

**Results Presentation**  
**Fiscal 2016 Interim**  
**(January 1, 2016 – June 30, 2016)**

Kyowa Hakko Kirin Co., Ltd.

## **FY2016 H1 highlights**

**Nobuo Hanai, Ph.D., President and CEO**

## **Financial review**

**Kazuyoshi Tachibana, Managing Executive Officer**

## **R & D review**

**Nobuo Hanai, Ph.D., 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.*

**In H1 of FY2016, despite a YoY decline in sales and profits, the Pharmaceuticals business saw an increase in sales and profits ahead of H1 plans, and in the Bio-Chemicals business, performance was largely in line with plans.**

- In the Pharmaceuticals business, Japan sales increased ¥1.5 billion YoY due to strong sales of new products G-Lasta<sup>®</sup>, NOURIAST<sup>®</sup>, Dovobet<sup>®</sup>, and Onglyza<sup>®</sup>, and key product NESP<sup>®</sup> and REGPARA<sup>®</sup>.
- In the Pharmaceuticals business, overseas sales declined ¥4.3 billion YoY due to a decrease in technology out-licensing revenue, currency effects, and other factors.
- In the Pharmaceuticals business, R&D expenses increased ¥3.1 billion YoY due to the steady progress of late-stage development products.
- In the Bio-Chemicals business, profits decreased ¥0.5 billion YoY due to decreased sales because of currency effects and other factors.

## Financial review

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# Summary of 2016 H1 results (consolidated)

**KYOWA KIRIN**

Despite growth in domestic pharmaceutical products, sales and profits declined on a consolidated basis due to the strong yen, lower technology revenue and increased R&D and other expenses.

( Unit: ¥bn )	FY2015 H1 results	FY2016 H1 results	Change	FY2016 forecast	Rate of progress
Net sales	178.8	174.0	-4.7(-3%)	344.0	51%
Operating Income <i>Operating margin</i>	22.4 [12.6%]	15.3 [8.8%]	-7.1(-32%)	32.0	48%
Ordinary income	20.0	13.6	-6.3(-32%)	26.0	53%
Net profit	9.5	10.7	1.2(+13%)	18.0	60%

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

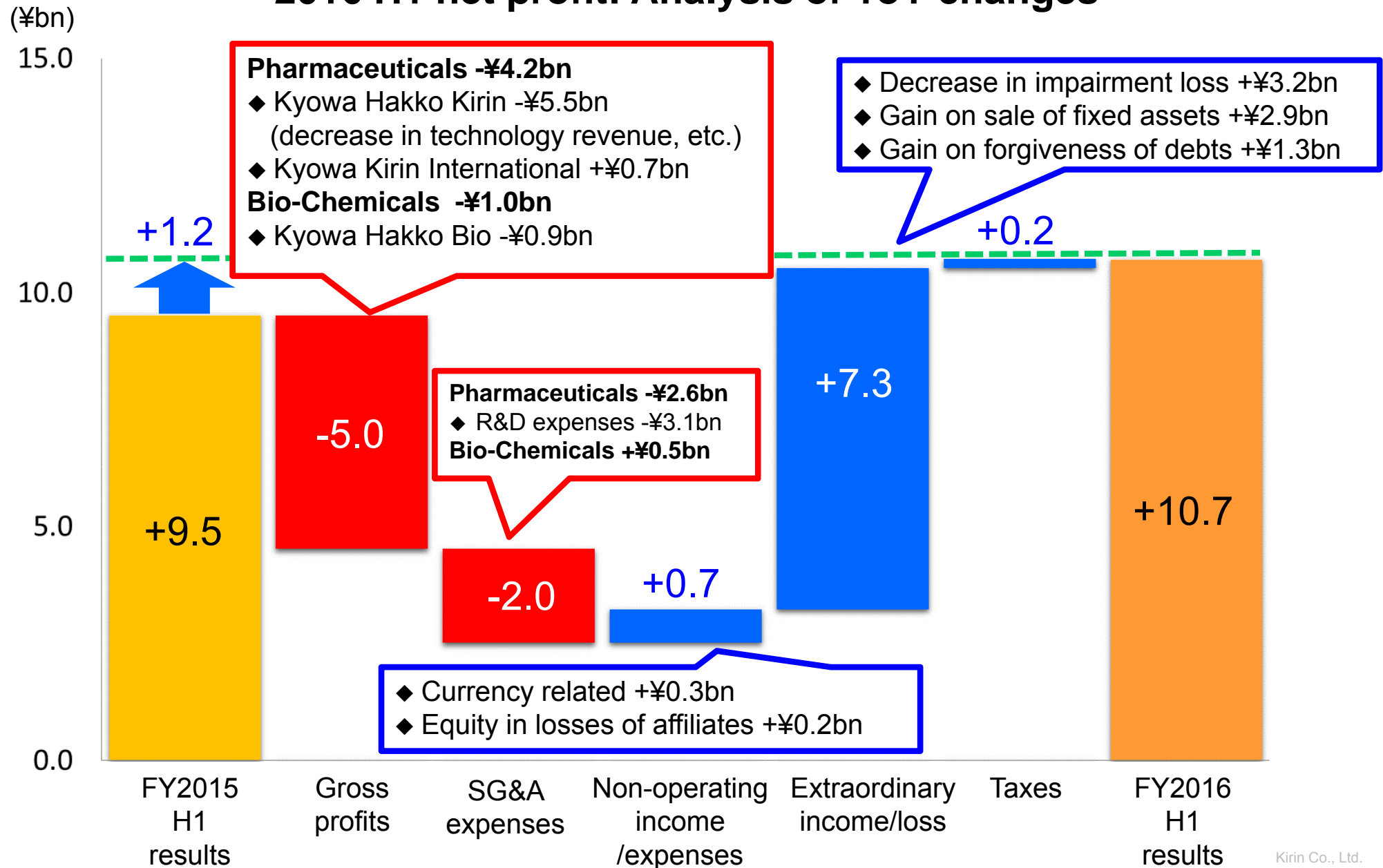
(Rate of progress of FY 2016 sales forecast, released on July 21, 2016)

- ✓ Ordinary income declined due to a decrease in operating income
- ✓ While ordinary income declined, net profit increased due to an increase in extraordinary income from gains on sale of fixed assets

# Summary of FY2016 H1 consolidated results: Analysis of YoY profit changes

**KYOWA KIRIN**

## 2016 H1 net profit: Analysis of YoY changes



# Summary of FY2016 H1 financial results by segment

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In the Pharmaceuticals business, despite growth in domestic products, especially new products, sales and profits declined due to the drug price revision, lower technology out-licensing revenue, increased R&D expenses.  
In the Bio-Chemicals businesses, sales and profits declined due to the strong yen.

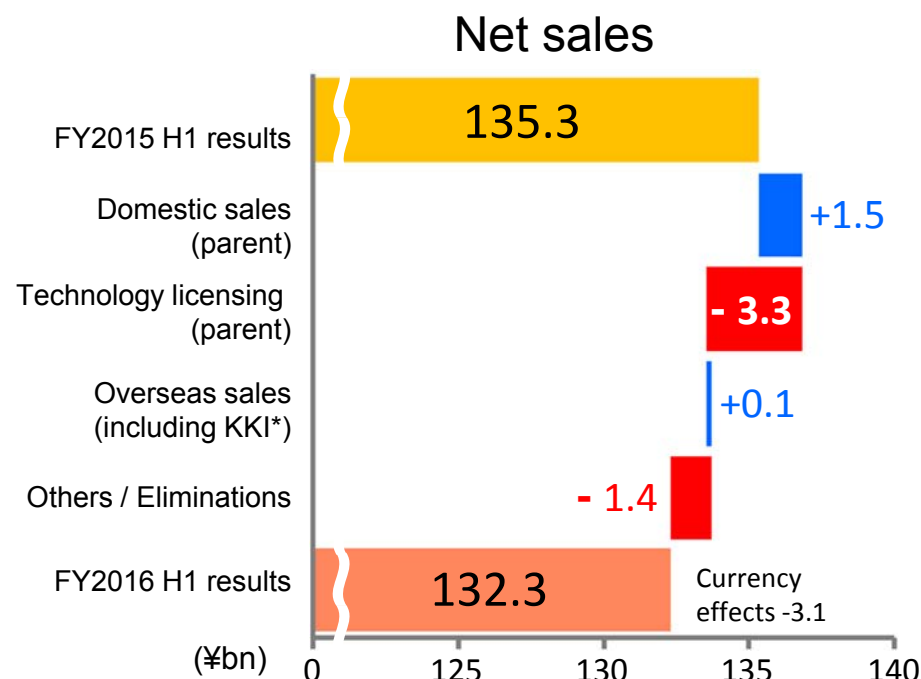
( Unit: ¥bn )		FY2015 H1 results	FY2016 H1 results	Change
Pharmaceuticals business	Net sales	135.3	132.2	-3.0 (-2%)
	Operating income <i>Operating margin</i>	18.5 13.7%	11.6 8.8%	-6.8 (-37%)
Bio-Chemicals business	Net sales	45.0	43.1	-1.8 (-4%)
	Operating income <i>Operating margin</i>	3.9 8.9%	3.4 8.1%	-0.5 (-13%)

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



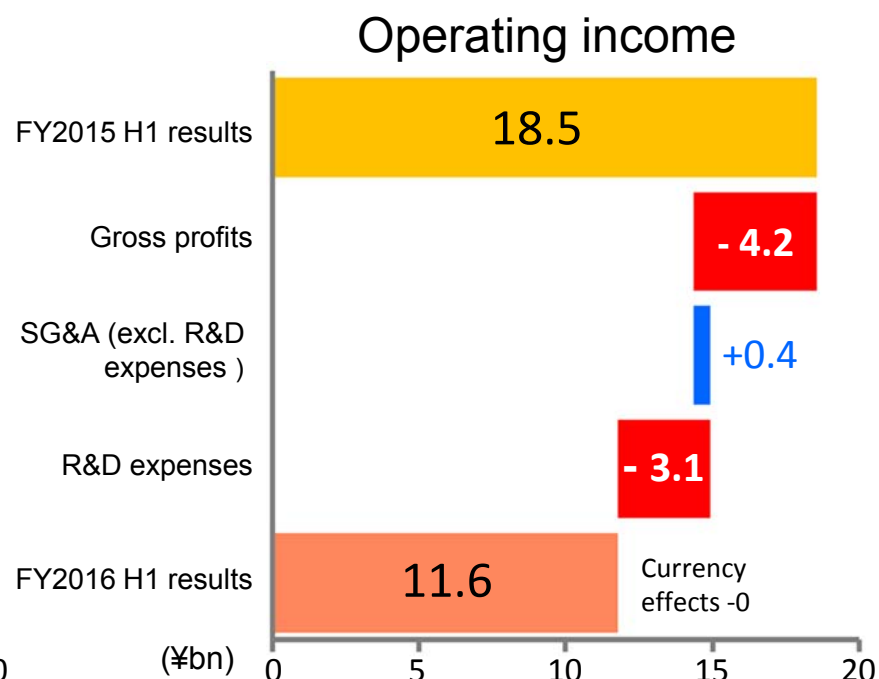
# Pharmaceuticals business: FY2016 H1 Analysis of YoY changes

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## Net sales (-¥3.0bn)

- Domestic pharmaceutical products (+¥1.5bn):
  - Despite the impact of drug price revision, key product NESP<sup>®</sup> recorded strong sales, and new products G-Lasta<sup>®</sup> and NOURIAST<sup>®</sup> grew steadily.
  - Sales of long-term prescription products such as ALLELOCK<sup>®</sup> decreased due to penetration of generics.
- Technology licensing, etc. (-¥3.3bn): Currency effects (-¥0.0bn)
  - Decrease in royalties, etc.
- Overseas sales (+¥0.1bn): Currency effects (-¥3.0bn)
  - KKI\* (+¥0.2bn): growth of Abstral and PecFent, etc.



## Operating income (-¥6.8bn)

- Gross profits (-¥4.2bn): Currency effects (-¥2.4bn)
  - Decrease in royalties and currency effects of the strong yen
- SG&A (+¥0.4bn): Currency effects (+¥1.6bn)
  - Increase in expenses due to introduction of Moventig
  - Decrease in overseas expenses due to strong yen
- R&D expenses (-¥3.1bn): Currency effects (+¥0.6bn)
  - Increase in expenses for late-stage development products in Japan
  - Increase in overseas R&D expenses, etc.

\* On February 22, 2016, ProStrakan Group plc's company name was changed to Kyowa Kirin International plc (KKI).

# Pharmaceuticals business:

## Domestic sales of key products

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Despite impact of the drug price revision, sales of domestic pharmaceutical products increased YoY due to expansion of the new product lineup and growth of key products such as NESP®

Product name, other information	FY2015 H1 results	FY2016 H1 results	Change	Reason for change	FY2016 Forecast	Rate of Progress*
NESP®	27.0	27.4	0.3 (+1%)	(+) Steady growth of the market (-) Drug price revisions	56.5	49%
REGPARA®	8.5	9.4	0.9 (+10%)	(+) Steady growth of the market	19.7	48%
ALLELOCK®	12.4	10.8	-1.6 (-13%)	(-) Market penetration of generics (-) Drug price revisions	17.8	61%
Patanol®	8.8	9.0	0.2 (+2%)	(-) Market penetration of competitors	12.8	70%
G-Lasta®	3.8	7.4	3.6 (+95%)	(+) Steady penetration of the market	15.9	47%
NOURIAST®	2.2	3.3	1.0 (+48%)	(+) Steady penetration of the market	7.0	47%
Technology out-licensing	3.7	0.7	-2.9 (-80%)	(-) Decrease in royalties	6.4	11%

\* Rate of progress compared to 2016 sales forecasts (as of July 29, 2016)

(Unit: ¥bn, figures rounded down)

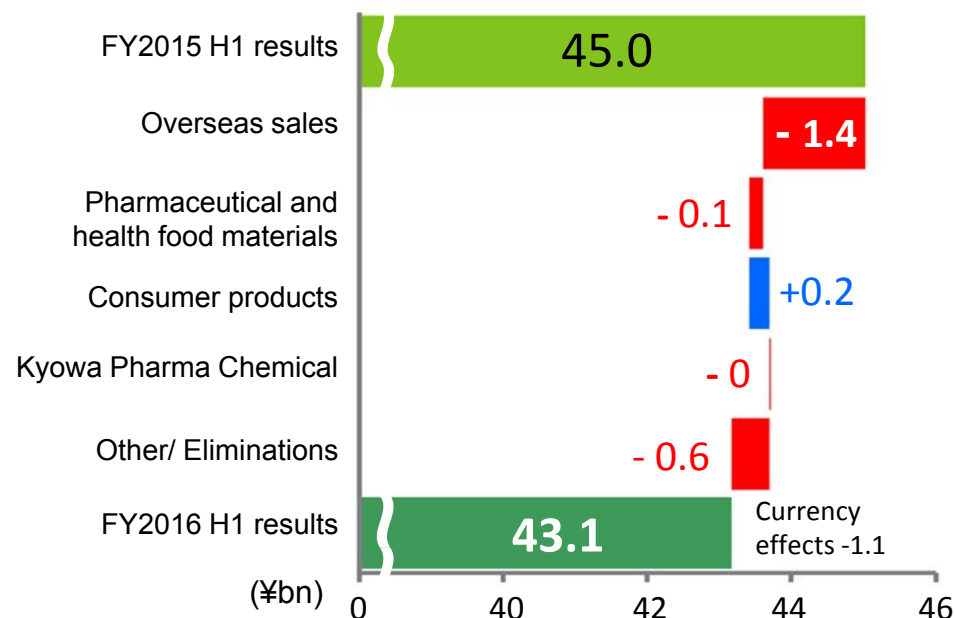
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# Bio-Chemicals business:

## FY2016 H1: Analysis of YoY profit

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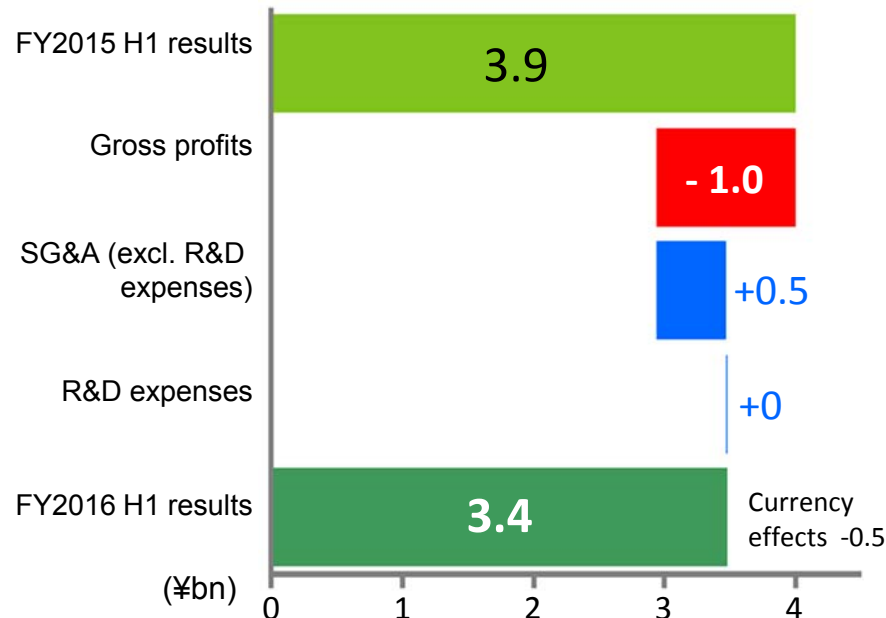
### Net sales



### Net sales (-¥1.8bn)

- Overseas sales (-¥1.4bn): Currency effects (-¥1.1bn)
  - Americas (+¥0.2bn): Currency effects (-¥0.2bn), growth in amino acids for cell culture medium, etc.
  - Europe (-¥0.7bn): Currency effects (-¥0.5bn), effects from the May 2015 transfer of cosmetics raw materials business.
  - Asia and others (-¥0.9bn): Currency effects (-¥0.3bn), intensified sales competition of active pharmaceutical ingredients for the Asian market.
- Pharma / health-food use (-¥0.1bn):
- Mail-order sales, etc. (+¥0.2bn): The mail-order business stayed strong supported by sales growth of new products.
- Kyowa Pharma Chemical (-¥0.0bn)

### Operating income



### Operating income (-¥0.5bn)

- Gross profit (-¥1.0bn): Currency effects (-¥0.7bn)
  - The decrease is attributable to the continued currency effect and the reduction of gross profit margins due to intensified competition in the Asian region.
- SG&A (+¥0.5bn): Currency effects (+¥0.1bn)
- Shift in a part of the sales promotion expenses for mail-order business from H1 to H2

# Revision to forecasts:

## Consolidated forecasts for FY2016 (full year)

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(Unit: ¥bn)	FY2015 results	FY2016 forecast released on 29/1 (a)	FY2016 forecast released on 21/7 (b)	Change (b)-(a)
Net sales	364.3	351.0	344.0	-7.0
Operating income	43.7	30.0	32.0	+2.0
Ordinary income	39.2	25.0	26.0	+1.0
Net profit	29.7	16.0	18.0	+2.0

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

### Main causes for revision

- Operating income: Negative factors such as continuing appreciation of the yen and recognition of costs related to acquisition of the sales rights of Moventig as well as positive factors such as increase in pharmaceutical product sales in Japan
- Net profit: Recognition of gain from sale of fixed assets

# Revision to forecasts:

## Forecasts for FY2016 (full year) by segment

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( Unit: ¥bn )		FY2015 results	FY2016 forecast released on 29/1 (a)	FY2016 forecast released on 29/7 (b)	Change
Pharmaceuticals business	Net sales	279.2	268.0	264.0	-4.0
	Operating income <i>Operating margin</i>	36.2 13.0%	23.0 8.6%	27.5 10.4%	+4.5
Bio-Chemicals business	Net sales	88.8	87.0	84.0	-3.0
	Operating income <i>Operating margin</i>	8.1 9.1%	7.0 8.0%	4.5 5.4%	-2.5

### Main causes for revision (Operating income)

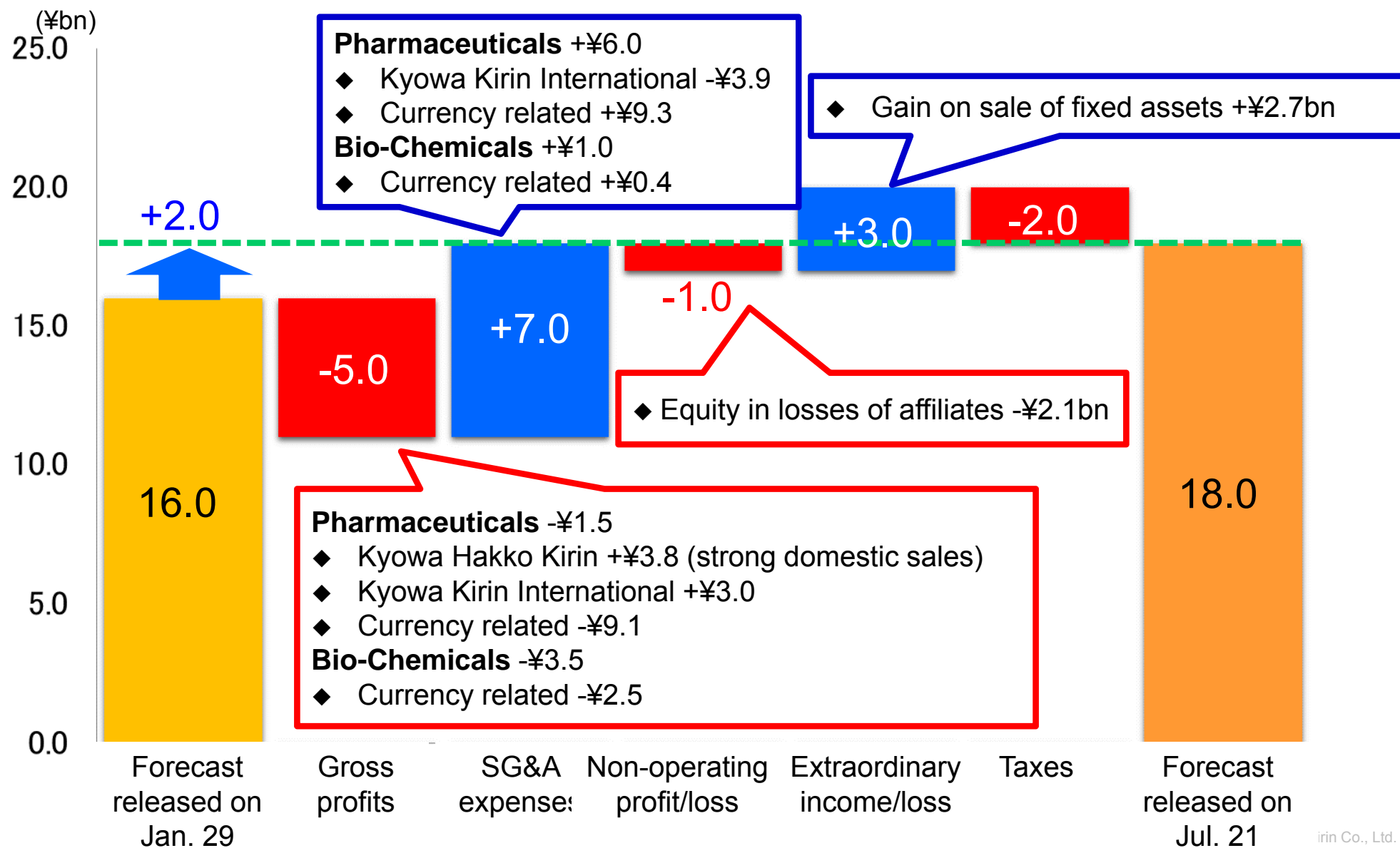
- Pharmaceuticals business: Negative factors such as recognition of costs related to acquisition of the sales rights of Moventig and positive factors such as increase in product sales in Japan
- Bio-Chemicals business: Negative factors such as continuing appreciation of the yen

# Revision to forecasts: Consolidated forecast of FY2016 (full year)

**KYOWA KIRIN**

## Net profit:

### Comparison between previous and current 2016 full year forecasts



## R&D review

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## Domestic:

- **Announcement of results of interim efficacy analysis of Phase 2 clinical study of RTA 402 targeting chronic kidney disease with type-2 diabetes (May)**
- **Initiation of Phase 2 study of KHK4563 targeting eosinophilic chronic rhinosinusitis (June)**
- **Approval received for fully human anti-IL-17 receptor A antibody KHK4827 (brand name in Japan: LUMICEF®) (July)**



## Overseas:

- **Initiation of Phase 1/2 trials of Nivolumab (Bristol-Myers Squibb) in combination with KW-0761 targeting solid tumors (February, U.S.)**
- **Announcement of results from Phase 3 trials of Benralizumab/KHK4563 targeting asthma (May)**
- **Announcement of results from Phase 2 study of KW-0761 targeting adult T cell leukemia-lymphoma (June, ASCO)**
- **Initiation of Phase 3 study of AMG531 targeting aplastic anemia (June, Japan, Korea)**
- **Breakthrough Therapy Designation granted by U.S. Food and Drug Administration (FDA) for KRN23 targeting pediatric X-Linked Hypophosphatemia (June, U.S.)**
- **Initiation of Phase 2 study of KRN23 targeting TIO or ENS (June, Japan, Korea)**
- **Initiation of Phase 2 study of KHK4083 targeting ulcerative colitis (June, North America, Europe)**

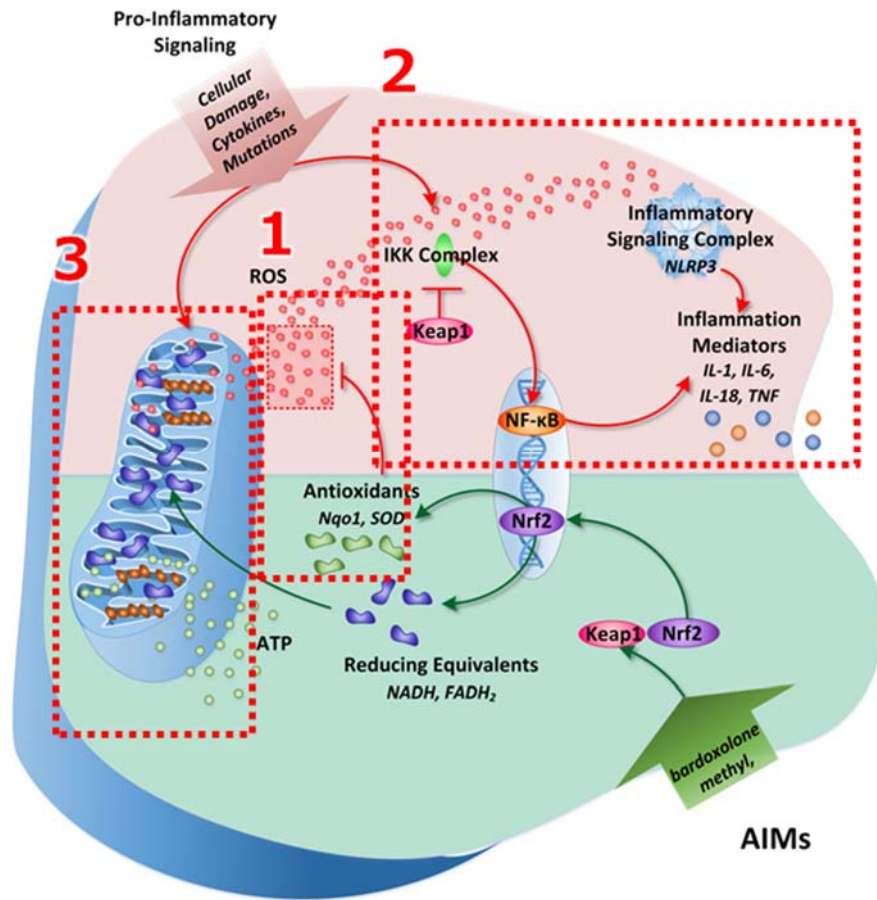
## RTA 402

Indication	Country/region	Development stage (Scheduled trial completion date)		Estimated enrollment
		Phase 2	Phase 3	
Chronic kidney disease with diabetes	Japan	(2017/12)		108

1

ClinialTrials.gov identifier:

<sup>1</sup> NCT02316821



AIMs: antioxidant inflammation modulators

- RTA 402 activates Keap1/Nrf2 system
  1. Increases the expression of antioxidant genes and removes excess reactive oxygen species
  2. Shows anti-inflammatory effect through suppression of NF-κB activation and/or pro-inflammatory cytokine production
  3. Improves mitochondria dysfunction and energy metabolism

## **A Randomized, Double-blind, Placebo-controlled RTA 402 Clinical Trial in Patients with Chronic Kidney Disease and Type 2 Diabetes (TSUBAKI study)**

Efficacy primary endpoint:	Changes in glomerular filtration rate after 16 weeks of study drug administration, compared to baseline ( <b>measured by inulin clearance</b> )
Target disease stage:	G3
Target sample size:	72 patients

**Data from interim analysis showed  
a significant improvement in renal function  
and there were no safety concerns related to RTA 402.**



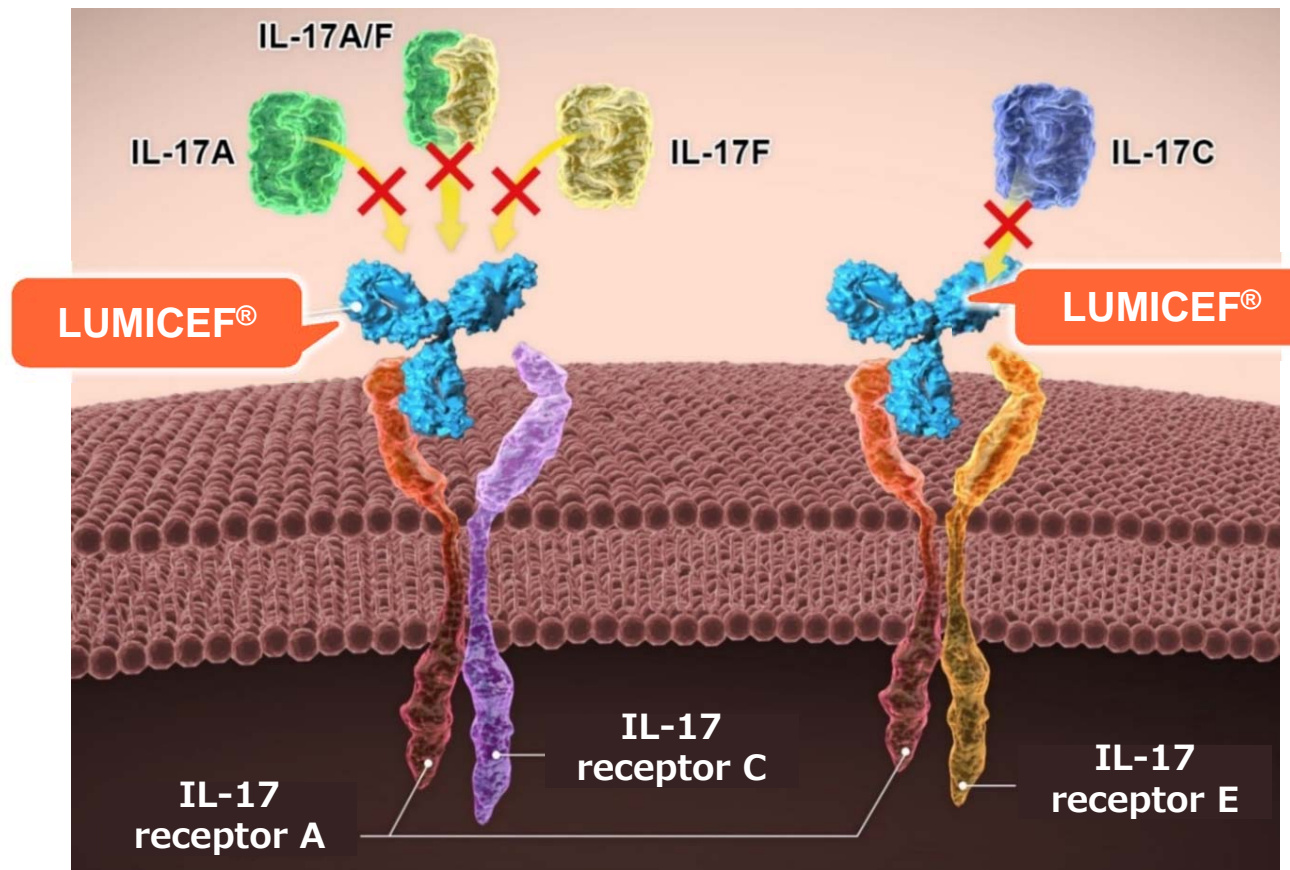
**Additional examination of patients with Stage G4 (36 patients)  
is planned with protocol amendment**

# LUMICEF<sup>®</sup> approved in Japan

LUMICEF<sup>®</sup> Subcutaneous Injection 210 mg Syringe (code name: KHK4827, generic name: Brodalumab (Genetical Recombination)) has been approved in Japan since July 4, 2016, the first approval of the product worldwide

## ● LUMICEF®: Mechanism of Action

LUMICEF® selectively binds with IL-17 receptor A, and improves the symptoms of psoriasis vulgaris, psoriatic arthritis, pustular psoriasis, and psoriatic erythroderma, by inhibiting the activities that IL-17A, IL-17F, IL-17A/F and IL-17C have via IL-17 receptor.



- IL-17 receptor A together with the IL-17 receptor C forms the IL-17A, IL-17F, and IL-17A/F receptor
- IL-17 receptor A together with IL-17 receptor E also forms IL-17 C receptor
- LUMICEF® is a fully human monoclonal antibody that selectively binds with IL-17 receptor A, and inhibits the combination of IL-17A, IL-17F, IL-17A/F and IL-17C with IL-17 receptor

<b>Brand name</b>	LUMICEF® Subcutaneous injection 210mg Syringe
<b>Generic name</b>	Brodalumab (Genetical recombination)
<b>Indication</b>	The following diseases that respond inadequately to existing therapies: Psoriasis vulgaris, psoriatic arthritis, pustular psoriasis, and psoriatic erythroderma
<b>Dosage and administration</b>	In adults, administer 210mg of Brodalumab subcutaneously at weeks 0, 1, and 2, followed by 210mg every 2 weeks
<b>Date of approval</b>	July 4, 2016 <sup>2</sup>

- The first approval worldwide for the marketing authorization of a fully human anti-IL-17 receptor A monoclonal antibody
- In clinical trials for Japanese psoriasis patients, approximately 60% of subjects achieved clear skin (PASI 100), clinically meaningful outcomes in psoriatic skin, after 12 weeks treatment and the high effectiveness of the drug were confirmed.<sup>1</sup>
- LUMICEF has been shown to improve clinical symptoms and QOL for the diseases it has been approved to treat, and is expected to increase treatment satisfaction.

<sup>1</sup> J Dermatol Sci 2016, 81, p44-52

<sup>2</sup> not yet listed in the NHI (National Health Insurance) drug price standard as of August 1, 2016



## KHK-4083

Indication	Country/region	Development stage (Scheduled trial completion date)		Estimated enrollment
		Phase 2	Phase 3	
Ulcerative Colitis	North America and Europe	(2018/9)		60 <sup>2</sup>

**Estimated no. of patients:** U.S. : approx. 650,000<sup>1</sup> patients

<sup>1</sup> Diagnosed Prevalent Cases, Decision Resources (2015)

ClinialTrials.gov identifier:

<sup>2</sup> NCT02647866



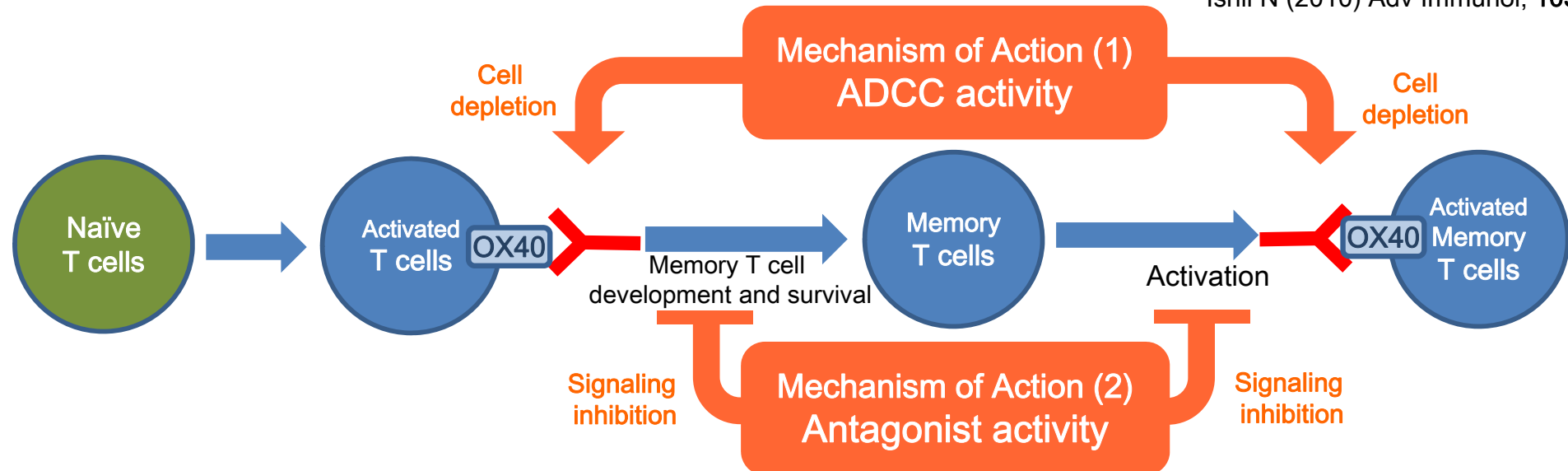
**KHK4083:**

A fully human antibody targeting OX40 created using human antibody-producing technology. It has the POTELLIGENT® technology-enhanced ADCC activity and antagonist activity against the OX40 ligand function.

**OX40:**

A molecule in the TNF receptor superfamily, OX40 is mainly expressed in activated T cells. OX40-OX40 ligand interaction promotes the survival of activated T cells, and accelerates the formation of memory T cells. OX40 also has an important role to play in the reactivation of memory T cells. OX40 involvement has been suggested in many autoimmune diseases including ulcerative colitis. <sup>1</sup>

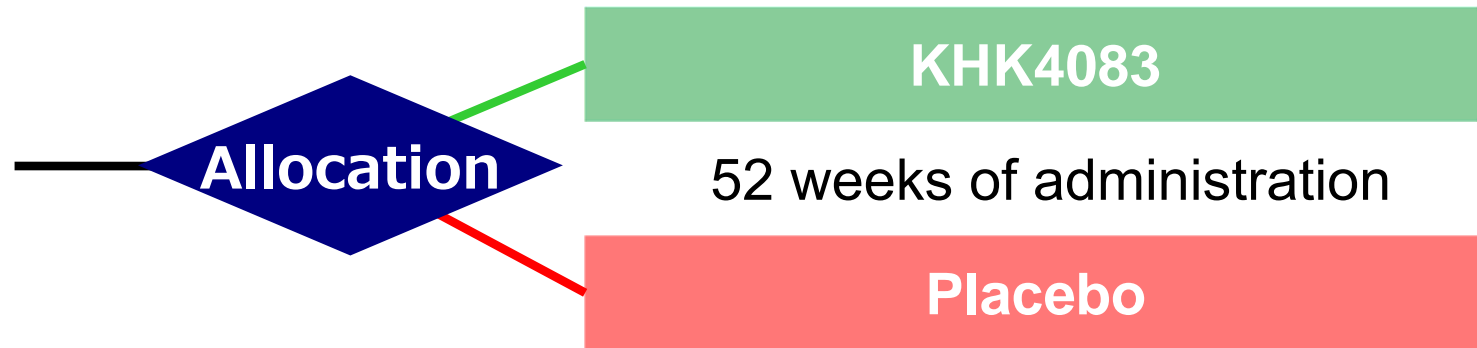
<sup>1</sup> Ishii N (2010) Adv Immunol, 105, 63



**Excellent therapeutic effect based on strong inhibition of adaptive immunity by the combination of actions (1) and (2) can be anticipated.**

## KHK4083 Phase II clinical trial

Randomized, Double-blind, Placebo-controlled Multiple Ascending Dose Study of an Anti-OX40 Fully Human Antibody (KHK4083) in Subjects With Active Ulcerative Colitis



Efficacy primary endpoint:

Changes in modified Mayo endoscopy sub-score (mMES)<sup>1</sup> at 12 weeks and 52 weeks

Target sample size:

72 patients

<sup>1</sup> An index for the assessment of symptom improvements in patients with ulcerative colitis using endoscopic images

## KW-0761 (hematological cancer)<sup>1</sup>

Indication		Country/region	Development stage (Scheduled trial completion date)			Estimated enrollment
			Phase 2	Phase 3	Application	
ATL	Relapsed/refractory	U.S., Europe, others <sup>2</sup>	(2016/11)			71 <sup>4</sup>
CTCL	Relapsed/refractory	U.S., Europe, Japan, others <sup>2</sup>		(2017/2)		372 <sup>5</sup>

**Annual incidence per disease:** U.S. CTCL: approx. 1,500<sup>3</sup> patients

<sup>1</sup> Launched in Japan (brand name POTELIGEO®)

<sup>2</sup> CCR4 not included in selection criteria

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

ClinialTrials.gov identifier:

<sup>4</sup> NCT01626664; <sup>5</sup> NCT01728805

## KW-0761 (solid tumor)

Indication	Country/ region	Concomitant Drug	Development stage (Scheduled trial completion date)	Partner	Estimated enrollment	
			Phase 1			
Solid tumor	U.S.	Durvalumab or Tremelimumab	(2017/11)	AstraZeneca	108	<sup>1</sup>
	U.S.	PF-05082566	(2018/12)	Pfizer	70	<sup>2</sup>
	Japan	Nivolumab	(2017/10)	ONO PHARMACEUTICAL Bristol-Myers Squibb	108	<sup>3</sup>
	U.S.	Nivolumab	(2017/8)	Bristol-Myers Squibb	187	<sup>4</sup>
	U.S.	Docetaxel	(2016/12)	-	13	<sup>5</sup>

ClinicalTrials.gov identifier:

<sup>1</sup> NCT02301130; <sup>2</sup> NCT02444793; <sup>3</sup> NCT02476123; <sup>4</sup> NCT02705105; <sup>5</sup> NCT02358473

# Key global development updates (4)

**KYOWA KIRIN**

## KW-6002<sup>1</sup>

Indication	Country/region	Development stage (Scheduled trial completion date)		Estimated enrollment
		Phase 3	Application	
Parkinson's disease	North America Europe, Others	(2016/11)		609 <sup>4</sup>

**Patient numbers:** Japan: approx. 140,000<sup>2</sup>, U.S.: approx. 570,000<sup>3</sup>

<sup>1</sup> Launched in Japan (brand name: NOURIAST®)

<sup>2</sup> Ministry of Health, Labour and Welfare: 2011 Patient survey (illness classification)

<sup>3</sup> Study by Decision Resources

ClinialTrials.gov identifier:

<sup>4</sup> NCT01968031

# Key global development updates (5)

## KRN23

Indication	Country/region	Development stage (Scheduled trial completion date)		Partner	Estimated enrollment	
		Phase 2	Phase 3			
XLH	Pediatric	U.S., Europe	(2017/3)	Ultragenyx Pharmaceutical (U.S., Europe)	50	2
		U.S.	(2017/12)		10	3
	Adult	U.S.	(2016/9)		25	4
		North America, Europe Japan, Korea	(2017/3)		120	5
		North America, Europe Japan, Korea	(2017/1)		10	6

**Estimated no. of patients:** XLH Japan: approx. 5,000<sup>1</sup> (adult), approx. 1,000<sup>1</sup> (pediatric)  
U.S.: approx. 12,000<sup>1</sup> (adult), approx. 3,000<sup>1</sup> (pediatric)

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

ClinicalTrials.gov identifier:

<sup>2</sup> NCT02163577; <sup>3</sup> NCT02750618;

<sup>4</sup> NCT02312687; <sup>5</sup> NCT02526160;

<sup>6</sup> NCT02537431

# Key global development updates (5)

**KYOWA KIRIN**

## KRN23

Indication	Country/region	Development stage (Scheduled trial completion date)		Partner	Estimated enrollment	
		Phase 2	Phase 3			
TIO/ENS	U.S.	(2016/9)		Ultragenyx Pharmaceutical (U.S., Europe)	15	3
	Japan / Korea	(2017/7)			6	4

**Estimated no. of patients: TIO/ENS**

Japan: approx. 30<sup>1</sup>, U.S.: approx. 500 - 1,000<sup>2</sup>

<sup>1</sup> 2010 Ministry of Health, Labour and Welfare Epidemiological Research on abnormalities in Hormone Receptor Mechanisms

<sup>2</sup> Survey by Ultragenyx Pharmaceutical

ClinicalTrials.gov identifier:

<sup>3</sup> NCT02304367; <sup>4</sup> NCT02722798

## Anti-FGF23 fully human antibody (KRN23) received breakthrough therapy designation for pediatric X-linked hypophosphatemia from FDA.<sup>1</sup>

### What is the Breakthrough Therapy Designation?

#### ■ Designation criteria

The designation may be granted to the drugs that are intended to treat a serious or life threatening disease or condition and demonstrate substantial improvement over existing therapies on clinically significant endpoints.

#### ■ Merits of designation

1. Intensive guidance from and communication with the FDA in the areas of trial design and analysis methods, with the aim of more effective development of the designated drug
2. Proactive and cooperative involvement of senior managers in review process
3. Possibility for application of rolling review which allows submission of portions of an application package in advance
4. May be eligible for accelerated approval or priority review

<sup>1</sup> Designation provided in the FDASIA<sup>3</sup> signed July 2012

<sup>2</sup> KRN23 has also received the Fast Track and Orphan Drug designations targeting X-linked Hypophosphatemia from the FDA

<sup>3</sup> Food and Drug Administration Safety and Innovation Act

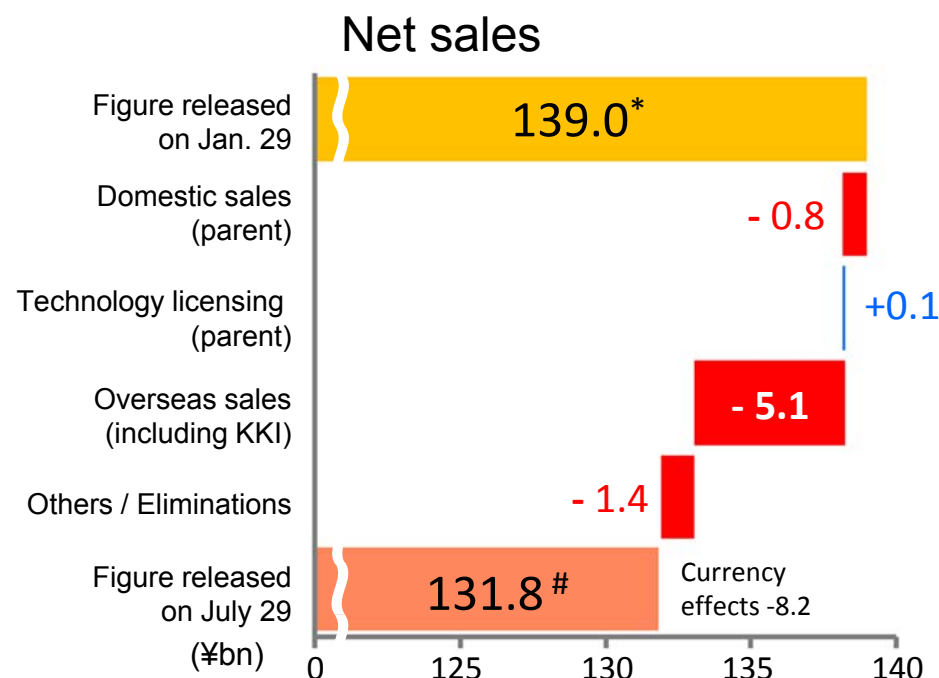


# Appendix

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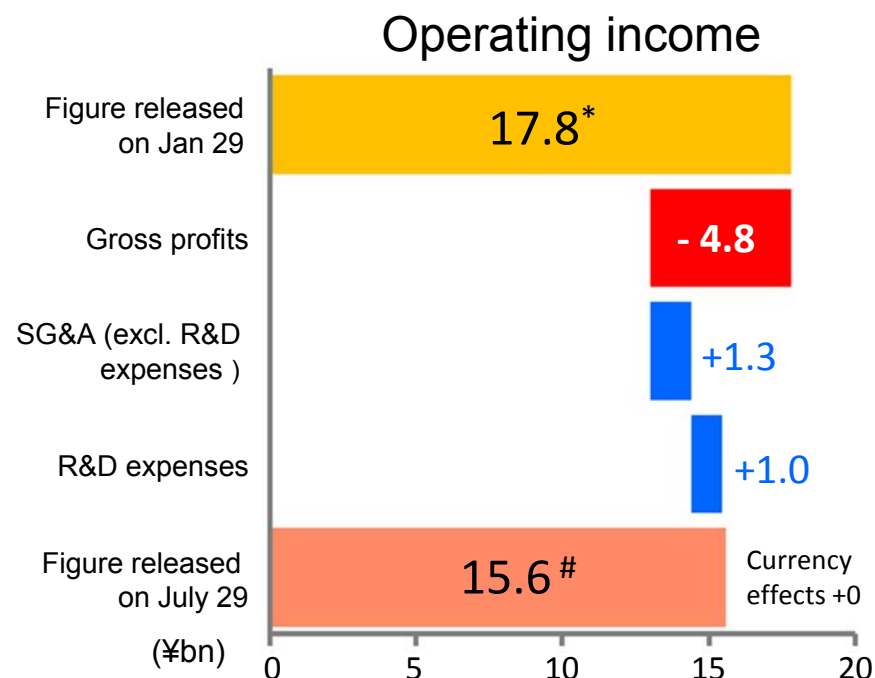
# Revisions to forecasts: Pharmaceuticals Business Changes from 2016 H2 forecasts

**KYOWA KIRIN**



## Net sales (-¥7.2bn)

- Domestic pharmaceutical products (-¥0.8bn):
  - Backlash from the H1 FY2016 results, etc.
- Technology licensing, etc. (+¥0.1bn): Currency effects (-¥0.2bn)
- Overseas sales (-¥5.1bn): Currency effects (-¥7.3bn)
  - Expected growth of some KKI products, etc.



## Operating income (-¥2.2bn)

- Gross profits (-¥4.8bn): Currency effects (-¥6.7bn)
  - Impact from increased revenue of KKI, etc.
- SG&A (+¥1.3bn): Currency effects (+¥4.7bn)
  - Increase in costs due to introduction of Moventig
- R&D expenses (+¥1.0bn): Currency effects (+¥2.0bn)
  - Expected carry-over from the first half and increased development costs

\* Full-year forecast (released on Jan. 29) minus H1 forecast (released on Jan. 29)

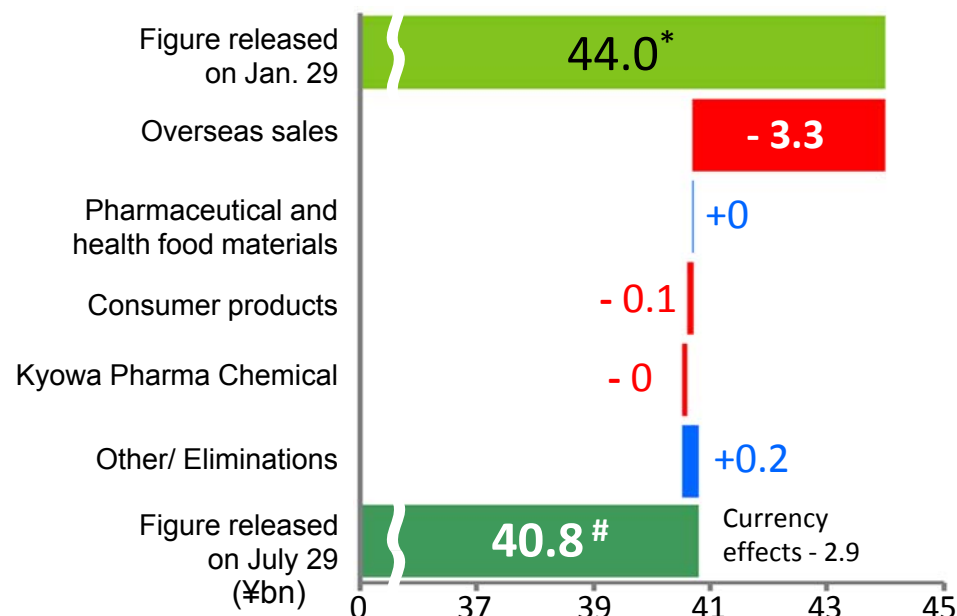
# Full-year forecast (released on July 29) minus H1 results

# Revisions to forecasts: Bio-Chemicals

## Business Changes from 2016 H2 forecasts

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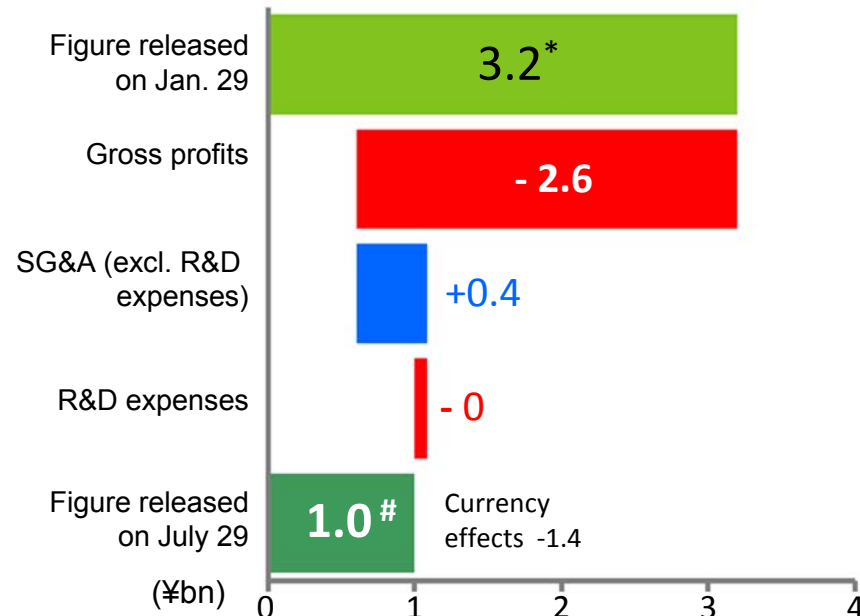
Net sales



### Net sales (-¥3.2bn)

- Overseas sales (-¥3.3bn): Currency effects (-¥2.9bn)
  - Americas (-¥0.9bn): Currency effects (-¥0.7bn)
  - Europe (-¥0.9bn): Currency effects (-¥1.3bn), Despite the currency effect, increase in sales of the products enjoying strong demand is expected.
  - Asia and others (-¥1.5bn): Currency effects (-¥0.9bn), Competitive products are expected to partly replace our active pharmaceutical ingredients destined for the Asian market
- Pharma / health-food use (+¥0.0bn):
- Mail order sales, etc. (-¥0.1bn)
- Kyowa Pharma Chemical (-¥0.0bn)

Operating income



### Operating income (-¥2.2bn)

- Gross profit (-¥2.6bn): Currency effects (-¥1.8bn)
  - Yen staying strong and competitive products penetrating the Asian market will put downward pressures on the income.
- SG&A (+¥0.4bn): Currency effects (+¥0.3bn)

\* Full-year forecast (released on Jan. 29) minus H1 forecast (released on Jan. 29)  
 # Full-year forecast (released on July 29) minus H1 results

# Agreement for the clinical development of anti-LIGHT monoclonal antibody

**KYOWA KIRIN**

**Entered into an agreement with Medgenics over development of anti-LIGHT monoclonal antibody for severe pediatric onset inflammatory bowel disease (IBD)**

## **Compound properties:**

- ◆ Human monoclonal antibody which binds the cytokine LIGHT<sup>1</sup> that contributes to IBD and other autoimmune diseases

## **Details of the agreement:**

- ◆ Medgenics to conduct signal finding study testing the drug on Severe Pediatric Onset IBD
- ◆ Following this study, Medgenics to decide on whether to pursue further development
- ◆ Kyowa Hakko Kirin to determine whether it will jointly develop the drug or license out its relevant intellectual properties to Medgenics.

## **Territories:**

- ◆ North America: Medgenics
- ◆ Europe: Medgenics or Kyowa Hakko Kirin<sup>2</sup>
- ◆ Others : Kyowa Hakko Kirin

<sup>1</sup>Lymphotoxin-like, exhibits Inducible expression, and competes with HSV Glycoprotein D for HVEM, a receptor expressed by T lymphocytes )

<sup>2</sup>Differs depending on whether Kyowa Hakko Kirin selects co-development or licensing arrangement option

# Biosimilar products development update

Development code	Reference bio medical product		Country/region	Development stage		
	Generic name	Brand name		Phase 1	Phase 2	Phase 3
FKB327	Adalimumab	HUMIRA	U.S., others			1
FKB238	Bevacizumab	Avastin	United Kingdom	2		
Not disclosed	Not disclosed	Not disclosed	Not disclosed	Determined target product		

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

ClinialTrials.gov identifier: <sup>1</sup> NCT02260791

<sup>2</sup> Development is currently conducted by Centus Biotherapeutics Limited.

# Development progress with outlicensed compounds

**KYOWA KIRIN**

Name	Partner	Phase			Filing	Remarks
		I	II	III		
Tivozanib	AVEO				EU	Advanced Renal Cell Cancer (VEGF receptor inhibitor) (KRN951)
Benralizumab (MEDI-563)	AstraZeneca /MedImmune					Asthma (Anti-IL-5R antibody) (KHK4563) POTELLIGENT®
						COPD
KRN5500	Midatech Pharma US					Peripheral neuropathy
RGI-2001	REGiMMUNE	Phase1/2				Immunosuppressive

(as of July 22th, 2016)

## Average Exchange Rate

Average exchange rate	2015 Q2 Results	2016 Q2 Results	Change	FY2016 H1 Forecast released on 29/1
¥/\$	¥120	¥114	-¥6	¥119
¥/€	¥135	¥127	-¥8	¥137
¥/£	¥183	¥165	-¥18	¥187

## FY2016 H1 Currency Effects (YoY)

Segment	Currency	Net sales	Operating income
Pharmaceuticals business	\$	-¥0.06bn	+¥0.28bn
	€	-¥0.02bn	-¥0.00bn
	£	-¥2.23bn	-¥0.01bn
Bio-Chemicals business	\$	-¥0.56bn	-¥0.31bn
	€	-¥0.50bn	-¥0.29bn
	£	-	-

## Forecasts of Annual Currency Exchange Rate in 2016

Exchange Rate	Previous Forecast Released on Jan. 29 (a)	Current Forecast Released on July 29 (b)	Change (b)-(a)	FY2016 H2 Forecast
¥/\$	¥119	¥109	-¥10	¥103
¥/€	¥137	¥121	-¥16	¥114
¥/£	¥187	¥150	-¥37	¥135

## Estimated Exchange Rate Sensitivity of the (consolidated) Earnings Forecast for the 2016 H2 (from July to December) <sup>1</sup>

Currency	Changes	Impact on Net Sales	Impact on Operating Income
¥/\$	+ ¥ 1	-¥0.13bn	-¥0.01bn
¥/€	+ ¥ 1	-¥0.06bn	-¥0.03bn
¥/£	+ ¥ 1	-¥0.11bn	-¥0.01bn

<sup>1</sup> Forecasts for the H2 revised according to possible changes to the assumed foreign exchange rate



ADCC	Antigen Dependent Cellular Cytotoxicity
ATL	Adult T-cell Leukemia/Lymphoma
CCR4	Chemokine (C-C motif) Receptor 4
CTCL	Cutaneous T-Cell Lymphoma
ENS	Epidermal Nevus Syndrome
Keap1	Kelch-like ECH-associated protein 1
NF-E2	Nuclear factor erythroid 2
Nrf2	NF-E2-related factor 2
TIO	Tumor Induced Osteomalacia
TNF	Tumor Necrosis Factor
XLH	X-linked Hypophosphatemia

# **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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