

# **Results Presentation**

## **Fiscal 2014**

**Kyowa Hakko Kirin Co., Ltd.**

**February 2, 2015**

## Business overview

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

## Financial review

**Kazuyoshi Tachibana,**  
Managing Executive Officer

## R & D review & Topics

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

## Q & A session

*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.*

## Business overview

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## Steady progress in line with medium-term business plan within a changing business environment

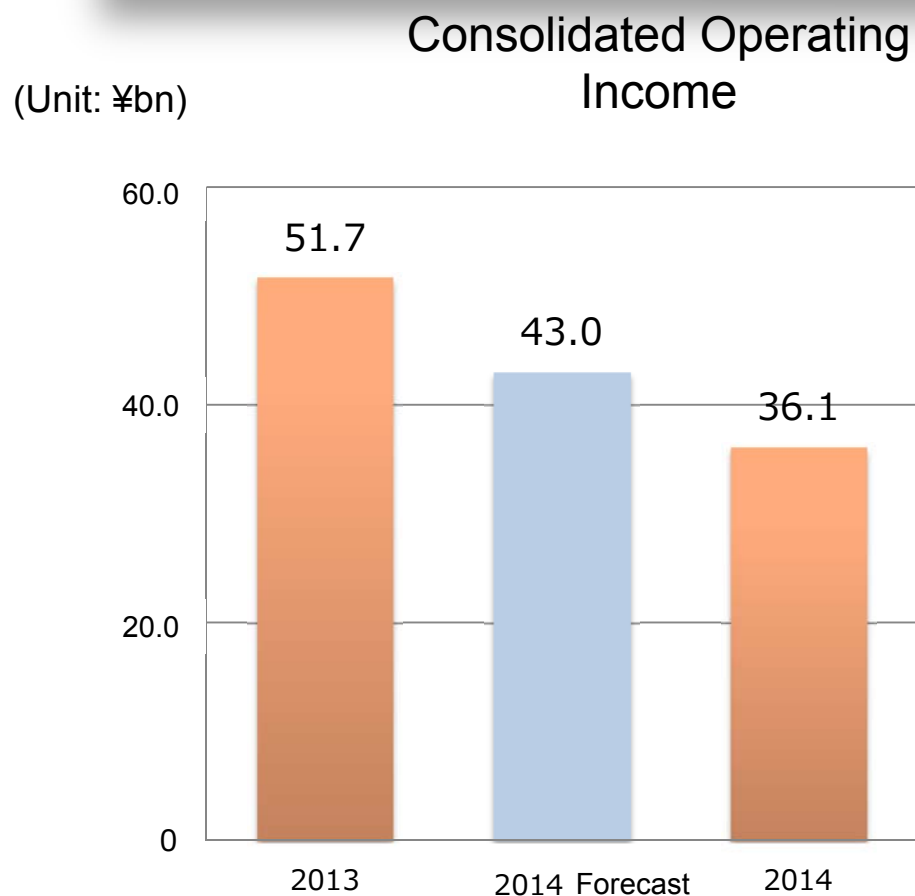
- Drug price revisions implemented in April 2014
- Impact of generics and biosimilars on core products ALLELOCK<sup>®</sup>, GRAN<sup>®</sup> and others is expanding
- Received approval for and began sale of new drugs G-Lasta<sup>®</sup> and Dovobet<sup>®</sup>
- ProStrakan completed acquisition of Archimedes
- Entered into clinical trial collaboration agreements for Mogamulizumab in the field of immuno-oncology
- Entered into license agreement with Syndax for entinostat, a Class I selective HDAC inhibitor

**Sales and profits declined due to the effects of drug price revisions in April and an increase in R&D expenses**

(Unit: ¥bn)	FY2013 results	FY2014 results	Change
Net sales	340.6	333.4	-7.1 (-2%)
Operating income <i>Operating margin</i>	51.7 15.2%	36.1 10.8%	-15.6 (-30%)
Ordinary income	49.5	29.5	-19.9 (-40%)
Net income	30.0	15.8	-14.1 (-47%)

- ✓ The decline in ordinary income was due to lower operating income, an increase in losses of equity accounted affiliates, and other factors
- ✓ The decline in net income was due to absence of gain on sales of subsidiaries and affiliates' stocks recorded in the previous period and other factors

## Main factors influencing actual performance compared to forecast for this period



Reasons for decrease in operating income (from beginning of FY2014):

- Impact of generics on long-listed products
- Delayed market penetration of new drugs

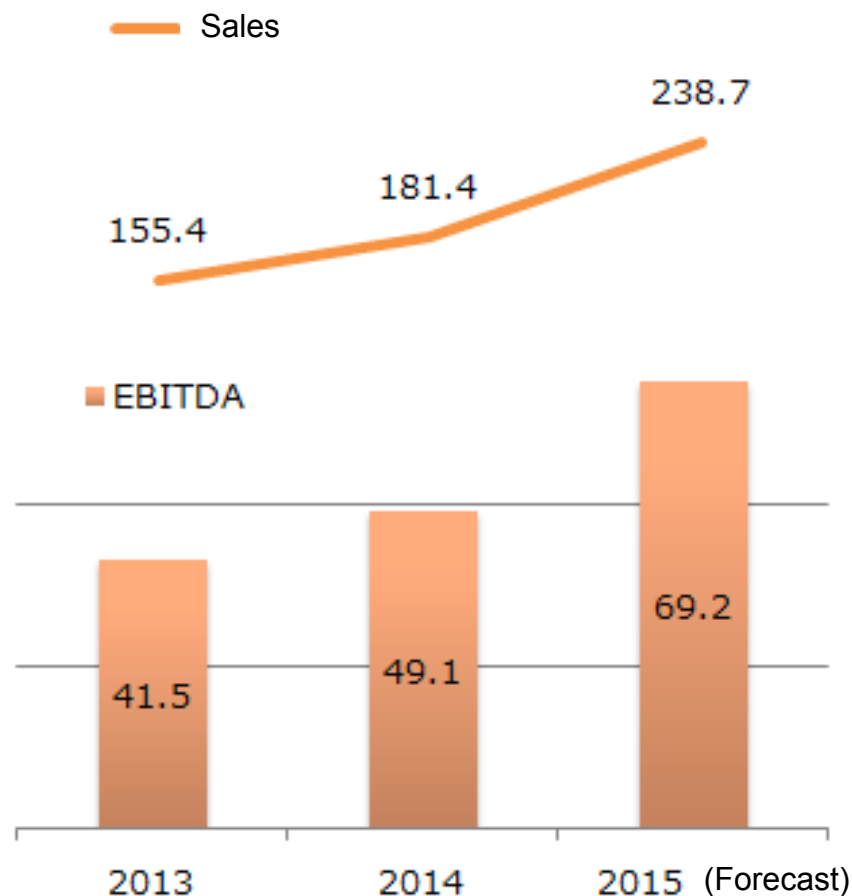
Reasons for decrease in operating income (from Q3):

- Upfront payment related to entinostat
- Overseas R&D investment for early launch
- Difference between unused SG&A expenses forecasts and actual results

## Proceed with expansion of overseas business base to become GSP with PSK at the core

### ProStrakan performance

(Unit: GBP million)



Strong performance due to 3 growth driver products

	2014	2015 (Forecast)
Abstral®	£55.8M→	£59.6 M
PecFent®	£7.5M →	£23.3 M
Sancuso®	£14.0M→	£17.0 M

Overseas sales ratio  
(pharmaceuticals business)

2014	2015 (Forecast)
22%	→ 26%



## Financial review

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# Summary of FY2014 financial results by segment (YoY) **KYOWA KIRIN**

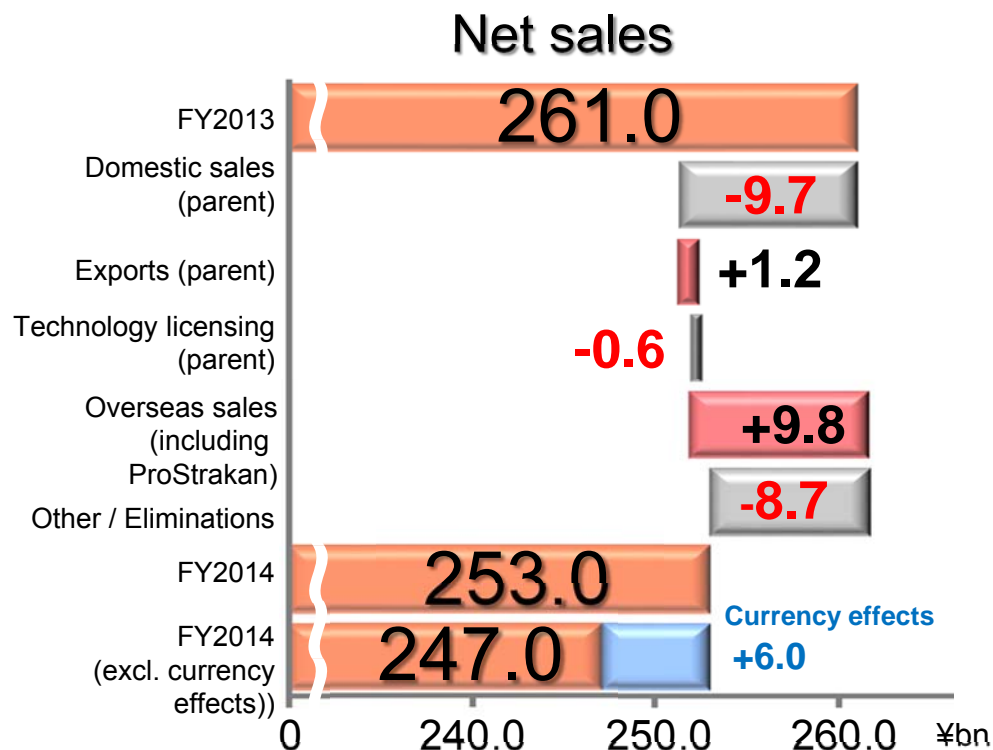
In the Pharmaceuticals business, sales and profits declined due to effects of drug price revisions and an increase in R&D expenses  
In the Bio-Chemicals business, sales and profits increased due to an growth in APIs and a weaker yen

(Unit: ¥bn)		FY2013 results	FY2014 results	Change
Pharmaceuticals business	Net sales	261.0	253.0	-7.9 (-3%)
	Operating income <i>Operating margin</i>	46.1 17.7%	29.0 11.5%	-17.0 (-37%)
Bio-Chemicals business	Net sales	82.9	83.9	1.0 (+1%)
	Operating income <i>Operating margin</i>	5.6 6.7%	7.2 8.7%	1.6 (+28%)

# Pharmaceuticals business:

## FY2014: Analysis of YoY profit changes

**KYOWA KIRIN**



Net sales

• Domestic pharmaceutical products (-¥9.7bn):

- Products (shipments): NOURIAST® +¥2.2, REGPARA® +¥1.1, Dovobet® +¥1.1, ALLELOCK® -¥4.0, CONIEL® -¥3.4, GRAN® -¥3.1
- NESP®: While impacted by the effects of drug price revisions, sales levels were maintained from 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 (+¥1.2bn): Currency effects, etc.

• Technology licensing, etc. (-¥6.0bn): Currency effects +¥0.6bn

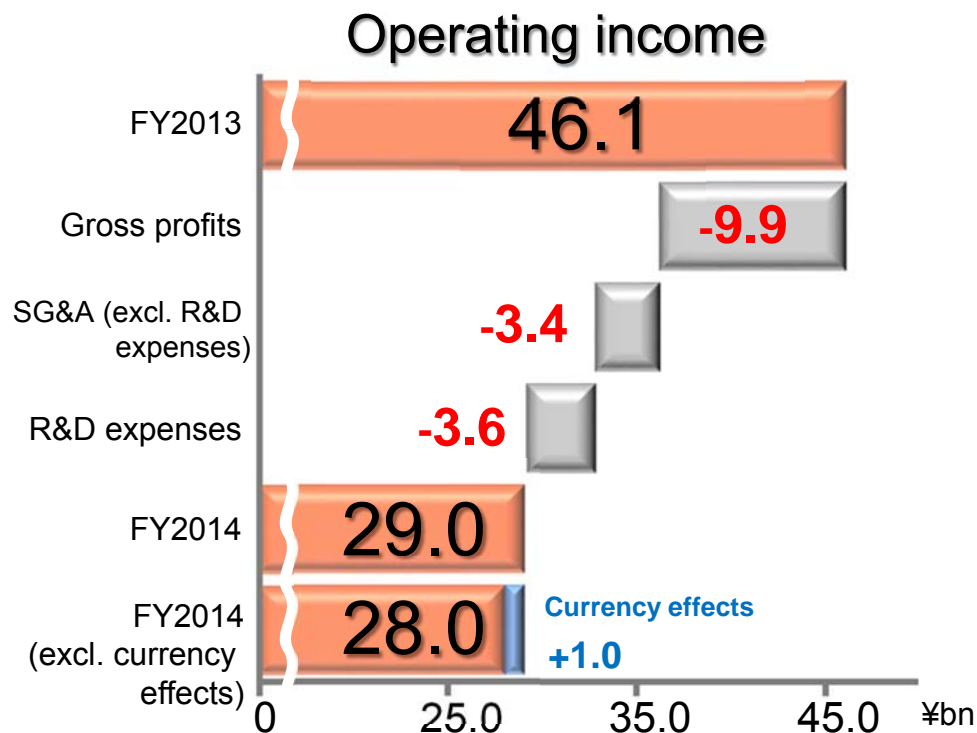
- Biosimilars-related (+¥1.0)
- Decrease in lump-sum payment (-¥2.1bn) reflecting return of Busulfex development and marketing rights in the previous fiscal year; etc.

• Overseas sales (+¥9.8bn); Currency effects +¥4.9bn.

- Expansion of ProStrakan's Abstral®, etc., effects of consolidation of Archimedes +¥8.0bn

• Other/Eliminations (-¥8.7bn):

- Decrease in sales as a result of transfer of consolidated subsidiary Chiyoda Kaihatsu's chemicals logistics business on September 1, 2013, etc. (-¥4.2bn)
- Decrease in licensing revenue from BioWa (-¥2.2)



Operating income

• Gross profits (-¥9.9bn):

- Decrease in sales due to effects of drug price revision and market penetration of generics as competition for long-listed products, decrease in lump-sum payments reflecting return of Busulfex development and sales rights in the previous fiscal year, could not be offset by increase in biosimilars-related licensing income and ProStrakan's growth

• SG&A (-¥3.4bn):

- Despite a reduction in SG&A at Kyowa Hakko Kirin (parent) and others, ProStrakan's acquisition of Archimedes led to an increase in costs

• R&D expenses (-¥3.6bn):

- Increased overseas R&D expenses due to licensing of entinostat from Syndax

# Pharmaceuticals business:

## Domestic sales of key products

**KYOWA KIRIN**

**The effects of drug price revisions significantly impacted long-listed products ALLELOCK® and GRAN®**

Product name, other information	FY2013	FY2014	Change	Reason for change	FY2014 forecast*	Rate of achievement
NESP®	56.0	55.3	-0.7 (-1%)	Drug price revision	54.9	+0.4 (101%)
REGPARA®	15.1	16.3	+1.1 (+8%)	Steady market penetration	16.0	+0.3 (102%)
ALLELOCK®	27.6	23.6	-4.0 (-14%)	Decrease in airborne pollen count, drug price revision, market penetration of generics	23.5	+0.1 (100%)
Patanol®	13.4	11.8	-1.5 (-11%)	Decrease in airborne pollen count	11.7	+0.1 (101%)
GRAN®	12.4	9.2	-3.1 (-25%)	Drug price revision, market penetration of biosimilars	8.5	+0.7 (108%)
Exports	10.4	11.6	+1.2 (+11%)		10.9	+0.7 (106%)
Technology out-licensing	15.3	13.9	-1.3 (-8%)	Licensing revenue in FY2013 benefited from one-time factor of return of Busulfex development and sales rights	14.1	-0.2 (99%)

(Unit: ¥bn, figures rounded down)

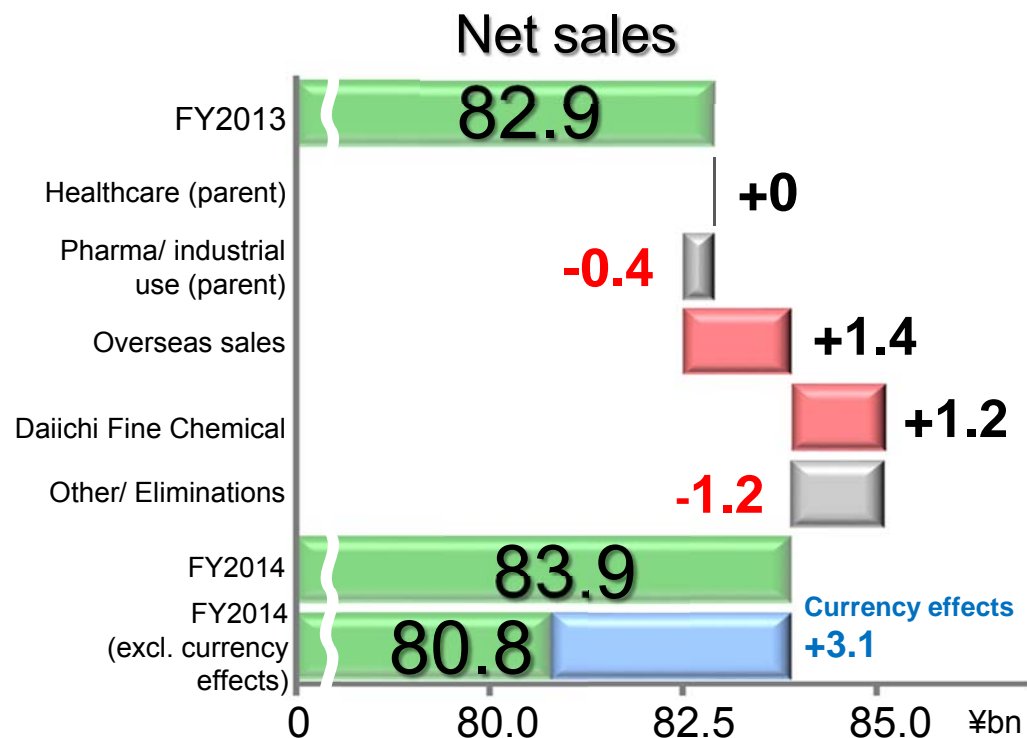
\*Rate of achievement compared to most recent FY2014 full-year sales forecasts

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# Bio-Chemicals business:

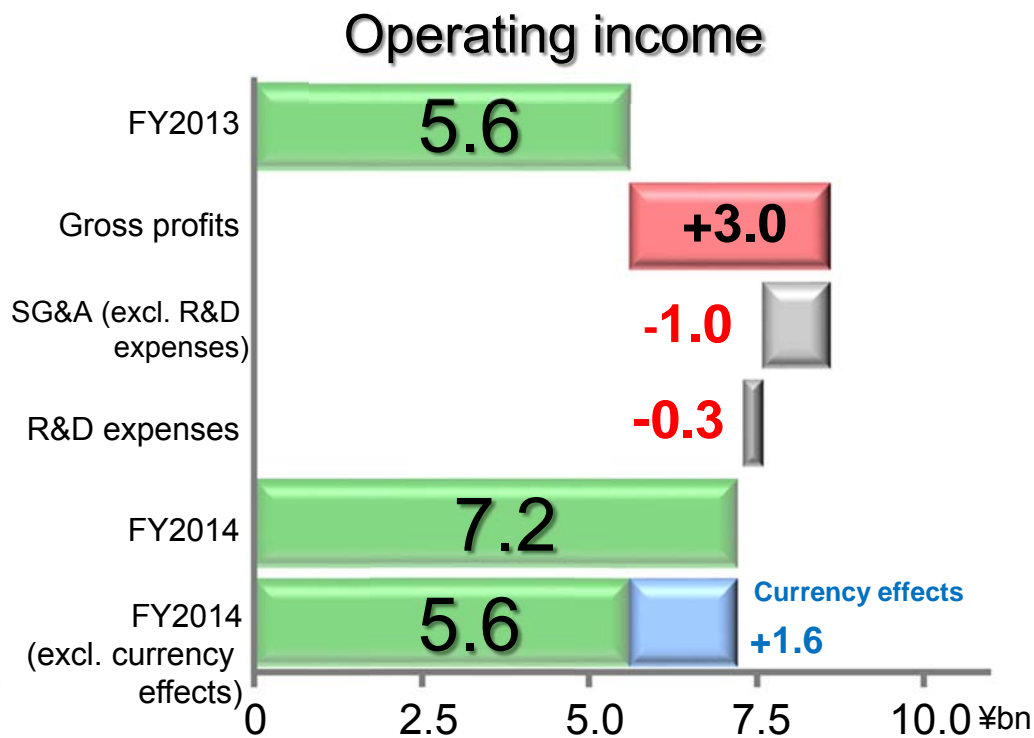
## FY2014: Analysis of YoY profit changes

**KYOWA KIRIN**



### Net sales

- Healthcare (+¥0.0bn):
  - 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 efforts to develop the market, and a decline in sales for use in food and beverages was due in part to unseasonable weather during the summertime.
- Pharma/industrial use (-¥0.4bn): Sales decreased from previous year due to inventory adjustments by major customers of amino acids, etc.
- Overseas sales (+¥1.4bn): Currency effects (+¥3.1bn)
  - U.S. (+¥0.2): Currency effects (+¥0.7), decline in amino acids for infusions due to slow sales of some customers, etc.
  - Europe (+¥1.4): Currency effects (+¥1.4), effects of increased demand for amino acids for infusions by some customers, etc.
  - Asia and others (-¥0.2): Currency effects (+¥1.0bn), temporary decrease in production of amino acids for infusions due to customers in China responding to pharmaceutical regulations, inventory adjustments of medical use amino acids, etc.
- Daiichi Fine Chemical (+¥1.2bn):
  - Increase in sales of generic bulk pharmaceuticals, etc.



### Operating income

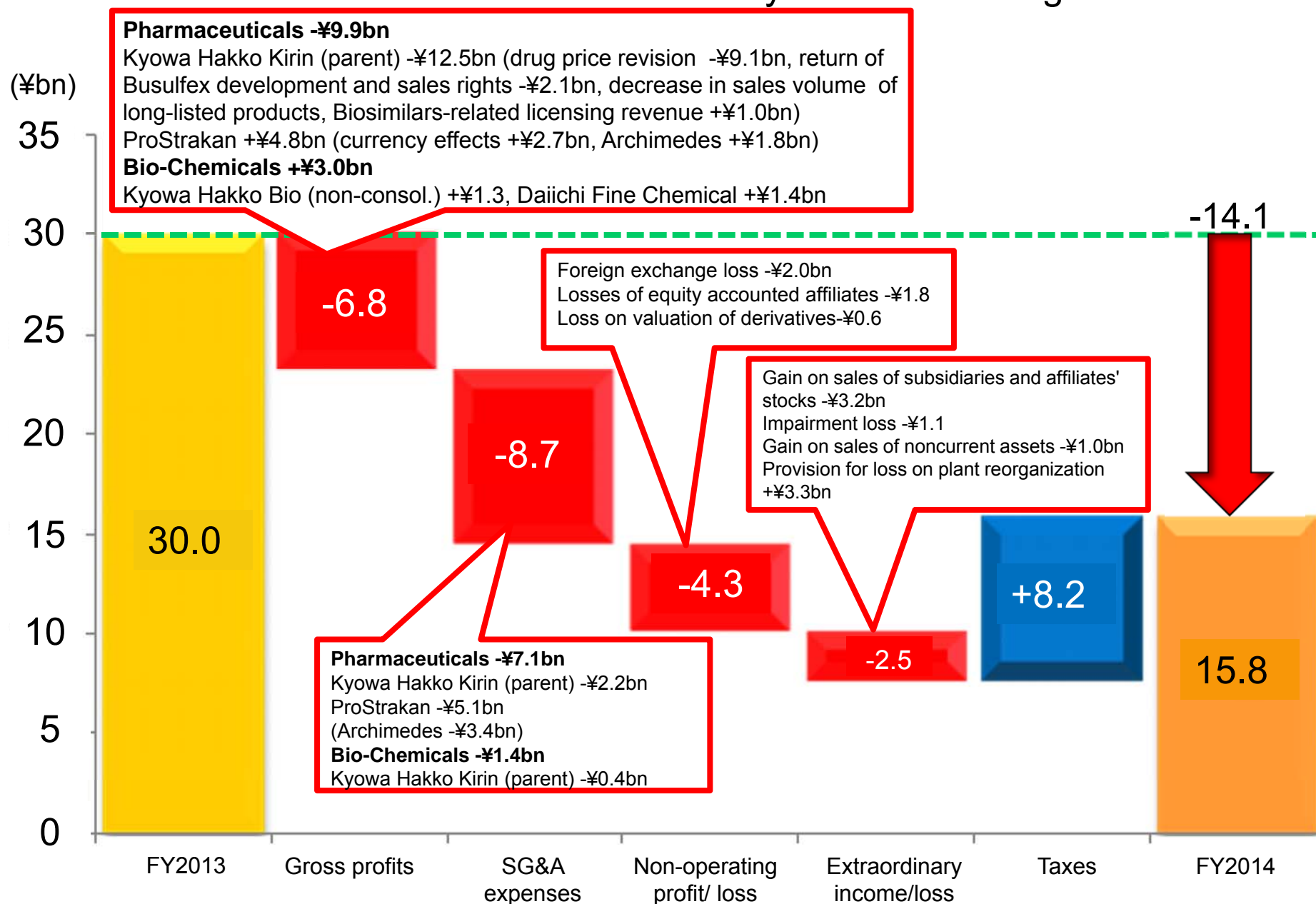
- Gross profits (+¥3.0bn): Currency effects (+¥2.0bn)
  - Increase in sales of highly-profitable products through overseas sales companies
  - Progress in structural reforms at Daiichi Fine Chemical, etc.
- SG&A (-¥1.0bn): Currency effects (-¥0.3bn)
  - Investment in systems for mail order sales, etc.

# Summary of full-year consolidated results:

## Analysis of YoY profit changes

**KYOWA KIRIN**

### FY2014 net income: Analysis of YoY changes



**Focus on market penetration of new products and  
sustained cash generation**  
**Continue to invest in R&D to raise business value**

(Unit: ¥bn)	FY2014 results	FY2015 forecasts	Change (%)
Net sales	333.4	354.0	20.5 (+6%)
Operating income <i>Operating margin</i>	36.1 10.8%	41.5 11.7%	5.3 (+15%)
Ordinary income	29.5	34.0	4.4 (+15%)
Net income	15.8	18.5	2.6 (+16%)

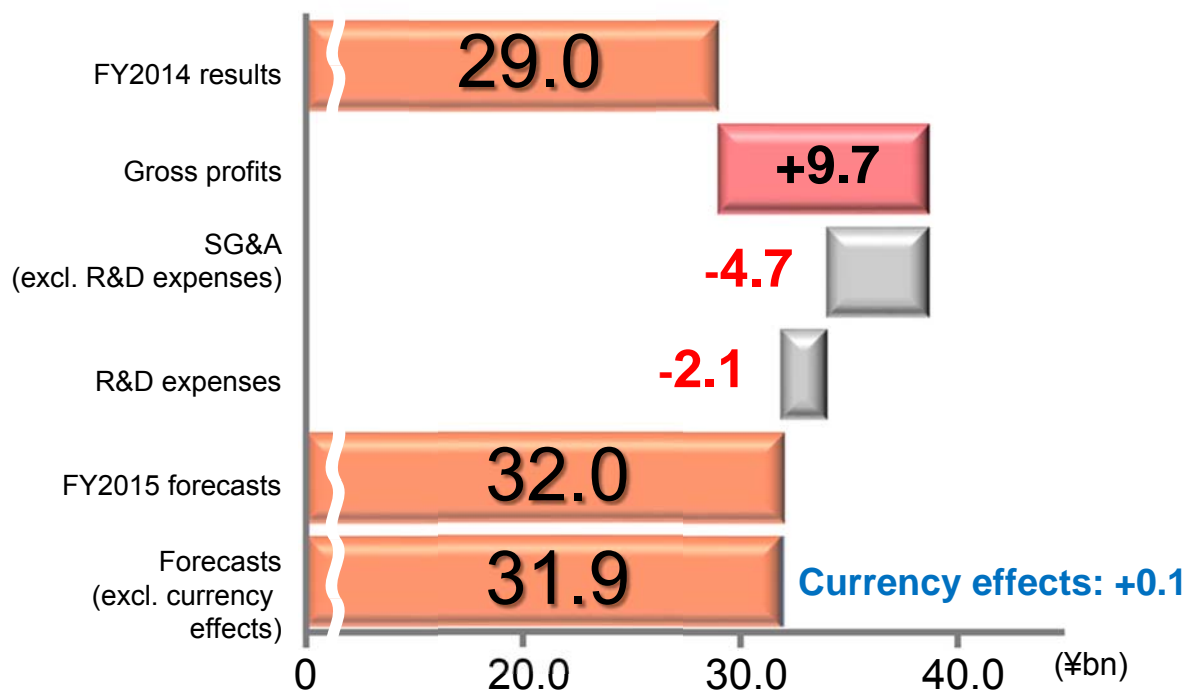


# Pharmaceuticals business FY2015 forecasts

**KYOWA KIRIN**

(Unit: ¥bn)	FY2014 results	FY2015 forecasts	Change
Net Sales	253.0	270.0	16.9 (+7%)
Operating income <i>Operating margin</i>	29.0 11.5%	32.0 11.9%	2.9 (+10%)

## [Operating income YoY change]



- Increase sales volumes, focused on new products such as G-Lasta® and Dovobet®
- Full-year contribution from Archimedes
- Increase in R&D expenses



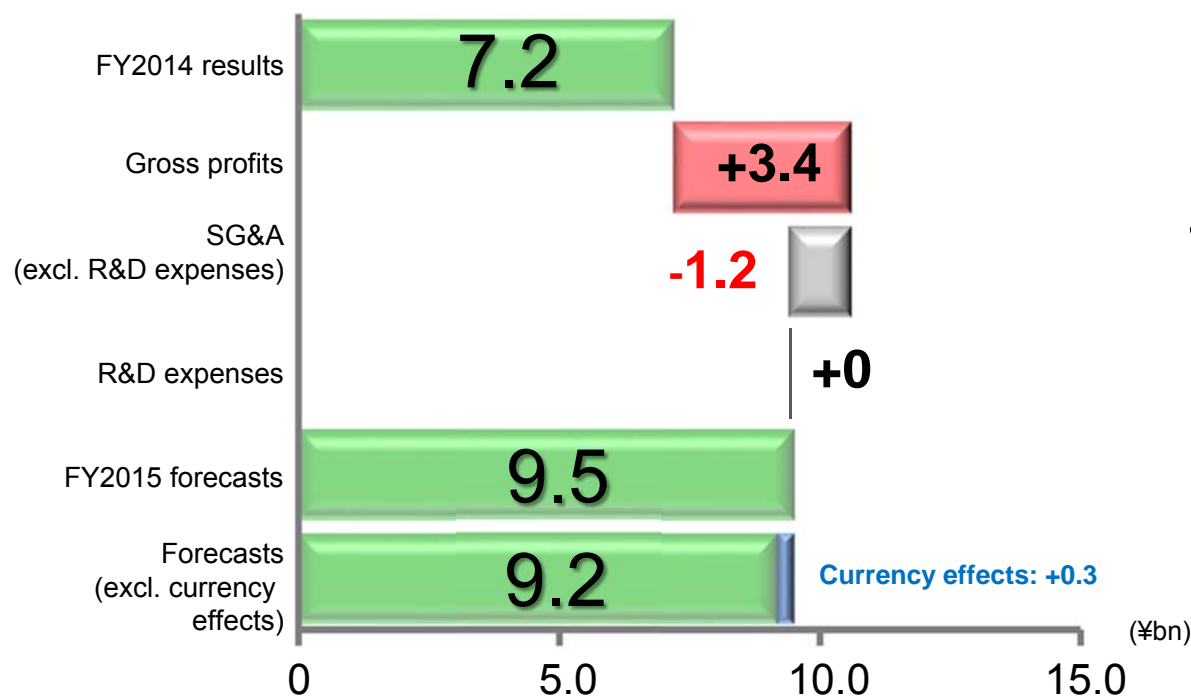
# Bio-Chemicals business FY2015 forecasts

**KYOWA KIRIN**

(Unit: ¥bn)	FY2014 results	FY2015 forecasts	Change
Net sales	83.9	89.0	5.0 (+6%)
Operating income Operating margin	7.2 8.7%	9.5 10.7%	2.2 (+31%)



## [Operating income YoY change]



- Increase in sales volumes of core products such as amino acids, nucleic acids and related substances, and ornithine
- Earnings recovery at Daiichi Fine Chemical



## Maximize corporate value = maximize shareholder value

### Global CMS (¥/\$/£/€)

Increase efficiency of group-wide treasury management and reduce currency risk

Introduced at U.S. and European subsidiaries in 2013



Expanded to Asia (Hong Kong/Singapore) in 2014

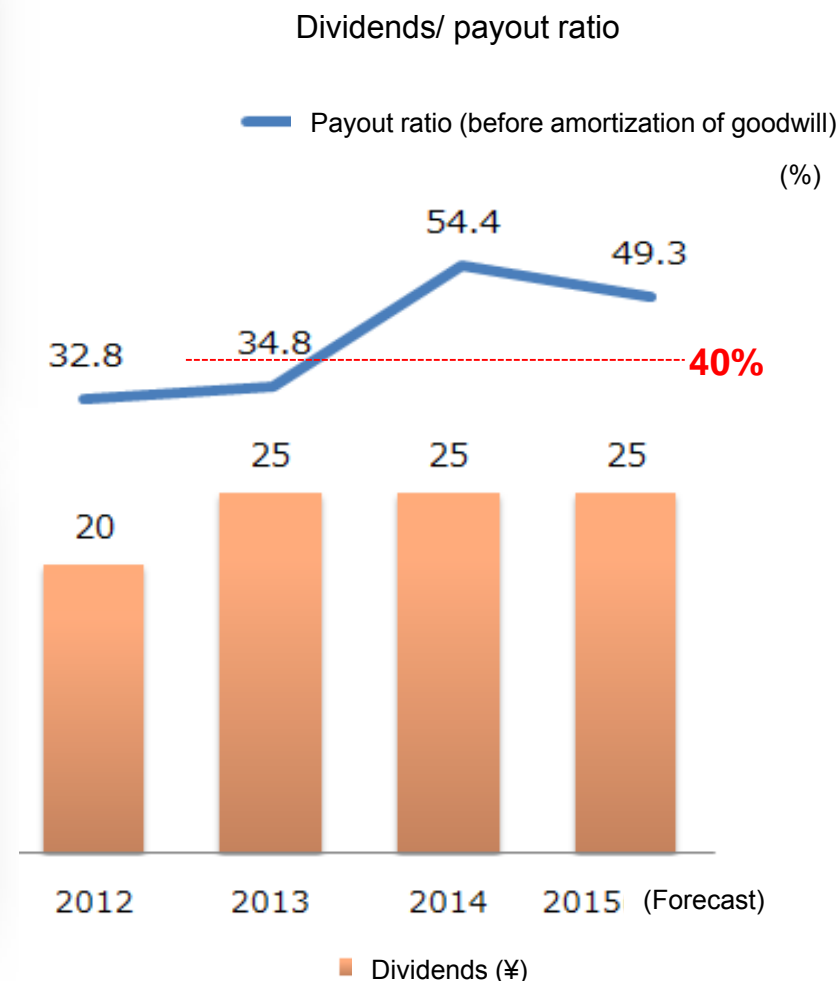
### Shareholder returns policy

Dividend payout ratio

Targeting a stable dividend payout ratio of 40% of profits before amortization of goodwill

Acquisition of treasury stock

Implement flexibly in response to market environment and finances



## R & D review

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- ☑ Approval for additional indications for humanized CCR4 monoclonal antibody POTELIGEO®
  - Untreated CCR4-positive adult T-cell leukemia/lymphoma (December)
  - Relapsed or refractory CCR4-positive peripheral T-cell lymphoma (March)
  - Relapsed or refractory CCR4-positive cutaneous T-cell lymphoma (March)
- ☑ Launch of sustained-duration G-CSF product G-Lasta® (November)
- ☑ NESP® granted orphan drug designation for treatment of anemia with myelodysplastic syndrome, application filed in March for approval for manufacture and sale, and approval acquired for additional indication (December)
- ☑ Start of Phase 3 trials of anti-IL-5 receptor humanized antibody, KHK4563 targeting asthma patients (April)
- ☑ Launch of Psoriasis Vulgaris drug Dovobet® (September)
- ☑ Application seeking approval for manufacture and sales of recombinant human antithrombin drug KW-3357 (July)

## KW-0761

Indication		Country/ region	Development stage	Annual incidence per disease, other
ATL	Untreated	Japan	Approved (Dec. 2014)	Japan: approx. 1,100 <sup>1</sup> patients
	Relapsed/ refractory	Japan	Approved (March 2012)	
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 <sup>2</sup> patients
PTCL	Relapsed/ refractory	Europe	Phase 2	US: approx. 3,600 <sup>3</sup> patients
CTCL	Relapsed/ refractory	Japan	Approved (March 2014)	Japan: PTCL/CTCL together: approx.2,000 <sup>2</sup> patients
CTCL	Relapsed/ refractory	US Europe Japan	Phase 3	US: approx. 1,500 <sup>3</sup> patients CCR4 positivity was not an inclusion criterion
Solid tumors		US	Phase 1	Entered clinical study collaboration with AstraZeneca of KW-0761 in combination with MEDI4736 and Tremelimumab

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

<sup>2</sup> Ministry of Health, Labour and Welfare: Number of patients on October 2011 clinical trial inspection chart 97, by basic illness

<sup>3</sup> SEER Data (2001-2007)

## 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 <sup>1</sup> patients Special Protocol Assessment agreed with FDA

## KRN23

Indication	Country/ region	Development stage	Patient numbers, other
X-linked Hypophosphatemia	U.S. Europe	<b>Phase 2</b> (Target: pediatrics)	U.S. <sup>2</sup> : Approx 3,000 pediatric patients, approx. 12,000 <sup>3</sup> adult patients Joint development with Ultragenyx Pharmaceutical
X-linked Hypophosphatemia/ Osteomalacia	U.S. Canada	<b>Phase1/2</b> (Target: adults)	
X-linked Hypophosphatemia/ Osteomalacia	Japan Korea	<b>Phase 1</b> (Target: adults)	

<sup>1</sup> Study by Decision Resources

<sup>2</sup> Patient numbers in Europe (5 main countries) are estimated to be at similar levels to those in the U.S.

<sup>3</sup> Estimate based on reported prevalence of 1 in 20,000 people

**Each development project is making strong progress  
in line with the initial plan**

	Development number	Reference medical product	Stage	Country/Region
Biosimilar	FKB327	Adalimumab (humira)	Phase 3	US, other
Biosimilar	FKB238	Bevacizumab (avastin)	Phase 1	UK
Biosimilar	Not disclosed	Not disclosed	Determined target reference medical product	

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



## **TOPICS**

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- 1. Mogamulizumab in immuno-oncology**
- 2. New market formation sought by G-Lasta®**
- 3. Further strengthen oncology category**

**Mogamulizumab (Japan trade name POTELIGEO®) is an anti-CCR4 antibody developed by Kyowa Hakko Kirin**

- The world's first therapeutic antibody utilizing POTE<sup>LL</sup>IGENT® enhanced antibody technology
- Indications approved in Japan for CCR4-positive hematopoietic organ tumors:
  - Adult T-cell leukemia-lymphoma
  - Relapsed or refractory cutaneous T-cell lymphoma
  - Relapsed or refractory peripheral T-cell lymphoma
- Proceeding with clinical development focused on hematopoietic organ tumors in Europe and the U.S.

Interest in cancer treatments based on the concept of immunoediting in recent years

Tregs expressing CCR4 contribute to suppression of immunoreactivity



 **POTE<sup>LL</sup>IGEO®** Injection

**New possibilities for Mogamulizumab in immuno-oncology**  
**Accelerate exploratory trials in solid tumors under**  
**Clinical trial collaboration agreements**

**AstraZeneca** 

**MEDI4736**

**Tremelimumab**



**PF-05082566**



**Bristol-Myers Squibb**

**Nivolumab**

**KYOWA KIRIN**

**Mogamulizumab**  
anti-CCR4

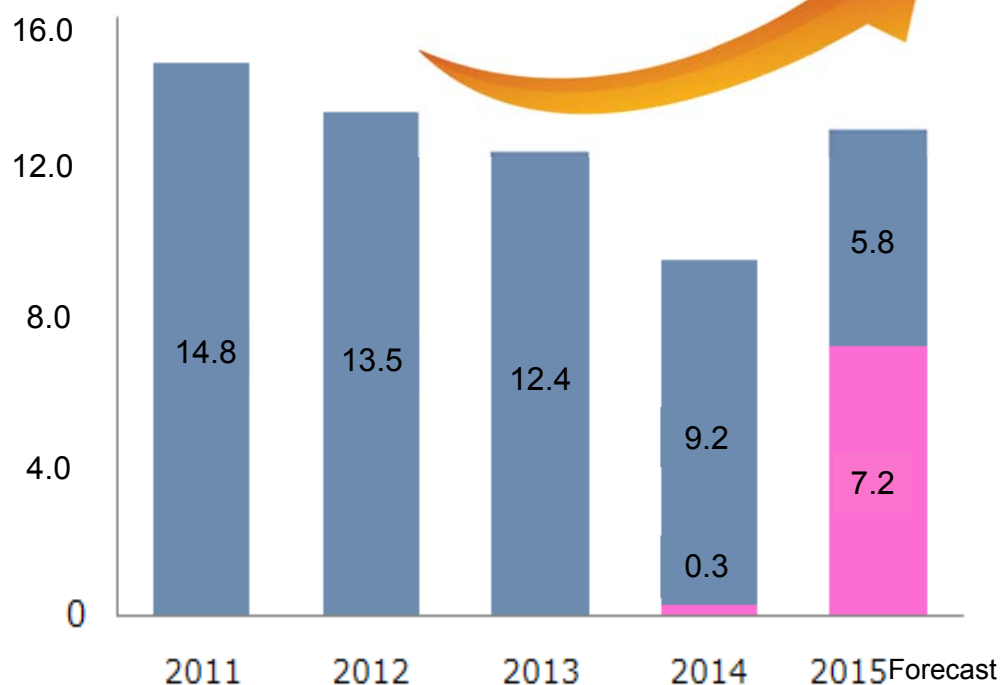
 **POTELIGEO**® Injection

Accumulation of drug information over the more than 20 years since the launch of GRAN®

Become clear category leader in this field with the launch of G-Lasta®

## Sales forecast to increase

(Unit: ¥bn)



■ G-Lasta® ■ GRAN®

**گران®** シリンジ/注射液  
75・150・M300

GRAN® Syringe/Injection: 75, 150, M300

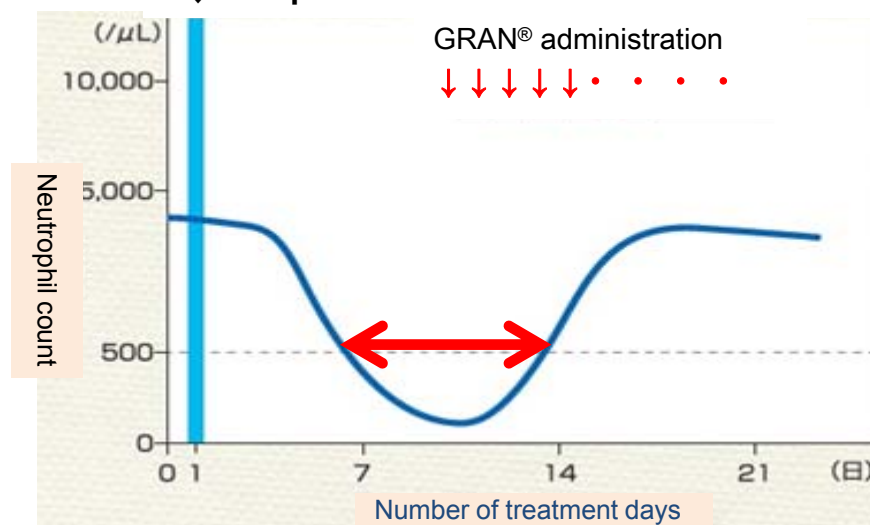
- Hematopoietic stem-cell transplantation

**ジーラスト®** 皮下注 3.6mg  
G-Lasta® subcutaneous injection 3.6mg

- For prevention of chemotherapy-induced febrile neutropenia
- Possibility of prophylactic administration with all cancers (before onset of febrile neutropenia)
- Plastic syringe formulation
- Prophylactic administration for patients undergoing chemotherapy with high risk of febrile neutropenia occurrence

## Indication for prophylactic administration gives support to patients and healthcare workers

↓ Completion of treatment with anti-cancer agents

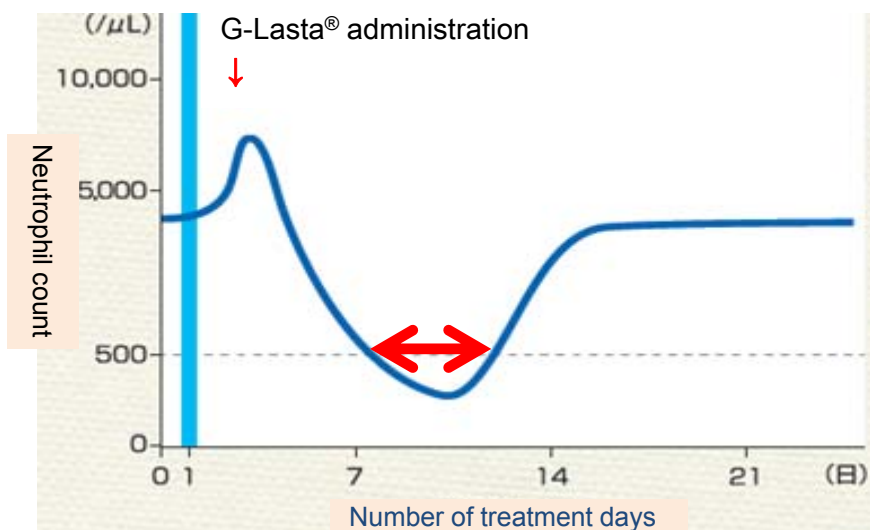


Convenience of treatment:

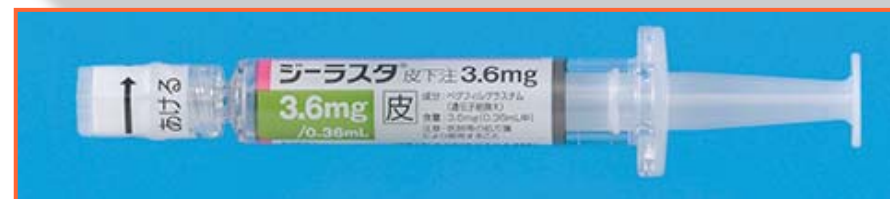
- Reduces the burden of drug administration on patients
- Decreases frequent hospital visits of outpatients undergoing chemotherapy

Merits of treatment:

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



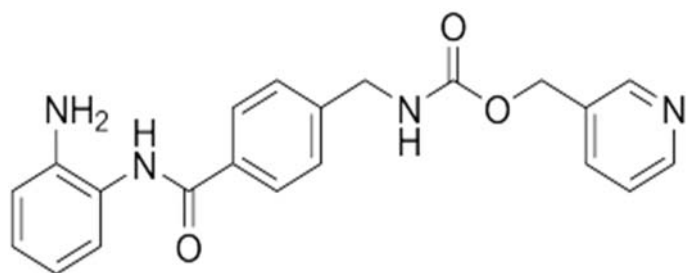
**Support hospitals and medical facilities**



## Entered license agreement for entinostat, a Class I selective HDAC inhibitor

### Overview of agreement with Syndax

- Date of agreement: December 19, 2014
- Scope: License agreement for exclusive rights to develop and commercialize entinostat
- Regions: Japan and South Korea
- Cost: Upfront payment of \$25 million. Agreement includes equity investment in Syndax



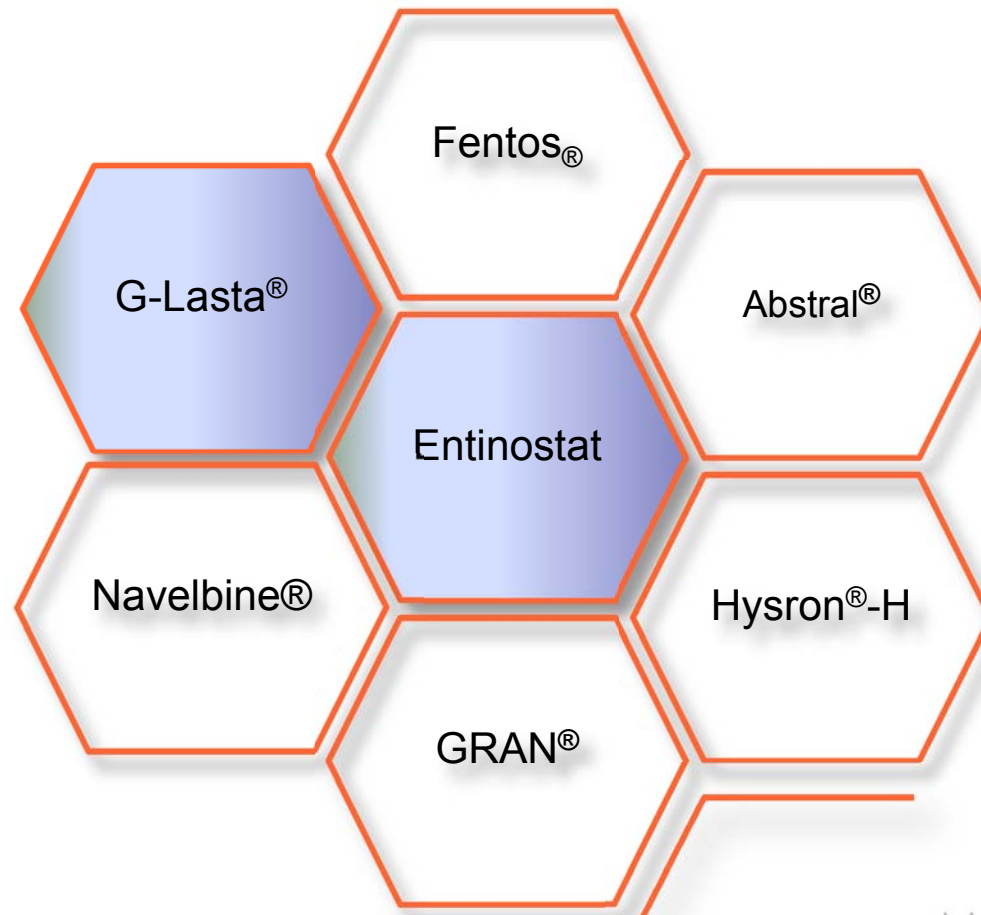
Chemical structure of entinostat

### In-progress Syndax Phase 3 trial of entinostat

- Target: Hormone receptor-positive metastatic breast cancer
- Administration: Entinostat administered once per week in combination with oral administration of exemestane
- Remarks: Designated as a Breakthrough Therapy by the FDA. Special Protocol Assessment agreement

## Expectation for synergies in oncology category Potential for use in combination with cancer immunotherapy

### Synergies centered on breast cancer treatment



### Cancer immunotherapy

Immune therapy combination drug  
entinostat

- Expectations for effectiveness against immunosuppressives MDSC and Treg

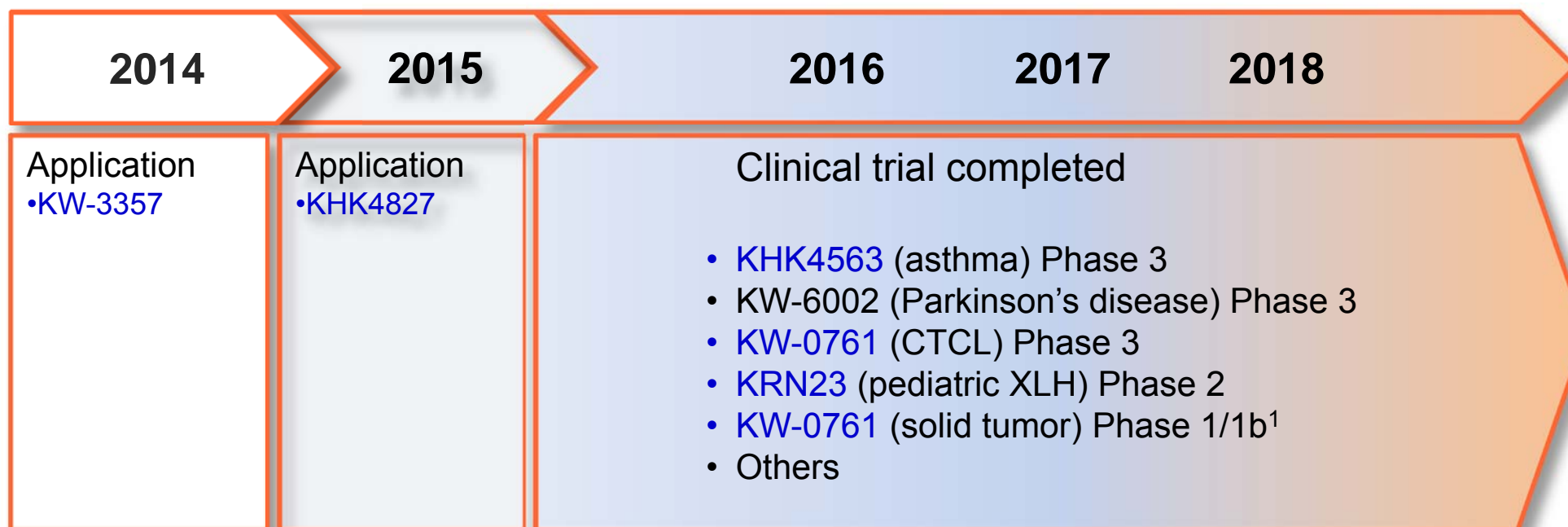


Syndax is currently conducting a clinical trial

- Target: NSCLC
- Administration: PD-1 antibody and combination treatment



**Close in on various milestones in 2016 and  
accelerate evolution towards GSP**



Notes:  
Biologics are in blue font.

2010  
onwards

**Reorganization plan for Japanese production facilities scheduled for  
completion in 2017**

<sup>1</sup>Trial based on joint development agreement with AstraZeneca



## Q & A session

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# **KYOWA KIRIN**

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**

# List of acronyms

APIs	Active Pharmaceutical Ingredients
ATL	Adult T-cell Leukemia/Lymphoma
CCR4	Chemokine ( C-C motif ) Receptor 4
CMS	Cash Management System
CTCL	Cutaneous T-Cell Lymphoma
G-CSF	Granulocyte - Colony Stimulating Factor
GSP	Global Specialty Pharmaceutical Company
HDAC	Histone Deacetylase
MDSC	Myeloid-Derived Suppressor Cell
MRs	Medical Representatives
NSCLC	Non Small Cell Lung Cancer
PD-1	Programmed Death -1
PD-L1	Programmed Death - Ligand 1
PPA	Purchase Price Allocation
PSK	ProStrakan
Treg	Regulatory T cell
PTCL	Peripheral T-Cell Lymphoma
XLH	X-linked Hypophosphatemic Rickets

# APPENDIX

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## Period average rate

Average exchange rate	FY2013 Results	2014 Results	Change	FY2015 Forecast
¥/\$	¥96	¥105	+ ¥9	¥109
¥/€	¥127	¥140	+¥13	¥139
¥/£	¥150	¥173	+¥23	¥178

## FY2014 currency effects (YoY)

Segment	Currency	Net sales	Operating income
Pharmaceuticals business	\$	+¥0.8bn	-¥0.0bn
	€	+¥0.1bn	+¥0.1bn
	£	+¥3.6bn	+¥0.2bn
Bio-Chemicals business	\$	+¥1.4bn	+¥0.9bn
	€	+¥1.5bn	+¥0.7bn
	£	-	-

# Appendix: Summary of FY2014 consolidated financial results and comparison with forecasts

**KYOWA KIRIN**

**One-time payment associated with licensing agreement, increase in R&D expenses associated with progress of overseas development**

(Unit: ¥bn)	FY2014 forecasts	FY2014 results	Change
Net sales	336.0	333.4	-2.6 (-1%)
Operating income <i>Operating margin</i>	43.0 12.7%	36.1 10.8%	-6.9 (-16%)
Ordinary income	35.0	29.5	-5.5 (-16%)
Net income	18.0	15.8	-2.2 (-12%)

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

# Appendix: Summary of FY2014 financial results by segment and comparison with forecasts

**KYOWA KIRIN**

**Pharmaceuticals business: Products licensed from Syndax, aggressive investment in overseas development**

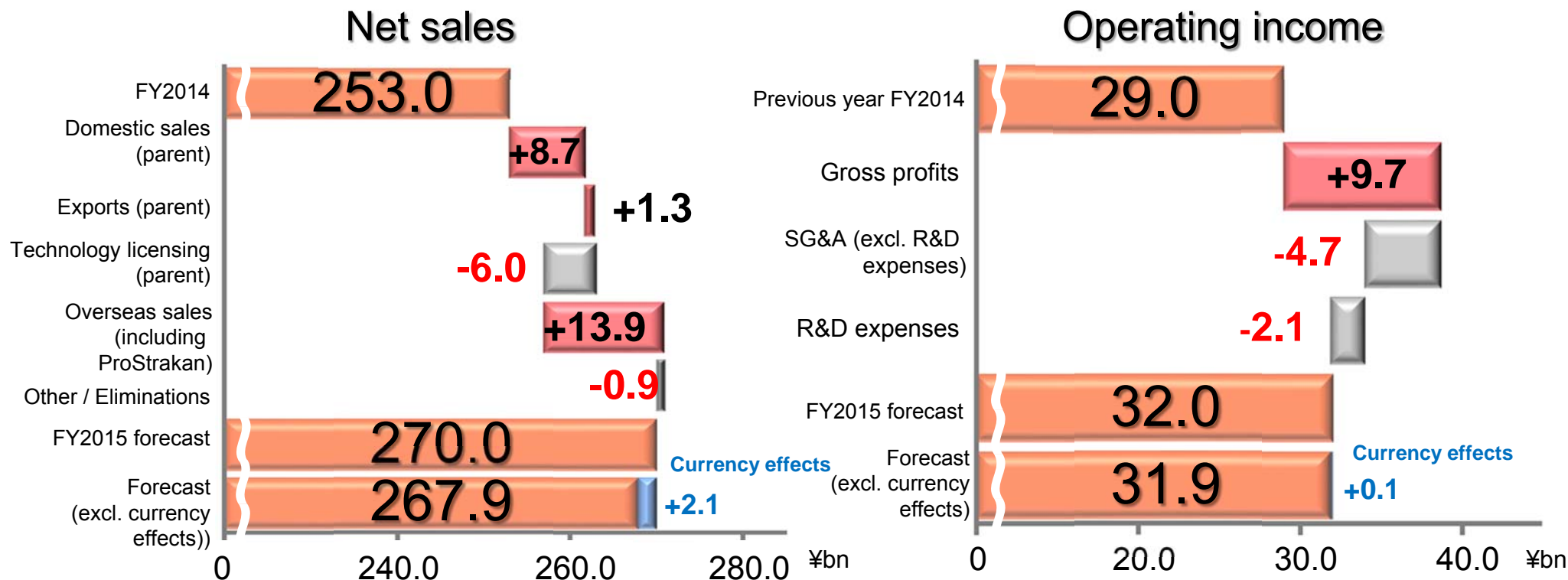
**Bio-Chemicals business: shipments of amino acids fell, in particular in Asia and the U.S.**

(Unit: ¥bn)		FY2014 forecasts	FY2014 results	Change
Pharmaceuticals business	Net sales	254.0	253.0	-1.0 (-0%)
	Operating income <i>Operating margin</i>	35.0 13.7%	29.0 11.5%	-6.0 (-17%)
Bio-Chemicals business	Net sales	85.0	83.9	-1.1 (-1%)
	Operating income <i>Operating margin</i>	8.0 9.4%	7.2 8.7%	-0.8 (-9%)

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

# Appendix: Pharmaceuticals business: FY2015 forecast: Analysis of YoY profit changes

**KYOWA KIRIN**



## Net sales

- Domestic pharmaceutical products (+¥8.7bn):
  - Products (shipments): G-Lasta® +¥6.8bn, Dovobet® +¥3.8bn, Onglyza® +¥3.3bn, NOURIAS® +¥2.8bn, ALLELOCK® -¥4.6bn, GRAN® -¥3.3bn, CONIEL® -¥2.5bn
  - NESP®: Taking into account expected impact from effects of drug price revisions and expansion of indications to MDS, aim for 101% sales in comparison to the previous year. No major changes to share expected.
- Exports (+¥1.3bn): 2016 shipments of olopatadine brought forward due to closure of Sakai plant in 2015, etc.
- Technology licensing, etc. (-¥6.0bn): Currency effects +¥0.2bn
  - Biosimilars-related (+¥6.0)
- Overseas sales (+¥13.9bn); Currency effects +¥1.8bn.
  - Expansion of ProStrakan's Abstral® and SANCUSO® etc., effects of consolidation of Archimedes +¥11.1bn

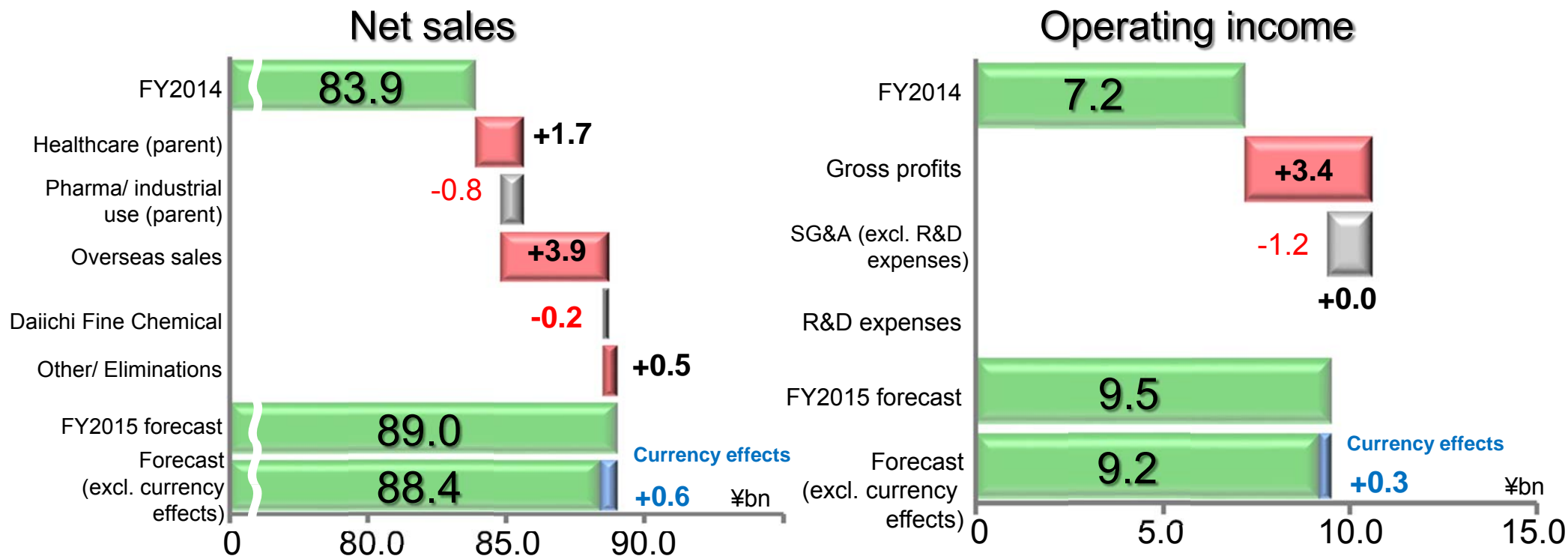
## Operating income

- Gross profits (+¥9.7bn):
  - Aim for increase income, offsetting decrease in licensing income with market penetration of new drugs in domestic market (G-Lasta®, Dovobet®, Onglyza®, NOURIAS®), expansion of ProStrakan's Abstral® and SANCUSO®, and effects of consolidation of Archimedes, etc.
- SG&A (-¥4.7bn):
  - Effects of consolidation of Archimedes
- R&D expenses (-¥2.1bn):
  - Increased overseas R&D expenses, etc.



# Appendix: Bio-Chemicals business: FY2015 forecast: Analysis of YoY profit changes

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## Net sales

- Healthcare (+¥1.7bn):
  - Mail order sales: Aggressively acquire regular customers through investment in sales promotion
  - Raw materials/OEM: Aim to expand sales for use in food and beverages and sports supplements
- Pharma/industrial use (-¥0.8bn): End of sales in some products, and other factors
- Overseas sales (+¥3.9bn): Currency effects (+¥0.6bn)
  - U.S. (+¥0.9): Currency effects (+¥0.3), Expand sales of amino acids for infusions, etc.
  - Europe (+¥1.0): Currency effects (-¥0.1), effects of increased demand for amino acids for infusions by some customers, etc.
  - Asia and others (+¥1.9bn): Currency effects (+¥0.4bn), forecast recovery from temporary decrease in production of amino acids for infusions due to customers in China responding to regulatory authorities, and recovery from inventory adjustments of medical use amino acids.
- Daiichi Fine Chemical (-¥0.2bn):
  - Sales of generic bulk pharmaceuticals will decrease but volume of sales of bulk pharmaceuticals to Kyowa Hakko Kirin will increase

## Operating income

- Gross profits (+¥3.4bn): Currency effects (+¥0.4bn)
  - Growth in overseas sales and mail order sales
  - Improvement in operating profit margin due to progress in structural reforms at Daiichi Fine Chemical, etc.
- SG&A (-¥1.2bn): Currency effects (-¥0.1bn)
  - Aggressive investment in sales promotion in mail order sales, etc.

# Appendix: Business combination accounting treatment

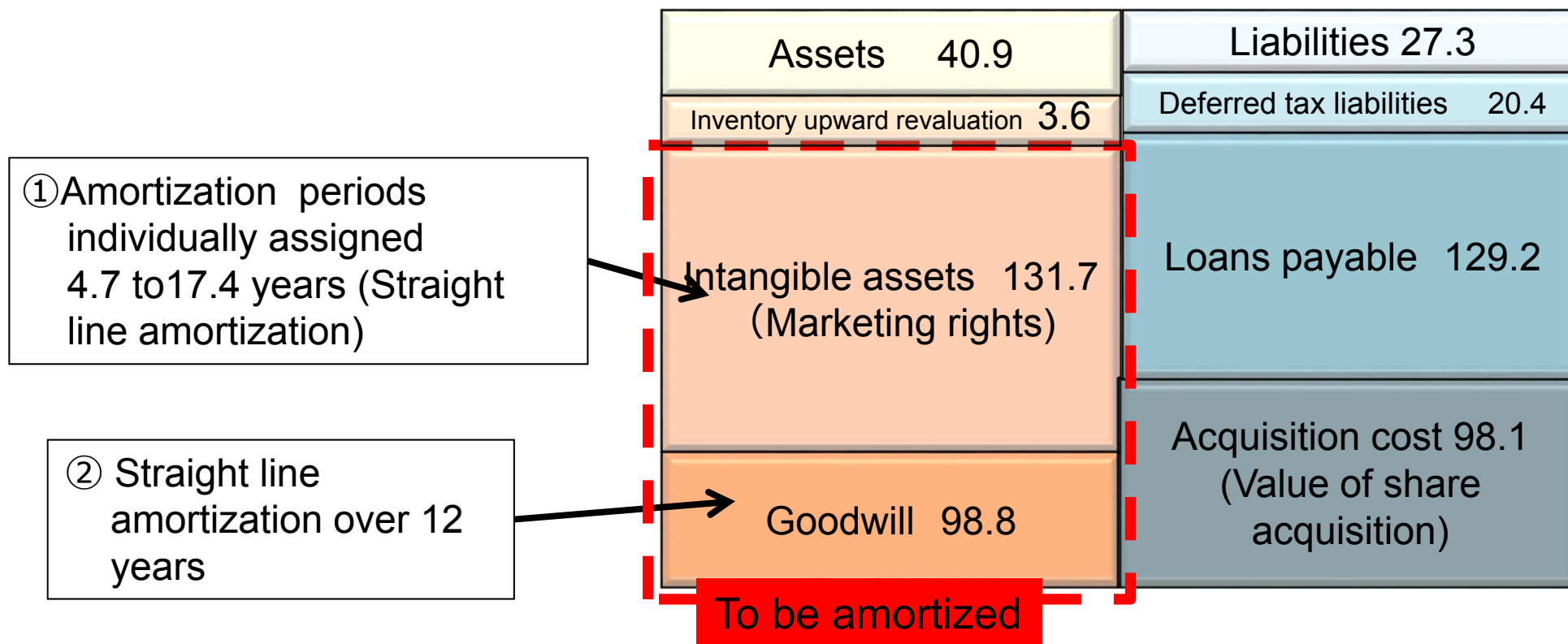
## Archimedes

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

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

(Unit: GBP million)



P&L effects of acquisition		2014 H2	FY 2015 forecasts
① Amortization of intangible assets	:	£ 5.3M	£ 12.0M
② Amortization of goodwill	:	£ 3.4M	£ 8.2M
③ Inventory upward revaluation	:	£ 3.6M	—
Total P&L effect	:	£ 12.3M	£ 20.2M

\*PPA: Purchase Price Allocation

# Appendix: Effect of consolidation of Archimedes

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## ProStrakan

(Unit: GBP million)

	FY2013 Results	FY2014 Results						
	Jan - Dec	Jan - Dec			Change amount	%	Jan - Dec latest forecasts	% of forecasts
		ProStrakan	Archimedes	Total				
Net sales	155.4	160.7	20.6	181.4	25.9	117%	179.4	101%
Cancer pain								
Abstral	47.1	55.8	-	55.8	8.7	119%	54.8	102%
Cancer pain								
PecFent	-	-	7.5	7.5	7.5	-	7.7	98%
Chemotherapy-induced nausea and vomiting drug								
Sancuso	13.8	14.0	-	14.0	0.2	101%	14.2	99%
Others	80.3	85.3	13.1	98.4	18.1	123%	97.1	104%
Product net sales (total)	141.2	155.2	20.6	175.9	34.6	125%	173.9	101%
Technology Out-Licensing and others	14.1	5.4	-	5.4	-8.6	39%	5.4	100%
Gross profit	116.5	-	-	129.1	12.6	111%	125.7	103%
Selling, general and administrative expenses *1	75.0	-	-	80.0	5.0	107%	81.8	98%
EBITDA *2	41.5	49.3	-0.2	49.1	7.5	118%	43.9	112%
Amortization of goodwill and marketing rights *1	39.9	40.3	8.9	49.2	9.2	123%	48.3	102%
Operating income	1.5	9.0	-9.1	-0.1	-1.6	-	-4.4	-

\*1 Amortization of goodwill and marketing rights is not included in Selling, general and administrative expenses  
Amortization of goodwill and marketing rights= Depreciation + amortization of goodwill

\*2 EBITDA=Operating income + depreciation + amortization of goodwill

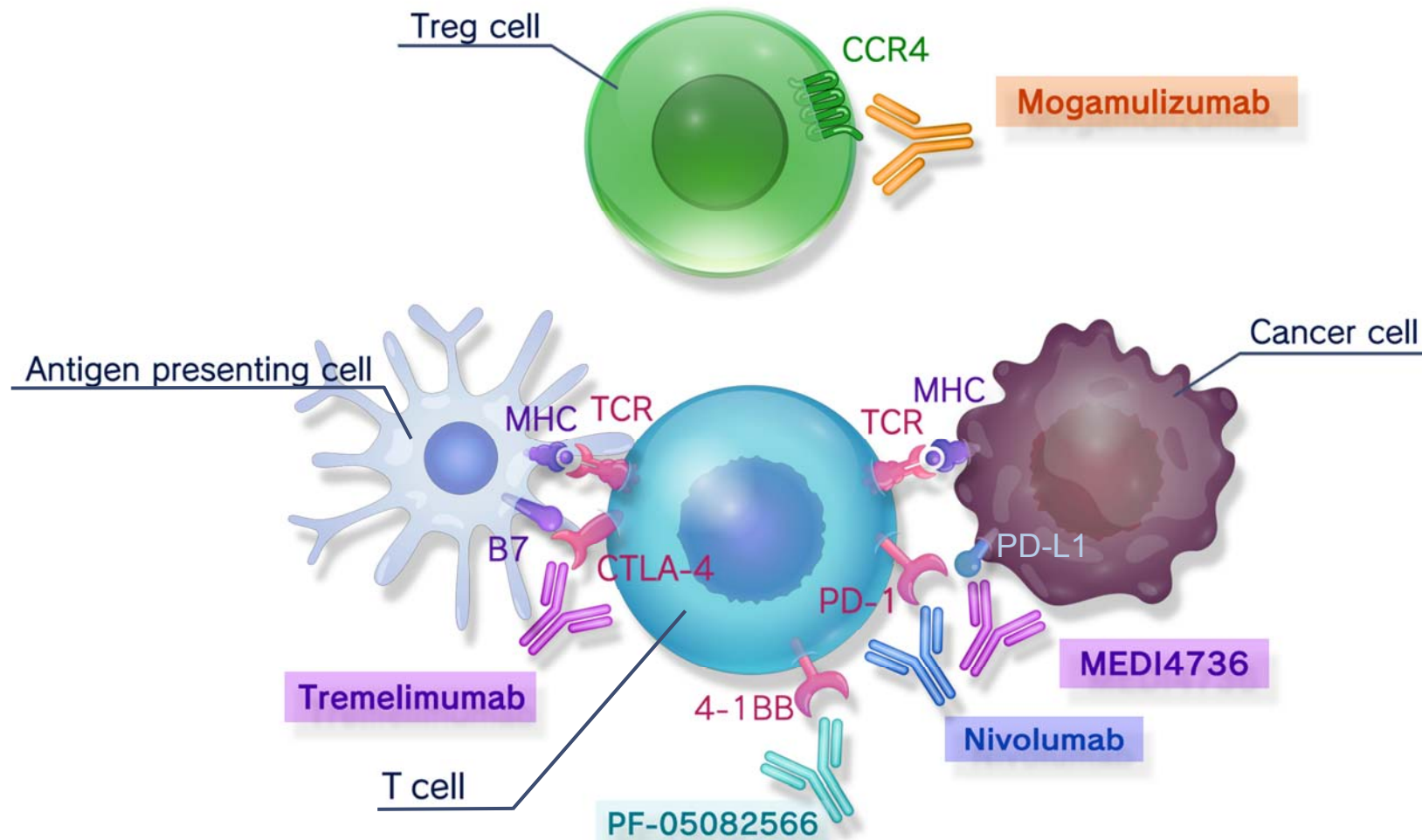
\*3 Archimedes was acquired by ProStrakan on August 5, 2014 and from August 2014, Archimedes' financial results

(Figures rounded down)

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# Appendix : Key antibody targets in cancer immunotherapy

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# Appendix: Development progress with outlicensed compounds

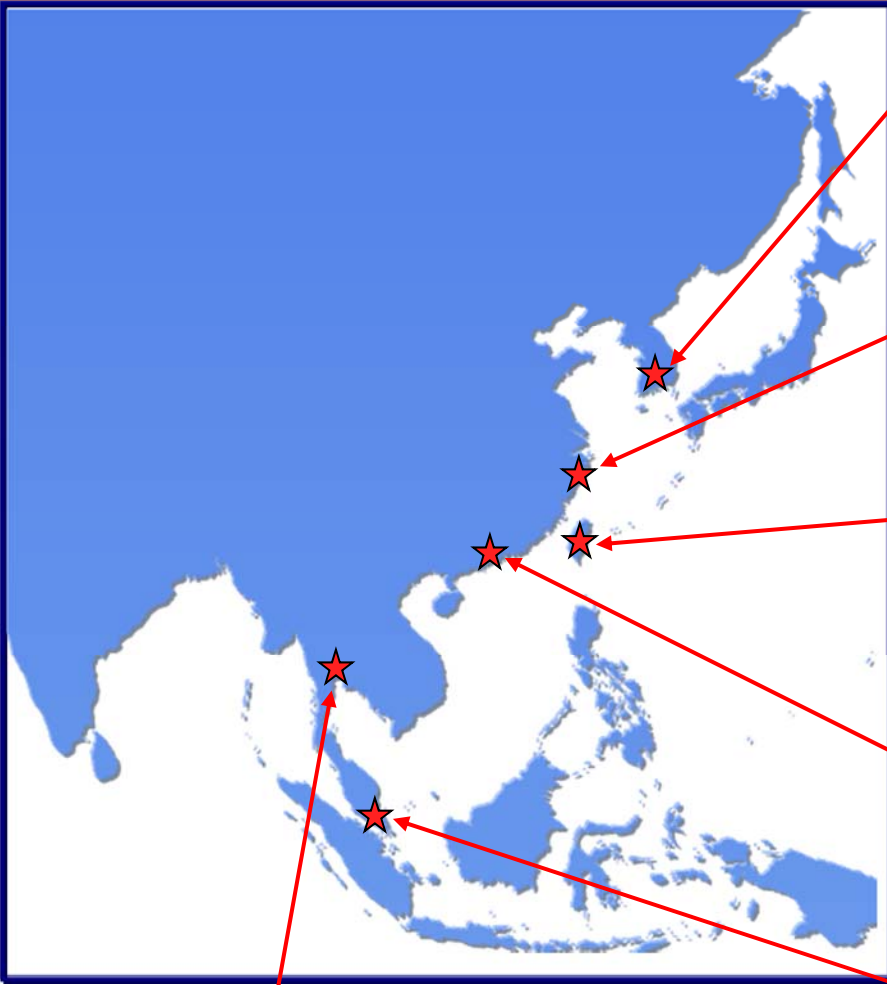
**KYOWA KIRIN**

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)
					COPD POTELLIGENT®
KRN5500	DARA				Peripheral neuropathy
RGI2001	REGiMMUNE	Phase1/2			Immunosuppressive
SAR252067	Sanofi				Ulcerative colitis and Crohn's disease (anti-LIGHT antibody)

(as of January 23, 2015)

# Appendix: Pharmaceuticals businesses in Asia

**KYOWA KIRIN**

Pharmaceuticals business across Asia	Consolidated subsidiary Year established	MRs	Net sales Products
	<b>South Korea</b> <b>Est. May 1991</b> Kyowa Hakko Kirin Korea Co.,Ltd.	30	<b>¥5.0bn</b> NESP®, GRAN®, Neulasta®, Renagel®, REGPARA®, ALLELOCK®, LEUNASE®, Mitomycin-C, Nplate®
	<b>China</b> <b>Est. Jun. 1997</b> Kyowa Hakko Kirin China Pharmaceutical Co., Ltd.	91	<b>¥3.3bn</b> GRAN®, ESPO®, CONIEL®
	<b>Taiwan</b> <b>Est. Apr. 1992</b> Kyowa Hakko Kirin (Taiwan) Co.,Ltd.	20	<b>¥3.1bn</b> NESP®, GRAN®, REGPARA®, Mitomycin-C, Neulasta®, LEUNASE®, Sancuso®, Nplate®
	<b>Hong Kong</b> <b>Est. Aug. 1993</b> Kyowa Hakko Kirin (Hong Kong) Co., Ltd.	7	<b>¥1.0bn</b> Aranesp®, REGPARA®, Renagel, Nplate®, Mitomycin- C, LEUNASE®, Sancuso®
	<b>Singapore</b> <b>Est. Mar. 2005</b> Kyowa Hakko Kirin (Singapore) Pte.Ltd.	10	<b>¥0.5bn</b> NESP®, Peglasta®, GRAN®, REGPARA®, Mitomycin-C, LEUNASE®, Nplate®, Sancuso®
<b>Thailand (non-consolidated)</b> Kyowa Hakko Kirin (Thailand) Co., Ltd.			

(As of Dec. 31, 2014)