Results Presentation
Fiscal 2014 Interim
(January 1, 2014 – June 30, 2014)

Kyowa Hakko Kirin Co., Ltd.

July 31, 2014

Agenda

KYOWA KIRIN

Financial review

Kazuyoshi Tachibana, Managing Executive Officer

R & D review
Business overview

Nobuo Hanai, Executive Director of the Board; President and CEO

Q & A session

Forward-looking statements

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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 of the business activities of the pharmaceutical industry in Japan and overseas, intellectual property risks, risk of side effects, legal regulation risks, product defect risks, risks of changes to prices for raw materials, risks of changes to market prices, as well as risks of changes to foreign exchange rates and financial markets.

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.

Financial review

Summary of H1 results (consolidated)

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Compared to FY2013 H1, sales and profits declined due to a decrease in licensing revenue and effects of the drug price revision

(Unit: ¥bn)	FY2013 H1	FY2014 H1	Change	FY2014 forecast	Rate of progress
Net sales	169.7	161.8	-7.8 (-5%)	337.0	48%
Operating income *Operating margin*	27.1 *16.0%*	18.4 *11.4%*	-8.7 (-32%)	45.0	40%
Ordinary income	26.5	16.8	-9.6 (-36%)	37.0	45%
Net income	17.6	9.1	-8.4 (-48%)	20.0	45%

(Profits are stated after amortization of goodwill. Figures rounded down)

- ✓ **The decline in ordinary income was due to lower operating income, forex losses and other factors**
- ✓ **The decline in net income was due to absence of gain on sales of subsidiaries and affiliates' stocks recorded in the coverable period and other factors**

Summary of FY2014 H1 results (consolidated): Analysis of YonY profit changes

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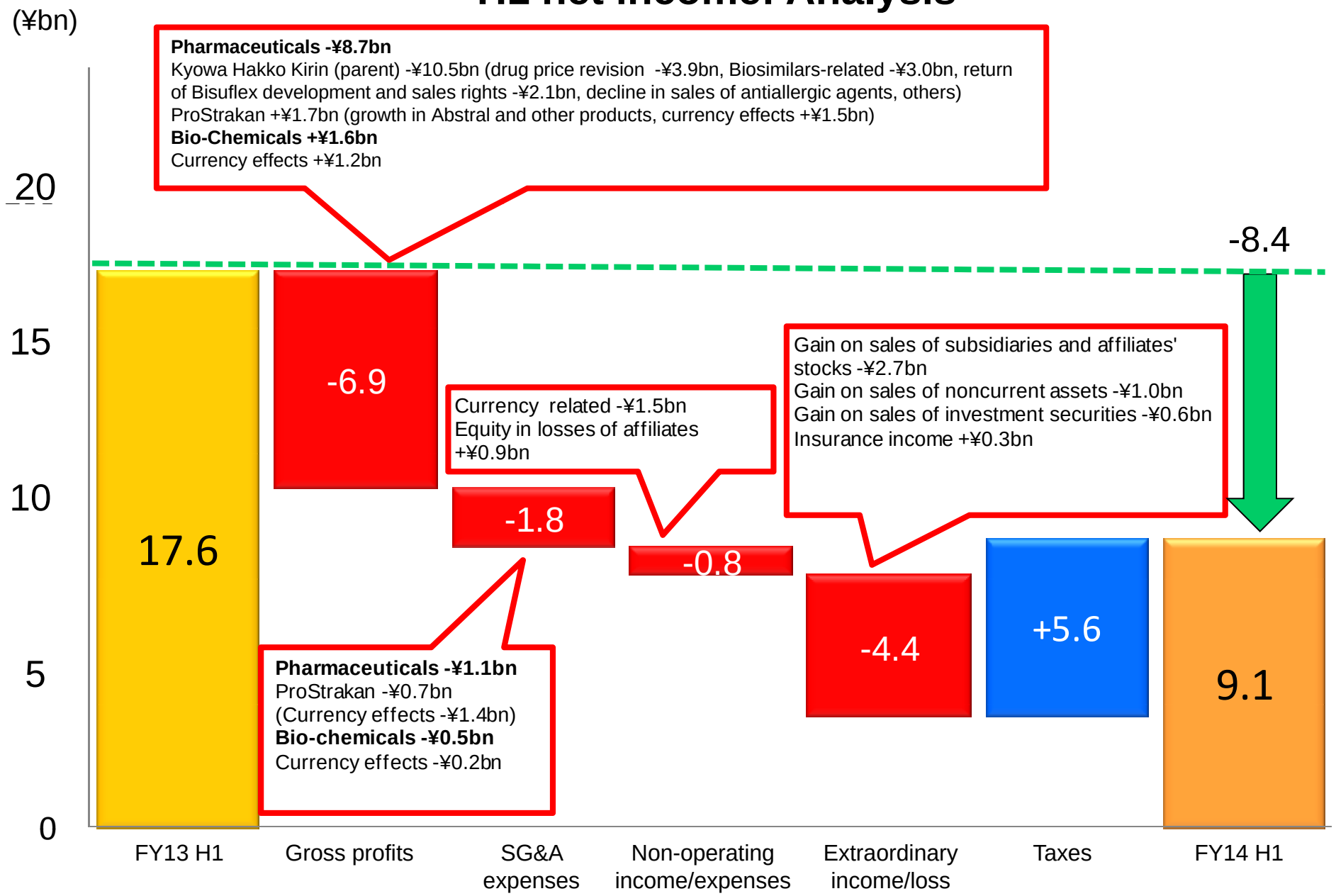
H1 net income: Analysis



Summary of FY2014 H1 financial results by segment

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In the Pharmaceuticals business, sales and profits declined due to effects of the drug price revision
In the Bio-Chemicals business, sales and profits increased due to expansion of generic APIs and other products

(Unit: ¥bn)		FY2013 H1	FY2014 H1	Change
Pharmaceuticals business	Net sales	129.9	119.5	-10.4 (-8%)
	Operating income *Operating margin*	24.1 *18.6%*	14.1 *11.8%*	-9.9 (-41%)
Bio-Chemicals business	Net sales	41.2	44.0	+2.8 (+7%)
	Operating income *Operating margin*	3.1 *7.5%*	4.2 *9.5%*	+1.1 (+36%)

(Operating income is stated after amortization of goodwill . Figures rounded down)

Pharmaceuticals business:
FY2014 H1: Analysis of YonY profit changes

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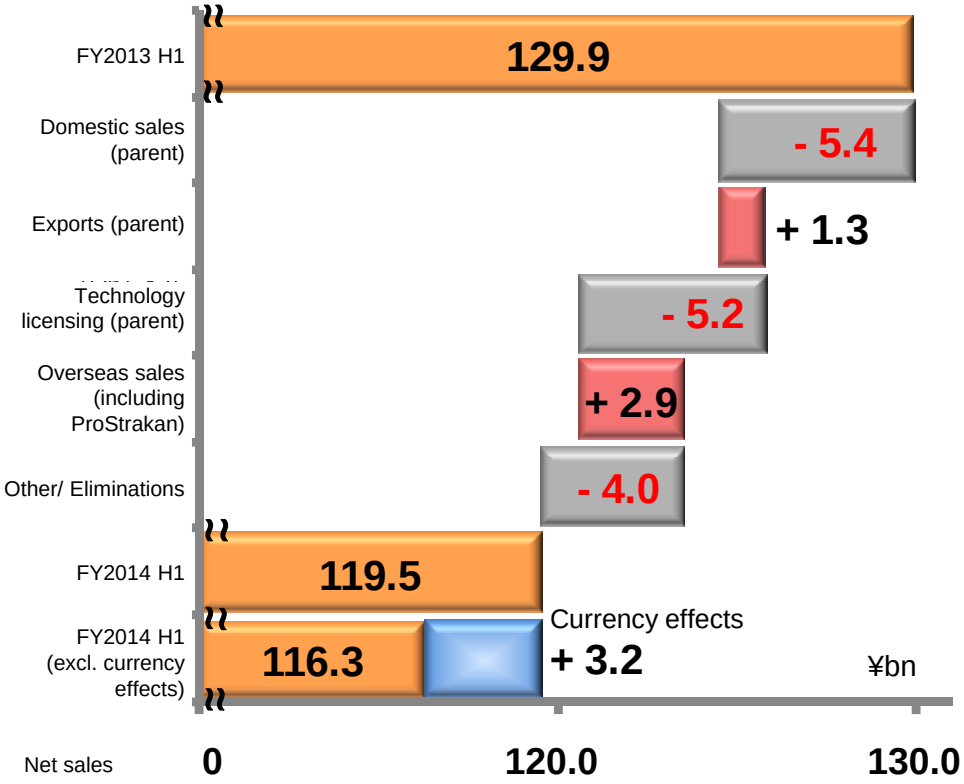
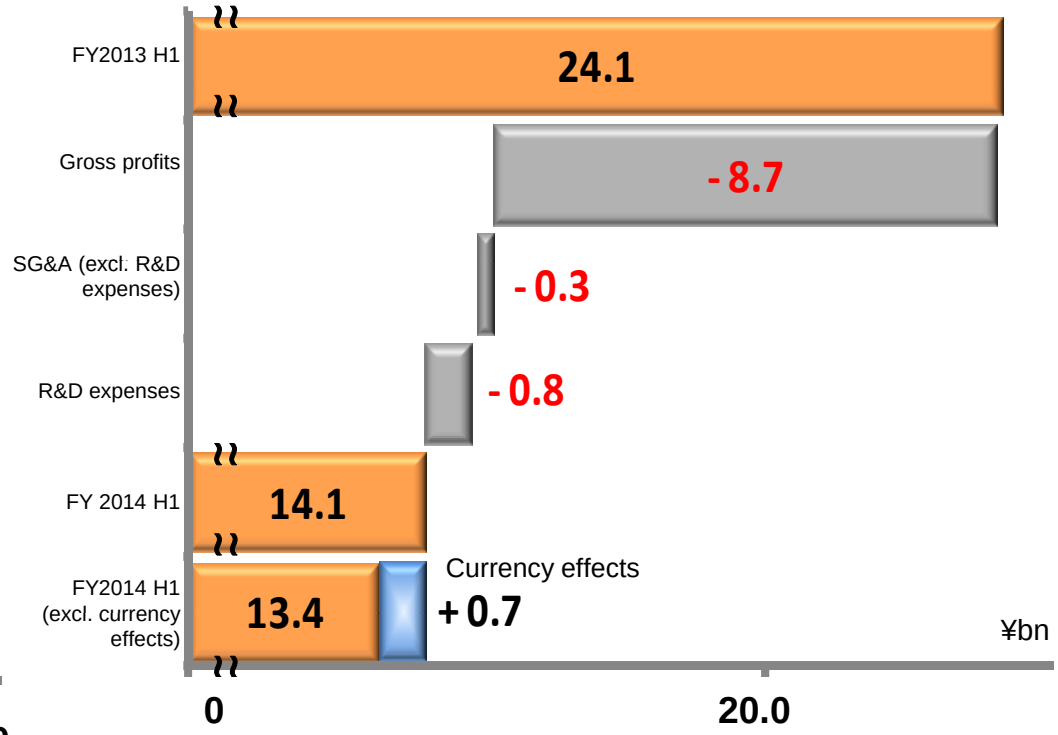
Net sales



- Domestic pharmaceutical products (-¥5.4bn):
  - Products (shipments): NESP® +¥0.8bn, REGPARA® +¥0.7bn, NOURIAST® +¥0.7bn, ALLELOCK® -¥2.5, Patanol® -¥1.9bn, GRAN® -¥1.4bn
  - NESP®: While impacted by the effects of the drug price revision, sales increased over the same period in the previous year, in which sales declined due to lower shipments following launch of unified dosage product and the end of 2012. Our share was maintained.
- Exports (+¥1.3bn): Delays, currency effects, etc.
- Technology licensing, etc.(-¥5.2bn):
  - Biosimilars-related (-¥3.0)
  - Decease in lump-sum payment (-¥2.1bn) reflecting return of Busulfex development and marketing rights in the previous fiscal year; etc.
- Overseas sales (+¥2.9bn); Currency effects +¥2.6bn. Expansion of ProStrakan's Abstral®, etc.
- Other/Eliminations (-¥4.0bn):
  - Decrease in sales as a result of transfer of consolidated subsidiary Chiyoda Kaihatsu's chemicals logistics business on September 1, 2013 -¥3.1bn

Operating income



Operating income

- Gross profits (-¥8.7bn):
  - Decrease in sales due to effects of drug price revision, fall in biosimilars-related licensing income, decrease in lump-sum payments reflecting return of Busulfex development and sales rights in the previous fiscal year, and the decline in sales of antiallergic agents, could not be offset by ProStrakan's growth
- SG&A (-¥0.3bn):
  - While cost control at Kyowa Hakko Kirin (parent), ProStrakan and others led to a reduction in SG&A, currency factors led to an increase in costs at overseas distributors and others
- R&D expenses (+¥0.8bn):
  - Increased overseas R&D expenses

Pharmaceuticals business: Domestic sales of key products

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Some products were impacted by generics and biosimilars, but sales of NESP® and REGPARA® , which are at the core of the nephrology category, exceeded forecasts

Product name/ Exports/ Technology out-licensing	FY2013 H1 results[1]	FY2014 H1 results[1]	Change	Reason for change	Rate of progress[2]
NESP®	25.0	25.9	0.8 (+4%)	Decrease due to temporary rebound in shipments in FY 2013 H1. Strong performance this year*	47%
REGPARA®	6.9	7.6	0.7 (+11%)	Steady market penetration	47%
ALLELOCK®	15.9	13.4	-2.5 (-16%)	Decrease in airborne pollen count Market penetration of generics*	57%
Patanol®	10.1	8.1	-1.9 (-19%)	Decrease in airborne pollen count	69%
GRAN®	5.8	4.4	-1.4 (-24%)	G-CSF market contraction Market penetration of biosimilars*	51%
Exports	5.4	6.7	1.3 (+24%)		61%
Technology out-licensing	9.7	4.1	-5.5 (-57%)	Licensing revenue in FY2013 H1 benefited from one–time factor of return of Busulflex development and sales rights	29%

[1]Unit: ¥bn, figures rounded down

[2]Rate of progress compared to 2014 full year sales forecasts (as of July 30, 2014). Figures rounded down

*Note: Also impacted by drug price revision

Bio-Chemicals business:
FY2014 H1: Analysis of YonY profit changes

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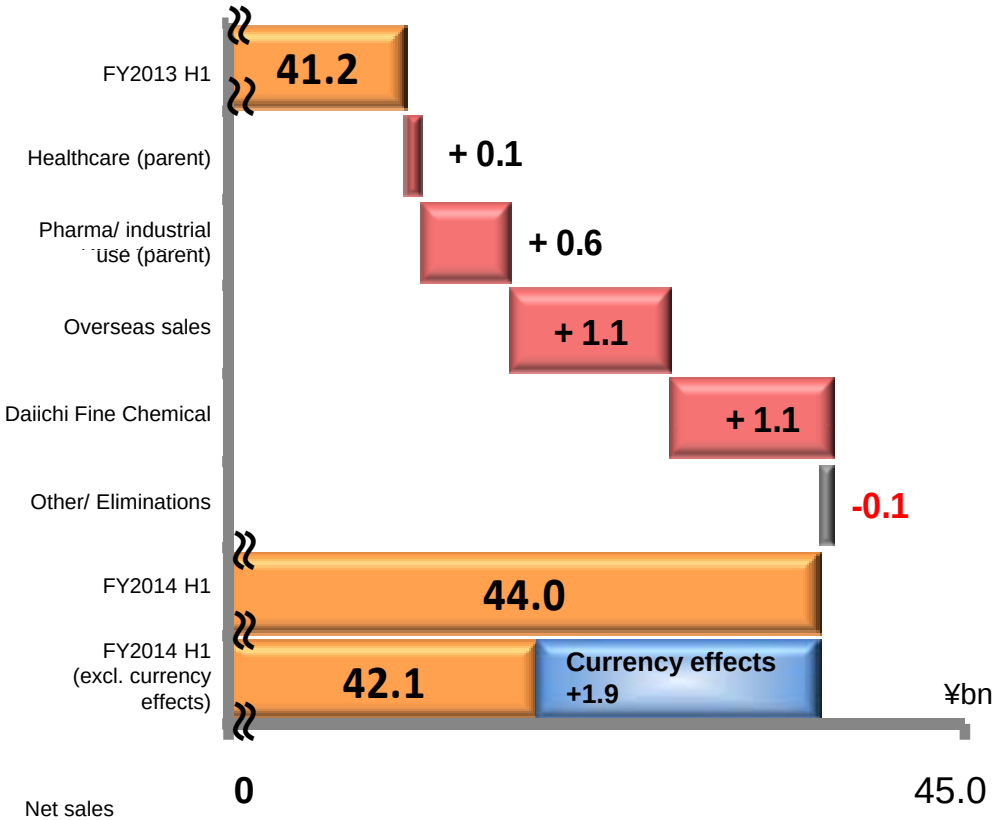
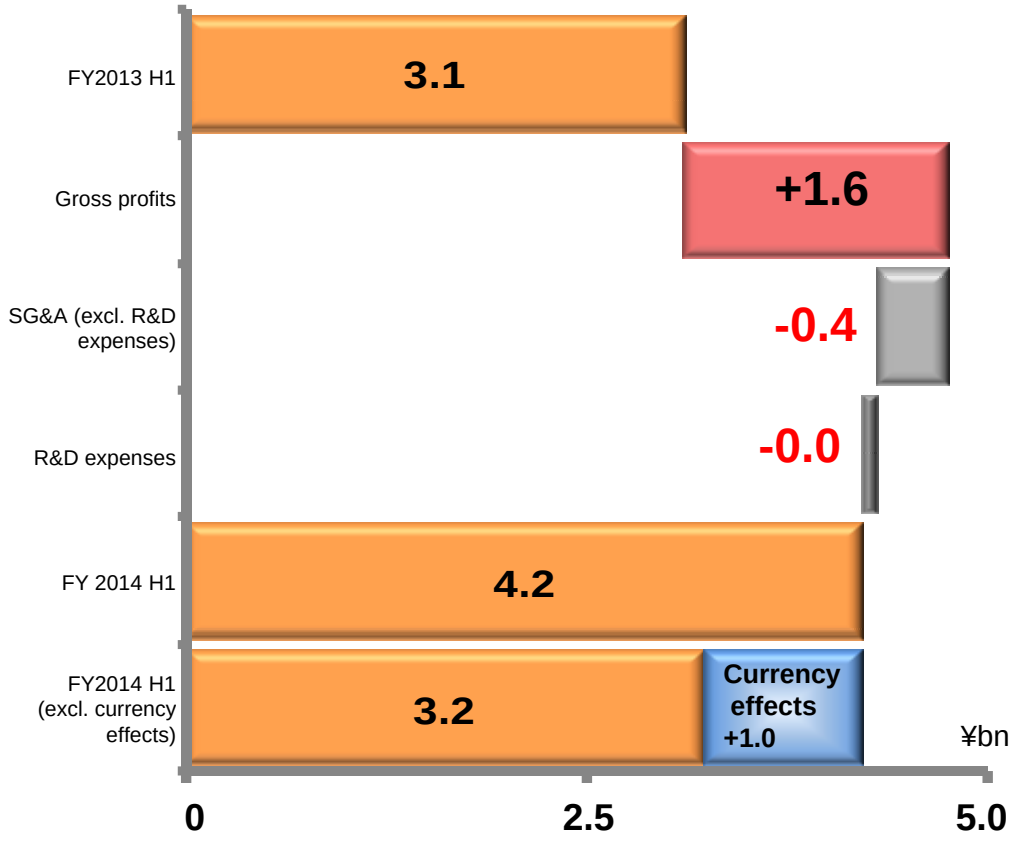
Net sales



Operating income



Net sales

Healthcare (+¥0.1bn):

- Mail order sales were strong and increased from the previous year
  - Raw materials/OEM: Reduced sales volumes to key customers could not be offset despite further development of the market, leading to a decreased sales from previous year
- Pharma/industrial use (+¥0.6bn): Raw materials for generic pharmaceuticals strong, etc.
- Overseas sales (+¥1.1bn): Currency effects (+¥1.9bn)
  - U.S. (-¥0.0): Currency effects (+¥0.3), impact of reduced sales due to changes in business trends of some products
  - Europe (+¥0.5): Currency effects (+¥1.0), inventory adjustments, etc. by some customers
  - Asia and others (+¥0.6bn): Currency effects (+¥0.5bn), Increase in income due to early shipments of some products to China
- Daiichi Fine Chemical (+¥1.1bn):
  - Increase in sales of raw materials for generic pharmaceuticals, etc.

Operating income

- Gross profits (+¥1.6bn): Currency effects (+¥1.2bn)
  - Increase in high-margin mail order sales
- SG&A (-¥0.4bn): Currency effects (-¥0.2bn)
  - Increased expenses due to investment in systems for mail order sales

Revision to consolidated full-year forecast for FY2014

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(Unit: ¥bn)	FY2013	FY2014 initial forecast (a)	FY2014 revised forecast (b)	Change (b)-(a)
Net sales	340.6	337.0	337.0	0.0
Operating income	51.7	41.0	45.0	+4.0
Ordinary income	49.5	35.0	37.0	+2.0
Net income	30.0	20.0	20.0	0.0

Main causes for revision

- Lower impact of the drug price revision than anticipated at time of initial forecast (+¥3.0bn)
- Reduction of SG&A expenses(+¥2.0bn)

(Profits are stated after amortization of goodwill. Figures rounded down)

R & D review

FY2014 H1: Update on key timeline events

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Domestic **(As of July 30, 2014)**

☑ Approval for additional indications for humanized CCR4 monoclonal antibody POTELIGEO®

- Untreated CCR4-positive adult T-cell leukemia/lymphoma[1]
- Relapsed or refractory CCR4-positive peripheral T-cell lymphoma (March)
- Relapsed or refractory CCR4-positive cutaneous T-cell lymphoma (March)

□ Application seeking approval for manufacture and sales of sustained-duration G-CSF product KRN125

□ Application seeking approval for manufacture and sales of recombinant human antithrombin drug KW-3357

☑ Start of Phase III trials of anti-IL-5 receptor humanized antibody, KHK4563 targeting asthma patients

☑ Topical Combination Drug Dovobet® ointment approved to treat Psoriasis Vulgaris[2]

☑ NESP® granted orphan drug designation for the treatment of anemia with myelodysplastic syndrome and application filed in March for approval for manufacture and sale

☑ Start of study of KRN23 in adult patients (July)

Overseas

☑ Start of study of KRN23 in pediatric patients (July)

[1] Application temporarily withdrawn but application re-filed on June 30, 2014

[2] Sales and manufacture application by LEO Pharma A/S

Domestic development and other key updates

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Re-filed application for additional indication of untreated ATL[1] for POTELIGEO®
Phase 1 trials for KRN23 targeting adults began in Japan and Korea

Category	Product name/development number	Mechanism of action, etc.	Stage (timing) / Target
Nephrology	RTA 402		Start of new Phase II trial fixed (July) / Chronic kidney disease associated with type 2 diabetes
Oncology	POTELIGEO®	Anti-CCR4 Humanized Antibody	Re-filed (June) / Untreated ATL[1]
Immunology/allergy	KHK4563	Anti-IL-5R Humanized Antibody	Phase3: Global clinical trial begun (April) / Asthma
CNS	KHK6640	Anti-Aβ Antibody	Phase 1: CTA[2] received (June) / Alzheimer's disease
Other	KRN23	Anti-FGF23 Fully Human Antibody	Phase 1: Begun in Japan and Korea (July) / Adult XLH [3]

[1]ATL：Adult T-Cell Leukemia/Lymphoma
[2]Clinical Trial Application（equivalent to Japanese clinical trial plan notification)
[3]XLH： X-linked Hypophosphatemia

Note: Bio-pharmaceutical products are underlined

Global development update (1)

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KW-0761

Indication		Country/ region	Development stage	Annual incidence per disease, other
ATL	Untreated	Japan	**Re-filing**	Japan: approx. 1,100[1] patients
ATL	Relapsed/ refractory	U.S. Europe Others	Phase 2	Europe, U.S.: Investigating CCR4 positivity was not an inclusion criterion
PTCL	Relapsed/ refractory	Japan	Approved (March 2014)	Japan: PTCL/CTCL together: approx.2,000 [2] patients
PTCL	Relapsed/ refractory	Europe	Phase 2	US：approx. 3,600[3] patients
CTCL	Relapsed/ refractory	Japan	Approved (March 2014)	Japan: PTCL/CTCL together: approx.2,000[2] patients
CTCL	Relapsed/ refractory	US Europe Japan	Phase 3	US: approx. 1,500[3] patients CCR4 positivity was not an inclusion criterion

[1]Survey of and countermeasures to HTLV-1 infection and related diseases in Japan. 2009 summary research report by Kazunari Yamaguchi (March 2010)

[2]Ministry of Health, Labour and Welfare: Number of patients on October 2011 clinical trial inspection chart 97, by basic illness

[3]SEER Data (2001-2007)

ATL: Adult T-cell Leukemia/Lymphoma
PTCL: Peripheral T-Cell Lymphoma
CTCL: Cutaneous T-Cell Lymphoma

Global development update (2)

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KW-6002

Indication	Country/ region	Development stage	Annual incidence per disease, other
Parkinson's disease	U.S. Europe Others	Phase 3	U.S.: More than 570,000[1] patients Special Protocol Assessment agreed with FDA

KRN23

Indication	Country/ region	Development stage	Annual incidence per disease, other
X-linked Hypophosphatemia	U.S. Europe	**Phase 2** (Target: pediatrics)	U.S.[2]: Approx 3,000 pediatric patients, approx. 12,000[3] adult patients Joint development with Ultragenyx Pharmaceutical
X-linked Hypophosphatemia/ Osteomalacia	Japan Korea	**Phase 1** (Target: adults)	

[1] Study by Decision Resources

[2]Patient numbers in Europe (5 main countries) are estimated to be at similar levels to those in the U.S.

[3]Estimate based on reported prevalence of 1 in 20,000 people

Biosimilars development update

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Strong progress on Phase 1 trial of FKB327 towards global launch
Launch of FKB238 Phase 1 trial this year is proceeding according to plan

	Development number	Reference medical product	Stage
Biosimilar	FKB327	Adalimumab (humira)	**Phase 1**
Biosimilar	FKB238	Bevacizumab (avastin)	Phase 1 (in preparation)
Biosimilar	Not disclosed	Not disclosed	Determined target reference medical product

FDA guidance regarding biosimilars (draft)

May 2014 :
Guidance for Industry (DRAFT)
Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product

Note: Biosimilar pharmaceutical products are developed by *FUJIFILM KYOWA KIRIN BIOLOGICS* Co., Ltd.

Enhance presence in immunology and allergy

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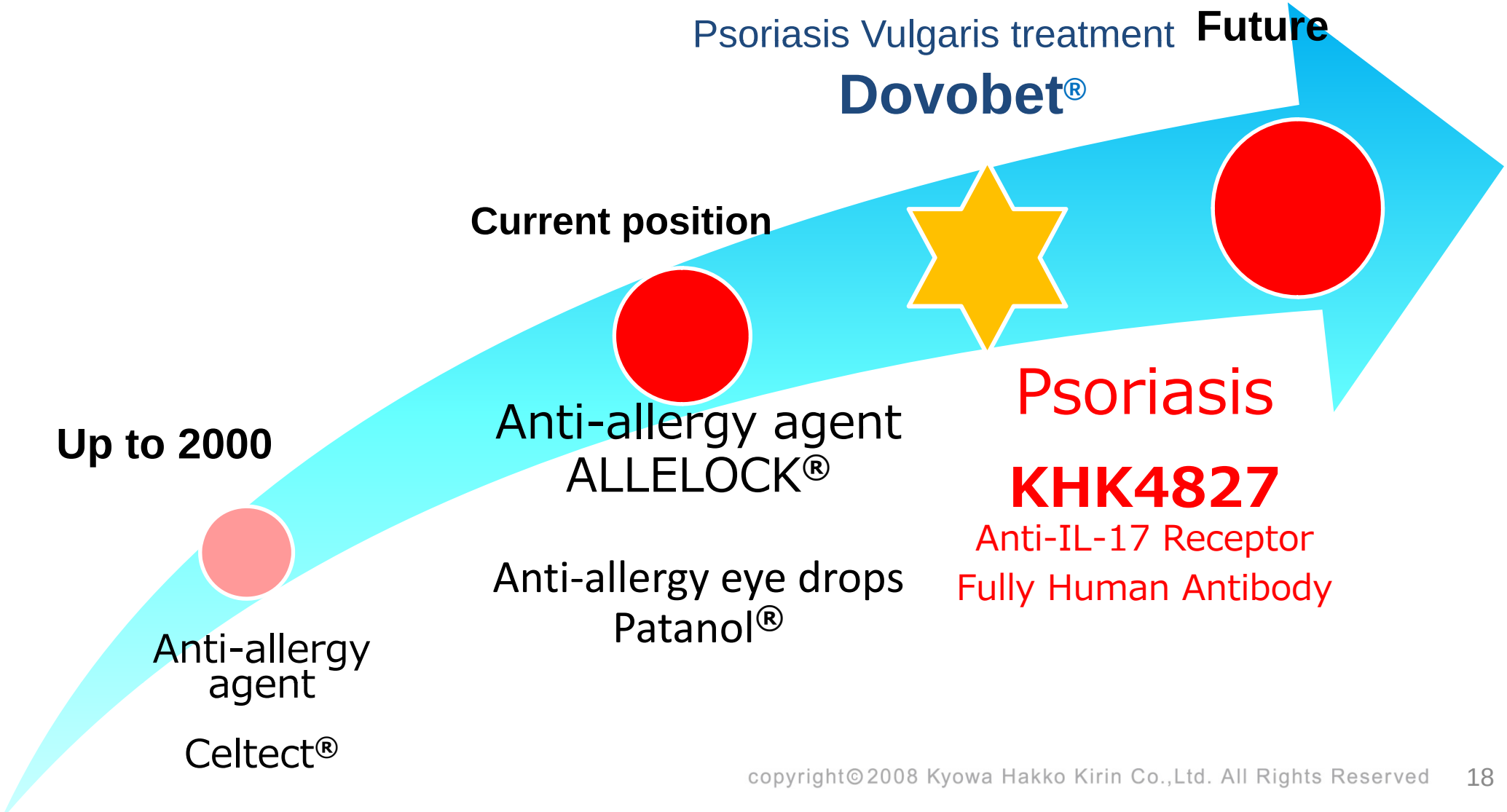
Leverage the dermatology network developed through anti-allergy agents such as ALLELOCK®
Further enhance presence by sustained launches of new psoriasis drugs



Psoriasis pyramid

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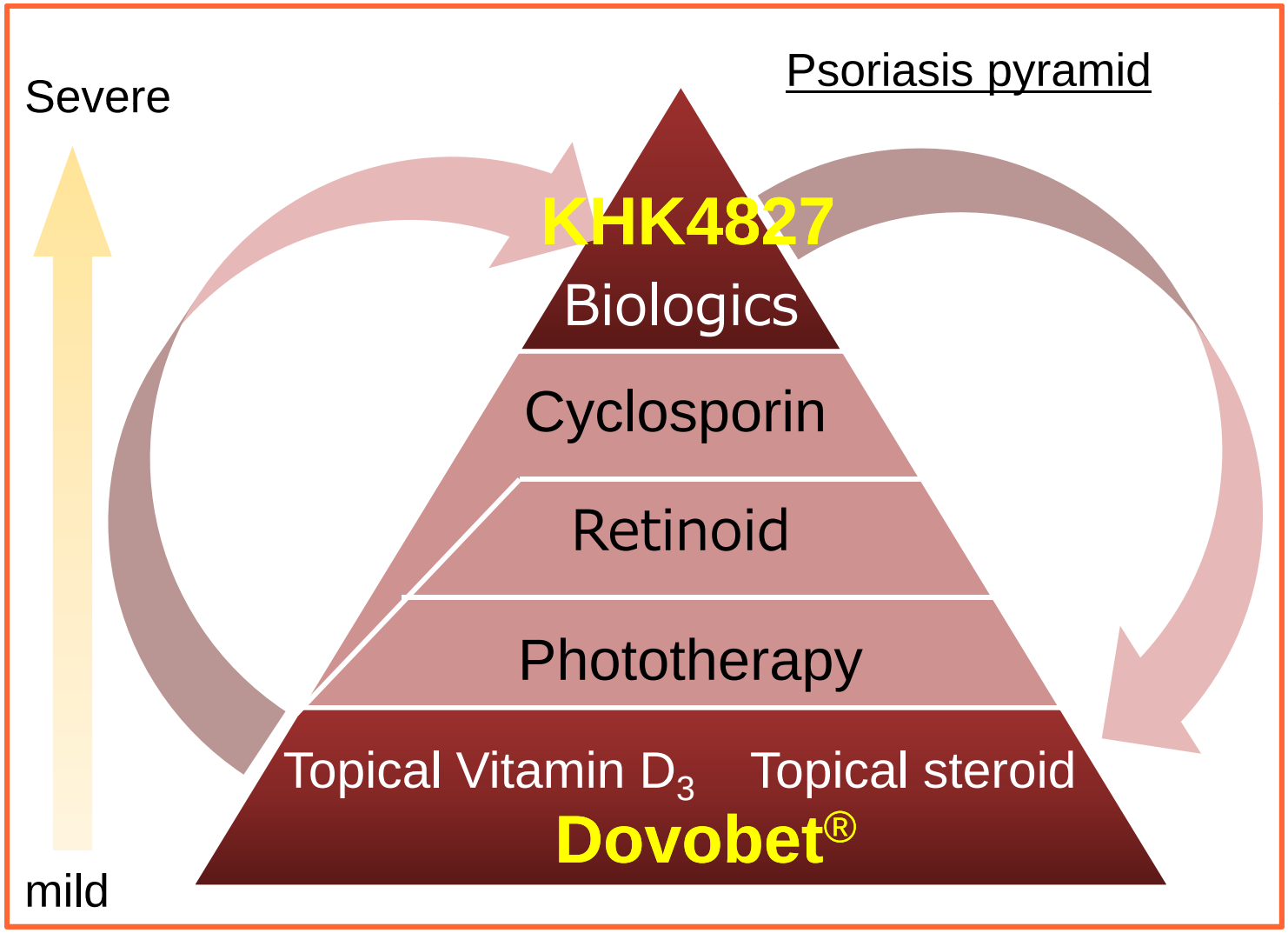
Leverage sales synergies between Dovobet® and KHK4827



- Vitamin D3 and steroid external preparations used in all segments as basal agents
- Biologics used in more severe segments

Contributing to building relationships in diagnosis collaboration

Source: Professor Iizuka, Japanese Dermatological Association, 116 (9), 1285-1293, 2006 (partially modified from original)

Business overview

Highlights

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1. Maximized the product value of Mogamulizumab (KW-0761)
   Joint development partnership with AstraZeneca targeting solid tumor

2. Further strengthened European business base
   Acquisition of Archimedes by ProStrakan

3. Signed domestic sales licensing agreement with Japan Blood Products Organization for early-stage market penetration of recombinant human antithrombin KW-3357

Maximize Mogamulizumab product value

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Combination therapy of mogamulizumab with anti-PD-L1 antibody MEDI4736 and anti-CTLA-4 antibody Tremelimumab, targeting solid tumors, with the goal of maximizing mogamulizumab product value

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KW-0761/mogamulizumab
anti-CCR4

AstraZeneca

MEDI4736
anti-PD-L1

Tremelimumab
anti-CTLA-4

POTELIGEO® Injection

Hypothesis: anti-tumor activity

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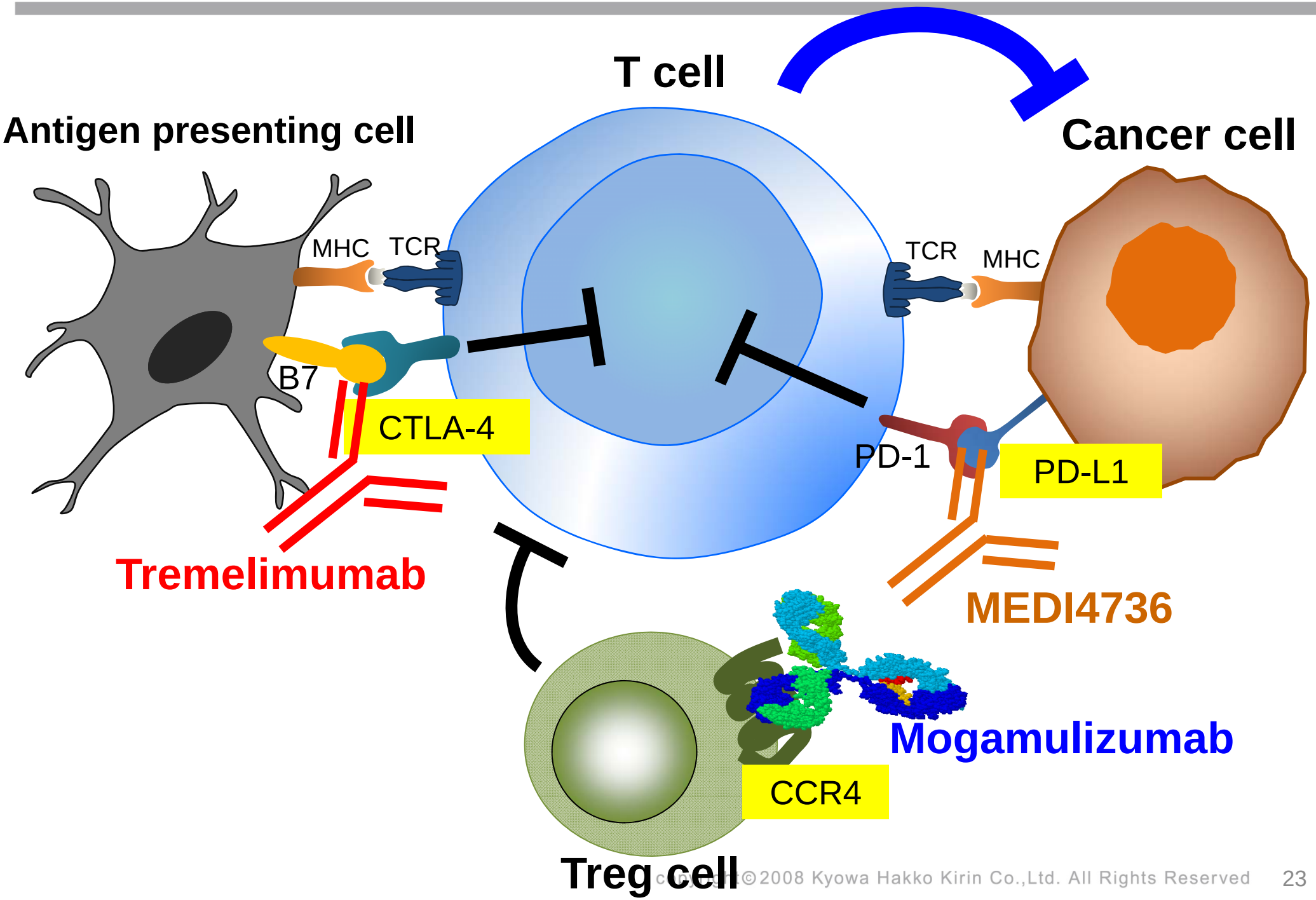

Hypothesis: anti-tumor activity

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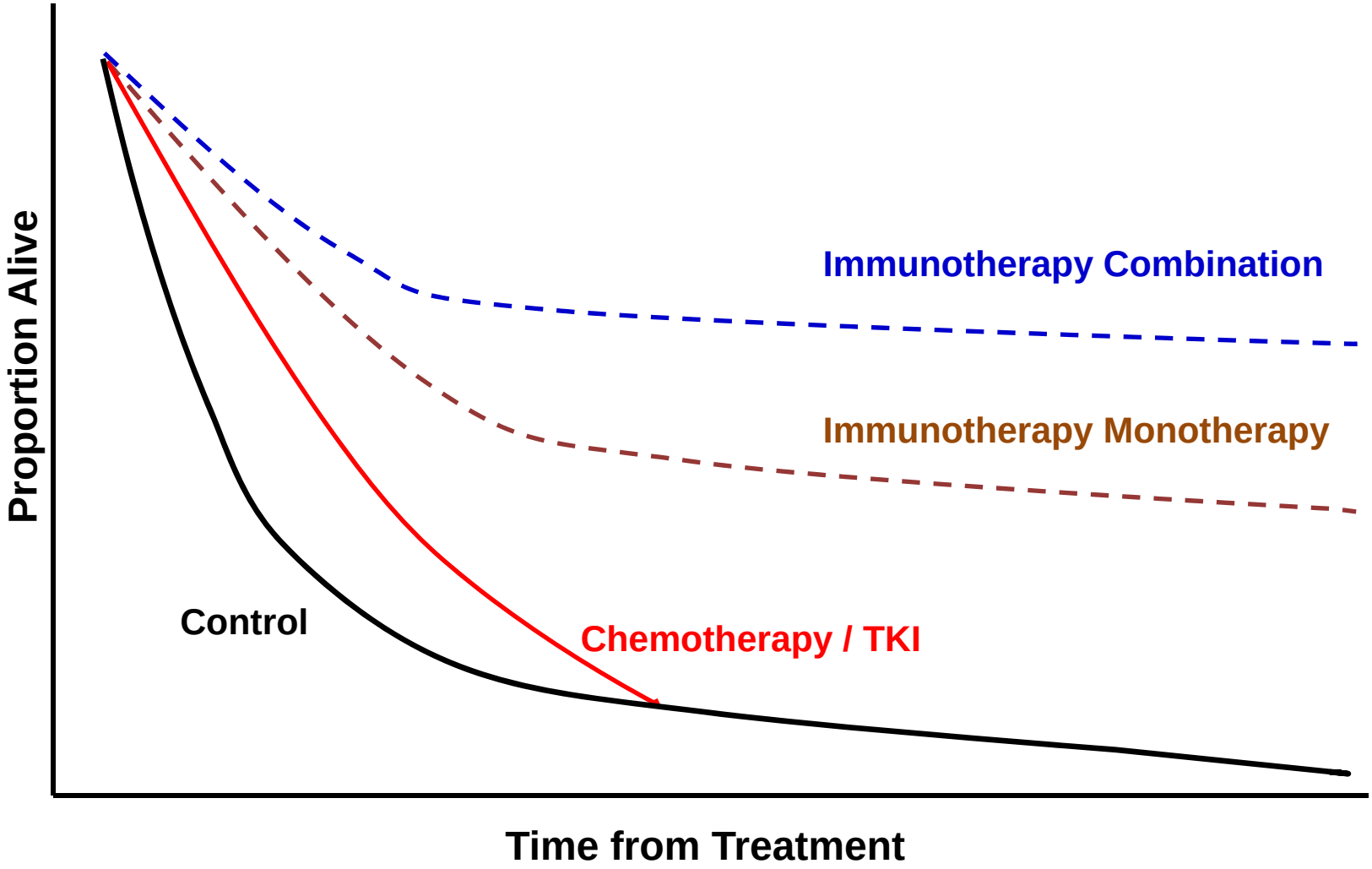
In cancer immunotherapy, the additive effect of combination therapy is more highly evaluated than monotherapy



Source: internal documents

Acquisition of Archimedes Pharma by ProStrakan

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Archimedes Pharma

Overview:	Specialty pharmaceutical company headquartered in Reading, England
Business:	Development and sales of ethical pharmaceuticals in Europe, primarily in the areas of pain, oncology, and critical care
Established:	2004
Employees:	161 (of which MRs: 85)
Sales and marketing:	Expand sales activities in England, France, Germany, Spain, and other European countries through sales and marketing subsidiary

Archimedes PHARMA

Overview of acquisition and earnings outlook

Acquisition cost:	•Estimated total acquisition cost: GBP230 million •Includes payment to Archimedes shareholders and partial repayment of debt held by target business •Kyowa Hakko Kirin will use its own cash on hand to fund the acquisition
Effect on consolidated results	To be announced following assessment of the effect of the acquisition on intangible assets such as amortization of goodwill and marketing rights, and other items
Closing	2014 Q3 (scheduled)

Further strengthen European business base

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Through the acquisition of Archimedes by ProStrakan, strengthen European business base with the aim of driving forward progress toward GSP[1]

Strategic significance of acquisition

- Strengthen sales framework in Europe through the acquisition of a product portfolio that fits strategically with ProStrakan's product lineup
- Strengthen position in area of cancer pain through joint sales of fentanyl nasal spray PecFent® and ProStrakan's sublingual fentanyl tablet, Abstral®
- Achieve efficient market penetration and maximize product value of new KHK[2] drug, which is scheduled for launch during the next medium-term plan

Sales

ProStrakan sales outlook

1) : Global Specialty Pharmaceutical Company
2) : Kyowa Hakko Kirin Co., Ltd.

Reference: 2013 sales (ProStrakan: £155.4m / Archimedes: £41.0m)

Early-stage market penetration of KW-3357

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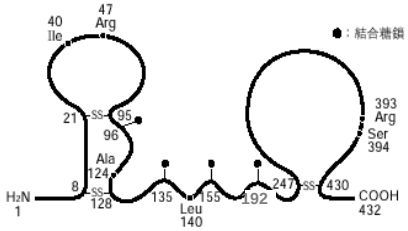
Sales partnership with Japan Blood Products Organization for KW-3357

KW-3357

KW-3357



- Recombinant human antithrombin drug
- Indicated for disseminated intravascular coagulation and congenital antithrombin deficiency. Holds promise for mitigation of the undeniable risks of infection from human blood associated with existing human plasma-derived products
- Application for approval for manufacture and sales scheduled for 2014

Sales partner

Japan Blood Products Organization

JB 一般社団法人 日本血液製剤機構 Japan Blood Products Organization

Reason for partnership

- Japan Blood Products Organization has strong sales capabilities among the diagnostic and treatment departments (critical care, intensive care, etc.) that use this drug
- In this highly competitive field, combining our biopharmaceutical manufacturing capabilities with Japan Blood Products Organization's sales strengths allows us to maximize product value more effectively than entering the market alone

Further accelerate global development

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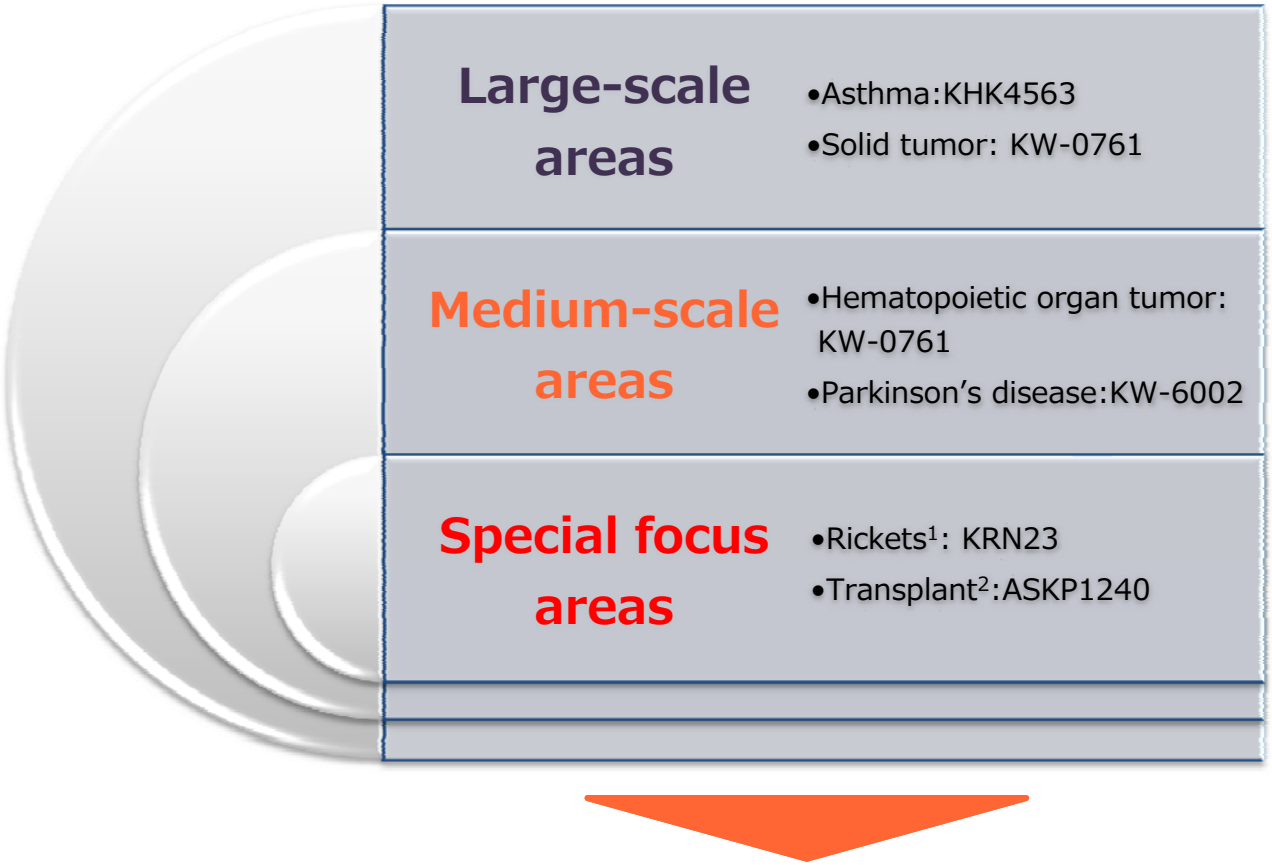
Actively pursue alliance strategy matched to market characteristics
Ensure efficient and effective allocation of R&D expenditure



AstraZeneca

MedImmune

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ultragenyx pharmaceutical

astellas Leading Light for Life

Deliver new and innovative in-house developed drugs to patients more swiftly

[1]X-linked Hypophosphatemic Rickets (XLH)
[2] Organ Transplant Rejection

Q & A session

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The Kyowa Hakko Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

If you have any inquiries regarding this presentation please call:

Corporate Communications Department, Kyowa Hakko Kirin Co., Ltd.

Tel: +81-3-3282-0009

APPENDIX

Appendix: POTELLIGENT® technology alliances

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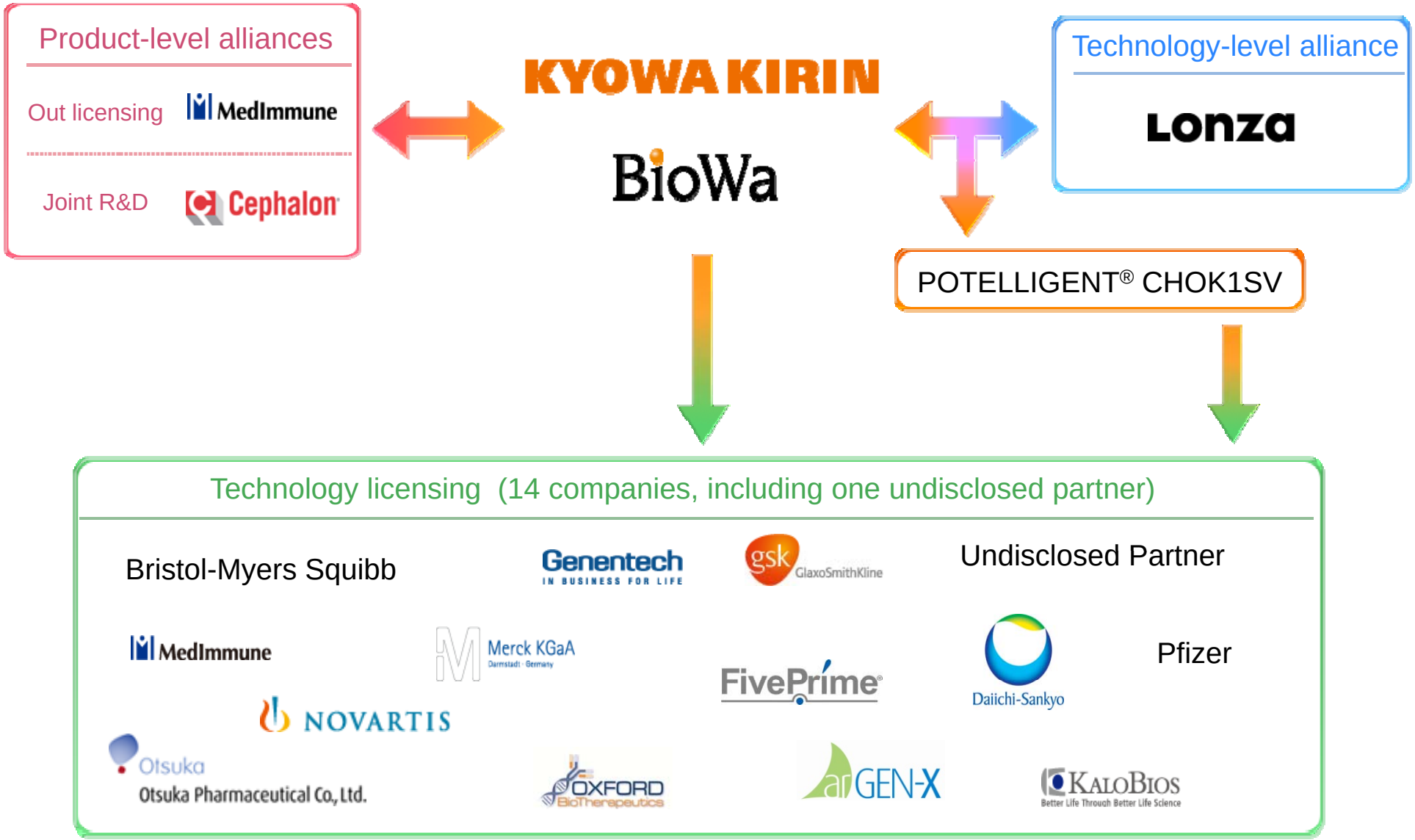
(As of July 10, 2014)



*There are currently 12 POTELLIGENT® contracted antibodies at the clinical trial stage

Appendix: Development progress with outlicensed compounds

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Name	Partner	Phase I	Phase II	Phase III	Remarks
Tivozanib	AVEO		■		Cancer (VEGF receptor inhibitor) (KRN951)
BenralizuMab (MEDI-563)	AstraZeneca /MedImmune			■	Asthma (Anti-IL-5R antibody) (KHK4563) POTELLIGENT®
			■		COPD
KRN5500	DARA		■		Peripheral neuropathy
RGI2001	REGiMMUNE	■	■		Immunosuppressive
SAR252067	Sanofi	■			Ulcerative colitis and Crohn's disease (anti-LIGHT antibody)

(as of July 23, 2014)

Appendix: FOREX related

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Period average rate

Average exchange rate	FY2013 H1 results	FY2014 H1 results	Change	*2014 Jan-Dec forecast*
¥/$	¥94	¥103	+¥9	*¥102*
¥/€	¥123	¥141	+¥18	*¥141*
¥/£	¥145	¥171	+¥26	*¥171*

FY2014 Q1 currency effects (YoY)

Segment	Currency	Net sales	Operating income
Pharmaceuticals business	$	+¥0.4bn	+¥0.1bn
	€	+¥0.1bn	+¥0.1bn
	£	+¥2.0bn	+¥0.1bn
Bio-Chemicals business	$	+¥0.7bn	+¥0.5bn
	€	+¥1.0bn	+¥0.4bn
	£	-	-