KYOWA KIRIN

Result Presentation Fiscal 2017 3rd Quarter

Kyowa Hakko Kirin Co., Ltd.

Agenda

KYOWA KIRIN

FY2017Q3 Highlights
Financial Review
Voluntary Adoption of IFRS

Kazuyoshi Tachibana
Director, Managing Executive Officer

R&D Review

Mitsuo Satoh, Ph.D.
Executive Officer, Head of R&D

Q&A

Forward-looking Statement

KYOWA KIRIN

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.

Q3 Consolidated Results

KYOWA KIRIN

	2016Q3 Results	2017Q3 Results	Change
Net Sales	257.7	258.4	＋0.6 (+0%)
Operating Income [Margin]	26.8 [10.4%]	34.3 [13.3%]	＋7.5 (+28%)
Ordinary Income	22.6	31.4	＋8.8 (+39%)
Net Profit	16.4	19.7	＋3.2 (+20%)

(↑) & (↓) indicate positive or negative impact in net profit, respectively.

- Benralizumab-related licensing revenue (↑)
- Drug price revision and generics penetration (↓)

- Benralizumab-related licensing revenue (↑)
- Decrease in SG&A costs (↑)

- Loss of equity method (↑)
  (Decrease in FKB*'s loss)

- Decrease in extraordinary income (↓)
- Increase in income taxes (↓)

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

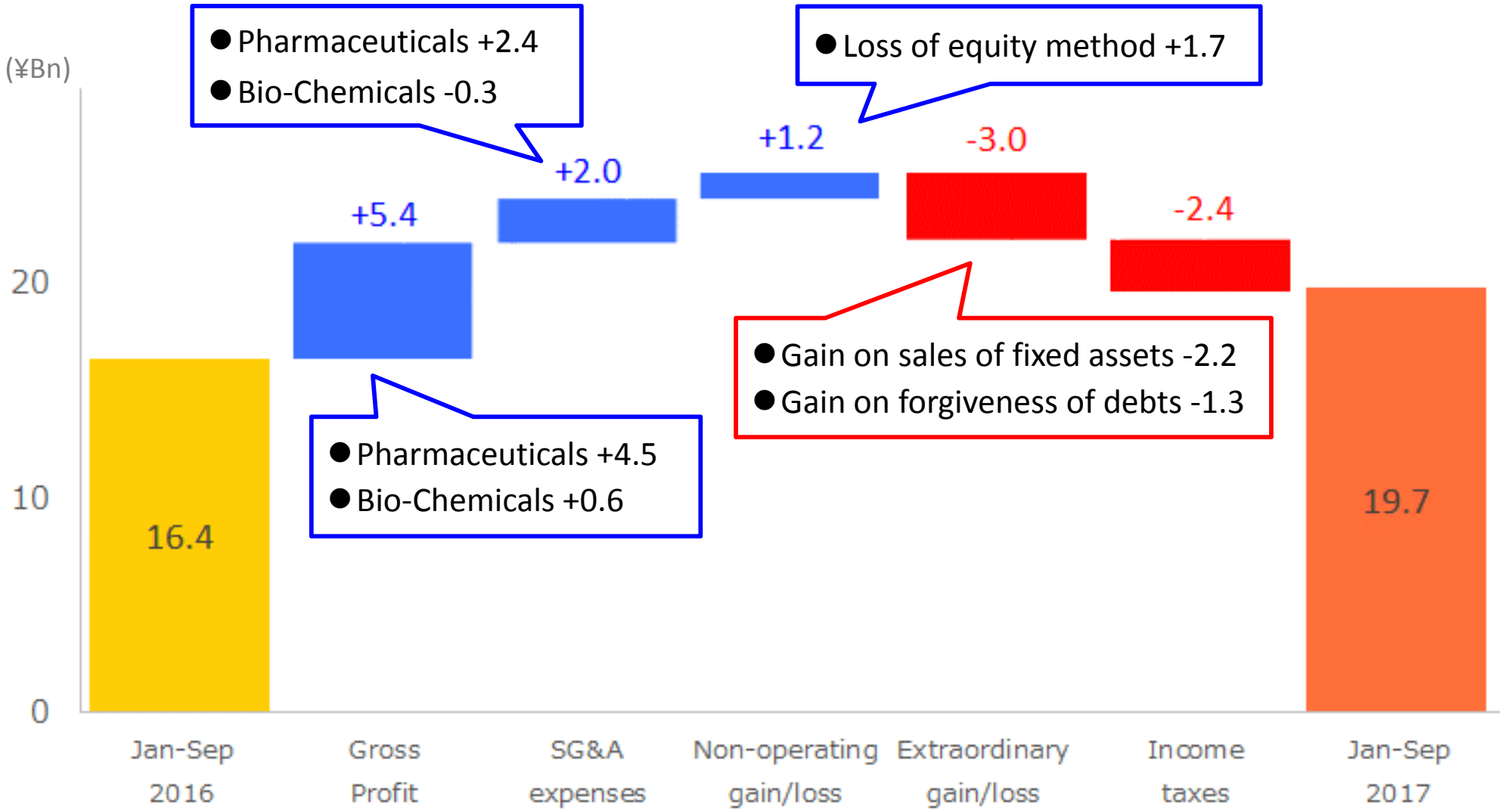
*FKB: FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.

Financial Review

Consolidated：YoY Analysis -Net Profit-

KYOWA KIRIN

Net Profit (Jan-Sep) +3.2 billion yen



Q3 Results by Segment

KYOWA KIRIN

- Pharmaceuticals' profit increased mainly due to the rise in tech-licensing revenue, despite a drop in domestic sales caused by the drug price revision and penetration of generics
- Bio-Chemicals' profit slightly increased despite a decrease in net sales

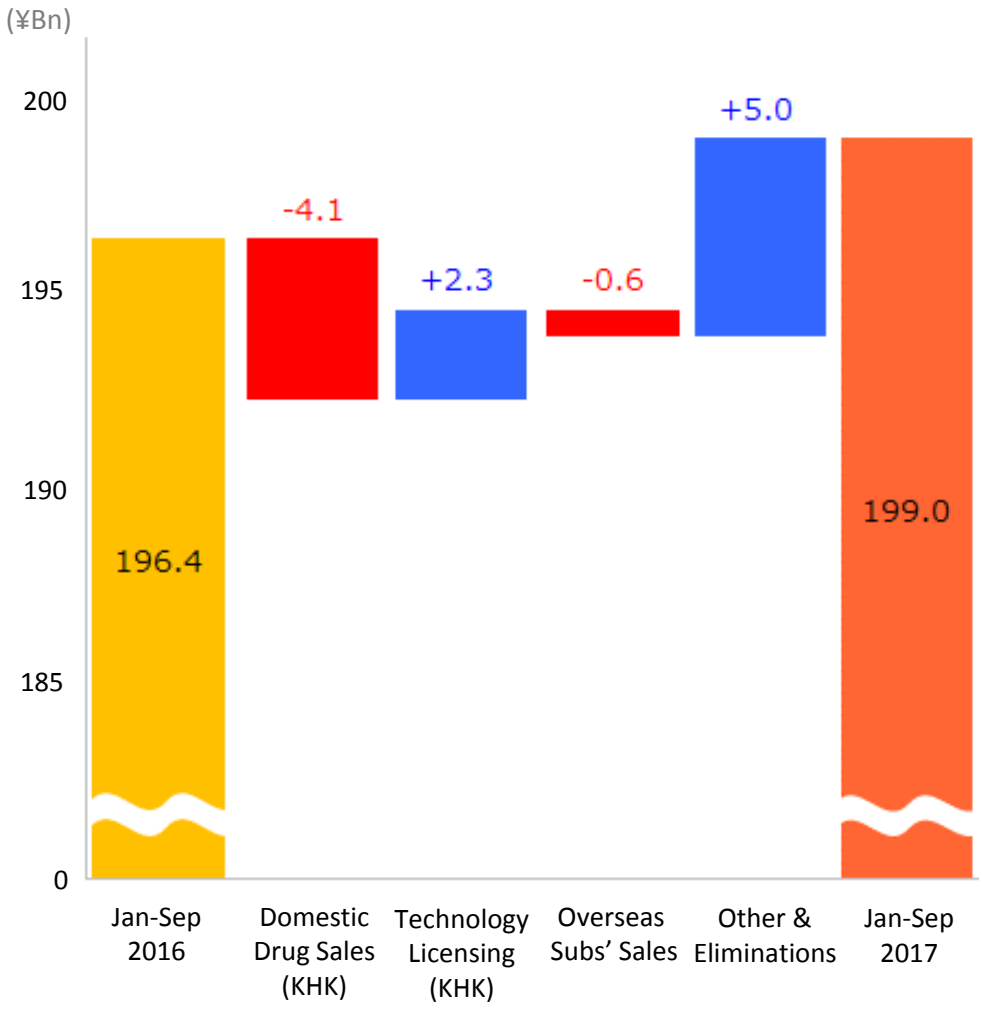
		2016Q3 Results	2017Q3 Results	Change
Pharmaceuticals Business	Net Sales	196.4	199.0	+2.5 (+1%)
	Operating Income [Margin]	22.0 [11.2%]	29.1 [14.6%]	+7.0 (+32%)
Bio-Chemicals Business	Net Sales	63.6	61.8	-1.8 (-3%)
	Operating Income [Margin]	4.7 [7.5%]	5.0 [8.1%]	+0.2 (+6%)

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

Pharmaceuticals: YoY Analysis -Sales-

KYOWA KIRIN

+2.5 billion yen
(incl. forex effect -2.2)



*KHK: Kyowa Hakko Kirin Co., Ltd

● Domestic Drug Sales (KHK*) -4.1

- 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 (KHK) +2.3

(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 -0.6

(incl. forex effect -2.2)

- 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 +5.0

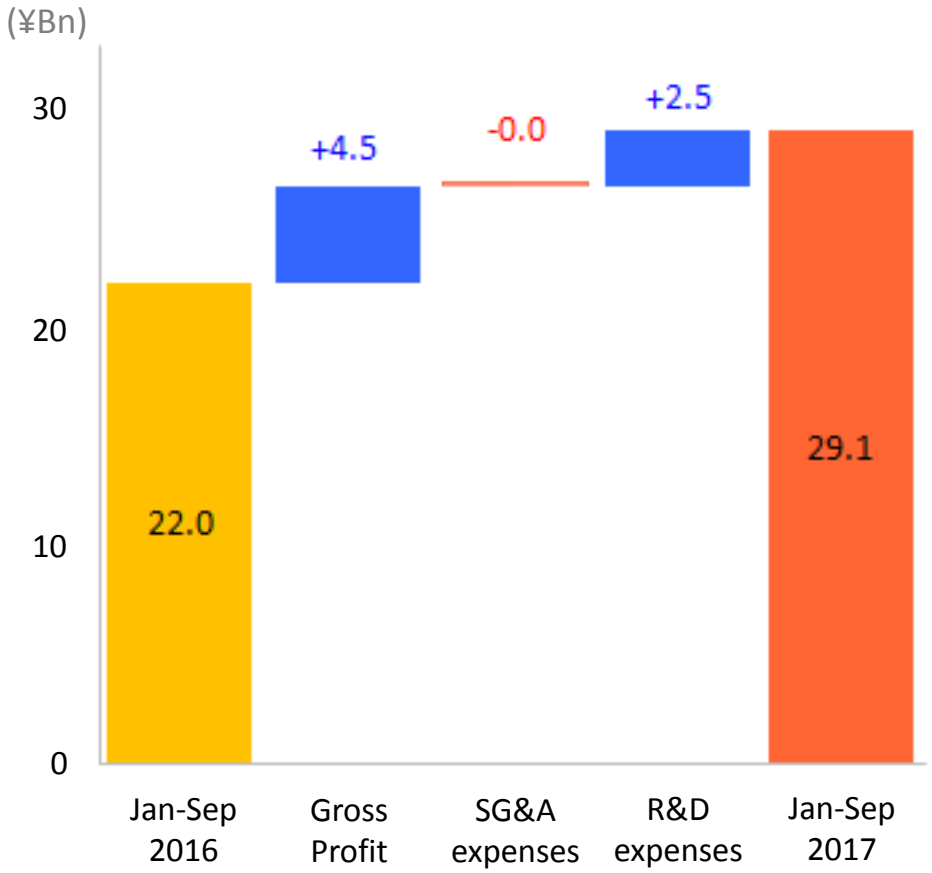
(incl. forex effect +0.0)

- Increase resulted from the gain in BioWa's tech-licensing revenue and favorable export sales of KHK.

Pharmaceuticals: YoY Analysis -Operating Income-

KYOWA KIRIN

+7.0 billion yen
(incl. forex effect +0.5)



- **Gross Profit +4.5 (incl. forex effect -1.6)**
  - Mainly due to the increase in technology licensing revenue.

Cost reducing effect by ¥1.9B due to strong yen
→ Increase by ¥1.9B in real term

- **SG&A -0.0 (incl. forex effect +1.9)**
  - Increased in real terms excluding the forex effect, mainly due to KKI's promotional activities for Moventig and launch preparation of burosumab.

Cost reducing effect by ¥0.2B due to strong yen
→ Decrease by ¥2.2B in real term

- **R&D +2.5 (incl. forex effect +0.2)**
  - Decreased 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

KYOWA KIRIN

- Domestic drug sales business decreased due to a drop in the key product NESP and the long-listed products
- Technology out-licensing revenue came mainly from benralizumab

Product	2016Q3 Results	2017Q3 Results	Change	Reason	2017Q4 Forecast	Progress*
NESP	41.6	40.9	-0.7 (-2%)	Drug price revision	56.4	73%
REGPARA	14.5	13.8	-0.6 (-4%)	Market penetration of competitors	18.3	76%
ALLELOCK	14.0	12.1	-1.9 (-14%)	Market penetration of generics & Drug price revision	15.4	79%
Patanol	10.9	10.7	-0.1 (-1%)	Market penetration of competitors	12.8	84%
G-Lasta	11.1	12.7	+1.5 (+14%)	Steady market penetration	17.6	73%
NOURIAST	5.1	6.1	+0.9 (+17%)	Steady market penetration	8.5	71%
Technology out-licensing	4.1	6.4	+2.3 (+56%)	Revenues related to benralizumab	7.4	87%

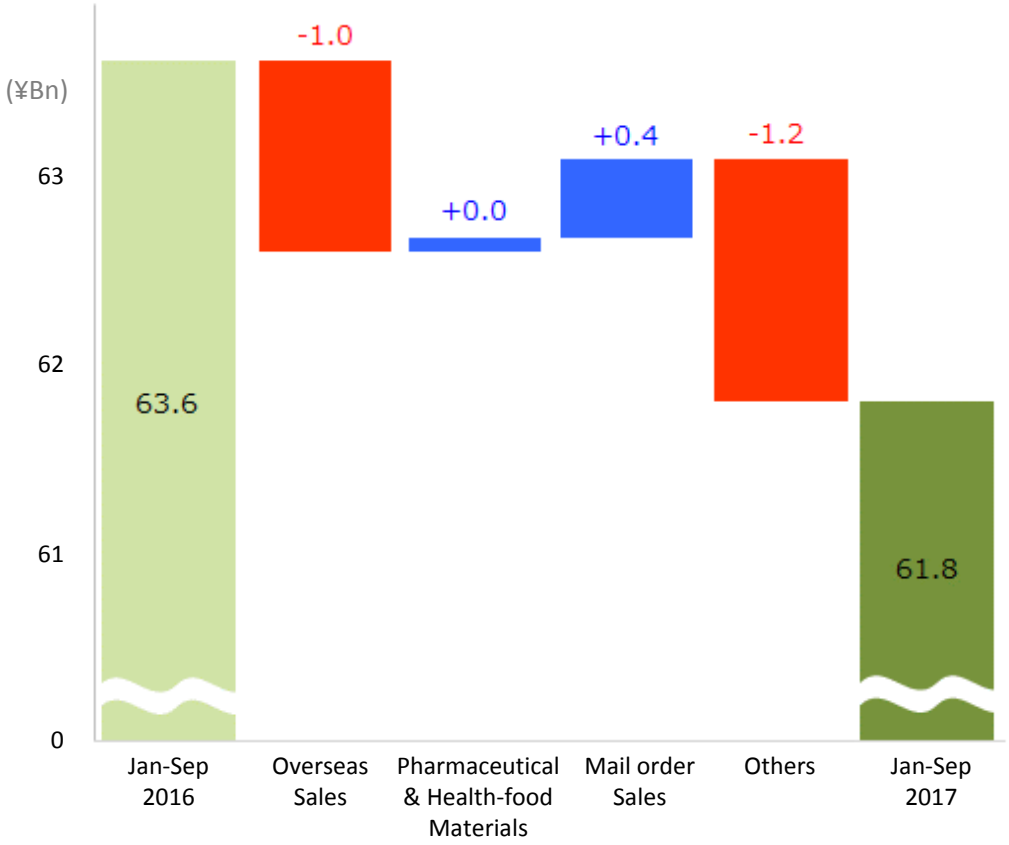
(Billion yen / Rounded down)

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

Bio-Chemicals: YoY Analysis -Sales-

KYOWA KIRIN

-1.8 billion yen
(incl. forex effect +0.1)



- **Overseas Sales -1.0 (incl. forex effect +0.1)**
  - **Americas -0.4 (incl. forex effect +0.0):** Decreased in health-food materials and amino acids for cell culture mediums.
  - **Europe +0.0 (incl. forex effect +0.0)**
  - **Asia + Others -0.6 (incl. forex effect -0.0):** Decreased due to the price competition in China.

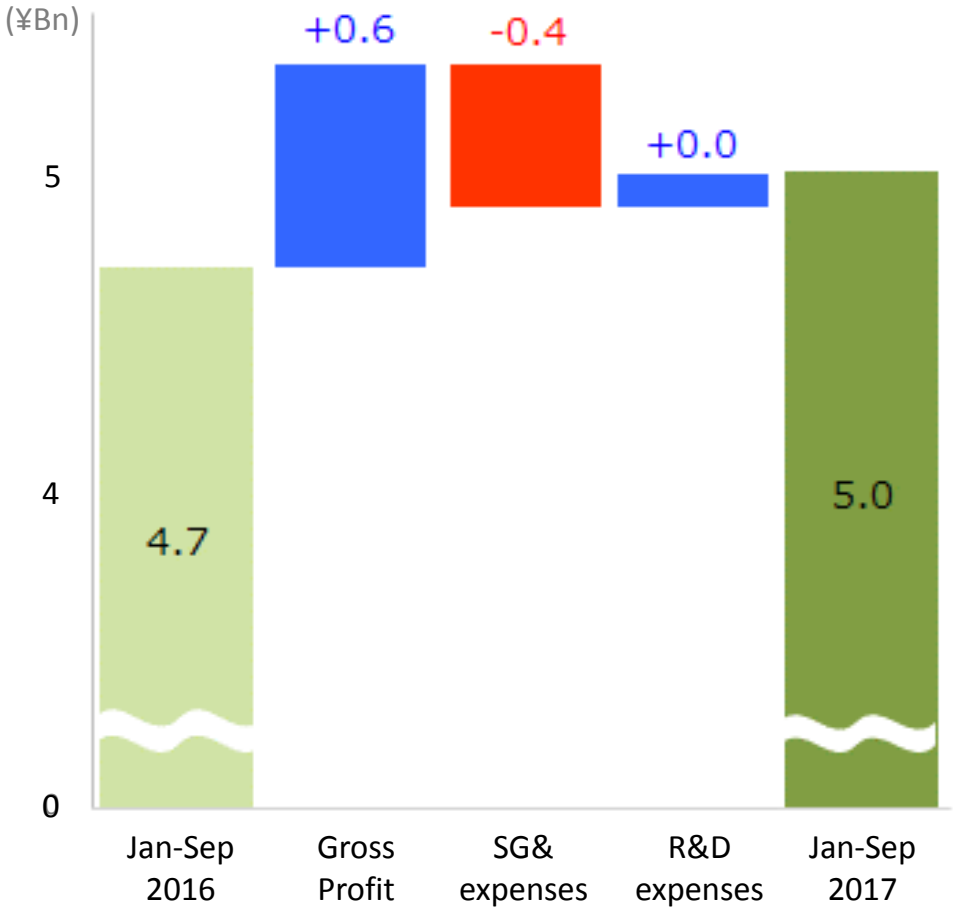
- **Mail Order Sales etc. +0.4**
  - Substantial growth in “KHB Arginine EX.”

- **Others -1.2**
  - Mainly due to decrease in Kyowa Engineering’s sales.

Bio-Chemicals: YoY Analysis -Operating Income-

KYOWA KIRIN

+0.2 billion yen
(incl. forex effect +0.0)



- **Gross Profit +0.6 (incl. forex effect +0.1)**
  - 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 -0.4 (incl. forex effect -0.0)**
  - Advertising cost etc. of the mail order business increased according to its sales' growth.

Voluntary Adoption of IFRS

Impact of IFRS Adoption and IFRS-based Forecast

KYOWA KIRIN

J-GAAP (28-Jul-2017)	IFRS -Approximation-
Sales ¥347B	**Sales ¥348B**
COGS	COGS
Gross Margin 216	**Gross Margin**
SG&A (excl. Goodwill Amortization)	SG&A
	Gain/Loss on Equity Method
Plus **(Core Operating Profit 47)**	**Core Operating Profit 51**
Goodwill Amortization 12.5	To be no longer amortized
Operating Profit 39	
Non-operating Gain/Loss (excl. followings)	Other Gain/Loss
Interest Earned/Paid, Exchange Gain/Loss, etc.	Financial Gain/Loss
Gain/Loss of Equity Method -4.5	
Ordinary Profit 35	
Extraordinary Gain/Loss	
Pretax Income 36	**Pretax Income**
Income Taxes	Income Taxes
Net Income 21	**Net Income 35**

Impact on Sales +1
- Deferment of Upfront Revenue +3
- Netting of Liquor Taxes -2

Impact on Core Operating Profit +4
- Deferment of Upfront Revenue +3
- Capitalization of In-process R&D +1

Impact on Net Income +14
- Cessation of Goodwill Amortization +12.5
- Deferment of Upfront Revenue +2.1
- Capitalization of In-process R&D +0.7
- Other -1.3 (Write-off of Intangible Asset, etc.)

※Core Operating Profit under J-GAAP = Operating Profit + Amortization of goodwill + Profit/loss of equities accounted for using equity method
Core Operating Profit under IFRS = Net Sales - COGs - SG&A expenses - R&D expenses + Profit/loss of equities accounted for using equity method

R&D Review

Key development events in 2017

KYOWA KIRIN

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 September 30, 2017.

Key development events in 2017

KYOWA KIRIN

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 September 30, 2017.

Key development events in 2017

KYOWA KIRIN

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 brodalumab (KHK4827) for the treatment of axial spondyloarthritis (April in Japan, Korea, and Taiwan)**
- **Initiation of phase 2 clinical study of bleselumab (ASKP1240) for the treatment of recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients (May in the U.S.)**
- **Application for approval of burosumab (KRN23) for the treatment of X-linked hypophosphatemia (August in the U.S.)**
- **Breakthrough therapy designation for mogamulizumab (KW-0761) granted by the U.S. Food and Drug Administration for the treatment of mycosis fungoides and Sézary syndrome (August in the U.S.)**

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

Key development events in 2017

KYOWA KIRIN

Overseas (cont.):

- **Announcement of positive results of phase 2 clinical studies of burosumab (KRN23) for the treatment of pediatric X-linked hypophosphatemia and adult tumor-induced osteomalacia (September at ASBMR)**
- **Application for approval of brodalumab (KHK4827) for the treatment of psoriasis (September in Singapore)**

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

Key global development updates (1)

KYOWA KIRIN

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)

KYOWA KIRIN

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	(2017/9)	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)

KYOWA KIRIN

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)

KYOWA KIRIN

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

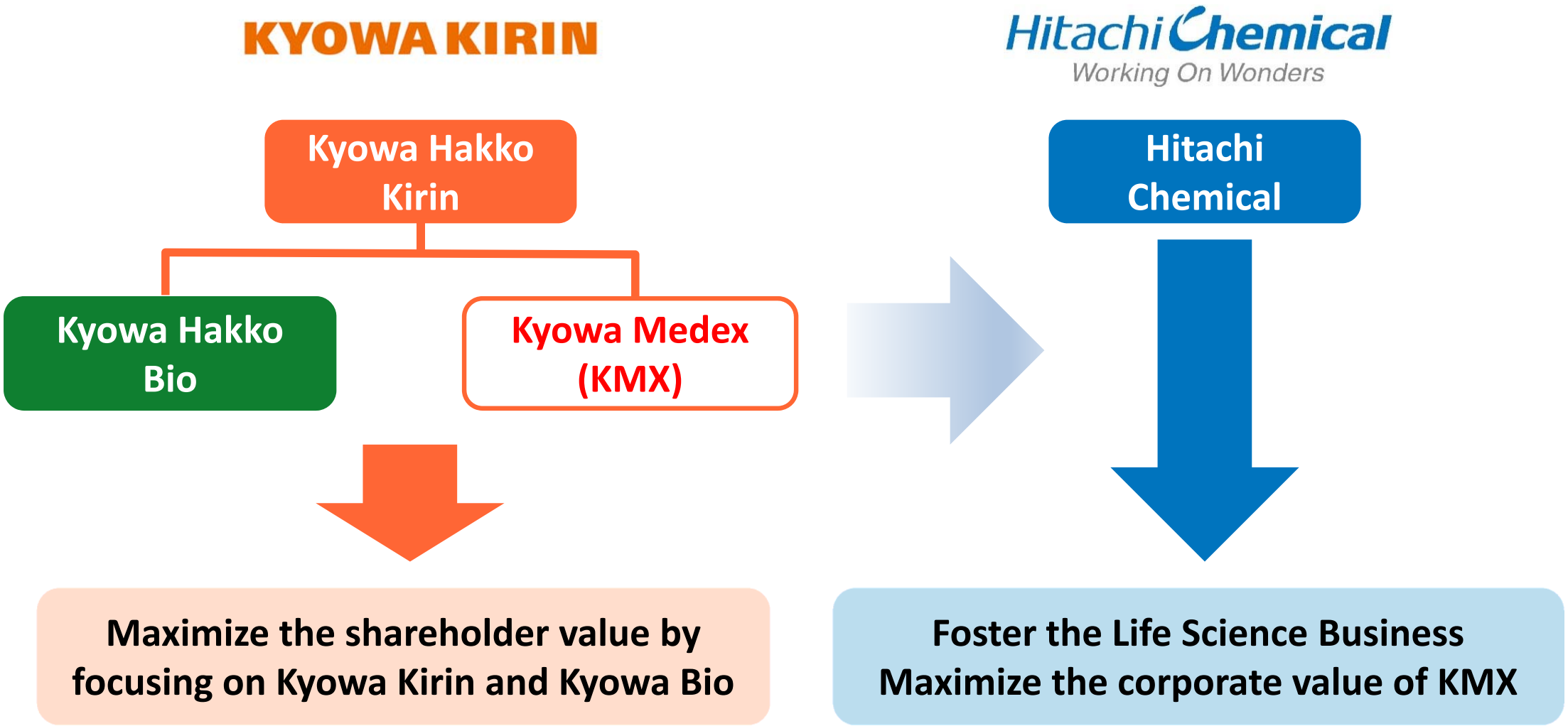
ClinicalTrials.gov identifier:
[3] NCT02304367; [4] NCT02722798

Q&A

Appendix

KMX's Share Transfer Agreement with Hitachi Chemical

KYOWA KIRIN



Kyowa Hakko Kirin will transfer 66.6%* of KMX shares to Hitachi Chemical on January 4 , 2018 (expected date of transfer)

*We will retain a put option and Hitachi Chemical will retain a call option for the remaining shares for approximately 3 years following this share transfer.

Development schedule of major late-stage pipeline

KYOWA KIRIN

* : 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

KYOWA KIRIN

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

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

KYOWA KIRIN

Average FOREX Rate

[¥]

Currency	2016Q3 Result	2017Q3 Result	Change	2017Q4 Revised Forecast
USD/JPY	111	112	+1	112
EUR/JPY	123	124	+1	121
GBP/JPY	156	142	-14	140

Q1-Q3 FOREX Effect (YoY)

[¥Bn]

Segment	Currency	Sales	Operating Income
Pharmaceuticals Business	USD	+0.05	-0.02
	EUR	+0.00	+0.00
	GBP	-2.65	+0.27
Bio-Chemicals Business	USD	+0.11	+0.07
	EUR	+0.09	+0.04

KYOWA KIRIN

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 Dept, Kyowa Hakko Kirin Co Ltd

Tel: +81-3-5205-7206