Kyowa Hakko Kirin

Fiscal 2010 Results

(Fiscal year to December 31, 2010)

January 28, 2011

President & CEO

Yuzuru Matsuda

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.

Note:

The fiscal period ended December 31, 2009 was a nine-month reporting period due the change in fiscal year-end from March 31 to December 31. As a result, figures in this presentation for the 12-month period ended December 31, 2009 are derived by subtracting figures for the April to December (9-month period) of FY ended March 31, 2009 from figures for the twelve-month period ended March 31, 2009, and adding these figures to the April to the December period (9-month period*) ended December 31, 2009.

*Since the following 11 consolidated subsidiaries already have a year-end date of December, and since the gap between the consolidated financial statements settlement dates does not exceed 3 months, consolidation is performed based on the subsidiary's financial statements for their 12-month reporting period from January 1, 2009 to December 31, 2009 and these have been used in the consolidated financial statements.

(P) Kyowa Hakko Kirin America, Inc.
(P) BioWa, Inc.
(P) Kyowa Hakko Kirin Pharna, Inc.
(B) BioKyowa Inc.
(B) Shanghai Kyowa Amino Acid Co., Ltd.
(B) Kyowa Hakko U.S.A., Inc.
(B) Kyowa Hakko Europe GmbH
(B) Kyowa Italiana Farmaceutici S.r.l.
(B) Kyowa Hakko Kirin (Hong Kong) Co., Ltd.
(B) Kyowa Hakko Bio U.S. Holdings, Inc.
(O) Kashiwagi Corporation

Legend: (P) Pharmaceuticals segment
(B) Bio-Chemicals segment
(O) Other segment

Contents

KYOWA KIRIN

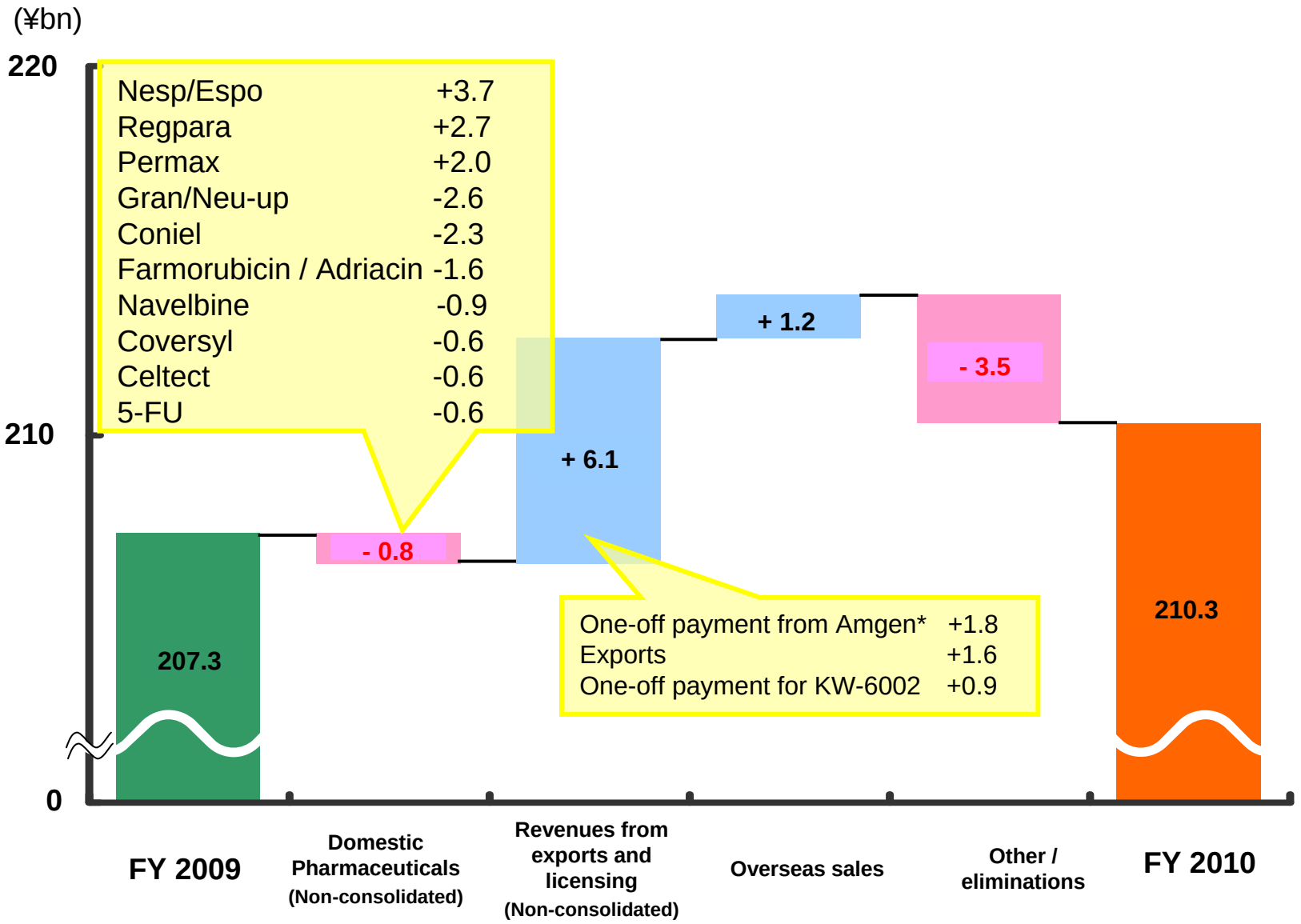
(¥bn)	Net sales	Operating income	Recurring income	Net income
FY2010	413.7	45.4	46.5	22.1
Change	+6.7 (+1.7%)	+14.4 (+46.8%)	+13.8 (+42.5%)	+12.1 (+121.1%)
FY2009	407.0	30.9	32.6	10.0

KYOWA KIRIN

(¥bn)	FY2009	FY2010	Change
Net sales	207.3	210.3	+2.9
Operating income	31.8	35.8	+4.0
R&D expenses	41.6	40.0	-1.6

Pharmaceuticals business: Increase (decrease) in net sales

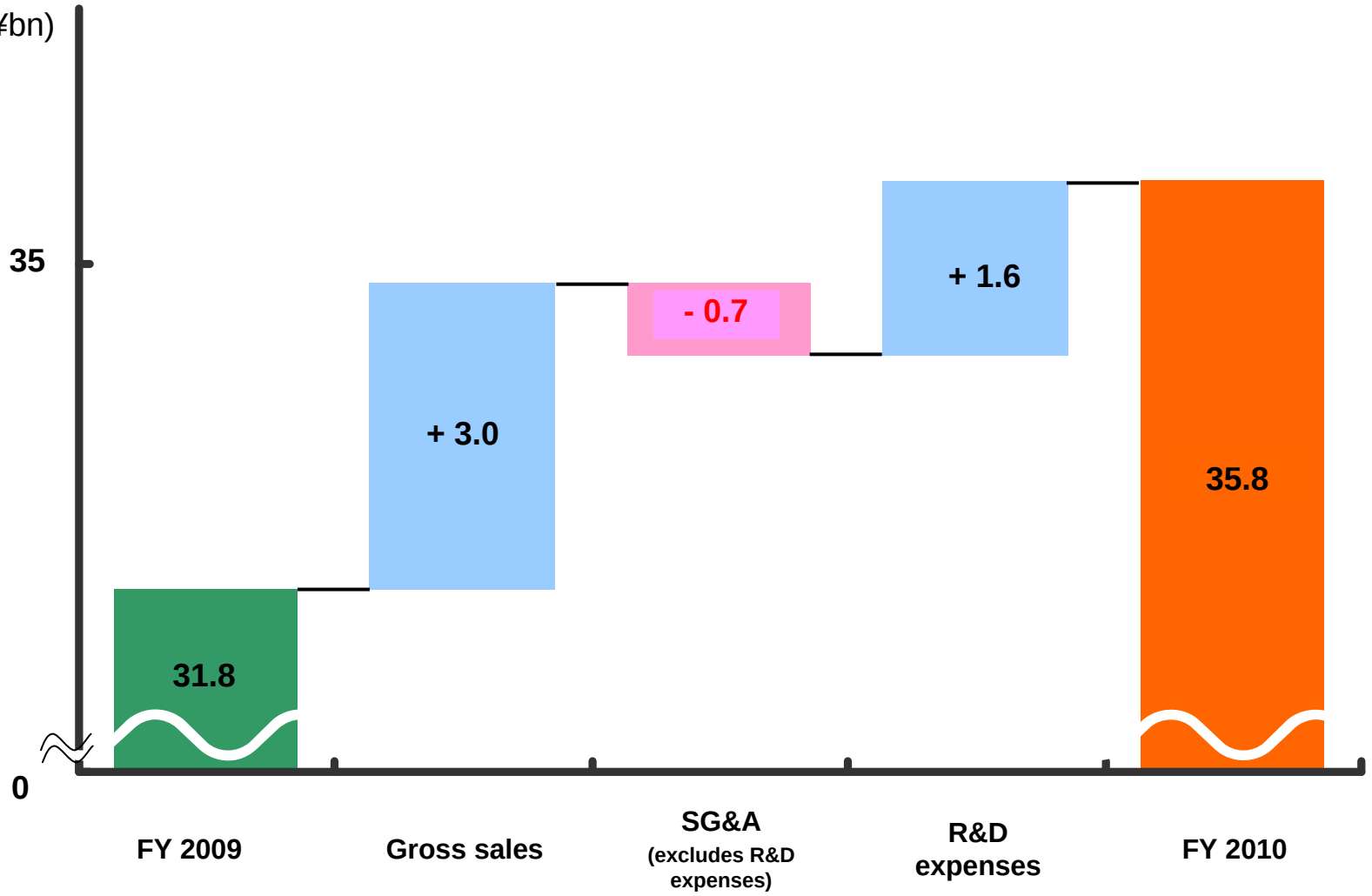
KYOWA KIRIN



• One-time contract payment from Amgen based on an outlicensing contract in March 2008, not milestone payments based on clinical trial developments.

Pharmaceuticals business: Increase (decrease) in operating income

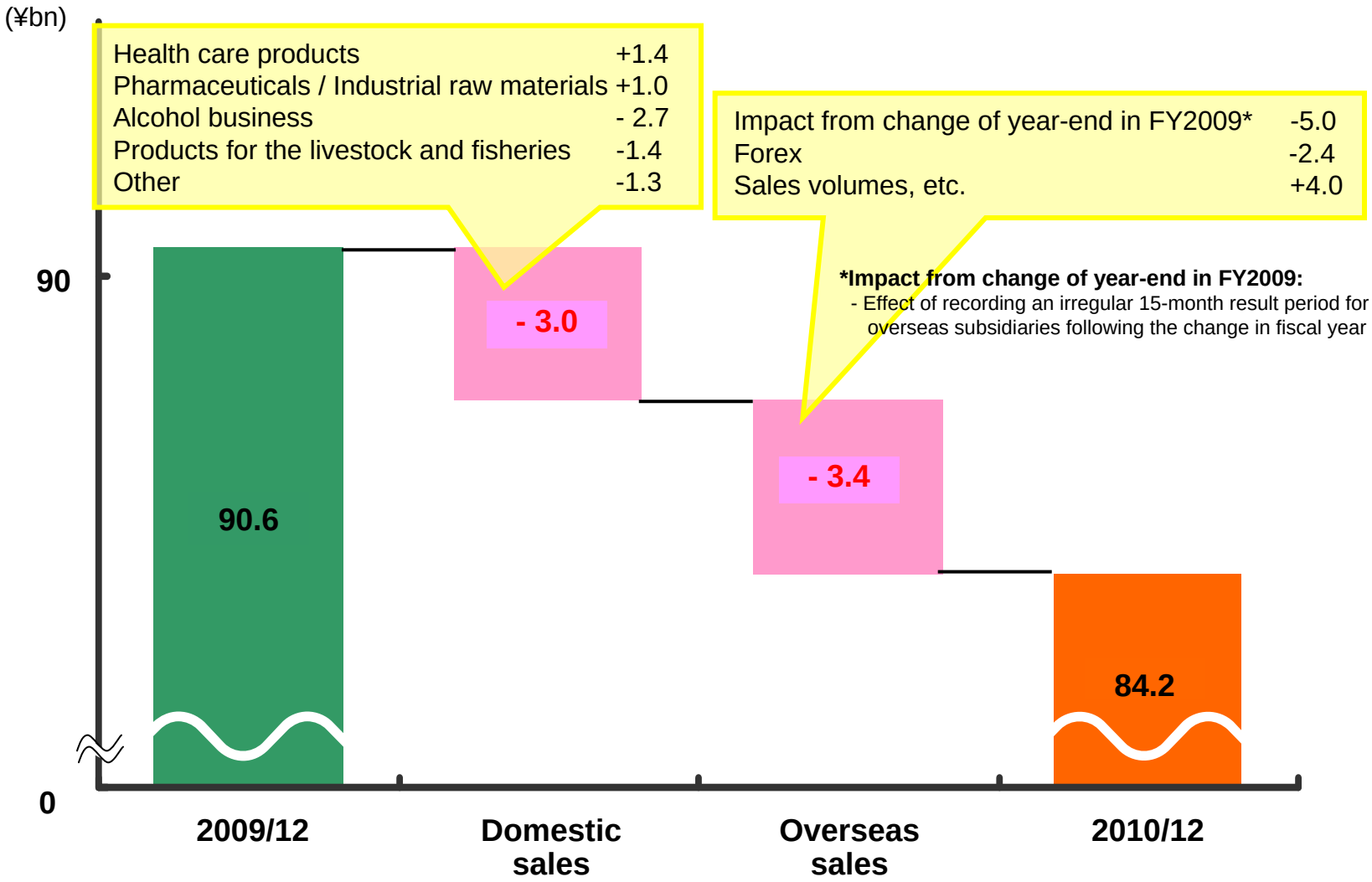
KYOWA KIRIN



	(¥bn)	FY 2009	FY 2010	Change
Bio-Chemicals	Net sales	90.6	84.2	-6.4
	Operating income	3.9	3.2	-0.6
Chemicals	Net sales	64.2	130.0	+65.8
	Operating income	-5.5	5.6	+11.2
Forex	¥/$	**¥94/$**	**¥88/$**	**-¥6/$**
	¥/€	**¥130/€**	**¥116/€**	**-¥14/€**
Naphtha	¥/Kl	**Approx. ¥36,000/kl**	**Approx. ¥46,400/kl**	**Approx. ¥10,400/kl**

Bio-Chemicals business: Increase (decrease) in net sales

KYOWA KIRIN



Bio-Chemicals business: Increase (decrease) in operating income

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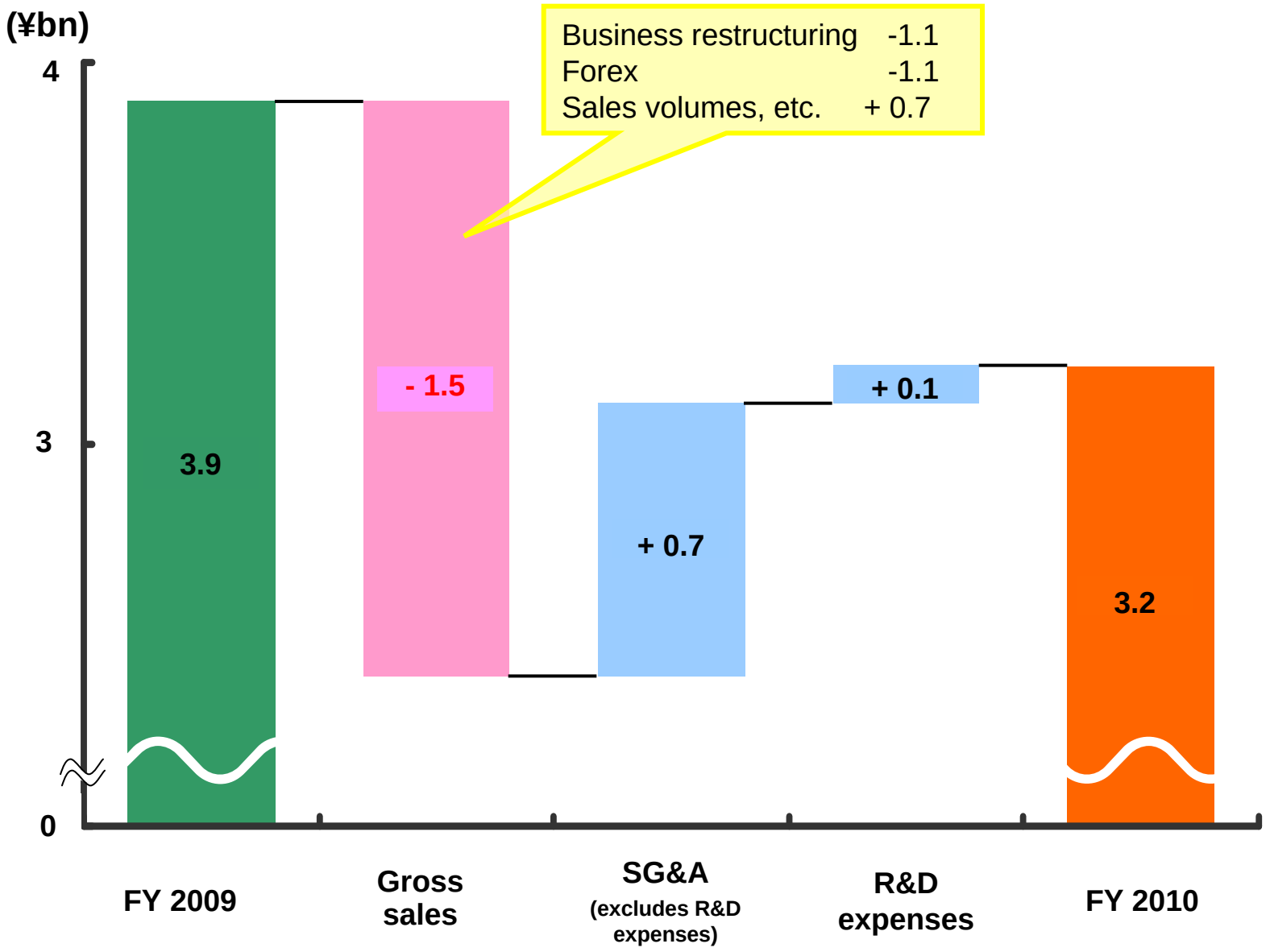

Chemicals business: Increase (decrease) in net sales

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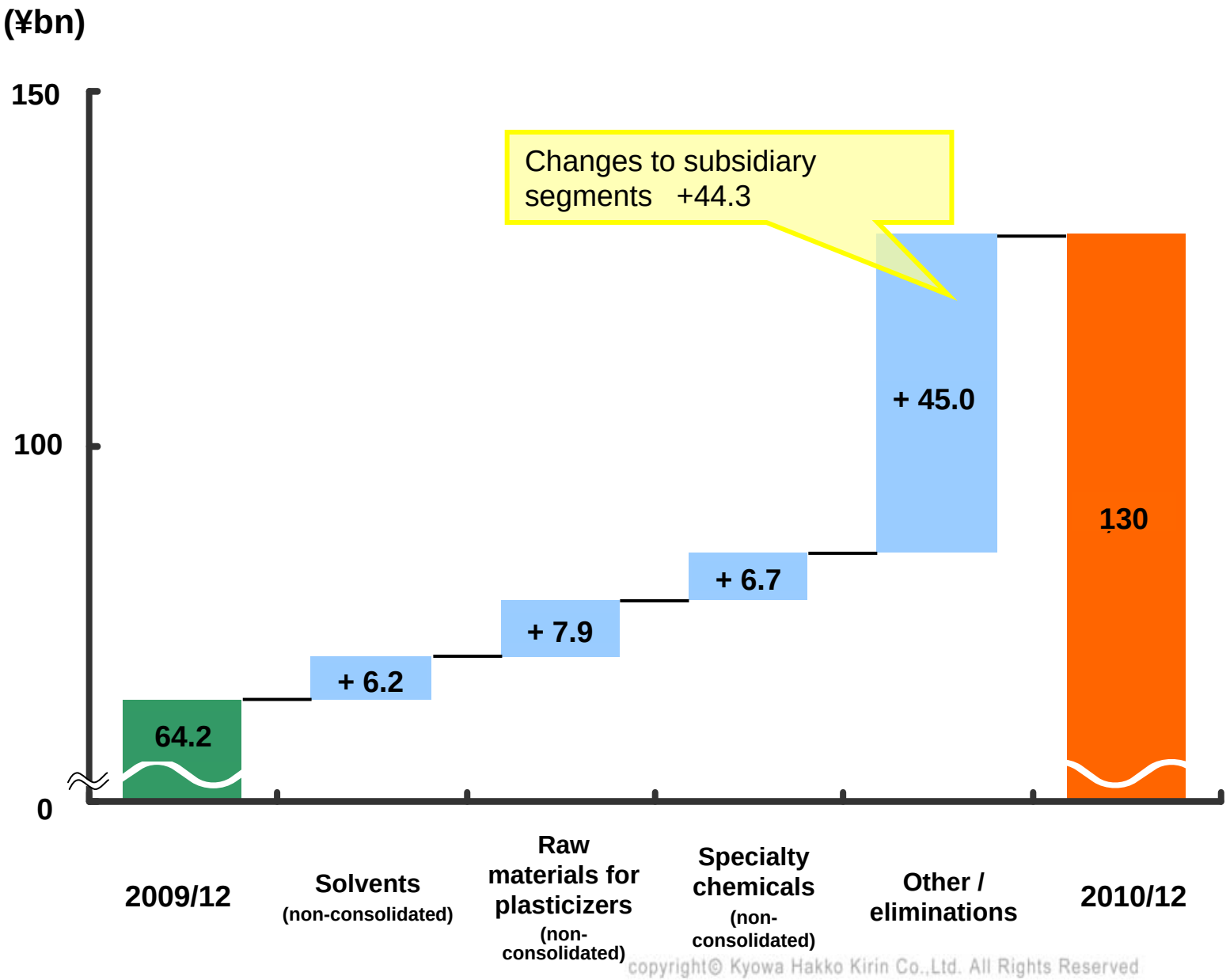

Chemicals business: Increase (decrease) in operating income

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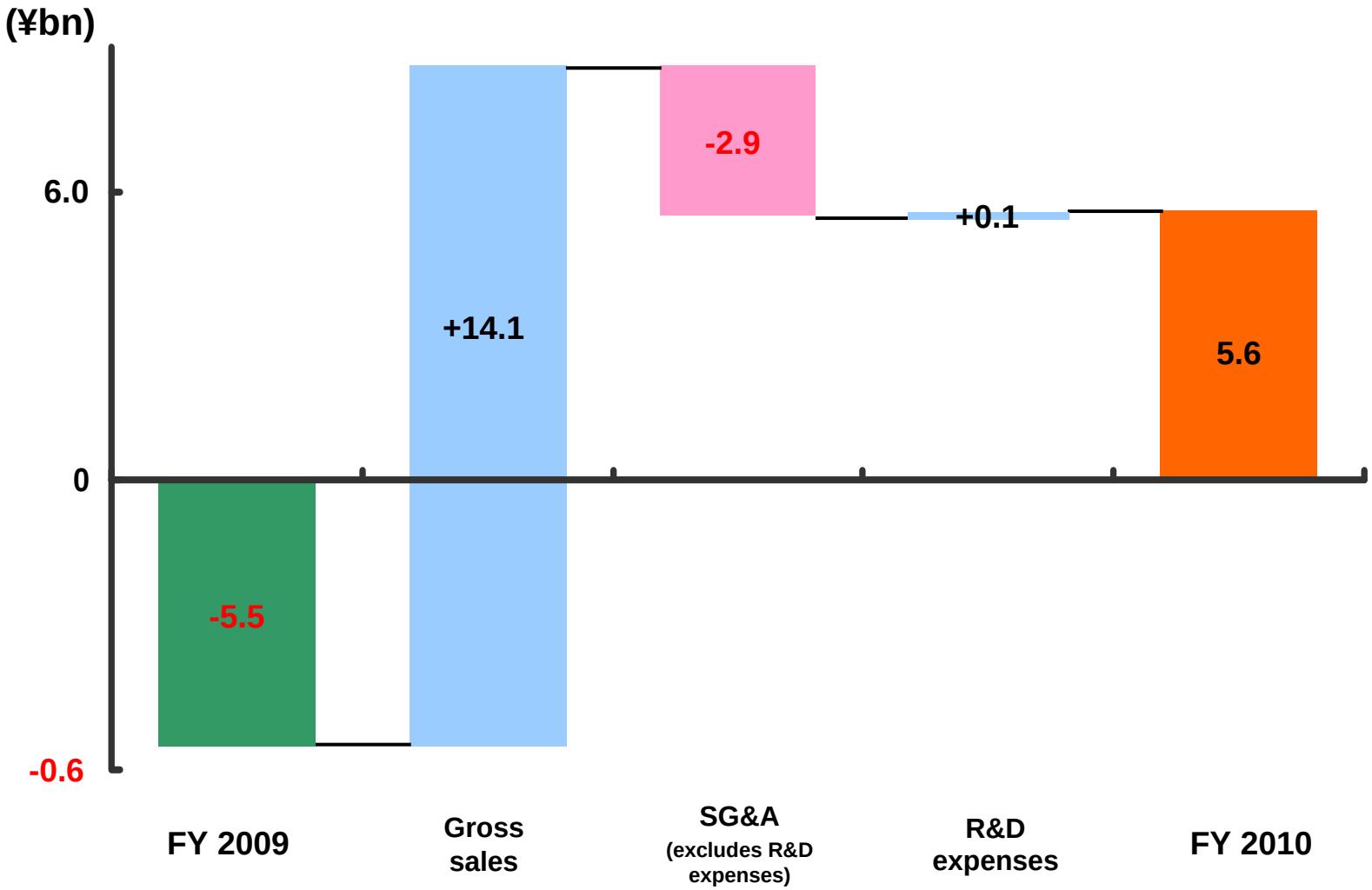

Fiscal 2011 full year forecasts

KYOWA KIRIN

(¥bn)	Net sales	Operating income	Recurring income	Net income
FY 2011	325.0	37.0	38.0	25.5
Change	(-21.4%)	(-18.5%)	(-18.3%)	(+14.9%)
FY 2010	413.7	45.4	46.5	22.1

Fiscal 2011 full year forecasts: Pharmaceuticals

KYOWA KIRIN

(¥bn)	FY 2010	FY 2011	Change
Net sales	210.3	212.0	+1.6
Operating income	35.8	32.0	-3.8
R&D expenses	40.0	46.5	+6.4

Fiscal 2011 full year forecasts: Sales of core pharmaceutical products

KYOWA KIRIN

(¥bn)	FY 2010	FY 2011	Change
Nesp	41.7	46.9	12% ↑
Espo	10.8	4.0	63% ↓
Nesp/Espo	52.6	50.9	3% ↓
Regpara	9.5	11.1	17% ↑
Allelock	26.8	29.8	11% ↑
Patanol	7.5	10.2	36% ↑
Gran/Neu-up	14.4	14.5	1% ↑
Fentos	0.8	2.4	200% ↑
Coniel	21.0	19.9	5% ↓
Coversyl	4.2	3.9	7% ↓
Depakene	11.0	11.0	0%
Permax	2.0	2.3	15% ↑
Asacol	0.7	2.6	271% ↑
Exports and technology out-licensing revenues	24.1	23.9	1% ↓

*Sales of Neu-up were transferred to Yakult Honsha as of March 2010
*Sales of Fentos began June 2010
*Sales of Permax were transferred from Eli Lilly as of April 2010
*Sales of Asacol began in December 2009

Fiscal 2011 full year forecasts: Bio-Chemicals and Chemicals businesses

KYOWA KIRIN

(¥bn)		FY 2010	FY 2011	Change
Bio-Chemicals	Net sales	84.2	80.0	-4.2
	Operating income	3.2	3.0	-0.2
Chemicals	Net sales	130.0	31.0	-99.0
	Operating income	5.6	1.5	-4.1
Forex	¥/$	**¥88/$**	**¥85/$**	**-¥3/$**
	¥/€	**¥116/€**	**¥110/€**	**-¥6/€**
Naphtha	¥/Kl	**Approx. ¥46,400/kl**	**Approx. ¥45,000/kl**	**Approx. -¥1,400/kl**

Fiscal 2011 full year forecasts: Relative to medium-term plan

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FY2011 (¥bn)		Medium-term plan	Current forecast	Difference
Pharmaceuticals	Sales	**215.0**	**212.0**	**-3.0**
	OP	**30.9**	**32.0**	**+1.1**
	R&D expense	**44.5**	**46.5**	**+2.0**
Bio-Chemicals	Sales	**84.0**	**80.0**	**-4.0**
	OP	**5.8**	**3.0**	**-2.8**
Chemicals	Sales	**135.0**	**31.0**	**-104.0**
	OP	**4.0**	**1.5**	**-2.5**
Other / Eliminations	Sales	**-7.0**	**2.0**	**+9.0**
	OP	**0.0**	**0.5**	**+0.5**
Total	Sales	**427.0**	**325.0**	**-102.0**
	OP	**40.7**	**37.0**	**-3.7**

- Pharmaceuticals: Expecting operating income to be higher than forecast in the medium-term business plan due to higher revenues from licensing and core products and despite negative factors such as the effects of the termination of sales of certain products and increased R&D expenses
- 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 (Forex: Medium-term plan: ¥91/$, ¥133/€; FY2011 ¥85/$, ¥110/€)
- Chemicals: Only figures for the Q1 of FY2011 will be consolidated

Kyowa Hakko Kirin (Phase II onwards)

(As of January 28, 2011)

Category	Code name/ Product name	Stage		Indication	Formulation	In-house or licensed	Remarks
		Japan	Other countries				
Oncology	KW-0761	Phase II		Cancer (Adult T-cell leukemia/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 for overseas markets in cancer-related areas where Amgen is not present. Kyowa Hakko Kirin now holds the development and commercialization rights worldwide for cancer-related areas.
			Phase I/IIa in USA	Cancer (Peripheral T-cell lymphoma and cutaneous T-cell lymphoma)			
		Phase II		Cancer Adult T-cell leukemia/lymphoma, Add-on therapy			
		Phase II		Cancer (Peripheral T/NK-cell Lymphoma)			
	KRN321 Darbepoetin Alfa	Filed Nov/2008		★Chemotherapy induced anemia	Injection	Kirin-Amgen	Launched for anemia of CKD patients
	KW-2246 Fentanyl citrate	Phase III		Cancer pain	Sublingual tablet	Licensed from Orexo	
	KRN125 Pegfilgrastim	Phase II		Neutropenia	Injection	Kirin-Amgen	
	ARQ 197	Phase II	Phase II in Korea	Cancer (Gastric cancer)	Oral	Licensed from ArQule.	Global Study
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)			
	KRN 1493 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

Updated since July 28th, 2010 (Area, Stage, Filed, Approved, Launched etc.)

★ New indications

Kyowa Hakko Kirin (Phase II onwards)

(As of January 28, 2011)

Category	Code name/ Product name	Stage		Indication	Formulation	In-house or licensed	Remarks
		Japan	Other countries				
CNS	KW-6002 Istradefylline	Phase III	Licensed-out in US in Jun/2010	Parkinson's disease	Oral	In-house	Entered into a license agreement with Biovail of North America
	KW-6500 Apomorphine Hydrochloride	Phase III		Parkinson's disease	Injection	Licensed from Britannia Pharma.	
	KW-6485 Topiramate	Phase III		☆ Pediatric epilepsy	Oral		
Other	AMG531 Romiplostim	Approved Jan/2011		Immune thrombocytopenic purpura	Injection	Kirin-Amgen	

Updated since July 28th, 2010 (Area, Stage, Filed, Approved, Launched etc.)

★ New indications

R&D Pipeline: October 2010

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Kyowa Hakko Kirin (Phase I)

(As of January 28, 2011)

Category	Code name/ Product name	Stage		Indication	Formulation	Developed in-house or licensed	Remarks
		Japan	Other countries				
Oncology	KW-2450		Phase I/IIa 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	
	ARQ197	Phase I		Cancer (Lung cancer)	Oral	Licensed from ArQule	
	KW-2478		Phase I/IIa in UK/USA	Cancer	Oral	In-house	
	KHK2866		Phase I in USA	Cancer	Injection	In-house	POTELLIGENT antibody
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

Updated since July 28th, 2010 (Area, Stage, Filed, Approved, Launched etc.)

★ New indications

Kyowa Hakko Kirin (Phase I)

(As of January 28, 2011)

Category	Code name/ Product name	Stage		Indication	Formulation	Developed in-house or licensed	Remarks
		Japan	Other countries				
Other	KHK6188	Phase I		Neuropathic pain	Oral	In-house	
	KW-3357 Antithrombin	Phase I	Phase I in Europe	Disseminated intravascular coagulation, Congenital antithrombin deficiency	Injection	In-house	
	KRN23		Phase I in USA	X-linked Hypophosphatemic rickets/osteomalacia (XLH)	Injection	In-house	
	Z-206 Mesalazine	Phase I		☆ Crohn's disease	Oral (pH dependent controlled-release formulation)	Licensed from Zeria Pharma.	Jointly developed with Zeria Pharma Launched in Japan for ulcerative colitis from December, 2009.

(Notes)
In Taiwan,Korea,Vietnam, an NDA of Pegfilgrastim has been filed.
In Thailand, Singapore, Malaysia and Philippines, an NDA of Darbepoetin Alfa has been filed.
In Singapore, an NDA of Cinacalcet Hydrochloride has been filed.
In Hong Kong, Malaysia, Singapore, Korea, an NDA of Romiplostim has been filed.

Updated since July 28th, 2010 (Area, Stage, Filed, Approved, Launched etc.)

★ New indications

AMG827 mechanisms

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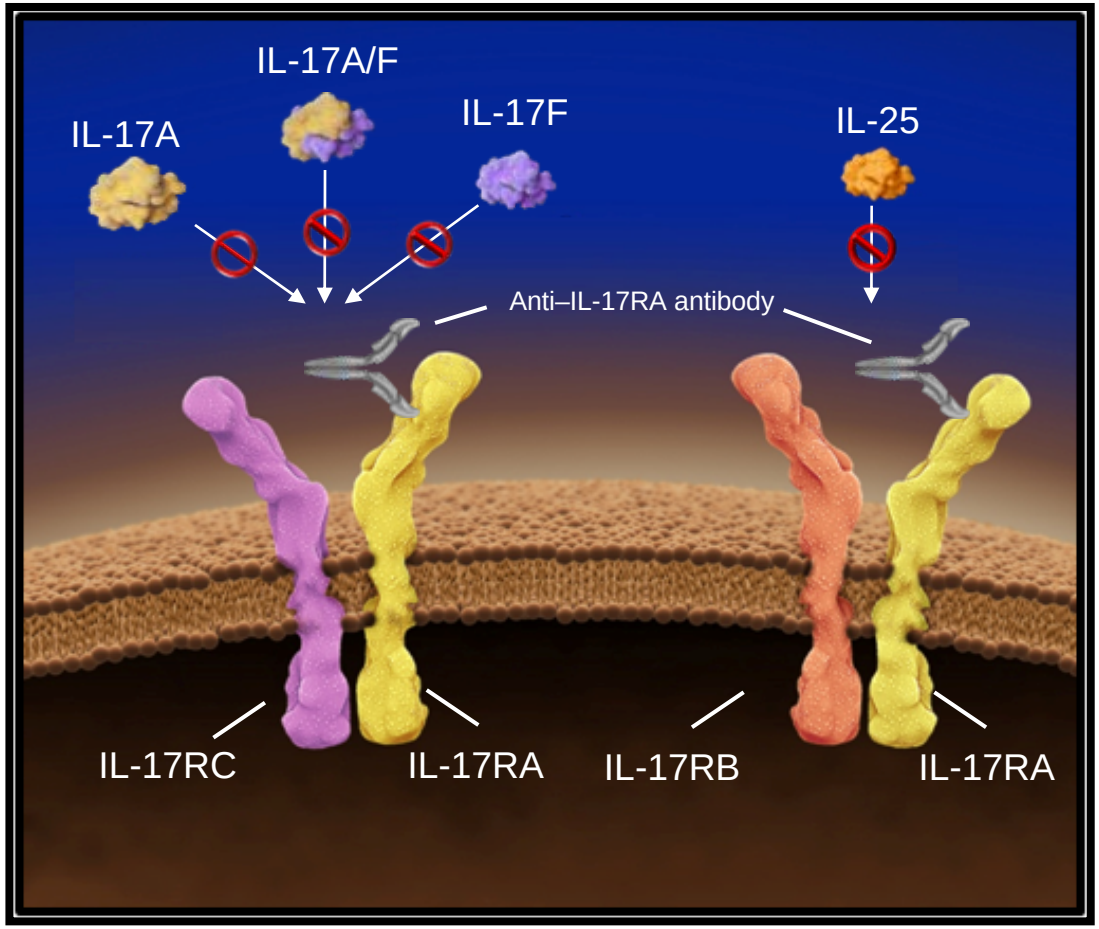
- Fully human IgG2 anti–IL-17RA[1] mAb
- Binds the human IL-17RA[1] subtype with high affinity
- Prevents IL-17A, IL-17F, IL-17A/F, and IL-25 signaling



1) IL-17 receptor A sub-unit

Overview of Development Pipeline

Therapeutic Area	Preclinical	Ph I	Ph II
Oncology	Ten Antibodies (seven POTELLIGENT® antibodies, five KM-Mouse antibodies)	KW-0761(CCR4) U.S. (Ph I/II) Japan (Ph II)	
		KRN330(A33) U.S. (Ph I/II)	
		BIW-8962(GM2) U.S. (Ph I/II)	
		KHK2866 U.S.	
Immunology/ Allergy		ASKP1240(CD40) Japan (Ph I) U.S. (Ph II) With Astellas	
		KHK4563(IL-5R) Japan	
Other		KRN23(FGF23) U.S.	

● : POTELLIGENT® Technology

● : KM-Mouse Technology

●POTELLIGENT® technology related alliances (as of January 2011)

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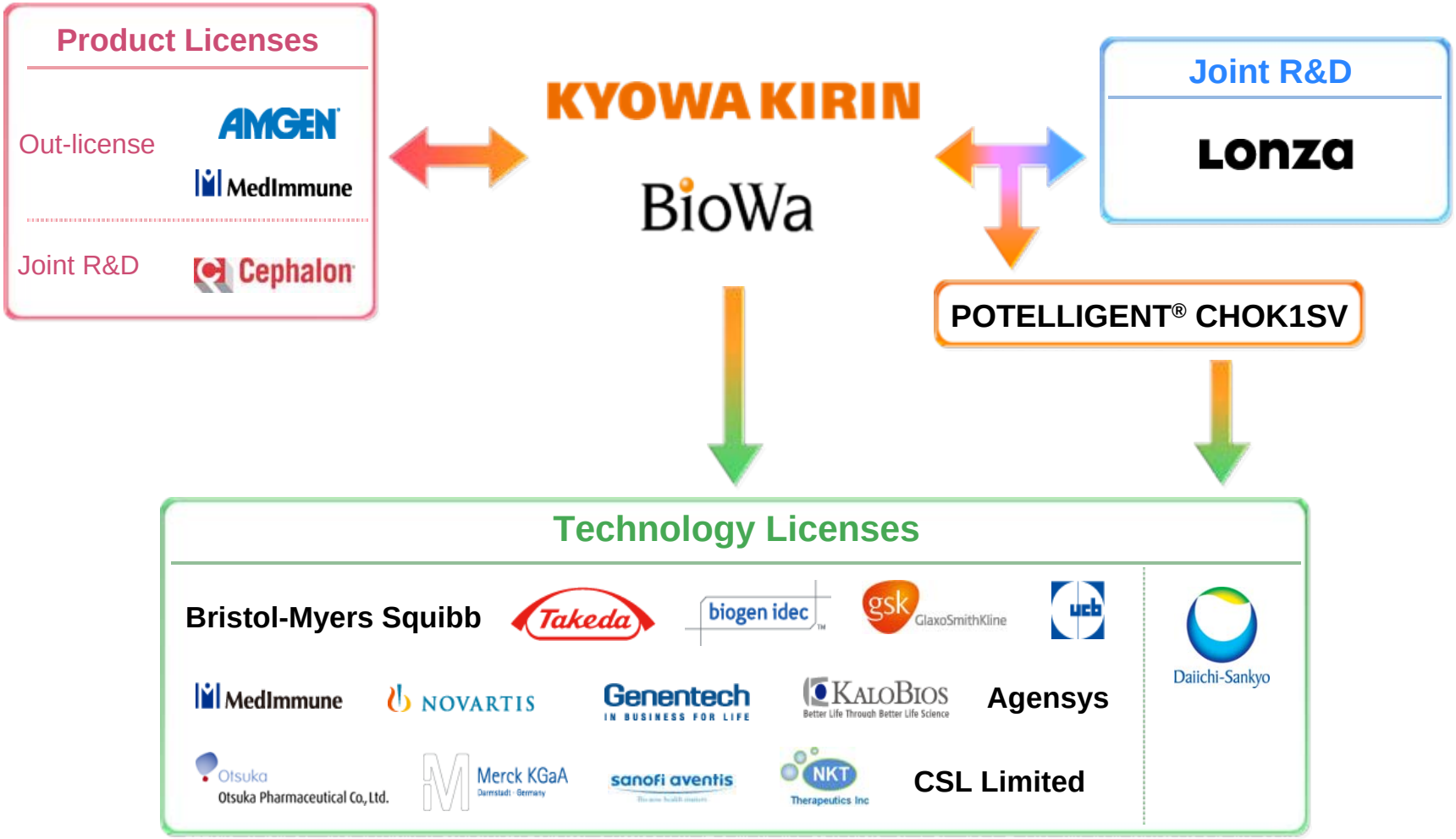

*Including POTELLIGENT contracts with Bristol-Myers Squibb and Genentech, six antibodies have entered clinical trials to date

Progress in licensed out compounds (as of January 2011)

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Name	Partner	Phase			Remarks
		I	II	III	
KW-6002	Biovail	Out-licensed in USA			Parkinson's disease **(adenosine A2A receptor antagonist)**
Tivozanib (KRN951)	AVEO				Malignant tumor **(VEGF receptor inhibitor)**
KW-2871 (Low-fucose antibody)	Life Science				Malignant tumor **(Anti-GD3 antibody)**
MEDI-563 (KHK4563:POTELLIGENT®)	MedImmune				Allergy **(Anti-IL-5R antibody)**
KRN5500	DARA				Cancer pain
LY2523355	Eli Lilly				Malignant tumor **(Mitotic kinesin Eg5 inhibitor)**
AMG 761 (KW-0761:POTELLIGENT®)	Amgen				Allergy **(Anti-CCR4 antibody)**

Progress in licensed in compounds (as of January 2011)

KYOWA KIRIN

Name	Partner	Phase			Remarks
		I	II	III	
HFT-290	Hisamitsu	Product has been launched			Cancer pain (μ-opioid receptor agonist)
SP-01	Solasia	Preparing to be filed			Vomiting (Serotonin antagonist)
KW-2246	Orexo				Cancer pain (μ-opioid receptor agonist)
KW-6500	Britannia				Parkinson's disease (Dopamine agonist)
ARQ 197	ArQule				Stomach cancer (c-met inhibitor)
Asacol	Zeria				Inflammatory bowel disease (Crohn's disease) *Application filed for ulcerative colitis
RTA 402	Reata				Diabetic nephropathy

Target disease

Relapsed subjects with CCR4-positive adult T-cell leukemia-lymphoma

Study objectives

To evaluate the efficacy, safety and pharmacokinetic profiles of KW-0761

Doses and schedules

KW-0761 is administered weekly for 8 weeks as an intravenous infusion at a dose of 1.0 mg/kg

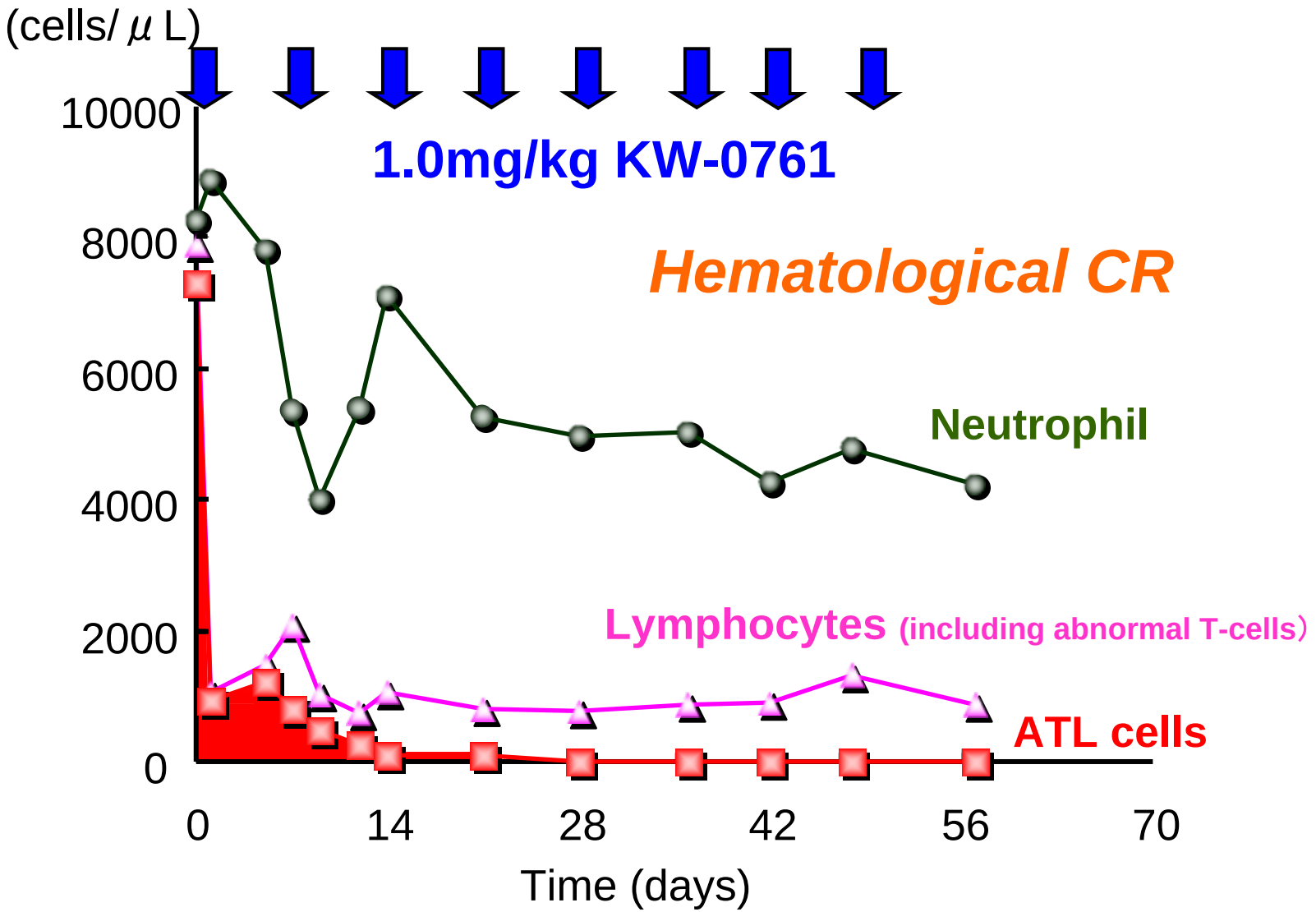
Summary

- Efficacy: 50% (8 CR + 5 PR / n=26)
- Major adverse events: infusion reaction, rash, ATL increase, AST increase, hypoxia and hematologic toxicities
- No anti-KW-0761 antibodies

Another studies

- Parallel-group study to compare mLSG15 + KW-0761 to mLSG15 in subjects with CCR4-positive adult T-cell leukemia-lymphoma (untreated primary disease)
- Study in subjects with CCR4-positive peripheral T/NK-cell lymphoma

Dr. Ishida Takashi presented in the 52nd American Society of Hematology annual meeting



Dr. Ishida Takashi presented in the 52nd American Society of Hematology annual meeting

KW-0761 Phase 1/2 Study in US

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Target disease

Subjects with previously treated peripheral T-cell lymphoma or cutaneous T-cell lymphoma

Study objectives

To evaluate the efficacy, safety, pharmacokinetic profiles and recommended phase 2 part dose of KW-0761

Doses and schedules

Phase 1 part: 0.1, 0.3 and 1.0 mg/kg administered i.v. once every week for four weeks, followed by a 2-week observation period

Phase 2 part: 1.0 mg/kg administered i.v. once every week for four weeks, followed by a 2-week observation period

After observation period, the subject may continue therapy on an every other week infusion schedule until disease progression occurs or other withdrawal criteria are met in both parts.

Summary1 (Phased 1 part)

- No dose limiting toxicity (DLT) observed at doses by 1.0 mg/kg
- Phase 2 part dose was 1.0 mg/kg

Summary2 (Phased 1/2 part)

- Efficacy: 42%（3 CR+13 PR /38, SS 50%、MF 36%）
- Major adverse events: nausea, headache, chills, pyrexia, rash, lymphopenia, etc.
- Anti-KW-0761 antibodies observed in a patient, but no neutralizing activity

Dr. Madeleine Duvic presented in the 52nd American Society of Hematology annual meeting

Changes to the Tokyo Research Park structure

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Improper management of recombinant mouse:

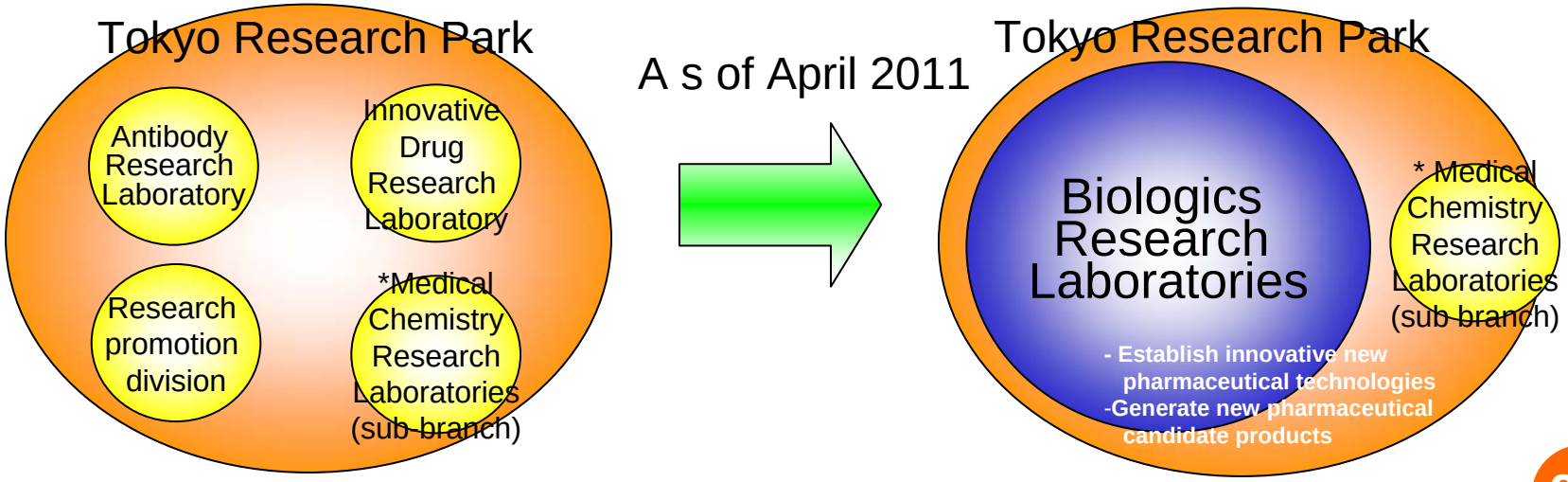
- At Tokyo Research Park, on August 4, and August 11 of 2010, it came to light that the actual number of recombinant mice bred and the number of mice accounted for, differed by two

Cause:

- Inadequate record keeping of the number of recombinant mice when delivered and when used
- Procedural documents had not been prepared and instructions were not clearly explained to staff

Initiatives to prevent a reoccurrence:

- Integrate three core divisions of Tokyo Research Park to establish a Biologics Research Laboratories and strengthen governance
- Once integrated, the Bio-pharma research laboratory will be a key research facility whose mission will be to create groundbreaking new drug candidates and leverage cutting edge bio-technology to establish innovative new pharmaceutical technologies



*Medical Chemistry Research Laboratories (sub-branch) is a sub-branch of Fuji Research Park

Events:

- On September 29, 2010, FDA submitted a warning letter to Kyowa Hakko Bio facilities in Yamaguchi(Hofu)

Contents of warning letter:

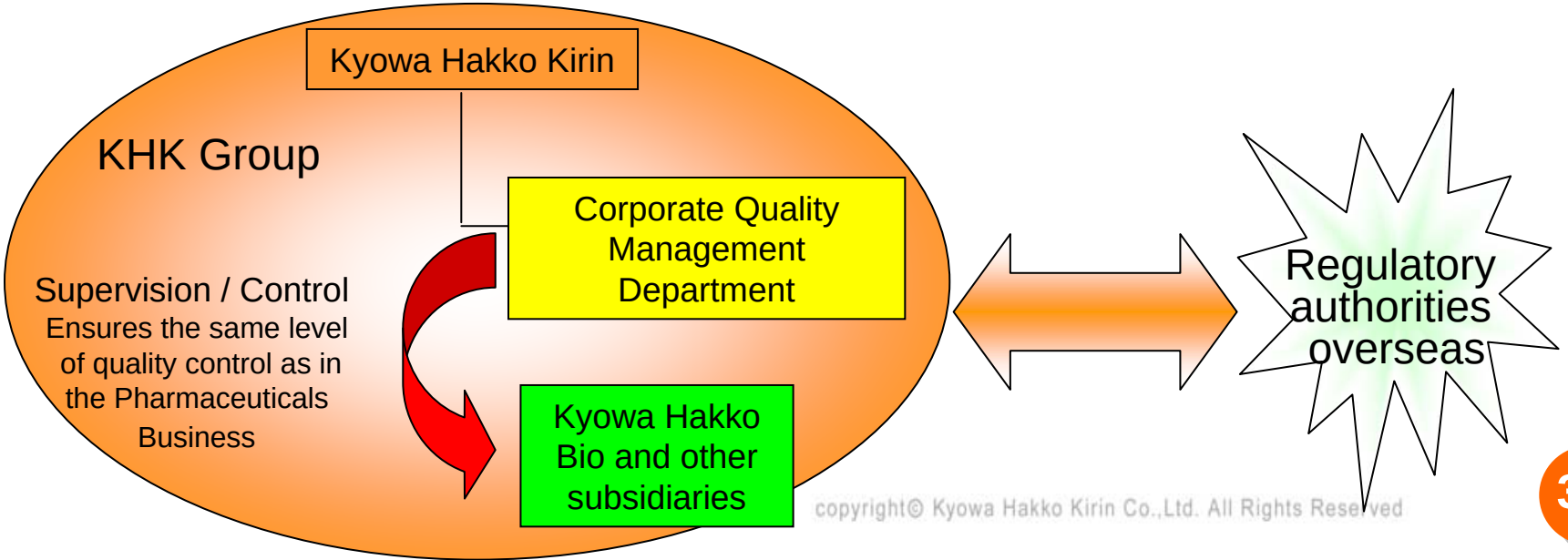
- Identified 9 problem points regarding quality control

Response:

- With advice from a US legal firm, US GMP consultants, etc., prepared a response document to address points identified by FDA
- Response document was sent to FDA on November 8

Initiatives to improve quality assurance:

- Established a Corporate Quality Management Department in the Pharmacovigilance and Quality Assurance Division to ensure the same level of quality assurance as the Pharmaceuticals business throughout the Group and to deal with regulatory authorities overseas



Reasons for share transfer:

- For Kyowa Hakko Kirin Group to focus management resources on drugs for pharmaceutical use and related areas
- For Kyowa Hakko Chemical to develop its business as a global niche player and to be able to actively invest in facilities to address diverse market needs

Accounting for the Chemicals segment:

- Results from the Chemicals segment will be consolidated until the end of the first quarter and the segment will be abolished thereafter

Impact on results:

- FY2010: In the consolidated accounts, a tax effect has been recognized due to a temporary difference in our consolidated financial statements (a temporary difference between the value recorded in our consolidated balance sheet and the book value of our non-consolidated balance sheet)
- FY2011: Anticipating gain from transfer of shares on day of share transfer
- Today's FY2011 results forecast include the results to the end of the first quarter of FY2011 and the anticipated transfer gain on transfer of shares

Application of Kyowa Hakko Chemical share transfer value

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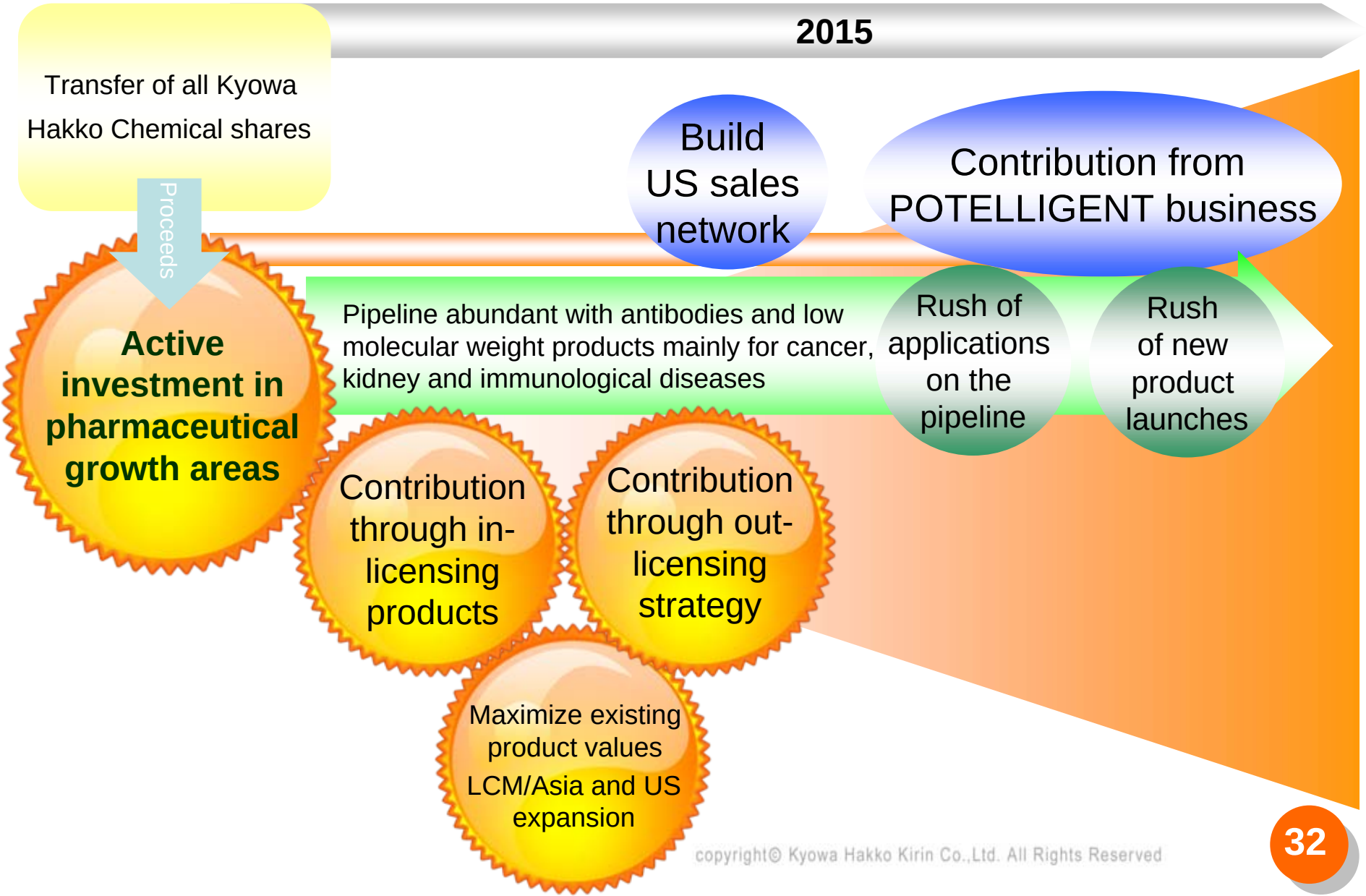

Pharmaceuticals Business: Current and future assets (in pipeline):

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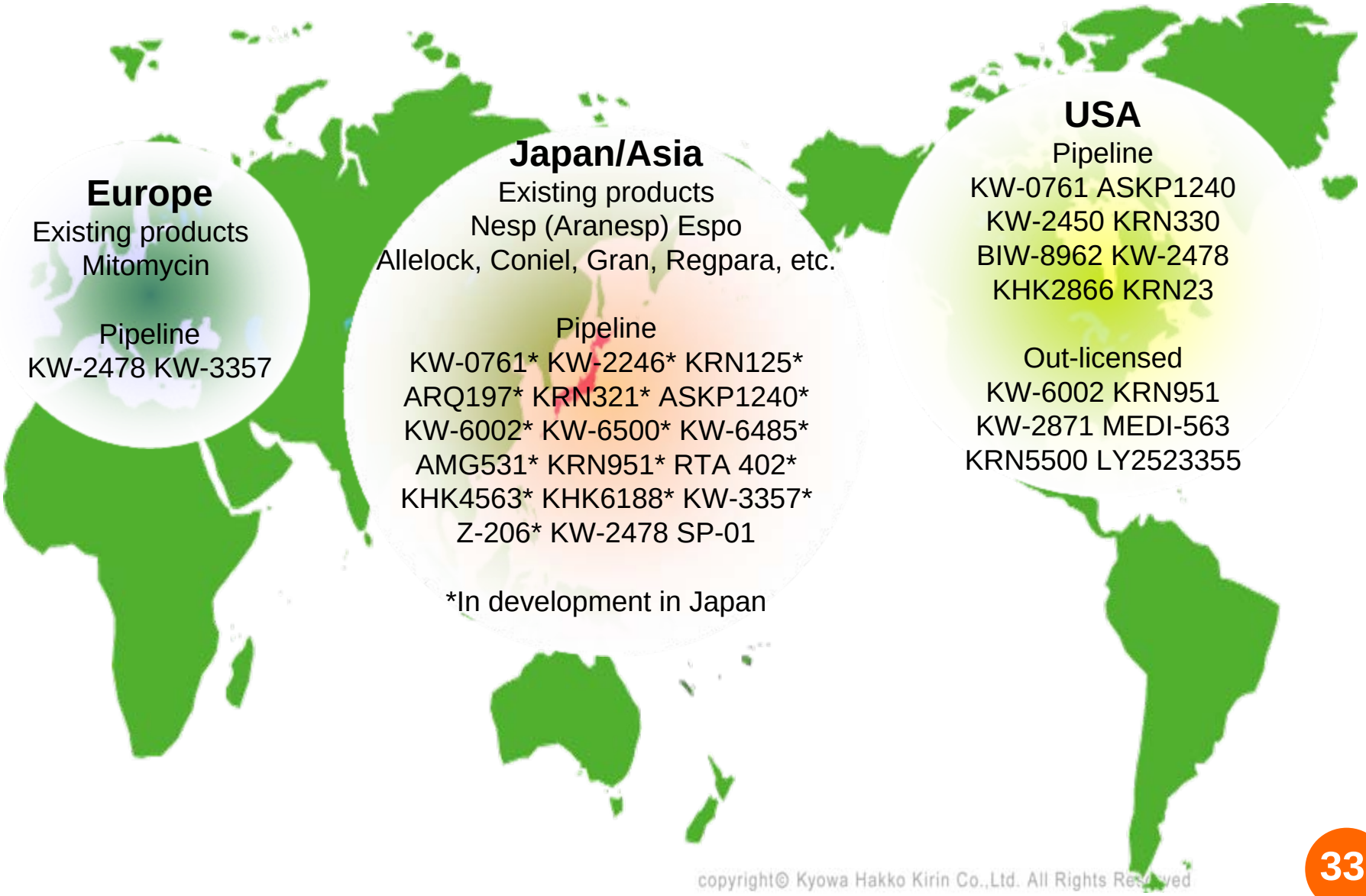

Europe

Existing products
Mitomycin

Pipeline
KW-2478 KW-3357

Japan/Asia

Existing products
Nesp (Aranesp) Espo
Allelock, Coniel, Gran, Regpara, etc.

Pipeline
KW-0761* KW-2246* KRN125*
ARQ197* KRN321* ASKP1240*
KW-6002* KW-6500* KW-6485*
AMG531* KRN951* RTA 402*
KHK4563* KHK6188* KW-3357*
Z-206* KW-2478 SP-01

*In development in Japan

USA

Pipeline
KW-0761 ASKP1240
KW-2450 KRN330
BIW-8962 KW-2478
KHK2866 KRN23

Out-licensed
KW-6002 KRN951
KW-2871 MEDI-563
KRN5500 LY2523355

Vertical Diversification

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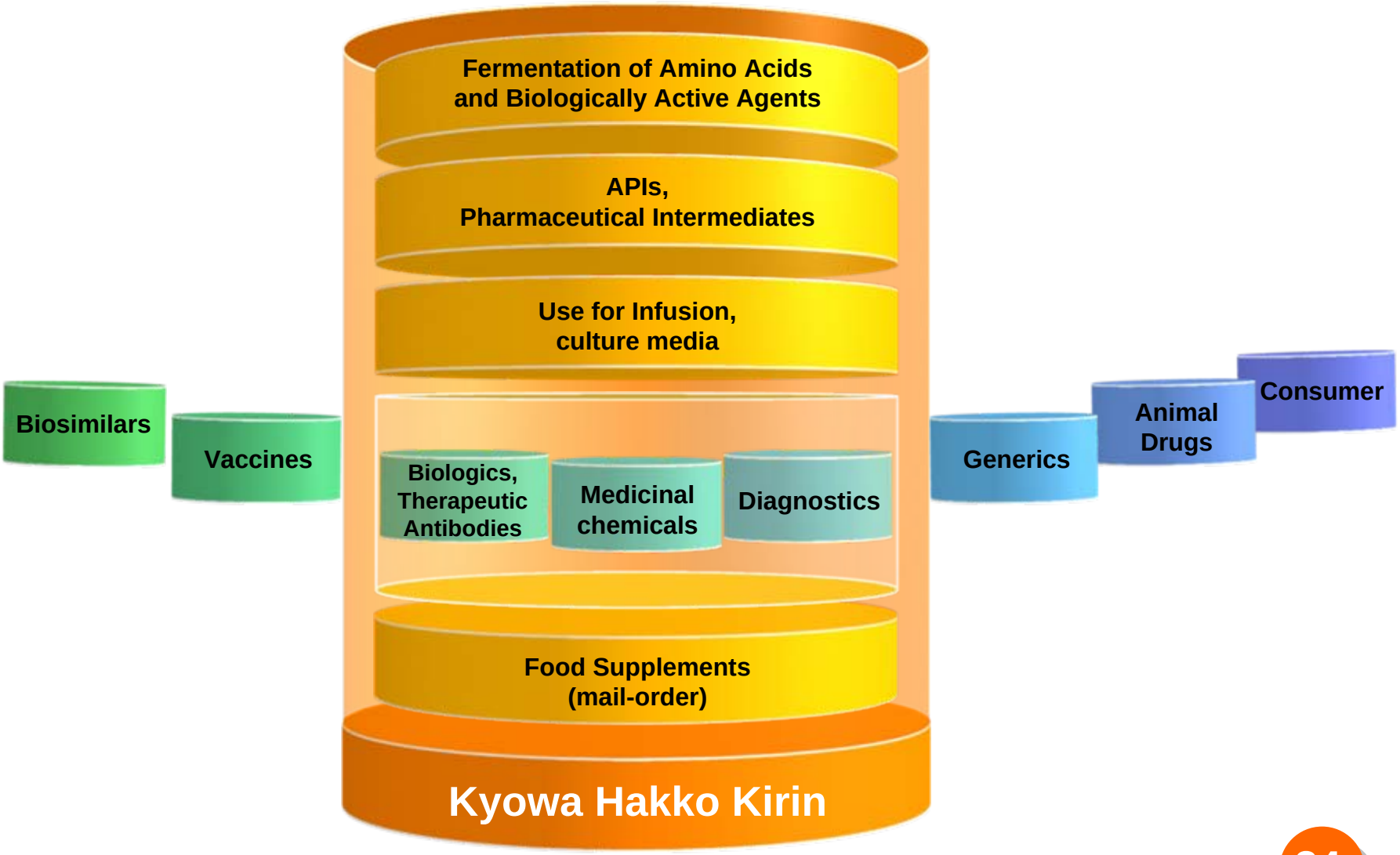


Amino acid business: High value added products primarily in pharmaceuticals and for pharmaceutical use

Current status:

- Record level manufacturing and sales volumes, revenues down due to effects form foreign exchange

Potential:

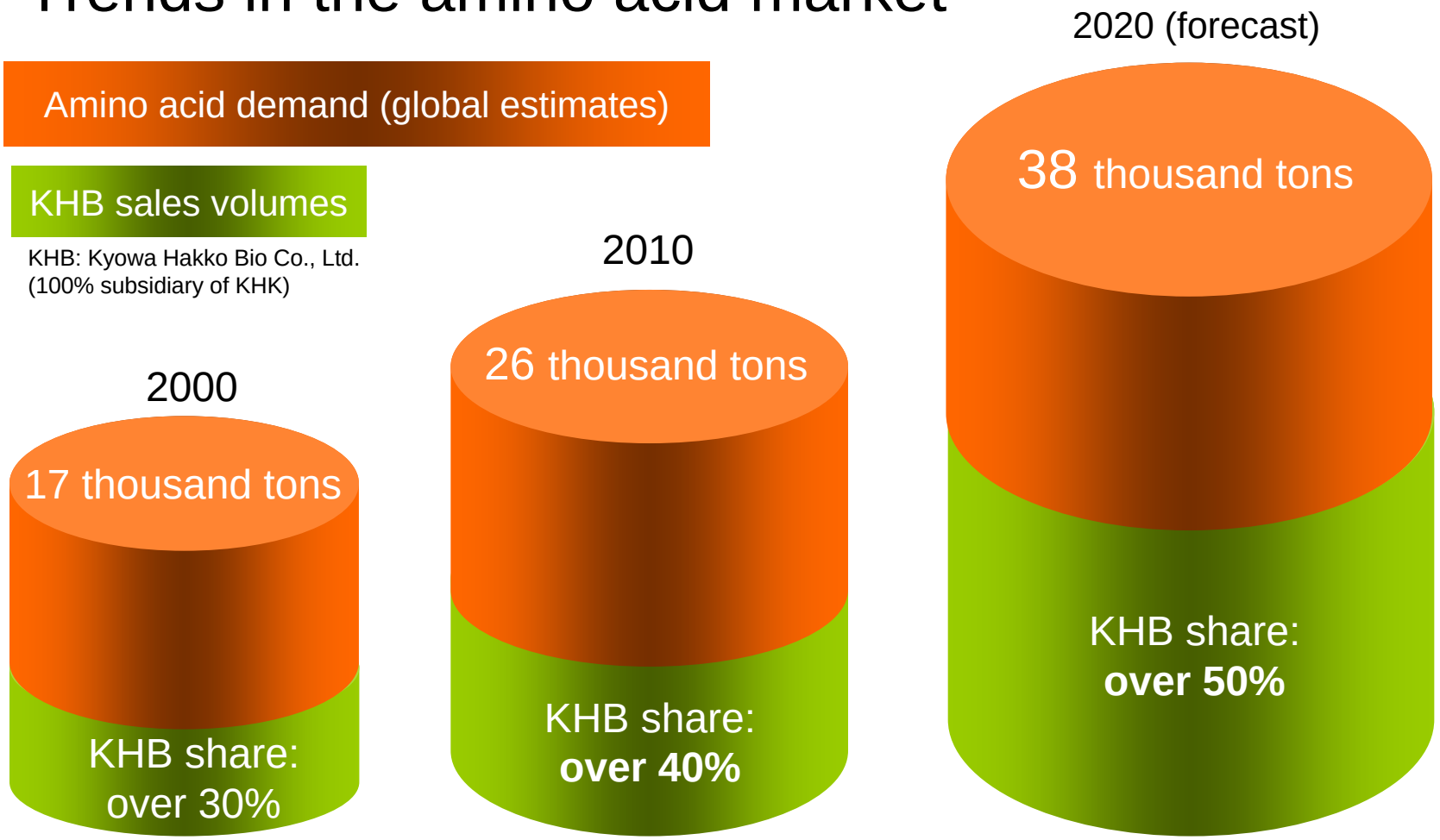
- Growing demand from newly emerging countries
- Strengthening our position in expanding markets

Goals:

- Strengthen manufacturing and sales capabilities
- Focus on pharmaceutical-related areas

e.g. Rapidly expanding culture materials, etc.

- Trends in the amino acid market -



Health care business

Current status:

- Strong, partly due to the effects of “Plus-i”, Kirin Group’s food and health project
- In particular, strong growth in sales from health food mail-order business (1.5 fold increase y-on-y, now more than 100,000 regular customer)

Potential: Heightened concern regarding health

- Grow our presence in the health food products market by expanding usage and functionality of amino acids and other in-house materials

キリンの健康プロジェクト
KIRIN Plus-i
それは、「おいしい」と「健康」の新しい絆づくり。

Daiichi Fine Chemical

Current status:

- Core product environment is changing: sluggish pantothenic acid Calcium market and a decrease in Cravit intermediary volu
- Investments in large-scale new product facilities underway

Potential: Further shift along API route

- Launch new major products such as tranexamic acid and others
- Transfer production from KHK and expand pharmaceutical raw material production capacity for generics market

KYOWA KIRIN

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