KYOWA KIRIN

Results Presentation
Fiscal 2018 Interim

Kyowa Hakko Kirin Co., Ltd.

Agenda

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2Q Summary	Masashi Miyamoto, Ph.D Executive Director of the board, President & COO
Financial Review	Motohiko Kawaguchi Executive Officer, Director of Accounting Department
R&D Review	Masashi Miyamoto, Ph.D Executive Director of the board, President & COO
Business Topics	Masashi Miyamoto, Ph.D Executive Director of the board, President & COO
Q&A	

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 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 is used only for the purpose of providing the information to investors. Though it may contain the information concerning pharmaceutical products (including products under development), it is not for the purpose of promotion, advertising, or medical advice.

2Q Summary

Summary of the Consolidated Results

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	2017Q2 Results	2018Q2 Results	Changes	2018Q4 Plan (published on Feb 8)	Progression Rate
Revenue	177.0	172.1	-4.9 (-3%)	335.0	51%
Core Operating Profit (Core OP) *[Margin]*	30.1 *[17.0%]*	32.1 *[18.7%]*	+2.0 (+7%)	51.0 *[15.2%]*	63%
Profit	20.3	34.3	+13.9 (+68%)	44.0	78%

(Billion Yen / Rounded)

Financial Review

Consolidated: YoY Analysis -Profit-

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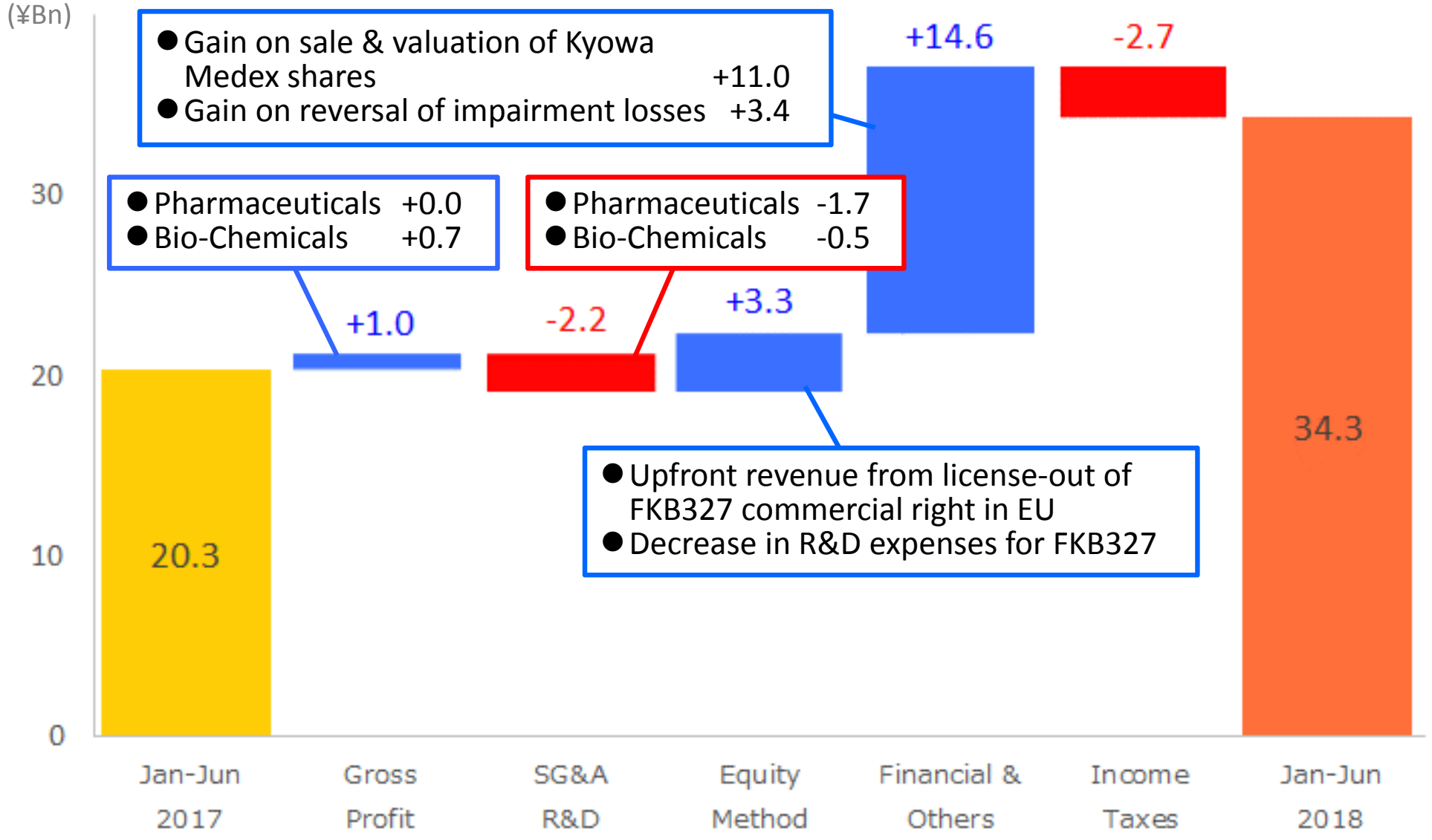
Profit (Jan-Jun) +13.9 billion yen



Summary of the Results by Segment

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- **Pharmaceuticals' Core OP increased due to improvement in the gain/loss by the equity method despite the decrease in revenue.**
- **Bio-Chemicals' Core OP also increased due to improved profitability despite the decrease in revenue.**

		2017Q2 Results	2018Q2 Results	Changes	2018Q4 Plan (published on Feb 8)	Progression Rate
Pharma-ceuticals	Revenue	138.0	134.3	-3.6 (-3%)	262.0	51%
	Core OP *[Margin]*	26.8 *[19.4%]*	28.4 *[21.1%]*	+1.6 (+6%)	43.0 *[16.4%]*	66%
Bio-Chemicals	Revenue	40.8	39.3	-1.5 (-4%)	76.0	52%
	Core OP *[Margin]*	3.2 *[7.9%]*	3.4 *[8.7%]*	+0.2 (+6%)	8.0 *[10.5%]*	43%

(Billion Yen / Rounded)

Pharmaceuticals: YoY Analysis -Revenue-

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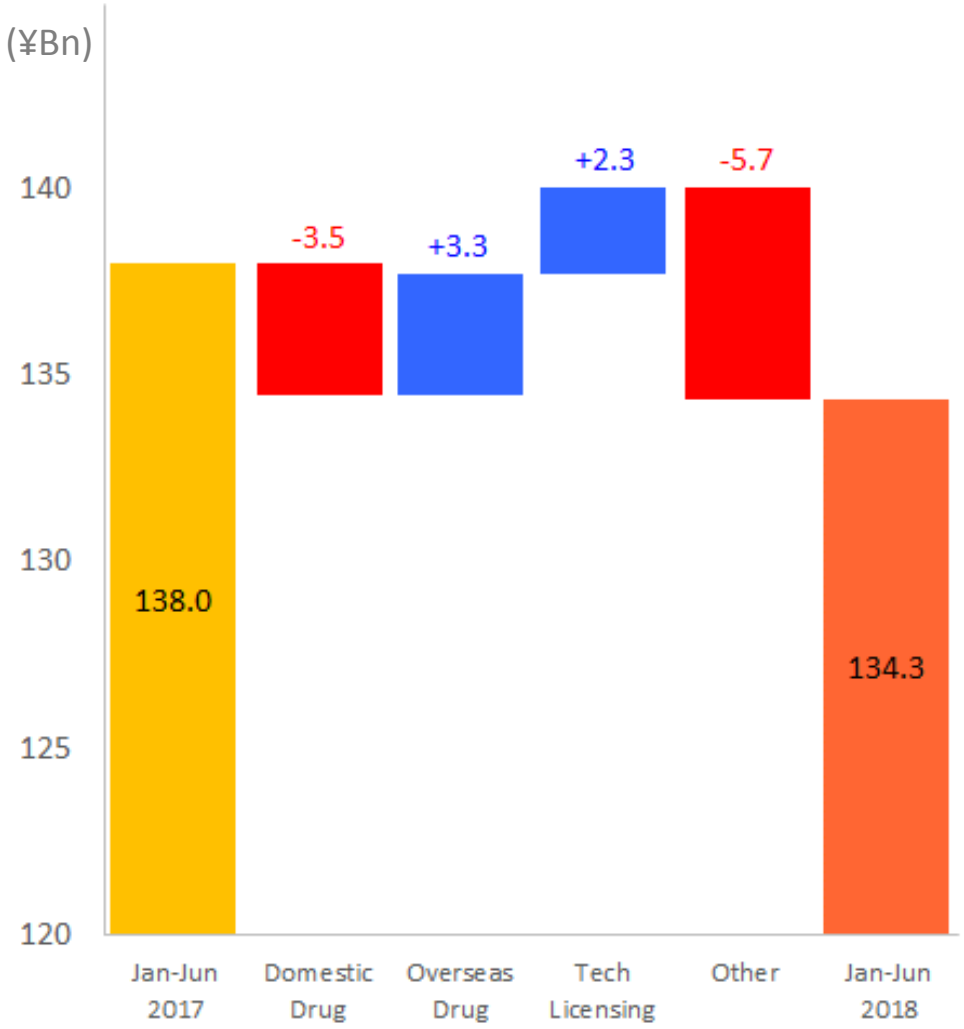
-3.6 billion yen
(incl. forex effect +1.1)



● Domestic Drug -3.5

- NEGATIVE・・・The main product Nesp declined due to the drug price cut. Regpara dropped due to the presence of competing product. Long-listed products including Allelock, Coniel, Asacol, and Depakene fell mainly due to the penetration of generic drugs.
- POSITIVE・・・Patanol increased due to the higher amounts of pollen dispersal. The new products such as G-Lasta, Lumicef, and Nouriast maintained steady growth. Rituximab-BS, which was launched in January, is smoothly penetrating into the market. Another new product Orkedia was launched in May.

● Overseas Drug +3.3 (incl. forex effect +1.3)

- EU/US・・・Crysvita, which was newly launched in the U.S. and Germany in April, started well. Abstral maintained strong growth.
- Asia・・・Favorable sales of Gran and Regpara especially in China and Korea.

● Tech Licensing +2.3 (incl. forex effect -0.2)

- Increased due to net proceeds from the Priority Review Voucher (US$80.6M×50%), despite the lower Benralizumab-related revenue.

● Others -5.7 (incl. forex effect +0.0)

- Mainly due to the deconsolidation of Kyowa Medex.

Pharmaceuticals: YoY Analysis -Core OP-

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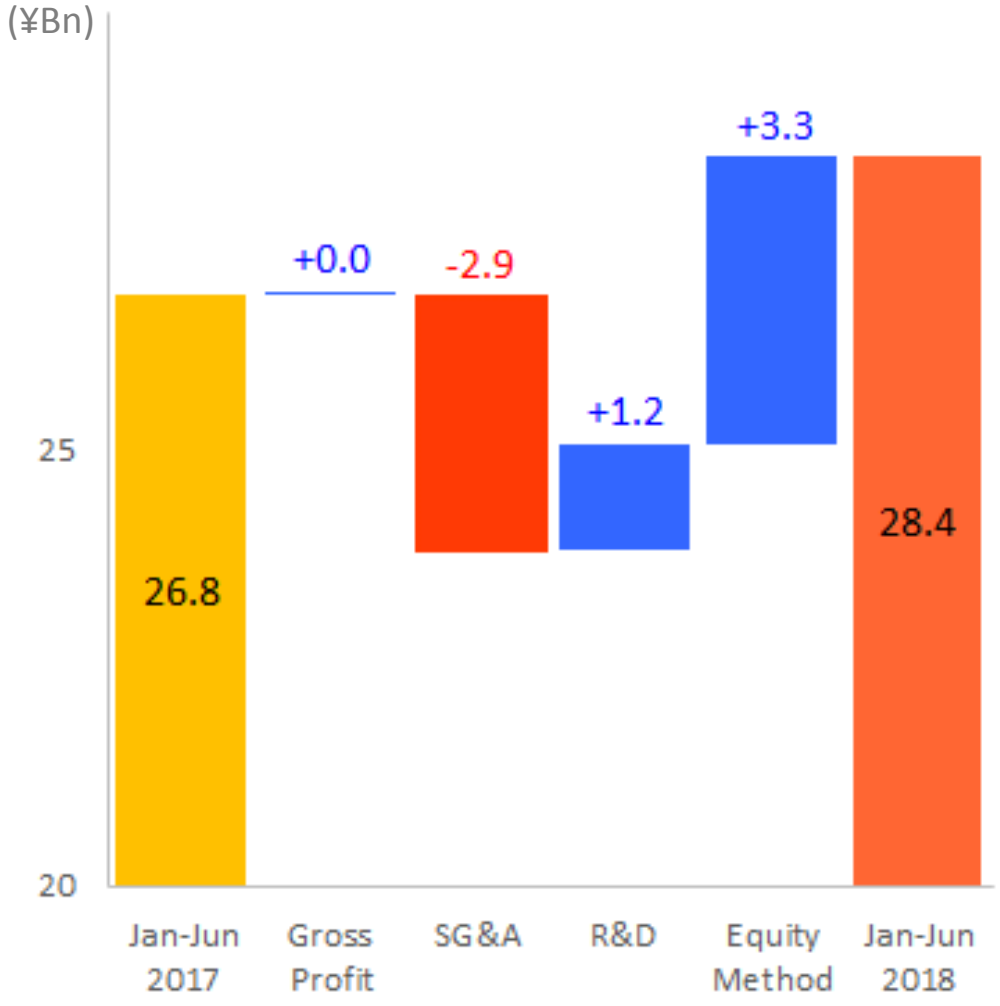
+1.6 billion yen (incl. forex effect -0.1)



- **Gross Profit +0.0 (incl. forex effect +0.9)**
  - Remained at the same level as the last year as the increased overseas & tech-licensing revenue covered the lower domestic drug sales and the impact of deconsolidation of Kyowa Medex.

- **SG&A -2.9 (incl. forex effect -1.0)**
  - Increased selling expenses for Crysvita and launch readiness expenses for Mogamulizumab in the EU/US .

- **R&D +1.2 (incl. forex effect - 0.1)**
  - Decreased mainly due to the decline in late-stage developments, including KRN23 and KW-0761.

- **Gain/Loss on Equity Method +3.3**
  - Upfront revenue from the license-out of the FKB327 commercial rights in the EU.
  - R&D expenses for FKB327 decreased.

Pharmaceuticals: Revenue of Major Items

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Item		2017Q2 Results	2018Q2 Results	Changes	Reason	2018Q4 Plan	Progression Rate
Nesp	JP	26.6	25.6	-1.1 (-4%)	Drug price cut	52.4	49%
Regpara	JP	9.4	7.8	-1.7 (-18%)	Market penetration of the competitor	13.2	59%
Allelock	JP	9.1	7.5	-1.7 (-18%)	Market penetration of GE drugs & higher amount of pollen dispersal	11.7	64%
Patanol	JP	8.8	9.7	+0.9 (+10%)	Higher amount of pollen dispersal	12.1	81%
G-Lasta	JP	8.2	9.5	+1.3 (+16%)	Steady market penetration	20.1	47%
Nouriast	JP	4.0	4.4	+0.4 (+11%)	Steady market penetration	9.4	47%
Technology licensing	JP	2.0	1.5	-0.6 (-27%)		4.6	32%
Crysvita	ex-JP	—	0.8	+0.8	Newly launched	Undisclosed	—
Abstral	ex-JP	5.7	6.5	+0.8 (+13%)	Steady market penetration	13.2	49%
Technology licensing	ex-JP	9.5	12.4	+2.9 (+30%)	Sale of priority review voucher	17.3	72%

(Billion yen / Rounded)

Bio-Chemicals: YoY Analysis -Revenue-

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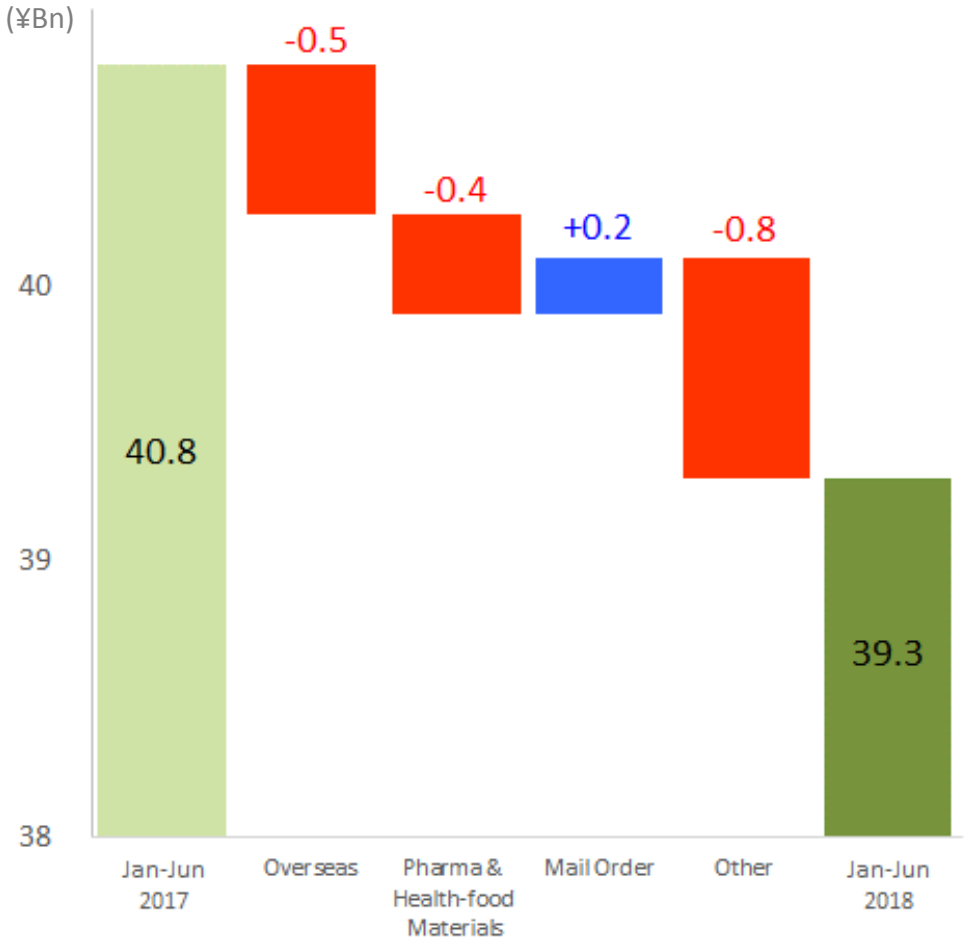
-1.5 billion yen
(incl. forex effect +0.3)



- **Overseas -0.5 (incl. forex effect +0.3)**
  - **Americas -0.2 (incl. forex effect -0.2)**
  - **Europe -0.0 (incl. forex effect +0.6):**
    Due to fiercer competition in certain products.
  - **Asia & others -0.3 (incl. forex effect -0.0):**
    Due to fiercer competition in certain products.

- **Pharma & Health-food Materials -0.4**
  - Declined due to the revamping of certain product lineups.

- **Mail Order +0.2**
  - "KHB Arginine EX" continues to grow .

- **Other -0.8**
  - Decreased mainly due to the transfer of the Plant Growth Regulator Business.

Bio-Chemicals: YoY Analysis -Core OP-

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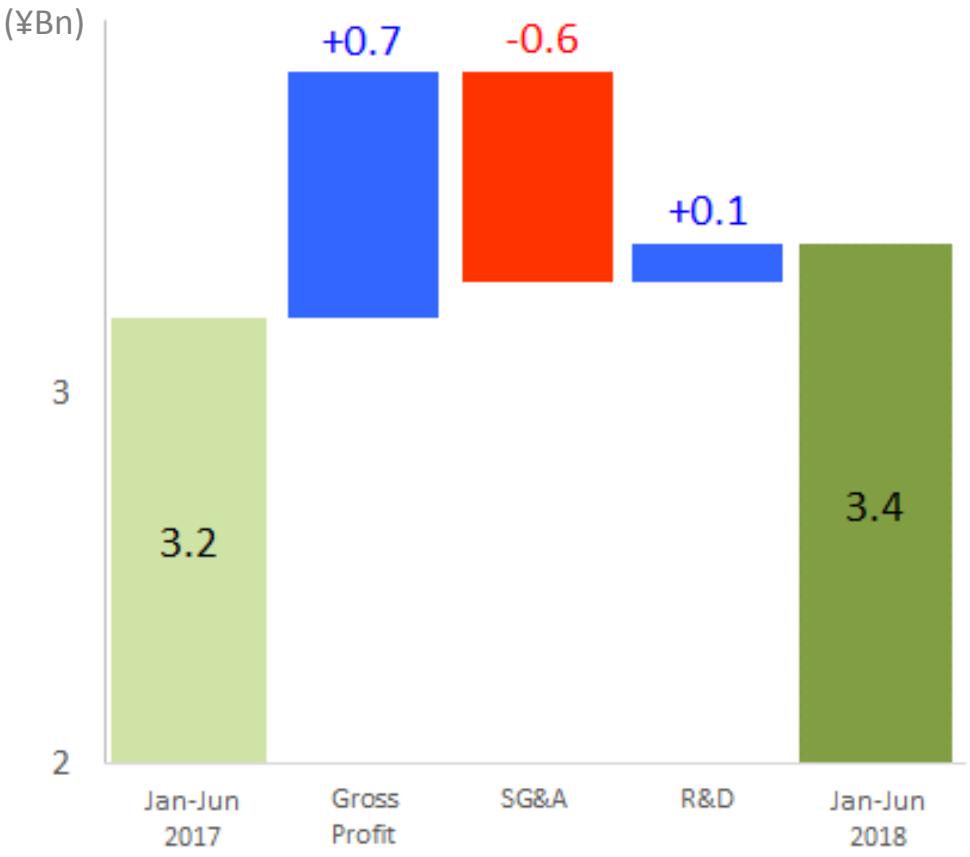
+0.2 billion yen
(incl. forex effect +0.1)



- **Gross Profit +0.7 (incl. forex effect +0.1)**
  - Improved profitability resulting from the lineup revamping and stable operation at the Thailand plant.

- **SG&A -0.6 (incl. forex effect +0.0)**
  - Increased advertisements aimed at expanding the mail order business.

R&D Review

Key development events in 2018 (1)

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Generic name Code	Indication	Country/ region	Month	Event
Bardoxolone methyl RTA 402	Diabetic kidney disease	Japan	Mar.	Designated under the SAKIGAKE system[1]
			May	Initiated phase 3 study
Benralizumab[2] KHK4563	Asthma	Europe	Jan.	Approved (BN: Fasenra)
		Japan	Jan.	Approved (BN: Fasenra subcutaneous infusion)
Brodalumab KHK4827	Psoriasis	Asia	April	Approved in Taiwan, Filed in Hong Kong
Burosumab KRN23	XLH (pediatric)	Europe	Feb.	Conditionally approved (BN: Crysvita)
		multiple[3]	May	Met primary endpoint in phase 3 study
	XLH (pediatric, adult)	U.S.	Apr.	Approved (BN: Crysvita)
		Canada	May	Filed

[1]The priority review and designation system by Ministry of Health, Labor and Welfare in Japan
[2]NDA holder is AstraZeneca
[3]North America, Europe, Japan, Korea, and Australia
BN: brand name
Note: Listed events were completed between January 1, 2018 and June 30, 2018.

Key development events in 2018 (2)

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Generic name Code	Indication	Country/ region	Month	Event
Evocalcet KHK7580	Secondary hyperparathyroidism	Japan	Mar.	Approved (BN: Orkedia tablets)
Granisetron -	Chemotherapy induced nausea and vomiting	Malaysia	Jan.	Approved (BN: Sancuso)
Mogamulizumab KW-0761	CTCL	U.S.	May	Extended PDUFA goal date by FDA

BN: brand name

Note: Listed events were completed between January 1, 2018 and June 30, 2018.

Key development update in 18Q2

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- **Initiation of phase 3 clinical study of bardoxolone methyl (RTA 402) for the treatment of diabetic kidney disease (DKD) in Japan**

RTA 402: Current situation regarding DKD in Japan

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The number of diabetes patients in Japan is increasing[1] and DKD is the leading cause in over 40% of new dialysis patients.

In a recent report[2] issued by the MHLW, the target number of new dialysis patients has been set as
39,344 pts (2016) → below 35,000 pts (2028)

Medical needs for diabetes and DKD drugs are further increasing,
and the expectations for innovative drugs
that protect and/or **improve renal function** is significantly increasing.

Bardoxolone methyl (RTA 402)

1 National Health and Nutrition Survey (2016) , MHLW/Ministry of Health, Labour and Welfare
2 Report from the investigative committee for kidney disease (managed by the MHLW) (July 12, 2018)

RTA 402: Current situation and environment

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Clinical efficacy of RTA 402

RTA 402 showed significant improvement in GFR measured by the inulin clearance method during the phase 2 study for the treatment of CKD patients with type 2 diabetes.

Update to the clinical guideline[1]

Japanese Society of Nephrology proposed a new surrogate endpoint (**30-40 % decline in the eGFR change ratio for 2-3 years in CKD**) to replace ESRD development.

Enhancing the healthcare system[2]

In order to strengthen the relationships between healthcare professionals, Industry-Government-Academia are jointly accelerating the efforts aimed at preventing severe chronic kidney diseases, including recommending checkups and the establishment of referral criteria.

RTA 402 has the possibility to become the first-ever breakthrough drug in Japan that meets the unmet medical needs of patients, healthcare professionals, and society.

→ Phase 3 study in patients with diabetic kidney disease has been initiated.

1 Clinical validation guideline for chronic diseases in renal area, Japanese Society of Nephrology (2018)
2 Report from the investigative committee for kidney disease (managed by the MHLW) (July 12, 2018)

RTA 402: clinical studies list

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RTA 402

Indication	Country/ region	Development stage (Scheduled) trial completion date		Dosed patients (Estimated enrollment)
		Phase 2	Phase 3	
Chronic kidney disease with diabetes[1]	Japan	2017/9		120
Diabetic kidney disease[2]	Japan		(2022/3)	(700)

ClinialTrials.gov identifier:
[1] NCT02316821
[2] NCT03550443

RTA 402: Phase 2 clinical study design and status

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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 (GFR) after 16 weeks of study drug administration, compared to baseline **(measured by inulin clearance)**
Disease stage:	G3, G4
Sample size:	G3 - Placebo (n=41), BARD (n=41) G4 - Placebo (n=14), BARD (n=24)

- BARD significantly improved renal function (GFR) as assessed by inulin clearance (+6.64 [mL/min/1.73m²] vs. Placebo)

- BARD may yield significant treatment benefits without major safety concerns

RTA 402: Phase 2 clinical study data

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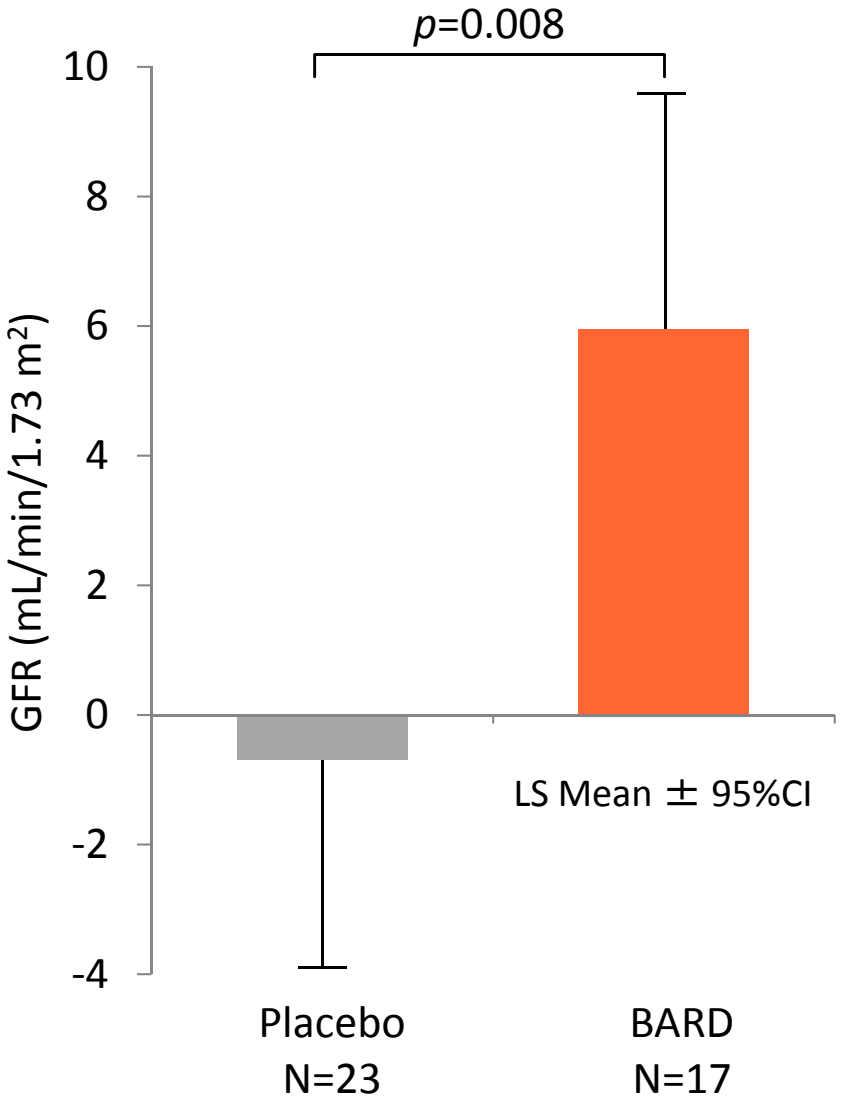
●Change in GFR assessed by inulin clearance from baseline at week 16



	Placebo N=25	BARD N=19	Between Groups
Baseline	48.13 ± 9.86	48.95 ± 9.62	—
Week 16	47.71 ± 11.63	54.54 ± 12.21	—
Difference	-0.69	5.95	6.64

Data are presented as mean ± SD or LS mean (mL/min/1.73 m²).
LS mean was adjusted by baseline eGFR and baseline ACR.

RTA 402: Phase 3 clinical study design

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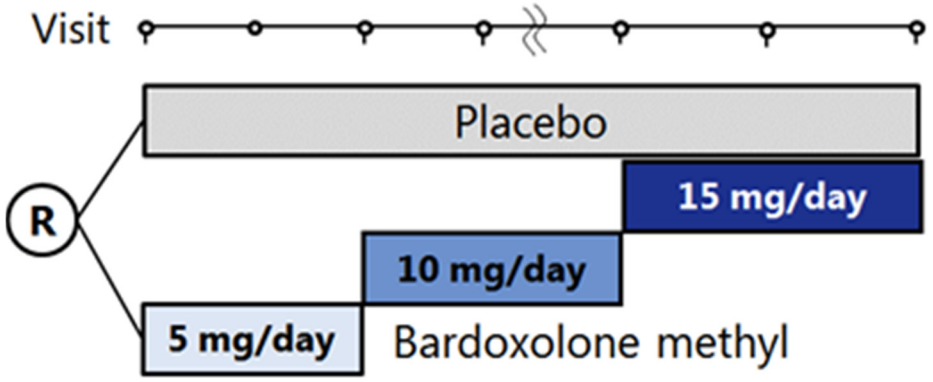
A Randomized, Double-blind, Placebo-controlled Clinical Trial in Patients with Diabetic Kidney Disease (DKD) (AYAME study)

Efficacy primary endpoint:	Time to onset of a ≥ 30% decrease in eGFR from baseline or ESRD
Target Disease stage:	G3, G4
Target Sample size:	700

AYAME
A phase 3 studY of bArdoxolone MEthyl in patients with diabetic kidney disease



KHK received the Priority Review Designation (SAKIGAKE Designation) by the Japanese Ministry of Health, Labour and Welfare for the treatment of DKD.

Business Topics

Progress in products under the alliances with partners

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Product	Indication	Country/ region	Month	Event
Dovobet Gel	• Psoriasis	Japan	Feb.	Approved
			Jun.	Launched
Rituximab BS Intravenous Infusion [KHK]	• CD20 positive, B-cell non Hodgkin's lymphoma • CD20 positive, B-cell lymphoma under immunosuppressed condition • Wegener's Granulomatosis, microscopic polyangiitis	Japan	Jan.	Launched

Note: Listed events were completed between January 1, 2018 and June 30, 2018.

Progress in the BS business -FUJIFILM KYOWA KIRIN BIOLOGICS-

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FKB327 (adalimumab, biosimilar to Humira)

- **Concluded an exclusive sales agreement in Europe with Mylan.**
  - **Mylan who has excellent sales capabilities in Europe and is the optimum partner for maximizing the value of FKB327.**
  - **Based on the agreement, FKB will receive an upfront payment, as well as a milestone payment upon the start of sales and sales royalties.**
- **On July 27, 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the marketing authorization of FKB327.**
- **The regulatory approval in Europe and initial shipment to Mylan are both expected within this year.**
- **Negotiations for exclusive sales agreements in additional territories with Mylan are ongoing.**

Appendix

FOREX Information

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Average FOREX Rate

[Yen]

Currency	2017Q2 Results	2018Q2 Results	Changes	2018Q4 Plan
USD/JPY	113	109	-4	110
EUR/JPY	122	132	+10	130
GBP/JPY	142	151	+9	150

2018Q2 FOREX Effect (YoY)

[Billion Yen]

Segment	Currency	Revenue	Core OP
Pharmaceuticals	USD	-0.2	-0.1
	EUR	+0.0	+0.0
	GBP	+1.1	-0.2
Bio-Chemicals	USD	-0.3	-0.2
	EUR	+0.6	+0.3

Burosumab： Collaboration with Ultragenyx (summary)

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	KHK group	Ultragenyx
U.S.A Canada	● Books sales ● Splits profits in half with Ultragenyx for first 5 years ● After 5 years, pays mid to high 20% range sales royalty to Ultragenyx	● Splits profits in half with KHK for first 5 years ● After 5 years, receives mid to high 20% range sales royalty from KKI
Europe	● Books sales ● Pay up to 10% sales royalty to Ultragenyx	● Receives up to 10% sales royalty from KKI
Latin America	● Receives low single-digit sales royalty from Ultragenyx	● Books sales ● Pays low single-digit sales royalty to KHK
Turkey	● Receives up to 20% sales royalty from Ultragenyx ● Retains an option to take over commercialization rights after a certain period	● Books sales ● Pays up to 20% sales royalty to KKI
Asia (incl. Japan) ROW	● Books sales	

* KHK supplies commercial product in all regions.

Development schedule of major pipeline

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As of June 30
+ : Estimated time of regulatory decisions

Generic name Code	Indication	Country/ region	2018	2019	2020~
Bardoxolone methyl RTA 402	Diabetic kidney disease	Japan	Phase 3		
Benralizumab[1] KHK4563	COPD	U.S., Europe	TBD		
		Japan	TBD		
Brodalumab KHK4827	Psoriasis	Asia	Submission / +		
	Axial spondyloarthritis	Japan, Korea, Taiwan	Phase 3		Submission
Burosumab[2] KRN23	XLH	Europe	Approved (Pediatric)	+ (Adult)	
		U.S.	Approved		
		Japan	Submission	+	
Entinostat KHK2375	Breast cancer	Japan	Phase 2		
Istradefylline KW-6002	Parkinson's disease	U.S.	Submission	+	
Mogamulizumab KW-0761	CTCL	U.S., Europe	+[3]		
Romiplostim AMG531	Aplastic anemia	Japan, Korea	Submission	+	
	ITP	China		Submission	+

[1]NDA holder is AstraZeneca [2]Jointly developed with Ultragenyx [3]PDUFA: September 4, 2018

Development schedule of major pipeline (cont.)

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As of June 30

Code	Indication	Country/ region	2018	2019	2020~
ASKP1240[4]	Recurrence of FSGS in de novo kidney transplant	U.S.	Phase 2		
KHK4083	Ulcerative colitis	U.S., Europe	Phase 2		
	Atopic dermatitis	U.S., Europe, Japan	Phase 2		
KW-6356	Parkinson's disease	Japan	Phase 2		

[4]Jointly developed with Astellas Pharma Inc

RTA 402 for Diabetic Kidney Disease (DKD) patients

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Diabetes Patients under Treatment
(Patient population: 7.7 million)*

RTA 402
Target Patients (DKD):
CKD Stage G3~G4

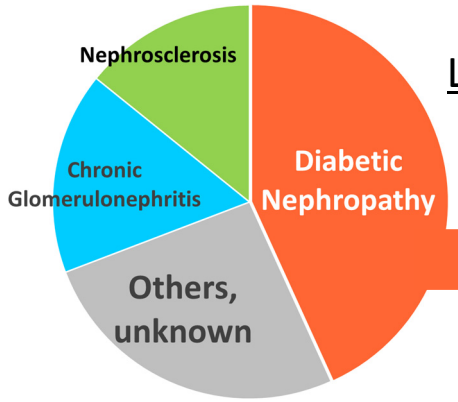
ESRD

Degradation of kidney function

- ✓ Glycemic Control
- ✓ Blood Pressure Control

- ✓ Protect renal function by some diabetes drugs including SGLT2 inhibitors

- ✓ Improve renal function by RTA 402



Leading causes of new dialysis patients in 2016

The leading cause of the new cases of dialysis was **Diabetic Nephropathy** (16,103 pts)**

* National Health and Nutrition Survey (2016) , MHLW/Ministry of Health, Labour and Welfare

** Report from The Japanese Society for Dialysis Therapy, http://docs.jsdt.or.jp/overview/pdf2017/p016.pdf

ESG indexes

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Included in all three ESG indexes selected by GPIF*

FTSE Blossom Japan

MSCI 2018 Constituent MSCI Japan ESG Select Leaders Index

Broad index

MSCI 2018 Constituent MSCI Japan Empowering Women Index (WIN)

Thematic/social (S)

Kyowa Hakko Kirin is also included in several of the major socially responsible investment (SRI) indexes

Member of SNAM Sustainability Index 2018

FTSE4Good

MS-SRI

MSCI 2018 Constituent MSCI ESG Leaders Indexes

* GPIF: Government Pension Investment Fund

List of acronyms

BS	Biosimilar
COPD	Chronic Obstructive Pulmonary Disease
CTCL	Cutaneous T-Cell Lymphoma
CKD	Chronic Kidney Disease
DKD	Diabetic Kidney Disease
ESRD	End Stage Renal Disease
FSGS	Focal Segmental Glomerulosclerosis
ITP	Idiopathic (immune) Thrombocytopenic Purpura
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.

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