KYOWA KIRIN

Result Presentation
Fiscal 2018 First Quarter

Kyowa Hakko Kirin Co., Ltd.

Agenda

KYOWA KIRIN

Results Summary & Financial Review

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R&D Review

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Business Topics

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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.

Results Summary & Financial Review

Summary of Consolidated Results

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	2017Q1 Results	2018Q1 Results	Changes	
Revenue	91.3	84.7	-6.6 (-7%)	• Shrink in domestic drug and technology licensing revenue (↓) • Deconsolidation of Kyowa Medex (↓)
Core Operating Profit (Core OP) *[Margin]*	16.8 *[18.4%]*	16.2 *[19.2%]*	-0.5 (-3%)	• Improvement of FKB's profit/loss (equity method) (↑)
Profit	12.0	22.0	+10.0 (+83%)	• Gain on sale & valuation of Kyowa Medex shares (↑)

(Billion Yen / Rounded)

*FKB: FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.

Consolidated：YoY Analysis -Profit-

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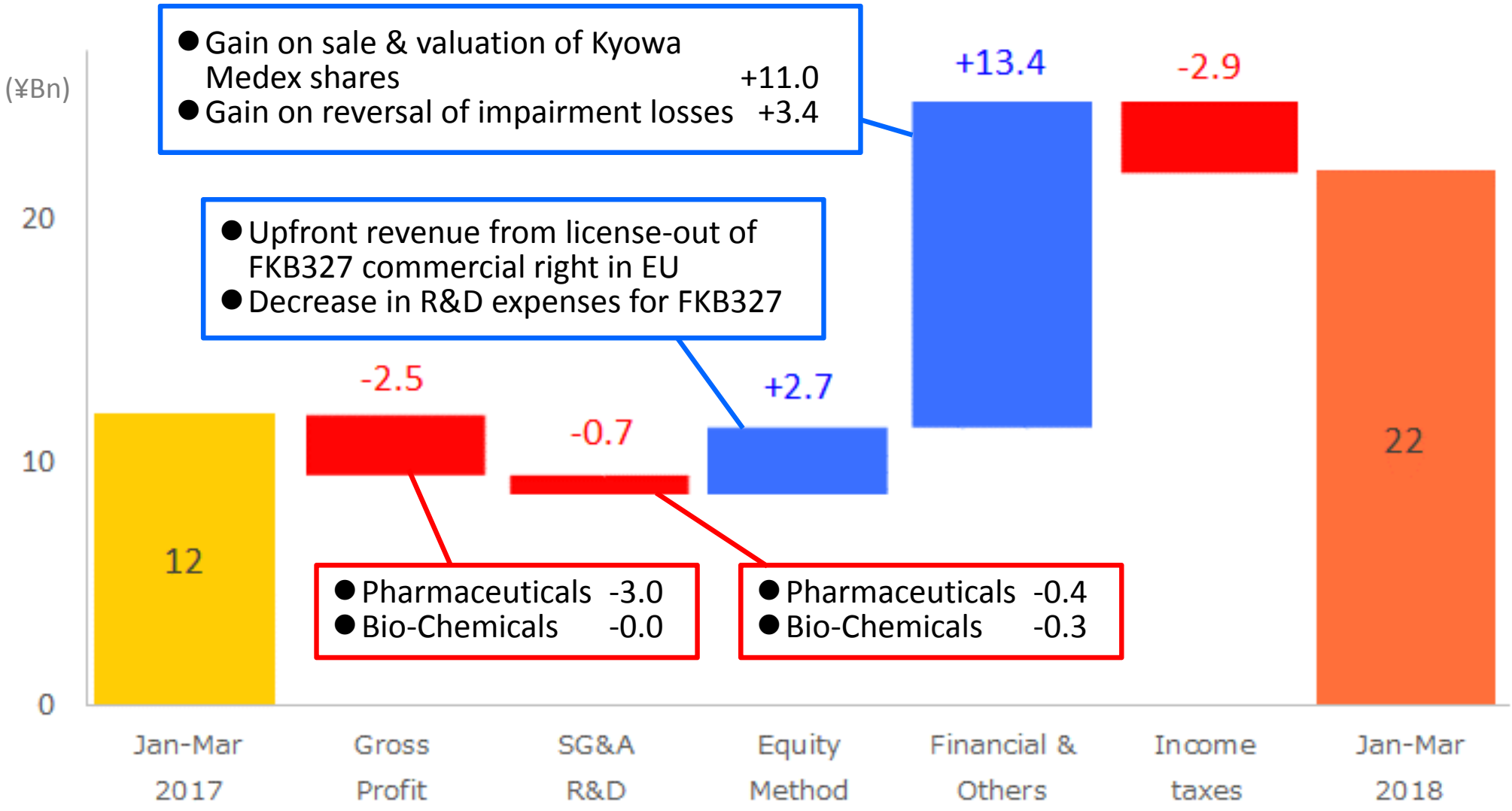
Profit +10.0 billion yen



Summary of Results by Segment

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- **Pharmaceuticals' Core OP decreased due to the shrink in the domestic drug sales & tech-licensing revenue**
- **Bio-Chemicals' Core OP fell due to aggressive advertisements for the future mail-order business' expansion**

		2017Q1 Results	2018Q1 Results	Changes	2018 Plan	Progression Rate
Pharma-ceuticals	Revenue	72.3	66.5	-5.8 (-8%)	262.0	25%
	Core OP *[Margin]*	15.1 *[20.9%]*	14.4 *[21.6%]*	-0.7 (-5%)	43.0 *[16.4%]*	34%
Bio-Chemicals	Revenue	20.0	19.0	-1.0 (-5%)	76.0	25%
	Core OP *[Margin]*	1.5 *[7.6%]*	1.2 *[6.3%]*	-0.3 (-22%)	8.0 *[10.5%]*	15%

(Billion Yen / Rounded)

Pharmaceuticals: YoY Analysis -Revenue-

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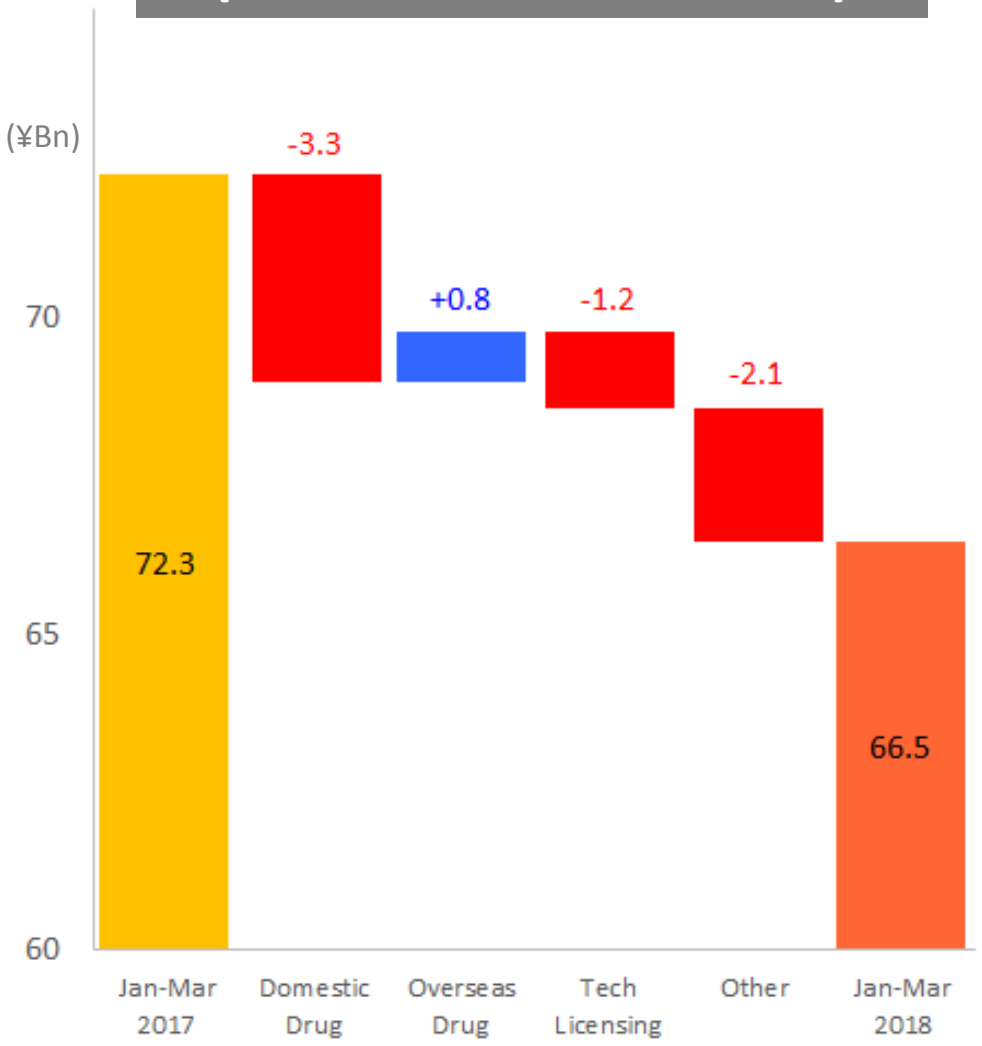
-5.8 billion yen
(incl. forex effect +0.4)



● Domestic Drug -3.3

- NEGATIVE・・・Regpara dropped due to the competing product. Long-listed products including Allelock, Coniel, Asacol, and Depakene decreased due mainly to the penetration of generic drugs.
- POSITIVE・・・Patanol increased due to the high pollen dispersal. New products such as G-Lasta and Lumicef sustained steady growth, and Rituximab-BS ,newly launched in January, was smoothly penetrating into the market.

● Overseas Drug +0.8 (incl. forex effect +0.6)

- EU・・・Abstral kept growing firmly. Moventig was also steadily penetrating into the market.
- Asia・・・Favorable sales of Gran & Nesp, especially in China & Taiwan.

● Tech Licensing -1.2 (incl. forex effect -0.2)

- Mainly due to fall in benralizumab-related revenue.

● Others -2.1 (incl. forex effect +0.0)

- Decreased by deconsolidation of Kyowa Medex.

Pharmaceuticals: YoY Analysis -Core OP-

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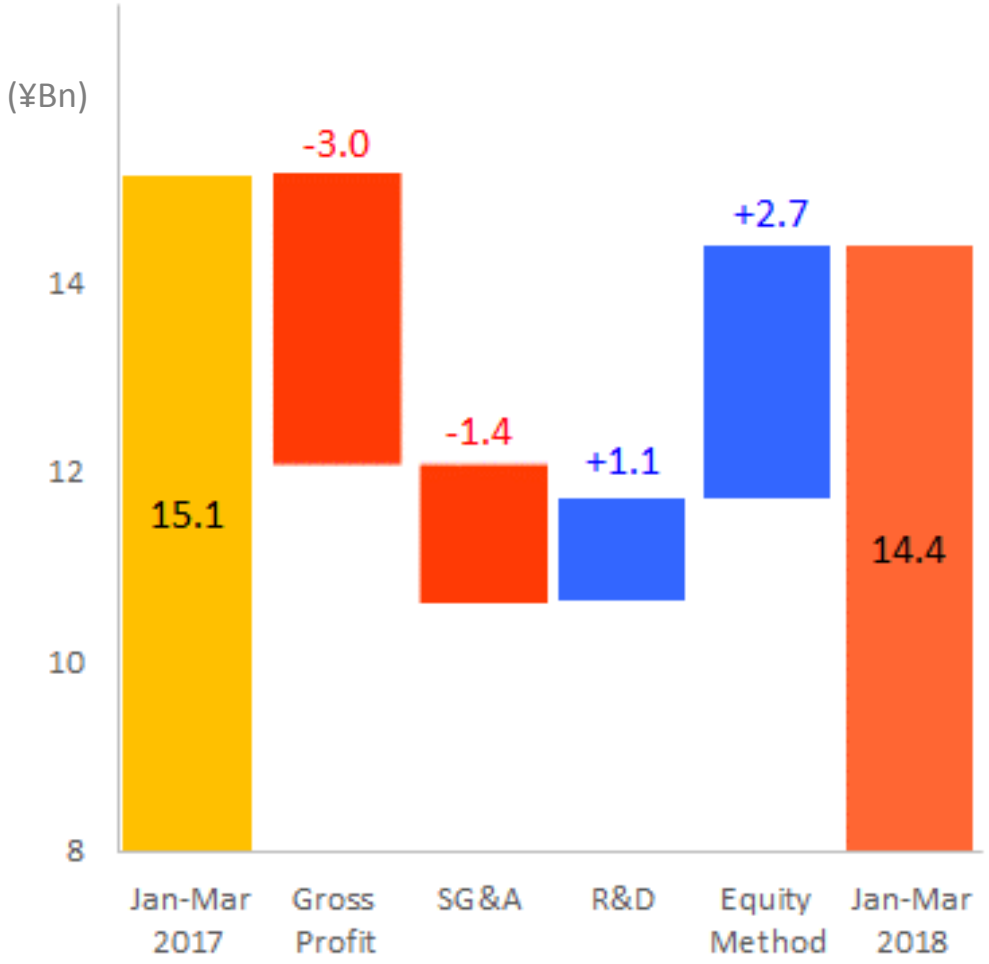
-0.7 billion yen
(incl. forex effect -0.2)



- **Gross Profit -3.0 (incl. forex effect +0.3)**
  - Due to decrease in the sales revenue.

- **SG&A -1.4 (incl. forex effect -0.5)**
  - Mainly due to boost in launch readiness expenses for Crysvita (burosumab).

- **R&D +1.1 (incl. forex effect +0.0)**
  - Due to the shrink in late-stage developments such as KRN23, KW-0761, KHK7580.

- **Income/Loss on Equity Method +2.7**
  - Upfront revenue upon the license-out of FKB327 commercial right in EU.
  - R&D expenses for FKB327 decreased.

Pharmaceuticals: Revenue of Major Items

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Item		2017Q1 Results	2018Q1 Results	Changes	Reason	2018 Plan	Progression Rate
NESP	JP	12.5	12.0	-0.5 (-4%)	Timing of shipment	52.4	23%
REGPARA	JP	4.6	3.6	-1.0 (-22%)	Market penetration of the competitor	13.2	27%
ALLELOCK	JP	5.6	4.6	-1.0 (-18%)	Market penetration of GE drugs & high pollen dispersal	11.7	39%
Patanol	JP	7.0	7.7	+0.7 (+11%)	High pollen dispersal	12.1	64%
G-Lasta	JP	3.8	4.3	+0.5 (+13%)	Steady market penetration	20.1	22%
NOURIAST	JP	1.8	1.9	+0.1 (+4%)	Steady market penetration	9.4	20%
Technology licensing	JP	0.8	1.1	+0.3 (+31%)		4.6	24%
Abstral	ex-JP	2.9	3.4	+0.4 (+15%)	Steady market penetration	13.2	25%
Technology licensing	ex-JP	8.0	6.5	-1.5 (-18%)	Decrease in benralizumab-related revenue	17.3	37%

(Billion yen / Rounded)

Bio-Chemicals: YoY Analysis -Revenue-

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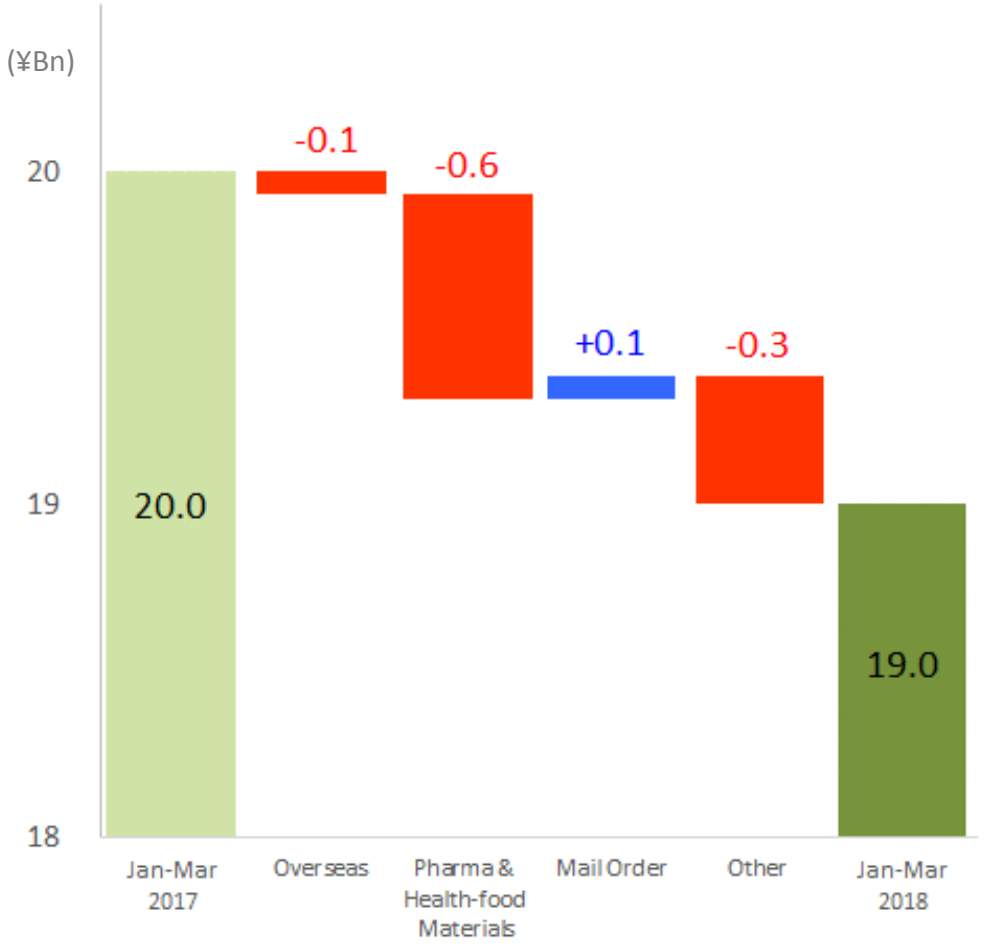
-1.0 billion yen
(incl. forex effect +0.2)



- **Overseas -0.1 (incl. forex effect +0.2)**
  - **Americas +0.0 (incl. forex effect -0.1)**
  - **Europe +0.2 (incl. forex effect +0.3)**
  - **Asia & others -0.3 (incl. forex effect -0.0):** Due to fiercer competition in China.

- **Pharma & Health-food Materials -0.6**
  - Dropped by revamping of certain product lineup.

- **Mail Order +0.1**
  - "KHB Arginine EX" is continuously growing.

- **Other -0.3**
  - Decreased due to transfer of the Plant Growth Regulator Business.

Bio-Chemicals: YoY Analysis -Core OP-

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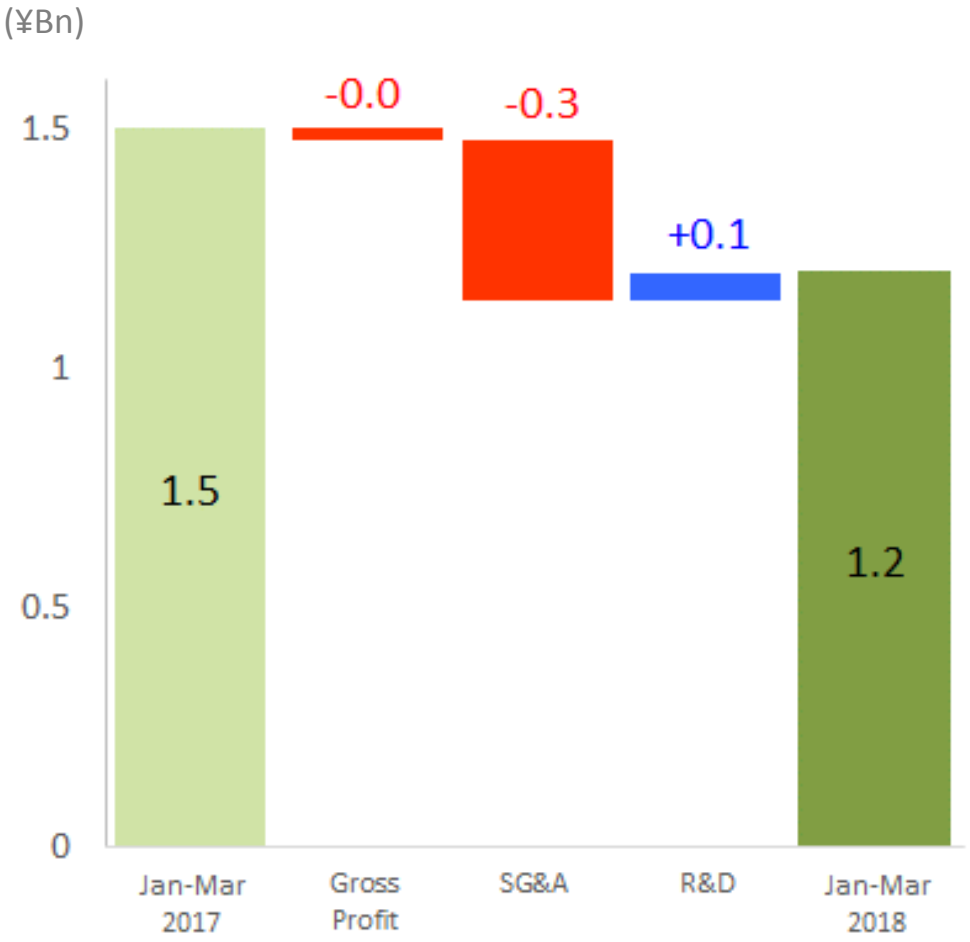
-0.3 billion yen
(incl. forex effect +0.1)



- **Gross Profit -0.0 (incl. forex effect +0.0)**
  - Maintained a same level as last year through the improvement of profitability.

- **SG&A -0.3 (incl. forex effect +0.0)**
  - Advertisement increased aiming for the mail order business' growth.

R&D Review

Key development events in 2018

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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]
Benralizumab[2] KHK4563	Asthma	Europe	Jan.	Approved (BN: Fasenra)
		Japan	Jan.	Approved (BN: Fasenra subcutaneous infusion)
Burosumab KRN23	XLH (pediatric)	Europe	Feb.	Conditionally approved (BN: Crysvita)
Evocalcet KHK7580	Secondary hyperparathyroidism	Japan	Mar.	Approved (BN: Orkedia tablets)
Granisetron -	Chemotherapy induced nausea and vomiting	Malaysia	Jan.	Approved (BN: Sancuso)

[1]The priority review and designation system by Ministry of Health, Labor and Welfare in Japan

[2]NDA holder is AstraZeneca

BN: brand name

Note: Listed events were completed between January 1, 2018 and March 31, 2018.

Key development events in 2018 (after April)

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- **Approval of burosumab-twza (brand name[1]: Crysvita) for the treatment of pediatric and adult patients with XLH in the U.S.**

[1]The brand name is used in the U.S. and Europe.

Note: Listed events were completed between April 1, 2018 and May 8, 2018.

Key development events in 2018 (after April, cont.)

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- **Discontinued development for mogamulizumab in combination with PF-05082566 for the treatment of solid tumors based on a collaboration agreement on immuno-oncology combination therapies with Pfizer**

- **Discontinued development for mogamulizumab in combination with durvalumab or tremelimumab for the treatment of solid tumors based on a collaboration agreement on immuno-oncology combination therapies with AstraZeneca**

Note: Listed events were completed between April 1, 2018 and May 8, 2018.

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
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 March 31, 2018.

Progress in the BS business (FUJIFILM KYOWA KIRIN BIOLOGICS)

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FKB327 (Biosimilar to Humira <adalimumab>)

- Submitted an application for marketing authorization to the European Medicines Agency in the EU, and it was accepted on May 18, 2017
- Concluded an exclusive sales agreement with Mylan for Europe
  - Mylan has excellent sales capabilities in Europe, and it 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
- Currently negotiating an exclusive sales agreement with Mylan for the other territories
- Responses are being made to the EU authorities in partnership with Mylan, and marketing authorization is expected to be received in the second half of 2018

Progress in the BS business (FUJIFILM KYOWA KIRIN BIOLOGICS)

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FKB238 (Biosimilar to Avastin <bevacizumab>)

- Concluded an agreement with AstraZeneca and established a joint venture (Centus Biotherapeutics) funded equally by both parties in 2015
- The above joint venture is currently conducting a phase 3 international joint clinical trial

Progress in the BS business (Fujifilm Kyowa Kirin Biologics)

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Summary of the biosimilar business at Fujifilm Kyowa Kirin Biologics

- Planning to start sales of FKB327 by Mylan in Europe from around 2019, and it is expected that capital recovery will begin before long
- Development of FKB238 by the joint venture with AstraZeneca is proceeding according to plan, and it is expected that capital recovery will begin in a few years
- In addition to FKB238, forming a sales alliance with a global pharmaceutical company for FKB327 as well is expected to improve profitability of this biosimilar business

Appendix

FOREX Information

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Average FOREX Rate

[Yen]

Currency	2017Q1 Results	2018Q1 Results	Changes	2018 Plan
USD/JPY	115	110	-5	110
EUR/JPY	122	134	+12	130
GBP/JPY	143	152	+9	150

2018Q1 FOREX Effect (YoY)

[Million Yen]

Segment	Currency	Revenue	Core OP
Pharmaceuticals	USD	-190	-70
	EUR	+20	+10
	GBP	+510	-130
Bio-Chemicals	USD	-180	-150
	EUR	+330	+150

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 March 31
+ : Estimated time of regulatory decisions

Generic name Code	Indication	Country/ region	2018	2019	2020~
Bardoxolone methyl RTA 402	Diabetic kidney disease	Japan	Phase 3		
Benralizumab1[1] KHK4563	COPD	U.S., Europe		Submission	
		Japan		Submission	
Brodalumab KHK4827	Psoriasis	Asia	Submission / +		
	Axial spondyloarthritis	Japan, Korea, Taiwan	Phase 3		Submission
Burosumab[2] KRN23	XLH	Europe	Approved (Pediatric)	+ (Adult)	
		U.S.	+[3]		
		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	+[4]		
Romiplostim AMG531	Aplastic anemia	Japan, Korea	Submission	+	
	ITP	China		Submission	+

[1]NDA holder is AstraZeneca [2]Jointly developed with Ultragenyx PDUFA: [3]April 17 and [4]June 4, 2018.

Development schedule of major pipeline (cont.)

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As of March 31

Code	Indication	Country/ region	2018	2019	2020~
ASKP1240[5]	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		

[5]Jointly developed with Astellas Pharma Inc

Biosimilar product 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

BS	Biosimilar
COPD	Chronic Obstructive Pulmonary Disease
CTCL	Cutaneous T-Cell Lymphoma
FSGS	Focal Segmental Glomerulosclerosis
HTLV-1	Human T-cell Leukemia Virus Type 1
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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