KYOWA KIRIN

Results Presentation
Fiscal 2017 First Quarter

Kyowa Hakko Kirin Co., Ltd.

Agenda

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FY 2017 Q1 highlights
Financial review

Kazuyoshi Tachibana, Managing Executive Officer

R&D review

Mitsuo Satoh, Executive Officer
Vice president, Head of R&D Division

Business topics

Masashi Miyamoto, Managing Executive Officer
Director, Corporate Strategy & Planning Dept.

Q & A session

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.

FY 2017 Q1 Highlights

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In Q1 of FY 2017, sales and profits increased in the Pharmaceuticals business YoY, while they declined in Bio-Chemicals business YoY. The consolidated sales and profits increased YoY and they saw a steady progress in line with 2017 business plan.

- Despite well-performing sales of REGPARA® and the new products, including G-Lasta®, NOURIAST®, Onglyza®, the sales of the pharmaceuticals business in Japan reported a decrease of ¥ 2.4 billion YoY, due to the penetration of generics and drug price revision.

- The Pharmaceuticals business saw an increase in overseas sales by ¥ 6.0 billion YoY due to the increase in technology licensing revenue and other factors.

- R&D expense in the Pharmaceuticals business decreased by ¥ 1.8 billion YoY partly because some excess R&D expenses in the previous fiscal year were adjusted.

- In the Bio-Chemicals business, sales and operating income decreased by ¥ 0.8 billion and ¥ 0.6 billion YoY respectively, due to the decrease in overseas sales and the end of sales of low-margin products and strong yen.

Financial review

Summary of 2017 Q1 results (consolidated)

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In Q1 of 2017, sales and profits increased, with sales growth of ¥ 2.4 billion and operating income growth of ¥ 6.1 billion.

(Unit: ¥bn)	FY2016 Q1 results	FY2017 Q1 results	Change
Net sales	88.4	90.9	+2.4 (+3%)
Operating Income [Operating margin]	8.5 [9.6%]	14.7 [16.2%]	+6.1 (+73%)
Ordinary income	7.8	13.6	+5.8 (+75%)
Net profit	7.3	8.4	+1.0 (+15%)

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

✓Ordinary income increased due to an increase in operating income.
✓Net profit increased for the quarter, despite a decline in the extraordinary income as recorded in the previous year.

Summary of FY2017 Q1 consolidated results: Analysis of YoY net profit changes

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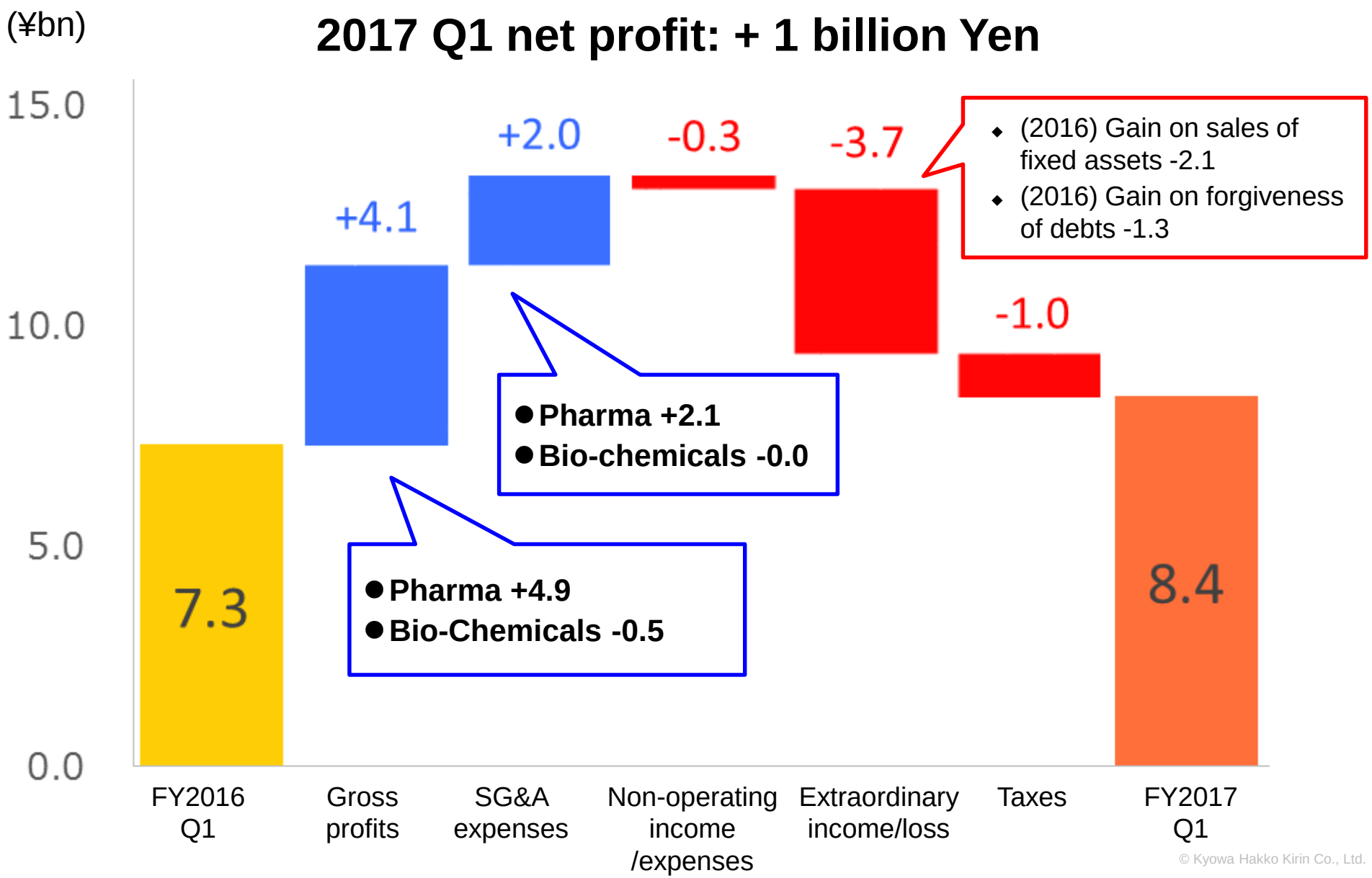

Summary of FY2017 Q1 financial results by segment

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The overall Pharmaceuticals business had increased in sales and profits mainly due to the increase in technology licensing revenue, despite a sales drop in Japan caused by drug price revision and penetration of generics into the market.
The Bio-Chemicals business had a decline in sales and operating income due to the poor overseas sales of amino acids and others.

(Unit: ¥bn)		FY2016 Q1 results	FY2017 Q1 results	Change
Pharmaceuticals business	Net sales	68.0	71.5	+3.4 (+5%)
	Operating income *Operating margin*	5.9 [8.7%]	12.9 [18.1%]	+7.0 (+119%)
Bio-Chemicals business	Net sales	21.2	20.3	-0.8 (-4%)
	Operating income *Operating margin*	2.3 [10.9%]	1.7 [8.3%]	-0.6 (-27%)

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

Pharmaceuticals business: FY2017 Q1 Analysis of YoY changes

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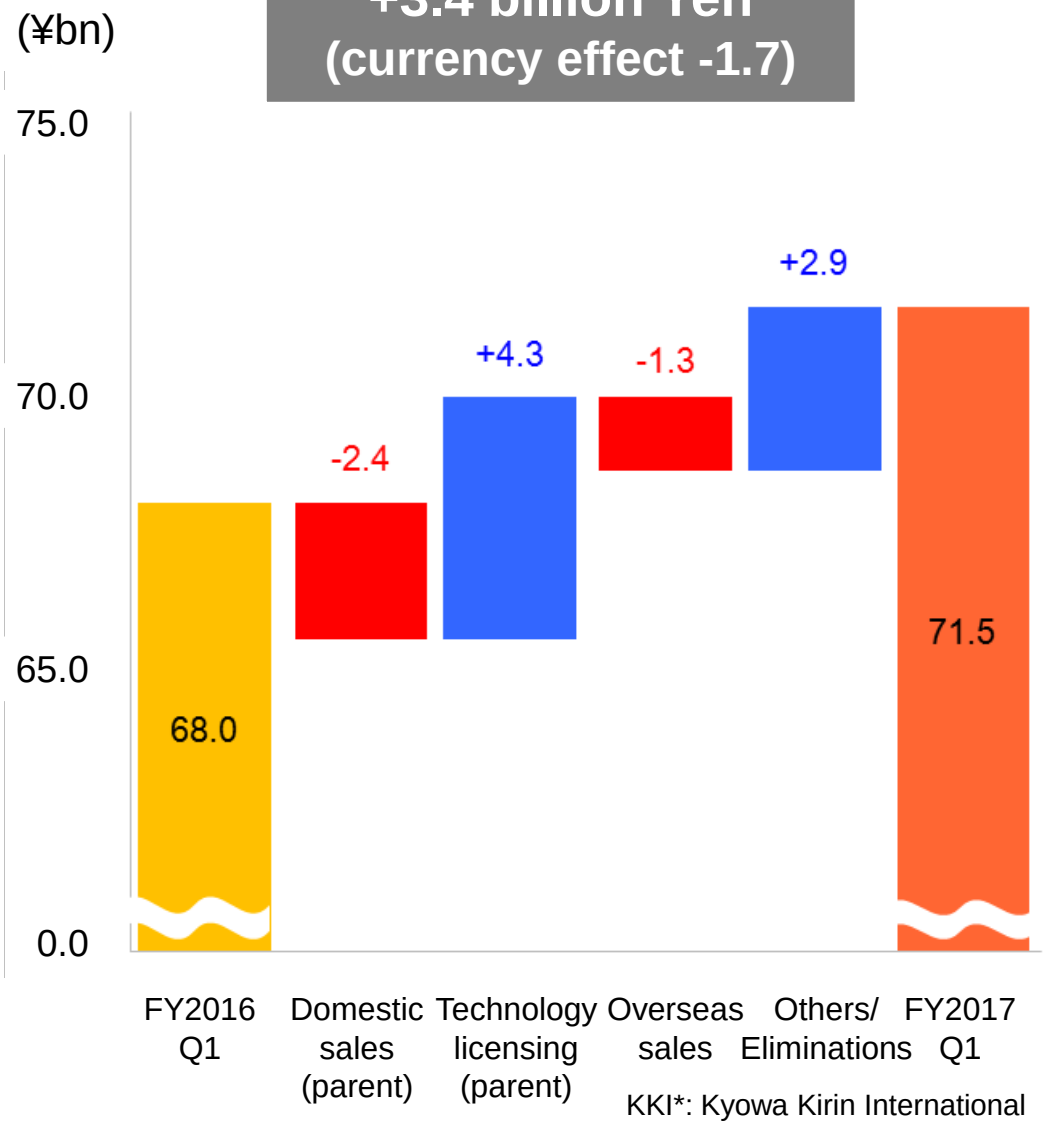
Sales
+3.4 billion Yen
(currency effect -1.7)



KKI*: Kyowa Kirin International

- **Domestic pharmaceutical products -2.4**
  - Our key product NESP® decreased in sales due to the impact of drug price revision, etc.
  - Sales of long-term prescription products such as ALLELOCK® also decreased due to the penetration of generics, etc.
  - New products including G-Lasta®, NOURIAST® and Onglyza® sustained steady sales, resulting in an increase of sales YoY.
- **Technology licensing, etc. +4.3** (currency effect -0.0)
  - The revenue increased due to the upfront and milestone payments under the license agreements of benralizumab in Asian regions including Japan.
- **Sales in overseas subsidiaries -1.3** (currency effect -1.6)
  - KKI* (-1.4) (currency effect -1.6): Due to the growth of Abstral and PecFent, its net sales increased, excluding the currency effect.
- **Others/ Eliminations +2.9** (currency effect -0.0)
  - The increase came from the increase of technology licensing revenue in subsidiaries.

Pharmaceuticals business: FY2017 Q1 Analysis of YoY changes

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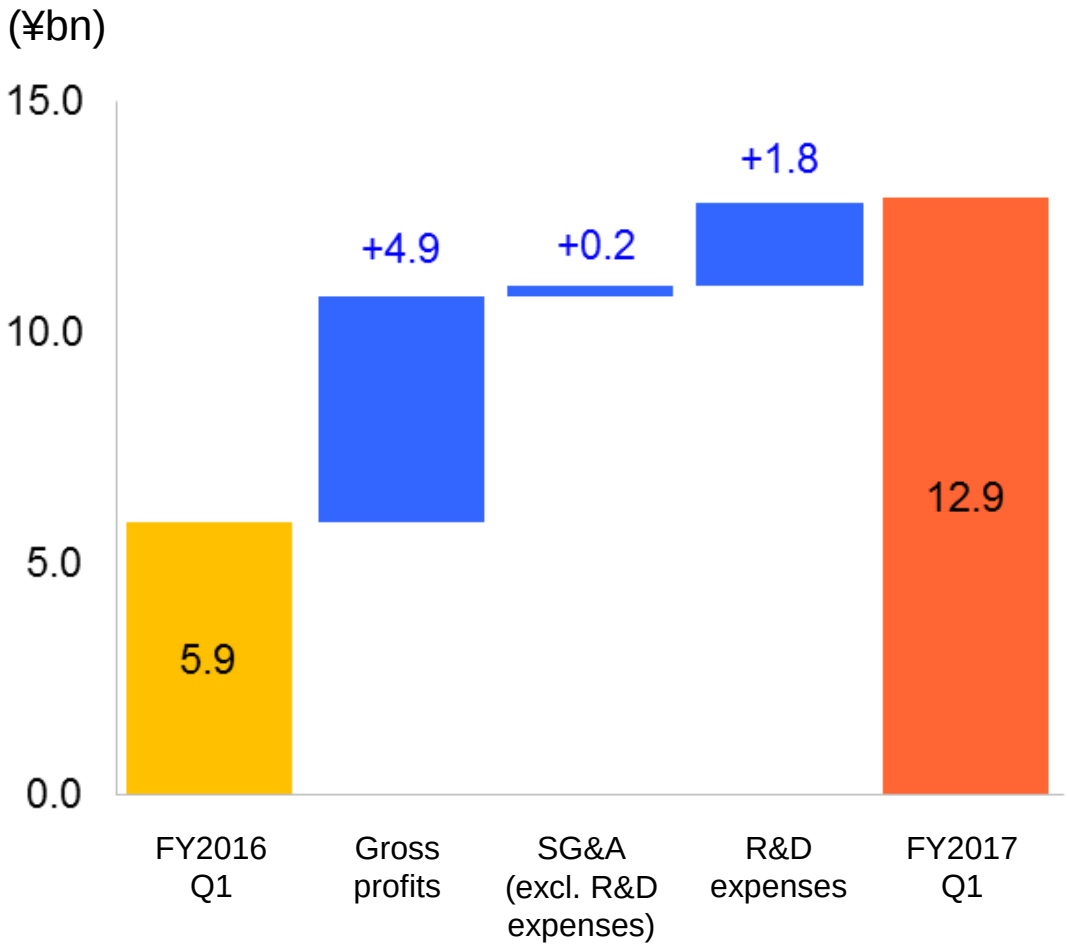
Operating income +7.0 billion Yen (currency effect +0.1)



- **Gross profits +4.9** (currency effects -1.3)
  - Increase in technology licensing revenue

- **SG&A +0.2** (currency effects +1.2)
  - Increase in costs related to Moventig and product launch expenses for burosumab (KRN23) incurred by KKI, in real terms, excluding currency effects.

- **R&D expenses +1.8** (currency effects +0.3)
  - Decrease in costs partly due to the adjustment of some excess R&D expenses in the previous fiscal year

Pharmaceuticals business: Domestic sales of key products

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Despite the sluggish sales of key product NESP® and long-term prescription products including ALLELOCK®, the significant increase of technology licensing revenue boosted overall Japan sales.

Product name etc.	FY2016 Q1 results	FY2017 Q1 results	Change	Reason for change	FY2017 Forecast	Rate of Progress*
NESP®	13.3	12.4	-0.9 (-7%)	(-) Drug price revisions	57.2	22%
REGPARA®	4.3	4.5	+0.2 (+6%)	(+) Steady penetration of the market	17.8	26%
ALLELOCK®	6.8	5.6	-1.2 (-18%)	(-) Market penetration of generics	14.1	40%
Patanol®	7.3	6.9	-0.3 (-4%)	(-) Market penetration of competitors	12.1	58%
G-Lasta®	3.6	3.8	+0.1 (+5%)	(+) Steady penetration of the market	17.8	22%
NOURIAST®	1.4	1.8	+0.3 (+26%)	(+) Steady penetration of the market	8.7	21%
Technology out-licensing	0.5	4.8	+4.3 (+860%)	(+) Milestone & upfront payments related to benralizumab	7.4	65%

(Unit: ¥bn, figures rounded down)

* Rate of progress compared to FY2017 sales forecasts (as of January 31, 2017)

Bio-Chemicals business: FY2017 Q1 Analysis of YoY changes

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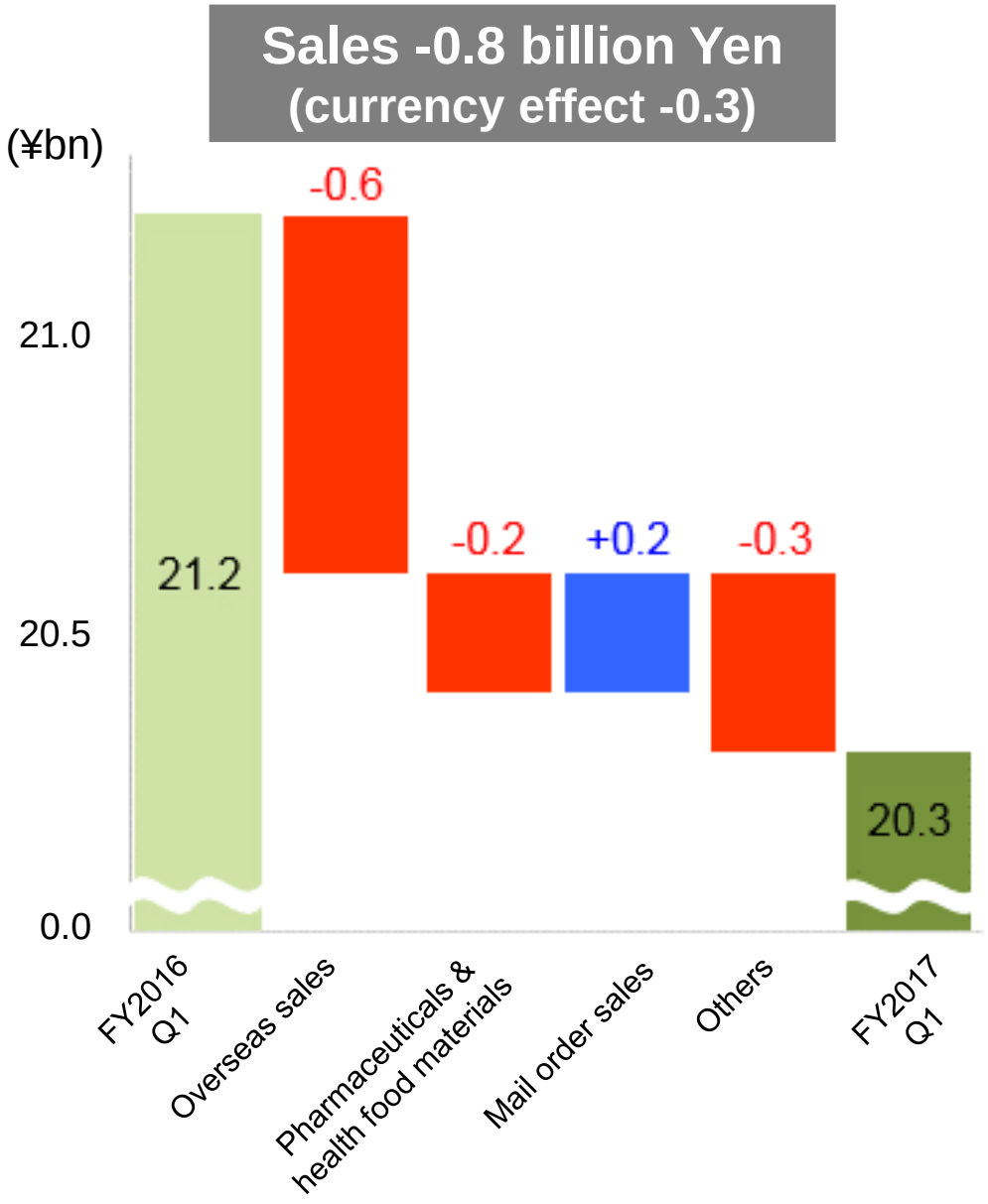

- **Overseas sales -0.6**(currency effect -0.3)
  - **Americas -0.4** (currency effect -0.0)
    - ✓ Decrease in sales of health-food materials and sales of amino acids for cell culture medium
  - **Europe -0.1** (currency effect -0.1)
    - ✓ Slight increase in sales in real terms, excluding currency effects.
  - **Asia and others -0.0** (currency effect -0.0)
    - ✓ Slight increase in sales in real terms, excluding currency effects.

- **Pharmaceutical & health-food materials -0.2**
  - Decrease in sales due to the carry over of some pharmaceutical intermediates shipments and sales termination of some products with narrow profit margin

- **Mail order sales, etc. +0.2**
  - Steady sales growth in “KHB Arginine EX”

Bio-Chemicals business: FY2017 Q1 Analysis of YoY changes

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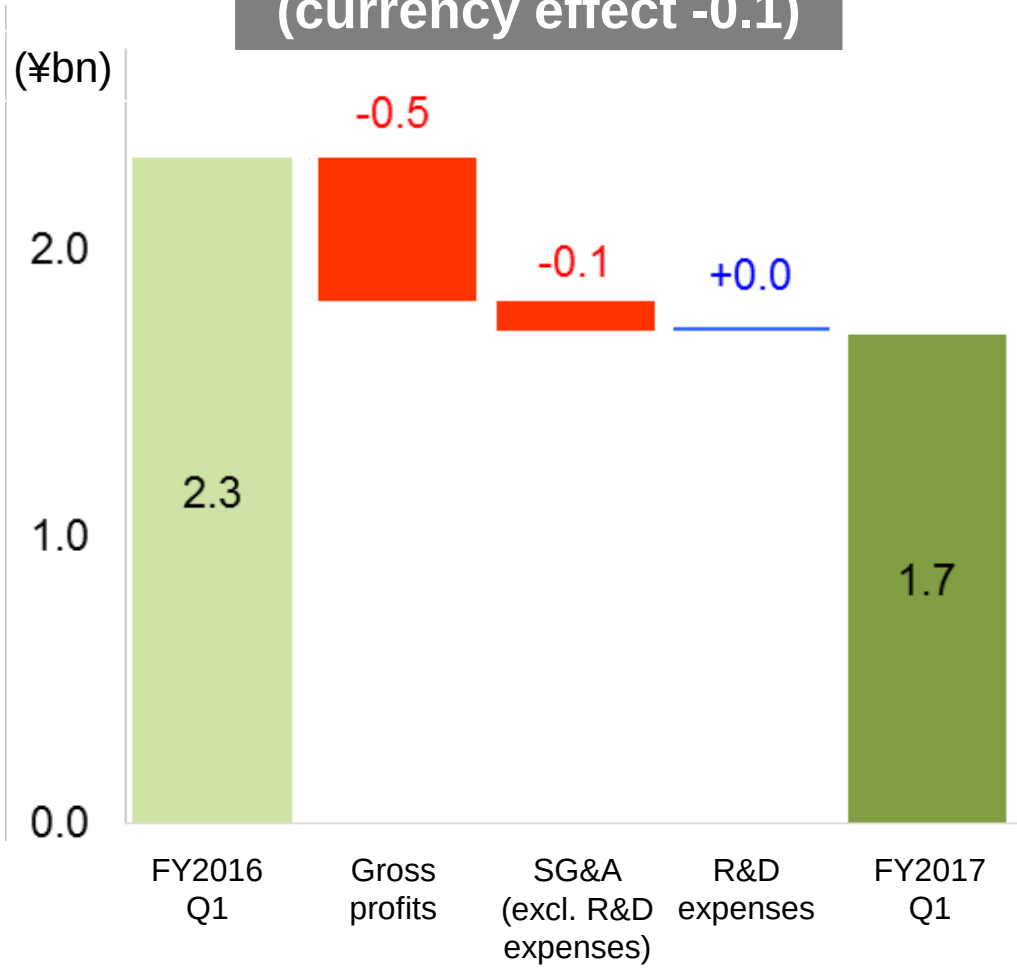
Operating income -0.6 billion Yen (currency effect -0.1)



- **Gross profits -0.5** (currency effects -0.1)
  - Decrease in sales
- **SG&A -0.1** (currency effects +0.0)
- **R&D expenses +0.0** (currency effects +0.0)

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) targeting secondary hyperparathyroidism (January)**
- **Application for approval of benralizumab (KHK4563) targeting asthma* (February)**
- **Announcement of top-line results of phase 3 clinical study of tivantinib (ARQ 197) targeting hepatocellular Carcinoma (March)**

* NDA holder is AstraZeneca

Note: Listed events were completed between January 25, 2017 and March 31, 2017.

Key development events in 2017

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Overseas:

- **Approval received for darbepoetin alfa (KRN321) targeting anemia with myelodysplastic syndrome (February, Singapore)**
- **Application for approval of brodalumab (KHK4827) targeting psoriasis (February, Taiwan)**
- **Approval received for romiplostim (AMG531) targeting chronic idiopathic (immune) thrombocytopenic purpura (March, Thailand)**

Note: Listed events were completed between January 25, 2017 and March 31, 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		(2017/12)		372 [4]

Annual incidence per disease: U.S.: CTCL: 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	(2017/11)	AstraZeneca	108	1
	U.S.	PF-05082566	(2019/8)	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.	(2016/9)			25	5
		U.S., Europe, Japan, Korea		(2017/3)		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

Business topics

Maximize product value of benralizumab

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Signed the agreement with AstraZeneca for the exclusive rights of Asthma and COPD in Asia to maximize the product value of benralizumab/KHK4563

- $ 15 million upfront payment
- Regulatory and commercial milestone payments
- Low-double digits sales royalties

AstraZeneca

- Exclusive rights for the treatment of asthma and COPD in the whole world
- Exclusive rights for the other indications in the world except Japan and Asian countries and regions

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- Exclusive rights in Japan and Asian countries and regions for the indications except asthma and COPD

List of acronyms

ATL	Adult T-cell Leukemia/Lymphoma
COPD	Chronic Obstructive Pulmonary Disease
CTCL	Cutaneous T-Cell Lymphoma
ENS	Epidermal Nevus Syndrome
TIO	Tumor Induced Osteomalacia
XLH	X-linked Hypophosphatemia

Appendix

Biosimilar products development

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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	U.S., Europe, others				2
Not disclosed	Not disclosed	Not disclosed	Not disclosed	Target product determined			

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

ClinialTrials.gov identifier: [1] NCT02260791; [2] NCT02810457

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

Period average rate

Average exchange rate	2016 Q1 Results	2017 Q1 Results	Change	*FY2017 Forecast*
¥/$	**117**	**115**	**-2**	***110***
¥/€	**128**	**122**	**-6**	***120***
¥/£	**169**	**143**	**-26**	***140***

FY2017 Q1 currency effects (YoY)

Segment	Currency	Net sales	Operating income
Pharmaceuticals business	$	**-¥0.07bn**	**-¥0.01bn**
	€	**-¥0.01bn**	**-¥0.01bn**
	£	**-¥1.60bn**	**+¥0.19bn**
Bio-Chemicals business	$	**-¥0.07bn**	**-¥0.04bn**
	€	**-¥0.17bn**	**-¥0.08bn**
	£	**-**	**-**

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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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