

Kyowa Hakko Kirin Co., Ltd.

Appendix to the Consolidated Financial Summary (IFRS) Fiscal 2018

(January 1, 2018 - December 31, 2018)

- These materials were made as a supplement to the Kessan Tanshin (Consolidated Financial Summary, IFRS), disclosed at the Tokyo Stock Exchange on February 5, 2019 for Fiscal 2018, from January 1, 2018 to December 31, 2018.
- 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.
- 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 2017 results				FY 2018 results				FY 2019 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Dec
USD	115	113	112	112	110	109	109	110	110
EUR	122	122	124	126	134	132	131	131	130
GBP	143	142	142	144	152	151	149	148	145

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I . Consolidated Financial Results (IFRS)
1. Trends in consolidated profit

<Accumulative>

Unit: Billions of yen

	FY 2017 results				FY 2018 results						
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Change amount	Jan - Dec latest forecasts	% of forecasts
Revenue	91.3	177.0	261.3	353.4	84.7	172.1	253.9	346.5	(6.8)	335.0	103%
Cost of sales	(35.1)	(66.0)	(96.3)	(129.1)	(31.0)	(60.2)	(88.0)	(119.3)	9.7	(114.0)	105%
Gross profit	56.2	111.0	165.0	224.3	53.8	112.0	166.0	227.2	2.9	221.0	103%
Selling, general and administrative expenses	(26.2)	(54.2)	(81.4)	(113.0)	(28.0)	(57.7)	(85.9)	(119.8)	(6.8)	(117.0)	102%
Research and development expenses	(12.0)	(24.3)	(35.8)	(49.2)	(10.9)	(23.1)	(34.4)	(48.6)	0.6	(49.5)	98%
Share of profit (loss) of investments accounted for using equity method	(1.3)	(2.4)	(3.1)	(4.5)	1.4	0.9	0.3	(0.1)	4.4	(0.5)	19%
Core operating profit	16.8	30.1	44.7	57.7	16.2	32.1	45.9	58.7	1.0	54.0	109%
Other income	0.8	1.0	1.2	6.6	14.5	14.7	18.5	19.0	12.4		
Other expenses	(0.2)	(2.1)	(2.3)	(8.4)	(0.2)	(0.7)	(1.1)	(3.5)	4.8		
Finance income (costs)	(0.0)	0.0	0.2	(0.1)	(0.3)	(0.4)	(0.5)	(0.8)	(0.6)		
Profit before tax	17.4	29.1	43.7	55.8	30.3	45.7	62.8	73.4	17.6	71.0	103%
Income tax expense	(5.4)	(8.7)	(14.3)	(13.0)	(8.3)	(11.4)	(15.4)	(19.0)	(6.1)		
Profit	12.0	20.3	29.5	42.9	22.0	34.3	47.4	54.4	11.5	52.0	105%
EPS (¥/share)	21.96	37.18	53.83	78.38	40.20	62.61	86.62	99.40	21.02	94.99	-
Annual dividend (¥/share)				27.00				35.00	8.00	30.00	-
Dividend payout ratio (%)				34.4				35.2	0.8	31.6	-
ROE (%)				7.2				8.6	1.4		-

* "Jan-Dec latest forecasts" represents pro forma forecasts of performance results for FY 2018, which were disclosed on October 30, 2018.

<Quarterly>

Unit: Billions of yen

	FY 2017 results				FY 2018 results				
	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Change amount
Revenue	91.3	85.7	84.2	92.1	84.7	87.4	81.8	92.6	0.5
Cost of sales	(35.1)	(31.0)	(30.2)	(32.8)	(31.0)	(29.2)	(27.8)	(31.4)	1.4
Gross profit	56.2	54.7	54.0	59.3	53.8	58.2	54.0	61.2	1.9
Selling, general and administrative expenses	(26.2)	(28.0)	(27.2)	(31.6)	(28.0)	(29.7)	(28.2)	(33.9)	(2.3)
Research and development expenses	(12.0)	(12.4)	(11.5)	(13.3)	(10.9)	(12.2)	(11.4)	(14.2)	(0.8)
Share of profit (loss) of investments accounted for using equity method	(1.3)	(1.1)	(0.8)	(1.3)	1.4	(0.5)	(0.6)	(0.4)	0.9
Core operating profit	16.8	13.3	14.6	13.1	16.2	15.9	13.8	12.8	(0.3)
Other income	0.8	0.2	0.2	5.4	14.5	0.2	3.8	0.5	(4.9)
Other expenses	(0.2)	(1.8)	(0.2)	(6.1)	(0.2)	(0.5)	(0.4)	(2.4)	3.7
Finance income (costs)	(0.0)	0.0	0.2	(0.3)	(0.3)	(0.1)	(0.1)	(0.2)	0.1
Profit before tax	17.4	11.7	14.7	12.1	30.3	15.4	17.1	10.7	(1.5)
Income tax expense	(5.4)	(3.3)	(5.5)	1.3	(8.3)	(3.1)	(3.9)	(3.7)	(5.0)
Profit	12.0	8.3	9.1	13.4	22.0	12.3	13.1	7.0	(6.4)

<Reclassified Table: Restated with the Bio-Chemicals Business Reclassified as Discontinued Operations>
Unit: Billions of yen

	FY 2018 results	FY 2019 forecasts	Change amount	%
Revenue	271.5	305.0	33.5	112%
Gross profit	198.1	224.0	25.9	113%
Core operating profit	50.3	53.0	2.7	105%
Profit before tax	67.0	47.0	(20.0)	70%
Profit from continuing operations	49.4	37.0	(12.4)	75%
Profit from discontinued operations	5.0	31.0	26.0	623%
Profit	54.4	68.0	13.6	125%

EPS (¥/share)	99.40	126.30	26.90	-
Annual dividend (¥/share)	35.00	40.00	5.00	-
Dividend payout ratio (%)	35.2	31.7	(3.5)	-
ROE (%)	8.6	10.5	1.9	-

* In accordance with the Company's decision to transfer the shares of Kyowa Hakko Bio Co., Ltd., the Company plans to categorize the Bio-Chemicals business as discontinued operations effective the first three months of fiscal 2019 (January 1, 2019 to March 31, 2019). Accordingly, profit from discontinued operations on the consolidated statement of profit or loss is planned to be presented separately from the continuing operations.

Revenue, gross profit, core operating profit, and profit before tax in the above Reclassified Table show figures for continuing operations, which exclude discontinued operations.

Furthermore, profit from the Bio-Chemicals business (up to the first three months of fiscal 2019) and gains on sale and valuation of investments in Kyowa Hakko Bio Co., Ltd. (net of tax) have been included in profit from discontinued operations. The "FY 2018 results" after reclassification have not been audited by an auditing firm.

2. Revenue by geographic region

Unit: Billions of yen

	FY 2017 results					FY 2018 results					FY 2019 forecasts	
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Percentage of consolidated revenue	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Percentage of consolidated revenue	Jan - Dec	Percentage of consolidated revenue
Japan	60.5	120.6	178.8	240.9	68.2%	55.2	111.6	164.9	224.4	64.8%	185.5	60.8%
International	30.8	56.4	82.5	112.5	31.8%	29.5	60.5	89.0	122.1	35.2%	119.5	39.2%
Americas	7.5	12.2	16.6	24.7	7.0%	6.7	15.6	21.6	31.9	9.2%	50.0	16.4%
Europe	15.8	28.9	42.4	56.0	15.8%	15.1	28.7	42.7	56.1	16.2%	45.0	14.8%
Asia	7.2	14.9	22.4	30.2	8.6%	7.5	15.8	24.0	33.4	9.7%	24.0	7.9%
Others	0.3	0.4	1.0	1.6	0.5%	0.3	0.4	0.6	0.7	0.2%	0.5	0.2%
Total consolidated revenue	91.3	177.0	261.3	353.4	100%	84.7	172.1	253.9	346.5	100%	305.0	100%

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

* "FY 2019 forecasts" shows figures for continuing operations and exclude discontinued operations. (The same applies on the following pages.)

3. Other trends

(1) Research and development expenses

Unit: Billions of yen

	FY 2017 results				FY 2018 results				FY 2019 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Dec
Research and development (R&D) expenses	12.0	24.4	35.9	49.2	10.9	23.1	34.5	48.6	52.5
<i>R&D expenses to revenue ratio</i>	13.1%	13.8%	13.7%	13.9%	12.9%	13.4%	13.6%	14.0%	17.2%
Pharmaceuticals	11.3	22.8	33.6	46.1	10.2	21.6	32.3	45.7	52.5
<i>R&D expenses to revenue ratio</i>	15.6%	16.5%	16.5%	16.7%	15.3%	16.1%	16.3%	16.8%	17.2%
Bio-Chemicals	0.8	1.6	2.3	3.1	0.8	1.5	2.2	3.0	

(2) Capital expenditures (property, plant and equipment)

Unit: Billions of yen

	FY 2017 results				FY 2018 results				FY 2019 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Dec
Capital expenditures	3.3	6.7	9.9	14.3	2.4	5.0	8.1	10.9	10.6
Pharmaceuticals	2.2	4.1	5.3	6.6	0.8	1.8	3.3	4.5	10.6
Bio-Chemicals	1.1	2.6	4.6	7.7	1.6	3.2	4.8	6.4	

(3) Depreciation and amortization (property, plant and equipment and intangible assets)

Unit: Billions of yen

	FY 2017 results				FY 2018 results				FY 2019 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Dec
Depreciation and amortization	5.5	10.9	16.4	22.0	5.1	10.5	16.0	22.2	17.9
<i>Amortization of intangible assets</i>	2.1	3.9	5.8	7.8	2.1	4.2	6.3	9.0	8.6
Pharmaceuticals	3.9	7.5	11.4	15.3	3.8	7.7	11.7	16.2	17.9
<i>Amortization of intangible assets</i>	2.1	3.8	5.7	7.7	2.1	4.2	6.2	8.9	8.6
Bio-Chemicals	1.6	3.3	5.0	6.7	1.4	2.8	4.4	6.0	

II. Consolidated Statement of Cash Flows (IFRS)

Unit: Billions of yen

	FY 2017 results				FY 2018 results				Change amount
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	
Cash flows from operating activities	18.9	32.0	49.1	64.9	19.5	29.8	46.4	56.2	(8.7)
Cash flows from investing activities	(10.1)	(23.1)	(35.0)	(45.3)	(14.5)	(23.0)	(30.8)	(39.9)	5.3
Cash flows from financing activities	(6.7)	(6.9)	(13.9)	(18.3)	(8.3)	(8.4)	(16.5)	(16.5)	1.8
Effect of exchange rate changes on cash and cash equivalents	1.2	0.8	1.1	1.3	(0.1)	(0.6)	(0.4)	0.4	(1.0)
Net increase (decrease) in cash and cash equivalents	3.3	2.8	1.3	2.7	(3.5)	(2.2)	(1.3)	0.1	(2.6)
Transfer to assets held for sale	-	-	(0.0)	(1.1)	1.1	1.1	1.1	1.1	2.1
Cash and cash equivalents at beginning of period	13.1	13.1	13.1	13.1	14.7	14.7	14.7	14.7	1.6
Cash and cash equivalents at end of period*	16.4	15.8	14.4	14.7	12.3	13.6	14.5	15.9	1.2

* Cash reserves at end of period

Cash and cash equivalents at end of period	16.4	15.8	14.4	14.7	12.3	13.6	14.5	15.9	1.2
+ Loans receivable from parent in excess of three months	120.0	128.0	135.2	143.2	168.0	172.4	179.6	181.3	38.1
+ Time deposits whose maturity periods exceed three months	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	(0.0)
Cash reserves at end of period	136.4	143.8	149.6	157.9	180.3	186.0	194.1	197.2	39.3

III. Core Operating Profit or Loss by Segment (IFRS)

1. Pharmaceuticals segment (Continuing operations)

Unit: Billions of yen

	FY 2017 results				FY 2018 results							FY 2019 forecasts	
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Change amount	Jan - Dec latest forecasts	% of forecasts	Jan - Dec	%
Revenue	72.3	138.0	203.0	275.8	66.5	134.3	197.7	271.5	(4.3)	262.0	104%	305.0	112%
Revenue from external customers	72.1	137.5	202.3	274.8	66.2	133.8	196.9	270.4	(4.3)	261.0	104%	305.0	113%
Japan	50.1	99.2	147.1	197.8	45.4	90.8	134.3	182.5	(15.4)	181.0	101%	185.5	102%
International	22.0	38.3	55.2	76.9	20.8	43.0	62.6	88.0	11.0	80.0	110%	119.5	136%
International revenue ratio	30%	28%	27%	28%	31%	32%	32%	33%	-	31%	-	39%	-
Americas	5.1	7.2	9.3	15.0	4.2	10.8	14.6	23.0	7.9	20.8	111%	50.0	218%
Europe	12.4	21.7	31.4	41.5	11.5	21.5	31.8	42.3	0.8	39.8	106%	45.0	106%
Asia	4.3	9.2	14.1	19.6	4.9	10.5	16.2	22.5	2.9	18.8	120%	24.0	107%
Others	0.2	0.2	0.5	0.8	0.2	0.1	0.1	0.2	(0.6)	0.6	28%	0.5	283%
Inter-segment revenue	0.2	0.5	0.7	1.0	0.3	0.6	0.8	1.1	0.1	1.0	107%	-	-
Cost of sales	(22.5)	(40.6)	(58.8)	(79.1)	(19.8)	(37.0)	(53.9)	(73.4)	5.7	(70.0)	105%	(81.0)	110%
Gross profit	49.7	97.4	144.2	196.7	46.7	97.4	143.8	198.1	1.5	192.0	103%	224.0	113%
Selling, general and administrative expenses	(22.1)	(45.4)	(68.3)	(95.5)	(23.5)	(48.3)	(72.3)	(102.1)	(6.6)	(99.0)	103%	(117.5)	115%
Research and development expenses	(11.3)	(22.8)	(33.6)	(46.1)	(10.2)	(21.6)	(32.3)	(45.7)	0.5	(46.5)	98%	(52.5)	115%
Share of profit (loss) of investments accounted for using equity method	(1.3)	(2.4)	(3.1)	(4.5)	1.4	0.9	0.3	(0.1)	4.4	(0.5)	20%	(1.0)	-
Core operating profit	15.1	26.8	39.2	50.5	14.4	28.4	39.5	50.3	(0.2)	46.0	109%	53.0	105%

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

* The figures represent amounts before elimination of inter-segment transactions.

2. Bio-Chemicals segment (Discontinued operations)

Unit: Billions of yen

	FY 2017 results				FY 2018 results							FY 2019 forecasts	
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Change amount	Jan - Dec latest forecasts	% of forecasts	Jan - Dec	%
Revenue	20.0	40.8	60.7	81.1	19.0	39.3	58.4	78.2	(2.9)	76.0	103%		
Revenue from external customers	19.2	39.5	59.0	78.6	18.5	38.3	57.0	76.1	(2.5)	74.0	103%		
Japan	10.4	21.4	31.7	43.0	9.8	20.7	30.7	41.9	(1.1)	40.2	104%		
International	8.8	18.1	27.3	35.6	8.7	17.6	26.3	34.2	(1.4)	33.8	101%		
International revenue ratio	46%	46%	46%	45%	47%	46%	46%	45%	-	46%	-		
Americas	2.5	5.0	7.4	9.7	2.5	4.8	7.1	8.9	(0.8)	9.0	99%		
Europe	3.4	7.2	11.0	14.4	3.6	7.2	11.0	13.8	(0.7)	15.4	89%		
Asia	2.9	5.7	8.3	10.7	2.6	5.3	7.8	11.0	0.3	9.2	120%		
Others	0.1	0.2	0.5	0.8	0.1	0.3	0.5	0.6	(0.3)	0.3	204%		
Inter-segment revenue	0.8	1.3	1.7	2.5	0.5	0.9	1.4	2.1	(0.4)	2.0	106%		
Cost of sales	(13.5)	(27.2)	(40.0)	(53.3)	(12.6)	(25.0)	(36.5)	(49.3)	4.1	(47.0)	105%		
Gross profit	6.5	13.6	20.6	27.8	6.4	14.3	21.9	28.9	1.1	29.0	100%		
Selling, general and administrative expenses	(4.2)	(8.8)	(13.2)	(17.6)	(4.5)	(9.4)	(13.7)	(17.9)	(0.3)	(18.0)	99%		
Research and development expenses	(0.8)	(1.6)	(2.3)	(3.1)	(0.7)	(1.5)	(2.2)	(2.9)	0.1	(3.0)	98%		
Core operating profit	1.5	3.2	5.2	7.2	1.2	3.4	6.0	8.1	0.9	8.0	102%		

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

* The figures represent amounts before elimination of inter-segment transactions.

IV. Revenue from Main Products of Pharmaceuticals Segment (IFRS)

<Accumulative>

Unit: Billions of yen

Indication / Product name		FY 2017 results				FY 2018 results							FY 2019 forecasts	
		Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Change amount	Jan - Dec latest forecasts	% of forecasts	Jan - Dec	%
Japan	Renal anemia treatment drug Nesp	12.5	26.6	41.0	56.3	12.0	25.6	39.2	53.7	(2.6)	52.4	102%	48.4	90%
	Secondary hyperparathyroidism Regpara	4.6	9.4	13.9	18.5	3.6	7.8	10.7	13.3	(5.3)	13.2	100%	5.1	38%
	Secondary hyperparathyroidism Orkedia	-	-	-	-	-	0.4	1.1	2.4	2.4	3.5	68%	9.5	397%
	Secondary hyperparathyroidism Rocaltrol	0.9	1.9	3.0	4.1	0.9	1.9	2.8	3.8	(0.3)	3.5	107%	3.6	96%
	Type-2 diabetes Onglyza	1.6	3.4	5.2	7.3	1.6	3.6	5.4	7.4	0.1	7.6	98%	7.6	102%
	Cardiovascular (Hypertension & angina pectoris) Coniel	1.6	3.2	4.7	6.3	1.2	2.5	3.6	4.8	(1.5)	4.9	99%	3.9	81%
	Agent for decreasing the incidence of febrile neutropenia G-Lasta	3.8	8.2	12.8	18.1	4.3	9.5	14.8	20.7	2.6	20.1	103%	22.8	110%
	Transdermal persistent pain Fentos	1.3	2.9	4.3	6.0	1.2	2.6	4.0	5.4	(0.6)	5.7	94%	4.8	89%
	Anticancer Poteligeo	0.4	0.9	1.4	1.9	0.4	0.9	1.3	1.8	(0.1)	1.8	100%	1.7	96%
	Anticancer Rituximab BS [KHK]	-	-	-	-	0.3	1.1	2.4	4.3	4.3	3.2	135%	8.4	195%
	Chronic idiopathic thrombocytopenic purpura Romipate	0.8	1.6	2.5	3.4	0.7	1.5	2.4	3.2	(0.2)	3.4	95%	4.4	136%
	Antiallergenic Allelock	5.6	9.1	12.2	15.9	4.6	7.5	9.7	12.6	(3.3)	11.7	107%	9.3	74%
	Antiallergic eyedrops Patanol	7.0	8.8	10.8	12.8	7.7	9.7	11.5	13.4	0.6	12.1	111%	11.3	84%
	Ulcerative colitis Asacol	1.0	2.1	3.2	4.2	0.7	1.5	2.2	2.9	(1.3)	3.4	86%	2.2	77%
	Psoriasis vulgaris Dovobet	1.2	2.7	3.9	5.3	1.2	2.8	4.2	5.9	0.6	6.2	96%	7.8	132%
	Psoriasis Lumicef	0.1	0.2	0.5	1.0	0.4	0.9	1.4	2.0	1.0	2.7	74%	2.7	134%
	Parkinson's disease Nouria	1.8	4.0	6.1	8.5	1.9	4.4	6.8	9.4	0.9	9.4	99%	10.0	107%
	Antiepileptic Depakene	1.6	3.2	4.8	6.5	1.3	2.7	4.0	5.3	(1.2)	5.4	99%	4.3	82%
	Technology out-licensing	0.8	2.0	2.8	2.4	1.1	1.5	2.2	2.7	0.3	4.6	60%	4.4	162%
International	X-linked hypophosphatemia (XLH) Crysvita	-	-	-	-	-	0.8	3.2	7.7	7.7				
	Anticancer POTELIGEO	-	-	-	-	-	-	-	2.1	2.1			10.0	478%
	Cancer pain Abstral	2.9	5.7	8.8	11.9	3.4	6.5	9.5	12.8	0.8	13.2	96%	12.3	96%
	Cancer pain PecFent	1.1	2.0	3.1	4.1	1.0	2.0	3.2	4.4	0.4	5.2	85%	5.0	113%
	Chemotherapy-induced nausea and vomiting drug Sancuso	0.6	1.3	2.0	3.0	0.6	1.3	2.1	3.0	(0.0)	2.8	107%	2.9	99%
	Opioid-induced constipation (OIC) Moventig	0.2	0.3	0.5	0.8	0.3	0.6	1.0	1.4	0.6	2.4	58%	2.5	174%
	Replacement therapy with testosterone for male hypogonadism Tostran/Fortesta	0.4	1.1	1.7	2.2	0.6	1.4	2.1	2.8	0.6	2.1	136%	1.9	68%
	Osteoporosis drug Adcal-D3	0.8	1.7	2.6	3.6	0.9	1.8	2.7	3.5	(0.1)	3.3	104%	3.1	90%
	Anticancer Mitomycin-C	0.8	1.6	2.5	3.4	0.6	1.3	1.7	2.3	(1.1)	2.0	120%	2.1	88%
	Renal anemia treatment drug Nesp	1.4	2.9	4.3	5.7	1.5	3.1	4.7	6.4	0.7	5.8	110%	5.9	93%
	Secondary hyperparathyroidism Regpara	0.5	1.1	1.6	2.2	0.7	1.5	2.3	3.2	1.0	2.8	116%	3.7	114%
	Agent for decreasing the incidence of febrile neutropenia Neulasta/Peglasta	0.5	1.0	1.5	2.0	0.4	1.0	1.7	2.4	0.4	2.0	122%	4.2	173%
	Neutropenia treatment drug Gran	1.0	2.3	3.8	5.2	1.4	2.7	4.2	5.4	0.2	4.4	122%	5.6	104%
	Technology out-licensing	8.0	9.5	10.8	16.0	6.5	12.4	13.9	15.8	(0.2)	17.3	91%	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.

IV. Revenue from Main Products of Pharmaceuticals Segment (IFRS)

<Quarterly>

Unit: Billions of yen

Indication / Product name		FY 2017 results				FY 2018 results				
		Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Change amount
Japan	Renal anemia treatment drug Nesp	12.5	14.2	14.4	15.3	12.0	13.6	13.6	14.5	(0.8)
	Secondary hyperparathyroidism Regpara	4.6	4.8	4.5	4.7	3.6	4.2	2.9	2.6	(2.1)
	Secondary hyperparathyroidism Orkedia	-	-	-	-	-	0.4	0.8	1.3	1.3
	Secondary hyperparathyroidism Rocaltrol	0.9	1.0	1.0	1.1	0.9	1.0	0.9	1.0	(0.1)
	Type-2 diabetes Onglyza	1.6	1.8	1.9	2.1	1.6	1.9	1.8	2.1	(0.0)
	Cardiovascular (Hypertension & angina pectoris) Coniel	1.6	1.6	1.5	1.6	1.2	1.3	1.1	1.2	(0.4)
	Agent for decreasing the incidence of febrile neutropenia G-Lasta	3.8	4.3	4.6	5.3	4.3	5.1	5.3	5.9	0.6
	Transdermal persistent pain Fentos	1.3	1.6	1.4	1.6	1.2	1.4	1.4	1.4	(0.2)
	Anticancer Poteligeo	0.4	0.5	0.4	0.5	0.4	0.5	0.4	0.5	(0.0)
	Anticancer Rituximab BS [KHK]	-	-	-	-	0.3	0.8	1.3	1.8	1.8
	Chronic idiopathic thrombocytopenic purpura Romiplate	0.8	0.9	0.8	0.9	0.7	0.8	0.8	0.9	(0.0)
	Antiallergenic Allelock	5.6	3.5	3.0	3.7	4.6	2.9	2.3	2.8	(0.9)
	Antiallergic eyedrops Patanol	7.0	1.8	1.9	2.1	7.7	2.0	1.7	1.9	(0.1)
	Ulcerative colitis Asacol	1.0	1.1	1.1	1.1	0.7	0.8	0.7	0.7	(0.4)
	Psoriasis vulgaris Dovobet	1.2	1.4	1.2	1.4	1.2	1.6	1.4	1.7	0.3
	Psoriasis Lumicef	0.1	0.1	0.3	0.4	0.4	0.5	0.5	0.6	0.2
	Parkinson's disease Nouria	1.8	2.1	2.1	2.4	1.9	2.5	2.4	2.6	0.2
	Antiepileptic Depakene	1.6	1.7	1.6	1.7	1.3	1.4	1.3	1.3	(0.3)
	Technology out-licensing	0.8	1.2	0.8	(0.5)	1.1	0.4	0.8	0.5	1.0
International	X-linked hypophosphatemia (XLH) Crysvita	-	-	-	-	-	0.8	2.4	4.5	4.5
	Anticancer POTELIGEO	-	-	-	-	-	-	-	2.1	2.1
	Cancer pain Abstral	2.9	2.8	3.1	3.1	3.4	3.1	3.1	3.2	0.1
	Cancer pain PecFent	1.1	0.9	1.1	1.0	1.0	1.0	1.2	1.2	0.2
	Chemotherapy-induced nausea and vomiting drug Sancuso	0.6	0.7	0.7	1.0	0.6	0.7	0.8	0.9	(0.1)
	Opioid-induced constipation (OIC) Moventig	0.2	0.1	0.2	0.3	0.3	0.3	0.4	0.4	0.1
	Replacement therapy with testosterone for male hypogonadism Tostran/Fortesta	0.4	0.6	0.6	0.5	0.6	0.8	0.7	0.7	0.2
	Osteoporosis drug Adcal-D3	0.8	0.9	0.9	1.0	0.9	0.9	0.9	0.8	(0.2)
	Anticancer Mitomycin-C	0.8	0.8	0.9	1.0	0.6	0.6	0.5	0.6	(0.4)
	Renal anemia treatment drug Nesp	1.4	1.5	1.5	1.3	1.5	1.6	1.6	1.7	0.4
	Secondary hyperparathyroidism Regpara	0.5	0.5	0.6	0.6	0.7	0.8	0.9	0.9	0.3
	Agent for decreasing the incidence of febrile neutropenia Neulasta/Peglasta	0.5	0.5	0.5	0.5	0.4	0.6	0.7	0.7	0.2
	Neutropenia treatment drug Gran	1.0	1.3	1.5	1.3	1.4	1.3	1.5	1.2	(0.1)
	Technology out-licensing	8.0	1.6	1.3	5.2	6.5	5.9	1.5	1.9	(3.3)

* 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).

* 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

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antibody



protein



small molecule

As of Dec. 31, 2018

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)	NDA in preparation in CN	Kirin-Amgen	
				Renal Anemia	Filed in ID		
Oncology		KW-0761 Mogamulizumab Injection	Anti-CCR4 Humanized Antibody	Mycosis Fungoides and Sézary Syndrome	Approved in EU	In-House	POTELLIGENT®
Immunology/A llergy		KHK4827 Brodalumab Injection	Anti-IL-17 Receptor A Fully Human Antibody	Psoriasis	Filed in KR	Kirin-Amgen	
					Filed in SG		
					Filed in MY		
					Filed in HK		
Central Nervous System		KW-6002 Istradefylline Oral	Adenosine A _{2A} Receptor Antagonist	Parkinson's Disease	NDA in preparation in US	In-House	
Other		©KRN23 Burosumab Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemia (XLH)	Approved in CA	In-House	Human Antibody-Producing Technology Jointly Developed with Ultragenyx in US and EU
					Filed in IL		
					Filed in CH		
					Filed 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	
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/A llergy		©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		
		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		
		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	Phase II/III in KR	Kirin-Amgen	
				Idiopathic (Immune) Thrombocytopenic Purpura	Phase III in CN		








Updated since Sep. 30, 2018 (Area, Stage, Filed, Approved, etc.)
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V. R&D Pipeline

Ph I

 antibody
  protein
  small molecule




As of Dec. 31, 2018

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/ Allergy		©KHK4083 Injection	Anti-OX40 Fully Human Antibody	Ulcerative Colitis	Phase I in JP	In-House	POTELLIGENT® Human Antibody-Producing Technology
		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	Licensed from Immunas Pharma	
					Phase I in JP		
Others		KW-3357 Antithrombin Gamma Injection	Recombinant Human Antithrombin	Disseminated Intravascular Coagulation, Congenital Antithrombin Deficiency	Phase I in EU	In-House	

 Updated since Sep. 30, 2018 (Area, Stage, Filed, Approved, etc.)
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Updated since Sep. 30, 2018 (Area, Stage, Filed, Approved, etc.)

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Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Oncology		KW-0761 Mogamulizumab Injection	Anti-CCR4 Humanized Antibody	Mycosis Fungoides and Sézary Syndrome	Approved in EU	In-House	POTELLIGENT®
Other		©KRN23 Burosumab Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemia (XLH)	Approved in CA	In-House	Human Antibody-Producing Technology Jointly Developed with Ultragenyx in US and EU
					Filed in IL		
					Filed in CH		
					Filed in AE		
Immunology/ Allergy		©KHK4083 Injection	Anti-OX40 Fully Human Antibody	Atopic Dermatitis	Phase II in JP, US, CA and EU	In-House	POTELLIGENT® Human Antibody-Producing Technology

<Appendix> Fujifilm Kyowa Kirin Biologics co. Ltd., Pipeline of Biosimilar

As of December 31th 2018

Code Name	Generic Name	Stage	Remarks
FKB327	Adalimumab (fully human anti-TNF- α monoclonal antibody)	Launched in EU (partnership with Mylan) NDA in preparation in Others	Fujifilm Kyowa Kirin Biologics Co., Ltd.
FKB238	Bevacizumab (humanized anti-VEGF monoclonal antibody)	Phase III in US, Europe and others	Centus Biotherapeutics Ltd. (*)

* Centus Biotherapeutics Ltd. is a fifty-fifty joint venture between Fujifilm Kyowa Kirin Biologics Co., Ltd. and AstraZeneca.