

Results Presentation Fiscal 2016

Kyowa Hakko Kirin Co., Ltd.



FY 2016 Highlights

Nobuo Hanai, Ph. D. President and CEO

Financial review 2017 Forecasts

Kazuyoshi Tachibana, Managing Executive Officer

R & D review Business Topics

Nobuo Hanai, Ph. D. President and CEO

Forward-looking statements



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.

In FY2016, sales and profits declined in the Pharmaceuticals and Bio-Chemicals businesses YoY due to the drug price revision, yen appreciation and increased R&D expenses.

FY2016 business plan was largely achieved.

- Despite well-performing sales of the new products, including G-Lasta[®], NOURIAST[®], Dovobet[®] and Onglyza[®], the sales of pharmaceuticals business declined in Japan due to the drug price revision that led to a decline in sales of our long-term prescription products, resulting in domestic net sales decline of ¥4.3 billion YoY.
- The overseas sales in the Pharmaceuticals business decreased by ¥ 13.8 billion
 YoY due to the decrease in licensing revenue, yen appreciation and other factors.
- Due to the steady progress of late-stage development products, R&D expense in the Pharmaceuticals business increased by ¥ 2.2 billion YoY.
- In the Bio-Chemical business, sales decreased by ¥ 5.2 billion YoY, and operating income decreased by ¥ 2.8 billion YoY due to the strong yen and more intensive competition in Asian market



Financial review

Summary of 2016 results (consolidated)



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

EV204 <i>E</i>				
FY2015 results	FY2016 results	Change	FY2016 forecast	Rate of progress
364.3	343.0	-21.2 (-6%)	344.0	100%
43.7 [12.0%]	31.6 [9.2%]	-12.1(-28%)	32.0	99%
39.2	26.3	-12.8(-33%)	26.0	102%
29.7	18.6	-11.1(-37%)	18.0	104%
	results 364.3 43.7 [12.0%] 39.2	results 364.3 343.0 43.7 [12.0%] 39.2 26.3	results results -21.2 (-6%) 43.7 [12.0%] 39.2 26.3 -12.8(-33%)	results results Change forecast 364.3 343.0 -21.2 (-6%) 344.0 43.7 31.6 -12.1(-28%) 32.0 39.2 26.3 -12.8(-33%) 26.0

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

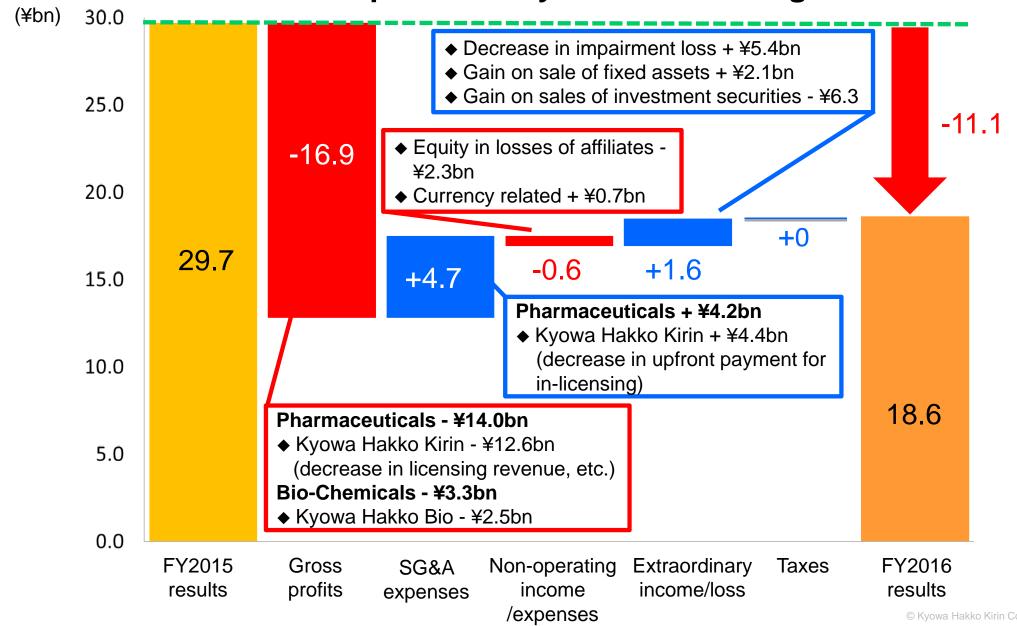
(Rate of progress of FY 2016 sales forecast, released on July 21, 2016)

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

Summary of FY2016 consolidated results: Analysis of YoY profit changes



2016 net profit: Analysis of YoY changes



Summary of FY2016 financial results by segment



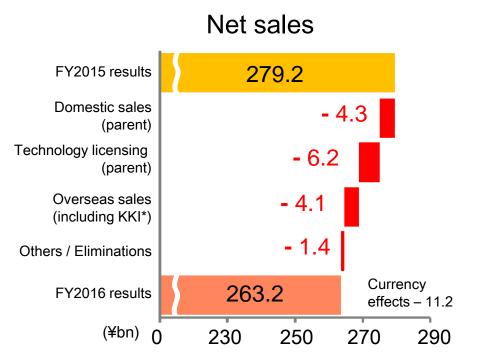
In the Pharmaceuticals business, despite strong sales of new products, the sales and profits declined due to the drug price revision, reduced licensing revenue and increased R&D expenses.

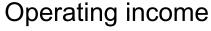
In the Bio-Chemicals businesses, sales and profits declined due to the yen appreciation.

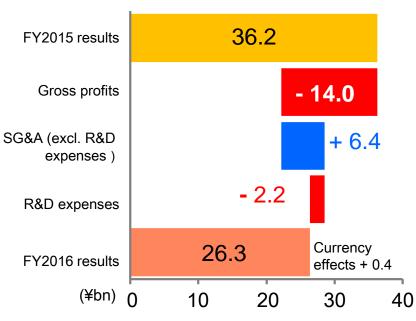
(Unit: ¥bn)		FY2015 results	FY2016 results	Change
Pharmaceuticals	Net sales	279.2	263.2	-16.0 (-6%)
business	Operating income Operating margin	36.2 [13.0%]	26.3 [10.0%]	-9.8 (-27%)
Bio-Chemicals	Net sales	88.8	83.6	-5.2 (-6%)
business	Operating income Operating margin	8.1 [9.1%]	5.3 [6.4%]	-2.8 (-35%)

Pharmaceuticals business: FY2016 Analysis of YoY changes









Net sales (- ¥16.0bn)

- Domestic pharmaceutical products (- ¥4.3bn):
- New products including G-Lasta and NOURIAST grew steadily.
- Our key product NESP 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. (- ¥6.2bn), Currency effects (- ¥0.1bn)
- 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 (- ¥4.1bn), Currency effects (- ¥10.9bn)
- KKI* (- ¥3.3bn): Despite the growth of Abstral and PecFent, its overall sales decreased due to the yen appreciation.

Operating income (-¥9.8bn)

- Gross profits (- ¥14.0bn), Currency effects(¥8.7bn)
- Decrease in licensing revenues and continued yen appreciation
- SG&A (+ ¥6.4bn), Currency effects (+ ¥6.7bn)
- Decrease in expenses due to the upfront payment for in-licensing in the previous year and continued yen appreciation
- Increase in expenses due to the in-licensing of Moventig.
- R&D expenses (- ¥2.2bn), Currency effects (+ ¥2.5bn)
 - Increase in expenses for late-stage developments, etc.

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

Pharmaceuticals business: Domestic sales of key products



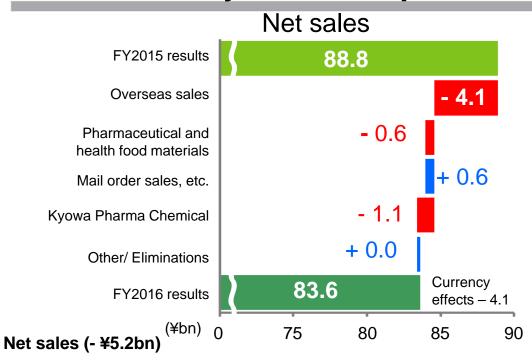
Despite the increased sales of new products, the sales of domestic pharmaceutical products decreased YoY due to the impact of the drug price revision, etc.

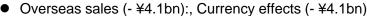
Product name, other information	FY2015 results	FY2016 results	Change	Reason for change	FY2016 Forecast	Rate of Progress*
NESP®	57.5	56.3	- 1.1 (- 2%)	(+) Steady growth of the market(-) Drug price revisions	56.5	100%
REGPARA®	18.2	19.9	+ 1.7 (+ 10%)	(+) Steady growth of the market	19.7	101%
ALLELOCK®	22.1	18.1	- 3.9 (- 18%)	(-) Drug price revisions(-) Market penetration of generics	17.8	102%
Patanol [®]	12.8	12.9	+ 0.1 (+ 1%)		12.8	101%
G-Lasta®	10.3	15.5	+ 5.1 (+ 50%)	(+) Steady penetration of the market	15.9	98%
NOURIAST®	5.3	7.2	+ 1.8 (+ 35%)	(+) Steady penetration of the market	7.0	103%
Technology out-licensing	11.9	5.9	- 6.0 (- 51%)	(-) The upfront payment received in the previous year(-) Decrease in royalties	6.4	91%

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

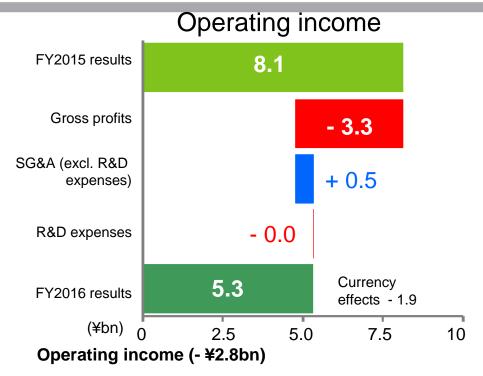
Bio-Chemicals business: FY2016: Analysis of YoY profit







- Americas (- ¥0.6bn), Currency effects (- ¥1.1bn): growth in amino acids for cell culture medium
- Europe (- ¥1.6bn), Currency effects (- ¥1.7bn): The reduction in sales resulting from transfer of cosmetics raw materials business was compensated by steady sales of APIs* and infusion use amino acids
- Asia and others (-¥1.8bn), Currency effects (-¥1.2): Intensified sales competition of APIs in the Asian market
- Pharma / health-food use (- ¥0.6bn)
- Reactionary reduction in sales resulting from massive shipment of APIs for generics in the previous year
- Mail order sales, etc. (+ ¥0.6bn)
- The mail-order sale business stayed strong supported by sales growth of new products
- Kyowa Pharma Chemical (- ¥1.1bn):
- A decline compared with last year when significant shipments of pharmaceutical intermediate occurred. The sales of some products with narrow profit margin were terminated.



- Gross profit (- ¥3.3bn), Currency effects (- ¥2.5bn)
- The decrease is attributable to the continued yen appreciation, reactionary reduction in domestic sales resulting from massive shipment of APIs for generics in the previous year and the reduction in gross profit margins due to intensified competition in the Asian market
- SG&A (+ ¥0.5bn), Currency effects (+ ¥0.5bn)
- Reduction in SG&A due to the continued yen appreciation



2017 Forecasts



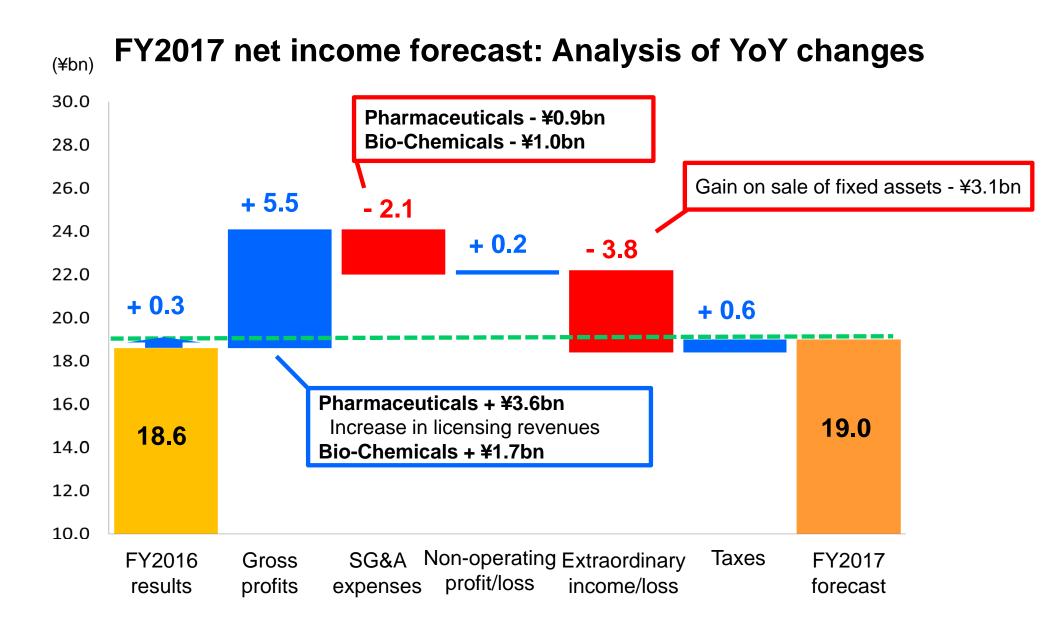
We forecast an increase in sales due to the licensing revenues and growth of the new products in Japan and overseas, and an increase in profits due to the reduction in costs for late-stage development products, despite continuing aggressive R&D investment.

7 forecasts (%)
+ 0.9 (+0%)
(+11%) + 3.3 (+11%)
+ 3.6 (+14%)
9.0 + 0.3 _(+2%)

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

Summary of FY2017 consolidated forecasts: Analysis of YoY profit changes



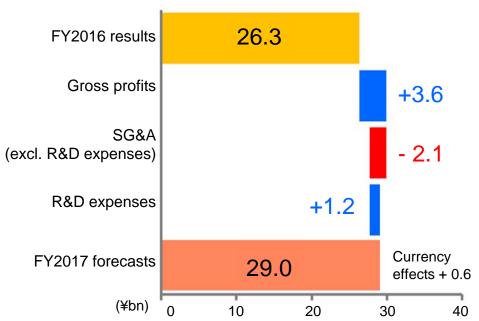


Pharmaceuticals business: FY2017 forecasts



(Unit: ¥bn)	FY2016 results	FY2017 forecasts	Change
Net sales	263.2	264.0	0.7 (+0%)
Operating income Operating margin	26.3 [10%]	29.0 [11.0%]	2.6 (+10%)

Operating income YoY change



(+)

- Increase in licensing revenue and strong sales of new products in domestic and overseas markets
- Currency effect of SG&A (excl. R&D expenses)
- Reduction in expenses for late-stage development products

(-)

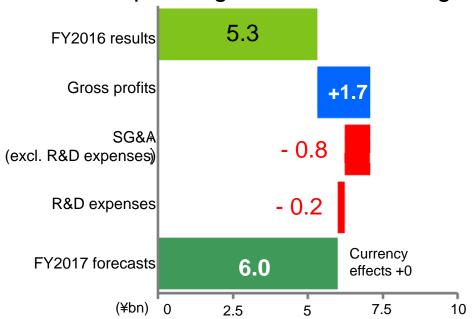
- Market penetration of competing products and generics and currency effect
- Preparation expense for marketing of the product developed by KKI

Bio-Chemical business: FY2017 forecasts





Operating income YoY change



(+)

- Increase in gross profit margin due to growth in sales of pharmaceutical and health food materials
- Reduction in costs for manufacturing pharmaceutical and health food materials
- Increase in gross profit margin driven by growth of mail order sales

(-)

Increase in sales promotion costs for mail order sales

Shareholder returns policy

Dividend payout ratio

From 2016 to 2018, pay out constant dividends in compliance with 2016-2020 Mid-Term Business Plan, which set a target dividend payout ratio of 40% on the basis of the net profit before amortization of goodwill

Acquisition of treasury stock
 Implement flexibly in response to market environment and finances

Planned dividends for period

(Including an interim dividend of ¥12.50 per share, the total dividend will be ¥25 per share)



R&D review

Key development events in 2016



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)
- Initiation of Phase 2 study of KW-6356 targeting Parkinson's disease (November)
- Initiation of Phase 1 study of KHK4083 targeting ulcerative colitis (December)



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)



Overseas (cont.):

- Initiation of Phase 1 study of KHK2455 in combination with KW-0761 targeting solid tumors (October, U.S.)
- Initiation of Phase 3 study of KRN23 targeting pediatric patients with X-Linked Hypophosphatemia (October in North America, EU, Japan, Korea and Australia)
- Announcement of top-line results of Phase 3 clinical study of KW-6002 targeting Parkinson's disease (December, U.S., Europe)
- EMA acceptance for review of marketing authorization application for KRN23 targeting X-Linked Hypophosphatemia (December, Europe)
- Initiation of Phase 3 study of KHK4827 targeting psoriasis (January, Korea)

Key domestic development updates



KW-6356

Indication	Country/	Development stage (Scheduled trial completion date)		Estimated enrollment	
mulcation	region	Phase 2			
Parkinson's disease	Japan	(2018/12)		150	2

Estimated no. of patients: Japan: approx. 160,000 1 patients

ClinialTrials.gov identifier:

¹ Ministry of Health, Labour and Welfare: 2014 Patient survey (illness classification)

² NCT02939391

KW-6356: Target product profile



Mode of Action: Non-dopaminergic PD* medication based on A2A receptor antagonism

Early stage: PD medication used as monotherapy or adjunct therapy for improving motor symptoms

Advanced stage: PD medication used as adjunct therapy for improving motor symptoms and motor complications











Early stage PD (without motor complications)

Monotherapy

Combination

therapy

Advanced stage PD (with motor complications)

Monotherapy

Combination therapy

KW-6356 (target product profile)

- •Improve motor symptoms when used as monotherapy
- ●Improve motor symptoms and complications when used as adjunct therapy. (-> adjunct concomitant medication when L-dopa or DA* has no sufficient effect)
- Explore efficacy for non-motor symptoms

NOURIAST® (Indication)

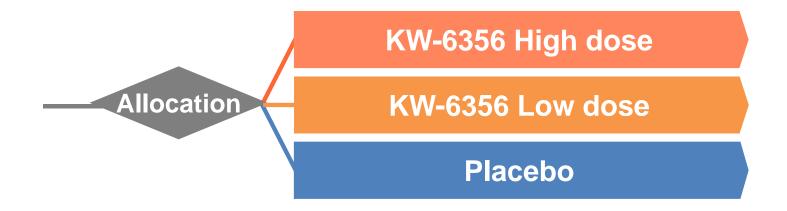
Improve WO* phenomenon in advanced stage

⇒ Concomitant medication in adjunct to L-dopa



KW-6353 Phase II Study Design:

Title: A Study of KW-6356 in Subject With Early PD (double-blind, placebo-controlled study in patients* with early PD)



Primary Outcome Measures: Change from baseline in MDS-UPDRS Part III score (motor symptoms)

Assessment period: 12 weeks

Estimated Enrollment: 150

Key global development updates (1)



KW-0761 (hematological cancer) 1

Indic	ation	Country/	Deve (Schedu	Estimated			
		region	Phase 2	Phase 3	Application	enrollment	
ATL	Relapsed/ refractory	U.S., Europe, others	(2016/11)			71	3
CTCL	Relapsed/ refractory	U.S., Europe, Japan, others		(2017/2)		373	4

Annual incidence per disease: U.S.: CTCL: approx. 1,500² patients

ClinialTrials.gov identifier:

¹ Launched in Japan (brand name POTELIGEO®)

² SEER Data (2001-2007)

³ NCT01626664; ⁴ NCT01728805

Key global development updates (2)



KW-0761 (solid tumor)

Indication	_	Concomitant	Developm (Scheduled trial	Partner	Estimate enrollme
	region	Drug	Phase 1		emonne
	U.S.	Durvalumab or Tremelimumab	(2017/11)	AstraZeneca	108
	U.S.	PF-05082566	(2019/8)	Pfizer	70
Solid	Japan	Nivolumab	(2017/10)	ONO PHARMACEUTICAL Bristol-Myers Squibb	108
tumor	U.S.	Nivolumab	(2018/3)	Bristol-Myers Squibb	188
	U.S.	Docetaxel	2016/12	-	13
	U.S.	KHK2455	(2019/8)	_	50

ClinicalTrials.gov identifier:

¹ NCT02301130; ² NCT02444793; ³ NCT02476123; ⁴ NCT02705105; ⁵ NCT02358473; ⁶ NCT02867007

Key global development updates (3)



KW-6002¹

Indication	Country/region	Developn (Scheduled trial	Estimated		
		Phase 3	Application	enrollment	
Parkinson's disease	U.S., Europe, others	2016/10		613	4

Estimated no. of patients: Japan: approx. 160,000²

Estimated no. of treatable patients: U.S.: approx. 800,000 3

ClinialTrials.gov identifier:

¹ Launched in Japan (brand name: NOURIAST®)

² Ministry of Health, Labour and Welfare: 2014 Patient survey (illness classification)

³ Study by Decision Resources

⁴ NCT01968031

Key global development updates (4)



KRN23

Indica	ntion	Development stage on Country/region (Scheduled trial completion date)		Partner	Estimated			
			Phase 2	Phase 3		enrollment		
		U.S., Europe	(2018/12)			50	2	
	Pediatric	Pediatric	U.S.	(2017/12)			13	3
N/LLL		N.A., Europe, Japan, Korea, Australia		(2018/9)	Ultragenyx Pharmaceutical	60	4	
XLH		U.S.	(2016/9)		(North America, Europe)	25	5	
	Adult	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. 12,000¹ Pediatric: Japan: approx.1,000, Europe: approx. 3,000, U.S.: approx. 3,000¹

ClinicalTrials.gov identifier:

N. A.: North America

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

² NCT02163577; ³ NCT02750618; ⁴ NCT02915705; ⁵ NCT02312687; ⁶ NCT02526160; ⁷ NCT02537431

Key global development updates (5)



KRN23

Indication	Country/region	n (Scheduled trial completion date)		Partner	Estimated	
			Phase 3		enrollment	
TIO/ENS	U.S.	(2016/9)		Ultragenyx Pharmaceutical	15	3
HO/ENS	Japan / Korea	(2017/7)		(U.S., Europe)	6	4

Estimated no. of patients: Japan: approx. 30¹, U.S.: approx.500 - 1,000²

ClinicalTrials.gov identifier:

¹ 2010 Ministry of Health, Labour and Welfare Epidemiological Research on abnormalities in Hormone Receptor Mechanisms

² Survey by Ultragenyx Pharmaceutical

³ NCT02304367; ⁴ NCT02722798



Business Topics



Establishment of Kyowa Kirin Frontier Co., Ltd.

List of acronyms

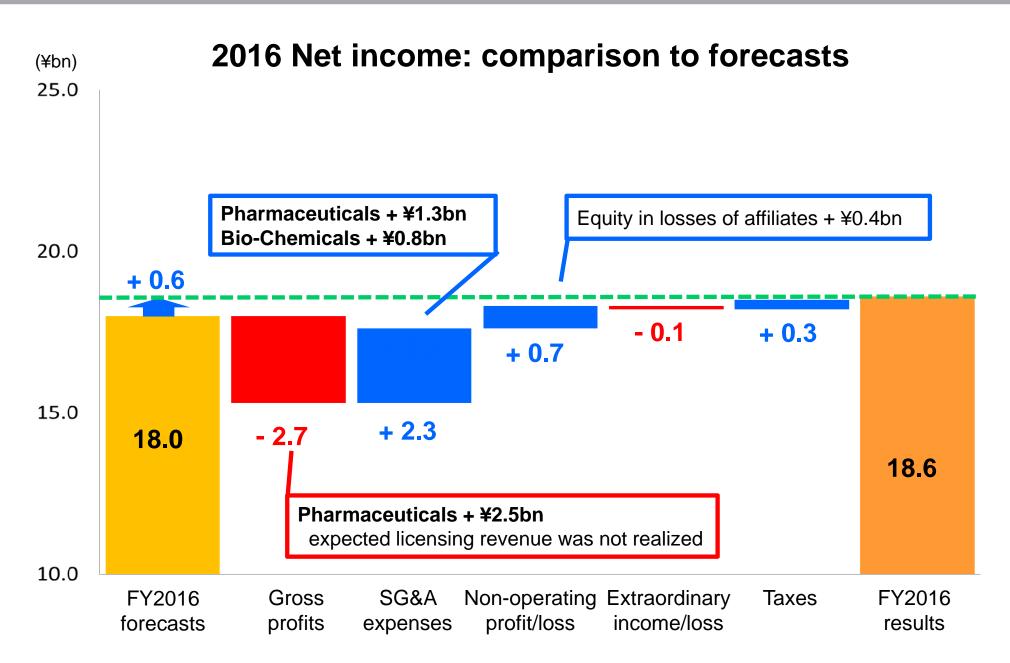


ATL	Adult T-cell Leukemia/Lymphoma
CCR4	Chemokine (C-C motif) Receptor 4
CTCL	Cutaneous T-Cell Lymphoma
ENS	Epidermal Nevus Syndrome
TIO	Tumor Induced Osteomalacia
XLH	X-linked Hypophosphatemia



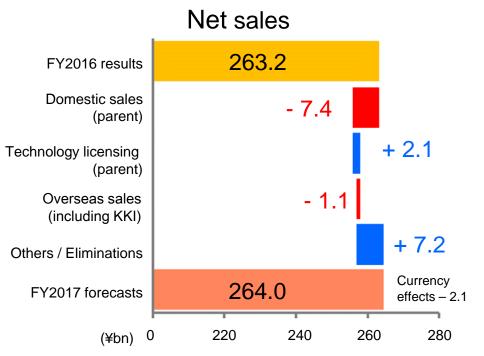
APPENDIX





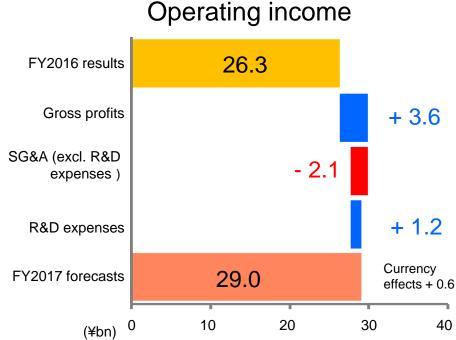
Appendix: Pharmaceuticals business FY2017 forecasts: Analysis of YoY changes





Net sales (+ ¥ 0.7bn)

- Domestic pharmaceutical products (-¥7.4bn):
- New products including G-Lasta® and NOURIAST® grow steadily
- Our key product NESP® increases in sales
- Sales of long-term prescription products such as ALLELOCK ® decrease due to the penetration of generics.
- ●Technology licensing, etc. (+ ¥2.1bn), Currency effects +¥0.0bn
- ●Overseas sales (-¥1.1bn), Currency effects ¥2.3bn
- KKI (- ¥2.0bn): Despite the growth of Abstral, PecFent and Sancuso, its overall sales decrease due to the yen appreciation
- ●Others (+ ¥7.2bn)
- Licensing revenues of overseas subsidiary increase



Operating income (+ ¥ 2.6bn)

●Gross profits (+ ¥3.6bn), Currency effects - ¥1.5bn

(profits up) Increase in licensing revenues, and increase in sales of new products in domestic and overseas markets

(profits down) Decrease in sales due to the strong competition and penetration of the generic drugs in domestic market

ulletSG&A (- \(\frac{\text{\frac{4}}}{2.1}\text{bn}\), Currency effects + \(\frac{\text{\frac{4}}}{2.2}\text{bn}\)

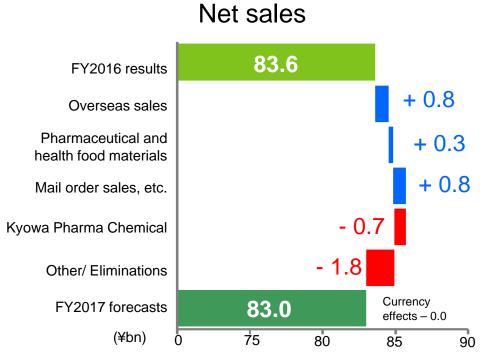
(costs up) Expenses incurred in preparation for launch of development products at KKI, etc.

(costs down) Yen appreciation

●R&D expenses (+ ¥1.2bn), Currency effects - ¥0.0bn
 (costs down) Decrease in R&D expenses especially for late stage development

Appendix: Bio-Chemicals business FY2017 forecasts: Analysis of YoY profit changes

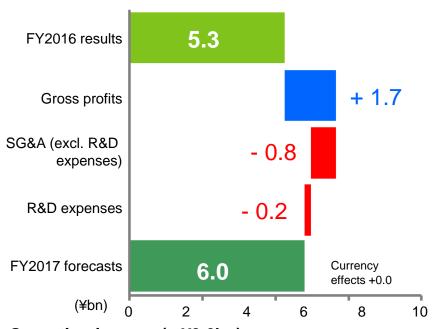




Net sales (-¥0.6bn)

- Overseas sales (+ ¥0.8bn): Currency effects -¥0.0bn
- Americas: (+ ¥0.9bn), Currency effects (+ ¥0.1bn): increase due to growth in health food use amino acids
- Europe (- ¥0.5), Currency effects (- ¥0.1bn): decrease due to in reduction of infusion use amino acids shipment, etc.
- Asia and others (+ ¥0.4bn), Currency effects (- ¥0.0bn): growth in health food use and infusion use amino acids, etc.
- Pharmaceutical and health food materials(+ ¥0.3bn): Steady growth in both pharmaceutical and health food use materials
- Consumer products(+ ¥0.8bn): Growth in mail order sales
- Kyowa Pharma Chemical (- ¥0.7bn): End of sales of low-margin agency sales, etc.

Operating income



Operating income (+ ¥0.6bn)

- Gross profit (+ ¥1.7bn), Currency effects ¥0.0bn
- Increase in gross profit margin due to growth in domestic and overseas sales of pharmaceutical and health food materials
- Reduction in manufacturing costs of pharmaceutical and health food materials to domestic and overseas markets
- Increase in gross profit margin due to growth of mail-order sales, etc.
- SG&A (-¥0.8bn), Currency effects + ¥0.0bn
- Increase in sales promotion costs for mail order sales, etc.
- R&D expenses (-¥0.2bn):

Biosimilar products development update



Development	Reference bio medical product		Country/region	Development stage			
code	Generic name	Brand name		Phase 1	Phase 2	Phase 3	
FKB327	Adalimumab	HUMIRA	U.S., others				
FKB238	Bevacizumab	Avastin	United Kingdom				
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.

Development progress with outlicensed compounds



Marsa	Doutoor	Phase		Filip a	Demontre		
Name	Partner	- 1	П	Ш	Filing	Remarks	
Tivozanib	AVEO				Europe	(VEGF red	enal Cell Cancer ceptor inhibitor) RN951)
Benralizumab	AstraZeneca					Asthma	(Anti-IL-5R antibody) (KHK4563)
(MEDI-563)	/MedImmune					COPD	POTELLIGENT®
RGI-2001	REGIMMUNE	Phas	se1/2	Immunosuppressive			

(as of January 24, 2017)

FOREX

Average Exchange Rate

Average exchange rate	2015 Results	2016 Results	Change	FY2017 Forecast
¥/\$	¥121	¥109	- ¥12	¥110
¥/€	¥135	¥121	- ¥14	¥120
¥/£	¥185	¥150	- ¥35	¥140

FY2016 Currency Effects (YoY)

Segment	Currency	Net sales	Operating income
Pharmaceuticals	\$	- ¥0.24bn	+ ¥1.20bn
business	€	- ¥0.09bn	- ¥0.04bn
	£	- ¥8.79bn	+ ¥0.28bn
Bio-Chemicals	\$	- ¥2.06bn	- ¥1.14bn
business	€	- ¥1.72bn	- ¥0.89bn
	£	-	■ (V. ravus Haldra Viria C



Estimated Exchange Rate Sensitivity of the (consolidated) Earnings Forecast for 2017*

Currency	Changes	Impact on Net Sales	Impact on Operating Income
¥/\$	+ ¥ 1	-¥0.30bn	-¥0.13bn
¥/€	+ ¥ 1	-¥0.13bn	-¥0.06bn
¥/£	+ ¥ 1	-¥0.25bn	+¥0.02bn

^{*} The values represent estimated cumulative outcome over the consecutive 12 months for a potential change in Japanese yen exchange rate.



KYOWA KIRIN

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