
FY December 2012 Interim Results Meeting

Kyowa Hakko Kirin Co., Ltd.

**President and CEO
Nobuo Hanai**

This document contains certain forward-looking statements relating to such items as the company's (including its domestic and overseas subsidiaries) forecasts, targets and plans. These forward-looking statements are based upon information available to the company at the present time and upon reasonable assumptions made by the company in making its forecasts, but actual results in practice may differ substantially due to uncertain factors.

These uncertain factors include, but are not limited to, potential risks associated with the pharmaceutical industry's domestic and international operating environment, intellectual property risks, the risk of adverse reactions to pharmaceutical products, legal risks, risks arising from product manufacturing deficiencies, risks due to fluctuations in the market prices of raw materials, fuel and products, as well as exchange rate and financial market volatility.

This document contains information on pharmaceutical products (including products under development), but its contents should not be construed as promotion, advertising or as a medical recommendation.

Pharmaceuticals business

- Drug prices cut in April, but revenues up year-on-year
- Share of erythropoiesis stimulating agent (ESA) market up, centered on NESP®
- Launch of POTELIGIO® and POTELIGIO® TEST for adult T-cell leukemia-lymphoma (ATL)
- Price listing of Apokyn® for Parkinson's disease

Bio-Chemicals business

- Affected by exchange rates, but sales maintained at last year's level on strong overseas demand for amino acids
- Structural reforms underway at Daiichi Fine Chemical

Overview of Results

Consolidated income statement

KYOWA KIRIN

(¥ billion)

	Actual Results		Change from last FY interim term	Forecast at start of term	Result relative to forecast
	Jan-Jun 2011	Jan-Jun 2012		Jan-Jun 2012	
Net Sales	186.3	166.2	-20.0	163.0	+2%
Operating income	29.9	25.5	-4.3	22.5	+14%
Recurring income	30.2	23.0	-7.1	19.5	+18%
Net income	17.7	11.5	-6.1	8.5	+36%

*1 Chemicals segment was eliminated from April 2011. The disposal reduced sales by ¥33.5 billion and operating income by ¥2.1 billion versus the same period of last fiscal year.

Pharmaceuticals business

KYOWA KIRIN

(¥ billion)

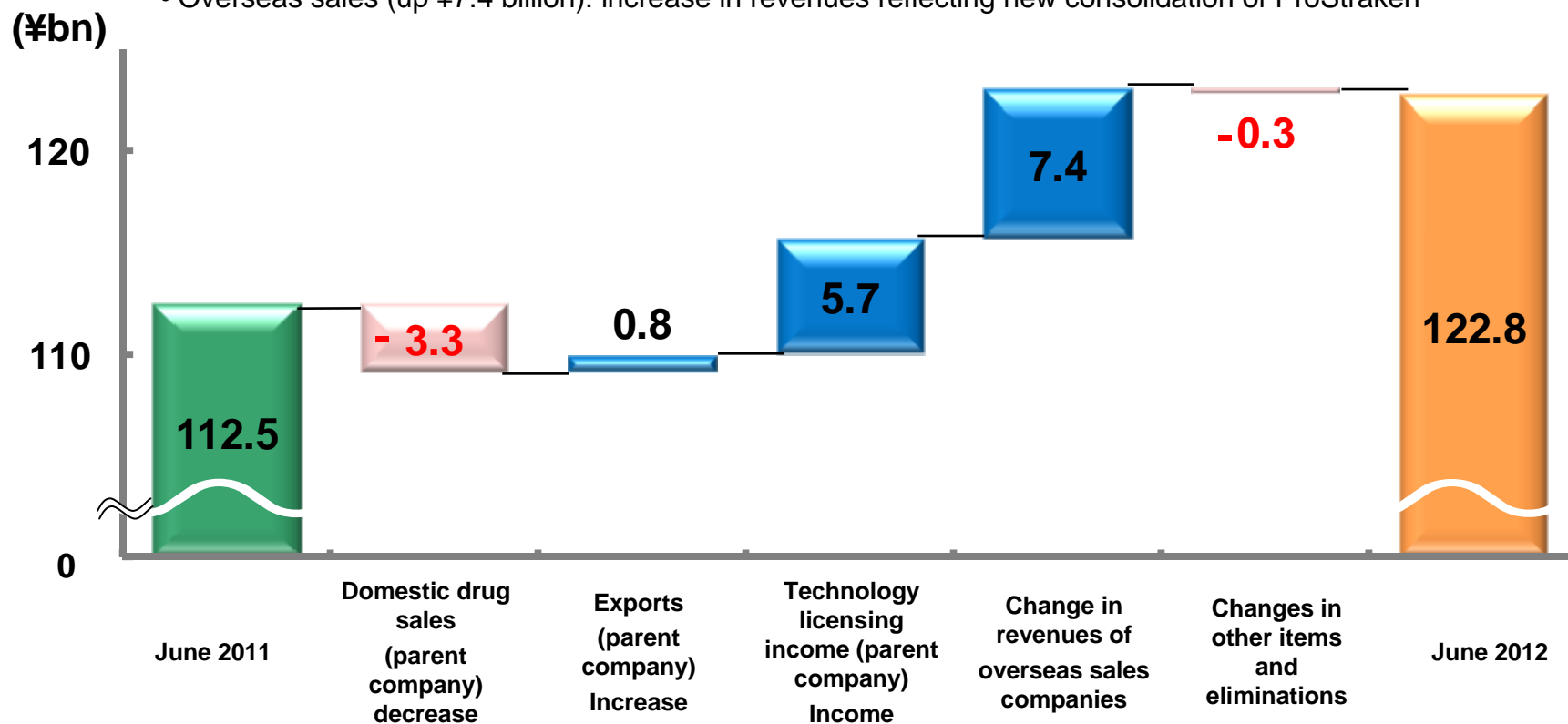
	Actual Results		Change from last FY interim term	Forecast at start of term	Result relative to forecast
	Jan-Jun 2011	Jan-Jun 2012		Jan-Jun 2012	
Net Sales	112.5	122.8	+10.2	120.0	+2%
Operating income	25.1	23.3	-1.7	21.5	+9%
R&D expenses	20.4	20.5	+0.1	22.3	- 8%

Pharmaceutical Business:

Analysis of sales changes

KYOWA KIRIN

- Domestic drug sales (down ¥3.3 billion): Despite growth in sales of Nesp, Fentos, Regpara and other products, lower airborne pollen counts than in the previous year depressed sales of Allelock and Patanol. The largest negative impact was caused by the drug price cuts
- Exports (up ¥0.8 billion): Exports focused on Asia are steady
- Technology licensing income (up ¥5.7 billion): technology revenue recorded from FUJIFILM KYOWA KIRIN BIOLOGICS
- Overseas sales (up ¥7.4 billion): increase in revenues reflecting new consolidation of ProStraken



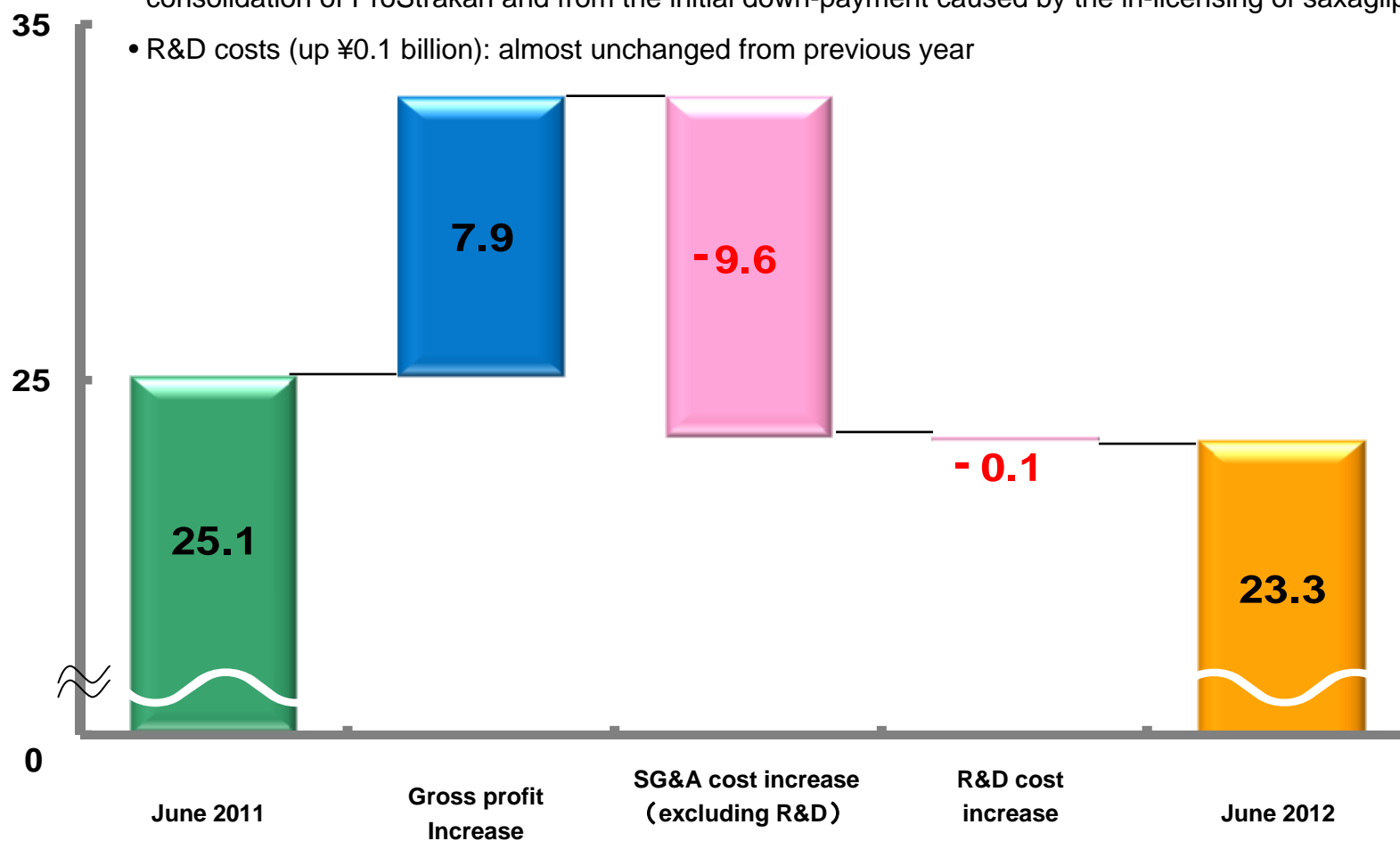
Pharmaceutical Business:

Analysis of operating income changes

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- Gross profit (up ¥7.9 billion): Decrease in gross profit from domestic drug sales offset by increase in FUJIFILM KYOWA KIRIN BIOLOGICS licensing income and new consolidation of ProStrakan
- Increase in SG&A costs (up ¥9.6 billion) was a factor depressing profits. Increase in costs arising from the consolidation of ProStrakan and from the initial down-payment caused by the in-licensing of saxagliptin.
- R&D costs (up ¥0.1 billion): almost unchanged from previous year

(¥bn)



Bio-Chemicals business

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(¥ billion)

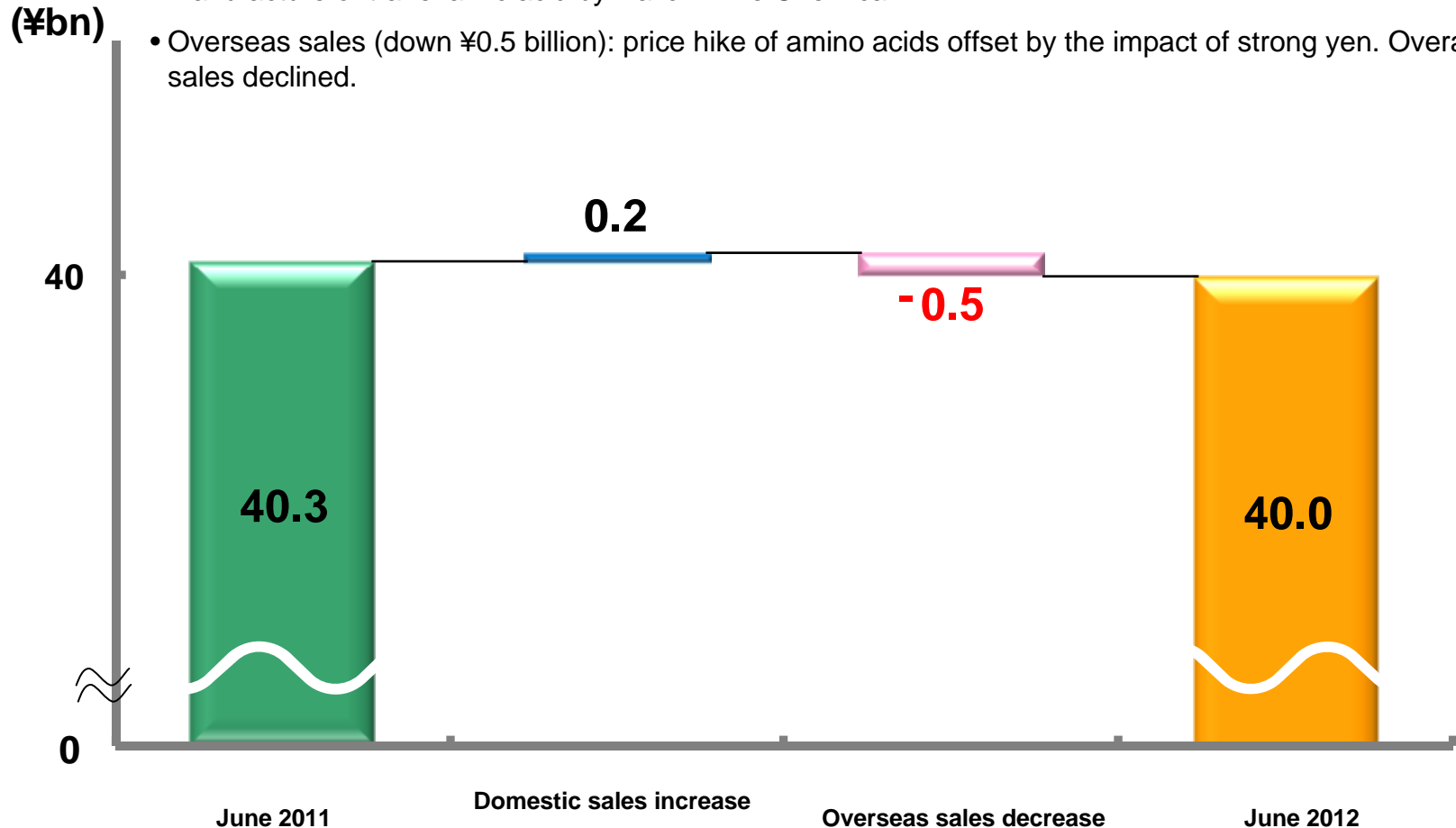
	Actual Results		Change from last FY interim term	Forecast at start of term	Result relative to forecast
	Jan-Jun 2011	Jan-Jun 2012		Jan-Jun 2012	
Net sales	40.3	40.0	-0.2	40.0	0%
Operating income	2.5	2.0	-0.4	0.8	+155.0%

Bio-chemical business:

Analysis of sales changes

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- Domestic sales (up ¥0.2 billion): Growth in mail order sales and increased revenue due to the sale and manufacture of tranexamic acid by Daiichi Fine Chemical
- Overseas sales (down ¥0.5 billion): price hike of amino acids offset by the impact of strong yen. Overall sales declined.

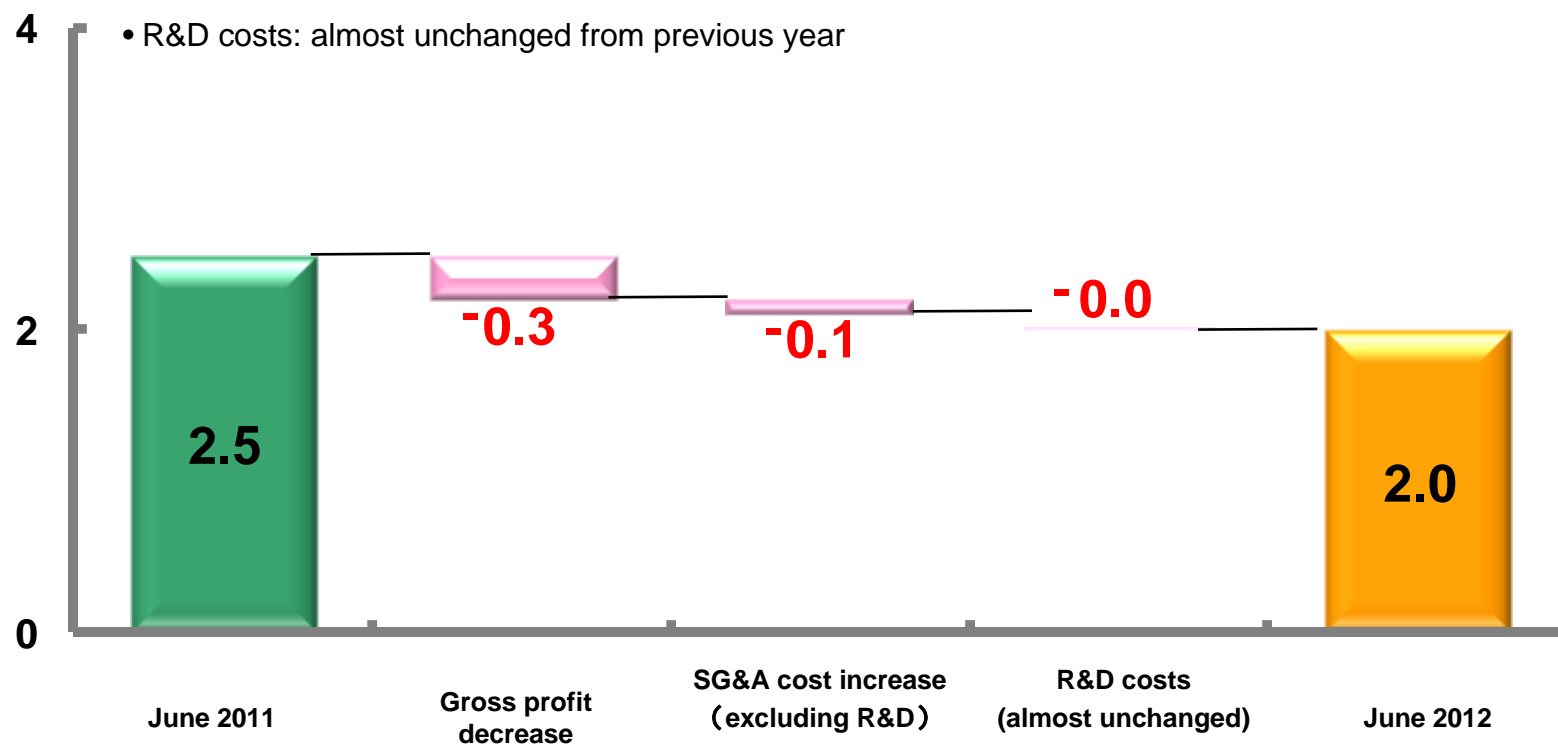


- Gross profit (down ¥0.3 billion): The negative profit impact of the strong yen more than offset the price hike for amino acid exports and the increase in mail order sales of Ornithine, which were boosted by improved brand recognition

(¥bn)

- SG&A costs (up ¥0.1 billion): costs were almost unchanged from previous year

- R&D costs: almost unchanged from previous year



Exchange rates

Exchange rate (average for accounting period)

	Jan-Jun2011	Jan-Jun 2012	Change from last FY interim term
US dollar	¥82	¥80	-¥2
Euro	¥115	¥103	-¥12
British pound	¥133	¥126	-¥7

Impact of exchange rates

	Jan-Jun 2012: impact on profits (vs. same period of last FY)		
	Pharmaceuticals	Bio-Chemicals	Consolidated
Net sales	-¥0.9 billion	-¥0.9 billion	-¥1.9 billion
Operating income	-¥0.3 billion	-¥0.6 billion	-¥0.9 billion

Sales of major products

Sales of major products (domestic)

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(¥ billion)

	Actual Results		Change from last FY interim term	Forecast at start of term	Result relative to forecast
	Jan-Jun 2011	Jan-Jun 2012		Jan-Jun 2012	
Nesp	25.4	26.8	+5%	25.5	+5%
Espo	2.7	1.9	-29%	2.0	-5%
Regpara	5.3	6.2	+17%	6.3	-1%
Allelock	18.1	16.1	-11%	16.9	-5%
Patanol	8.6	6.9	-20%	8.1	-15%
Gran	6.7	6.4	-5%	6.3	+1%
Fentos	1.2	2.0	+70%	2.3	-14%
Asacol	1.1	1.8	+52%	1.9	-6%
Exports	4.8	5.7	+18%	4.9	+17%
Technology outlicensing income	6.5	12.2	+86%	11.3	+8%

Sales of major products (ProStrakan)

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(Million pounds)

	Actual Results		Change from last FY interim term	Forecast at start of term	Result relative to forecast
	Jan-Jun 2011	Jan-Jun 2012		Jan-Jun 2012	
Sancuso	4	5	+47%	7	-14%
Abstral	12	16	+29%	18	-9%
Tostran	2	2	+32%	2	+46%
Xomolix	4	4	-7%	4	+6%
Rectogesic	4	4	0%	5	-3%
Adcal D3	11	12	+7%	11	+14%
Others	8	14	+74%	10	+45%

Full year forecasts

Consolidated income statement

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(¥ billion)

	Actual result (1)	Revised forecast (2)	Change (2) – (1)	Forecast at start of term (3)	Difference between original and revised forecast (2) - (3)
	Jan-Dec 2011	Jan-Dec 2012		Jan-Dec 2012	
Net Sales	343.7	333.0	-10.7	326.0	+7.0
Operating income	46.6	52.0	+5.4	48.0	+4.0
Recurring income	46.7	46.5	-0.3	42.5	+4.0
Net income	25.6	23.0	-2.6	20.0	+3.0

*1 The Chemicals segment was eliminated from April 2011. The disposal reduced sales by ¥33.5 billion and operating income by ¥2.1 billion compared with the same period of last fiscal year.

*2 ProStrakan results were consolidated from the second half of fiscal 2011.

Pharmaceuticals business

KYOWA KIRIN

(¥ billion)

	Actual results (1)	Revised forecast (2)	Change (2) – (1)	Forecast at start of term (3)	Difference between original and revised forecast (2) - (3)
	Jan-Dec 2011	Jan-Dec 2012		Jan-Dec 2012	
Net sales	229.3	248.0	+18.7	242.0	+6.0
Operating income	41.3	48.7	+7.4	45.7	+3.0
R&D expense	44.5	41.0	-3.5	42.9	-1.9

*ProStrakan results were consolidated from the second half of fiscal 2011

FY2012 forecasts for sales of major products

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(¥ billion)

	Fiscal 2011	Fiscal 2012 Revised forecasts	Change y/y	Fiscal 2012 Original forecast
Nesp	56.4	53.7	-5%	50.5
Espo	5.3	4.0	-25%	4.0
Regpara	11.5	13.0	+13%	13.1
Allelock	29.1	29.1	+0%	29.7
Patanol	11.4	10.1	-12%	11.3
Gran	14.8	13.4	-9%	13.3
Fentos	3.1	4.5	+45%	4.9
Asacol	2.8	3.8	+35%	4.1
Exports	9.2	9.2	-1%	8.3
Technology outlicensing income	13.0	25.6	+96%	25.0

FY2012 forecasts for sales of major products (ProStrakan)

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(GBP million)

	Fiscal 2011	Fiscal 2012 Revised forecast	Change y/y	Fiscal 2012 Original forecast
Sancuso	9	16	+76%	16
Abstral	27	36	+34%	38
Tostran	5	4	-10%	4
Xomolix	8	9	+6%	9
Rectogesic	9	9	+6%	10
Adcal D3	24	25	+3%	24
Others	20	37	+83%	38

Bio-Chemicals business

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(¥ billion)

	Actual Results (1)	Revised forecast (2)	Change (2) - (1)	Forecast at start of term (3)	Difference between original and revised forecast (2) - (3)
	Jan-Dec 2011	Jan-Dec 2012		Jan-Dec 2012	
Net sales	77.5	79.0	+1.4	78.0	+1.0
Operating income	2.8	3.0	+0.1	2.0	+1.0

FY 2012 forecasts (Forex)

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(Exchange rate average for FY 2012)

	Actual Result (1)	Revised forecast (2)	Change (2) - (1)	Forecast at start of term (3)	Difference between original and revised forecast (2) - (3)
	Jan-Dec 2011	Jan-Dec 2012		Jan-Dec 2012	
USD	¥80	¥81	+ ¥1	¥77	+ ¥4
EUR	¥111	¥102	-¥9	¥98	+ ¥4
GBP	¥128	¥124	-¥4	¥119	+ ¥5

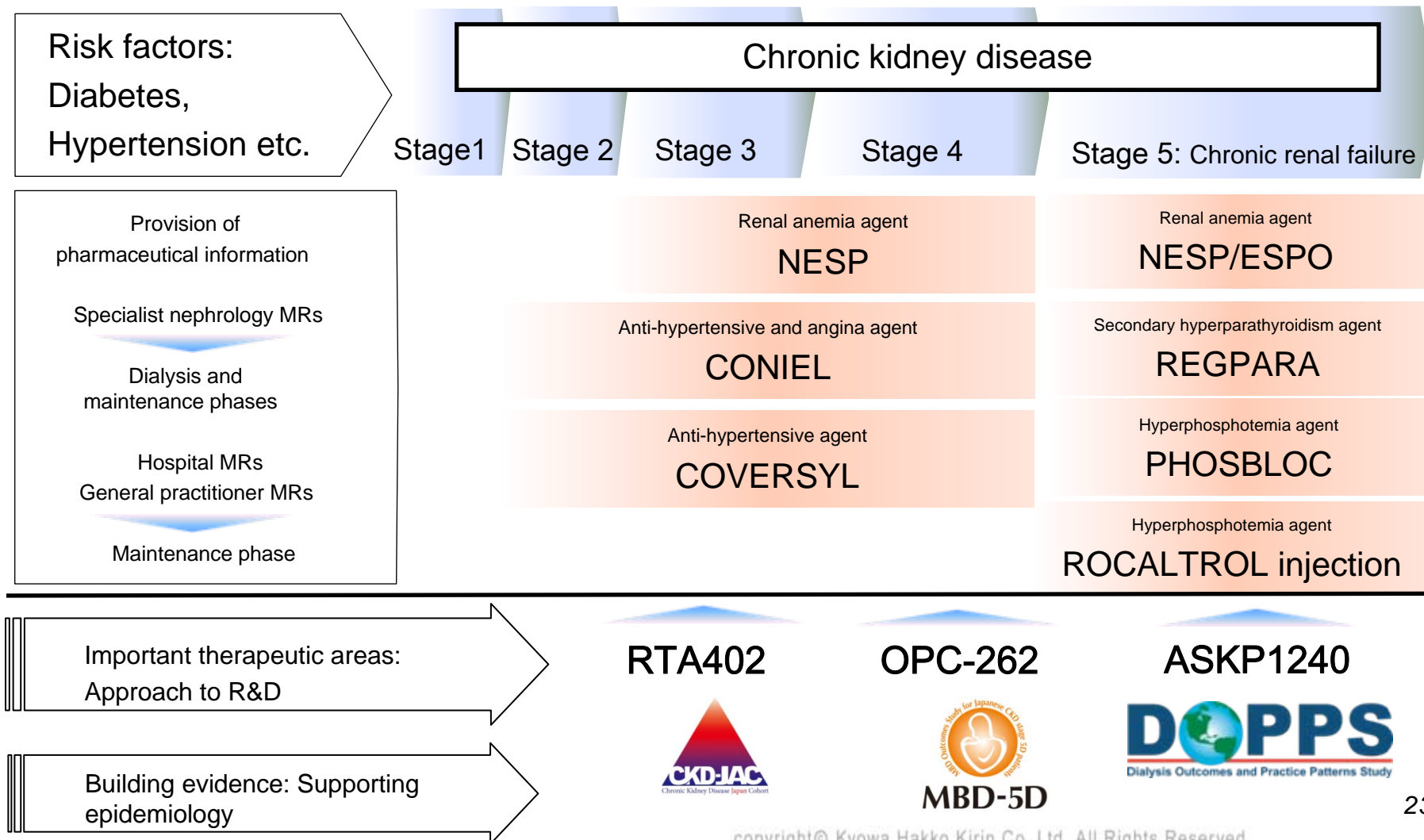
Pharmaceuticals business highlights

Established presence in nephrology

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Multiple product offerings centered on chronic kidney disease (CKD)

Supporting healthcare professionals through comprehensive information provision



Renal anemia agent: NESP

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NESP: Accumulated evidence from five years of clinical experience since launch

Pre-Dialysis phase

Dialysis phase

CKD stage

~ 4

5

5 D (renal failure)

Varying the period between administration to take account of CKD disease progression and appropriately manage Hb

Administration frequency

Maintenance dose

Once per two weeks
Once per four weeks

Once per two weeks
Once per four weeks

Once per week
Once per two weeks



Promote individualized medicine through launch of antibody pharmaceuticals and companion diagnostics

POTELIGEO® TEST

- March 2012: Approved
- May 2012: Launched
- CCR4 positive diagnosis

POTELIGEO® Infusion

- March 2012: Approved
- May 2012: Launched
- Indications: Relapsed or refractory CCR4-positive ATL*

POTELIGEO® TEST IHC



POTELIGEO® TEST FCM



Diagnostics development by
Kyowa Medex



Therapeutic development by
Kyowa Hakko Kirin

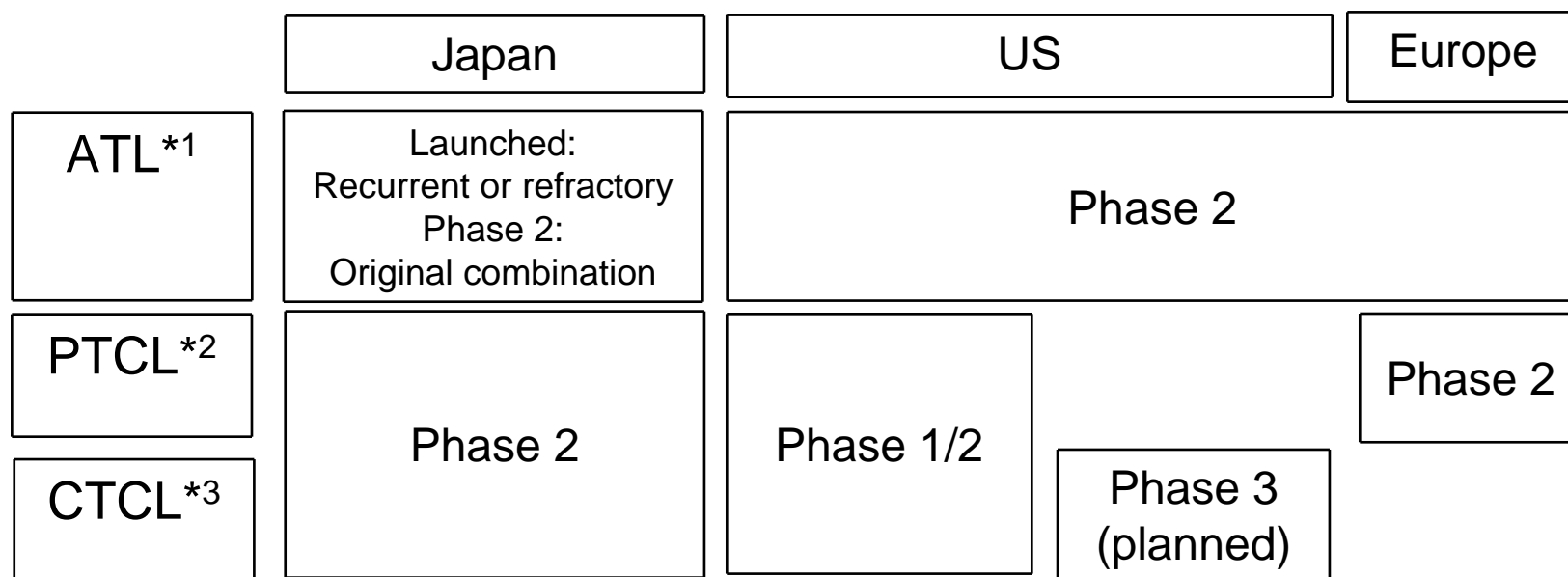
Development strategy leveraging group synergies

simultaneous launch

*ATL: Adult T-cell Leukemia-Lymphoma

Accelerating development strategy to maximize KW-0761 value

Clinical trials for T-cell Lymphoma



Companion diagnostics

Exploring future development opportunities with Kyowa Medex

*Enhancing product line-up in kidney disease (core therapeutic area)
and advancing drug development in oncology*

Aims of strategic alliance

Kyowa Hakko Kirin secures exclusive Japanese development and marketing rights to saxagliptin

Pursue strategic alliance in Japan and Asia for Kyowa Hakko Kirin's oncology products

Most common underlying disease in renal failure is diabetic nephropathy. Renal disease product line-up enhanced by acquiring a diabetes treatment.

Aim for efficient and fastest possible launch by reducing development costs and accelerating development speed of the oncology pipeline.

The DPP-4 inhibitor saxagliptin

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Japanese guidelines for clinical evaluation of oral hypoglycemic agents



The first DPP-4 inhibitor filed in Japan after implementation of the Japanese guidelines

US guidance for Industry. Diabetes Mellitus – Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes.



DPP-4 inhibitors launched after clearing new FDA guidelines

Update on biosimilar business

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*FUJIFILM KYOWA KIRIN BIOLOGICS(FKB) is accelerating
towards start of clinical trials in 2013*

Business plan:

- One biosimilar agent per year into clinical trials from 2013
- First product *Humira*; 4 product launches planned
- Target markets are Europe, North America and Japan

FKB's strength

Biopharmaceutical
manufacturing technology

High reliability and
high quality

Regulatory demands

Quality equivalent to
patented products

External environment:

- FDA: Draft guidance for industry on biosimilars.
- EMA: Guideline on similar biological medicinal products
- MHLW: Guidelines on approval applications for biosimilar medicines

Development pipeline

Pipeline progress over the three-month period since the Q1 results announcement

Domestic

- ✓ May: Launched POTELIGEO® for adult T-cell leukemia-lymphoma
- ✓ May: Kyowa Medex launched *in vitro* diagnostic POTELIGEO® TEST
- ✓ May: Began phase II studies on KHK6188, a postherpetic analgesic agent

Overseas

- ✓ May: Pegfilgrastim (brand name Neulasta) approved in South Korea
- ✓ April: ProStrakan wins approval for Sancuso® in Europe

Phase III product pipeline (1)

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Development Code	Indication	Location	Phase	Annual Incidence	Expected filling date
KW-0761	<i>Relapsed/refractory ATL</i>	Japan	Launched in 2012	1,100 ¹⁾	(Launched in 2012)
	<i>Naive ATL, 1st line combination therapy</i>	Japan	Late Ph2		2013
	<i>PLCL & CTCL</i>	Japan	Late Ph2	1,800-2,900 ²⁾	2013
	<i>ATL</i>	USA and EU	Ph2	Investigating	2015
	<i>CTCL</i>	USA	Ph3 (planned)	2,400 ³⁾	2016
AQR 197	<i>NSCLC</i>	Japan, Korea and Taiwan	Ph3	93,402 ⁴⁾	2015

(Japan , Korea and Taiwan international study)

1) Survey of and countermeasures to HTLV-1 infection and related diseases in Japan (Reported by Kazunari Yamaguchi, 2009)

2) in-house

3) SEER Data (2001-2007)

4) Monitoring of cancer incidence in Japan, MCIJ 2007 by NCC-CIS, 2012

Phase III product pipeline (2)

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Development Code	Indication	Location	Phase	Prevalence	Expected filling date
KRN125	<i>Chemotherapy-induced febrile neutropenia</i>	<i>Japan</i>	<i>Ph3</i>	664,398 ¹⁾	2013
KW-2246	<i>Cancer pain</i>	<i>Japan</i>	<i>Ph3</i>	115,000 ²⁾	2012
KW-3357	<i>Disseminated Intravascular Coagulation, Congenital Antithrombin Deficiency</i>	<i>Japan</i>	<i>Ph3</i>	73,000 ³⁾	2014

1) Monitoring of cancer incidence in Japan, MCIJ 2006 by NCC-CIS, 2011

2) Data Monitor, DMHC2245

3) Report of the MHLW's specific hematologic disease survey group, blood coagulation abnormality sub-team, 1998

Phase III product pipeline (3)

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Development Code	Indication	Location	Phase	Prevalence	Expected filling date
KW-6500	<i>Parkinson's Disease</i>	<i>Japan</i>	<i>Launched in 2012*</i>	139,000 ¹⁾	(Launched in 2012)
KW-6002	<i>Parkinson's Disease</i>	<i>Japan</i>	<i>NDA</i> <i>(in USA, filed in 2009)</i>	139,000 ¹⁾	(Filed in 2012)
OPC-262 (saxagliptin)	<i>Diabetes</i>	<i>Japan</i>	<i>NDA</i>	10,674,320 ²⁾	2013

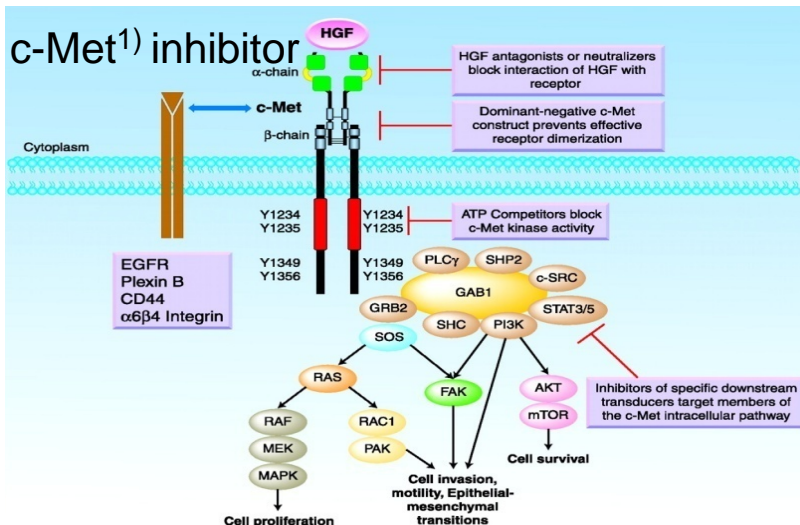
1) Number of patients survey by Ministry of Health, Labor and Welfare , 2008.

2) 5th Edition of the Diabetes Atlas released on World Diabetes Day (International Diabetes Federation), 2011.

Next major project: ARQ 197

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Structure / MoA



Clin. Cancer Res. 2009;15:2207-2214

Clinical Trial Status

- Clinical Stage: Phase III (ATTENTION study)
- Region: Japan, South Korea and Taiwan
- Indication: Non-small cell lung cancer (NSCLC)
- Dosing Route: Oral
- Number of Patients: 460
- Primary Endpoint: Overall survival
- Study Start Date (FPI²⁾): Aug. 2011
- Estimated Primary Completion Date: Dec. 2013

Remarks

Origin: ArQule

Development Area:

Japan, China, South Korea and Taiwan

Generic name : Tivantinib

Potential Competitors:

Onartuzumab (MetMAb)/Genentech (Roche)

Other information

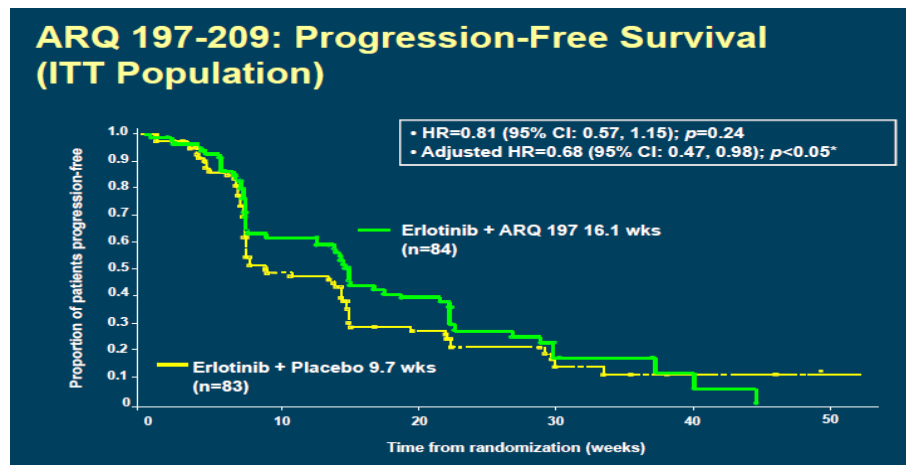
- ARQ 197 is being developed by Daiichi-Sankyo/ ArQule (DS/A) in U.S., Europe etc.
- Progression free survival (PFS) extended with ARQ 197/erlotinib vs. placebo/erlotinib in NSCLC Phase II study.
- Phase III study (MARQUEE) conducted by DS/A.

1) c-Met is a hepatocyte growth factor receptor highly expressed and active in many solid cancers. It is implicated in tumor cell migration, invasion, survival and proliferation.

2) First patient in

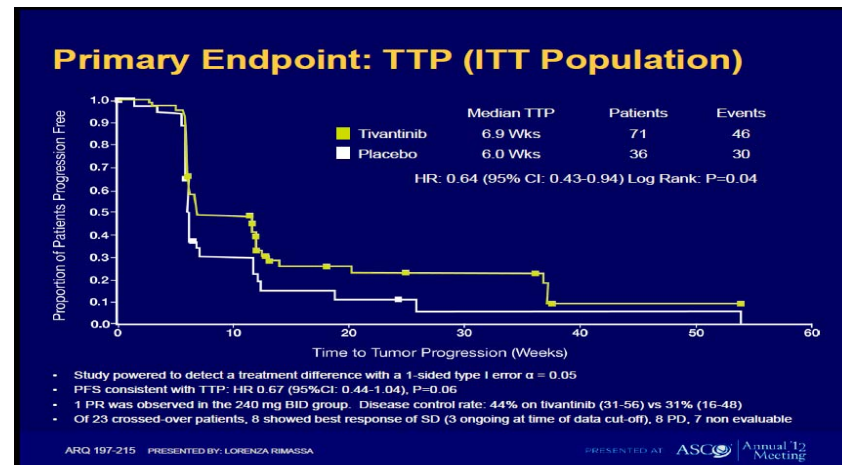
ARQ 197: future prospects

Non-small cell lung cancer

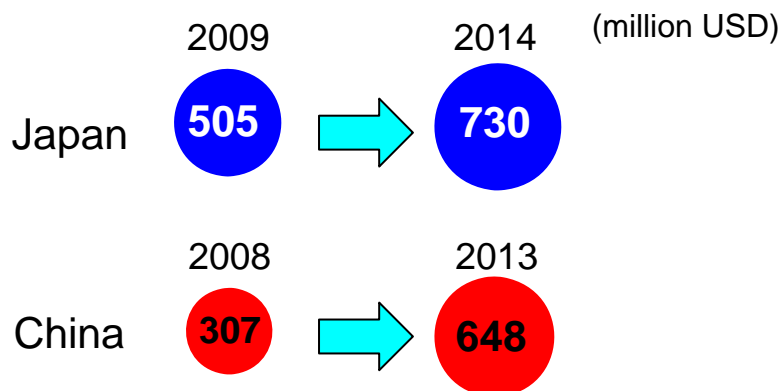


J Clin Oncol 28:18s, 2010 (suppl; abstr LBA7502)

Hepatocellular carcinoma

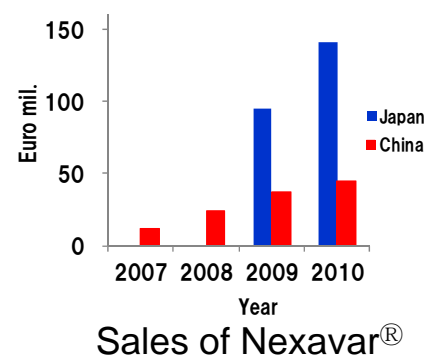


J Clin Oncol 30, 2012 (suppl; abstr 4006)



Market Forecasts for NSCLC drugs

Decision Resources Pharmacor Oncos Study (2011),
Emerging Market Study (2009)



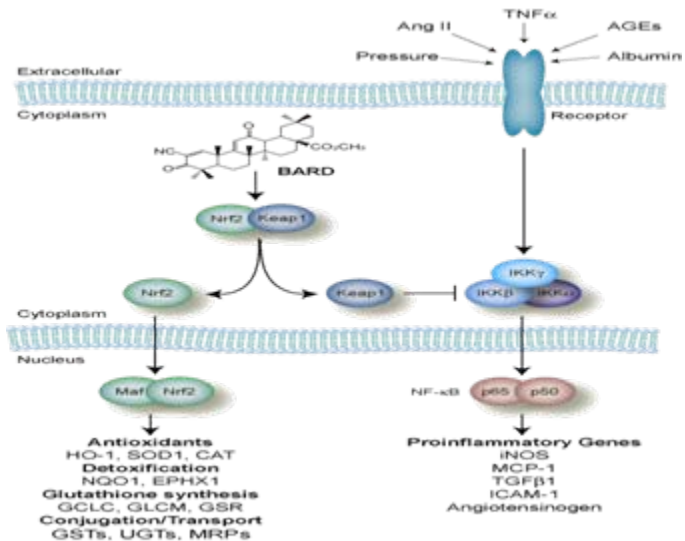
Data include sales for all indications, not only hepatocellular carcinoma (HCC)
Sales in China cited from Bayer's HP
Sales in Japan announced by Bayer on NHI reimbursement price-basis
were incorporated into the figure using an exchange rate of 103 yen/euro.

Next major project: RTA 402

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Structure / MoA

Antioxidant inflammation modulator via Nrf2 ¹⁾



Remarks

Origin: Reata Pharmaceuticals.

Development Area:

Japan, China, South Korea and Taiwan

Other Asian Countries except India

Generic name: Bardoxolone Methyl

Potential Competitors: None

Clinical Trial Status

- Clinical Stage: Phase II
- Region: Japan
- Indication: CKD in patients with type 2 diabetes
- Dosing Route: Oral
- Number of Patients: 40
- Primary Endpoint: Changes in eGFR from baseline
- Study Start Date (FPI): Feb. 2012
- Estimated Completion Date: Dec. 2013

Other information

- Under development by Reata and Abbott in the US and EU.
- Significant and sustained improvements in eGFR²⁾ were observed in Phase II studies.
- Confirmatory Phase III study is ongoing in the US and EU.

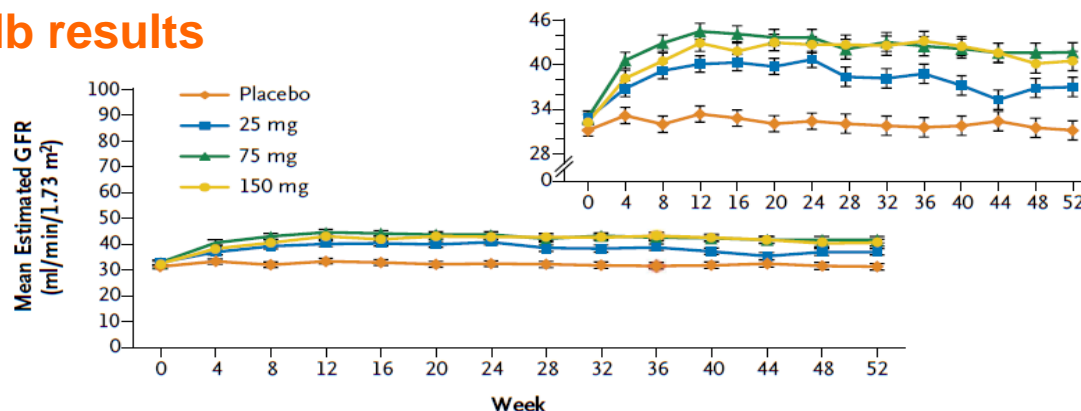
1) Nrf2 is a transcription factor that promotes the production of many antioxidant and anti-inflammatory factors. Activating Nrf2 is thought to protect tissues from inflammation by increasing production of various antioxidant factors and inhibiting inflammatory signal pathways.

2) eGFR : estimated glomerular filtration rate

RTA 402: overseas data

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Phase IIb results



Improvement in eGFR* sustained over 52 weeks

* eGFR: estimated glomerular filtration rate

No. at Risk

Placebo	57	56	55	53	54	54	54	53	53	52	53	51	53	52
Bardoxolone methyl, 25 mg	57	53	52	52	52	51	51	49	49	47	48	48	48	48
Bardoxolone methyl, 75 mg	57	55	51	51	53	52	52	51	48	50	50	48	48	48
Bardoxolone methyl, 150 mg	56	55	55	54	53	52	52	48	48	47	47	46	46	44

Pergola, et al. NEJM, 365;4, 327-36. July, 2011

Phase III results

Study design: RTA402 (20mg) and placebo, 1:1 randomized, controlled study

Subjects: CKD stage 4 with accompanying type 2 diabetes

Patient numbers: 2,000

Primary endpoint : time to end-stage kidney failure (dialysis/transplantation) or vascular death

Secondary endpoints: (1) volume change in eGFR,

(2) hospitalization or death due to heart disease

(3) composite evaluation of cardiovascular function

Domestic

- ✓ Launch Parkinson's disease agent Apokyn®
- File for approval of KW-2246 in development for cancer pain
- Begin phase I study on ARQ197 in hepatocellular carcinoma

Overseas

- Begin US phase III studies on KW-0761 in CTLC

KYOWA KIRIN

Enquiries regarding this document should be directed to:

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Corporate Communications Department: 81-3- 3282-0009

Fiscal 2012 full year forecasts relative to medium-term plan

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FY2012		(¥bn)	Medium-term plan	Current forecast	Difference
Pharmaceuticals	Sales		225.0	248.0	+23.0
	OP		36.4	48.7	+12.3
	R&D expense		40.0	41.0	+1.0
Bio-Chemicals	Sales		88.0	79.0	-9.0
	OP		8.4	3.0	-5.4
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	333.0	-121.0
	OP		51.7	52.0	+0.3

- Pharmaceuticals: Negative factors include the effects of the National Health reimbursement prices while positive factors include the effects of FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. The acquisition of ProStrakan has a positive effect on sales and a negative effect on operating income due to the amortization of goodwill, etc.
- Bio-Chemicals: Amino acid sales volumes are expected to be higher than forecast in the medium-term business plan, but revenues and profits are expected to be lower structural changes at Daiichi Fine Chemical and the effects of the strong yen
(Exchange rates assumed: medium-term plan ¥91/\$, ¥133/€, FY2012 ¥77/\$, ¥98/€)
- Chemicals: The Chemicals segment has been eliminated

Reference materials

Development pipeline details






Development pipeline (1)

KYOWA KIRIN

(On file/approved)



Denotes development progress since 18 April 2012 (region, development stage, filing, approval, launch etc)







	Development number Generic name Presentation/Formulation	Mechanism of action	Target disease	Development stage	In-house/licensed	Notes
	Pegfilgrastim Injection	Long-acting granulocyte colony stimulation factor	Chemotherapy-induced febrile neutropenia	Approved S. Korea May 2012 Approved Vietnam June 2012	Kirin-Amgen	
	Cinacalcet Hydrochloride Oral	Calcium receptor agonist	Secondary hyperparathyroidism	Filed in Asia	NPS	Philippines, Malaysia, Thailand, China
	KW-6002 Istradefylline Oral	Angiotensin A2a receptor antagonist	Parkinson's disease	Filed in US Filed in Japan	In-house	
	AMG531 Romiplostim Injection	Thrombopoietin receptor agonist	Chronic, idiopathic immune thrombocytopenic purpura	Filed in Taiwan	Kirin-Amgen	
	Granisetron Patch	5HT ₃ serotonin receptor antagonist	Nausea and vomiting induced by emetic chemotherapy	Filed in Asia	Solasia Pharma (ProStrakan)	Taiwan, Singapore Marketed in the US by ProStrakan as Sancuso

Development pipeline (2)

KYOWA KIRIN

(Phase II-III)

☆: New indication

	Development number Generic name Presentation/Formulation	Mechanism of action	Target disease	Development stage	In-house or licensed	Notes
	KW-2246 Fentanyl citrate Sub-lingual	Opioid receptor agonist	Cancer pain	Japan Phase III	Orexo	Marketed by ProStrakan as Abstral
	KRN125 Pegfilgrastim Injection	Long-acting granulocyte colony stimulation factor	Chemotherapy-induced febrile neutropenia	Japan Phase III	Kirin-Amgen	
	ARQ 197 Tivantinib Oral	c-Met inhibitor	Lung cancer Stomach cancer	Japan, S. Korea, Taiwan Phase III Japan, S. Korea Phase II	ArQule	
	KRN321 Darbepoetin Alfa Injection	Long-acting erythropoietic stimulation factor	☆Pediatric renal anemia Renal anemia (under dialysis) ☆Anemia accompanied by myelodysplastic syndrome	Japan Phase III China Phase II India Phase III Japan, S. Korea Phase II	Kirin-Amgen	On the market in Japan for renal anemia
	KRN1493 Cinacalcet Hydrochloride Oral	Calcium receptor agonist	☆Hypercalcemia accompanying parathyroid cancer and refractory, primary hyperparathyroidism	Japan Phase III	NPS	On the market in Japan for secondary hyperparathyroidism
	KW-6485 Topiramate Oral	Anti-epileptic	☆Pediatric epilepsy	Japan Phase III	Janssen Pharmaceutical K.K.	On the market in Japan for epilepsy

Development pipeline (3)

KYOWA KIRIN

(Phase II-III)



Denotes development progress since 18 April 2012 (region, development stage, filing, approval, launch etc) ☆: New indication












	Development number Generic name Presentation/Formulation	Mechanism of action	Target disease	Development stage	In-house or licensed	Notes
	KW-3357 Antithrombin Injection	Recombinant human antithrombin	Disseminated Intravascular Coagulation, Tendency to thrombosis due to congenital antithrombin deficiency	Japan phase III Europe Phase I	In-house	
	KW-0761 Mogamulizumab Injection	Anti-CCR4humanized antibody	Peripheral T/NK cell lymphoma	Japan Phase II	In-house	Potelligent antibody
			Adult T-cell leukemia-lymphoma combination therapy (treatment naïve)	Japan Phase II		
			Peripheral T-cell lymphoma and cutaneous T-cell lymphoma	US Phase I/II		
			Peripheral T-cell lymphoma	Europe Phase II		
	KW-2478 Injection	HSP90 inhibitor	Multiple myeloma	UK, US, Philippines Phase I/II	In-house	
	ASKP1240 Injection	Anti-CD40 complete human antibody	Transplant rejection	Japan Phase I US Phase II	In-house	Joint development with Astellas KM mouse used
	RTA 402 Bardoxolone Methyl Oral	Antioxidant Inflammation modulator	Chronic kidney disease accompanied by type 2 diabetes	Japan Phase II	Reata	
	KHK4563 Benralizumab Injection	Anti-IL-5 receptor humanized antibody	Bronchial asthma	Japan, South Korea Phase II	In-house	Excluding Japan and Asia, under development by MedImmune as MEDI-563. Potelligent antibody
	KHK6188 Oral	Cannabinoid receptor CB2 agonist	Neuropathic pain	Japan Phase II	In-house	
	Z-206 Mesalazine Oral dissolving	pH-dependent release modulator	☆Crohn's disease	Japan Phase II	Zeria Pharm.	Joint development with Zeria Pharm. On the market for ulcerative colitis

Development pipeline (4)

KYOWA KIRIN

(Phase I)

☆: New indication

	Development code Generic name Presentation/formulation	Mechanism of action	Target disease	Development stage	In-house or Licensed	Notes
	KW-2450 Oral	IGF-1 receptor signal inhibitor	Malignant tumors	US Phase I/II	In-house	
	KRN330 Injection	Anti-A33complete human antibody	Malignant tumors	US Phase I/IIa	In-house	KM mouse used
	BIW-8962 Injection	Anti-GM2 humanized antibody	Malignant tumors	US Phase I/IIa	In-house	Potelligent antibody
	KRN951 Tivozanib Oral	VEGF receptor tyrosine kinase inhibitor	Malignant tumors	Japan Phase I	In-house	
	KHK2866 Injection	Anti-HB-EGF humanized antibody	Malignant tumors	US Phase I	In-house	Potelligent antibody
	LY252355 Litronesib Injection	Mitotic kinsen Eg5 inhibitor	Malignant tumors	Japan Phase I	In-house	
	CEP-37250/ KHK2804 Injection	Anti-cancer specific carbohydrate antigen humanized antibody	Malignant tumors	US Phase I	Cephalon	Joint development with Cephalon Potelligent antibody
	KHK2898 Injection	Anti-CD98 complete human antibody	Malignant tumors	Singapore Phase I	In-house	Potelligent antibody KM mouse used
	KW-0761 Mogamulizumab Injection	Anti-CCR4 humanized antibody	☆Bronchial asthma	Japan Phase I	In-house	Potelligent antibody
	KHK4827 Injection	Anti-IL-17receptor complete human antibody	Psoriasis	Japan Phase I	Kirin-Amgen	
	KRN23 Injection	Anti-FGF23 complete human antibody	X-chromosome hereditary hypophosphatemic rickets (XLH)	US/Canada Phase I/II	In-house	KM mouse used

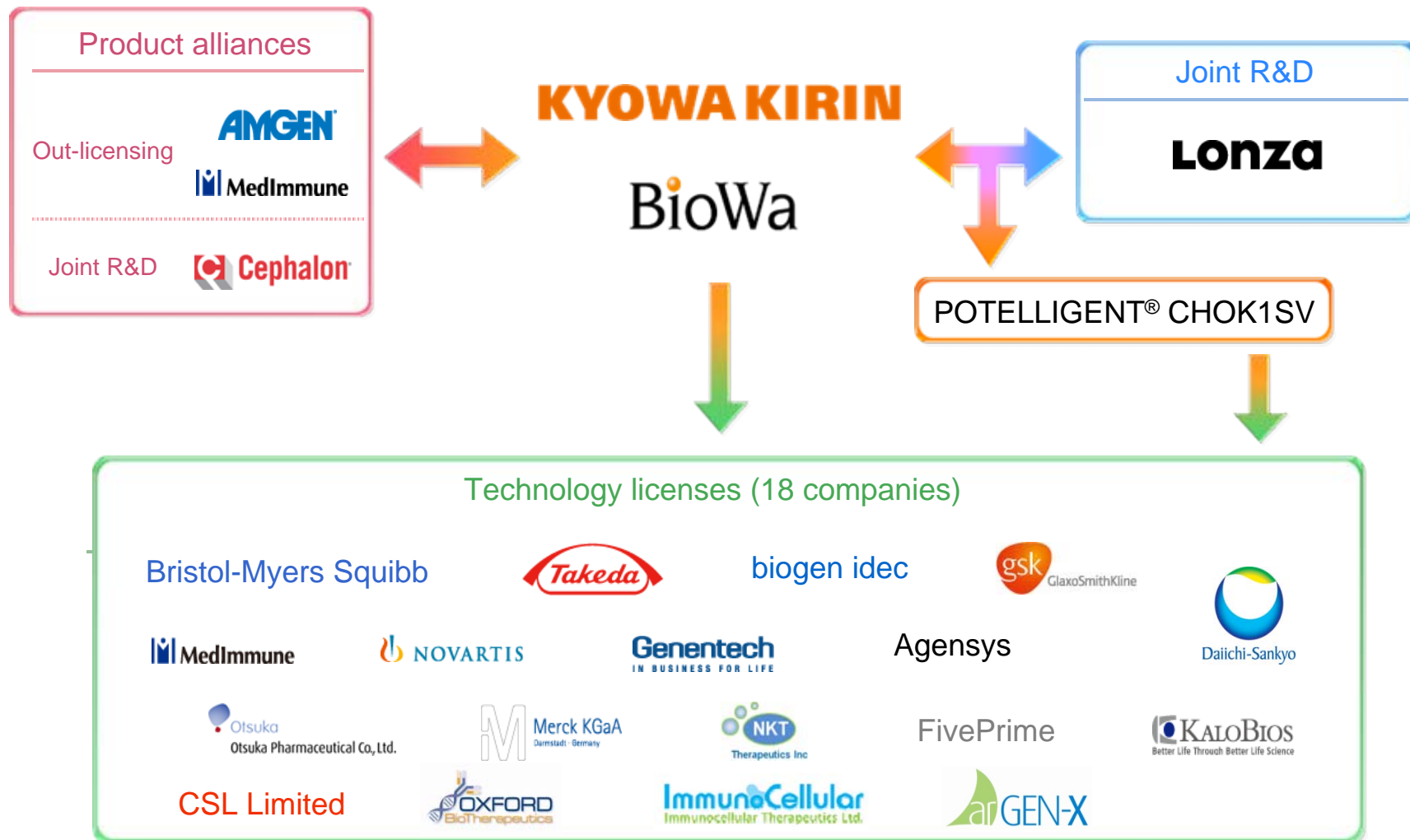
Progress with out-licensing

KYOWA KIRIN

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

POTELLIGENT® technology alliances

KYOWA KIRIN



NB: 7 licensed POTELLIGENT® antibodies have entered clinical trials up to the present time, including agents licensed to Bristol Myers Squibb and Genentech

Antibody development pipeline (1)

KYOWA KIRIN





Therapeutic area	Development code	Phase I	Phase II	Phase III	On file
Oncology	● KW-0761	ATL (treatment naïve) (Japan) Peripheral T/NK-cell lymphoma (Japan) Peripheral T-Cell lymphoma (EU) PTCL, CTCL(US)		Launched in Japan on 29 May 2012 for relapsing or refractory CCR4-positive ATL	
	● KRN330	Cancer (US)			
	● BIW-8962	Cancer (US)			
	● KHK2866	Cancer (US)			
	● CEP-37250/ KHK2804	Cancer (US)	With Cephalon		
	● KHK2898	Cancer (SG)			

● POTELLIGENT® technology


● KM mouse technology

Antibody development pipeline (2)

KYOWA KIRIN

Therapeutic area	Development code	Phase I	Phase II	Phase III	On file
Immunology/ Allergy	 ASKP1240	Prevention of transplant rejection (US) As above (Japan)		With Astellas	
	 KHK4563	Bronchial asthma (Japan, South Korea)			
	KHK4827	Psoriasis (Japan)	From Kirin-Amgen		
	 KW-0761	Bronchial asthma (Japan)			
Others	 KRN23	Hypophosphatemic rickets (US, Canada)			

 POTELLIGENT® technology

 KM mouse technology