

Kyowa Hakko Kirin Co., Ltd.

Appendix to the Consolidated Financial Summary (IFRS) Fiscal 2019 First Quarter

(January 1, 2019 - March 31, 2019)

- These materials were made as a supplement to the Kessan Tanshin (Consolidated Financial Summary, IFRS), disclosed at the Tokyo Stock Exchange on May 8, 2019 for the first three months of Fiscal 2019, from January 1, 2019 to March 31, 2019.
- This document is an English translation of parts of the Japanese-language original. The statements, including earnings forecasts, contained in these materials are based on the information currently available to the Company and on certain assumptions deemed to be reasonable by management. As such, they do not constitute guarantees by the Company of future performance. Actual results may differ materially from these projections for a wide variety of reasons.
- "FY 2019 forecasts" have not been revised from the consolidated earnings forecasts released on February 5, 2019.
- Following the conclusion of an agreement to transfer shares of Kyowa Hakko Bio Co., Ltd., the Bio-Chemicals business is categorized as a discontinued operation, effective the first quarter of Fiscal 2019 for accounting on a consolidated basis. Accordingly, FY 2018 results presented herein have been restated in order to present them similarly to the FY 2019 results.
- Figures presented in these materials have been rounded to the nearest tenth.
- Figures inside parenthesis presented in these materials indicate negative values.

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The average exchange rates for each period were as follows:

Unit: Yen

	FY 2018 results		FY 2019 results	FY 2019 forecasts
	Jan - Mar	Jan - Dec	Jan - Mar	Jan - Dec
USD	110	110	110	110
EUR	134	131	126	130
GBP	152	148	143	145

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I . Consolidated Financial Results
1. Trends in consolidated profit

<Accumulative>

Unit: Billions of yen

	FY 2018 results		FY 2019 results		FY 2019 forecasts
	Jan - Mar	Jan - Dec	Jan - Mar	Change amount	Jan - Dec
Revenue	66.5	271.5	75.8	9.3	305.0
Cost of sales	(19.8)	(73.4)	(19.8)	0.0	(81.0)
Gross profit	46.7	198.1	56.1	9.4	224.0
<i>Gross profit to revenue ratio</i>	70.2%	73.0%	74.0%	-	73.4%
Selling, general and administrative expenses	(23.5)	(102.1)	(26.7)	(3.2)	(117.5)
Research and development expenses	(10.2)	(45.7)	(11.9)	(1.7)	(52.5)
<i>R&D expenses to revenue ratio</i>	15.3%	16.8%	15.7%	-	17.2%
Share of profit (loss) of investments accounted for using equity method	1.4	(0.1)	(0.2)	(1.5)	(1.0)
Core operating profit	14.4	50.3	17.3	2.9	53.0
<i>Core operation profit to revenue ratio</i>	21.6%	18.5%	22.9%	-	17.4%
Other income	14.4	18.6	0.1	(14.3)	
Other expenses	(0.1)	(1.4)	(5.3)	(5.2)	
Finance income (costs)	(0.1)	(0.6)	0.1	0.3	
Profit before tax	28.6	66.8	12.3	(16.3)	47.0
Income tax expense	(7.7)	(17.6)	(3.0)	4.8	
<i>Ratio of income tax burden</i>	27.0%	26.3%	24.1%	-	
Profit from continuing operations	20.9	49.2	9.3	(11.6)	37.0
<i>Profit from continuing operations to revenue ratio</i>	31.4%	18.1%	12.3%	-	12.1%
Profit from discontinued operations	1.1	5.2	(1.2)	(2.3)	31.0
Profit	22.0	54.4	8.1	(13.9)	68.0
<i>Profit to revenue ratio</i>	33.1%	20.0%	10.7%	-	22.3%

EPS (¥/share) 40.20 99.40 14.97 (25.23) 126.30

Annual dividend (¥/share) 35.00 40.00

Dividend payout ratio (%) 35.2 31.7

ROE (%) 8.6 10.5

* Profit from discontinued operations is presented separately from continuing operations on the condensed quarterly consolidated statement of profit or loss. Accordingly, the amounts displayed from revenue through profit from continuing operations are amounts of the continuing operations and exclude the discontinued operations.

<Breakdown of profit for FY 2019 Jan - Mar from discontinued operations>

Unit: Billions of yen

	FY 2018 results		FY 2019 results	
	Jan - Mar	Jan - Dec	Jan - Mar	Change amount
Revenue	18.2	75.0	18.1	(0.1)
Gross profit	7.1	29.0	6.8	(0.2)
Core operating profit	1.9	8.4	1.3	(0.5)
Profit before tax	1.7	6.6	(0.6)	(2.3)
Profit	1.1	5.2	(1.2)	(2.3)

* Regarding transactions between continuing operations and discontinued operations, considering the continuity of the transactions in the future, revenue and the expenses generated from transactions between such operations have been eliminated from the results of discontinued operations.

2. Revenue by geographic region (continuing operations)
Unit: Billions of yen

	FY 2018 results			FY 2019 results		FY 2019 forecasts	
	Jan - Mar	Jan - Dec	Percentage of consolidated revenue	Jan - Mar	Percentage of consolidated revenue	Jan - Dec	Percentage of consolidated revenue
Japan	45.7	183.5	67.6%	48.8	64.3%	185.5	60.8%
International	20.8	88.0	32.4%	27.1	35.7%	119.5	39.2%
Americas	4.2	23.0	8.5%	8.9	11.7%	50.0	16.4%
Europe	11.5	42.3	15.6%	11.8	15.6%	45.0	14.8%
Asia	4.9	22.5	8.3%	6.3	8.4%	24.0	7.9%
Others	0.2	0.2	0.1%	0.0	0.1%	0.5	0.2%
Total consolidated revenue	66.5	271.5	100%	75.8	100%	305.0	100%

* Revenue is classified by region or country based on location of customer.

3. Capital expenditures and intangible assets investment (continuing operations)
Unit: Billions of yen

	FY 2018 results		FY 2019 results	FY 2019 forecasts
	Jan - Mar	Jan - Dec	Jan - Mar	Jan - Dec
Capital expenditures (property, plant and equipment)	0.8	4.5	2.6	10.6
Intangible assets investment	0.6	9.0	3.4	11.5
Total	1.4	13.5	6.0	22.1

* Acquisitions of right-of-use assets are not included.

4. Depreciation and amortization (continuing operations)
Unit: Billions of yen

	FY 2018 results		FY 2019 results	FY 2019 forecasts
	Jan - Mar	Jan - Dec	Jan - Mar	Jan - Dec
Depreciation (property, plant and equipment)	1.6	7.3	2.5	9.3
Amortization (intangible assets)	2.1	8.9	2.2	8.6
Total	3.8	16.2	4.7	17.9

II. Consolidated Statement of Cash Flows
Unit: Billions of yen

	FY 2018 results		FY 2019 results	
	Jan - Mar	Jan - Dec	Jan - Mar	Change amount
Cash flows from operating activities	19.5	56.2	9.2	(10.3)
<i>Of which, cash flows of discontinued operations</i>	1.6	6.8	6.3	4.7
Cash flows from investing activities	(14.5)	(39.9)	29.3	43.8
<i>Of which, cash flows of discontinued operations</i>	(2.3)	(6.4)	(1.9)	0.4
Cash flows from financing activities	(8.3)	(16.5)	(34.5)	(26.1)
<i>Of which, cash flows of discontinued operations</i>	(0.3)	(0.2)	(0.0)	0.3
Effect of exchange rate changes on cash and cash equivalents	(0.1)	0.4	(0.4)	(0.3)
Net increase (decrease) in cash and cash equivalents	(3.5)	0.1	3.7	7.1
Transfer to assets held for sale	1.1	1.1	(3.6)	(4.7)
Cash and cash equivalents at beginning of period	14.7	14.7	15.9	1.2
Cash and cash equivalents at end of period*	12.3	15.9	15.9	3.6

* Cash reserves at end of period

Cash and cash equivalents at end of period	12.3	15.9	15.9	3.6
+ Loans receivable from parent in excess of three months	168.0	181.3	144.6	(23.4)
+ Time deposits whose maturity periods exceed three months	0.0	0.0	-	(0.0)
Cash reserves at end of period	180.3	197.2	160.5	(19.8)

III. Revenue from Main Products

<Accumulative>

Unit: Billions of yen

Indication / Product name		FY 2018 results				FY 2019 results		FY 2019 forecasts		
		Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Change amount	Jan - Dec	%	
Japan	Renal anemia treatment drug Nesp	12.0	25.6	39.2	53.7	11.8	(0.2)	48.4	90%	
	Secondary hyperparathyroidism Regpara	3.6	7.8	10.7	13.3	1.8	(1.7)	5.1	38%	
	Secondary hyperparathyroidism Orkedia	-	0.4	1.1	2.4	1.2	1.2	9.5	397%	
	Secondary hyperparathyroidism Rocaltrol	0.9	1.9	2.8	3.8	0.8	(0.1)	3.6	96%	
	Type-2 diabetes Onglyza	1.6	3.6	5.4	7.4	1.7	0.0	7.6	102%	
	Cardiovascular (Hypertension & angina pectoris) Coniel	1.2	2.5	3.6	4.8	1.0	(0.3)	3.9	81%	
	Agent for decreasing the incidence of febrile neutropenia G-Lasta	4.3	9.5	14.8	20.7	5.3	0.9	22.8	110%	
	Transdermal persistent pain Fentos	1.2	2.6	4.0	5.4	1.1	(0.1)	4.8	89%	
	Anticancer Poteligeo	0.4	0.9	1.3	1.8	0.4	0.0	1.7	96%	
	Anticancer Rituximab BS [KHK]	0.3	1.1	2.4	4.3	1.8	1.5	8.4	195%	
	Chronic idiopathic thrombocytopenic purpura Romiplate	0.7	1.5	2.4	3.2	0.8	0.0	4.4	136%	
	Antiallergenic Allelock	4.6	7.5	9.7	12.6	4.0	(0.6)	9.3	74%	
	Antiallergic eyedrops Patanol	7.7	9.7	11.5	13.4	8.5	0.8	11.3	84%	
	Ulcerative colitis Asacol	0.7	1.5	2.2	2.9	0.6	(0.1)	2.2	77%	
	Psoriasis vulgaris Dovobet	1.2	2.8	4.2	5.9	1.5	0.4	7.8	132%	
	Psoriasis Lumicef	0.4	0.9	1.4	2.0	0.5	0.2	2.7	134%	
	Parkinson's disease Nourias	1.9	4.4	6.8	9.4	2.2	0.3	10.0	107%	
	Antiepileptic Depakene	1.3	2.7	4.0	5.3	1.1	(0.2)	4.3	82%	
	Technology out-licensing		1.1	1.5	2.2	2.7	0.9	(0.2)	4.4	162%
	International	X-linked hypophosphatemia (XLH) Crysvita	-	0.8	3.2	7.7	5.7	5.7		
		Anticancer Poteligeo	-	-	-	2.1	2.4	2.4	10.0	478%
		Cancer pain Abstral	3.4	6.5	9.5	12.8	3.1	(0.3)	12.3	96%
		Cancer pain Pecfent	1.0	2.0	3.2	4.4	1.1	0.0	5.0	113%
Chemotherapy-induced nausea and vomiting drug Sancuso		0.6	1.3	2.1	3.0	0.7	0.2	2.9	99%	
Opioid-induced constipation (OIC) Moventig		0.3	0.6	1.0	1.4	0.5	0.2	2.5	174%	
Replacement therapy with testosterone for male hypogonadism Tostran/Fortesta		0.6	1.4	2.1	2.8	0.6	(0.0)	1.9	68%	
Osteoporosis drug Adcal-D3		0.9	1.8	2.7	3.5	0.8	(0.0)	3.1	90%	
Anticancer Mitomycin-C		0.6	1.3	1.7	2.3	0.6	(0.0)	2.1	88%	
Renal anemia treatment drug Nesp		1.5	3.1	4.7	6.4	1.7	0.2	5.9	93%	
Secondary hyperparathyroidism Regpara		0.7	1.5	2.3	3.2	1.1	0.5	3.7	114%	
Agent for decreasing the incidence of febrile neutropenia Neulasta/Peglasta		0.4	1.0	1.7	2.4	1.0	0.5	4.2	173%	
Neutropenia treatment drug Gran		1.4	2.7	4.2	5.4	1.5	0.0	5.6	104%	
Technology out-licensing		6.5	12.4	13.9	15.8	3.2	(3.3)	12.9	82%	

* Revenue is classified as Japan or International (other than Japan) based on customer location.

* Revenue from main products does not include revenue from the Early Access Program (EAP).

* FY 2019 forecasts for Nesp include revenue of authorized generics ("Darbepoetin Alfa Injection Syringe [KKF]") planned to start sales in the third quarter of fiscal 2019.

* Revenue listed as "Technology out-licensing" specifies revenue from the upfront payment, milestone revenue, and running royalties revenue that are obtained based on licensing agreements recognizing the granting to third parties the rights for development, manufacturing and sales of the Group's pipeline compounds or the use of technology, etc.

V. R&D Pipeline

Filed • Approved



antibody



protein



small molecule

As of Mar. 31, 2019

Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Nephrology		KRN321 Darbepoetin Alfa Injection	Long-Acting Erythropoiesis Stimulating Agent	Renal Anemia (on Dialysis)	Filed in CN	Kirin-Amgen	
				Renal Anemia	Filed in ID		
Immunology/Allergy		KHK4827 Brodalumab Injection	Anti-IL-17 Receptor A Fully Human Antibody	Psoriasis	Filed in KR	Kirin-Amgen	
					Filed in SG		
					Filed in MY		
					Approved in HK		
Central Nervous System		KW-6002 Istradefylline Oral	Adenosine A _{2A} Receptor Antagonist	Parkinson's Disease	Filed in US	In-House	
Other		©KRN23 Burosumab Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemia (XLH)	Approved in IL	In-House	Human Antibody-Producing Technology Jointly Developed with Ultragenyx in US and EU
					Filed in TW		
					Filed in CH		
					Filed in KW		
	Approved in AE						
		AMG531 Romiplostim Injection	Thrombopoietin Receptor Agonist	Aplastic Anemia	Filed in JP	Kirin-Amgen	

Phase II, Phase III




Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Nephrology		©RTA 402 Bardoxolone Methyl Oral	Antioxidant Inflammation Modulator	Diabetic Kidney Disease	Phase III in JP	Licensed from Reata	
		KHK7580 Evocalcet Oral	Calcium Receptor Agonist	Hypercalcemia In Patients With Parathyroid Carcinoma or Primary Hyperparathyroidism	Phase III in JP	Licensed from Mitsubishi Tanabe Pharma	
		©KHK7791 Tenapanor Oral	NHE3 inhibitor	Hyperphosphatemia Under Maintenance Dialysis	Phase II in JP	Licensed from Ardelyx	
Oncology		©KHK2375 Entinostat Oral	HDAC Inhibitor	Breast Cancer	Phase II in JP	Syndax	
		KW-0761 Mogamulizumab Injection	Anti-CCR4 Humanized Antibody	Adult T-cell Leukemia/Lymphoma	Phase II in US, EU and others	In-House	POTELLIGENT®
Immunology/Allergy		©KHK4083 Injection	Anti-OX40 Fully Human Antibody	Ulcerative Colitis	Phase II in US, EU and others	In-House	POTELLIGENT® Human Antibody-Producing Technology
				Atopic Dermatitis	Phase II in JP, US, CA and EU		
		KHK4827 Brodalumab Injection	Anti-IL-17 Receptor A Fully Human Antibody	Axial Spondyloarthritis (axSpA)	Phase III in JP, KR and TW	Kirin-Amgen	
		©ASKP1240 Bleselumab Injection	Anti-CD40 Fully Human Antibody	Recurrence of Focal Segmental Glomerulosclerosis (FSGS) in <i>de novo</i> kidney transplant recipients	Phase II in US	In-House	Human Antibody-Producing Technology Jointly Developed with Astellas
Central Nervous System		KW-0761 Mogamulizumab Injection	Anti-CCR4 Humanized Antibody	HTLV-1 associated myelopathy (HAM)	Phase III in JP	In-House	POTELLIGENT®
		©KW-6356 Oral	Adenosine A _{2A} Receptor Antagonist	Parkinson's Disease	Phase II in JP	In-House	
Other		©KRN23 Burosumab Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemia (XLH) in adult patients	Phase III in US, CA, EU, JP and KR	In-House	Human Antibody-Producing Technology Jointly Developed with Ultragenyx in US and EU
				X-linked Hypophosphatemia (XLH) in pediatric patients	Phase III in US, CA, EU, AU, JP and KR		
				Tumor Induced Osteomalacia (TIO)/Epidermal Nevus Syndrome (ENS)	Phase II in US		
					Phase II in JP and KR		
			AMG531 Romiplostim Injection	Thrombopoietin Receptor Agonist	Aplastic Anemia Idiopathic (Immune) Thrombocytopenic Purpura	Phase II/III in KR Phase III in CN	Kirin-Amgen

Updated since Dec. 31, 2018 (Area, Stage, Filed, Approved, etc.)









© New Molecular Entity


V. R&D Pipeline

Ph I

 antibody  protein  small molecule





As of Mar. 31, 2019

Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Oncology		©KHK2455 Oral	IDO1 Inhibitor	Solid Tumor	Phase I in US	In-House	Combination with KW-0761
		©KHK2823 Injection	Anti-CD123 Fully Human Antibody	Cancer	Phase I in UK	In-House	POTELLIGENT® Human Antibody-Producing Technology
		KW-0761 Mogamulizumab Injection	Anti-CCR4 Humanized Antibody	Solid Tumor	Phase I / II in US	In-House	POTELLIGENT® Combination with Nivolumab (Jointly Developed with Bristol-Myers Squibb)
Immunology/A llergy		©KHK4083 Injection	Anti-OX40 Fully Human Antibody	Ulcerative Colitis	Phase I in JP	In-House	POTELLIGENT® Human Antibody-Producing Technology
		KHK4323 Injection		Atopic Dermatitis	Phase I in JP	In-House	
		KHK4827 Brodalumab Injection	Anti-IL-17 Receptor A Fully Human Antibody	Autoimmune Disease	Phase I in JP	Kirin-Amgen	
Central Nervous System		©KHK6640 Injection	Anti-Amyloid Beta Peptide Antibody	Alzheimer's Disease	Phase I in EU Phase I in JP	Licensed from Immunas Pharma	
Others		KW-3357 Antithrombin Gamma Injection	Recombinant Human Antithrombin	Disseminated Intravascular Coagulation, Congenital Antithrombin Deficiency	Phase I in EU	In-House	


 Updated since Dec. 31, 2018 (Area, Stage, Filed, Approved, etc.)
 © New Molecular Entity

Updated since Dec. 31, 2018 (Area, Stage, Filed, Approved, etc.)


Filed • Approved

Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Nephrology		KRN321 Darbepoetin Alfa Injection	Long-Acting Erythropoiesis Stimulating Agent	Renal Anemia (on Dialysis)	Filed in CN	Kirin-Amgen	
Immunology/A llergy		KHK4827 Brodalumab Injection	Anti-IL-17 Receptor A Fully Human Antibody	Psoriasis	Approved in HK	Kirin-Amgen	
Central Nervous System		KW-6002 Istradefylline Oral	Adenosine A _{2A} Receptor Antagonist	Parkinson's Disease	Filed in US	In-House	
Other		©KRN23 Burosumab Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemia (XLH) FGF23-Related Hypophosphatemic Rickets and Osteomalacia	Approved in IL	In-House	Human Antibody-Producing Technology Jointly Developed with Ultragenyx in US and EU
					Filed in TW		
					Filed in KW		
					Approved in AE		
					Filed in JP		


Phase II, Phase III

Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Nephrology		©KHK7791 Tenapanor Oral	NHE3 inhibitor	Hyperphosphatemia Under Maintenance Dialysis	Phase II in JP	Licensed from Ardelyx	

Phase I

Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Immunology/A llergy		KHK4323 Injection		Atopic Dermatitis	Phase I in JP	In-House	

Terminated (Due to license out)

Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Immunology/A llergy		KHK4563 Benralizumab Injection	Anti-IL-5 Receptor Humanized Antibody	Chronic Obstructive Pulmonary Disease (COPD)	Phase III in JP	In-House	POTELLIGENT® Jointly Developed with AstraZeneca/MedImmune
				Eosinophilic Chronic Rhinosinusitis (ECRS)	Phase II in JP		