

# Fiscal 2013 Results Presentation

(Fiscal year to December 31, 2013)

February 3, 2014  
Kyowa Hakko Kirin Co., Ltd.

## Business overview

President and CEO Nobuo Hanai

## Financial review

Managing Executive Officer Kazuyoshi Tachibana

## R & D review

President and CEO Nobuo Hanai

## Medium-term business plan review

President and CEO Nobuo Hanai

## 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

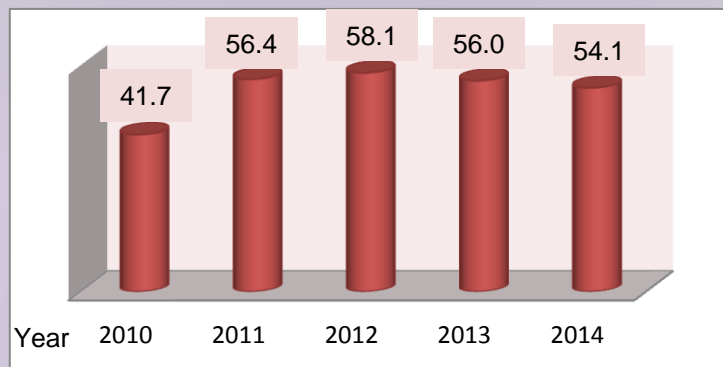
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- NESP<sup>®</sup> maintained its No 1. position in sales in the Japanese ESA<sup>1</sup> market
  - <sup>1</sup>Erythropoietin Stimulating Agent
- In Europe, Abstral<sup>®</sup> achieved swift market penetration and expanded sales
- Acquired approval for and launched three new pharmaceutical products<sup>2</sup> in the Japanese market
  - <sup>2</sup>Onglyza<sup>®</sup>, a treatment for type-two diabetes, NOURIAST<sup>®</sup>, an antiparkinsonian agent, and Abstral<sup>®</sup> a treatment for cancer pain
- KW-6002 began phase III trials in Europe and the U.S.  
Collaboration with Ultragenyx for the development and commercialization of KRN23
- Achieved record ordinary income and net income
- Overseas subsidiary ProStrakan achieved profitability on a consolidated basis

- NESP<sup>®</sup> maintained its No 1. position in sales in the Japanese ESA\* market
- In Europe, Abstral<sup>®</sup> achieved swift market penetration and expanded sales

## No. 1 in sales in the Japanese ESA market

- Effective frontline anemia treatment
- Indications expanded to include pediatric anemia
- Information provided by 400 nephrology MRs



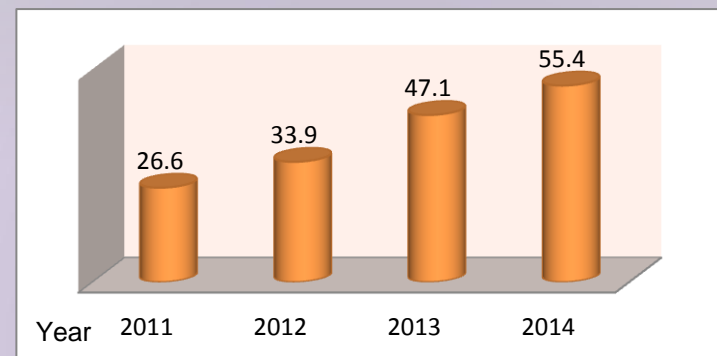
**ネスプ**<sup>®</sup>

Unit: Billion yen

Figures for 2014 are forecasts

## Top fentanyl brand in Europe

- First sublingual fentanyl citrate tablet
- Easy to administer and can be used for cancer pain patients for whom ingestion and swallowing can be painful
- Rapidly dissolves under the tongue, absorbed through the oral mucosa



**Abstral**  
SUBLINGUAL FENTANYL CITRATE TABLET

Unit: Million pounds

Figures for 2014 are forecasts

- Acquired approval for and launched three new products for the Japanese market
- Began phase III trials of KW-6002 in Europe and the U.S. Also accelerated development of KRN23

## Launched three new products including a first-in-class drug

1. Treatment for type-two diabetes



**オングリザ<sup>®</sup>錠**

2. Antiparkinsonian agent



**ノウリアスト<sup>®</sup>錠**

3. Treatment for cancer pain

**アブストラル<sup>®</sup>舌下錠**

## Accelerated global deployment

### **KW-0761**

- Began global phase 3 trials in Japan, the U.S. and Europe targeting CTCL<sup>1</sup>

### **KW-6002**

- Began phase 2 trials in Europe and the U.S.
- Agreement with FDA<sup>2</sup> based on SPA<sup>3</sup>

### **KRN23**

- Development and commercialization collaboration with Ultragenyx, (strong in orphan-drug development)

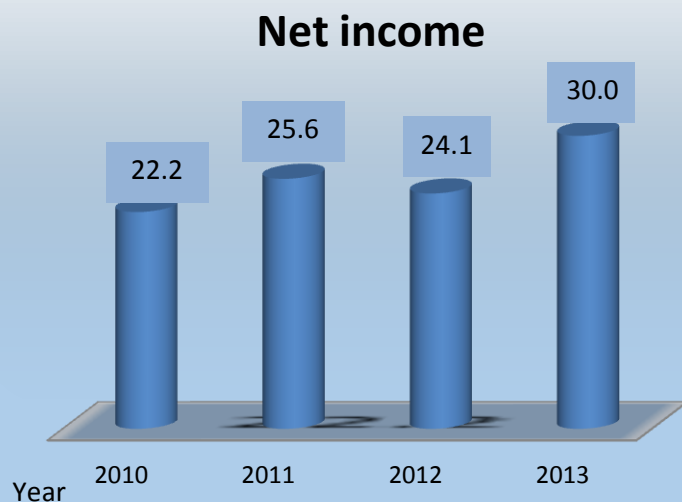
<sup>1</sup>Cutaneous T-Cell Lymphoma

<sup>2</sup>Food and Drug Administration

<sup>3</sup>Special Protocol Assessment

- Achieved record ordinary income and net income
- Overseas subsidiary ProStrakan achieved profitability on a consolidated basis

## Achieved record high in net income

**KYOWA KIRIN**

Unit: Billion yen

## Achieved profitability in third year following acquisition

- Expanded sales, centered on growth drivers Abstral® and Sancuso®
- Drove market penetration of existing products by leveraging strengths in sales and marketing.
- Launch of Fareston® in the U.S. also contributed to sales

 **ProStrakan**



# Financial review

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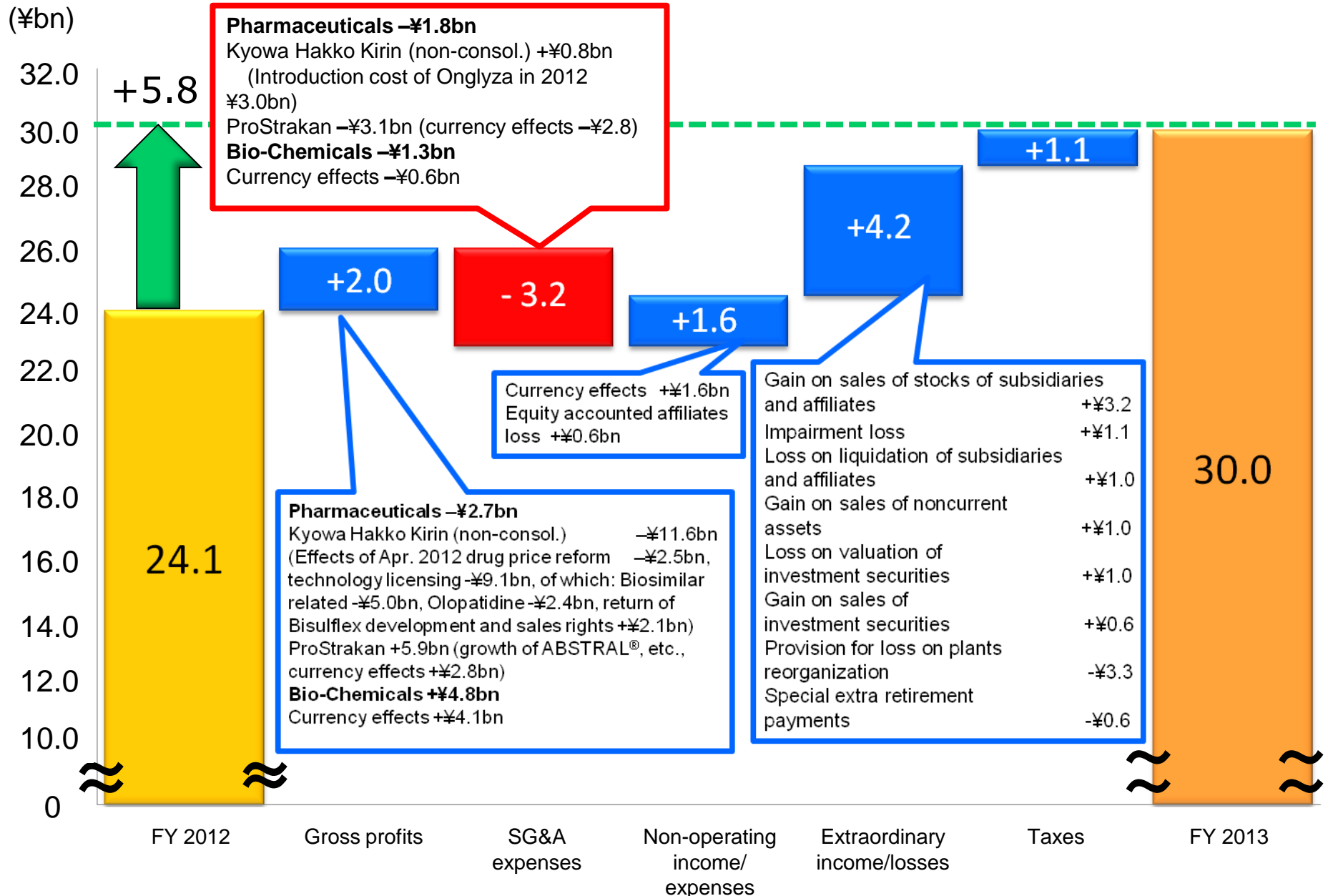
Revenue increased due to strong sales of pharmaceutical products in Japan and ProStrakan's steady growth as well as the effect of yen weakness.

(Unit: billion yen)	FY2012	FY2013	Change	2013 Forecast	Rate of achievement
Net sales	333.1	340.6	+7.4 (+2.2%)	339.0	+1.6 (+0.4%)
Operating income <i>Operating margin</i>	52.9 15.9%	51.7 15.2%	-1.1 -2.1%	51.0 15.0%	+0.7 (+1.3%)
Ordinary income	49.0	49.5	+0.5 (+1.0%)	48.0	+1.5 (+3.1%)
Net income	24.1	30.0	+5.8 (+24.3%)	28.0	+2.0 (+7.1%)

- ✓ Growth in ordinary income was the result of forex gains and lower losses from equity-accounted affiliates.
- ✓ The increase in net income was the result of extraordinary income including gains on sale of related companies' shares.

# Summary of full-year consolidated results: Analysis of YoY profit changes

## FY2013 net income (total): Analysis of YoY changes



# Summary of FY 2013 financial results by segment

In the Pharmaceuticals business, sales and profit increased due to strong domestic sales and despite a decline in technology licensing income.  
 In the Biochemicals business, sales and profit increased due in part to yen weakness.

(Unit: ¥bn)		FY2012	FY2013	Change
<b>Pharmaceuticals business</b>	Net sales	259.3	261.0	+1.6 (+0.6%)
	Operating income <i>Operating margin</i>	50.7 19.5%	46.1 17.7%	-4.6 (- 9.0%)
<b>Bio-Chemicals business</b>	Net sales	76.9	82.9	+5.9 (+7.7%)
	Operating income <i>Operating margin</i>	2.1 2.7%	5.6 6.8%	+3.5 (+166.4%)

(Profits are stated after amortization of goodwill)

**Domestic sales were impacted by generics and biosimilars but targets were achieved.**

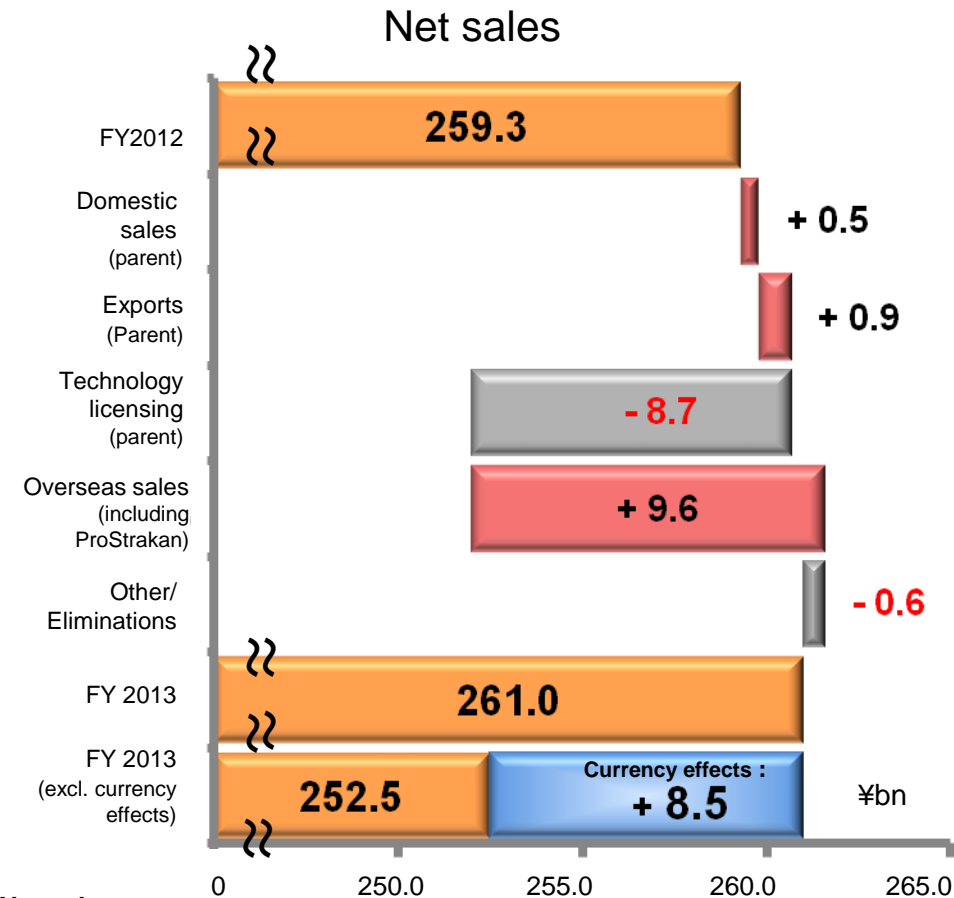
Product name/ Exports / Technology out- licensing	FY2012 (a)*	FY2013 (b)*		Change (b)- (a)	Reason for change	Rate of progress (%) **
<b>NESP®</b>	58.1	56.0		-2.0	Impacted by lower shipments following launch of unified dosage product last year Strong performance in recent months	102
<b>REGPARA®</b>	13.4	15.1		1.7	Steady market penetration	105
<b>ALLELOCK®</b>	29.9	27.6		-2.2	Impacted by market penetration of generics	100
<b>Patanol®</b>	10.2	13.4		3.1	Increase in pollen count	99
<b>GRAN®</b>	13.5	12.4		-1.1	G-CSF market contraction Impacted by launch of biosimilars	100
<b>Exports</b>	9.4	10.4		0.9	Currency effects	106
<b>Technology out-licensing</b>	24.4	15.3		-9.1	Decline in licensing income in Biosimilars-related business	103

\*Unit: ¥bn

\*\*Rate of progress compared to 2013 sales forecasts (as of July 26, 2013). Figures rounded.

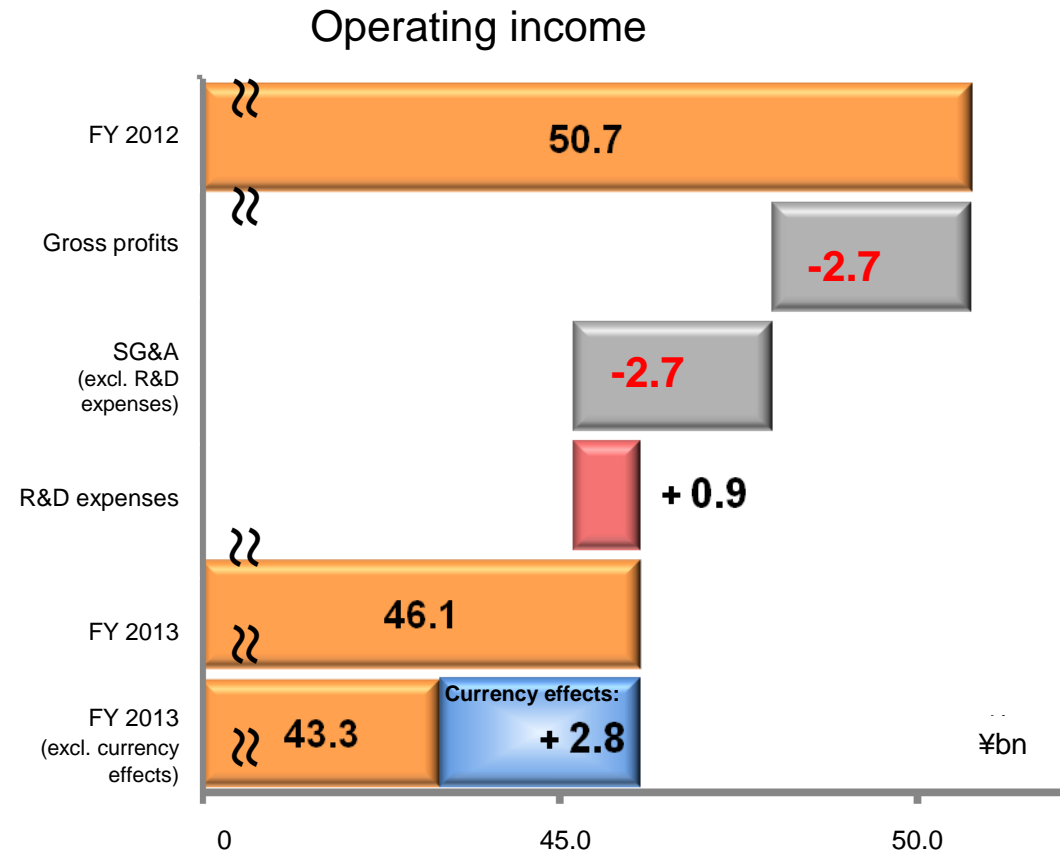
# Pharmaceuticals Business: FY2013 results: Analysis of YoY profit changes

**KYOWA KIRIN**



#### Net sales

- Domestic pharmaceutical products (+¥0.5bn):
- Products (shipments): Patanol®+¥3.1bn, REGPARA® +¥1.7bn, ASACOL®+¥1.3bn, Romiplate® +¥0.7bn, Fentos® +¥0.7bn, ALLELOCK® -¥2.2, NESP® -¥2.0bn, CONIEL®-¥1.5, GRAN®-¥1.1bn
- NESP® : Sales declined due to lower shipments following launch of unified dosage product last year, reductions in NHI drug prices. Our share was maintained.
- Exports (+¥0.9bn): Currency effects, etc.
- Technology licensing, etc. (-¥8.7bn): Currency effects +¥1.3bn
- Biosimilars related (- ¥5.0bn), Olopatadine (-¥2.4bn), etc.
- Overseas sales (+¥9.6bn): Currency effects +¥5.9bn
- ProStrakan +¥3.2bn (excluding currency effects), remainder Asia sales.

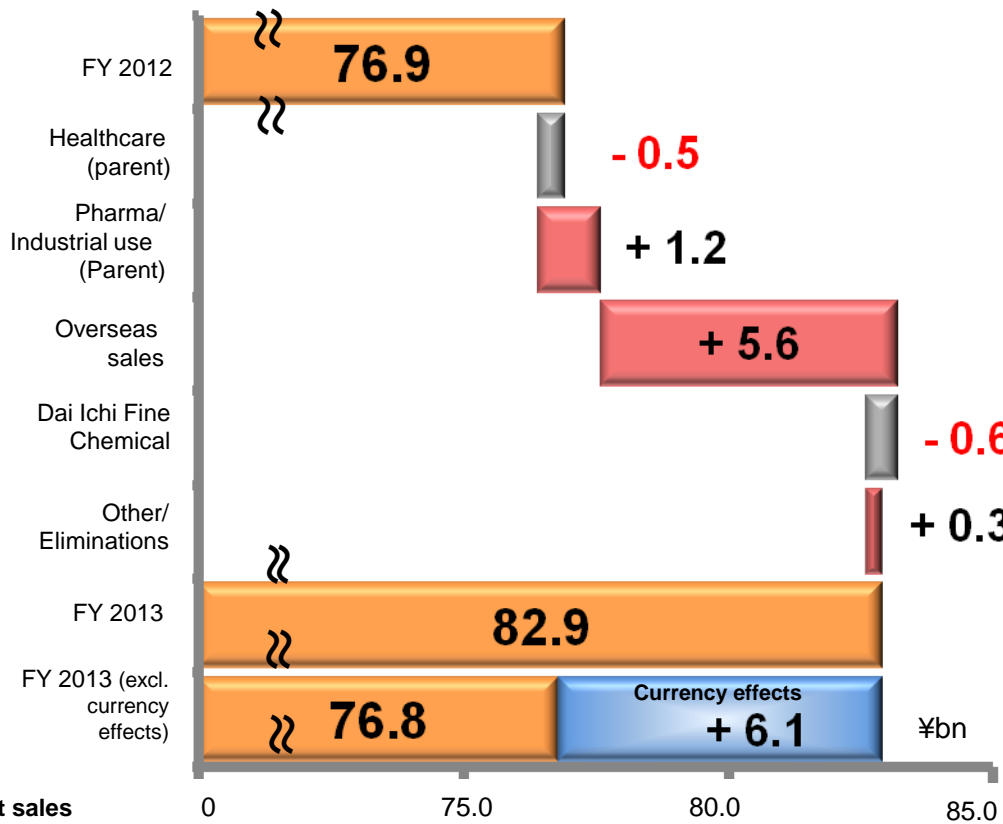


#### Operating income

- Gross profits (-¥2.7bn):
- Lower profits, resulting from the effects of NHI drug price cuts, a fall in licensing income from biosimilars, and other factors, could not be offset by ProStrakan's growth.
- SG&A (-¥2.7bn)
- A factor in the decrease was the introduction cost of Onglyza (+¥3.0bn) in 2012 but costs increased due to currency effects.
- R&D expenses (+¥0.9bn):
- While there was an increase in the cost burden for overseas development, decrease in depreciation and amortization expenses were larger than in the previous fiscal year and R&D expenses were down overall.

# Bio-Chemicals Business: FY 2013 results: Analysis of YonY profit changes

## Net sales



## Operating income



- Net sales**
- Healthcare (-¥0.5bn):
    - Mail order sales increased from the previous year
    - Raw materials/OEM: Down due to exit from unprofitable items, sluggish sales of amino acids for beverages, and delay in sales of distributors' new products.
  - Pharma/ Industrial use (+¥1.2bn): Raw materials for generic pharmaceuticals strong, etc.
  - Overseas sales (+¥5.6bn): currency effects approx. +¥6.1bn
  - U.S.: Currency effects (+¥1.3bn), impact of intensifying competition in sales of some raw materials for supplements (-¥0.2bn)
  - Europe: Currency effects (+¥2.7bn), decline in demand accompanying customer production timing in industrial-use products (-¥0.6bn)
  - Asia and others: Currency effects (+¥2.1bn), some pharmaceutical raw materials were sluggish but infusion-use amino acids were strong (+¥0.2bn),
  - Daiichi Fine Chemical (-¥0.6): Disposal of unprofitable items and change to product mix (-¥0.6bn)

### Operating income

- Gross profits (+¥4.8bn): Currency effects, approx. +¥4.1bn
- Improved product mix by disposing of unprofitable items
- Gross profit increased due to growth in mail-order sales and pharmaceutical and industrial-use raw materials
- SG&A (-¥1.5bn): Currency effects, approx. +¥0.6bn
- Impact of currency effects on overseas sales and increased mail order promotion expenses, etc.

# FY2014 Forecasts

**KYOWA KIRIN**

(Unit: Billion yen)	FY2012	FY2013 Results (a)	FY2014 Forecasts (b)	Difference (b)-(a)
Net sales	333.1	340.6	337.0	-3.6 (- 1.1%)
Operating income <i>Operating margin</i>	52.9 15.9%	51.7 15.2%	41.0 12.2%	-10.7 (-20.8%)
Ordinary income	49.0	49.5	35.0	-14.5 (-29.3%)
Net income	24.1	30.0	20.0	-10.0 (-33.5%)

Assumptions: Period average FOREX rate

US\$	¥80	¥96	¥100	-4 yen
EUR	¥103	¥127	¥130	-3 yen
GBP	¥127	¥150	¥155	-5 yen



# FY2014 forecasts by segment

In the Pharmaceuticals business, we forecast a decline in sales and profits due to the significant impact of drug price revisions.

In the Bio-Chemicals business, we forecast an increase in sales and profits due to an increase in sales volumes of core amino acids and other products and currency effects.

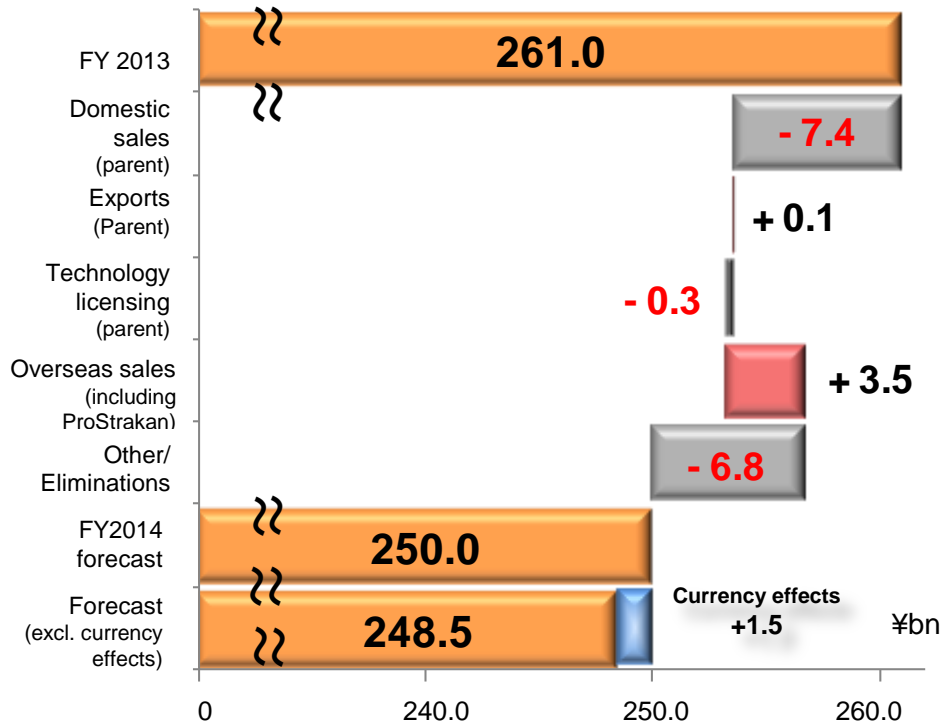
(Unit: ¥bn)		FY2013 Results	2014 Forecasts	Change
<b>Pharmaceuticals business</b>	Net sales	261.0	250.0	-11.0 (-4.2%)
	Operating income <i>Operating margin</i>	46.1 17.7%	33.0 13.2%	-13.1 (-28.4%)
<b>Bio-Chemicals business</b>	Net sales	82.9	90.0	+7.0 (+8.5%)
	Operating income <i>Operating margin</i>	5.6 6.8%	8.0 8.9%	+2.3 (+41.1%)

(Profits are stated after amortization of goodwill)

# Pharmaceuticals Business: 2014 outlook: Analysis of YoY profit changes

**KYOWA KIRIN**

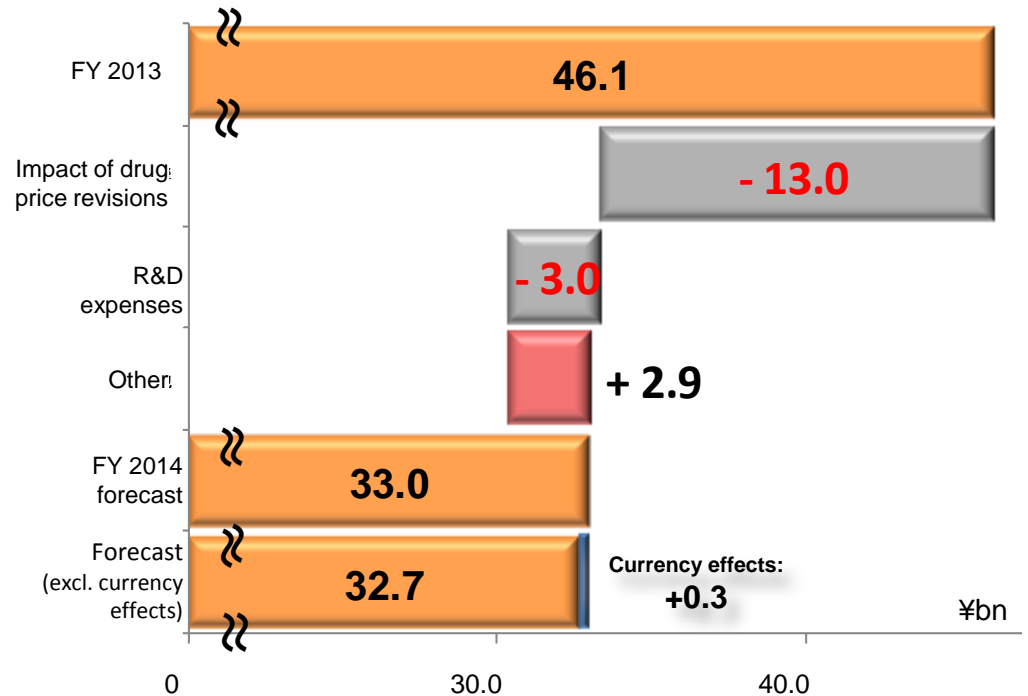
## Net sales



### Net sales

- Domestic pharmaceutical products (-¥7.4bn):
  - Products (shipments): NOURIAST® +¥3.3bn, Onglyza® +¥1.3bn, Fentos® +¥1.0bn, ALLELOCK® -¥3.9bn, GRAN® -¥3.8bn, CONIEL® -¥3.1bn, NESP® -¥1.9bn, Patanol® -¥1.3bn
  - NESP® : Decline expected due to effect of drug price revisions.
- Exports (+¥0.1bn): Currency effects, etc.
- Technology licensing, etc. (-¥0.3bn): Return of Bisulflex development and sales rights (-¥2.1bn), biosimilars related, etc.
- Overseas sales (+¥3.5bn): Currency effects +¥1.1bn
- ProStrakan +¥2.0bn (excluding currency effects), remainder Asia sales.
- Other (-¥6.8bn): Effect of transfer of Chiyoda Kaihatsu's chemicals distribution business, etc.

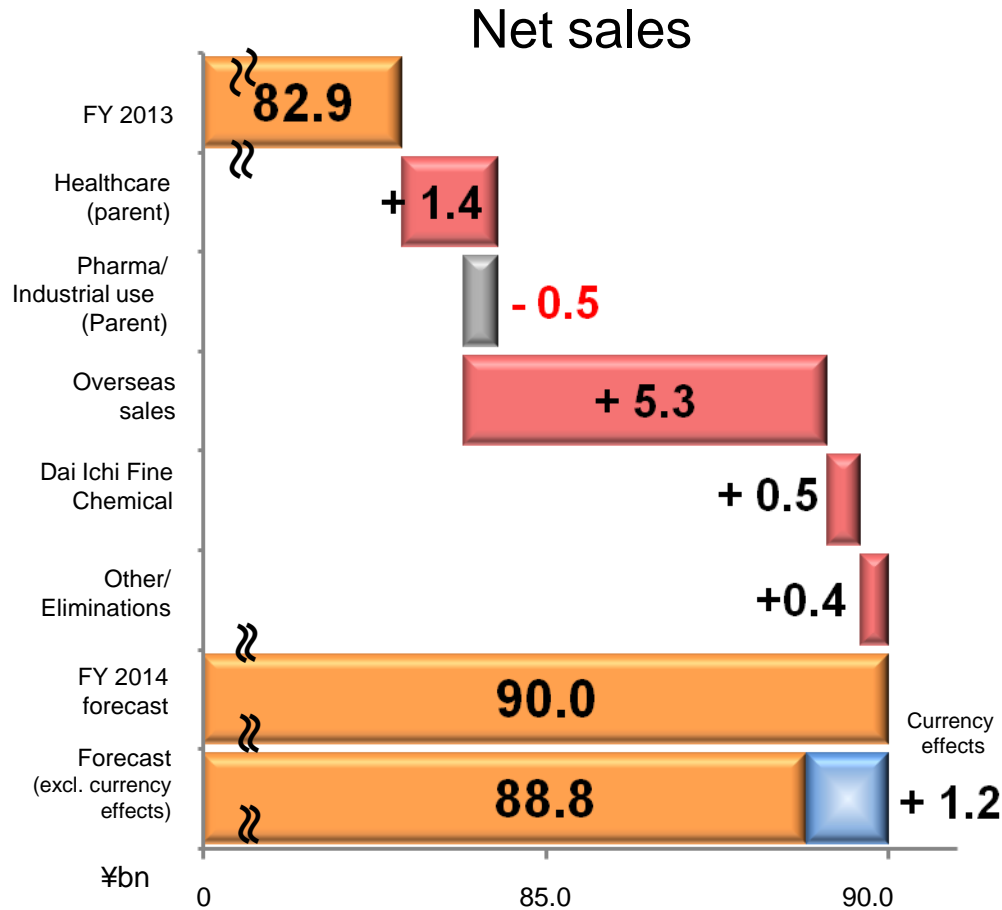
## Operating income



### Operating income

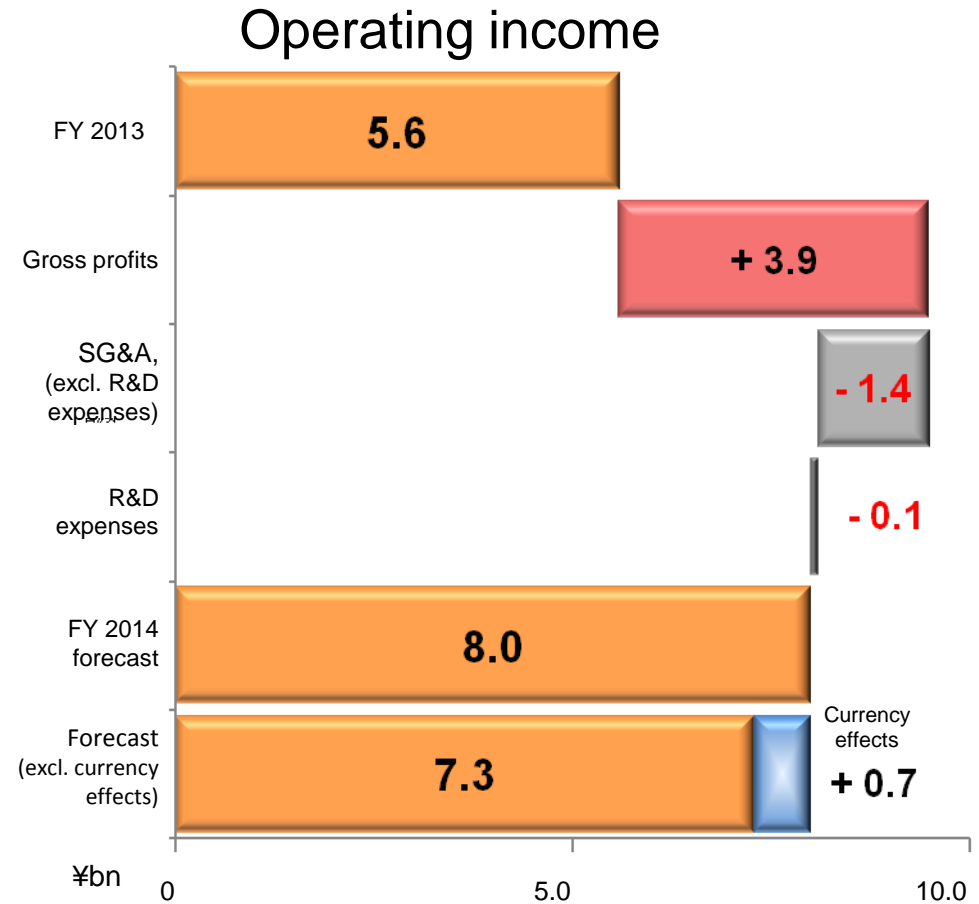
- Effect of drug price revision (approx. -¥13.0bn)
- R&D expenses increase (-¥3.0bn):
  - Increase in development costs associated with late-stage development products, etc.
- Other (approx. +¥2.9bn)
  - Volume growth in domestic pharmaceutical products such as NESP®, as well as in new products such as NOURIAST® and Onglyza®, growth in sales at ProStrakan, etc.

# Bio-Chemicals Business: 2014 outlook: Analysis of YoY profit changes



#### Net sales

- Healthcare (+¥1.4bn):
  - Mail order sales up due to growth in number of regular customers
  - Raw materials/OEM: Increased sales in existing market, launch of new products by customers
- Pharma/ Industrial use (-¥0.5bn):
  - Impact of drug price revisions, etc.
- Overseas sales (+¥5.3bn): currency effects, approx. +¥1.2bn
  - Tapping demand for infusion-use amino acids, growth in volumes of raw materials for supplements and industrial-use products, etc.
- Daiichi Fine Chemical (DFK) (+¥0.5):
  - Manufacture of APIs for Kyowa Hakko Kirin gets underway



#### Operating income

- Gross profits (+¥3.9bn): Currency effects, approx. +¥0.8bn
  - DFK manufacturing of APIs for Kyowa Hakko Kirin gets under way
  - Improve DFK product mix by disposing of unprofitable items
  - Gross profit increased due to growth in mail-order sales
- SG&A (-¥1.4bn): Currency effects, approx. -¥0.1bn
  - Increased mail order sales promotion expenses, delivery costs, etc.

The return of profits to shareholders is the top priority.  
Maximizing corporate value maximizes shareholder value.

## Shareholder return

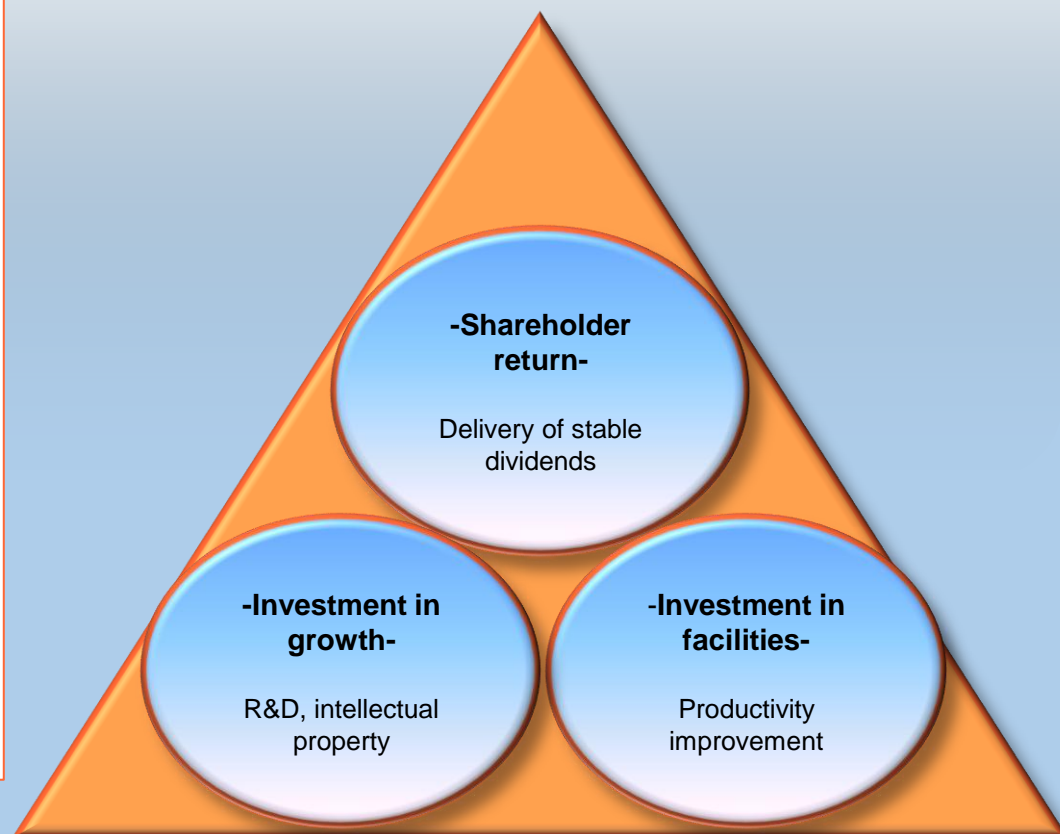
- We will aim for a stable dividend return with a dividend payout ratio of 40% of profits prior to amortization of goodwill
- Regarding the repurchase of the company's own shares, we will act flexibly based on market and financial conditions

## Investment in growth

- Active R&D investment for sustainable growth
- Investment in intellectual property to maximize value of the development pipeline

## Investment in facilities

- Reorganization and improvement of the Group's overseas and domestic production facilities and upgrading of production equipment



# R & D review

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**Approval and launch of three new drugs including NOURIAST<sup>®</sup>, a first-in-class drug.**  
**Four biopharmaceutical products\* in late-stage development.**

\*Development numbers of these four products are underlined below.

Category	Product name/development number	Mechanism of action, etc.	Stage
Nephrology	Onglyza <sup>®</sup>	DPP-4 inhibitor	Launched <sup>1</sup> (May)
	NESP <sup>®</sup>	Long-acting ESA formulation	Approval for expanded indication <sup>2</sup> (September)
Oncology	<u>KRN125</u>	Long-acting G-CSF	Filed (June)
	POTELIGEO <sup>®</sup>	Anti-CCR4 Humanized Antibody	Application for additional indication <sup>3</sup> (July)
	Abstral <sup>®</sup>	μ-opioid receptor agonist	Launched (December)
	ARQ 197	c-Met Inhibitor	Phase 3 (In preparation)
Immunology/allergy	<u>KHK4827</u>	Anti-IL-17 Receptor Fully Human Antibody	Phase 3 (March)
	<u>KHK4563</u>	Anti-IL-5R Humanized Antibody	Phase 3 (In preparation)
CNS	NOURIAST <sup>®</sup>	Adenosine A <sub>2A</sub> Receptor Antagonist	Launched (May)
Other	<u>KW-3357</u>	Recombinant Antithrombin	Phase 3 (Completed)

<sup>1</sup>Licensed from Otsuka Pharmaceutical

<sup>2</sup>Pediatric indication

<sup>3</sup>Untreated CCR4-positive adult T-cell leukemia-lymphoma (ATL); Relapsed or refractory CCR4-positive peripheral T-cell lymphoma (PTCL); Relapsed or refractory CCR4-positive cutaneous T-cell lymphoma (CTCL)

**Began global phase III trial for KW-6002.  
Completed phase I trial for KRN23 and preparing for pediatric trials.**

Category	Development number	Mechanism of action, etc.	Stage
Oncology	KW-0761	Anti-CCR4 Humanized Antibody	Phase 3 (In progress)
CNS	KW-6002	Adenosine A <sub>2A</sub> Receptor Antagonist	Phase 3 (November)
Other	KRN23	Anti-FGF23 Fully Human Antibody	Pediatric trial (In preparation)

**In the UK began phase 1 trials for FKB327, a biosimilar of Adalimumab**

	Development number*	Reference medical product	Stage
Biosimilar	FKB327	Adalimumab	Phase 1 (April)
Biosimilar	FKB238	Bevacizumab	Phase 1 (In preparation)
Biosimilar	Not disclosed	Not disclosed	Determined target Reference medical product

## Structure / MoA

**Anti-IL-5Ra humanized MAb with enhanced ADCC using POTELLIGENT<sup>®</sup> technology**

- (1) Antibody binding
- (2) Recognition by the effector cells
- (3) Target cell killing

## Remarks

Development Area: Asia

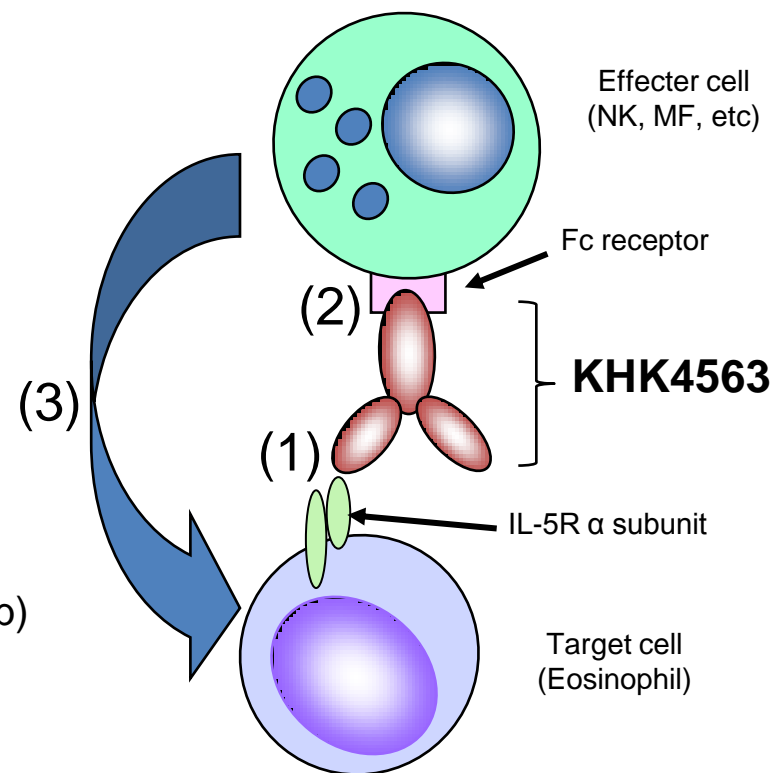
Generic name: Benralizumab

Origin: in-House

Potential Competitors: Anti-IL5 (Mepolizumab, Reslizumab)

## License-out

- KHK4563 is being developed by AstraZeneca/MedImmune as MEDI-563.
- Global phase 3 program in patients with asthma started in October 2013.
- Phase 2b study results are expected to be shared in 1H 2014

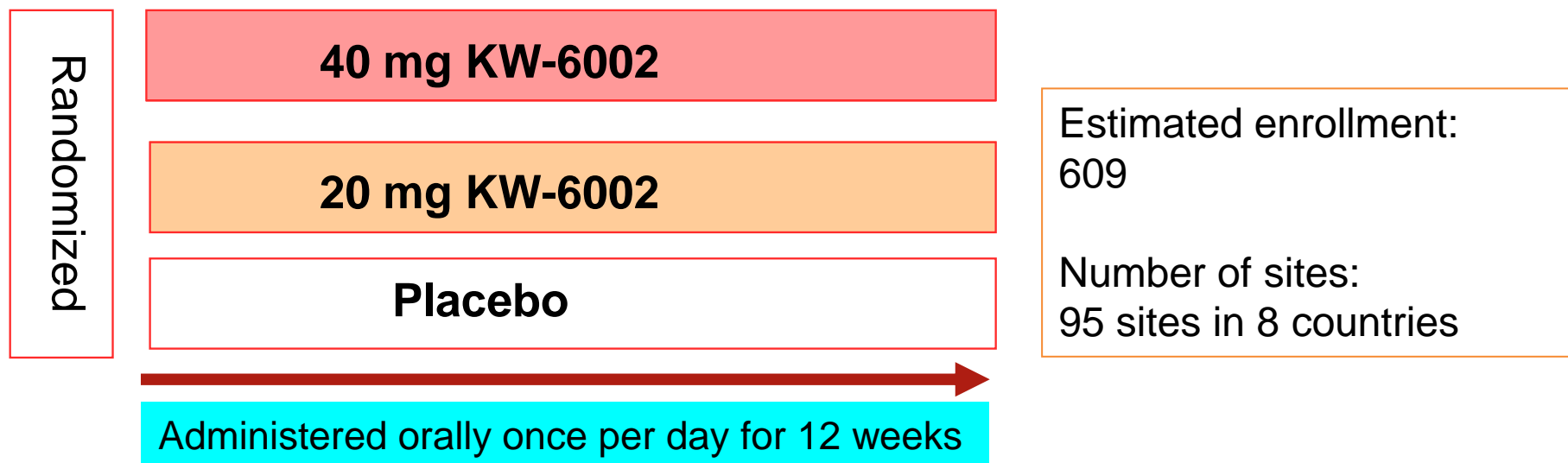




**KW-6002 began global phase 3 trial under SPA<sup>1</sup> agreement with the FDA.**

## Target:

Patients with moderate to severe Parkinson's Disease who are being treated with Levodopa and have shown symptoms of wearing-off phenomenon<sup>2</sup>



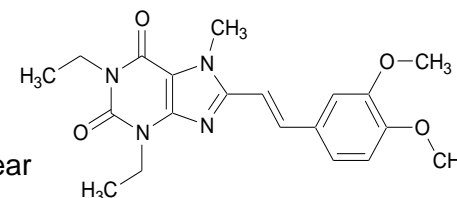
Primary endpoint: change from baseline in OFF hours per day (assessed at week 6, week 10, week 12)

Study start date (first patient in): November 2013

Scheduled final data collection date (last patient out): October 2015

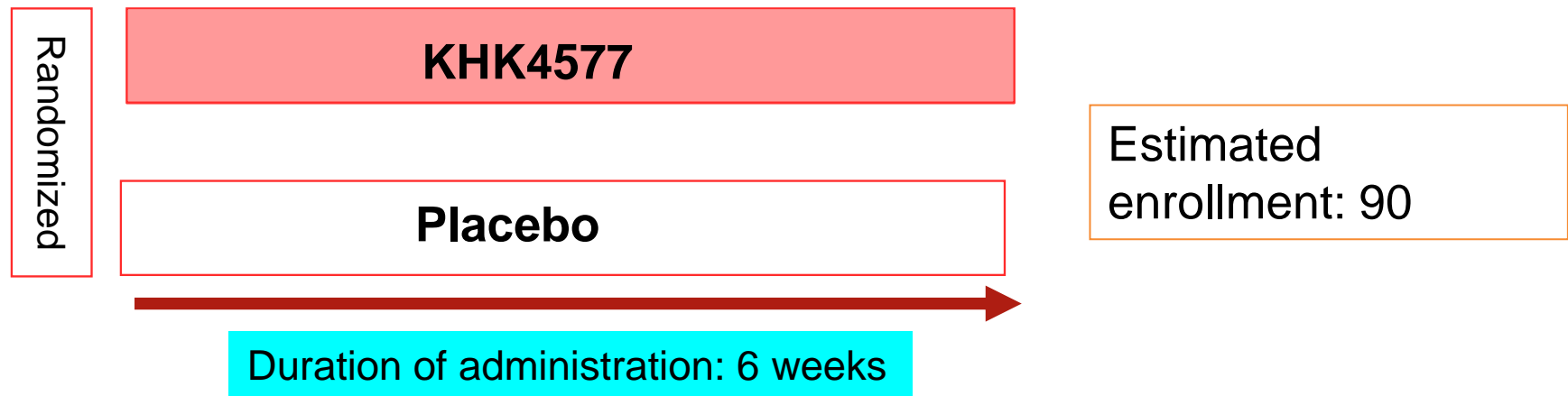
<sup>1</sup>Special Protocol Assessment

<sup>2</sup>Wearing-off phenomenon is a shortening of efficacy time of Levodopa, whereby the effects of the drug wear off a short time after administration



**In-house low-molecular weight oral compound.  
Evaluate the efficacy, safety, and pharmacokinetics of KHK4577 in  
patients with atopic dermatitis.**

**Target:** Patients with moderate to severe atopic dermatitis



Primary endpoint: Percent improvement in EASI\* score

Scheduled duration of trial: November 2013 – April 2015

Increase in KW-0761 indications accelerating value maximization.

Indication		Country/ region	Development stage	Annual incidence per disease, other
ATL	Untreated	Japan	Filed (Jul 2013)	ATL: 1,100 <sup>1</sup>
ATL	Relapsed/ refractory	U.S. Europe	Phase 2	Europe, U.S.: Investigating
PTCL	Relapsed/ refractory	Japan	Filed (Jul 2013)	PTCL/CTCL together: 2,000 <sup>2</sup>
PTCL	Relapsed/ refractory	Europe	Phase 2	US: approx. 3,600 <sup>3</sup>
CTCL	Relapsed/ refractory	Japan	Filed (Jul 2013)	PTCL/CTCL together: 2,000 <sup>2</sup>
CTCL	Relapsed/ refractory	US Europe	Phase 3	US: approx. 1,500 <sup>3</sup>

#### Sources

- 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, Labor and Welfare: Number of patients on October 2011 clinical trial inspection chart 97, divided by basic illness
- 3) SEER Data (2001-2007)

## Domestic

- Approval for additional indication for humanized CCR4 monoclonal antibody POTELLIGENT®
  - Untreated CCR4-positive adult T-cell leukemia-lymphoma (ATL)
  - Relapsed CCR4-positive peripheral T-cell lymphoma (PTCL)
  - Relapsed or refractory CCR4-positive cutaneous T-cell lymphoma (CTCL)
- Approval for manufacture and sale of long-acting G-CSF product (KRN125)
- Application seeking approval for manufacture and sales of recombinant antithrombin KW-3357
- Began Phase 3 study of anti-IL-5 receptor humanized antibody KHK4563 targeting asthma patients
- Approval for topical calcipotriol/betamethasone dipropionate combination product<sup>1</sup>

## Overseas

Began pediatric trials of KRN23

<sup>1</sup>Sales and manufacture application by LEO Pharma

# Medium-term Business Plan review

## Steady progress towards becoming GSP\* under three basic strategies.

### 1. Further strengthen competitiveness in Japan through our category-based strategy

Strengthen category product capabilities:

Cancer: Application for expansion of applications for anti-CCR4 antibody KW-0761

Nephrology: Approval of renal anemia treatment NESP® for pediatric patients

Nephrology: Launch of Onglyza® tablets for Type 2 Diabetes

Central nervous system: Launched NOURIAST®, an antiparkinsonian agent

Strengthened category-based strategy function:  
Reorganization of R&D Division

### 2. Expand our business base in the U.S., Europe and Asia and aim to become a global specialty pharmaceutical company

Global development through ODDO\*\*

Progress with late-stage development of KW-0761 in Europe and the U.S.

Began Phase 3 studies on KW-6002 in Europe and the U.S.

Developed KRN23 with Ultragenyx, announced sales partnership

### 3. Strengthen the revenue base of our Bio-Chemicals business

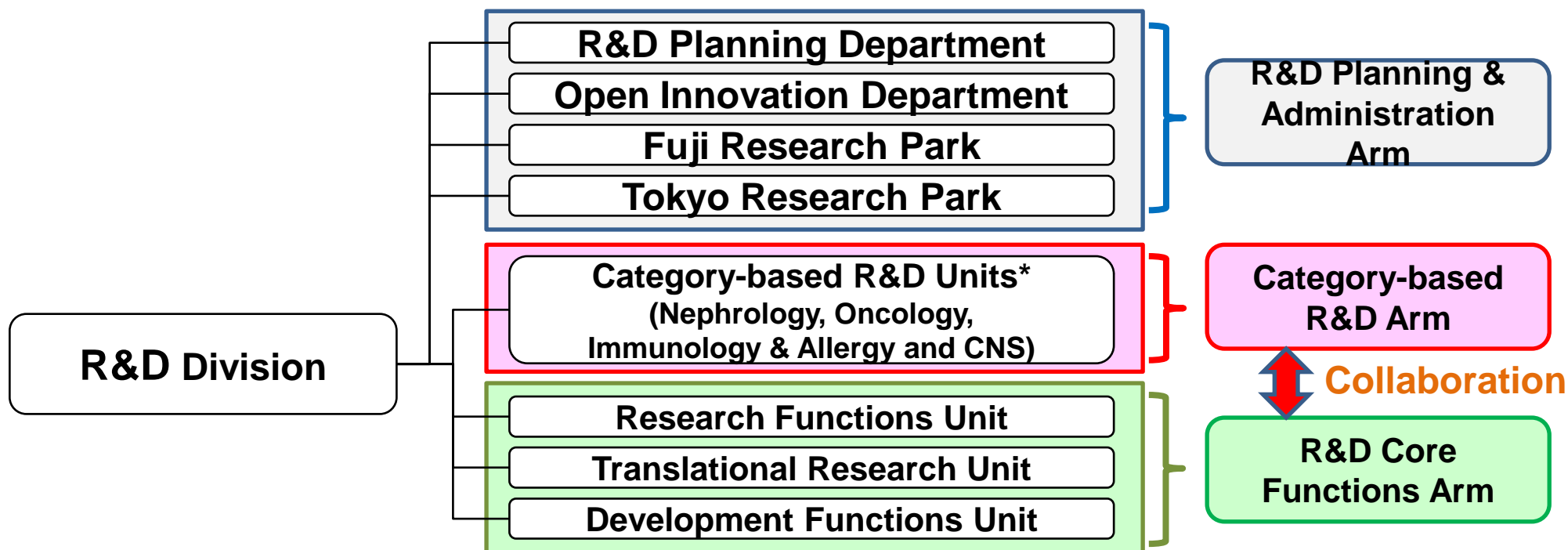
Expansion of overseas production facilities, progress with initiatives to consolidate domestic production facilities

**【Purpose】**

**To advance “Category-based Strategy” and enhance productivity of KHK’s R&D activities**

**【Essential points】**

1. Integrate operations of drug discovery research, project management of development products and value creation research of launched products in each Category-based R&D Unit
2. Speed up R&D through close collaboration between Category-based Units and R&D Core Functions Units
3. Enhancing drug discovery and preclinical research through open innovation style utilizing external opportunities



**Stable progress in strengthening our revenue base—a basic strategy of the medium-term business plan.**

**Steady progress with reorganization of production facilities with a future focus.**

## Fine chemicals

- ◆ Global high-function amino acid market gradually expanding
- ◆ Maintaining share and steadily expanding sales in transfusion and API<sup>1</sup> fields through customer relationship building
- ◆ Improving revenue base by enhancing product mix and intensifying competition in some markets

## Healthcare

- ◆ Continued YoY improvement in mail-order sales business due to increased awareness of Ornithine<sup>2</sup>
- ◆ Focus on diffusion, expansion of sales of fermented materials and original materials

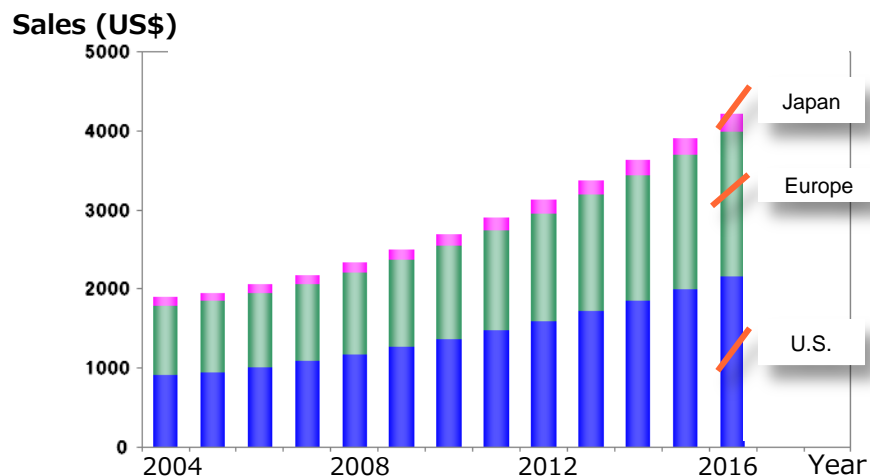
## Synthetic APIs (Daichi Fine Chemical)

- ◆ Steady progress on reorganization of business structure; gradually launching operations at new plants
- ◆ Established API<sup>1</sup> supply system by progressively putting state-of-the-art plants into operation

<sup>1</sup>Active pharmaceutical ingredients

<sup>2</sup>Ornithine awareness based on in-house study

Trends in infusion market in Japan, The U.S. and Europe



## Production facility improvement

- Investments in existing plants to contribute to earnings from 2014
- Steady progress in reorganization of Yamaguchi Production Center, construction of new Kyowa Thailand production facility





# Medium-term Business Plan – revision of FY2015 guidance

**KYOWA KIRIN**

(Unit: ¥bn)	FY2013 results	FY2014 forecasts	FY2015 guidance	( At time of Medium-term business plan announcement ) FY2015 initial guidance
Net sales	340.6	337.0	355.0	358.0
Operating income <sup>1</sup>	51.7	41.0	55.0	60.0
<i>Operating profit margin</i>	<i>15.2%</i>	<i>12.2%</i>	<i>15.5%</i>	<i>16.8%</i>
Ordinary income <sup>1</sup>	49.5	35.0	47.0	53.0
Net income <sup>1</sup>	30.0	20.0	27.0	30.0
EPS <sup>2</sup> ( yen )	71.9	53.5	70.6	71.7

<sup>1</sup>Income after amortization of goodwill    <sup>2</sup>EPS calculated using net income before amortization of goodwill

# Medium-term Business Plan – revision of FY2015 guidance

**KYOWA KIRIN**

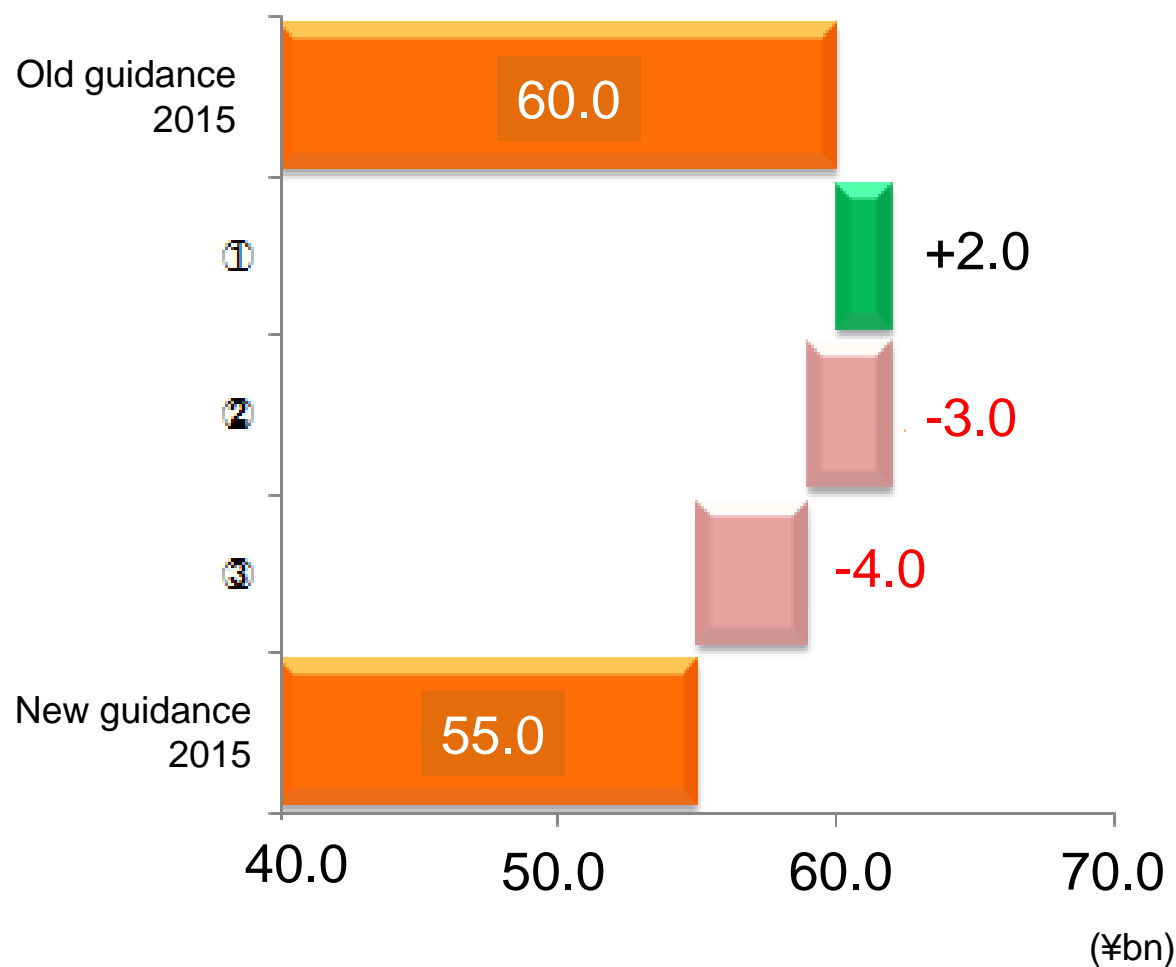
(Unit: ¥bn)	FY2013 results	FY2014 Forecast	FY2015 guidance	FY2015 guidance at time of Medium-term business plan announcement <sup>1</sup>
Net sales	340.6	337.0	355.0	358.0
Pharmaceuticals business	261.0	250.0	265.0	270.0
Bio-Chemicals business	82.9	90.0	93.0	91.0
Operating income <sup>2</sup>	<b>51.7</b>	<b>41.0</b>	<b>55.0</b>	<b>60.0</b>
Pharmaceuticals business	46.1	33.0	45.0	52.0
Bio-Chemicals business	5.6	8.0	10.0	8.0
R&D cost	<b>43.6</b> (12.8%)	<b>47.0</b> (13.9%)	<b>47.5</b> (13.4%)	<b>43.0</b> (12.0%)
Pharmaceuticals business	40.4 (15.5%)	43.5 (17.4%)	44.0 (16.6%)	40.0 (14.8%)
Bio-Chemicals business	3.2 (3.8%)	3.5 (3.9%)	3.5 (3.8%)	3.0 (3.3%)

( ) : R&D: Sales ratio

<sup>1</sup>From fiscal 2013, classification has been reviewed due to the discontinuation of the Other segment

<sup>2</sup>Operating income is income after amortization of goodwill

Revision of guidance from time of announcement of Medium-term Business Plan.  
Continued progress of investment in R&D, despite impact of weaker yen.



### Key factors

- ① Bio-Chemicals business
  - Currency effects (+¥4.0bn)
  - Increased competition in health food use amino acids market in some regions
- ② Pharmaceuticals business: Domestic sales
  - Impact of generic drugs, etc.
- ③ Pharmaceuticals business: R&D cost
  - R&D cost increase (-¥4.0bn)

#### Currency effects:

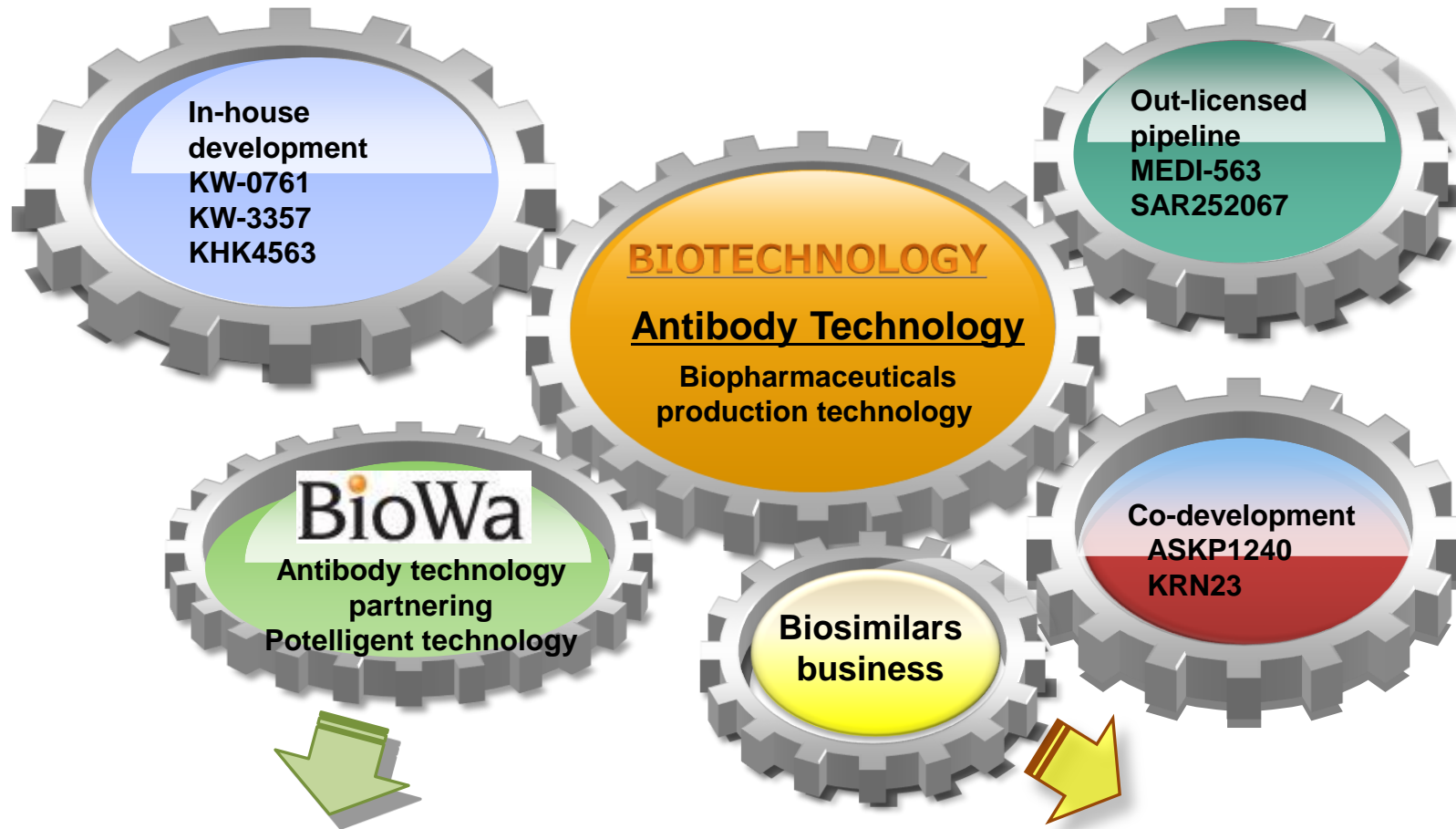
- Pharmaceuticals business: +¥2.0bn
- Bio-Chemicals business: +¥4.0bn



**Maximize corporate value and achieve sustainable growth**

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Multi-matrix expansion of antibody-technology based drug discovery of new biopharmaceuticals.



Drug discovery by BioWa partner (public information only):

- ARGX-110 (Phase1b, target: CD70)
- ARGX-111 (Phase1b, target: c-Met)

- Provision of production cells for BS\* development/Transfer of production technology
- FKB327 (adalimumab)
- FKB238 (bevacizumab) :

Utilizing antibody technology and other strengths to address unmet medical needs.  
 Utilizing bio production technologies to contribute to unmet health economics needs.

## Unmet medical needs

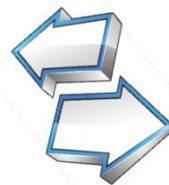
Utilizing independently developed antibody technologies to create new drugs in house for diseases with low treatment satisfaction levels

### Clinical studies currently being conducted

Target disease	Codename	Technology used
ATL	KW-0761	POTELLIGENT®
CTCL	KW-0761	POTELLIGENT®
PTCL	KW-0761	POTELLIGENT®
Ricketts	KRN23	KM-Mouse

### Clinical studies in preparation

Alzheimer's disease	Not disclosed
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## Unmet health economics needs

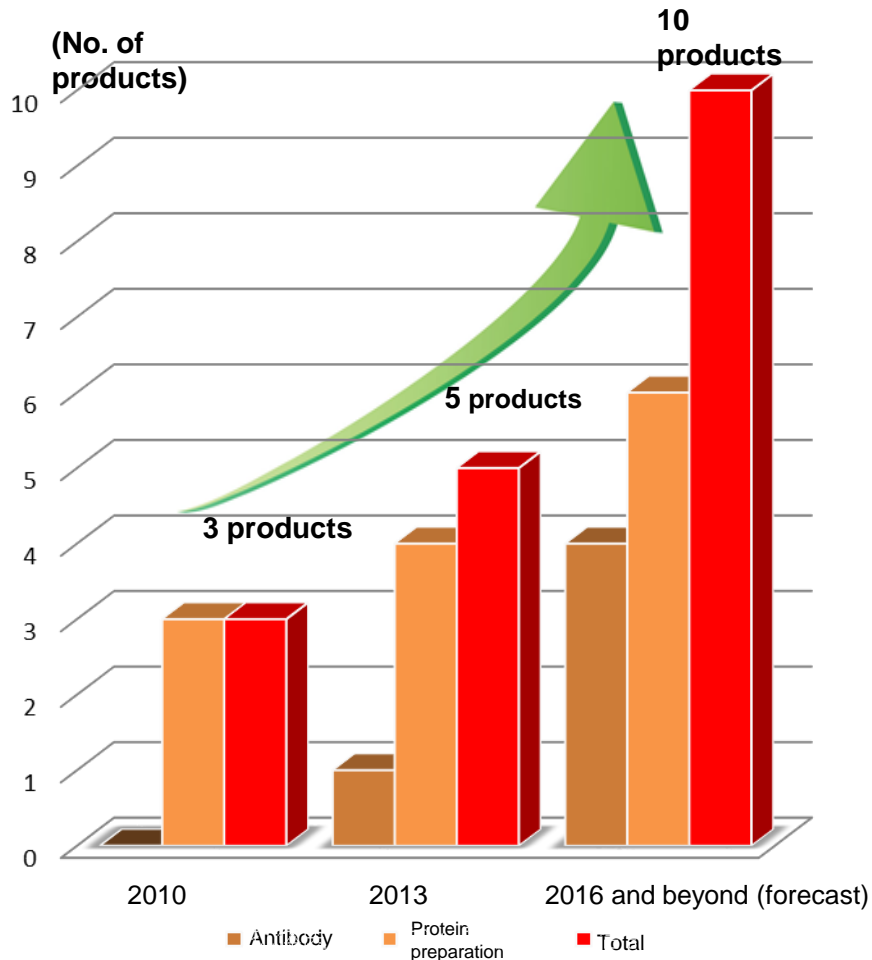
For high-cost bio-medicines, use in-house bio-pharmaceutical production technology to enter biosimilar business

Kyowa Hakko Kirin Takasaki Plant



## Bio-medical products expected to grow beyond FY2016.

### Number of key bio-medical products



Note: FY2010, 2013 results limited to products with non-consolidated results disclosed. Biosimilars not included in FY2016 and beyond

### Bio-medical product application status/schedule<sup>1</sup>

	Antibody	Protein preparation
FY2013	KW-0761 expansion application filed	KRN125 application filed
FY2014		KW-3357 application filed
FY2015	<u>KW-0761 application filed</u>	
FY2016 onward	<u>KHK4563 application filed</u> <u>KRN23 application filed</u> <u>KW-0761 expansion application filed</u>	
	Biosimilar <sup>2</sup>	Innovator product
FY2016 onward	<u>FKB327 application filed</u> <u>FBK238 application filed</u>	Adalimumab Bevacizumab

\*Global development projects are underlined

<sup>1</sup>Public information only

\*Global development projects are underlined

<sup>2</sup>FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.

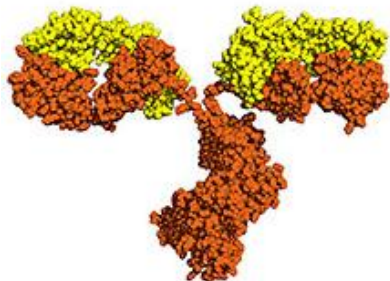
Creation of new value, backed by experience and proven capabilities in bio-medical research and development.

**KYOWA KIRIN**



**Bio-medical drug discovery technology:**

- POTELLIGENT® technology
- COMPLEGENT® technology
- KM-Mouse



**Bio-medical manufacturing technology:**

- More than 200 process research engineers
- High productivity strains
- System that meets international **GMP\*** standards



**Bio-medical technology information/alliance:**

- Collection of information on cutting-edge technology
- Partnering involving company assets



# Q & A

# **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**

# APPENDIX

## Period average rate

Average exchange rate	FY2012	FY2013	FY2014
¥/\$	¥80/\$	¥96/\$	¥100/\$
¥/€	¥103/€	¥127/€	¥130/€
¥/£	¥127/£	¥150/£	¥155/£

## FY2013 currency effects (YoY)

Segment	Currency	Net sales	Operating income
Pharmaceuticals business	\$	+¥2.3bn	+1.4bn
	€	+¥0.2bn	+0.2bn
	£	+¥3.7bn	+0.0bn
Bio-chemical business	\$	+¥2.8bn	+1.8bn
	€	+¥2.8bn	+1.5bn
	£	-	-

# Development progress with out-licensed compounds

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 January 24, 2014)