KYOWA KIRIN

Result Presentation
Fiscal 2017 Interim

Kyowa Hakko Kirin Co., Ltd.

Agenda

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FY2017 Q2 Highlights	Nobuo Hanai, Ph.D. President, Chief Executive Officer
Financial Review	Kazuyoshi Tachibana Director, Managing Executive Officer
R&D Review	Nobuo Hanai, Ph.D. President, Chief Executive Officer
Q&A	

Forward-looking Statement

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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 the 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 in the pharmaceutical industry in Japan and overseas, intellectual property risks, risk of side effects, regulatory risks, product defect risks, risks of changes to the 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 medical recommendation.

Summary of Q2 Consolidated Results

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	2016Q2 Results	2017Q2 Results	Change	
Net Sales	174.0	175.6	+1.6 (+1%)	• Benralizumab-related licensing revenue (↑) • Drug price revision and generics' penetration (↓)
Operating Income [Margin]	15.3 [8.8%]	24.1 [13.7%]	+8.7 (+57%)	• Benralizumab-related licensing revenue (↑) • Decrease in SG&A costs (↑)
Ordinary Income	13.6	22.0	+8.3 (+61%)	• Non-operating gain/loss is on the same level as the previous year (→)
Net Profit	10.7	13.6	+2.9 (+27%)	• Decrease in extraordinary income (↓) • Increase in income tax (↓)

(Billion yen / Rounded down / After amortization of goodwill)

Financial Review

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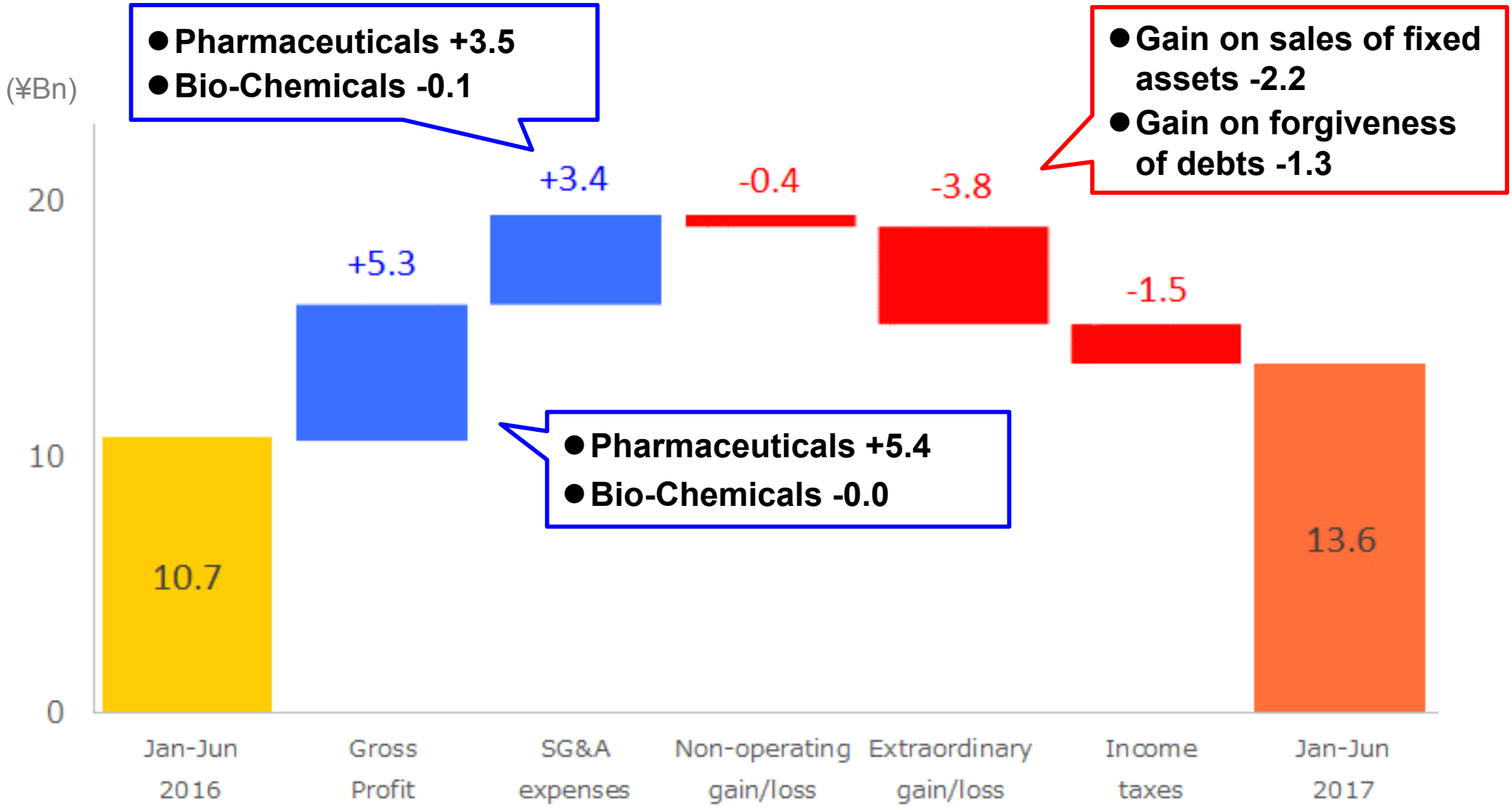
Net Profit (Jan-Jun) +2.9 billion yen



Summary of Q2 Results by Segment

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- **Results in the Pharmaceuticals business increased mainly due to a rise in technology licensing revenue, despite a drop in domestic sales caused by the drug price revision and generics' penetration**
- **Bio-Chemicals business declined due to unfavorable overseas sales of amino acids and other materials**

		2016Q2 Results	2017Q2 Results	Change
Pharmaceuticals Business	Net Sales	132.2	135.7	+3.4 (+3%)
	Operating Income [Margin]	11.6 [8.8%]	20.7 [15.3%]	+9.0 (+78%)
Bio-Chemicals Business	Net Sales	43.1	41.7	-1.4 (-3%)
	Operating Income [Margin]	3.4 [8.1%]	3.3 [7.9%]	-0.1 (-5%)

(Billion yen / Rounded down / After amortization of goodwill)

Pharmaceuticals: YoY Analysis -Sales-

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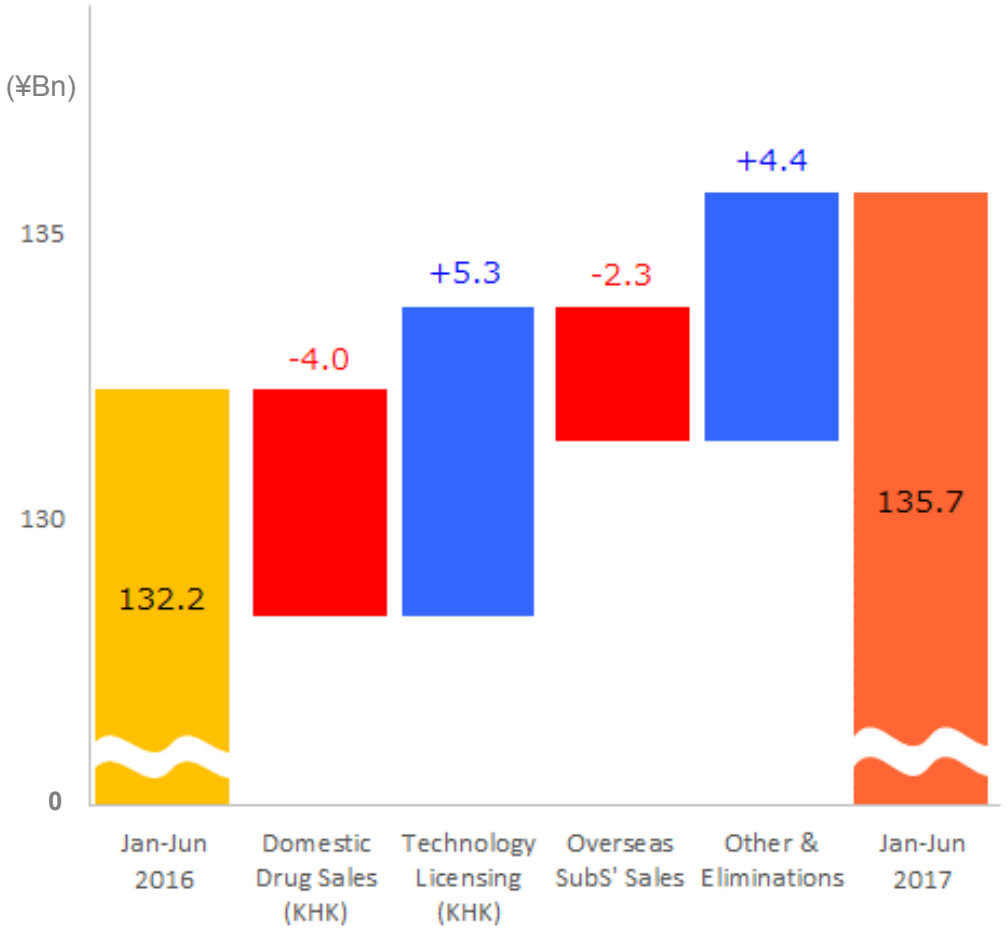
+3.4 billion yen
(incl. forex effect -2.9)



- **Domestic Drug Sales -4.0**
  - Our key product NESP decreased due to the drug price revision.
  - Long-listed products such as ALLELOCK and Coniel also decreased due to the market penetration of generic drugs.
  - New products including G-Lasta, NOURIAST and Onglyza sustained steady growth, resulting in a YoY increase.

- **Technology Licensing +5.3 (incl. forex effect +0.0)**
  - Due mainly to the upfront/milestone payments under the license agreements for benralizumab in the Asian regions including Japan.

- **Overseas Subsidiaries' Sales -2.3 (incl. forex effect -2.8)**
  - Increased excluding the forex effect due to the growth of KKI's* Abstral & PecFent and favorable sales in Korea & Taiwan.

(*) KKI: Kyowa Kirin International

- **Other Sales & Eliminations +4.4 (incl. forex effect -0.1)**
  - Increase resulted from the gain in BioWa's technology licensing revenue and favorable export sales.

Pharmaceuticals: YoY Analysis -Operating Income-

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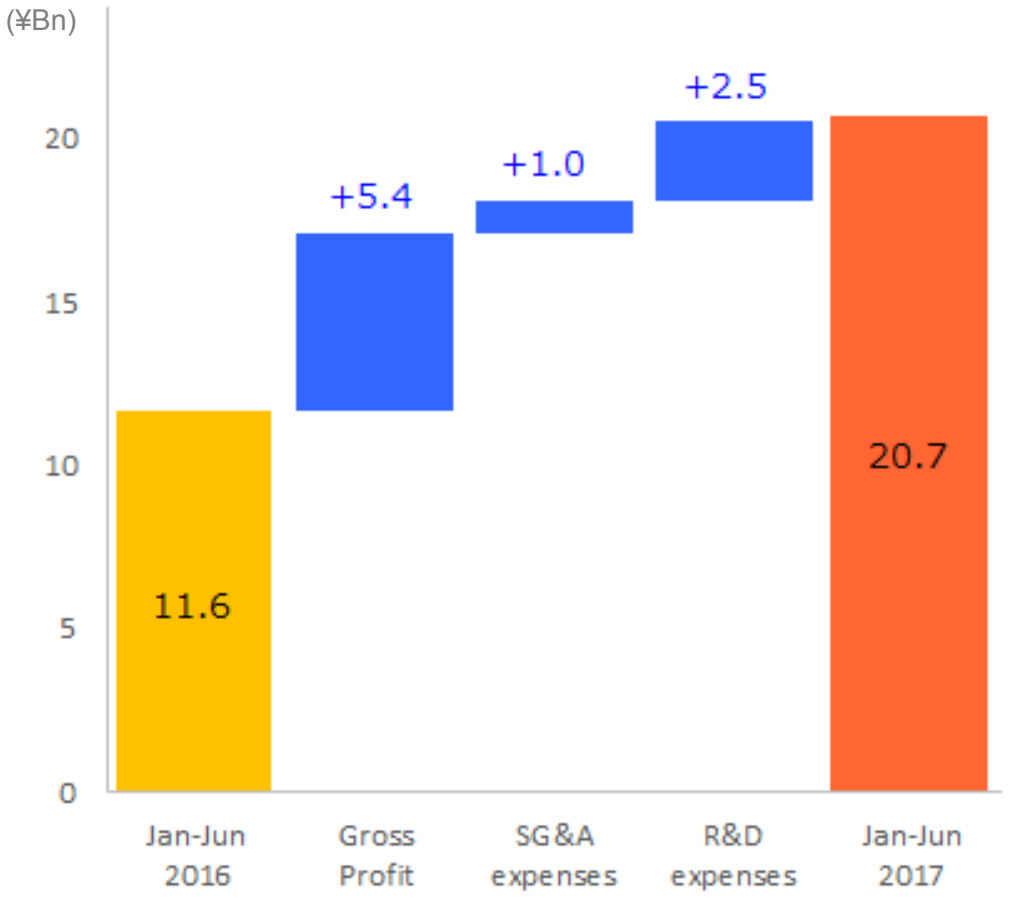
+9.0 billion yen
(incl. forex effect +0.3)



- **Gross Profit +5.4**
  (incl. forex effect -2.3)
  - Mainly due to the increase in technology licensing revenue.

- **SG&A expenses +1.0**
  (incl. forex effect +2.2)
  - In real terms excluding the forex effect, KKI's expenses increased as a result of the promotional activities for Moventig and the launch preparation of burosumab.

- **R&D expenses +2.5**
  (incl. forex effect +0.5)
  - Decrease in costs partly due to the adjustment of some excess R&D expenses in the previous fiscal year.
  - Fewer late-stage clinical trials were conducted.

Pharmaceuticals: KHK's Sales by Product

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- Domestic drug sales decreased due to sluggish sales of the key product NESP and long-listed products
- Significant increase in technology licensing revenue came mainly from benralizumab

Product	2016Q2 Results	2017Q2 Results	Change	Reason	2017Q4 Forecast	Progress (＊)
NESP	27.4	26.6	-0.8 (-3%)	Drug price revision	57.2→ 56.4	47%
REGPARA	9.4	9.4	-0.0 (-1%)		17.8→ 18.3	52%
ALLELOCK	10.8	9.1	-1.6 (-16%)	Market penetration of generics	14.1→ 15.4	59%
Patanol	9.0	8.8	-0.2 (-2%)	Market penetration of competitors	12.1→ 12.8	69%
G-Lasta	7.4	8.1	+0.7 (+10%)	Steady market penetration	17.8→ 17.6	46%
NOURIAST	3.3	3.9	+0.6 (+20%)	Steady market penetration	8.7→ 8.5	46%
Technology out-licensing	0.7	6.1	+5.3 (+727%)	Revenues related to benralizumab	7.4→ 7.4	83%

(Billion yen / Rounded down)

＊ Progression rate against the revised FY2017 forecast disclosed on July 28, 2017

Bio-Chemicals: YoY Analysis -Sales-

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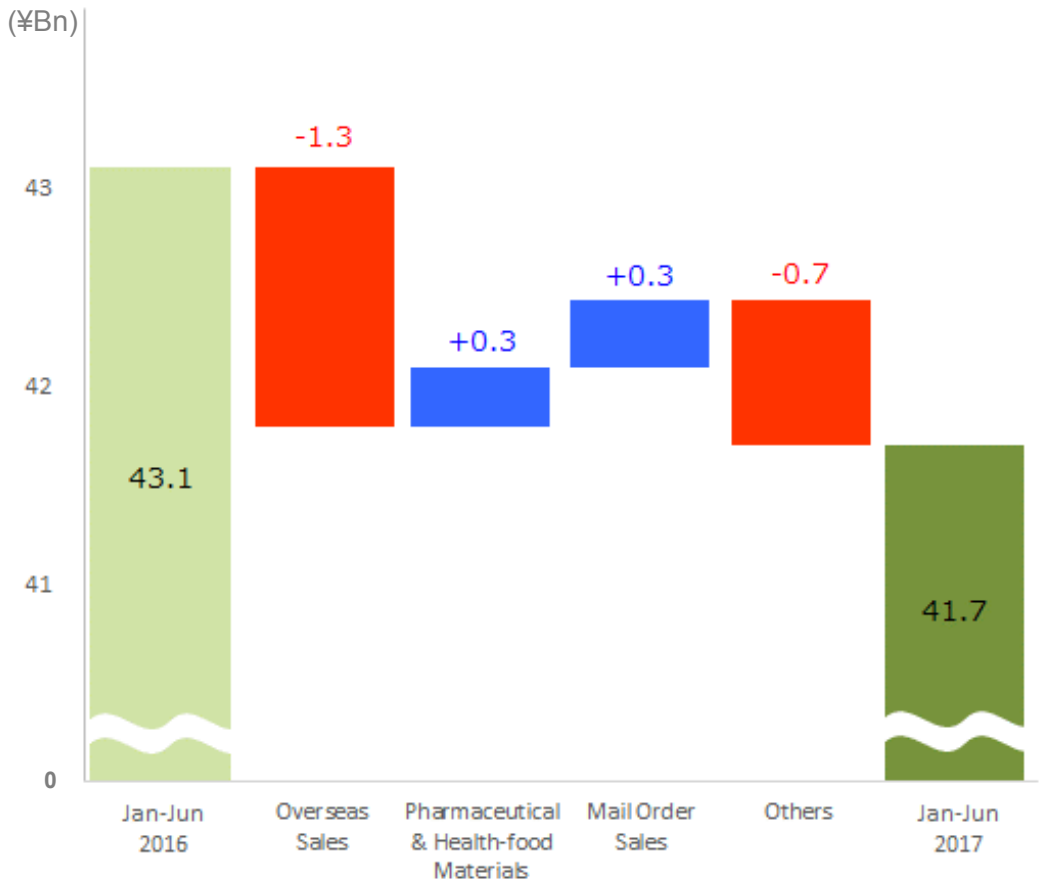
-1.4 billion yen
(incl. forex effect -0.5)



- **Overseas Sales -1.3 (incl. forex effect -0.5)**
  - **Americas -0.6 (incl. forex effect -0.0):**
    Decreased in health-food materials and amino acids for cell culture mediums.
  - **Europe -0.2 (incl. forex effect -0.3):**
    Slightly increased in real terms excluding the forex effect.
  - **Asia + Others -0.5 (incl. forex effect -0.1):**
    Decreased due to the price competition in China.

- **Pharmaceutical & Health-food Materials +0.3**
  - Increased in sales due to the overall steady growth.

- **Mail Order Sales etc. +0.3**
  - Substantial growth in “KHB Arginine EX.”

- **Others -0.7**
  - Due mainly to decrease in the sales of Kyowa Engineering.

Bio-Chemicals: YoY Analysis -Operating Income-

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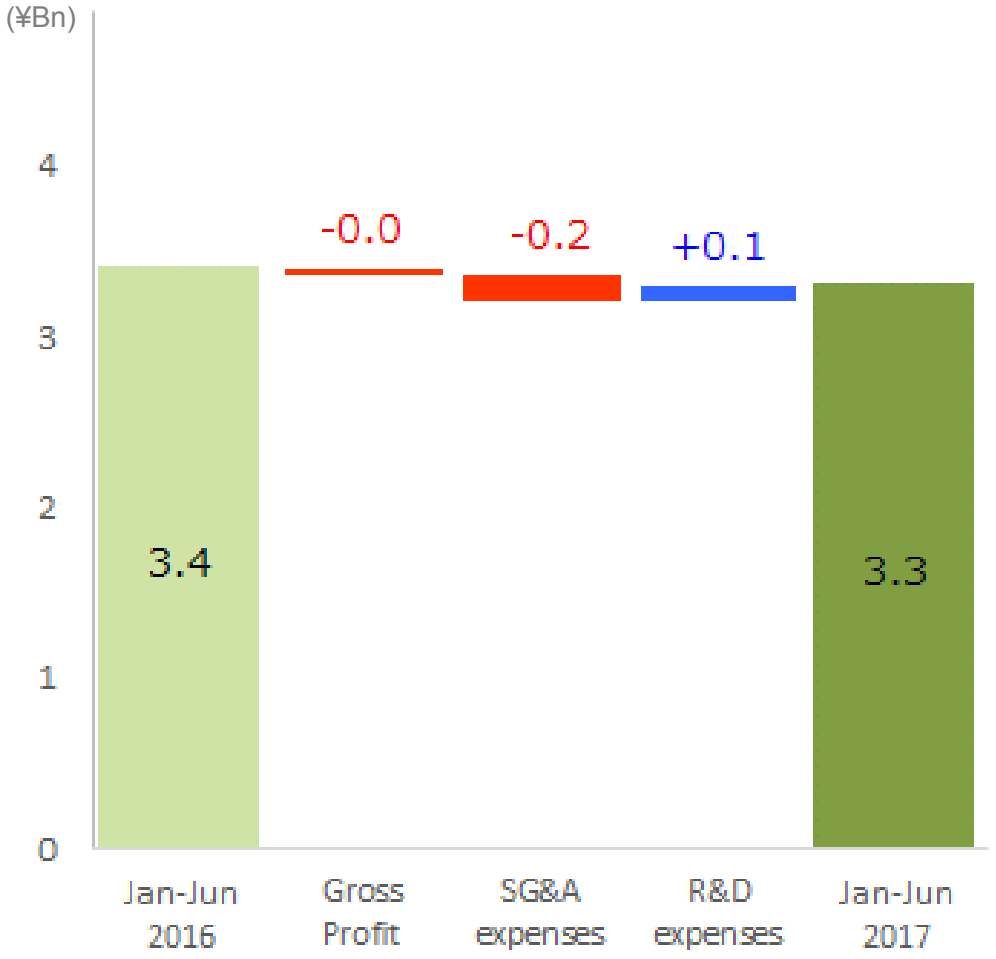
-0.1 billion yen
(incl. forex effect -0.2)



- **Gross Profit -0.0 (incl. forex effect -0.2)**
  - Increased in real terms excluding the forex effect, reflecting steady growth in the domestic business.
  - No big impact arising from the fall in Kyowa Engineering's sales.

- **SG&A expenses -0.2 (incl. forex effect +0.0)**
  - Direct cost of the mail order business increased according to its sales' growth.

- **R&D expenses +0.1 (incl. forex effect +0.0)**

Revision to Full-Year Forecast

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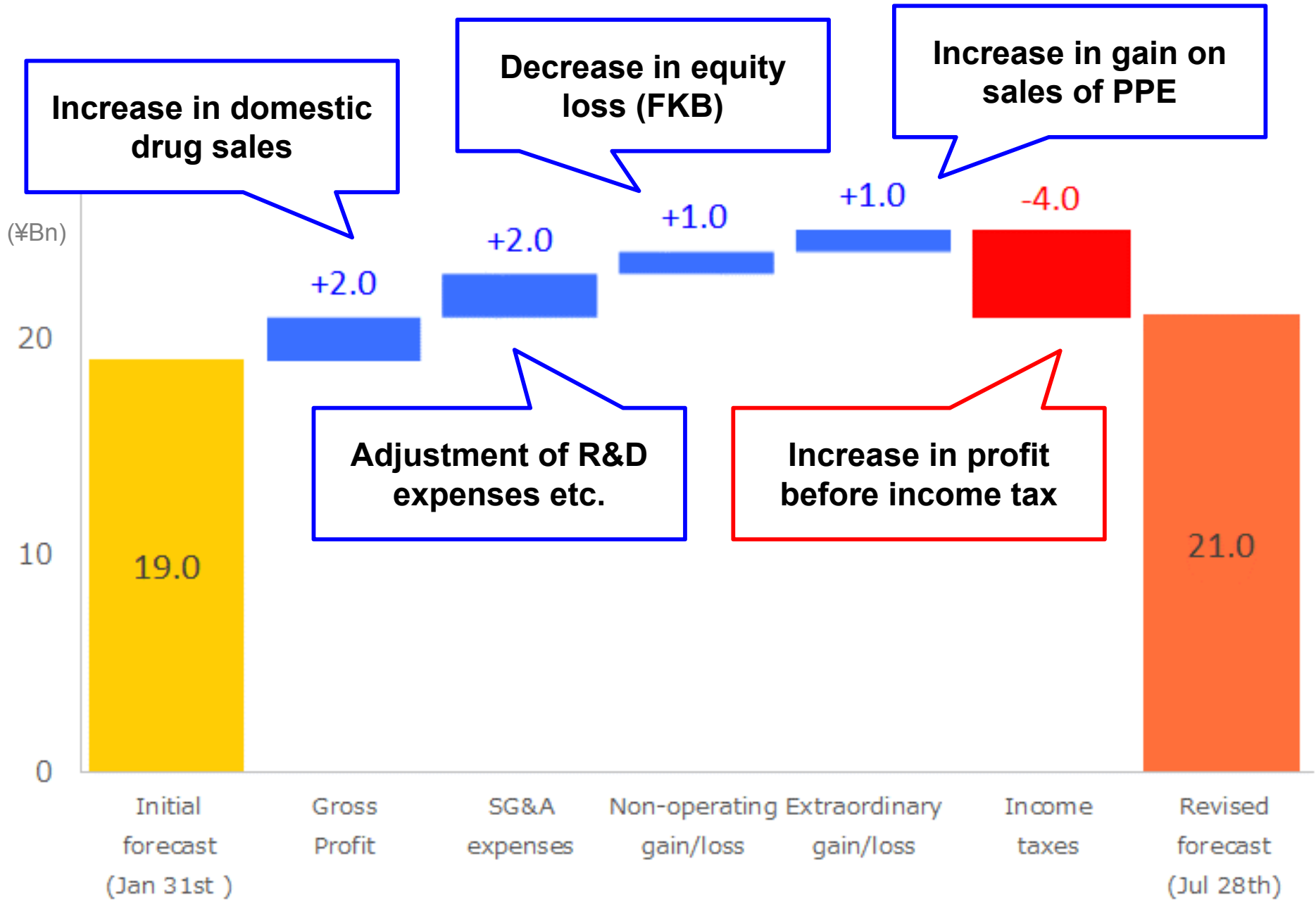
- **Pharmaceuticals business is expected to drift upward mainly due to favorable sales and SG&A underspent**
- **Bio-Chemicals is not expected to change from the initial plan**

	2016Q4 Results	2017Q4 Initial Forecast (31-Jan-17)	2017Q4 Revised Forecast (28-Jul-17)	Change
Net Sales	343.0	344.0	347.0	+3.0 (+ 1%)
Operating Income	31.6	35.0	39.0	+4.0 (+11%)
Ordinary Income	26.3	30.0	35.0	+5.0 (+17%)
Net Profit	18.6	19.0	21.0	+2.0 (+11%)

(Billion yen / Rounded down / After amortization of goodwill)

Revision to Full-Year Forecast (Main Reasons)



R&D Review

Key development events in 2017

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Domestic:

- **Announcement of top-line results of phase 3 clinical study of evocalcet (KHK7580) for the treatment of secondary hyperparathyroidism (January) and application for approval (April)**
- **Application for approval of benralizumab (KHK4563) for the treatment of asthma* (February)**
- **Announcement of top-line results of phase 3 clinical study of tivantinib (ARQ 197) for the treatment of hepatocellular carcinoma (March)**
- **Initiation of phase 3 clinical study of mogamulizumab (KW-0761) for the treatment of HTLV-1 associated myelopathy (June)**

* NDA holder is AstraZeneca

Note: Listed events were completed between January 25, 2017 and June 30, 2017.

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Overseas:

- Approval received for darbepoetin alfa (KRN321) for the treatment of anemia with myelodysplastic syndrome (February in Singapore and May in Malaysia)
- Application for approval of brodalumab (KHK4827) for the treatment of psoriasis (February in Taiwan and June in Thailand)
- Approval received for romiplostim (AMG531) for the treatment of chronic idiopathic (immune) thrombocytopenic purpura (March in Thailand)
- Announcement of positive results of phase 2 clinical study of burosumab (KRN23) for the treatment of pediatric X-Linked Hypophosphatemia (April in the U.S. and Europe)
- Announcement of positive results of phase 3 clinical study of mogamulizumab (KW-0761) for the treatment of cutaneous T-cell lymphoma (April in the U.S., Europe, Japan, and others)

Note: Listed events were completed between January 25, 2017 and June 30, 2017.

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Overseas (cont.):

- **Announcement of positive results of phase 3 clinical study of burosumab (KRN23) for the treatment of adult X-Linked Hypophosphatemia (April in the U.S., Europe, Canada, Japan, and Korea)**
- **Initiation of phase 3 clinical study of KHK4827 (brodalumab) for the treatment of axial spondyloarthritis (April in Japan, Korea, and Taiwan)**
- **Initiation of phase 2 clinical study of ASKP1240 for the treatment of recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients (May in the U.S.)**

Note: Listed events were completed between January 25, 2017 and June 30, 2017.

Key global development updates (1)

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mogamulizumab/KW-0761 (hematological cancer) [1]

Indication		Country/ region	Development stage (Scheduled trial completion date)			Estimated enrollment	
			Phase 2	Phase 3	Application		
ATL	Relapsed/ refractory	U.S., Europe, others	(2017/12)			71	[3]
CTCL	Relapsed/ refractory	U.S., Europe, Japan, others		(2018/12)		372	[4]

CTCL/Annual incidence: U.S.: approx. 1,500 [2] patients

[1] Launched in Japan (brand name POTELIGEO®)
[2] SEER Data (2001-2007)

ClinialTrials.gov identifier:
[3] NCT01626664; [4] NCT01728805

Key global development updates (2)

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mogamulizumab/KW-0761 (solid tumor)

Indication	Country/ region	Concomitant Drug	Development stage (Scheduled trial completion date) Phase 1	Partner	Estimated enrollment	
Solid tumor	U.S.	durvalumab or tremelimumab	(2018/5)	AstraZeneca	81	1
	U.S.	PF-05082566	(2017/8)	Pfizer	70	2
	Japan	nivolumab	(2017/10)	ONO PHARMACEUTICAL Bristol-Myers Squibb	108	3
	U.S.	nivolumab	(2018/3)	Bristol-Myers Squibb	188	4
	U.S.	docetaxel	2016/12	-	13	5
	U.S.	KHK2455	(2019/8)	-	50	6

ClinicalTrials.gov identifier:
[1] NCT02301130; [2] NCT02444793; [3] NCT02476123; [4] NCT02705105; [5] NCT02358473; [6] NCT02867007

Key global development updates (3)

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burosumab/KRN23

Indication		Country/region	Development stage (Scheduled trial completion date)		Partner	Estimated enrollment	
			Phase 2	Phase 3			
XLH	Pediatric	U.S., Europe	(2018/12)		Ultragenyx Pharmaceutical (North America, Europe)	50	2
		U.S.	(2017/12)			13	3
		N.A., Europe, Japan, Korea, Australia		(2018/9)		60	4
	Adult	U.S.	(2018/8)			25	5
		U.S., Europe, Japan, Korea		(2018/3)		134	6
		N.A., Europe, Japan, Korea		(2017/8)		14	7

Estimated no. of patients: Adults: Japan: approx. 5,000, Europe: approx. 12,000, U.S.: approx. 12,000 [1]
Pediatric: Japan: approx.1,000, Europe: approx. 3,000, U.S.: approx. 3,000 [1]

[1] Estimate based on reported prevalence of 1 in 20,000 people

ClinicalTrials.gov identifier:
[2] NCT02163577; [3] NCT02750618; [4] NCT02915705; [5] NCT02312687; [6] NCT02526160; [7] NCT02537431

N. A.: North America

Key global development updates (4)

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burosumab/KRN23

Indication	Country/region	Development stage (Scheduled trial completion date)		Partner	Estimated enrollment	
		Phase 2	Phase 3			
TIO/ENS	U.S.	(2019/5)		Ultragenyx Pharmaceutical (North America, Europe)	17	[3]
	Japan / Korea	(2017/7)			6	[4]

Estimated no. of patients: Japan: approx. 30[1], U.S.: approx.500 - 1,000[2]

[1] 2010 Ministry of Health, Labour and Welfare Epidemiological Research on abnormalities in Hormone Receptor Mechanisms
[2] Survey by Ultragenyx Pharmaceutical

ClinicalTrials.gov identifier:
[3] NCT02304367; [4] NCT02722798

Appendix

Development schedule of major late-stage pipeline

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* : NDA holder is AstraZeneca
\+ : Estimated time of regulatory decisions

Generic name Code	Indication	Country/ region	2017	2018	2019~
bardoxolone methyl RTA 402	diabetic kidney disease	Japan	Phase 2	Phase 3	
benralizumab KHK4563	asthma	U.S.	+*		
		Europe		+*	
		Japan	filed*	+*	
	COPD	U.S., Europe		submission*	
		Japan			submission*
brodalumab KHK4827	psoriasis	Taiwan, Thailand, Singapore, etc.	submission		
burosumab KRN23	XLH	Europe	filed	+ (pediatric)	+ (adult)
		U.S.	submission	+	
		Japan		submission	
evocalcet KHK7580	secondary hyperparathyroidism	Japan	filed	+	
mogamulizumab KW-0761	CTCL	U.S., Europe	submission	+	
romiplostim AMG531	aplastic anemia	Japan, Korea		submission	
	ITP	China		submission	+

Biosimilar products development

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Development code	Reference bio medical product		Country/region	Development stage		
	Generic name	Brand name		Phase 2	Phase 3	Application
FKB327	adalimumab	HUMIRA	U.S., others			
FKB238	bevacizumab	Avastin	U.S., Europe, others			
Not disclosed	Not disclosed	Not disclosed	Not disclosed (Target product determined)			

1

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

ClinialTrials.gov identifier: [1] NCT02810457

[1] Development is currently conducted by Centus Biotherapeutics Limited.

List of acronyms

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ATL	Adult T-cell Leukemia/Lymphoma
COPD	Chronic Obstructive Pulmonary Disease
CTCL	Cutaneous T-Cell Lymphoma
ENS	Epidermal Nevus Syndrome
HTLV-1	Human T-cell Leukemia Virus Type 1
ITP	Idiopathic (immune) Thrombocytopenic Purpura
TIO	Tumor Induced Osteomalacia
XLH	X-linked Hypophosphatemia

FOREX Information

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Average FOREX Rate

[¥]

Currency	2016Q2 Result	2017Q2 Result	Change	2017Q4 Revised Forecast
USD/JPY	114	113	-1	110→112
EUR/JPY	127	122	-5	120→121
GBP/JPY	165	142	-23	140→140

2017Q2 FOREX Effect (YoY)

[¥Bn]

Segment	Currency	Sales	Operating Income
Pharmaceuticals Business	USD	-0.05	+0.01
	EUR	-0.03	-0.03
	GBP	-2.89	+0.27
Bio-Chemicals Business	USD	-0.08	-0.04
	EUR	-0.32	-0.14
	GBP	N/A	N/A

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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:

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