KYOWA KIRIN

Results Presentation

Fiscal 2014 Third Quarter

(January 1, 2014 – September 30, 2014)

Kyowa Hakko Kirin Co., Ltd.

October 28, 2014

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.

Agenda

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Financial review

Kazuyoshi Tachibana, Managing Executive Officer

Topics

Kazuyoshi Tachibana, Managing Executive Officer

R & D review

Toshiyuki Amemiya, Fellow & Director, Clinical Developments Center, Development Functions Unit, R&D Division

Financial review

Summary of FY2014 Q3 results (consolidated)

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Compared to FY2013 Q3, sales and profits declined due to the effects of the drug price revision and market penetration of generics drugs, and a decrease in licensing revenue

(Unit: ¥bn)	FY2013 Q3	FY2014 Q3	Change	FY2014 forecast*	Rate of progress
Net sales	252.1	238.9	-13.1 (-5%)	336.0	71%
Operating income *Operating margin*	41.4 *16.4%*	26.2 *10.9%*	-15.1 (-37%)	43.0	60%
Ordinary income	39.2	23.8	-15.4 (-39%)	35.0	68%
Net income	23.3	12.0	-11.2 (-48%)	18.0	66%

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

*Announced October 28, 2014

- ✓ **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 Q3 results (consolidated): Analysis of YonY profit changes

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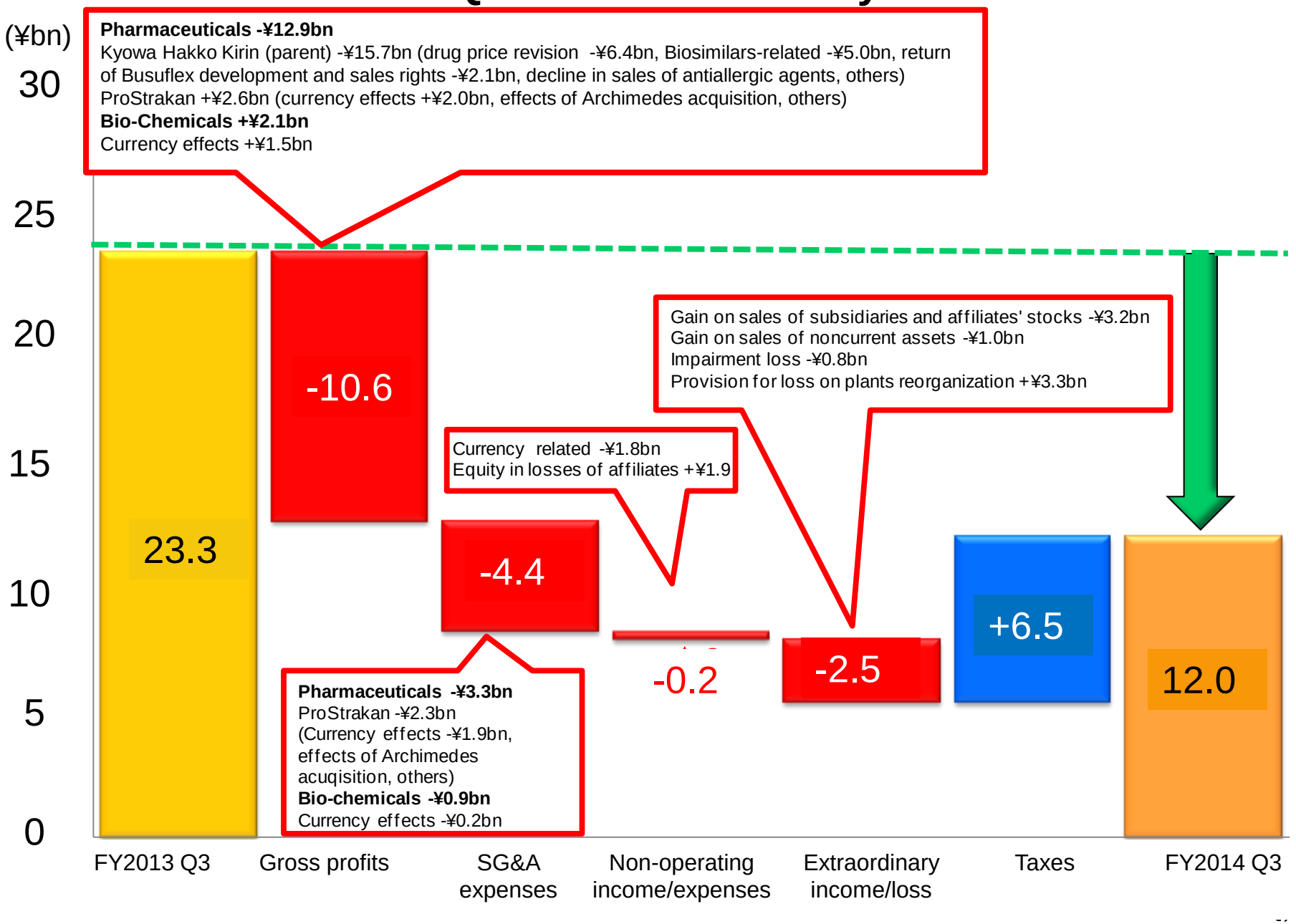
Q3 net income: Analysis



Summary of FY2014 Q3 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 Q3	FY2014 Q3	Change
Pharmaceuticals business	Net sales	192.7	178.6	-14.1 (-7%)
	Operating income *Operating margin*	36.9 *19.1%*	20.6 *11.5%*	-16.3 (-44%)
Bio-Chemicals business	Net sales	61.5	62.7	+1.1 (+2%)
	Operating income *Operating margin*	4.5 *7.3%*	5.6 *8.9%*	+1.1 (+26%)

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

Pharmaceuticals business:
FY2014 Q3: Analysis of YonY profit changes

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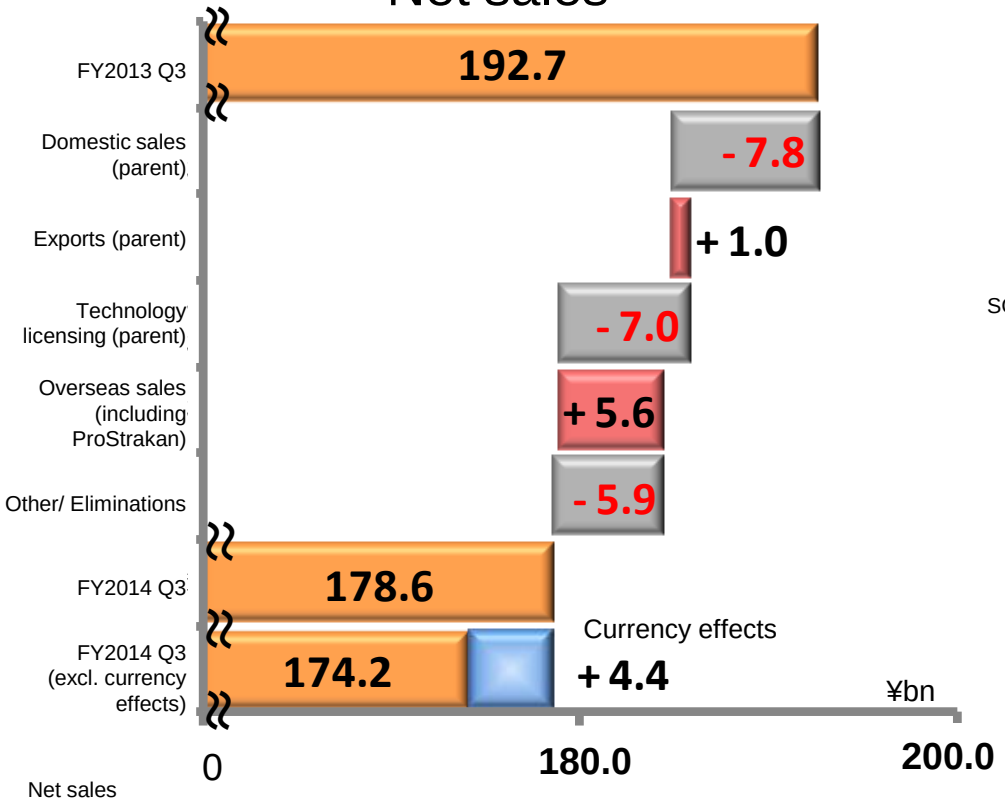
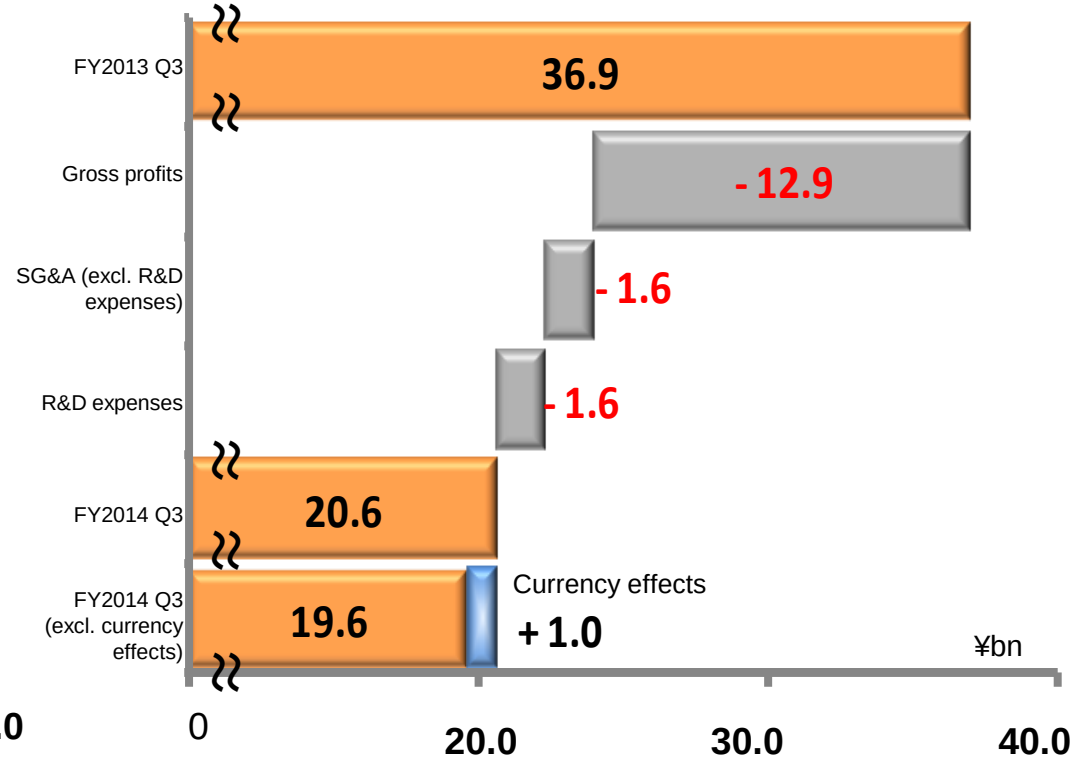
Net sales



Operating income



Net sales

- Domestic pharmaceutical products (-¥7.8bn):
  - Products (shipments): NOURIAST® +¥1.4, REGPARA® +¥1.0, ALLELOCK® -¥3.0, CONIEL® -¥2.3, GRAN® -¥2.2 Patanol® -¥1.5.
  - 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 (+¥1.0bn): Currency effects, etc.
- Technology licensing, etc.(-¥7.0bn): Currency effects +¥0.4bn
  - Biosimilars-related (-¥5.0)
  - Decease in lump-sum payment (-¥2.1bn) reflecting return of Busulfex development and marketing rights in the previous fiscal year; etc.
- Overseas sales (+¥5.6bn); Currency effects +¥3.6bn.
  - Expansion of ProStrakan's Abstral®, etc., effects of consolidation of Archimedes +¥4.6bn
- Other/Eliminations (-¥5.9bn):
  - Decrease in sales as a result of transfer of consolidated subsidiary Chiyoda Kaihatsu's chemicals logistics business on September 1, 2013, etc. -¥4.1bn

Operating income

- Gross profits (-¥12.9bn):
  - 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 (-¥1.6bn):
  - 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 (-¥1.6bn):
  - Increased overseas R&D expenses

Pharmaceuticals business: Domestic sales of key products

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Sales of key product NESP® performed strongly, but were impacted by the effects of the drug price revision and penetration of generics

Product name/ Exports/ Technology out-licensing	FY2013 Q3 results[1]	FY2014 Q3 results[1]	Change	Reason for change	Rate of progress[2]
NESP®	39.7	40.1	0.3 (+1%)	Decrease due to temporary rebound in shipments in FY 2013 Q3. Strong performance this year*	73%
REGPARA®	10.6	11.7	1.0 (+10%)	Steady market penetration	73%
ALLELOCK®	20.9	17.9	-3.0 (-14%)	Decrease in airborne pollen count Market penetration of generics*	76%
Patanol®	11.4	9.9	-1.5 (-13%)	Decrease in airborne pollen count	84%
GRAN®	9.0	6.7	-2.2 (-25%)	G-CSF market contraction Market penetration of biosimilars*	78%
Exports	8.1	9.1	1.0 (+13%)		83%
Technology out-licensing	13.8	6.4	-7.3 (-53%)	Licensing revenue in FY2013 Q3 benefited from one–time factor of return of Busulflex development and sales rights	45%

[1]Unit: ¥bn, figures rounded down

*Note: Also impacted by drug price revision

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

Bio-Chemicals business:
FY2014 Q3: Analysis of YonY profit changes

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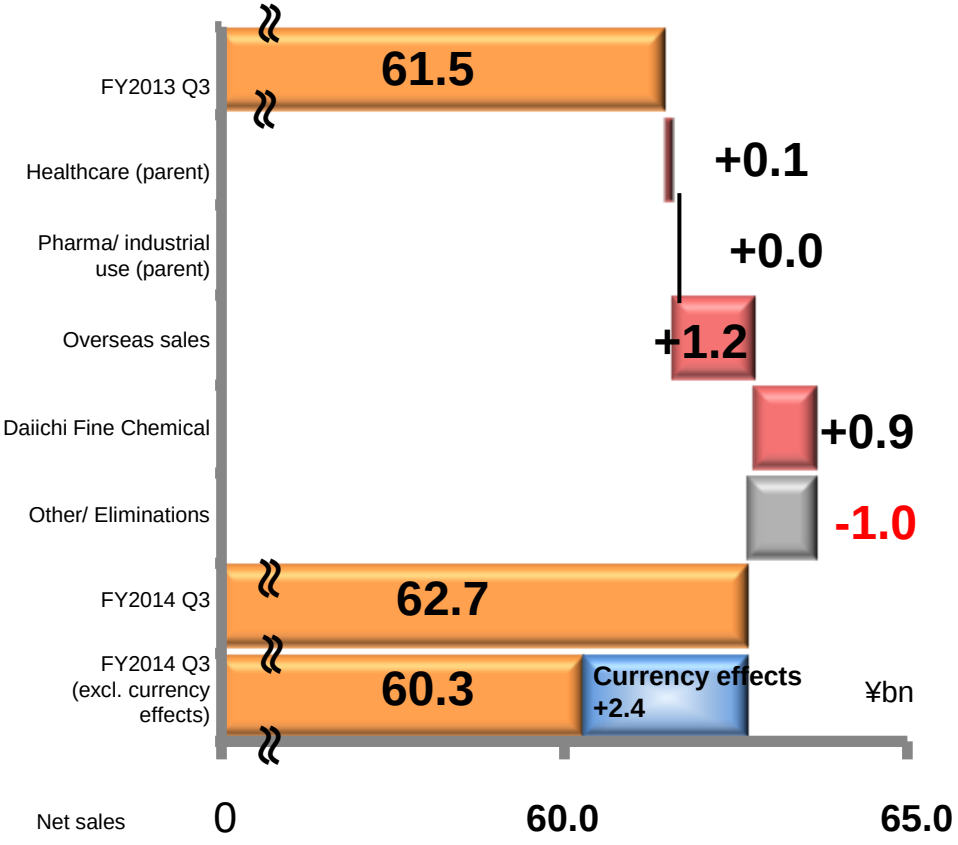
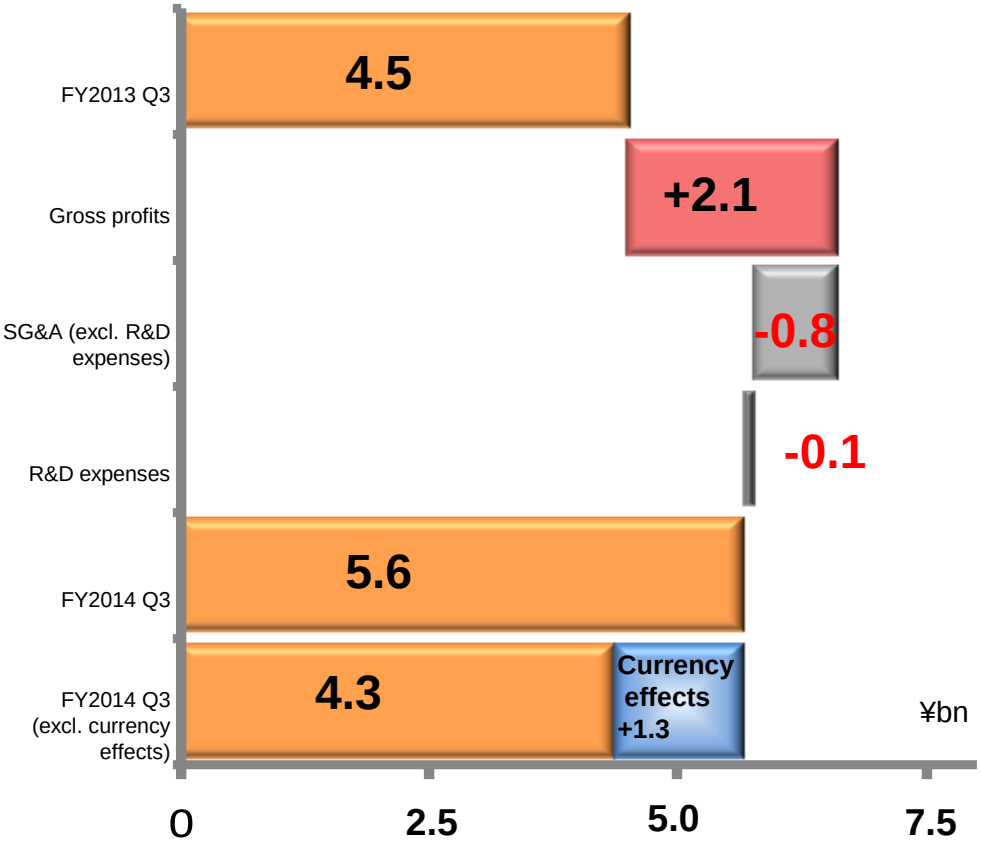
Net sales



- 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, and a decline in sales for use in food and beverages due in part to unseasonable weather during the summertime lead to a decreased sales from previous year.
- Pharma/industrial use (+¥0.0bn): Sales largely unchanged from previous year due to inventory adjustments by major customers of amino acids, etc.
- Overseas sales (+¥1.2bn): Currency effects (+¥2.4bn)
  - U.S. (+¥0.2): Currency effects (+¥0.4), reduction in product business due to low sales of some customers, etc.
  - Europe (+¥1.0): Currency effects (+¥1.2), effects of H1 inventory adjustments by some customers, etc.
  - Asia and others (+¥0.0): Currency effects (+¥0.7bn), temporary reduction in product business due to customers in China responding to regulatory authorities, etc.
- Daiichi Fine Chemical (+¥0.9bn):
  - Increase in sales generic pharmaceuticals, etc.

Operating income



Operating income

- Gross profits (+¥2.1bn): Currency effects (+¥1.5bn)
  - Improvements to product mix due to shift to sales of highly-profitable products through overseas sales companies
  - Increase in high-margin mail order sales, etc.
- SG&A (-¥0.8bn): Currency effects (-¥0.2bn)
  - Increased expenses due to investment in systems for mail order sales, etc.

Topics

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1. **KW-0761 development tie-ups with goal of maximizing product value**

- AstraZeneca (July)
  MEDI4736 / Tremelimumab

- Pfizer (September)
  PF-05082566

2. **ProStrakan completes acquisition of Archimedes** (August)

3. **Sustained-duration G-CSF product G-Lasta® approval in Japan** (September)

1. KW-0761 development tie-up expansion

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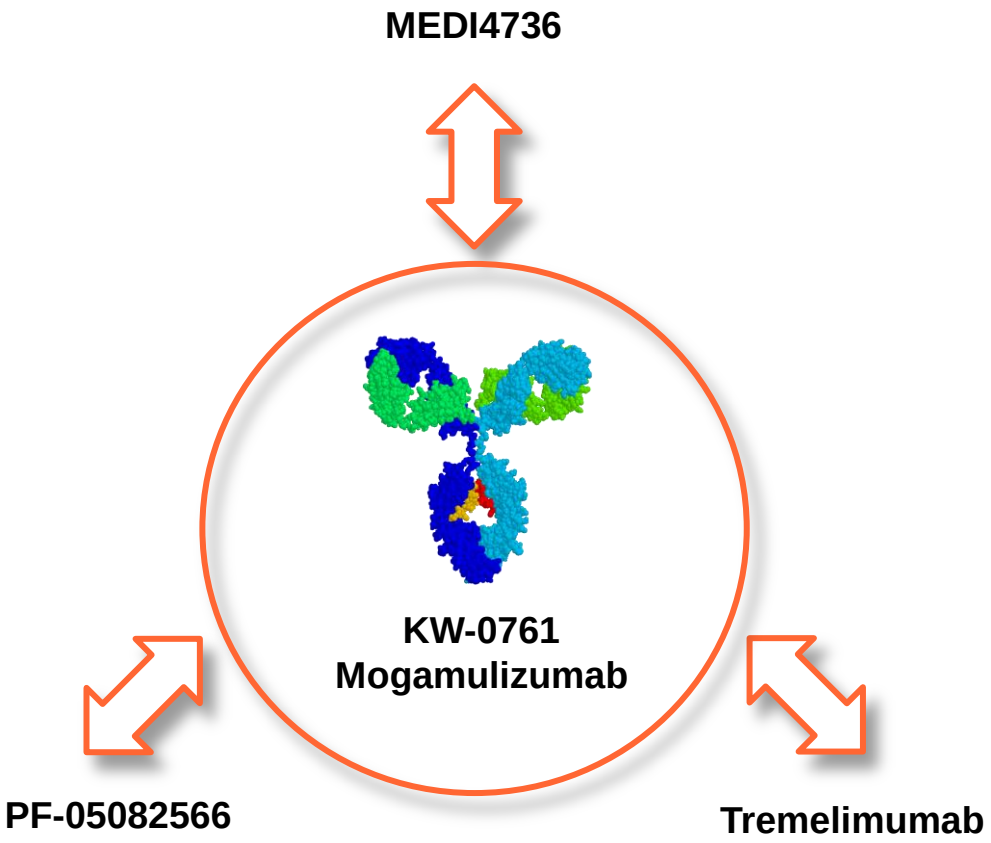
KW-0761 development tie-ups with goal of maximizing product value advance
Rapidly explore opportunities in the tumor immunity field



Expected therapeutic value in combination immunotherapy

- KW-0761 + MEDI4736
  - -Target：Solid tumors
  - -Phase1/1b (plan to register this year)
- KW-0761 + Tremelimumab
  - -Target：Solid tumors
  - -Phase1/1b (plan to register this year)
- KW-0761 + PF-05082566
  - -Target: Solid tumors
  - -Phase1b (Plan to initiate in 2015)

Research with the aim of acquiring position for KW-0761 in tumor immunity field

2. Business combination accounting treatment of Archimedes

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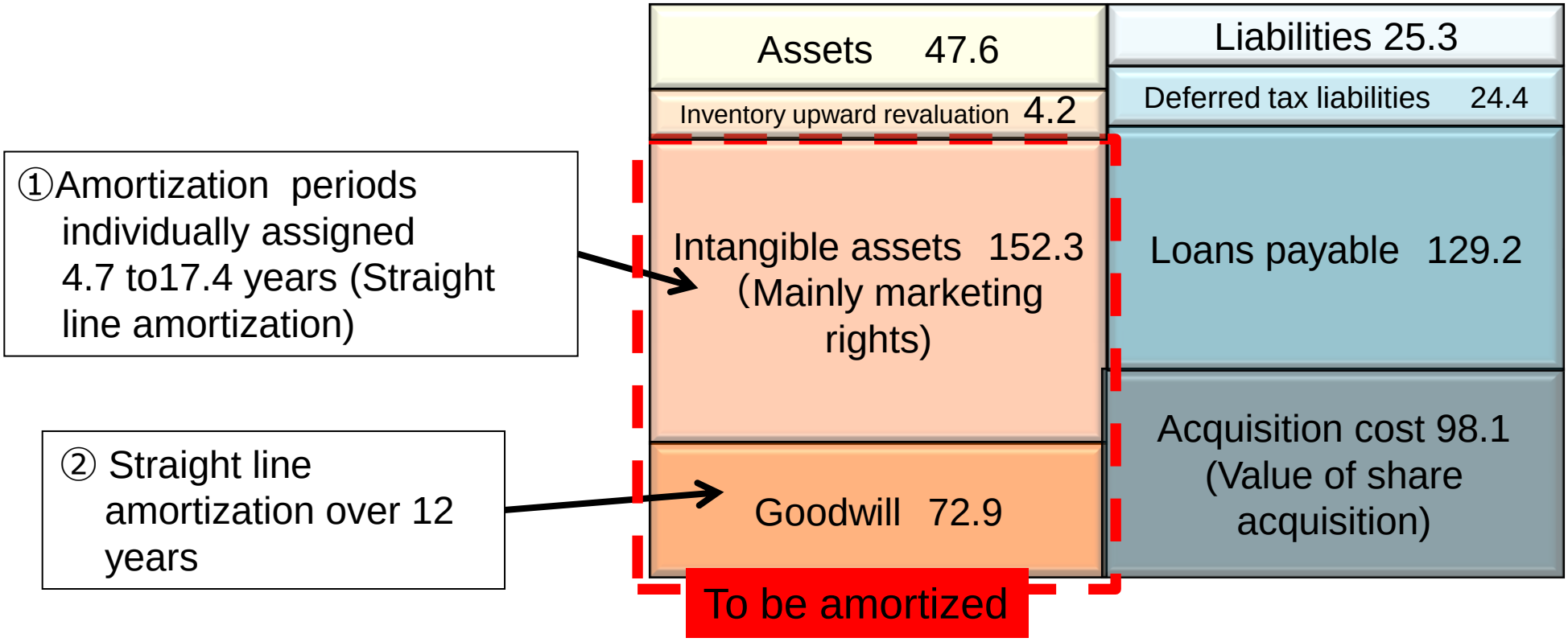
Opening balance sheet（Provisional accounting treatment as of August 5, 2014)

－Balance sheet after appraisal of intangible assets according to the PPA* method

（Unit: GBP million)



Expected effects of acquisition		2014 H2	(Ref) FY 2015
①Amortization of intangible assets	:	£ 5.2M	£ 12.5M
②Amortization of goodwill	:	£ 2.5M	£ 6.0M
③Inventory upward revaluation	:	£ 4.2M	—
Total P&L effect	:	£ 11.9M	£ 18.5M

*PPA: Purchase Price Allocation

3. Approval for G-Lasta® in Japan

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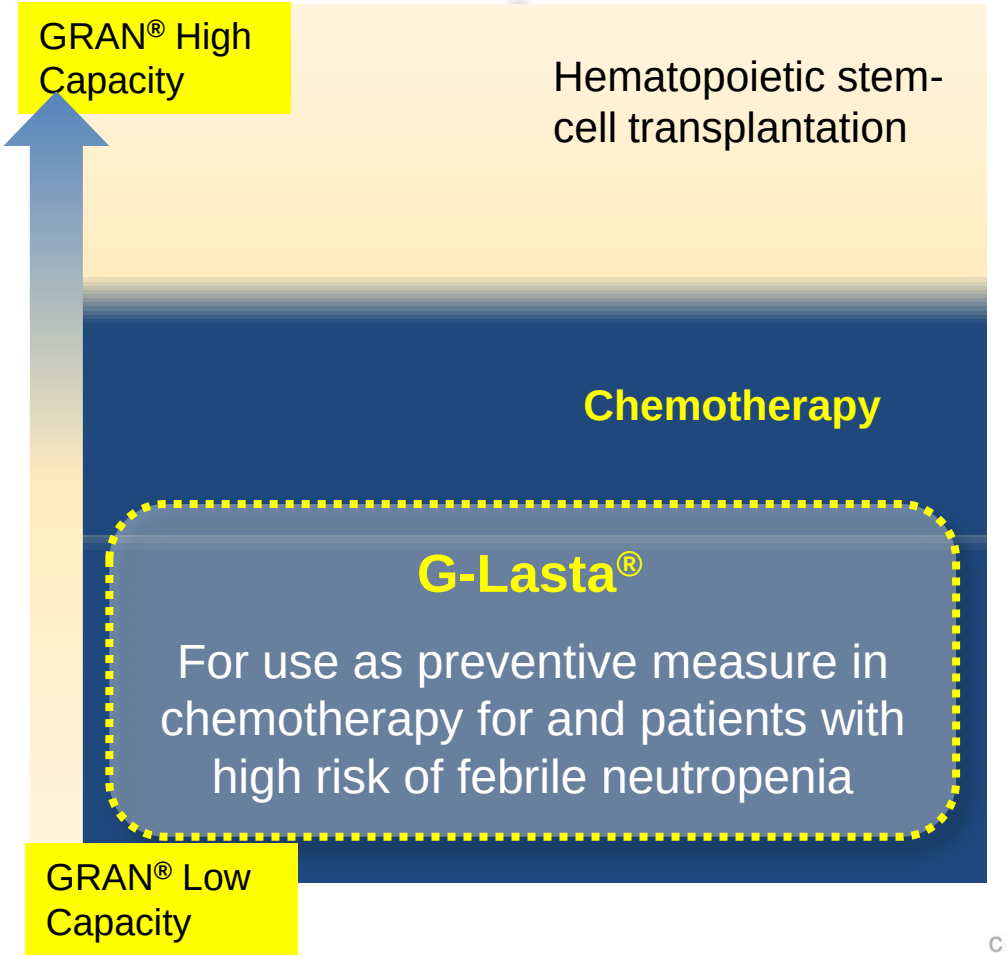
Gained approval for G-Lasta®, the first sustained-duration G-CSF product in Japan
Indication: Febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy

G-Lasta® 's position in the GRAN® marketplace



Convenience in medical treatment：

- Reduce the burden of drug administration
- Decrease frequent hospital visits of outpatients undergoing chemotherapy

Merits for medical treatment：

- Reduce risk of infection due to neutropenia
- Improves compliance with doses and schedules of chemotherapy

Can contribute to clinical practice on various fronts

R & D review

Domestic development and other key updates

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Category	Product name/development number	Mechanism of action, etc.	Stage (timing) / Target
Nephrology	KHK7580	Calcium receptor agonist	Phase 2 (August)/Secondary hyperparathyroidism
Oncology	G-Lasta®	Sustained-duration G-CSF product	Approved (September)/[1]
Oncology	BIW-8962	Anti-GM2 humanized antibody	Phase 2 (October)/Cancer
Other	KW-3357	Recombinant human antithrombin	Filing (July)/[2]

Note: Bio-pharmaceutical products are underlined
Only Phase 2 trials or later are shown

[1]Indications: Febrile neutropenia in patients treated with cytoxic chemotherapy for malignancy
[2]Planned indications: Thrombophilia due to congenital AT III deficiency and disseminated intravascular coagulation accompanied by a decrease in AT III.

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	NA 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	U.S. Canada	**Phase1/2** (Target: adults)	
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 development is proceeding according to initial 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

Note: Information about Phrase 3 trials (n preparation) is listed on ClinicalTrial.org (NCT02260791)
Its status is listed as “Not yet recruiting”.

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

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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:

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Tel: +81-3-3282-0009

APPENDIX

Appendix: Development progress with outlicensed compounds

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Name	Partner	Phase			Remarks
		I	II	III	
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		Phase1/2		Immunosuppressive
SAR252067	Sanofi				Ulcerative colitis and Crohn's disease (anti-LIGHT antibody)

(as of October 21, 2014)

Appendix: Breakdown of total acquisition cost and acquisition value

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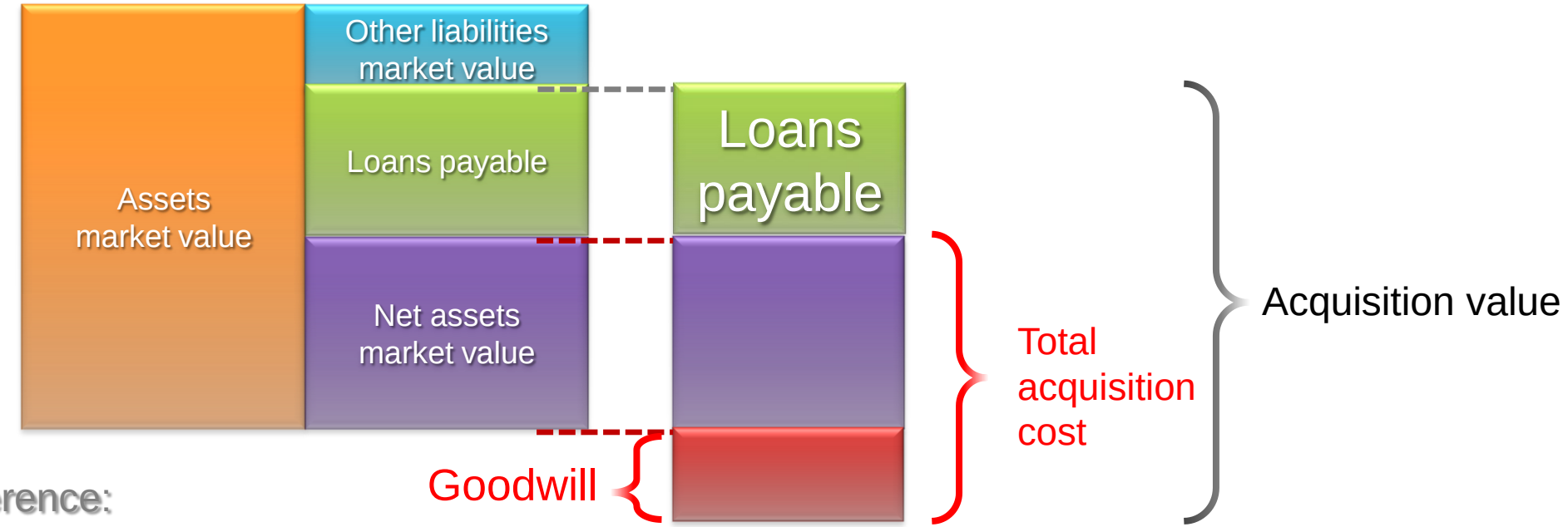
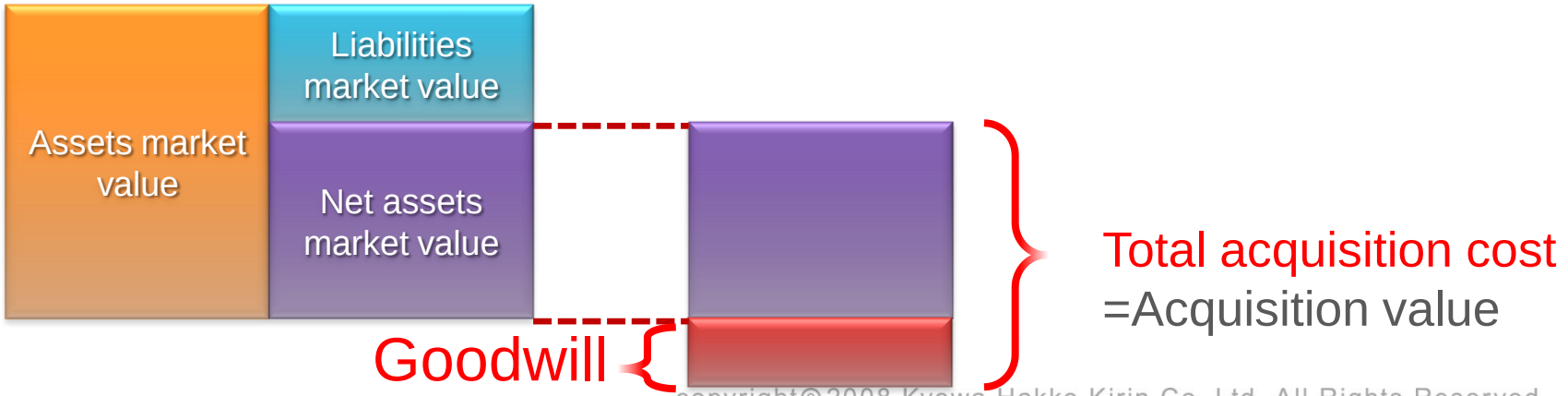
(Archimedes at time of acquisition)

Acquired company BS



Reference:
(ProStrakan at time of acquisition)



Appendix: FOREX related

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Period average rate

Average exchange rate	FY2013 Jan-Sept results	FY2014 Jan.-Sept results	Change	*2014 Jan-Dec forecast*
¥/$	¥95	¥103	+¥8	*¥104*
¥/€	¥125	¥140	+¥15	*¥139*
¥/£	¥147	¥171	+¥24	*¥171*

FY2014 Q3 currency effects (YoY)

Segment	Currency	Net sales	Operating income
Pharmaceuticals business	$	+¥0.6bn	+¥0.1bn
	€	+¥0.1bn	+¥0.1bn
	£	+¥2.8bn	+¥0.2bn
Bio-Chemicals business	$	+¥0.9bn	+¥0.6bn
	€	+¥1.3bn	+¥0.6bn
	£	-	-