	Cephalon				Cancer (Anti-tumor specific Glycoprotein Humanized Antibody)
KHK4827	Kirin-Amgen				Psoriasis (Anti-IL-17 receptor fully Human antibody)

Biosimilar joint venture with Fujifilm

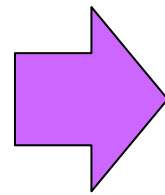
● Biosimilar merger company: Overview

Provide an advanced level of reliability and quality and superior cost-competitive products

Develop ground-breaking biopharmaceutical production technology leveraging synergies between both companies

Joint venture company
- To be established spring, 2012 (planned)
- Investment ratio 50:50

Development and production of biosimilars



Aiming to begin clinical trials in 2013

Biopharmaceutical research, development and manufacturing technology, and knowhow

Production, quality control and analysis technology
Know-how to improve technology and production processes

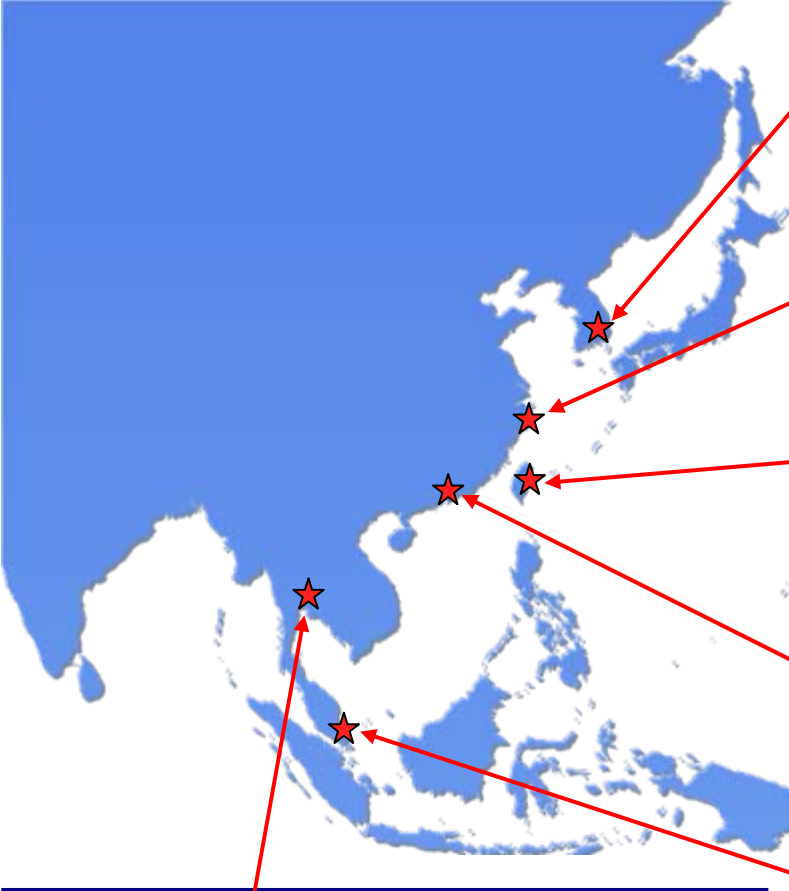


● Leveraging technology developed by Fujifilm

- In the short-term
 - Optimization of production process (culture, refinement, etc.) using by production and quality control technologies that allow precision control
 - Improve cell culture process leveraging analysis technology from photographic film diagnosis
 - Improve capital expenditure efficiencies that use advanced engineering technologies
- In the medium to long-term
 - Practical application of cutting-edge culture technologies
 - Practical application of new refining processes
- KHK will use newly developed technologies for new drugs, JV will use newly developed technologies for biosimilar

Business in Asia

● Pharmaceutical business in Asia (End Dec 2011)

Pharmaceutical businesses across Asia	Consolidated subsidiaries	MRs	Net sales Products
	Korea Est. May 1991 Jeil-Kirin Pharmaceutical Inc.	25	¥3.0 bn Nesp, Regpara, Renagel, Gran, Busulfex, MitomycinC, Leunase
	China Est. Jun. 1997 Kirin Kunpeng (China) Bio Pharmaceutical Co., Ltd.	114	¥2.8 bn Espo, Gran, Busulfex, Mitomycin C, Leunase, Coniel, Allelock
	Taiwan Est. Apr. 1992 Kyowa Hakko Kirin (Taiwan) Co., Ltd.	18	¥2.0 bn Nesp, Regpara, Gran, Busulfex, MitomycinC, Leunase
	Hong Kong Est. Aug. 1993 Kyowa Hakko Kirin (Hong Kong) Co., Ltd.	5	¥0.5 bn Aranesp, Regpara, Renagel, Busulfex, MitomycinC, Leunase
	Singapore Est. Mar. 2005 Kyowa Hakko Kirin (Singapore) Pte., Ltd.	6	¥0.3 bn Aranesp, Gran, Peglasta, Busulfex, MitomycinC, Leunase
Thailand (non-consolidated) Kyowa Hakko Kirin(Thailand) Co., Ltd			

● Development and sales in Asian markets-1

⊙:Launched ○:Approved ☆:Filed

As of December 31, 2011

	Korea	China	Taiwan	Hong Kong	Singapore	Thailand	Malaysia	The Philippines	Indonesia	Vietnam	India
Espo		⊙									
Nesp	⊙	Phase 2	⊙	○	☆	⊙	○	○			Phase 3
Aranesp				⊙	⊙						
Renagel	⊙			⊙							
Gran	⊙	⊙	⊙		⊙	⊙	⊙	○		⊙	
Peglasta					⊙	⊙	⊙	⊙		☆	
Neulasta	☆		○								
Nplate	○		☆	○	○		○				
Busulfex	⊙	⊙	⊙	⊙	⊙	⊙	⊙				
Regpara	⊙	☆	⊙	⊙	○	☆	☆	☆			

● Development and sales in Asian markets-2

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◎:Launched ○:Approved ☆:Filed

As of December 31, 2011

		Korea	China	Taiwan	Hong Kong	Singapore	Thailand	Malaysia	The Philippines	Indonesia	Vietnam	India
Mitomycin C		◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎
Leunase		◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎
Coniel		◎	◎	○					◎			
Allelock		◎	◎									
Sancuso				☆								
ARQ 197	NSCLC	Phase 3 (MRCT)*1		Phase 3 (MRCT)*1								
	Gastric Cancer	Phase 2 (MRCT)*1										
KHK4563		Phase 2 (MRCT)*1										
KW-2478									Phase 1/2 (MRCT)*1			
Nesp MDS*2		Phase 2 (MRCT)*1										

*1 MRCT: Multi Region Clinical Trial

*2 Nesp MDS::Nesp treatment for Anemia from myelodysplastic syndrome

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**If you have any inquiries regarding this presentation please call:
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