

**Results Presentation**

**Fiscal 2014 First Quarter**

**(January 1, 2014 – March 31, 2014)**

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

## Business overview

Kazuyoshi Tachibana, Managing Executive Officer

## Financial review

Kazuyoshi Tachibana, Managing Executive Officer

## R & D review

Yoichi Sato, Managing Executive Officer  
Vice President, Head of R&D Division

## 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, risks associated with R&D investment, intellectual property risks, risk of side effects, risks related to pharmaceutical regulations, various legal regulation risks, risks of changes to foreign exchange rates, as well as disaster-related and accident-related risks.*

*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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- Received approval for additional indications for relapsed or refractory CCR4-positive PTCL<sup>1</sup> and CTCL<sup>2</sup> for POTELIGEO® (March)
- NESP® granted orphan drug designation for the treatment of anemia with myelodysplastic syndrome and application filed for approval for manufacture and sale (March)
- Sancuso® countries and regions of sale are expanding according to plan. The drug is sold in Europe by ProStrakan
- KHK4563 included in global trial conducted by AstraZeneca PLC /MedImmune, LCC. (April)

<sup>1</sup>PTCL: Peripheral T-Cell Lymphoma

<sup>2</sup>CTCL: Cutaneous T-Cell Lymphoma

## Financial review

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# Summary of FY2014 Q1 results (consolidated)

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Compared to FY13 Q1, sales and profits declined due to large decline in licensing revenue  
Compared to forecast, Q1 started strongly and according to plan

(Unit: billion yen)	FY2013 Q1	FY2014 Q1	Change	2014 Forecast	Rate of achievement of forecast
Net sales	86.6	86.0	-0.5	337.0	25.5%
Operating income <i>Operating margin</i>	14.4 (16.7%)	12.4 (14.5%)	-2.0	41.0	30.2%
Ordinary income	14.8	12.0	-2.7	35.0	34.2%
Net income	10.4	6.3	-4.1	20.0	31.5%

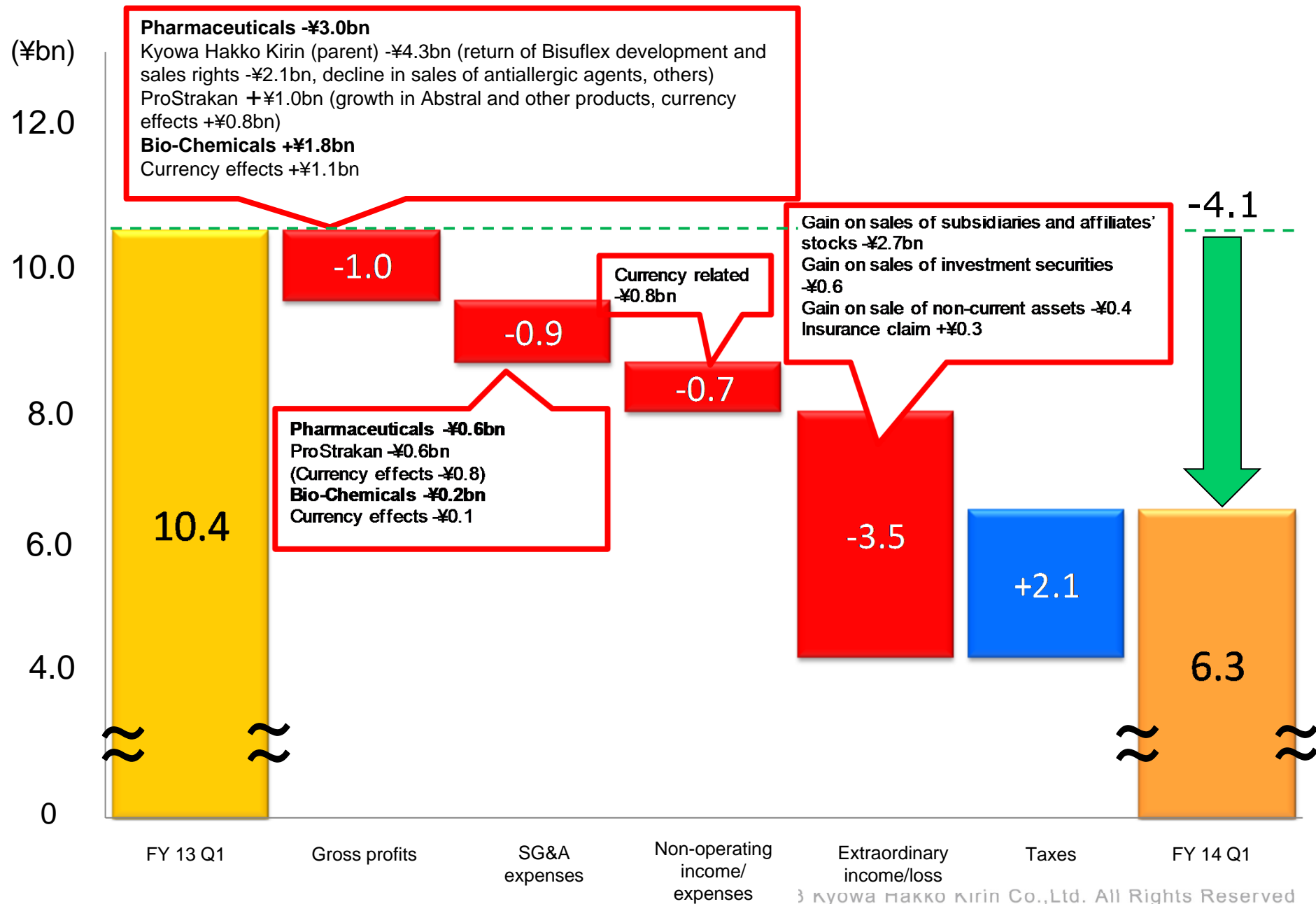
(Profits are stated after amortization of goodwill)

- ✓ The decline in ordinary income was due to lower operating income, the booking of 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 previous fiscal year, and other factors.

# Summary of FY2014 Q1 results (consolidated): Analysis of YonY profit changes

**KYOWA KIRIN**

## Q1 net income: Analysis of YonY changes





# Summary of FY2014 Q1 financial results by segment

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In the Pharmaceuticals business, sales and profits declined due to a YonY decrease in sales of antiallergic drugs as a result of lower amounts of airborne pollen, and a decline in licensing revenue.

In the Bio-Chemicals business, sales and profits increased due in particular to steady sales of pharmaceutical-use amino acids and a result of yen weakness

(Unit: ¥bn)		FY2013 Q1	FY2014 Q1	Change
Pharmaceuticals business	Net sales	67.4	63.1	-4.2 (-6%)
	Operating income <i>Operating margin</i>	13.0 19.4%	9.4 14.9%	-3.6 (-28%)
Bio-chemicals business	Net sales	19.9	23.5	+3.5 (+18%)
	Operating income <i>Operating margin</i>	1.4 7.4%	3.0 12.9%	+1.5 (+106%)

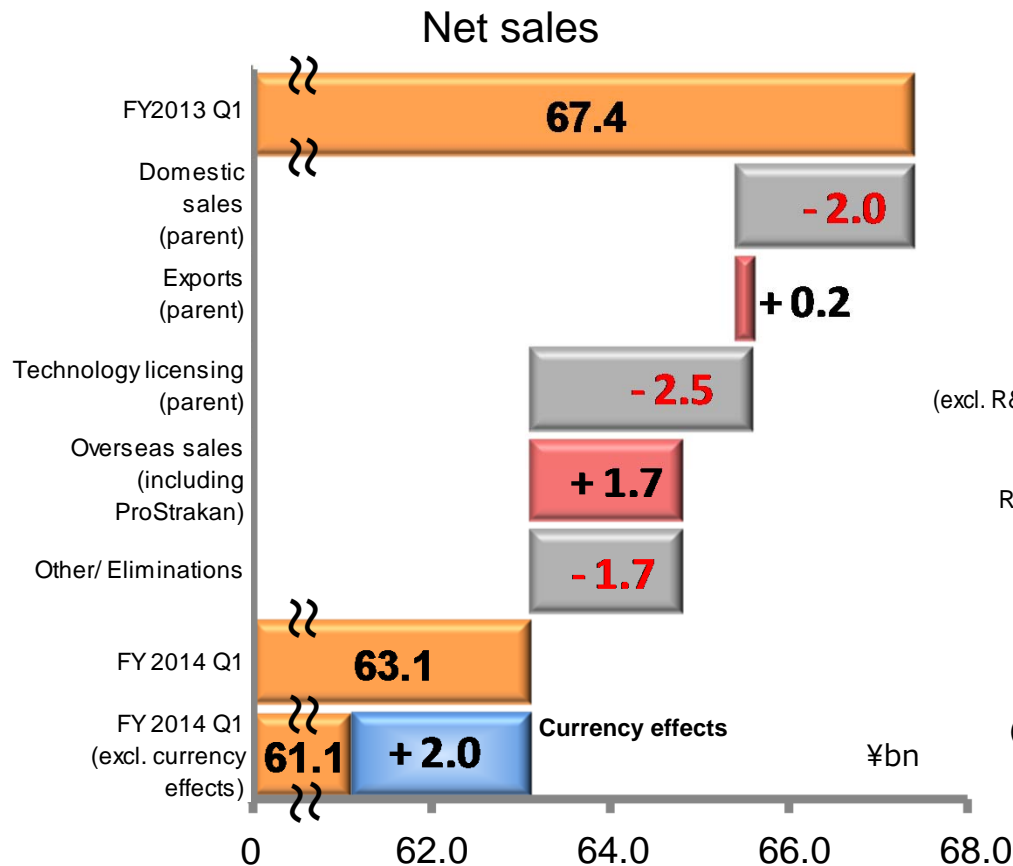
(Profits are stated after amortization of goodwill)

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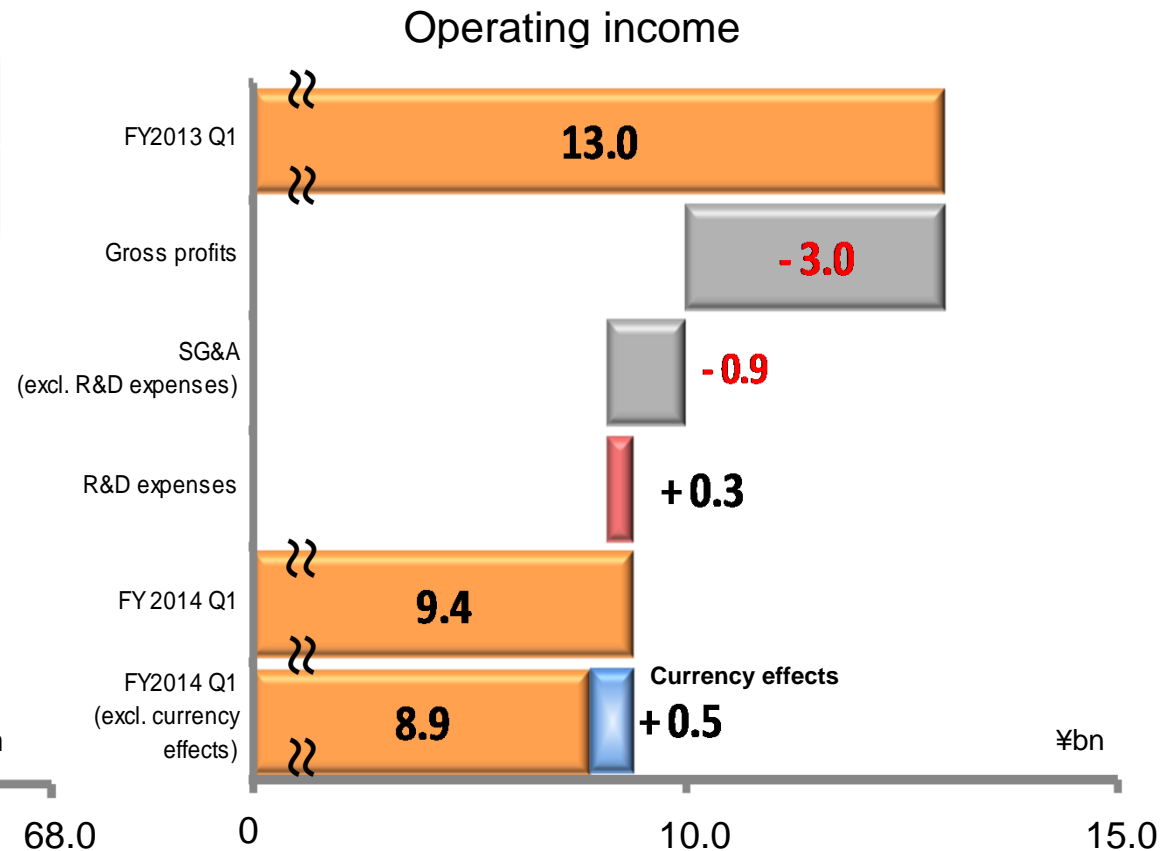
# Pharmaceuticals business:

## FY2014 Q1: Analysis of YonY profit changes

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- Domestic pharmaceutical products (-¥2.0bn):
  - Products (shipments): NESP® +¥1.5bn, REGPARA® +¥1.4bn, ASACOL® +¥0.4bn, ALLELOCK® -¥2.3, Patanol® -¥2.3bn, GRAN® -¥0.4bn
  - NESP®: 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 (+¥0.2bn): Currency effects, etc.
- Technology licensing, etc. (-¥2.5bn)
  - Decrease in lump-sum payment (-¥2.1bn) reflecting return of Bisulflex development and sales rights in the previous fiscal year; etc.
- Overseas sales (+¥1.7bn); Currency effects +¥1.5bn
  - ProStrakan +¥0.3bn (excl. currency effects), etc.
- Other (-¥1.7bn);
  - Decrease in sales as a result of transfer of consolidated subsidiary Chiyoda Kaihatsu's chemicals logistics business on September 1, 2013 -¥1.6bn




- Gross profits (-¥3.0bn):
  - Decrease in lump-sum payments reflecting return of Bisulflex development and sales rights in the previous fiscal year; and decline in sales of antiallergic agents, and other factors, could not be offset by ProStrakan's growth
- SG&A (-¥0.9bn):
  - Currency factors led to an increase in costs at ProStrakan and other overseas distributors
- R&D expenses (+¥0.3bn): Decrease in depreciation and amortization, etc.

# Pharmaceuticals business:

## Domestic sales of key products

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**Some products were impacted by generics and biosimilars, but sales in the nephrology category exceeded forecasts and overall targets were achieved in the domestic business**

Product name/ Exports / Technology out- licensing	FY2013 Q1 (a) <sup>1</sup>	FY2014 Q1 (b) <sup>1</sup>		Change (b)-(a)	Reason for change	Rate of progress (%) <sup>2</sup>
<b>NESP®</b>	<b>10.6</b>	<b>12.1</b>		<b>1.5</b>	Decrease due to temporary decline in shipments in FY 2013 Q1. Strong performance this year.	<b>46</b>
<b>REGPARA®</b>	<b>3.0</b>	<b>4.5</b>		<b>1.4</b>	Steady market penetration Rush demand ahead of drug price revision	<b>59</b>
<b>ALLELOCK®</b>	<b>10.7</b>	<b>8.4</b>		<b>-2.3</b>	Decrease in airborne pollen count Market penetration of generics	<b>60</b>
<b>Patanol®</b>	<b>9.4</b>	<b>7.1</b>		<b>-2.3</b>	Decrease in airborne pollen count	<b>82</b>
<b>GRAN®</b>	<b>2.5</b>	<b>2.0</b>		<b>-0.4</b>	G-CSF market contraction Market penetration of biosimilars	<b>46</b>
<b>Exports</b>	<b>3.2</b>	<b>3.4</b>		<b>0.2</b>		<b>57</b>
<b>Technology out-licensing</b>	<b>4.8</b>	<b>2.0</b>		<b>-2.8</b>	Licensing revenue in FY 2013 Q1 benefited from one –time factor of return of Busulfex development and sales rights	<b>43</b>

<sup>1</sup>Unit: ¥bn, figures rounded down

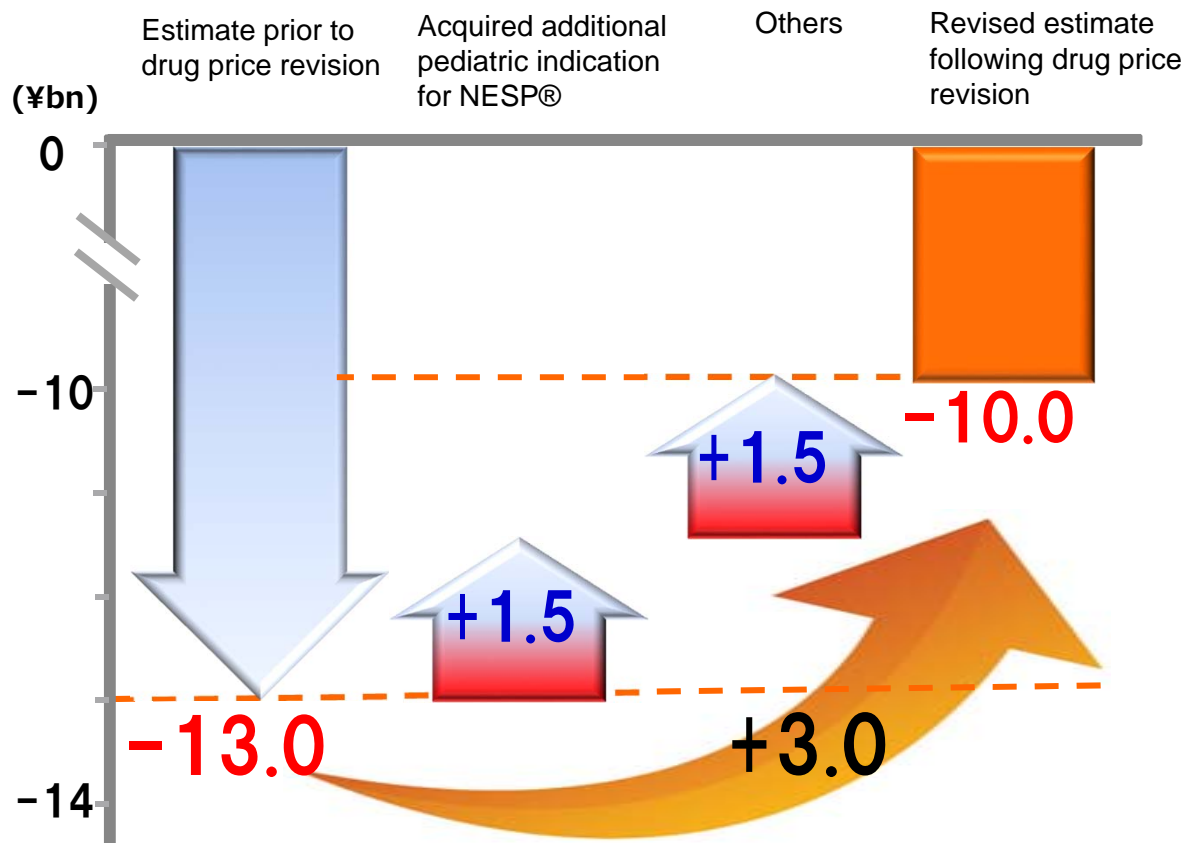
<sup>2</sup>Rate of progress compared to 2014 H1 sales forecasts (as of January 31, 2014). Figures rounded down.

# Pharmaceutical business: Impact of drug price revision in FY 2014

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Compared to initial forecast operating income around +¥3bn  
Main reason for lower than expected effect was  
additional pediatric indication for NESP<sup>®</sup>

## Impact of drug price revision on operating income - Review of targets from start of period -



## Products developed under New Premium System\*

REGPARA<sup>®</sup>  
Fentos<sup>®</sup>  
POTELIGEO<sup>®</sup>  
ASACOL<sup>®</sup>  
Patanol<sup>®</sup>  
NOURIAST<sup>®</sup>  
Others

Rush demand seen for some  
products

Additional long term NHI product listing  
GRAN<sup>®</sup>  
ALLELOCK<sup>®</sup>

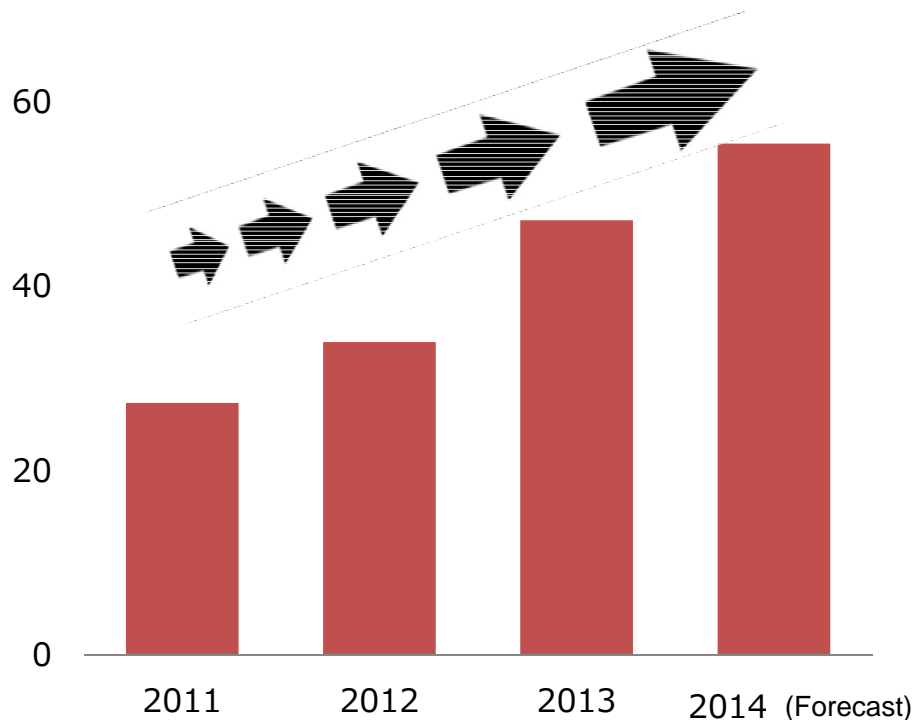
\*The New Premium System for the Promotion of Innovative Drug Discovery and Resolution of Off-label Use

# Pharmaceuticals business:

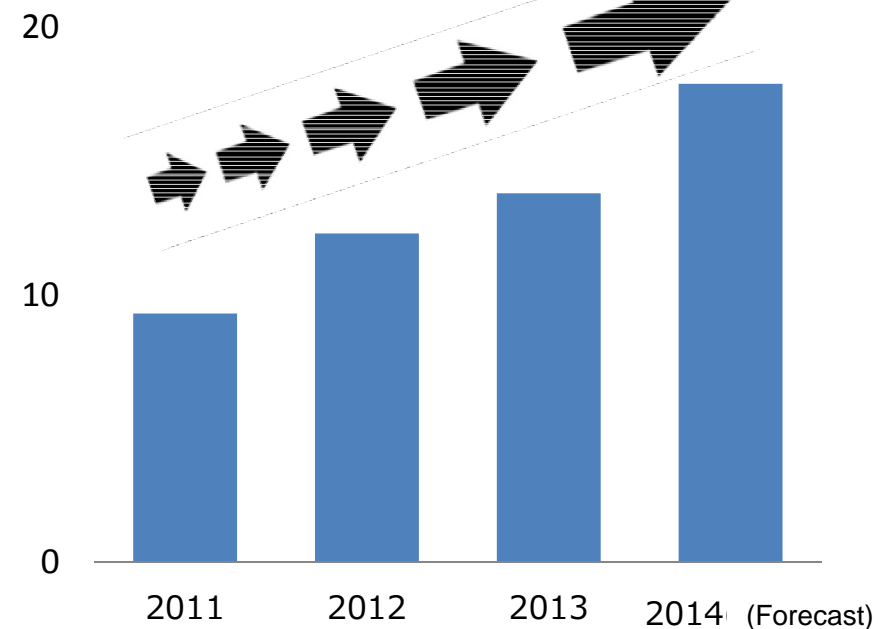
ProStrakan steadily developing as contributor to group profit **KYOWA KIRIN**

Continuing growth trend with strategy that leverages strong marketing ability  
Achieved steady market penetration with growth drivers Abstral® and Sancuso®

 **Abstral**



 **Sancuso®**  
(Granisetron Transdermal System)



Unit : £ million

# Pharmaceuticals business: Biosimilars development update

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**Phase 1 trials for FKB327 progressing steadily in the UK  
Preparation underway for start of phase I trials for FKB238 within the year**

	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

## **Accelerate development in Biosimilars business**

### **Branch opening**

Name: Europe Branch

Location: Galashiels, UK

Purpose: Development of biosimilar products

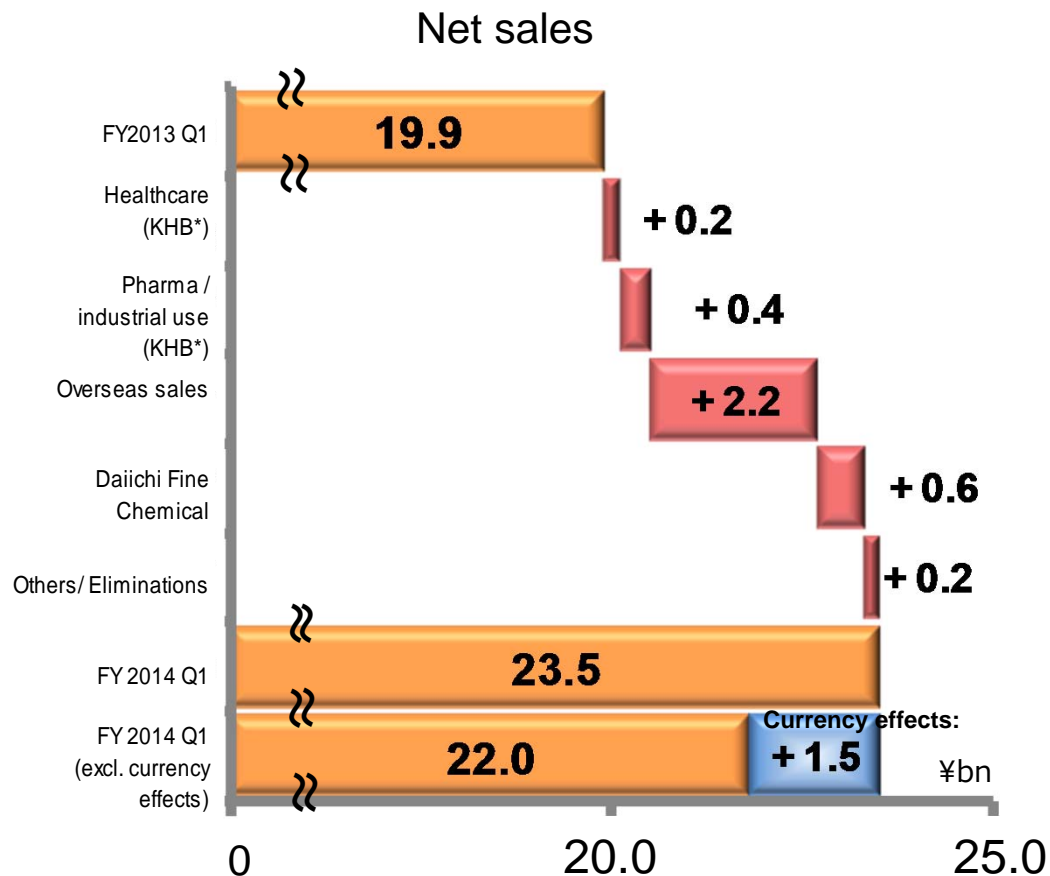


Note: Biosimilar pharmaceutical products are developed by *FUJIFILM KYOWA KIRIN BIOLOGICS* Co., Ltd.

# Bio-Chemicals business:

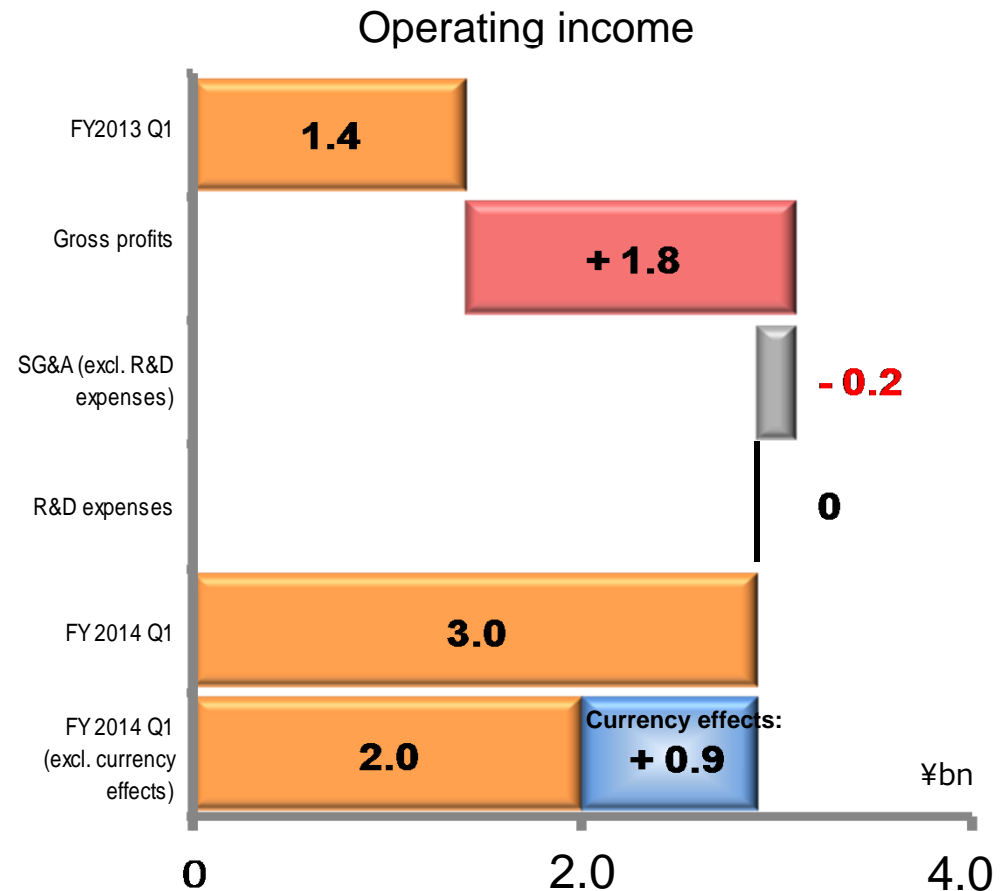
## FY2014 Q1: Analysis of YonY profit changes

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Net sales

- Healthcare (+¥0.2bn):
  - Mail order sales were strong and increased from the previous year
  - Raw materials/OEM: Increased from the previous year due in part to launch of new products by key customers
- Pharma/industrial use (+¥0.4bn): Raw materials for generic pharmaceuticals strong, etc.
- Overseas sales (+¥2.2bn): Currency effects (+¥1.5bn)
  - U.S.: Currency effects (+¥0.2), impact of intensifying competition in sales of some raw materials for supplements (-¥0.1)
  - Europe: Currency effects (+¥0.6), inventory adjustments, etc. by some customers (-¥0.1)
  - Asia and others: Currency effects (+¥0.6bn), Increase in income due to early shipments of some products to China (+¥0.9bn)
- Daiichi Fine Chemical (+¥0.6bn):
  - Difference in timing of receipt of products by major customers, etc.



Operating income

- Gross profits (+¥1.8bn): Currency effects (+¥1.1bn)
  - Higher profits as a result of increase in net sales
- SG&A (-¥0.2bn): Currency effects (-¥0.1bn)

\*KHB: Kyowa Hakko Bio



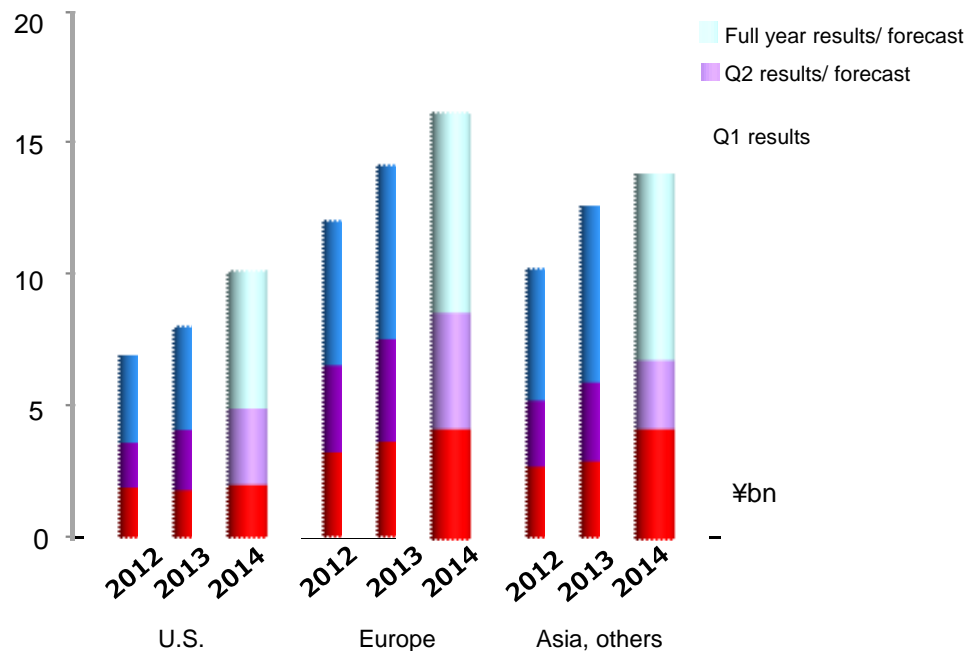
# Bio-Chemicals business: Strengthening of revenue base

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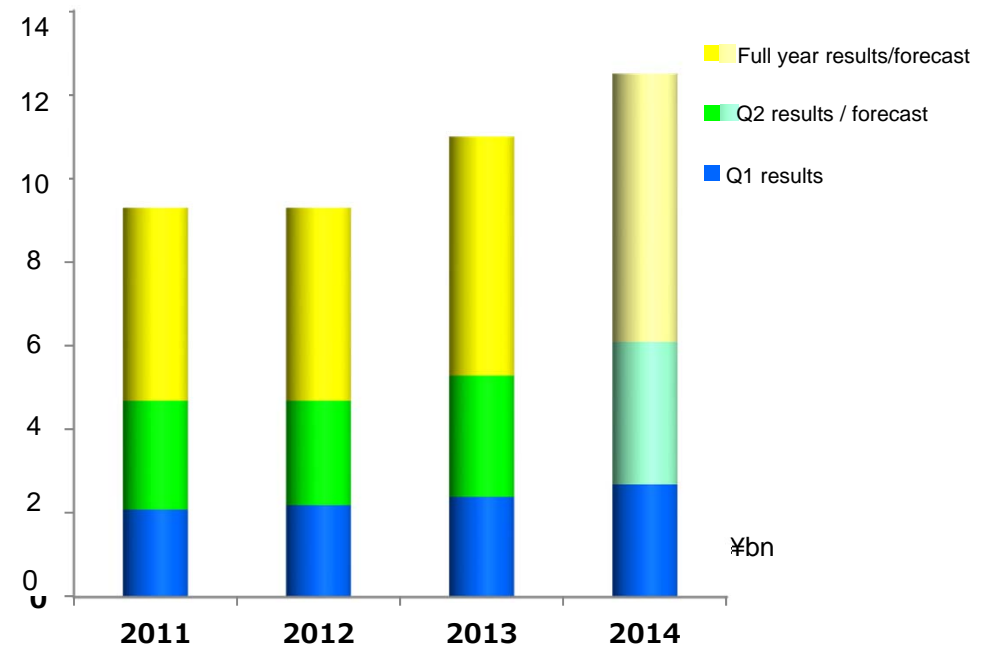
Overseas: Early shipments of some amino acids and other products in Asia  
Japan: Growth in healthcare field due to mail order sales growth

## Improvement in net sales and operating margin centered on Kyowa Hakko Bio

### Overseas sales



### Domestic healthcare sales





## R&D review

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## Domestic

- ☒ Approval for additional indications for humanized CCR4 monoclonal antibody POTELLIGEO®
  - Untreated CCR4-positive adult T-cell leukemia/lymphoma<sup>1</sup>
  - Relapsed or refractory CCR4-positive peripheral T-cell lymphoma
  - Relapsed or refractory CCR4-positive cutaneous T-cell lymphoma
- ☐ Application seeking approval for manufacture and sales of sustained-duration G-CSF product KRN125
- ☐ Application seeking approval for manufacture and sales of recombinant antithrombin KW-3357
- ☒ Start of Phase III trials of anti-IL-5 receptor humanized antibody, KHK4563 targeting asthma patients
- ☐ Approval for topical calcipotriol/betamethasone dipropionate combination product<sup>2</sup>
- ☒ NESP® granted orphan drug designation for the treatment of anemia with myelodysplastic syndrome and application filed in March for approval for manufacture and sale

## Overseas

- ☐ Start of study of KRN23 in pediatric patients

<sup>1</sup>Application temporarily withdrawn on February 10, 2014

<sup>2</sup>Sales and manufacture application by LEO Pharma A/S

Approval for additional indications for PTCL/CTCL<sup>1</sup> for POTELIGEO®  
KHK4563 included in global trial conducted by AstraZeneca/MedImmune

Category	Product name/development number	Mechanism of action, etc.	Stage (timing) / Target
Nephrology	<u>NESP®</u>	Long-acting ESA <sup>2</sup>	Application for expanded indication (filed March) Anemia with myelodysplastic syndrome
Oncology	<u>POTELIGEO®</u>	Anti-CCR4 Humanized Antibody	Approval for additional indications (March) PTCL/CTCL <sup>1</sup>
Oncology	ARQ 197	c-Met Inhibitor	Phase 3 (February) Hepatocellular Carcinoma
Immunology/allergy	<u>KHK4563</u>	Anti-IL-5R Humanized Antibody	Phase 3: began global clinical trials (April) Asthma
CNS	TOPINA®	Anti-epileptic drug	Approval for manufacture and sales (January) Topina® granules 10%

1.PTCL: Peripheral T-Cell Lymphoma; CTCL: Cutaneous T-Cell Lymphoma

2. ESA: Erythropoiesis Stimulating Agent

Note: Bio-pharmaceutical products are underlined

# NESP®: Application for manufacture and sales for indication of anemia with MDS<sup>1</sup>

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## First product designation for ESA<sup>2</sup> in Japan

### Market scale. Standard treatment

No. of patients: The treatment targets a segment of the estimated approx. 11,000<sup>3</sup> MDS<sup>1</sup> patients in Japan.

Current treatment: Patients for whom first-line treatment with ESA<sup>2,4</sup> is recommended under international guidelines currently receive blood transfusions as main treatment in Japan



### Key points

- NESP® is designated as orphan drug treatment for MDS<sup>1</sup> anemia
- Recommended as ESA<sup>2</sup> therapy in guidelines of major overseas markets

## Overseas MDS<sup>1</sup> treatment guidelines

Guidelines: NCCN Clinical practice Guidelines in Oncology™.

MDS V.2.2014

Others

<sup>1</sup>MDS: Myelodysplastic Syndromes

<sup>2</sup>ESA: Erythropoiesis Stimulating Agent

<sup>3</sup>Source: Results of 2011 survey conducted by Statistics and Information Department, Minister's Secretariat, MHLW

<sup>4</sup>Epoetin alfa, epoetin beta, darbepoetin alfa only

**KW-0761**

Indication		Country/ region	Development stage	Annual incidence per disease, other
ATL	Untreated	Japan	Preparing for filing	Japan: approx. 1,100 <sup>1</sup> patients
ATL	Relapsed/ refractory	U.S. Europe Others	Phase 2	Europe, U.S.: Investigating
PTCL	Relapsed/ refractory	Japan	Approval (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	Approval (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

- 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

## KW-6002

Indication	Country/ region	Development stage	Annual incidence per disease, other
Parkinson's disease	U.S.	Filed (April 2007)	U.S.: More than 570,000 <sup>1</sup> patients treated
Parkinson's disease	U.S. Europe Others	Phase 3	Special Protocol Assessment with FDA

## KRN23

Indication	Country/ region	Development stage	Annual incidence per disease, other
X-linked Hypophosphatemia	U.S. Canada	Phase1/2 (completed)	U.S.: approx. 12,000 <sup>2</sup> adult patients Europe: approx. 24,000 <sup>2</sup> adult patients
X-linked Hypophosphatemia	U.S. Europe	Target: pediatrics (preparation)	U.S.: approx. 3,000 <sup>2</sup> pediatric patients Europe: approx. 6,000 <sup>2</sup> pediatric patients Joint development with Ultragenyx Pharmaceutical Inc.

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

<sup>2</sup> Estimate based on reported prevalence of 1 in 20,000 people

# **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:  
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# 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 April 17, 2014)

## Period average rate

Average exchange rate	FY2013 Q1 results	FY2014 Q1 results	Change	2014 Full-year forecast
¥/\$	¥89	¥103	+¥14	¥100
¥/€	¥118	¥141	+¥23	¥130
¥/£	¥141	¥171	+¥30	¥155

## FY2014 Q1 currency effects (YoY)

Segment	Currency	Net sales	Operating income
Pharmaceuticals business	\$	+¥0.3bn	+¥0.1bn
	€	+¥0.0bn	+¥0.0bn
	£	+¥1.1bn	+¥0.0bn
Bio-Chemicals business	\$	+¥0.7bn	+¥0.6bn
	€	+¥0.7bn	+¥0.3bn
	£	-	-