KYOWA KIRIN

Results Presentation

Fiscal 2016 Third Quarter

(January 1, 2016 – September 30, 2016)

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Agenda

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FY 2016 Q3 Highlights
Financial review

Kazuyoshi Tachibana, Managing Executive Officer

R & D review

Yoichi Sato, Managing Executive Officer,
Vice President Head R&D Division

Q & A session

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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.

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FY 2016 Q3 highlights

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In Q3 of FY 2016, sales and profits declined in the Pharmaceuticals and Bio-Chemicals businesses YoY. The consolidated sales and profits decreased YoY, although they saw a steady progress in line with 2016 business plan.

- Despite well-performing sales of REGPARA® and the new products, G-Lasta®, NOURIAST®, Dovobet® and Onglyza®, the pharmaceuticals business in Japan had a decline in sales of our long-term prescription products due to the drug price revisions and other factors, resulting in a net sales decline of ¥ 1.3 billion YoY.
- The overseas sales in the Pharmaceuticals business decreased by ¥ 13.5 billion YoY due to the decrease in licensing revenue, currency effect, and other factors.
- Due to the steady progress of late-stage development products, R&D expense in the Pharmaceuticals business increased by ¥ 2.5 billion YoY.
- In the Bio-Chemicals business, operating income decreased ¥ 1.6 billion YoY due to the strong yen and more intensive competition with other companies exporting to Asia.

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Financial review

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Summary of 2016 Q3 results (consolidated)

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Despite strong sales of new products, the consolidated sales and profits declined due to the reduced licensing revenue, increased R&D expense and continued currency effects of the strong yen.

(Unit: ¥bn)	FY2015 Q3 results	FY2016 Q3 results	Change	FY2016 forecast	Rate of progress
Net sales	272.9	257.7	-15.1 (-6%)	344.0	75%
Operating Income *Operating margin*	40.8 [15.0%]	26.8 [10.4 %]	-14.0 (-34%)	32.0	84%
Ordinary income	36.6	22.6	-14.0 (-38%)	26.0	87%
Net profit	26.0	16.4	-9.5 (-37%)	18.0	91%

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

(Rate of progress of FY 2016 sales forecast, released on July 21, 2016)

✓Ordinary income and net profit declined due to a decrease in operating income.

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Summary of FY2016 Q3 consolidated results: Analysis of YoY profit changes

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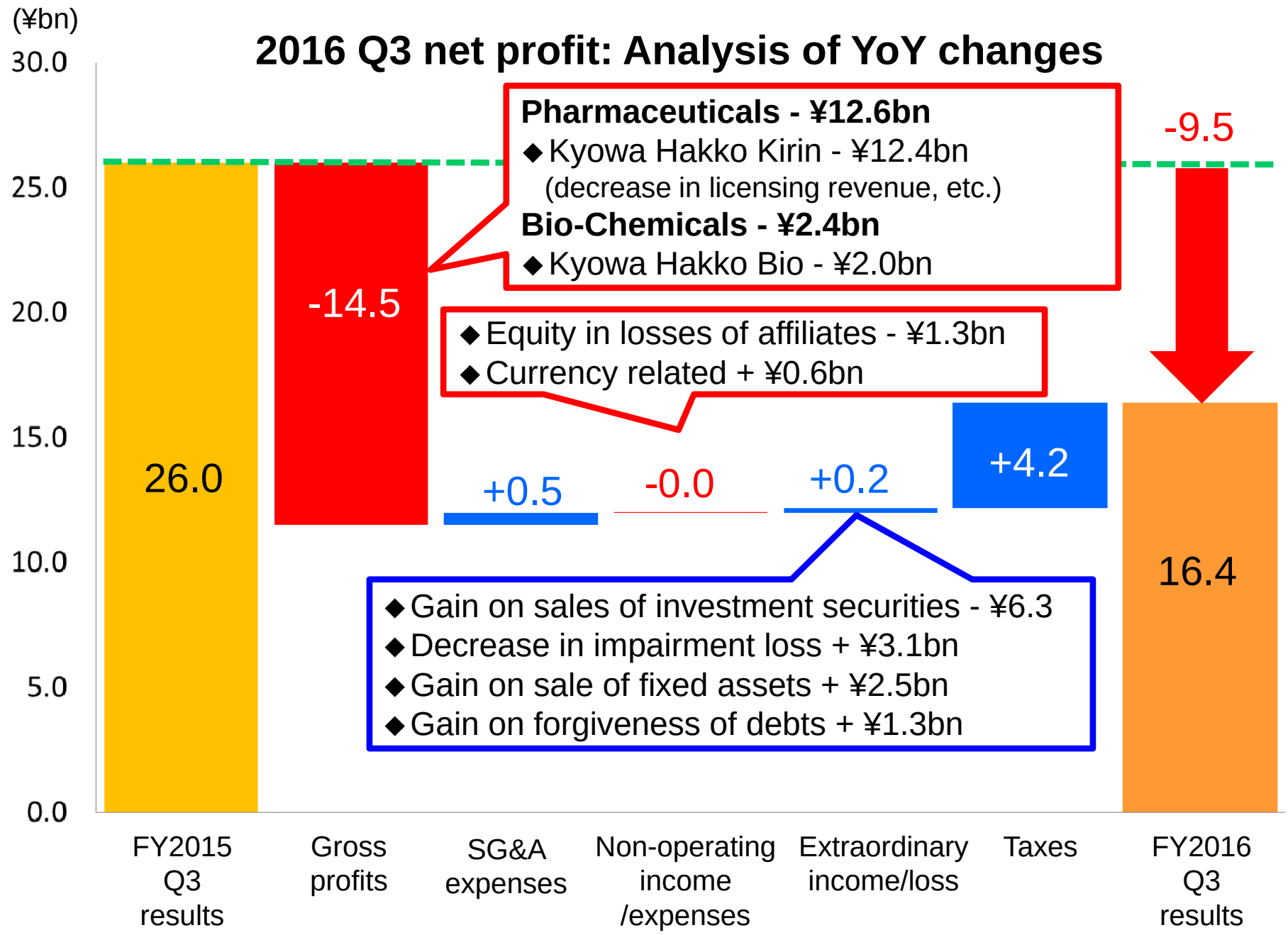

Summary of FY2016 Q3 financial results by segment

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In the Pharmaceuticals business, despite strong sales of new products, the sales and profits declined due to the drug price revision, reduced licensing revenue, and increased R&D and other expenses.
In the Bio-Chemicals businesses, sales and profits declined due to the strong yen.

(Unit: ¥bn)		FY2015 Q3 results	FY2016 Q3 results	Change
Pharmaceuticals business	Net sales	208.7	196.4	- 12.3 (- 6%)
	Operating income *Operating margin*	34.9 *16.7%*	22.0 *11.2%*	- 12.9 (- 37%)
Bio-Chemicals business	Net sales	67.1	63.6	- 3.4 (- 5%)
	Operating income *Operating margin*	6.4 *9.6%*	4.7 *7.5%*	- 1.6 (- 26%)

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

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Pharmaceuticals business: FY2016 Q3 Analysis of YoY changes

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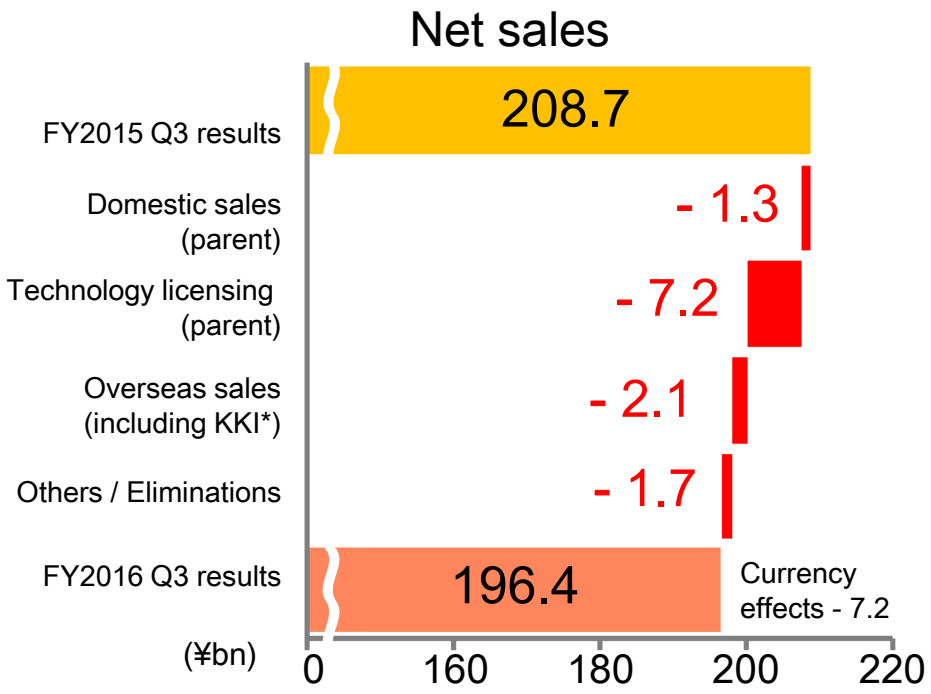

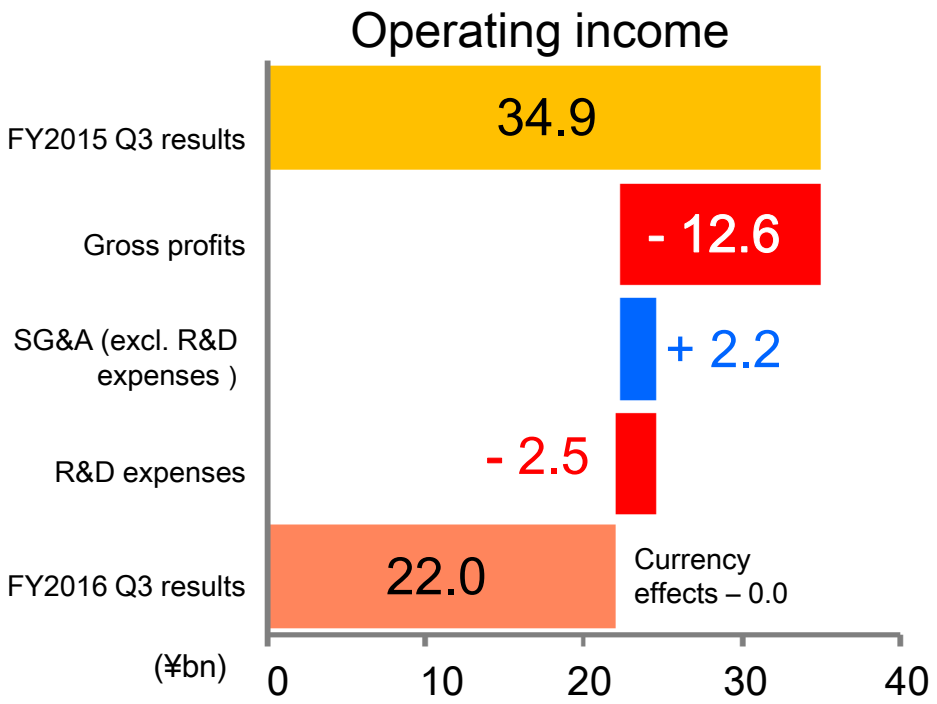

Net sales (-12.3 bn)

- Domestic pharmaceutical products (- ¥1.3bn):
  - New products including G-Lasta ® and NOURIAST ® grew steadily.
  - Our key product NESP ® slightly decreased in sales due to the impact of drug price revision.
  - Sales of long-term prescription products such as ALLELOCK ® decreased due to the impact of drug price revision and penetration of generics.
- Technology licensing, etc. (- ¥7.2bn): Currency effects - ¥0.0bn
  - The decrease is attributable to the upfront payment ($45mn) under the option agreement for KHK4563 made in the previous year and decrease in royalties, etc.
- Overseas sales (- ¥2.1bn): Currency effects - ¥7.1bn
  - KKI* (- ¥1.5bn): Despite growth of Abstral and PecFent, its overall sales decreased due to the currency effects of the strong yen.

Operating income (- ¥12.9bn)

- Gross profits (- ¥12.6bn): Currency effects(- ¥5.6bn)
  - Decrease in technology licensing and continued currency effects of the strong yen
- SG&A (+ ¥2.2bn): Currency effects (+ ¥4.0bn)
  - Increase in expenses due to introduction of Moventig.
  - Decrease in expenses due to the continued currency effects of the strong yen
- R&D expenses (- ¥2.5bn): Currency effects (+ ¥1.4bn)
  - Increase in expenses for late-stage development, etc.

* On February 22, 2016, ProStrakan Group plc's company name was changed to Kyowa Kirin International plc (KKI).

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Pharmaceuticals business: Domestic sales of key products

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Despite the increased sales of new products, the sales of domestic pharmaceutical products decreased YoY due to the impact of the drug price revision, etc.

Product name, other information	FY2015 Q3 results	FY2016 Q3 results	Change	Reason for change	FY2016 Forecast	Rate of Progress*
NESP®	42.0	41.6	-0.3 (-1%)	(+) Steady growth of the market (-) Drug price revisions	56.5	74%
REGPARA®	13.2	14.5	+1.3 (+10%)	(+) Steady growth of the market	19.7	74%
ALLELOCK®	16.8	14.0	-2.7 (-17%)	(-) Drug price revisions (-) Market penetration of generics	17.8	79%
Patanol®	10.7	10.9	+0.1 (+2%)		12.8	85%
G-Lasta®	6.7	11.1	+4.4 (+67%)	(+) Steady penetration of the market	15.9	70%
NOURIAST®	3.6	5.1	+1.5 (+41%)	(+) Steady penetration of the market	7.0	73%
Technology out-licensing	11.3	4.1	-7.2 (-63%)	(-) The upfront payment made in the previous year (-) Decrease in royalties	6.4	64%

* Rate of progress compared to 2016 sales forecasts (as of July 29, 2016)

(Unit: ¥bn, figures rounded down)

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Bio-Chemicals business:
FY2016 Q3: Analysis of YoY profit

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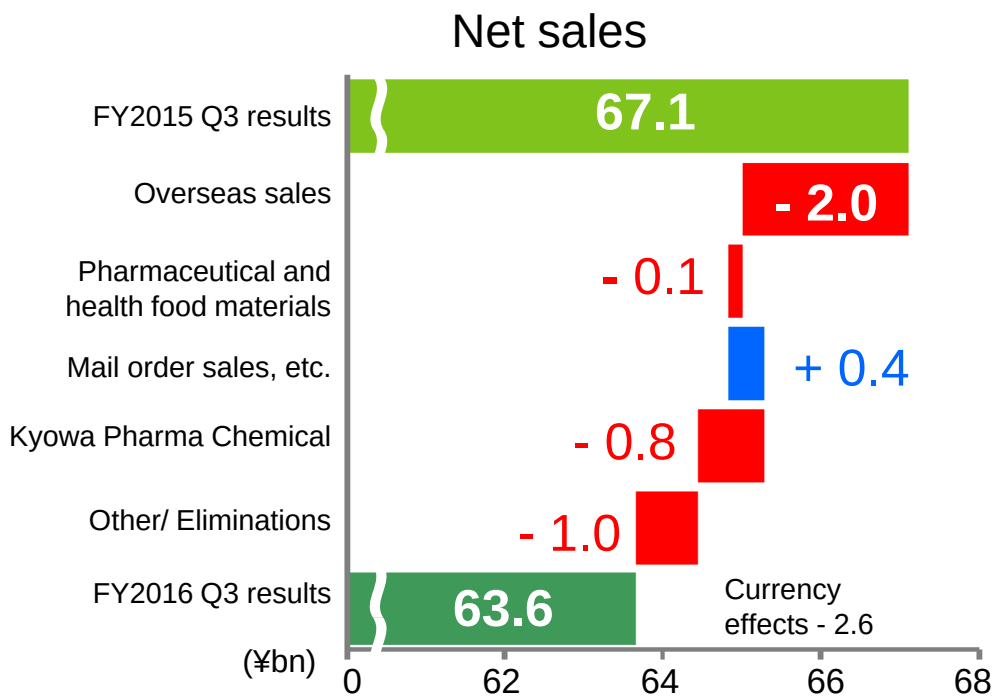

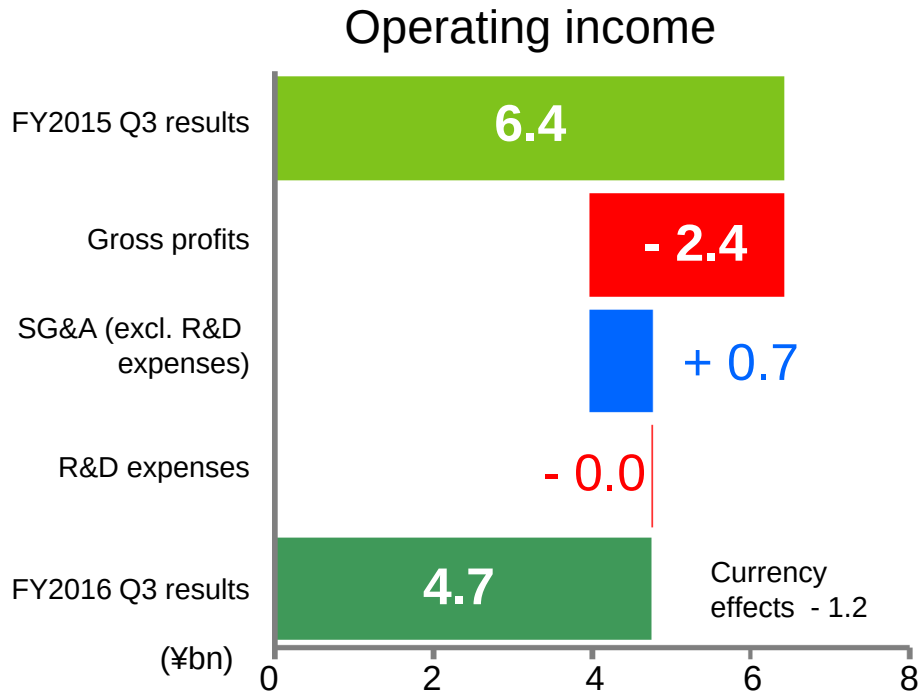

Net sales (-¥3.4bn)

- Overseas sales (- ¥2.0bn): Currency effects - ¥2.6bn
  - Americas (- ¥0.1bn): Currency effects (-¥0.6bn), growth in amino acids for cell culture medium
  - Europe (- ¥1.1bn): Currency effects (- ¥1.1bn)

    The reduction in sales resulting from transfer of cosmetics raw materials business was compensated by steady sales of APIs* and amino acid infusion, etc.
  - Asia and others (- ¥0.8bn): Currency effects (- ¥0.7)

    Intensified sales competition of APIs in the Asian market
- Pharma / health-food use (- ¥0.1bn)
- Mail order sales, etc. (+ ¥0.4bn): The mail-order sale business stayed strong supported by sales growth of new products
- Kyowa Pharma Chemical (- ¥0.8bn): A decline compared with the same period last year when significant shipments of pharmaceutical intermediate occurred. The sales of some products with narrow profit margin were terminated.

Operating income (- ¥1.6bn)

- Gross profit (- ¥2.4bn): Currency effects - ¥1.5bn
  - The decrease is attributable to the continued currency effect and the reduction of gross profit margins due to intensified competition in the Asian market.
- SG&A (+ ¥0.7bn): Currency effects + ¥0.3bn
  - The sales promotion expenses for mail-order business were partly shifted from the first half to the second half of the year.

*API: active pharmaceutical ingredient

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R&D review

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Key development events in 2016

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Domestic:

- **Announcement of results of interim efficacy analysis of Phase 2 clinical study of RTA 402 targeting chronic kidney disease with type-2 diabetes (May)**
- **Initiation of Phase 2 study of KHK4563 targeting eosinophilic chronic rhinosinusitis (June)**
- **Approval received for fully human anti-IL-17 receptor A antibody KHK4827 (brand name in Japan: LUMICEF®) (July) and launch (September)**

Note: Listed events were completed between January 23, 2016 and October 21, 2016.

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Key development events in 2016

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Overseas:

- **Initiation of Phase 1/2 trials of Nivolumab (Bristol-Myers Squibb) in combination with KW-0761 targeting solid tumors (February, U.S.)**
- **Announcement of results from Phase 3 trials of Benralizumab/KHK4563 targeting asthma (May)**
- **Announcement of results from Phase 2 study of KW-0761 targeting adult T cell leukemia-lymphoma (June, ASCO)**
- **Initiation of Phase 3 study of AMG531 targeting aplastic anemia (June, Japan, Korea)**
- **Breakthrough Therapy Designation granted by U.S. Food and Drug Administration (FDA) for KRN23 targeting pediatric X-Linked Hypophosphatemia (June, U.S.)**
- **Initiation of Phase 2 study of KRN23 targeting TIO or ENS (June, Japan, Korea)**
- **Initiation of Phase 2 study of KHK4083 targeting ulcerative colitis (June, North America, Europe)**

Note: Listed events were completed between January 23, 2016 and October 21, 2016.

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Key development events in 2016

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Overseas (cont.):

- **Initiation of Phase 1 study of KHK2455 in combination with KW-0761 targeting solid tumors (October, U.S.)**

Note: Listed events were completed between January 23, 2016 and October 21, 2016.

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Key global development updates (1)

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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 [2]	(2016/11)			71	[4]
CTCL	Relapsed/ refractory	U.S., Europe, Japan, others [2]		(2017/2)		373	[5]

Annual incidence per disease: U.S. CTCL: approx. 1,500 [3] patients

[1] Launched in Japan (brand name POTELIGEO®)
[2] CCR4 not included in selection criteria
[3] SEER Data (2001-2007)

ClinialTrials.gov identifier:
[4] NCT01626664; [5] NCT01728805

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Key global development updates (2)

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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	(2018/12)	Pfizer	70	2
	Japan	Nivolumab	(2017/10)	ONO PHARMACEUTICAL Bristol-Myers Squibb	108	3
	U.S.	Nivolumab	(2017/8)	Bristol-Myers Squibb	187	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

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Clinical study of KHK2455 (IDO inhibitor) combined with KW-0761 was started

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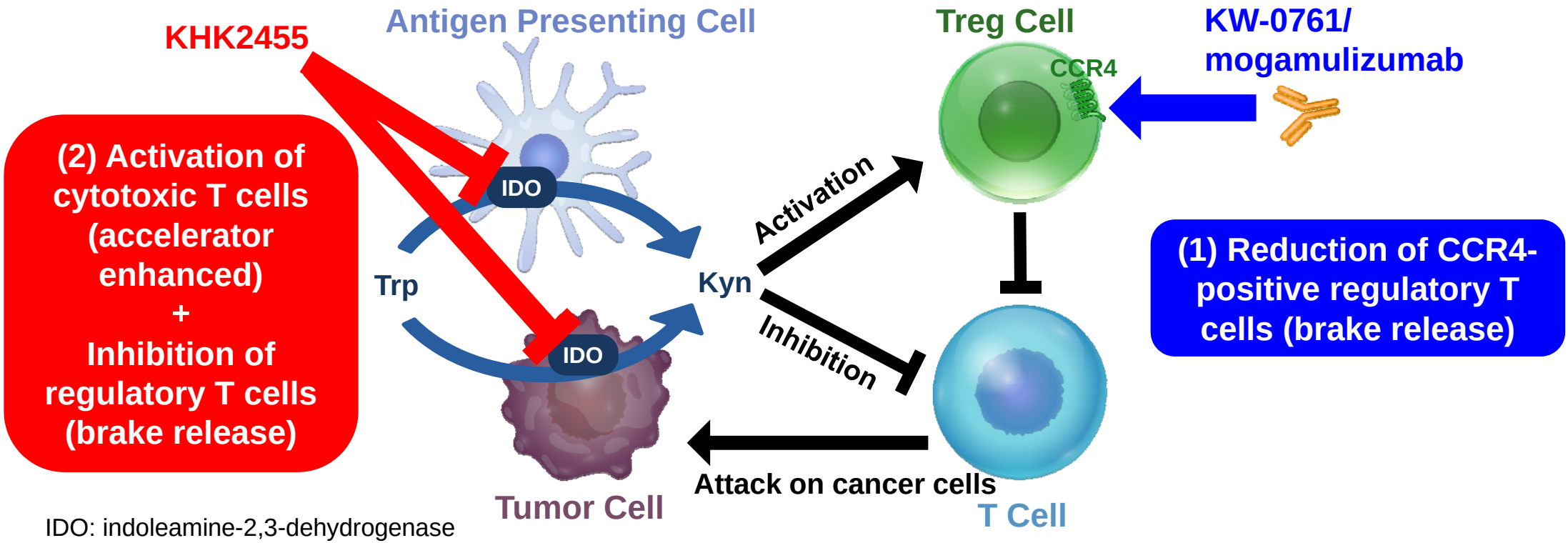
IDO：The enzyme is involved in inhibition of cytotoxic T cells and activation of regulatory T cells by mediating degradation of Trp to Kyn.



IDO: indoleamine-2,3-dehydrogenase
Trp：tryptophan
Kyn: kynurenine

New class tumor immunotherapy combination, (1) and (2), is expected to enhance tumor immunity in cancer patients.

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Key global development updates (3)

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KW-6002 [1]

Indication	Country/region	Development stage (Scheduled trial completion date)		Estimated enrollment
		Phase 3	Application	
Parkinson's disease	North America Europe, Others	(2016/11)		609 [4]

Estimated no. of patients: Japan: approx. 160,000 [2]
Estimated no. of treatable patients: U.S.: approx. 800,000 [3]

[1] Launched in Japan (brand name: NOURIAST®)
[2] Ministry of Health, Labour and Welfare: 2014 Patient survey (illness classification)
[3] Study by Decision Resources

ClinialTrials.gov identifier:
[4] NCT01968031

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Key global development updates (4)

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KRN23

Indication		Country/region	Development stage (Scheduled trial completion date)		Partner	Estimated enrollment	
			Phase 2	Phase 3			
XLH	Pediatric	U.S., Europe	(2017/3)		Ultragenyx Pharmaceutical (U.S., Europe)	50	2
		U.S.	(2017/12)			13	3
	Adult	U.S.	(2016/9)			25	4
		North America, Europe Japan, Korea		(2017/3)		120	5
		North America, Europe Japan, Korea		(2017/8)		14	6

Estimated no. of patients: Japan: approx. 5,000[1] (adult), approx. 1,000[1] (pediatric)
U.S.: approx.12,000[1] (adult), approx. 3,000[1] (pediatric)

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

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

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Key global development updates (5)

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KRN23

Indication	Country/region	Development stage (Scheduled trial completion date)		Partner	Estimated enrollment
		Phase 2	Phase 3		
TIO/ENS	U.S.	(2016/9)		Ultragenyx Pharmaceutical (U.S., Europe)	15 [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

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List of acronyms

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ADCC	Antigen Dependent Cellular Cytotoxicity
ATL	Adult T-cell Leukemia/Lymphoma
CCR4	Chemokine (C-C motif) Receptor 4
CTCL	Cutaneous T-Cell Lymphoma
ENS	Epidermal Nevus Syndrome
TIO	Tumor Induced Osteomalacia
XLH	X-linked Hypophosphatemia

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APPENDIX

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Biosimilar products development update

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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	United Kingdom				[2]
Not disclosed	Not disclosed	Not disclosed	Not disclosed	Determined target product			

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.

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Development progress with outlicensed compounds

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Name	Partner	Phase			Filing	Remarks
		I	II	III		
Tivozanib	AVEO				EU	Advanced Renal Cell Cancer (VEGF receptor inhibitor) (KRN951)
Benralizumab (MEDI-563)	AstraZeneca /MedImmune					Asthma (Anti-IL-5R antibody) (KHK4563) POTELLIGENT®
						COPD
KRN5500	Midatech Pharma US					Peripheral neuropathy
RGI-2001	REGiMMUNE		Phase1/2			Immunosuppressive

(as of October 21st, 2016)

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FOREX

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Average Exchange Rate

Average exchange rate	2015 Q3 Results	2016 Q3 Results	Change	*FY2016 Forecast released on 29/7*
¥/$	¥120	¥111	- ¥9	*¥109*
¥/€	¥135	¥123	- ¥12	*¥121*
¥/£	¥186	¥156	- ¥30	*¥151*

FY2016 Q3 Currency Effects (YoY)

Segment	Currency	Net sales	Operating income
Pharmaceuticals business	$	- ¥0.14bn	+ ¥0.62bn
	€	- ¥0.05bn	- ¥0.02bn
	£	- ¥5.54bn	- ¥0.00bn
Bio-Chemicals business	$	- ¥1.23bn	- ¥0.67bn
	€	- ¥1.15bn	- ¥0.59bn
	£	-	-

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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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