KYOWA KIRIN

Results Presentation
Fiscal 2015 Interim

Kyowa Hakko Kirin Co., Ltd.

August 3, 2015

Forward-looking statements

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This document contains certain forward-looking statements relating to such items as the company's (including its domestic and overseas subsidiaries) forecasts, targets and plans. These forward-looking statements are based upon information available to the company at the present time and upon reasonable assumptions made by the company in making its forecasts, but actual results in practice may differ substantially due to uncertain factors.

These uncertain factors include, but are not limited to, potential risks of the business activities of the pharmaceutical industry in Japan and overseas, intellectual property risks, risk of side effects, legal regulation risks, product defect risks, risks of changes to prices for raw materials, risks of changes to market prices, as well as risks of changes to foreign exchange rates and financial markets.

This document contains information on pharmaceutical products (including products under development), but its contents should not be construed as promotion, advertising or as a medical recommendation.

Agenda

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FY2015 H1 Highlights
Nobuo Hanai, President and CEO

Financial review
Kazuyoshi Tachibana, Managing Executive Officer

R & D review
Topics
Nobuo Hanai, President and CEO

Q & A session

FY 2015 H1 Highlights

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In H1 of the final year of the medium-term business plan, the Pharmaceuticals business saw increases in sales and profits, whereas the Bio-Chemicals business saw an increase in sales and a decline in profits, resulting overall in an increase in sales and profits on a consolidated basis

- In the Pharmaceuticals business, new products G-Lasta®, Dovobet®, Onglyza®, and NOURIAST® progressed steadily (¥9.2 billion increase year on year), and sales increased 13% year on year to ¥135.3 billion , including a significant increase in ProStrakan sales
- In the Pharmaceuticals business, operating income increased 31% YoY to ¥18.5 billion despite increased R&D expenses due to the steady progression of overseas late-stage development products, and an increase in ProStrakan's SG&A expenses
- In the Bio-Chemicals business, influenced by active investment in sales promotion and other factors in the healthcare field, sales increased 2% year on year to ¥45 billion, but operating income declined 5% to ¥3.9 billion
- The full-year forecast for net income has been revised to ¥26 billion, a 64% increase over the previous year

Financial review

Summary of 2015 Q2 results

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Sales and profits increased YoY on a consolidated basis due to the growth of domestic products and other factors despite increased R&D expenses in the Pharmaceuticals business

(Unit: ¥bn)	FY2014 Q2 results	FY2015 Q2 results	Change	FY2015 forecast	Rate of progress
Net sales	161.8	178.8	16.9 (+10%)	360.0	50%
Operating Income *Operating margin*	18.4 [11.4%]	22.4 [12.6%]	4.0 (+22%)	47.0	48%
Ordinary income	16.8	20.0	3.2 (+19%)	41.0	49%
Net income	9.1	9.5	0.3 (+4%)	26.0	37%

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

(Rate of progress of FY 2015 sales forecast, disclosed July 24, 2015)

✓ The increase in ordinary income and net income was due to a higher operating income and other factors

Summary of FY2015 Q2 consolidated results: Analysis of YoY profit changes

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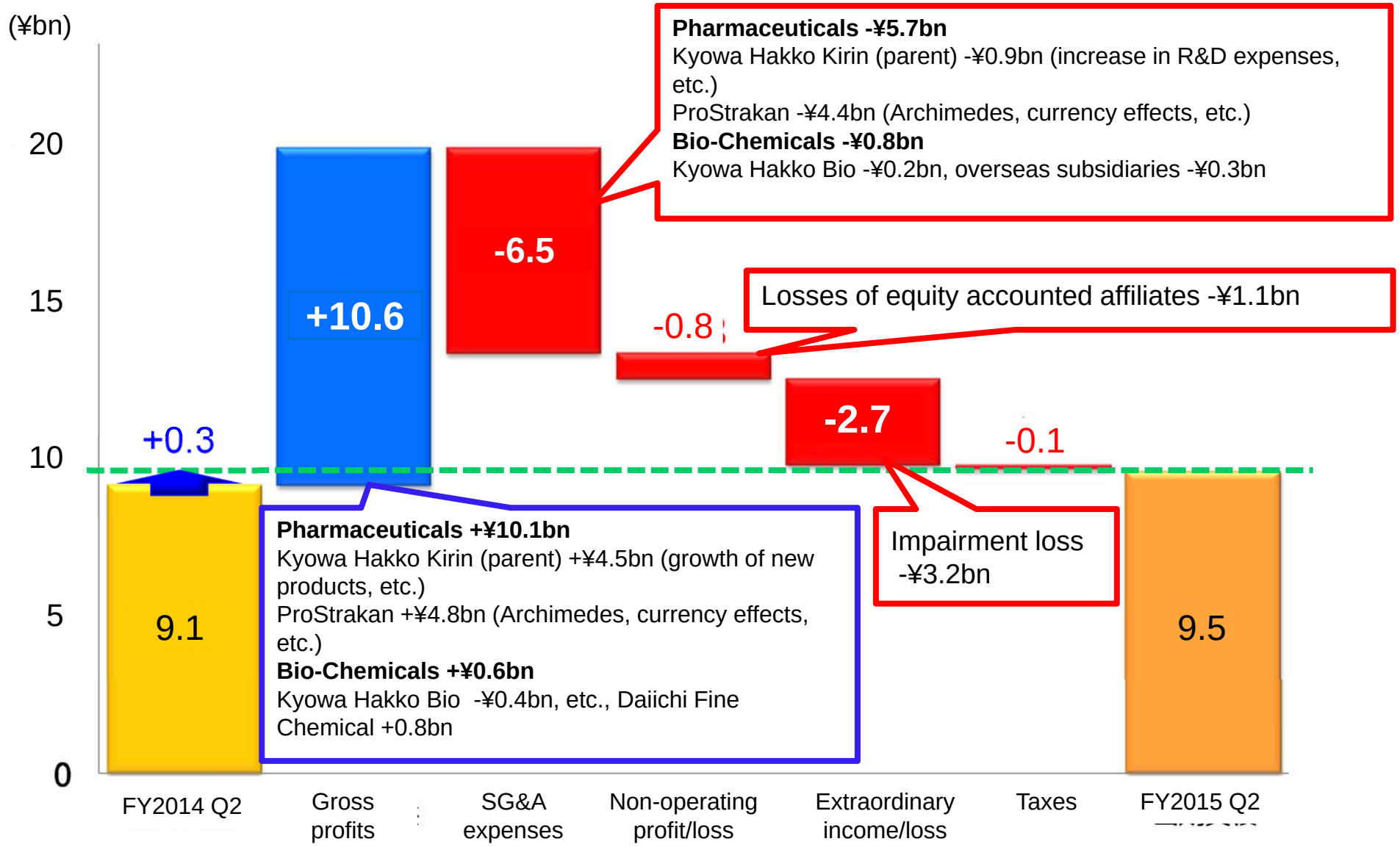
Q2 net income: Analysis of YoY changes



Summary of FY2015 Q2 financial results by segment

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In the Pharmaceuticals business, sales and profits increased due to growth of domestic products, in particular new products, and other factors.
In the Bio-Chemicals business, growth in amino acids for overseas supplements and for infusion-use and others was offset by higher SG&A expenses, resulting in increased sales but decreased profit

(Unit：¥bn)		FY2014 2Q results	FY2015 2Q results	Change
Pharmaceuticals business	Net sales	119.5	135.3	15.8 (+13%)
	Operating income *Operating margin*	14.1 [11.9%]	18.5 [13.7%]	4.3 (+31%)
Bio-Chemicals business	Net sales	44.0	45.0	0.9 (+2%)
	Operating income *Operating margin*	4.2 [9.6%]	3.9 [8.9%]	-0.2 (-5%)

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

Pharmaceuticals business: FY2015 Q2: Analysis of YoY profit changes

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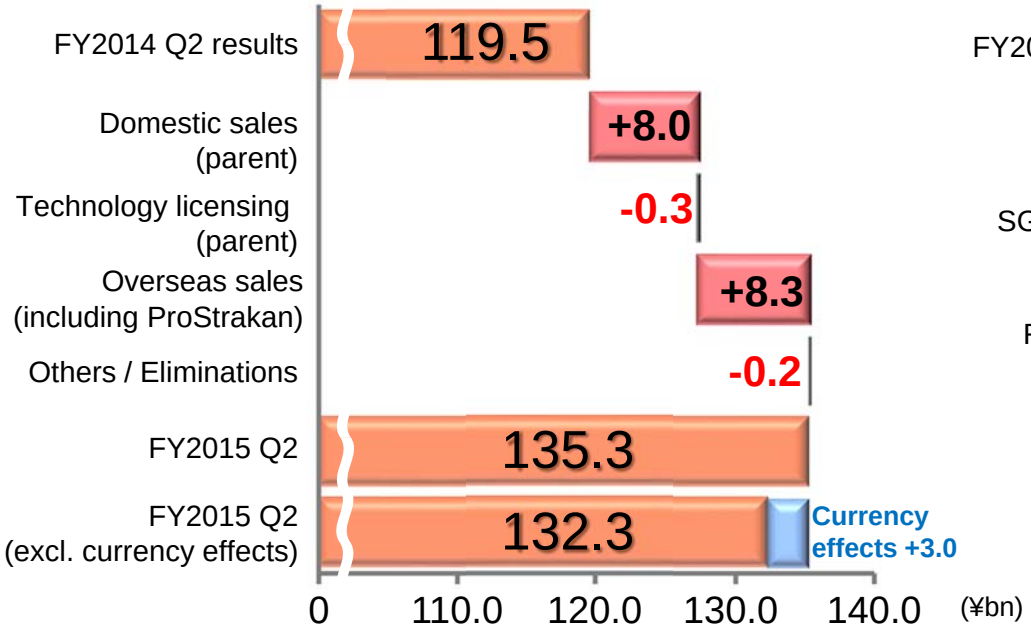
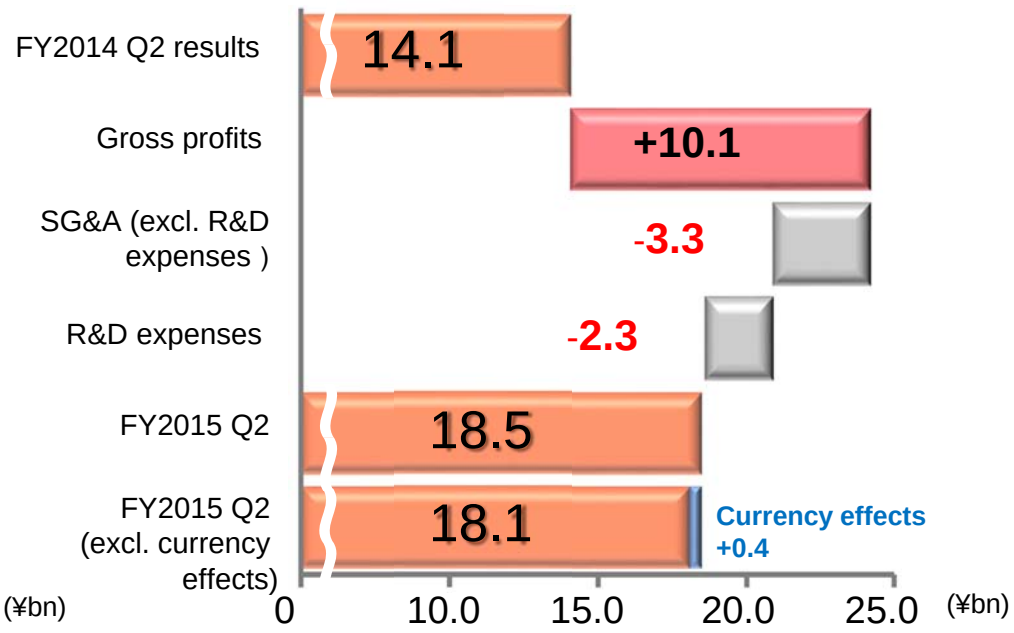
Net sales



Operating income



Net sales (+¥15.8bn):

- ●Domestic pharmaceutical products (+¥8bn):
  - ・Products (shipments): New products G-Lasta® +¥3.8bn, Dovobel® +¥2.1bn, Onglyza® +¥1.8bn, NOURIAST® +¥1.3bn

    ALLELOCK® -¥0.9bn, CONIEL® -¥1.1bn, GRAN® -¥1.5bn
  - ・NESP® (+¥1.1bn): Sales volume and net sales increased YoY due to additional indication for Anemia with Myelodysplastic Syndrome and other factors despite the impact of the drug price revision. Our share was maintained.
- ●Technology licensing, etc. (-¥0.3bn): Currency effects +¥0.5bn
  - ・Accumulation of minor factors
- ● Overseas sales (+¥8.3bn): Currency effects +¥2.2bn
  - ・ProStrakan (+¥6.5bn): Effects of consolidation of Archimedes, etc.

Operating income (+¥4.3bn)

- ●Gross profits (+¥10.1bn): Currency effects +¥2.4bn
  - • The decline in profits due to drug price revision in the previous year was offset by growth in domestic products (in particular new products such as G-Lasta®) and ProStrakan.
- ●SG&A (-¥3.3bn): Currency effects -¥1.1bn
  - • Despite a reduction in SG&A at Kyowa Hakko Kirin (parent) and others, ProStrakan's costs, etc. increased
- ●R&D expenses (-¥2.3bn): Currency effects -¥0.9bn
  - • Increase in overseas R&D expenses and other factors

Pharmaceuticals business: Domestic sales of key products

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While sales were affected by the drug price revision in the previous year and the market penetration of generics, sales increased year on year as a result of the market penetration of new products and growth of key products such as NESP®

Product name, other information	FY2014 Q2 results	FY2015 Q2 results	Change	Reason for change	FY2015 forecast	Rate of progress*
NESP®	25.9	27.0	1.1 (+5%)	(+) Effect of additional indication for MDS※ (-) Drug price revisions in the previous year	56.9	48%
REGPARA®	7.6	8.5	0.9 (+12%)	(+)Steady growth in the market	17.7	48%
ALLELOCK®	13.4	12.4	-0.9 (-7%)	(+) Increase in airborne pollen count level (-) Drug price revisions in the previous year, market penetration of generics	20.5	60%
Patanol®	8.1	8.8	0.6 (+ 8%)	(+) Market expansion due to increase in airborne pollen level	11.9	74%
G-Lasta®	-	3.8	3.8 (-%)	(+) Steady penetration of the market following launch end of November, 2014	8.9	42%
NOURIAST®	0.8	2.2	1.3 (+163%)	(+) Steady penetration of the market	5.5	41%
Technology out-licensing	4.1	3.7	-0.4 (-10%)		12.8	29%

※ Myelodysplastic Syndrome
* Rate of progress of FY2015 sales forecast, disclosed on July 31, 2015

(Unit: ¥bn, figures rounded down)

Bio-Chemicals business: FY2015 Q2: Analysis of YoY profit changes

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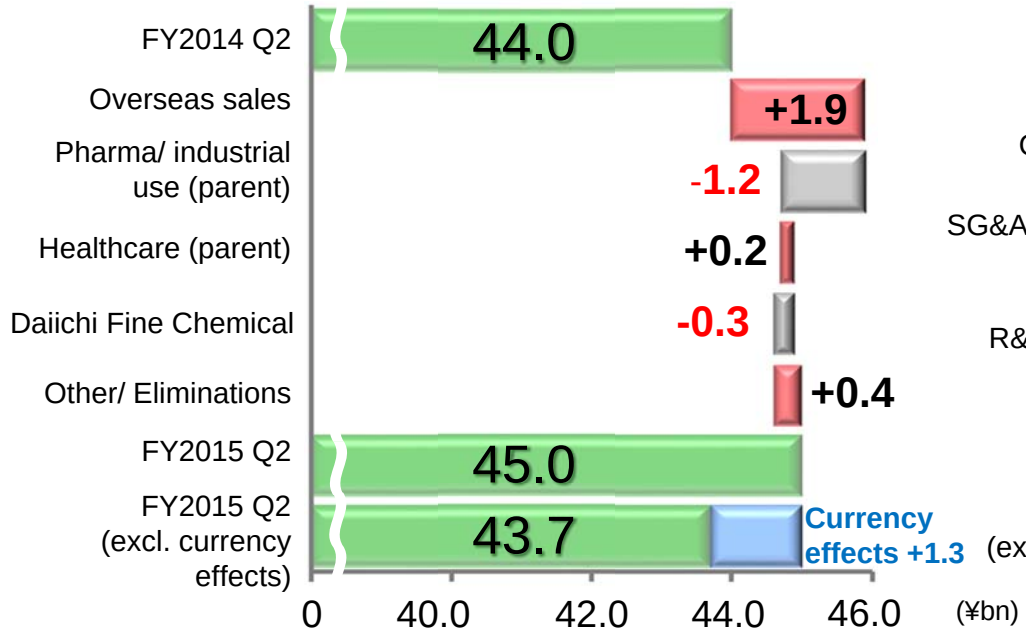
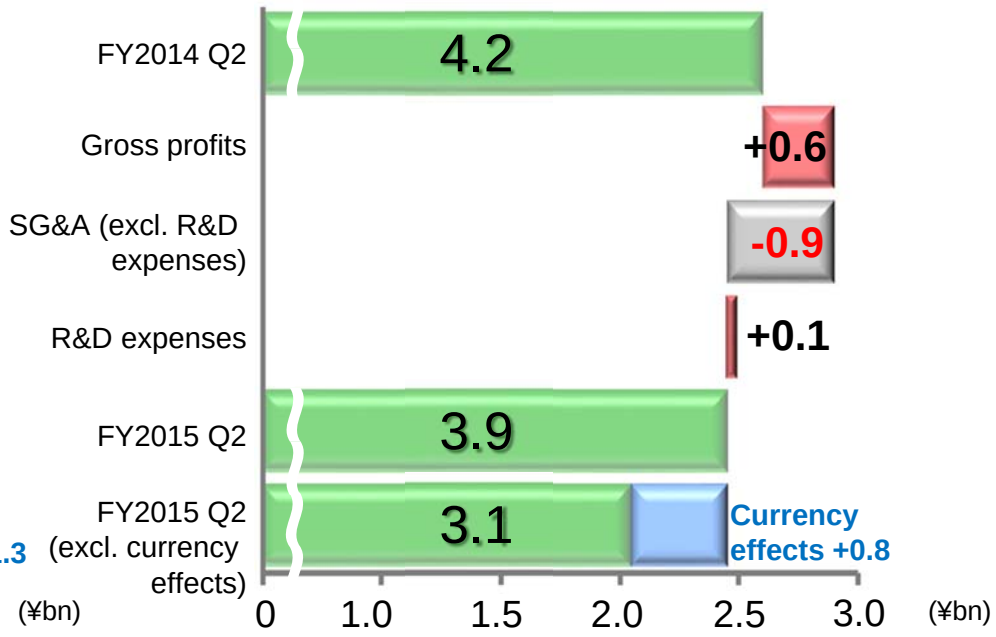
Net sales



Operating income



Net sales (+¥0.9bn)

- Overseas sales (+¥1.9bn): Currency effects +¥1.3bn
  - •U.S. (+¥1.1bn): Currency effects (+¥0.7bn), sales increased due to growth in health-food-use amino acids, etc.
  - •Europe (+¥0.2bn): Currency effects (-¥0.3bn), recovery in demand of infusion-use amino acids from some customers
  - •Asia and others (+¥0.7bn): Currency effects (+¥0.9bn), concentrated shipments of some APIs in the previous year driven by a renewal of import licenses and other factors
- Pharma/industrial use (-¥1.2bn): concentrated shipments of some generic drugs in the previous year and other factors
- Healthcare (+¥0.2bn):
  - ・Mail order sales were strong and increased from the previous year
  - ・Raw materials/OEM sales decreased due to impact of reduced shipments before the renewal of OEM customers' products
- Daiichi Fine Chemical (-¥0.3bn): concentrated shipments of APIs in previous year and other factors

Operating income (-¥0.2bn)

- Gross profit (+¥0.6bn): Currency effects (+¥1bn)
  - ・ Positive factors were cost improvements in some of Daiichi Fine Chemical's products, etc.
  - ・ Negative factors were concentrated shipments of some APIs in the previous year driven by renewal of import licenses, etc.
- SG&A (-¥0.9bn): Currency effects (-¥0.2bn)
  - ・ Increase in sales promotion costs for mail order sales

Revision to forecasts: Consolidated forecast for FY2015 (full year)

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(Unit: ¥bn)	FY2014	FY2015 forecast disclosed 30/1 (a)	FY2015 forecast disclosed 24/7 (b)	Change (b)-(a)
Net sales	333.4	354.0	360.0	+6.0
Operating income	36.1	41.5	47.0	+5.5
Ordinary income	29.5	34.0	41.0	+7.0
Net income	15.8	18.5	26.0	+7.5

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

Main causes for revision

- Operating income: in addition to the booking of the KHK4563 upfront option fee, domestic pharmaceutical products such as G-Lasta® are expected to grow and R&D expenditure is expected to increase

- Net income: the share of loss of entities accounted for using the equity method and the income tax rate are expected to decline

Revision to forecasts: Consolidated forecast of FY2015 (full year)

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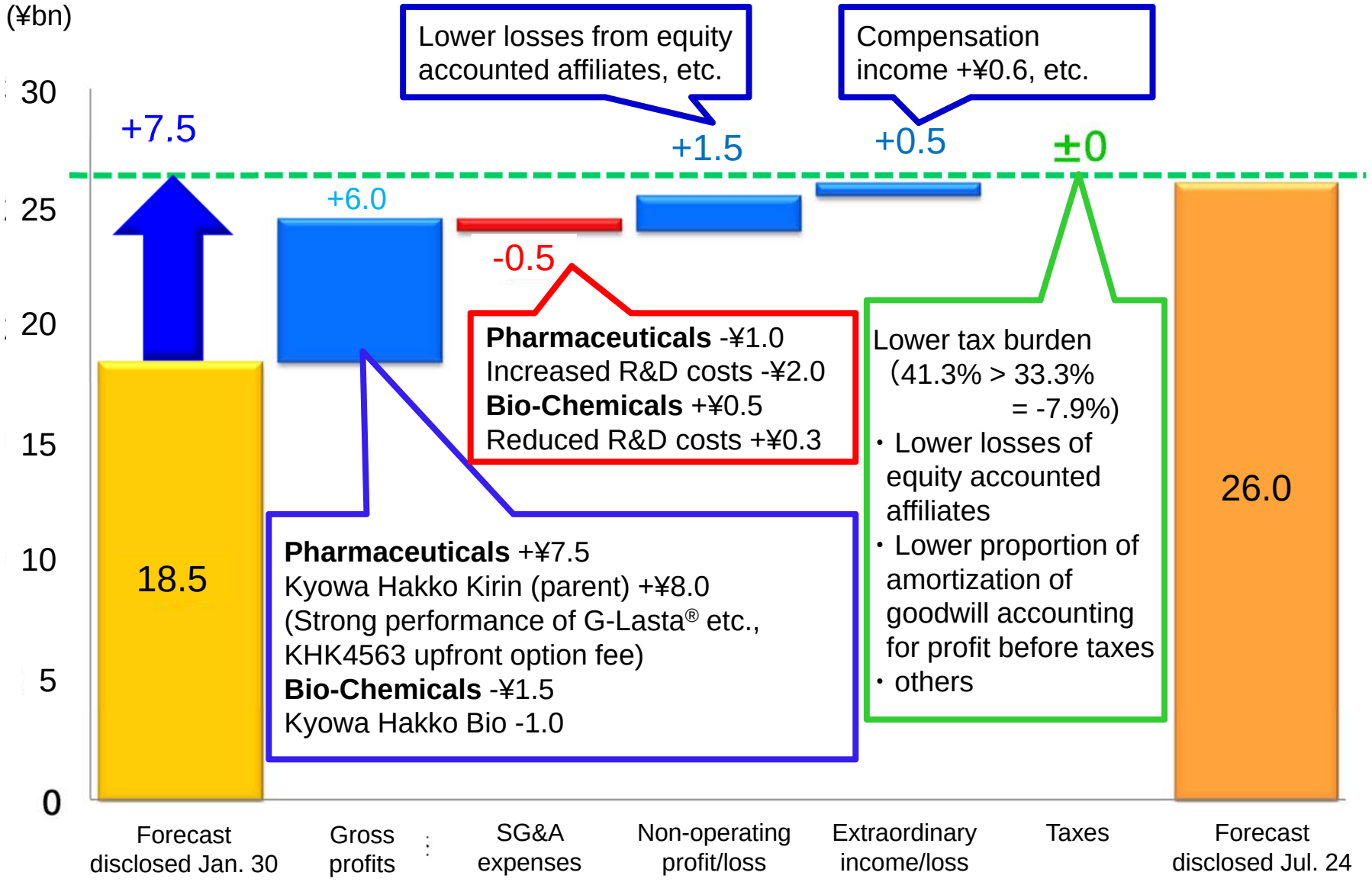
Net income: Comparison between old and current 2015 full year forecast



R & D review

Key development events timeline

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Domestic:

☑ Initiation of Phase 2 trials of RTA 402 targeting chronic kidney disease with type-2 diabetes (March)

☑ Initiation of Phase 1 trials of Nivolumab (ONO PHARMACEUTICAL CO., LTD/Bristol-Myers Squibb) in combination with KW-0761 (brand name in Japan: POTELIGEO®) targeting solid tumors (July)

☐ Application seeking approval for marketing authorization of fully human anti-IL-17 receptor antibody KHK4827

☑Approval for marketing authorization of recombinant human antithrombin drug KW-3357 (brand name in Japan: ACOALAN®) (July)

☑Initiation of Phase 3 trials of KHK4563 targeting COPD (July)

Overseas:

☑ Initiation of Phase 1 trials of PF-05082566 (Pfizer) in combination with KW-0761 targeting solid tumors (June)

☐ Agreement to collaborate on development of Phase 1/2 trials of Nivolumab (Bristol-Myers Squibb) in combination with KW-0761 targeting solid tumors (July)

Note: Events with a ticked checkbox were completed between Jan. 1, 2015-Jul. 24, 2015.

Key domestic development updates (1)

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KHK4827

Indication	Country/ region	Development stage (Scheduled trial completion date)			# of enrollment
		Phase 2	Phase 3	Application	
Psoriasis	Japan		2015/2	2015/7	145[2]

Estimated number of patients Japan: approx. 550,000[1]

[1] *Investigation of psoriasis using of National Health Insurance Organization receipt information*, Rinsho Iyaku 2014, 30, p279-285

ClinicalTrials.gov identifier:
[2] NCT01782924

Key domestic development updates (2)

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KW-3357

Indication	Country/ region	Development stage			# of enrollment
		Phase 3	Application	Approval	
DIC accompanied by a decrease in AT/Thrombilia due to CAD*	Japan	2013/5	2014/7	2015/7[2]	221[3]

[4]

Estimated number of patients Japan: approx. 48,000[1]

[1] Calculated based on *Plan (proposal) to secure stable supply of safe blood products* documents issued by Blood Business Council, Pharmaceutical Affairs and Food Sanitation Council, Ministry of Health, Labour and Welfare
[2] Brand name in Japan: ACOALAN®
[3] *Audit report intravenous use of ACOALAN,* Pharmaceuticals and Medical Devices Agency

ClinicalTrials.gov identifier:
[4] NCT01384903

*AT: Antithrombin;
CAD: Congenital Antithrombin Deficiency
DIC: Disseminated intravascular coagulation

Key global development updates (1)

KYOWA KIRIN

KW-0761 (hematological cancer)

Indication		Country/ region	Development stage (Scheduled trial completion date)				Estimated enrollment
			Phase 2	Phase 3	Application	Approval	
ATL	Untreated	Japan				2014/12[2]	
	Relapsed/ refractory	Japan				2012/3[2]	
		U.S., Europe, others[1]	(2015/8)				70[6]
PTCL	Relapsed/ refractory	Japan				2014/3[2]	
		Europe	(2015/5)				35[7]
CTCL	Relapsed/ refractory	Japan				2014/3[2]	
		U.S., Europe, Japan, others[1]		(2017/2)			317[8]

Annual incidence per disease Japan ATL: approx. 1,100[3] patients; PTCL/CTCL: approx. 2,000[4] patients;
U.S. PTCL: approx. 3,600[5] patients; CTCL: approx. 1,500[5] patients

[1]CCR4 not included in selection criteria
[2]Launched in Japan (brand name POTELIGEO®)
[3]Survey of and countermeasures to HTLV-1 infection and related diseases in Japan. 2009 summary research report by Kazunari Yamaguchi (March 2010)
[4]Ministry of Health, Labour and Welfare: Patient survey in October 2011 (chart 97), by basic illness
[5]SEER Data (2001-2007)
ClinialTrials.gov identifier:
[6]NCT01626664; [7]NCT01611142; [8]NCT01728805

Key global development updates (2)

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KW-0761 (solid tumor)

Indication	Country/ region	Concomitant Drug	Development stage (Scheduled trial completion date) Phase 1	Partner	Estimated enrollment
Solid tumor	U.S.	MEDI4736 or Tremelimumab	(2016/6)	AstraZeneca	108[1]
	U.S.	PF-05082566	(2018/6)	Pfizer	70[2]
	Japan	Nivolumab	(2017/10)	ONO PHARMACEUTICAL CO., LTD. Bristol-Myers Squibb	108[3]
	U.S.	Nivolumab	To be determined	Bristol-Myers Squibb	-
	U.S.	Docetaxel	(2016/2)	-	27[4]

ClinicalTrials.gov identifier:
[1] NCT02301130; [2] NCT02444793; [3] NCT02476123; [4] NCT02358473

Key global development updates (3)

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KW-6002

Indication	Country/ region	Development stage (Scheduled trial completion date)				Estimated enrollment
		Phase 2	Phase 3	Application	Approval	
Parkinson's disease	Japan				2013/3[1]	
	North America, Europe, others		(2016/2)			609[4]

Patient numbers Japan: approx. 140,000[2]
U.S.: approx. 570,000[3]

[1]Launched in Japan (brand name: NOURIAST®)
[2] Ministry of Health, Labour and Welfare: 2011 Patient survey (illness classification)
[3]Study by Decision Resources
ClinialTrials.gov identifier:
[4]NCT01968031

Key global development updates (4)

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KRN23

Indication		Country/ region	Development stage (Scheduled trial completion date)		Partner	Estimated enrollment
			Phase 1	Phase 2		
XLH	Pediatric	U.S., Europe		(2017/3)	Ultragenyx Pharmaceutical (U.S., Europe)	50[4]
	Adult	U.S.		(2016/9)		25[5]
		Japan, Korea	(2015/12)			15[6]
Tumor-Induced Osteomalacia (TIO) Epidermal nevus syndrome (ENS)		U.S.		(2016/9)		6[7]

Estimated no. of patients

XLH
Japan: approx. 5,000[1] adult patients
approx. 1,000[1] pediatric patients
U.S.: approx.12,000[1] adult patients
approx. 3,000[1] pediatric cases

TIO / ENS
Japan: approx. 30[2] patients
U.S.: approx.500 – 1,000[3] patients

[1]Estimate based on reported prevalence of 1 in 20,000 people
[2]2010 Ministry of Health, Labour and Welfare Epidemiological Research on abnormalities in Hormone Receptor Mechanisms
[3]Survey by Ultragenyx Pharmaceutical

ClinialTrials.gov identifier:
[4]NCT02163577; [5]NCT02312687; [6]NCT02181764; [7]NCT02304367

Biosimilar pharmaceutical products development update

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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			
Not disclosed	Not disclosed	Not disclosed	Not disclosed	Determined target product		

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

ClinialTrials.gov identifier: [1]NCT02260791

Topics

Topics

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1. Approval for marketing authorization of KW-3357 (ACOALAN®) in Japan
   - Collaboration with Japan Blood Products Organization

2. Maximize product value of KHK4563
   - Collaboration with AstraZeneca in Japan market

3. Maximize product value of Biosimilar FKB238
   - Collaboration with AstraZeneca

Approval for marketing authorization of KW-3357 (ACOALAN®) in Japan

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Following NHI drug price listing, the drug will be launched in line with the 2014 sales agreement with Japan Blood Products Organization.

Features:

Developed using KHK's unique sugar-chain control technology, KW-3357 is the world's first recombinant anti-thrombin (AT) with the same amino-acid sequence and sugar-chain profile as human-plasma-derived AT

Development significance:

It is now possible to provide Congenital AT Deficiency (CAD) patients and Disseminated Intravascular Coagulation (DIC) patients accompanied by a decrease in AT with an anti-thrombin preparation without a human plasma-derived component.

Sales partner:

Japan Blood Products Organization

JB 一般社団法人 日本血液製剤機構 Japan Blood Products Organization

Manufacturer/distributor:

Kyowa Hakko Kirin (Kyowa Hakko Kirin to supply preparation only)

Maximize product value of KHK4563

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Signed option agreement with AstraZeneca with the objective of maximizing product value of KHK4563 in Japan market. Aiming for significant market penetration.

AstraZeneca

Responsible for marketing and sales in Japan, if option right is exercised

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Remain responsible for development of KHK4563 in Japan

AstraZeneca will make a one-off payment (US$45m), milestone payments at the application and approval and royalty payments in line with earnings

KHK has the right to engage in promotion in Japan with AstraZeneca

Maximize product value of FKB238

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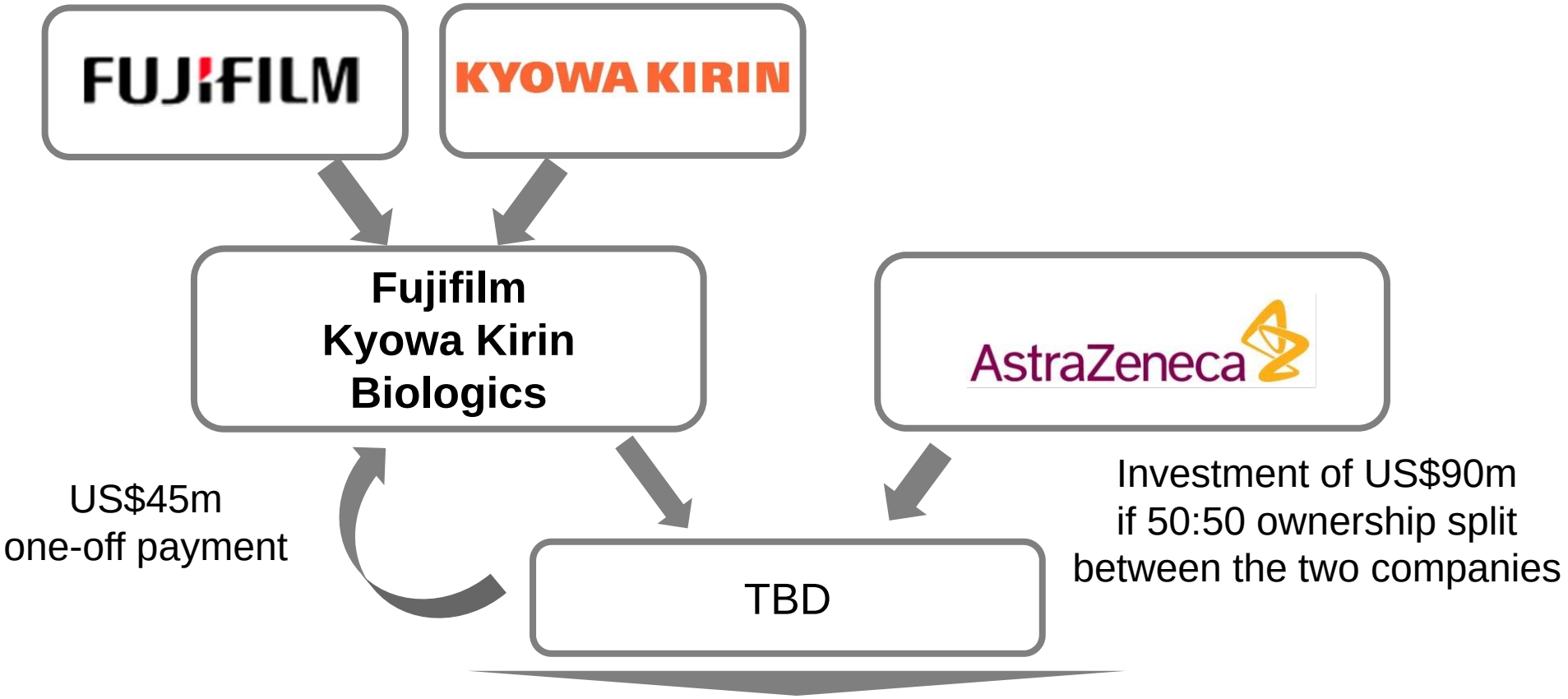
AstraZeneca and Fujifilm Kyowa Kirin Biologics will establish a new company under the scheme below to advance global development and sales of FKB238.



Responsible for global development and sales

Q & A session

List of acronyms

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AT	Antithrombin
ATL	Adult T-cell Leukemia/Lymphoma
CAD	Congenital Antithrombin Deficiency
CCR4	Chemokine (C-C motif) Receptor 4
COPD	Chronic Obstructive Pulmonary Disease
CTCL	Cutaneous T-Cell Lymphoma
DIC	Disseminated Intravascular Coagulation
ENS	Epidermal Nevus Syndrome
TIO	Tumor Induced Osteomalacia
PTCL	Peripheral T-Cell Lymphoma
XLH	X-linked Hypophosphatemia

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The Kyowa Hakko Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

If you have any inquiries regarding this presentation please call:

Corporate Communications Department, Kyowa Hakko Kirin Co., Ltd.

Tel: +81-3-3282-0009

APPENDIX

Revisions to forecasts: Pharmaceuticals
Business Changes from 2015 (H2) forecasts

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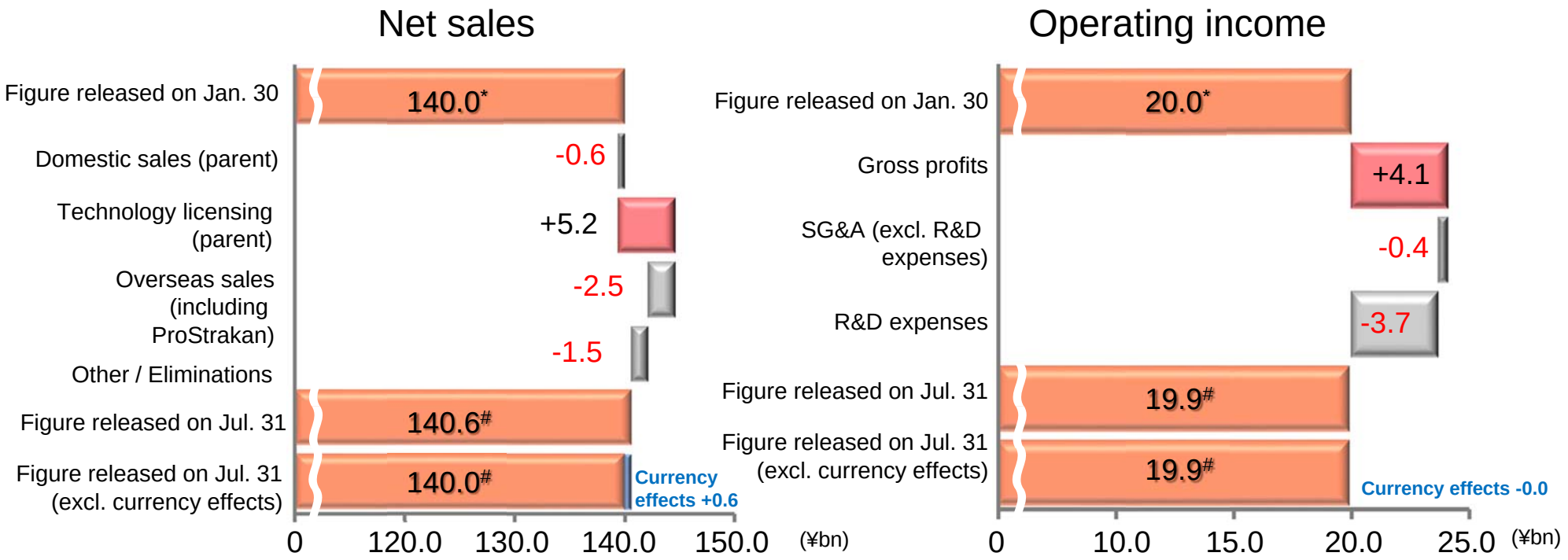

*Full-year forecast (disclosed Jan. 30) minus H1 forecast (disclosed Jan. 30)
Full-year forecast (disclosed Jul. 31) minus H1 results

Net sales (+¥0.6bn):

- Domestic pharmaceutical products (-¥.6bn):
  - Sales of NESP®, G-Lasta®, and other products will exceed full-year forecasts. Assumes penetration of generic versions of a number of products
- Technology licensing, etc. (+¥5.2bn): Currency effects +¥0.2bn
  - Upfront payment associated with an option agreement for exclusive sales of KHK4563 in Japan (US$45 mil), others
- Overseas sales (-¥2.5bn): Currency effects +¥0.4bn
  - Impacted by ProStrakan's difficulty in achieving expected in-licensing product

Operating income (-¥0.0bn)

- Gross profits (+¥4.1bn): Currency effects +¥0.6bn
  - Positive factors included an upfront payment associated with an option agreement for exclusive sales of KHK4563 in Japan (US$45 mil)
  - A negative factor was ProStrakan's failure to achieve expected in-licensing product
- SG&A (-¥0.4bn): Currency effects -¥0.1bn
- R&D expenses (-¥3.7bn): Currency effects -¥0.5bn
  - Increase in domestic and overseas development expenses due to bringing clinical trial schedules forward, currency effects, and other factors

Revisions to forecasts: Bio-Chemicals
Business Changes from 2015 (H2) forecasts

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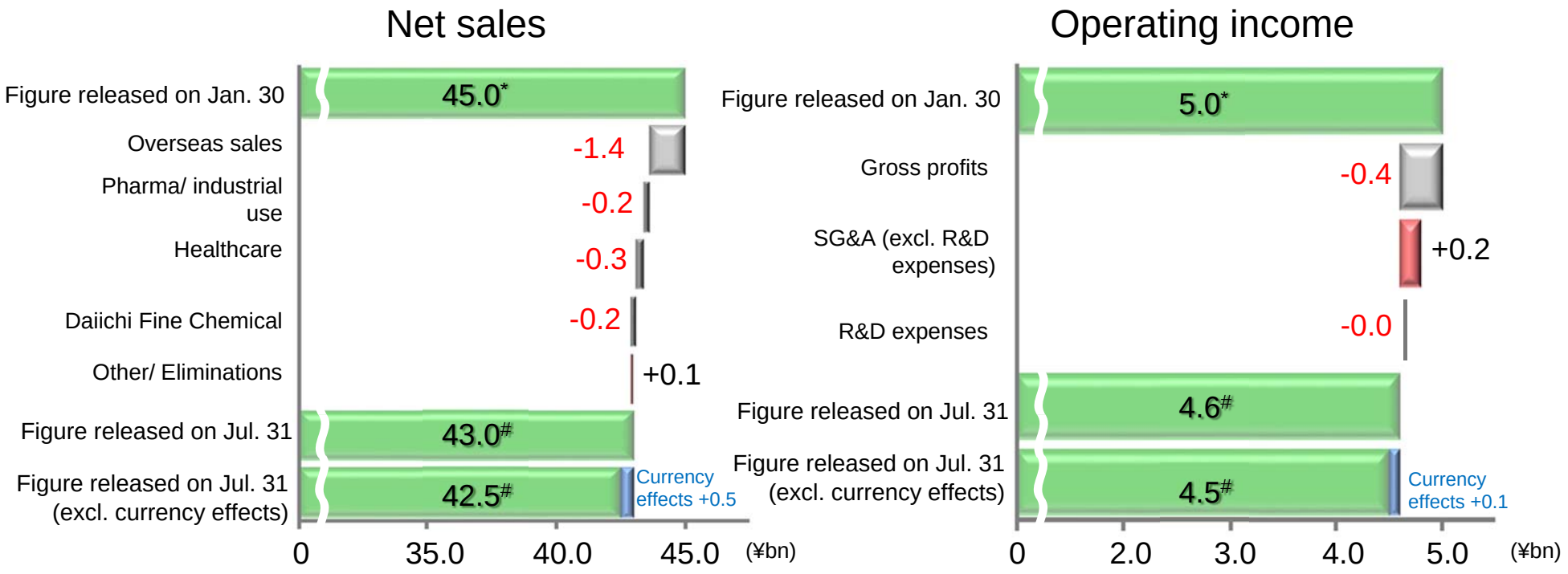

*Full-year forecast (disclosed Jan. 30) minus H1 forecast (disclosed Jan. 30)
Full-year forecast (disclosed Jul. 31) minus H1 forecast (disclosed Jul. 31)

Net sales (-¥2.0bn)

- Overseas sales (-¥1.4bn): Currency effects (+¥0.5bn)
  - U.S. (+¥0.1bn): Currency effects (+¥0.3bn), anticipation of inventory adjustments by some infusion-use amino acid customers, etc.
  - Europe (-¥1.3bn): Currency effects (-¥0.4bn), influence of transfer of cosmetics ingredients business, etc.
  - Asia and others (-¥0.1): Currency effects (+¥0.5bn) anticipation of inventory adjustments by some infusion-use amino acid customers, etc.
- Pharma/industrial use (-¥0.2bn):
  - Anticipation of inventory adjustments by some generic pharmaceuticals API customers
- Healthcare (-¥0.3bn):
  - Downward revision of mail order sales and raw materials/OEM sales in H2, etc.
- Daiichi Fine Chemical (-¥0.2bn):
  - Primarily influenced by shift of sales into following quarter, etc.

Operating income (-¥0.4bn)

- Gross profits (-¥0.4bn): Currency effects (+¥0.3bn)
  - Downward revision of mail order sales and gross profits in H2, etc.
- SG&A (+¥0.2bn): Currency effects (-¥0.1bn)

Development progress with outlicensed
Changes from 2015 (H2) forecasts

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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	
RGI-2001	REGiMMUNE	Phase1/2			Immunosuppressive	

(as of July 24th, 2015)

FOREX related

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Period average rate

Average exchange rate	FY2014 H1 Results	2015 H1 Results	Change	*FY2015 full-year Forecast*
¥/$	**¥103**	**¥120**	**+¥17**	***¥120***
¥/€	**¥141**	**¥135**	**-¥6**	***¥133***
¥/£	**¥171**	**¥183**	**+¥12**	***¥181***

FY2015 interim currency effects (YoY)

Segment	Currency	Net sales	Operating income
Pharmaceuticals business	$	**+¥0.8bn**	**-¥0bn**
	€	**-¥0bn**	**-¥0bn**
	£	**+¥1.3bn**	**+¥0bn**
Bio-Chemicals business	$	**+¥1.6bn**	**+¥1.0bn**
	€	**-¥0.3bn**	**-¥0.2bn**
	£	**-**	**-**