

Listed Company Name: Kyowa Hakko Kirin Co., Ltd.

Representative: Nobuo Hanai, President and CEO

(Code no.: 4151, First Section of TSE)

Inquiries: Shigeru Morotomi, Executive Officer

Corporate Communications Department

Telephone: +81-3-3282-0009

Notice of revisions to the Appendix to the Fiscal 2013 Third Quarter Consolidated Financial Statements

Figures for Sales of main products, in the Appendix to the Fiscal 2013 Third Quarter Consolidated Financial Statements issued at 13:30 on October 25, 2013, have been revised as follows. Amended figures have been underlined.

Page 6: Section IV. Kyowa Hakko Kirin, Sales of main products

Accumulative

Billions of yen, rounded down

	Before revision			After revision		
	FY 2013 results			FY 2013 results		
	Jan - Sep	Change Amount	%	Jan - Sep	Change Amount	%
<i>ESA formulation</i>						
Nesp	<u>39.1</u>	<u>(1.9)</u>	<u>95%</u>	<u>39.7</u>	<u>(1.3)</u>	<u>97%</u>
Nesp/Espo	<u>41.5</u>	<u>(2.4)</u>	<u>94%</u>	<u>42.1</u>	<u>(1.8)</u>	<u>96%</u>

Page 7: Section IV. Kyowa Hakko Kirin, Sales of main products

Quarterly

Billions of yen, rounded down

	Before revision			After revision		
	FY 2013 results			FY 2013 results		
	Jul - Sep	Change Amount	%	Jul - Sep	Change Amount	%
<i>ESA formulation</i>						
Nesp	<u>14.1</u>	<u>(0.0)</u>	<u>99%</u>	<u>14.7</u>	<u>0.5</u>	<u>104%</u>
Nesp/Espo	<u>14.9</u>	<u>(0.2)</u>	<u>98%</u>	<u>15.5</u>	<u>0.3</u>	<u>102%</u>

ENDS

Kyowa Hakko Kirin Co., Ltd.

Appendix to the Fiscal 2013 Third Quarter Consolidated Financial Statements

Third quarter results for Fiscal 2013
(January 1, 2013 - September 30, 2013)

- This document was made as a supplement to the Kessan Tanshin (financial report), disclosed at the Tokyo Stock Exchange on October 25, 2013, for the third quarter of Fiscal 2013, the nine-month period from January 1, 2013 to September 30, 2013.
- This document contains forward-looking statements based on a number of assumptions and beliefs made by management in light of information currently available. For a variety of reasons, actual financial results may differ materially from the forecasts presented here.
- Figures presented in this document have been rounded down to the nearest whole number.

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The average exchange rate for each period was as follows

Unit: yen

	2012 results				2013 results				2013 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Dec
US \$	79	80	79	80	89	94	95	-	95
EURO	104	103	102	103	118	123	125	-	124
GBP	125	126	125	127	141	145	147	-	145

Contact
 Kyowa Hakko Kirin Co., Ltd.
 Corporate Communications Department
 Tel 81 3 3282 0009

I. Consolidated Financial Results

1. Trends in consolidated income

Accumulative

Billions of yen, rounded down

	FY 2012 results				FY 2013 results								FY 2013 forecasts			
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	%	Jan - Jun	%	Jan - Sep	Change amount	%	Jan - Dec	%	Jan - Dec	Change Amount	%
Net sales	87.1	166.2	244.6	333.1	86.6	99%	169.7	102%	252.1	7.4	103%	-	-	339.0	5.8	102%
Gross Profit	55.0	104.3	154.3	210.6	52.3	95%	105.1	101%	157.2	2.8	102%	-	-	-	-	-
Selling, general and administrative expenses	36.9	78.7	117.0	157.7	37.8	102%	77.9	99%	115.8	(1.1)	99%	-	-	-	-	-
Operating income (prior to amortization of goodwill)	20.3	30.2	44.2	62.1	16.7	82%	31.8	105%	48.3	4.0	109%	-	-	60.2	(1.9)	97%
Operating income	18.0	25.5	37.3	52.9	14.4	80%	27.1	106%	41.4	4.0	111%	-	-	51.0	(1.9)	96%
Non-operating income	1.6	1.4	1.9	4.1	1.0	63%	2.4	169%	2.9	1.0	155%	-	-	-	-	-
Non-operating expenses	3.1	3.9	6.6	8.0	0.6	22%	3.0	78%	5.1	(1.4)	78%	-	-	-	-	-
Ordinary income	16.5	23.0	32.5	49.0	14.8	90%	26.5	115%	39.2	6.6	120%	-	-	48.0	(1.0)	98%
Extraordinary income	-	-	-	-	3.8	-	4.4	-	4.9	4.9	-	-	-	-	-	-
Extraordinary loss	0.3	0.3	1.2	3.9	-	-	0.1	38%	3.6	2.4	294%	-	-	-	-	-
Income before income taxes and minority interests	16.2	22.7	31.3	45.0	18.6	115%	30.8	136%	40.4	9.1	129%	-	-	49.0	3.9	109%
Income taxes	7.7	11.2	15.8	20.6	8.1	106%	13.1	117%	17.1	1.2	108%	-	-	-	-	-
Minority interests in income	0.0	0.0	0.0	0.2	0.0	52%	0.0	135%	0.0	0.0	142%	-	-	-	-	-
Net income	8.5	11.5	15.4	24.1	10.4	123%	17.6	153%	23.3	7.8	151%	-	-	28.0	3.8	116%
Comprehensive income	15.0	13.3	18.3	34.7	16.8	112%	28.9	217%	36.7	18.4	200%	-	-	-	-	-
EPS prior to amortization of goodwill (¥/share)	19.66	29.40	40.79	61.00	23.39	119%	40.75	139%	55.29	14.50	136%	-	-	68.06	7.06	112%

*1 "Prior to amortization of goodwill" refers to profits prior to the deduction of amortization of the goodwill *arising on the reverse acquisition in April 2008 (Kirin Pharma share transfer).

(Note: This adjustment does not include goodwill amortization in respect of the acquisition of ProStrakan.)

*2 All fiscal 2013 forecasts shown in this report are as disclosed in the Appendix to the Fiscal 2013 Interim Consolidated Financial Statements published on July 26, 2013.

Quarterly

Billions of yen, rounded down

	FY 2012 results				FY 2013 results								
	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	%	Apr - Jun	%	Jul - Sep	Change amount	%	Oct - Dec	%
Net sales	87.1	79.1	78.4	88.4	86.6	99%	83.0	105%	82.3	3.9	105%	-	-
Gross Profit	55.0	49.3	50.0	56.3	52.3	95%	52.7	107%	52.1	2.0	104%	-	-
Selling, general and administrative expenses	36.9	41.7	38.3	40.7	37.8	102%	40.0	96%	37.8	(0.4)	99%	-	-
Operating income (Prior to amortization of goodwill)	20.3	9.8	14.0	17.8	16.7	82%	15.0	152%	16.5	2.4	118%	-	-
Operating income	18.0	7.5	11.7	15.5	14.4	80%	12.7	168%	14.2	2.4	121%	-	-
Non-operating income	1.6	(0.2)	0.5	2.2	1.0	63%	1.3	-	0.5	0.0	115%	-	-
Non-operating expenses	3.1	0.7	2.7	1.3	0.6	22%	2.3	304%	2.1	(0.6)	77%	-	-
Ordinary income	16.5	6.5	9.4	16.4	14.8	90%	11.6	179%	12.6	3.1	134%	-	-
Extraordinary income	-	-	-	-	3.8	-	0.6	-	0.5	0.5	-	-	-
Extraordinary loss	0.3	-	0.9	2.7	-	-	0.1	-	3.5	2.6	384%	-	-
Income before income taxes and minority interests	16.2	6.5	8.5	13.6	18.6	115%	12.2	187%	9.6	1.0	113%	-	-
Income taxes	7.7	3.4	4.6	4.7	8.1	106%	4.9	142%	3.9	(0.6)	86%	-	-
Minority interests in income	0.0	0.0	0.0	0.1	0.0	52%	0.0	219%	0.0	0.0	157%	-	-
Net income	8.5	3.0	3.9	8.7	10.4	123%	7.1	239%	5.6	1.7	144%	-	-
EPS prior to amortization of goodwill (¥/share)	19.66	9.72	11.38	20.23	23.39	119%	17.36	179%	14.54	3.16	128%	-	-

I. Consolidated Financial Results

2. Trends in results by segment

Accumulative

Billions of yen, rounded down

	FY 2012 results				FY 2013 results								FY 2013 forecasts			
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	%	Jan - Jun	%	Jan - Sep	Change amount	%	Jan - Dec	%	Jan - Dec	Change Amount	%
Net sales	87.1	166.2	244.6	333.1	86.6	99%	169.7	102%	252.1	7.4	103%	-	-	339.0	5.8	102%
Pharmaceuticals	67.2	127.5	189.4	259.3	67.4	100%	129.9	102%	192.7	3.2	102%	-	-	258.0	(1.3)	99%
Bio-Chemicals	20.5	40.0	57.4	76.9	19.9	97%	41.2	103%	61.5	4.0	107%	-	-	84.0	7.0	109%
Total	87.8	167.6	246.9	336.3	87.4	100%	171.1	102%	254.3	7.3	103%	-	-	342.0	5.6	102%
Eliminations	(0.6)	(1.3)	(2.2)	(3.1)	(0.7)	-	(1.4)	-	(2.2)	0.0	-	-	-	(3.0)	0.1	-
Operating income	18.0	25.5	37.3	52.9	14.4	80%	27.1	106%	41.4	4.0	111%	-	-	51.0	(1.9)	96%
*Before goodwill amortization	20.3	30.2	44.2	62.1	16.7	82%	31.8	105%	48.3	4.0	109%	-	-	60.2	(1.9)	97%
Pharmaceuticals	16.7	23.5	35.1	50.7	13.0	78%	24.1	103%	36.9	1.8	105%	-	-	45.0	(5.7)	89%
Bio-Chemicals	18.8	27.8	41.5	59.3	15.2	81%	28.4	102%	43.4	1.8	104%	-	-	53.6	(5.7)	90%
	1.3	2.0	2.2	2.1	1.4	114%	3.1	152%	4.5	2.2	204%	-	-	6.0	3.8	282%
	1.4	2.3	2.6	2.7	1.6	112%	3.4	145%	4.9	2.2	186%	-	-	6.6	3.8	241%
Total	18.0	25.5	37.3	52.8	14.5	81%	27.2	106%	41.4	4.1	111%	-	-	51.0	(1.8)	96%
	20.3	30.1	44.2	62.1	16.8	83%	31.8	106%	48.4	4.1	109%	-	-	60.2	(1.8)	97%
Eliminations	0.0	0.0	0.0	0.0	(0.0)	-	(0.0)	-	(0.0)	(0.0)	-	-	-	-	(0.0)	-

*The Other segment has been discontinued from 2013. As a result, figures for 2012 results have been restated in accordance with the 2013 revised segmental classification.

Quarterly

Billions of yen, rounded down

	FY 2012 results				FY 2013 results								
	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	%	Apr - Jun	%	Jul - Sep	Change Amount	%	Oct - Dec	%
Net sales	87.1	79.1	78.4	88.4	86.6	99%	83.0	105%	82.3	3.9	105%	-	-
Pharmaceuticals	67.2	60.3	61.8	69.8	67.4	100%	62.5	104%	62.8	0.9	102%	-	-
Bio-Chemicals	20.5	19.4	17.4	19.4	19.9	97%	21.2	109%	20.3	2.9	117%	-	-
Total	87.8	79.8	79.3	89.3	87.4	100%	83.7	105%	83.2	3.9	105%	-	-
Eliminations	(0.6)	(0.6)	(0.9)	(0.8)	(0.7)	-	(0.6)	-	(0.8)	0.0	-	-	-
Operating income	18.0	7.5	11.7	15.5	14.4	80%	12.7	168%	14.2	2.4	121%	-	-
*Before goodwill amortization	20.3	9.8	14.0	17.8	16.7	82%	15.0	152%	16.5	2.4	118%	-	-
Pharmaceuticals	16.7	6.7	11.5	15.6	13.0	78%	11.0	163%	12.8	1.2	111%	-	-
Bio-Chemicals	18.8	8.9	13.7	17.7	15.2	81%	13.2	148%	14.9	1.2	109%	-	-
	1.3	0.7	0.1	(0.0)	1.4	114%	1.6	220%	1.4	1.2	811%	-	-
	1.4	0.8	0.3	0.0	1.6	112%	1.7	199%	1.5	1.2	474%	-	-
Total	18.0	7.5	11.7	15.5	14.5	81%	12.6	169%	14.2	2.4	121%	-	-
	20.3	9.8	14.0	17.8	16.8	83%	15.0	152%	16.5	2.4	118%	-	-
Eliminations	0.0	0.0	0.0	0.0	(0.0)	-	0.0	151%	(0.0)	(0.0)	-	-	-

(2) Regional sales

Billions of yen, rounded down

	FY 2012 results				FY 2013 results											
	Jan - Mar	Percentage of consolidated sales	Jan - Jun	Percentage of consolidated sales	Jan - Sep	Percentage of consolidated sales	Jan - Dec	Percentage of consolidated sales	Jan - Mar	Percentage of consolidated sales	Jan - Jun	Percentage of consolidated sales	Jan - Sep	Percentage of consolidated sales	Jan - Dec	Percentage of consolidated sales
Japan sales	68.9	79.1%	128.8	77.5%	189.9	77.6%	260.5	78.2%	66.1	76.3%	127.7	75.3%	188.9	75.0%	-	-
Overseas sales	18.1	20.9%	37.3	22.5%	54.7	22.4%	72.6	21.8%	20.5	23.7%	41.9	24.7%	63.1	25.0%	-	-
America	4.6	5.3%	10.0	6.1%	15.0	6.2%	21.2	6.4%	5.2	6.0%	11.1	6.6%	16.3	6.5%	-	-
Europe	8.4	9.7%	16.9	10.2%	24.0	9.8%	30.9	9.3%	9.4	10.9%	18.5	10.9%	28.1	11.1%	-	-
Asia	4.9	5.7%	10.0	6.1%	15.2	6.2%	19.8	6.0%	5.7	6.6%	11.8	7.0%	18.0	7.1%	-	-
Other regions	0.1	0.1%	0.2	0.2%	0.4	0.2%	0.5	0.2%	0.1	0.2%	0.3	0.2%	0.6	0.3%	-	-
Total consolidated net sales	87.1	100%	166.2	100%	244.6	100%	333.1	100%	86.6	100%	169.7	100%	252.1	100%	-	-

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

I. Consolidated Financial Results

3. Other trends

(1) R&D Expenses

Billions of yen, rounded down

	FY 2012 results				FY 2013 results				FY 2013 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Dec
R&D expenses	11.0	22.1	33.6	44.8	10.6	21.0	30.7	-	42.7
<i>R&D to net sales ratio</i>	12.7%	13.3%	13.8%	13.4%	12.3%	12.4%	12.2%	-	12.6%
Pharmaceuticals	10.3	20.5	31.3	41.3	9.8	19.3	28.3	-	39.5
<i>R&D to net sales ratio</i>	15.3%	16.1%	16.5%	15.9%	14.7%	14.9%	14.7%	-	15.3%
Bio-Chemicals	0.7	1.5	2.3	3.4	0.7	1.6	2.4	-	3.2

(2) Capital Expenditure (Tangible fixed assets)

Billions of yen, rounded down

	FY 2012 results				FY 2013 results				FY 2013 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Dec
Capital expenditure	4.1	7.9	14.7	19.7	5.3	9.6	16.6	-	24.5
Pharmaceuticals	2.1	4.0	7.3	10.3	1.8	4.4	7.4	-	12.4
Bio-Chemicals	1.9	3.9	7.4	9.4	3.5	5.1	9.2	-	12.1

(3) Depreciation Expenses (Tangible and intangible fixed assets)

Billions of yen, rounded down

	FY 2012 results				FY 2013 results				FY 2013 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Dec
Depreciation and amortization expenses	4.6	9.6	14.5	20.9	4.8	9.9	15.5	-	21.7
<i>Amortization of intangible fixed assets</i>	1.0	2.4	3.5	5.4	1.5	3.1	4.9	-	6.6
Pharmaceuticals	3.1	6.6	10.1	14.5	3.3	6.8	10.7	-	15.1
<i>Amortization of intangible fixed assets</i>	1.0	2.4	3.5	5.4	1.5	3.1	4.9	-	6.6
Bio-Chemicals	1.5	2.9	4.4	6.2	1.5	3.0	4.7	-	6.6

*Depreciation expenses for intangible fixed assets do not include goodwill amortization expenses

(4) Goodwill Amortization Expenses

Billions of yen, rounded down

	FY 2012 results				FY 2013 results				FY 2013 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Dec
Amortization expenses	3.0	6.0	9.1	12.0	2.8	5.7	8.6	-	11.5
<i>Reverse acquisition goodwill amortization expenses</i>	2.3	4.6	6.9	9.2	2.3	4.6	6.9	-	9.2
Pharmaceuticals	2.9	5.7	8.6	11.4	2.7	5.4	8.1	-	10.8
<i>Reverse acquisition goodwill amortization expenses</i>	2.1	4.3	6.4	8.6	2.1	4.3	6.4	-	8.6
Bio-Chemicals	0.1	0.3	0.4	0.6	0.1	0.3	0.4	-	0.6
<i>Reverse acquisition goodwill amortization expenses</i>	0.1	0.3	0.4	0.6	0.1	0.3	0.4	-	0.6

*Reverse acquisition goodwill amortization expenses" refers to amortization of goodwill arising on the reverse acquisition in April 2008 (Kirin Pharma share transfer).

II. Consolidated Balance Sheets

Billions of yen, rounded down

	2011	2012				2013				
	Dec 31	Mar 31	June 30	Sep 30	Dec 31	Mar 31	June 30	Sep 30	Change previous year end	Dec 31
Assets	658.8	664.7	659.0	656.9	679.3	694.1	691.4	691.2	11.9	-
Current assets	284.2	289.2	285.4	283.0	303.9	310.0	306.5	305.5	1.5	-
Cash and deposits	27.0	28.6	27.7	26.5	21.5	23.2	24.8	21.4	(0.1)	-
Notes and accounts receivable-trade	99.1	107.4	93.9	92.3	101.5	103.5	98.5	92.0	(9.5)	-
Inventories	58.9	62.5	61.9	62.9	63.4	68.7	70.9	72.8	9.3	-
Deferred tax assets	8.6	8.9	9.0	9.0	10.3	10.6	10.6	10.7	0.3	-
Short-term loans receivable	82.9	74.0	84.6	84.0	98.1	97.3	94.1	101.1	2.9	-
Other	7.4	7.5	8.1	8.1	8.8	6.5	7.3	7.4	(1.4)	-
Noncurrent assets	374.6	375.5	373.6	373.8	375.3	384.0	384.8	385.7	10.4	-
Property, plant and equipment	122.9	123.9	123.4	126.1	126.8	129.6	130.2	133.4	6.5	-
Buildings and structures	37.3	36.9	38.3	37.8	40.7	40.5	40.4	40.4	(0.3)	-
Machinery, equipment and vehicles	19.0	18.3	17.4	16.7	19.3	19.0	19.8	19.5	0.1	-
Land	53.9	53.9	53.6	53.5	53.3	55.2	54.8	54.6	1.2	-
Other	12.6	14.7	14.0	17.9	13.3	14.7	15.1	18.7	5.4	-
Intangible assets	210.6	211.3	209.8	208.2	207.5	214.5	212.9	210.9	3.4	-
Goodwill	177.2	176.8	172.2	169.9	168.8	166.7	165.2	163.7	(5.0)	-
Marketing rights	29.0	30.3	33.8	34.9	36.2	45.5	45.5	45.2	9.0	-
Other	4.3	4.0	3.7	3.4	2.4	2.2	2.1	1.9	(0.5)	-
Investments and other assets	41.0	40.2	40.3	39.4	40.9	39.9	41.7	41.3	0.4	-
Investment securities	24.8	24.2	23.6	22.5	23.6	22.9	24.7	24.0	0.3	-
Deferred tax assets	6.6	6.5	7.1	7.3	7.7	6.7	6.3	6.4	(1.2)	-
Other	9.5	9.4	9.4	9.5	9.5	10.2	10.6	10.9	1.3	-
Liabilities	118.8	122.7	118.6	117.3	123.4	126.9	112.0	110.9	(12.5)	-
Current liabilities	78.3	79.9	79.3	77.5	85.7	89.9	77.3	73.1	(12.6)	-
Notes and accounts payable-trade	27.3	30.3	23.2	24.1	26.3	30.5	23.4	17.9	(8.3)	-
Short-term loans payable	5.9	6.0	5.8	5.6	5.6	5.7	5.8	5.5	(0.1)	-
Accounts payable-other	31.0	23.0	30.1	26.6	29.0	32.5	26.5	26.4	(2.5)	-
Income taxes payable	7.8	8.7	12.3	9.6	15.7	8.0	12.8	11.2	(4.5)	-
Provision	0.9	4.9	0.8	4.8	1.2	5.1	1.2	5.2	4.0	-
Other	5.2	6.9	6.8	6.5	7.7	7.8	7.4	6.7	(1.0)	-
Noncurrent liabilities	40.4	42.7	39.3	39.7	37.6	36.9	34.6	37.7	0.1	-
Long-term loans payable	0.0	0.1	0.0	0.0	-	-	-	-	-	-
Deferred tax liabilities	10.9	11.3	10.8	10.6	11.2	11.3	11.5	11.4	0.1	-
Provision	21.4	21.0	20.6	20.4	19.9	19.5	19.6	22.9	2.9	-
Other	7.9	10.2	7.8	8.5	6.4	6.0	3.4	3.4	(3.0)	-
Net assets	540.0	542.0	540.3	539.6	555.8	567.2	579.3	580.3	24.4	-
Shareholders' equity	554.8	550.4	553.4	551.9	560.6	565.6	572.8	571.6	10.9	-
Capital stock	26.7	26.7	26.7	26.7	26.7	26.7	26.7	26.7	-	-
Capital surplus	512.3	512.3	512.3	512.3	512.3	512.3	512.3	512.3	(0.0)	-
Retained earnings	34.9	37.9	40.9	39.3	48.1	53.1	60.3	59.1	11.0	-
Treasury stock	(19.1)	(26.5)	(26.5)	(26.5)	(26.5)	(26.5)	(26.5)	(26.5)	(0.0)	-
Accumulated other comprehensive income	(15.9)	(9.5)	(14.2)	(13.1)	(5.7)	0.4	5.2	7.4	13.2	-
Valuation difference on available-for-sale securities	(3.1)	(1.9)	(2.8)	(2.2)	(2.2)	(0.0)	0.9	1.0	3.3	-
Foreign currency translation adjustment	(12.8)	(7.6)	(11.3)	(10.9)	(3.5)	0.4	4.2	6.3	9.8	-
Subscription rights to shares	0.2	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.0	-
Minority interests	0.9	0.9	0.9	0.7	0.8	0.9	1.0	1.0	0.2	-
Total liabilities and net assets	658.8	664.7	659.0	656.9	679.3	694.1	691.4	691.2	11.9	-

III. Consolidated Subsidiaries and Affiliates

(As of September 30, 2013)

Segment	Type	Region	Company name	Percentage owned (direct and indirect)	Principal business
Pharmaceuticals	Consolidated subsidiary	Japan	Kyowa Medex Co., Ltd.	100.0%	Manufacture and sale of diagnostic reagents
			Kyowa Medical Promotion Co., Ltd.	100.0%	Promotion and sales of pharmaceuticals
			Chiyoda Kaihatsu Co., Ltd. *1	100.0%	Contracting, wholesale and retail and insurance agency business
		The Americas	Kyowa Hakko Kirin America, Inc.	100.0%	Holding company for administration and management of subsidiaries (US)
			BioWa, Inc.	100.0%	Out-licensing of anti-body technology and accelerating research collaborations (US)
			Kyowa Hakko Kirin Pharma, Inc.	100.0%	Development of outsourced pharmaceutical products (US)
			Kyowa Hakko Kirin California, Inc.	100.0%	Generate new candidate substances and develop pharmaceuticals (US)
			Hematech, Inc.	100.0%	(Company to be discontinued)
			ProStrakan Inc.	100.0%	Sales of pharmaceuticals (US)
			Europe	ProStrakan Group plc	100.0%
		Strakan International S.a.r.l.		100.0%	Sales, licensing-in and licensing-out of pharmaceuticals (UK)
		Strakan Pharmaceuticals Limited		100.0%	Development of pharmaceuticals (UK)
		ProStrakan Limited		100.0%	Sales of pharmaceuticals (UK)
		ProStrakan Pharma S.A.S		100.0%	Sales of pharmaceuticals (France)
		ProStrakan Farmaceutica SLU		100.0%	Sales of pharmaceuticals (Spain)
		ProStrakan Pharma GmbH		100.0%	Sales of pharmaceuticals (Germany)
		ProStrakan Holdings B.V.		100.0%	Holding company for special companies (Netherlands)
		ProStrakan Pharma B.V.		100.0%	Sales of pharmaceuticals (Netherlands)
		Asia	ProStrakan S.r.l.	100.0%	Sales of pharmaceuticals (Italy)
	ProStrakan AB		100.0%	Sales of pharmaceuticals (Sweden)	
	Kyowa Hakko Kirin China Pharmaceutical Co., Ltd.		100.0%	Manufacture and sale of pharmaceuticals (China)	
	Kyowa Hakko Kirin Korea Co., Ltd.		100.0%	Sales of pharmaceuticals (Korea)	
	Kyowa Hakko Kirin (Taiwan) Co., Ltd.		100.0%	Sales of pharmaceuticals (Taiwan)	
Affiliate accounted for by the equity method	Japan	Kyowa Hakko Kirin (Hong Kong) Co., Ltd.	100.0%	Sales of pharmaceuticals (Hong Kong)	
		Kyowa Hakko Kirin (Singapore) Pte. Ltd.	100.0%	Research and sale of pharmaceuticals (Singapore)	
Bio-Chemicals	Consolidated subsidiary	Japan	FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.	50.0%	Development, manufacture and sale of biosimilar pharmaceuticals
			Japan Synthetic Alcohol Co., Ltd. *1□	33.3%	Manufacture and sale of industrial alcohol
			Kyowa Hakko Bio Co., Ltd.	100.0%	Manufacture and sale of pharmaceutical and industrial raw materials, and health care products
		The Americas	Daiichi Fine Chemical Co., Ltd.	100.0%	Manufacture and sale of active pharmaceutical ingredients and pharmaceutical intermediates
			Kyowa Engineering Co., Ltd.	100.0%	Design and installation of plant facilities and equipment
			BioKyowa Inc.	100.0%	Manufacture and sale of amino acids (US)
		Europe	Kyowa Hakko U.S.A., Inc.	100.0%	Sale and import/export of fine chemicals including amino acids (US)
			Kyowa Hakko Bio U.S. Holdings, Inc.	100.0%	Holding company for administration and management of US special companies (US)
			Kyowa Hakko Europe GmbH	100.0%	Sale and import/export of fine chemicals including amino acids (Germany)
			Kyowa Hakko Bio Italia S.r.l.	100.0%	Sale and import/export of fine chemicals including amino acids (Italy)
		Asia	Shanghai Kyowa Amino Acid Co., Ltd.	70.0%	Manufacture and sale of amino acids (China)
			Thai Kyowa Biotechnologies Co., Ltd.	100.0%	Manufacture and sale of amino acids (Thailand)
			Kyowa Hakko (H.K.) Co., Ltd.	100.0%	Sale and import/export of fine chemicals including amino acids (Hong Kong)
Kyowa Hakko Bio Singapore Pte. Ltd.	100.0%		Sale and import/export of fine chemicals including amino acids (Singapore)		

Changes in scope of consolidation resulting in changes in subsidiaries (2013.1.1~2013.9.30)

New: None

Exclusions: One: Kyowa Hakko Wellness (see Note 2)

Notes: 1. As a result of the discontinuation of the 'Other' segment from 2013 Chiyoda Kaihatsu Co., and Japan Synthetic Alcohol Co., Ltd. have been included in the Pharmaceutical segment.
2. Kyowa Hakko Wellness no longer exists following its merger with Kyowa Hakko Bio on January 1, 2013.

IV. Kyowa Hakko Kirin Sales of main products

Accumulative

Billions of yen, rounded down

	FY 2012 results				FY 2013 results								FY 2013 forecasts		
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	%	Jan - Jun	%	Jan - Sep	Change Amount	%	Jan - Dec	%	Jan - Dec	%
Kyowa Hakko Kirin total	57.8	107.8	159.4	218.1	56.4	98%	106.4	99%	157.0	(2.4)	98%	-	-	208.5	96%
Indication / Product name															
<i>ESA formulation</i> Nesp	13.8	26.8	41.0	58.1	10.6	77%	25.0	93%	39.7	(1.3)	97%	-	-	54.7	94%
<i>ESA formulation</i> Espo	0.9	1.9	2.9	3.9	0.7	71%	1.5	80%	2.3	(0.5)	81%	-	-	3.2	82%
Nesp/Espo	14.8	28.8	43.9	62.0	11.3	77%	26.5	92%	42.1	(1.8)	96%	-	-	58.0	93%
<i>Secondary hyperparathyroidism</i> Regpara	2.8	6.2	9.5	13.4	3.0	110%	6.9	111%	10.6	1.1	112%	-	-	14.4	107%
<i>Secondary hyperparathyroidism</i> Rocaltrol	0.7	1.6	2.5	3.6	0.7	104%	1.8	108%	2.8	0.2	110%	-	-	3.8	106%
<i>Antiallergenic</i> Allelock	9.9	16.1	21.8	29.9	10.7	109%	15.9	99%	20.9	(0.9)	96%	-	-	27.5	92%
<i>Antiallergenic</i> Celect	0.5	1.0	1.4	1.9	0.4	89%	0.8	85%	1.2	(0.2)	86%	-	-	1.6	88%
<i>Antiallergic eyedrops</i> Patanol	5.4	6.9	8.5	10.2	9.4	172%	10.1	146%	11.4	2.9	134%	-	-	13.5	132%
<i>G-CSF</i> Gran	2.9	6.4	9.8	13.5	2.5	87%	5.8	91%	9.0	(0.8)	92%	-	-	12.3	91%
<i>Transdermal persistent cancer pain</i> Fentos	0.8	2.0	3.2	4.6	1.0	118%	2.3	115%	3.7	0.4	115%	-	-	5.4	116%
<i>Anticancer</i> 5-FU	0.6	1.4	2.1	2.8	0.6	90%	1.3	95%	2.0	(0.0)	96%	-	-	2.6	94%
<i>Anticancer</i> Navelbine	0.3	0.6	0.9	1.3	0.2	79%	0.5	82%	0.8	(0.1)	83%	-	-	1.0	80%
<i>Chronic idiopathic thrombocytopenic purpura</i> Romiplate	0.3	0.7	1.2	1.7	0.4	138%	1.1	142%	1.7	0.5	142%	-	-	2.3	130%
<i>Cardiovascular</i> Coniel	4.2	8.5	12.5	17.1	3.5	84%	7.6	89%	11.3	(1.1)	90%	-	-	15.3	90%
<i>Cardiovascular (Hypertension)</i> Coversyl	0.8	1.7	2.5	3.5	0.7	95%	1.6	96%	2.5	(0.0)	98%	-	-	3.2	91%
<i>Cardiovascular</i> Inovan / Pre Dopa *1	0.6	1.1	1.7	2.4	0.4	76%	0.8	76%	1.3	(0.4)	76%	-	-	1.8	77%
<i>Antiepileptic</i> Depakene	2.4	5.2	7.8	10.7	2.3	95%	5.0	97%	7.7	(0.1)	99%	-	-	10.4	98%
<i>Parkinson's disease</i> Permax	0.3	0.8	1.2	1.7	0.3	76%	0.6	74%	0.9	(0.3)	75%	-	-	1.3	77%
<i>Gastrointestinal</i> Nauzelin	1.1	2.2	3.2	4.9	1.0	95%	2.1	95%	3.1	(0.1)	96%	-	-	4.7	94%
<i>Inflammatory bowel disease</i> Asacol	0.8	1.8	2.8	4.1	1.0	135%	2.4	134%	3.8	0.9	135%	-	-	4.9	122%
Exports and Technology Out-Licensing															
Exports	3.1	5.7	7.5	9.4	3.2	103%	5.4	96%	8.1	0.5	107%	-	-	9.8	104%
Technology Out-Licensing	8.1	12.0	18.9	24.4	4.8	60%	9.7	81%	13.8	(5.1)	73%	-	-	14.9	61%

*1 Sales of Pre Dopa terminated on February 28, 2013. As a result Inovan/ Pre Dopa from March 2013 are figures for Inovan only.

IV. Kyowa Hakko Kirin Sales of main products

Quarterly

Billions of yen, rounded down

	FY 2012 results				FY 2013 results								
	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	%	Apr - Jun	%	Jul - Sep	Change Amount	%	Oct - Dec	%
Kyowa Hakko Kirin total	57.8	49.9	51.6	58.6	56.4	98%	50.0	100%	50.5	(1.0)	98%	-	-
Indication / Product name													
<i>ESA formulation</i>													
Nesp	13.8	12.9	14.2	17.0	10.6	77%	14.3	111%	14.7	0.5	104%	-	-
<i>ESA formulation</i>													
Espo	0.9	0.9	0.9	0.9	0.7	71%	0.8	89%	8.0	(0.1)	84%	-	-
Nesp/Espo	14.8	13.9	15.1	18.0	11.3	77%	15.2	109%	15.5	0.3	102%	-	-
<i>Secondary hyperparathyroidism</i>													
Regpara	2.8	3.4	3.3	3.8	3.0	110%	3.8	111%	3.7	0.4	114%	-	-
<i>Secondary hyperparathyroidism</i>													
Rocaltrol	0.7	0.9	0.9	1.0	0.7	104%	1.0	111%	1.0	0.1	115%	-	-
<i>Antiallergenic</i>													
Allelock	9.9	6.2	5.7	8.0	10.7	109%	5.2	84%	4.9	(0.7)	87%	-	-
<i>Antiallergenic</i>													
Cellect	0.5	0.4	0.3	0.4	0.4	89%	0.4	81%	0.3	(0.0)	87%	-	-
<i>Antiallergic eyedrops</i>													
Patanol	5.4	1.4	1.6	1.7	9.4	172%	0.6	46%	1.3	(0.2)	83%	-	-
<i>G-CSF</i>													
Gran	2.9	3.4	3.4	3.7	2.5	87%	3.2	94%	3.1	(0.2)	93%	-	-
<i>Transdermal persistent cancer pain</i>													
Fentos	0.8	1.1	1.1	1.4	1.0	118%	1.3	112%	1.3	0.1	116%	-	-
<i>Anticancer</i>													
5-FU	0.6	0.7	0.6	0.7	0.6	90%	0.7	100%	0.6	(0.0)	98%	-	-
<i>Anticancer</i>													
Navelbine	0.3	0.3	0.3	0.3	0.2	79%	0.2	85%	0.2	(0.0)	85%	-	-
<i>Chronic idiopathic thrombocytopenic purpura</i>													
Romiplate	0.3	0.4	0.4	0.5	0.4	138%	0.6	145%	0.6	0.1	143%	-	-
<i>Cardiovascular</i>													
Coniel	4.2	4.3	4.0	4.5	3.5	84%	4.0	93%	3.7	(0.2)	94%	-	-
<i>Cardiovascular (Hypertension)</i>													
Coversyl	0.8	0.9	0.8	0.9	0.7	95%	0.9	96%	0.8	0.0	102%	-	-
<i>Cardiovascular</i>													
Inovan / Pre Dopa *1	0.6	0.5	0.5	0.6	0.4	76%	0.4	76%	0.4	(0.1)	77%	-	-
<i>Antiepileptic</i>													
Depakene	2.4	2.7	2.5	2.9	2.3	95%	2.7	99%	2.6	0.0	102%	-	-
<i>Parkinson's disease</i>													
Permax	0.3	0.4	0.4	0.4	0.3	76%	0.3	73%	0.3	(0.0)	76%	-	-
<i>Gastrointestinal</i>													
Nauzelin	1.1	1.1	0.9	1.7	1.0	95%	1.1	94%	0.9	(0.0)	99%	-	-
<i>Inflammatory bowel disease</i>													
Asacol	0.8	1.0	1.0	1.2	1.0	135%	1.3	134%	1.4	0.3	136%	-	-
Exports and Technology Out-Licensing													
Exports	3.1	2.5	1.8	1.8	3.2	103%	2.2	88%	2.6	0.7	142%	-	-
Technology Out-Licensing	8.1	3.8	6.9	5.5	4.8	60%	4.8	126%	4.0	(2.8)	59%	-	-

*1 Sales of Pre Dopa terminated on February 28, 2013. As a result Inovan/ Pre Dopa from March 2013 are figures for Inovan only.

V. Segment information and main subsidiaries operating profit or loss

1. Pharmaceuticals segment

(1) Pharmaceuticals segment total

Billions of yen, rounded down

	FY 2012 results				FY 2013 results								FY 2013 forecasts		
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	%	Jan - Jun	%	Jan - Sep	Change amount	%	Jan - Dec	%	Jan - Dec	%
Net sales	67.2	127.5	189.4	259.3	67.4	100%	129.9	102%	192.7	3.2	102%	-	-	258.0	99%
Japan sales	56.9	105.6	157.2	215.9	55.2	97%	105.7	100%	155.8	(1.3)	99%	-	-	209.7	97%
Overseas sales	10.3	21.9	32.2	43.3	12.1	118%	24.2	111%	36.9	4.6	114%	-	-	48.2	111%
America	2.6	6.4	9.8	14.2	3.3	126%	7.0	109%	10.3	0.4	105%	-	-	13.9	98%
Europe	5.2	10.3	14.6	18.9	5.8	111%	10.9	106%	17.1	2.4	117%	-	-	21.5	113%
Asia and others	2.4	5.1	7.7	10.1	2.9	122%	6.2	122%	9.4	1.7	123%	-	-	12.7	125%
Operating income	16.7	23.5	35.1	50.7	13.0	78%	24.1	103%	36.9	1.8	105%	-	-	45.0	89%

(2) ProStrakan (GBP)

Millions of GBP, rounded down

	FY 2012 results				FY 2013 results								FY 2013 forecasts		
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	%	Jan - Jun	%	Jan - Sep	Change Amount	%	Jan - Dec	%	Jan - Dec	%
Net sales	29.3	61.4	92.6	129.4	35.7	122%	74.2	121%	113.8	21.2	123%	-	-	153.5	119%
Chemotherapy-induced nausea and vomiting drug Sancuso	2.8	5.9	9.5	12.3	3.0	107%	6.2	104%	9.3	(0.1)	99%	-	-	13.8	112%
Cancer pain Abstral	7.2	16.3	24.5	33.9	10.5	144%	22.1	135%	34.3	9.7	140%	-	-	44.5	131%
Replacement therapy with testosterone for male hypogonadism Tostran	1.6	2.9	4.3	7.5	1.8	113%	4.9	170%	8.7	4.3	199%	-	-	11.8	157%
Relief of pain associated with chronic anal fissures Rectogesic	2.4	4.8	7.2	10.1	2.9	121%	6.3	131%	9.2	2.0	129%	-	-	12.7	126%
Osteoporosis drug Adcal-D3	5.9	12.5	19.0	26.3	6.7	113%	13.5	108%	20.6	1.6	109%	-	-	28.1	107%
Others	6.0	12.0	18.1	25.8	7.0	117%	14.0	117%	20.8	2.7	115%	-	-	27.6	107%
Product net sales (subtotal)	26.3	54.7	82.8	116.2	32.2	123%	67.2	123%	103.2	20.3	125%	-	-	138.8	119%
Technology Out-Licensing and others	2.9	6.6	9.8	13.1	3.4	116%	6.9	103%	10.6	0.8	108%	-	-	14.7	112%
Gross profit	19.5	40.9	64.4	91.9	27.4	140%	57.0	139%	87.6	23.2	136%	-	-	116.1	126%
Selling, general and administrative expenses *1	18.5	38.2	55.6	72.4	19.3	105%	39.7	104%	56.8	1.1	102%	-	-	77.9	108%
EBIDTA *2	1.0	2.6	8.7	19.5	8.0	785%	17.2	657%	30.8	22.1	354%	-	-	38.2	196%
Goodwill amortization *3	9.8	19.1	29.4	39.4	9.9	101%	19.9	104%	29.8	0.4	101%	-	-	39.8	101%
Operating income	(8.8)	(16.5)	(20.7)	(19.9)	(1.8)	-	(2.6)	-	0.9	21.6	-	-	-	(1.6)	-

*1 Amortization of goodwill is not included in Selling, general and administrative expenses.

Goodwill amortization= Depreciation + Goodwill amortization

*2 EBITDA=Operating income + depreciation + goodwill amortization.

*3 Geographical breakdown of sales for Jan. - Sept. 2013 is as follows:

UK	Europe (excluding UK)	USA	Other
30.2%	42.6%	24.7%	2.5%

(3) Kyowa Medex

Billions of yen, rounded down

	FY 2012 results				FY 2013 results								FY 2013 forecasts		
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	%	Jan - Jun	%	Jan - Sep	Change Amount	%	Jan - Dec	%	Jan - Dec	%
Net sales	2.7	5.8	8.8	11.9	2.5	92%	5.4	94%	8.4	(0.3)	96%	-	-	11.8	99%
Japan sales	2.0	4.6	7.1	9.7	2.0	99%	4.5	98%	6.9	(0.1)	98%	-	-	9.8	101%
Biochemical Diagnostic Reagent	0.8	1.8	2.9	4.0	0.8	99%	1.8	100%	2.8	(0.0)	100%	-	-	4.0	101%
Immunological Diagnostic Reagent	1.0	2.2	3.4	4.7	1.0	101%	2.2	100%	3.4	(0.0)	99%	-	-	4.7	101%
Other	0.2	0.5	0.7	0.9	0.2	95%	0.3	78%	0.6	(0.1)	85%	-	-	0.9	98%
Exports	0.6	1.1	1.6	2.2	0.4	71%	0.9	78%	1.5	(0.1)	90%	-	-	2.0	91%
Operating income	0.2	0.5	0.8	1.2	0.0	20%	0.2	42%	0.4	(0.3)	56%	-	-	0.9	80%

V. Segment information and main subsidiaries operating profit or loss

2. Bio-Chemicals segment

(1) Bio-Chemicals segment total

Billions of yen, rounded down

	FY 2012 results				FY 2013 results								FY 2013 forecasts		
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	%	Jan - Jun	%	Jan - Sep	Change Amount	%	Jan - Dec	%	Jan - Dec	%
Net sales	20.5	40.0	57.4	76.9	19.9	97%	41.2	103%	61.5	4.0	107%	-	-	84.0	109%
Japan sales	12.7	24.5	35.0	47.7	11.5	91%	23.4	95%	35.3	0.3	101%	-	-	48.1	101%
Overseas sales	7.8	15.4	22.4	29.2	8.4	107%	17.7	114%	26.2	3.7	117%	-	-	35.9	123%
America	1.9	3.6	5.2	6.9	1.8	95%	4.1	114%	5.9	0.7	115%	-	-	8.3	119%
Europe	3.2	6.5	9.3	12.0	3.6	113%	7.5	115%	11.0	1.6	118%	-	-	15.0	125%
Asia and others	2.7	5.2	7.8	10.2	2.9	109%	5.9	114%	9.2	1.3	117%	-	-	12.4	122%
Operating income	1.3	2.0	2.2	2.1	1.4	114%	3.1	152%	4.5	2.2	204%	-	-	6.0	282%

(2) Kyowa Hakko Bio Co., Ltd.

Billions of yen, rounded down

	FY 2012 results				FY 2013 results								FY 2013 forecasts		
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	%	Jan - Jun	%	Jan - Sep	Change Amount	%	Jan - Dec	%	Jan - Dec	%
Net sales	12.9	25.9	38.0	51.2	13.8	107%	27.8	108%	42.2	4.2	111%	-	-	57.7	113%
Japan sales	8.1	16.4	24.2	32.7	8.8	108%	17.8	109%	26.8	2.5	110%	-	-	36.2	111%
Pharmaceutical and industrial materials	3.4	7.0	10.7	14.1	3.8	109%	7.5	106%	11.3	0.6	106%	-	-	14.8	105%
Healthcare	2.2	4.7	7.1	9.3	2.4	108%	5.3	113%	8.0	0.9	114%	-	-	11.6	124%
Other	2.3	4.6	6.4	9.2	2.5	106%	5.0	107%	7.3	0.9	115%	-	-	9.7	106%
Exports	4.7	9.4	13.7	18.5	4.9	105%	10.0	106%	15.4	1.6	112%	-	-	21.4	116%
Operating income	0.5	1.2	1.4	1.1	1.2	227%	2.2	182%	3.4	2.0	243%	-	-	4.2	360%

(3) Dailchi Fine Chemical Co., Ltd.











Billions of yen, rounded down

	FY 2012 results				FY 2013 results								FY 2013 forecasts		
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	%	Jan - Jun	%	Jan - Sep	Change Amount	%	Jan - Dec	%	Jan - Dec	%
Net sales	3.7	6.7	8.8	12.8	2.9	77%	5.8	86%	8.4	(0.4)	95%	-	-	12.2	95%
Operating income	0.2	(0.2)	(0.6)	(1.0)	(0.0)	-	(0.2)	-	(0.5)	0.0	-	-	-	(0.6)	-













VI. R&D Pipeline


Filed · Approved  antibody  protein  small molecule

As of Oct 18th, 2013

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	Adult T-cell Leukemia/Lymphoma, Add-on Therapy (for Untreated Patients) Peripheral T/NK-cell Lymphoma	Filed in JP	In-House	POTELLIGENT®
		KW-2246 Fentanyl citrate Sublingual Tablet	μ -Opioid Receptor Agonist	Cancer Pain	Approved in JP September 2013	Licensed from Orexo	
		Granisetron Patch	5-HT ₃ Serotonin Receptor Antagonist	Chemotherapy induced Nausea and Vomiting	Approved in SG August 2013 Filed in Malaysia	Licensed from Solasia Pharma (ProStrakan)	
		KRN125 Pegfilgrastim Injection	Long-Acting Granulocyte Colony Stimulating Factor	Chemotherapy induced Febrile Neutropenia	Filed in JP	Kirin-Amgen	
		KRN1493 Cinacalcet Hydrochloride Oral	Calcium Receptor Agonist	Hypercalcaemia with Parathyroid Carcinoma or Intractable Primary Hyperparathyroidism	Filed in JP	Licensed from NPS	
Nephrology		Cinacalcet Hydrochloride Oral	Calcium Receptor Agonist	Secondary Hyperparathyroidism	Filed in Philippine and China	Licensed from NPS	
		KRN321 Darbepoetin Alfa Injection	Long-Acting Erythropoiesis Stimulating Agent	Pediatric Renal Anemia	Approved in JP September 2013	Kirin-Amgen	
Central Nervous System		KW-6002 Istradefylline Oral	Adenosine A _{2A} Receptor Antagonist	Parkinson's Disease	Filed in US	In-House	
		KW-6485 Topiramate Oral	Antiepileptic Drug	Pediatric Epilepsy	Filed in JP	Licensed from Janssen Research & Development, LLC	
Other		AMG531 Romiplostim Injection	Thrombopoietin Receptor Agonist	Idiopathic (Immune) Thrombocytopenic Purpura	Filed in HK	Kirin-Amgen	

Phase II, Phase III

Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Oncology		Ⓞ ARQ 197 Tivantinib Oral	c-Met Inhibitor	Lung Cancer (EGF-receptor mutated) Gastric Cancer	Phase II in JP Phase II in JP and KR	ArQule	
		KW-0761 Mogamulizumab Injection	Anti-CCR4 Humanized Antibody	Peripheral T-cell Lymphoma Adult T-cell Leukemia/Lymphoma Cutaneous T-cell Lymphoma	Phase II in EU Phase II in US and EU Phase III in US and EU	In-House	POTELLIGENT®
		Ⓞ KW-2478 Injection	HSP90 inhibitor	Multiple Myeloma	Phase I / II in UK/US/PH	In-House	
		KRN321 Darbepoetin Alfa Injection	Long-Acting Erythropoiesis Stimulating Agent	Myelodysplastic Syndrome related Anemia	Phase II in JP and KR	Kirin-Amgen	
	Nephrology		KRN321 Darbepoetin Alfa Injection	Long-Acting Erythropoiesis Stimulating Agent	Renal Anemia (on Dialysis)	Phase III in CN	Kirin-Amgen
		Ⓞ RTA 402 Bardoxolone Methyl Oral	Antioxidant Inflammation Modulator	CKD in patients with type 2 diabetes	Phase II in JP	Reata	
		Ⓞ KHK7580 Oral	Calcium Receptor Agonist	Secondary Hyperparathyroidism	Phase I / II in JP	Licensed from Mitsubishi Tanabe	
Immunology /Allergy		Ⓞ KHK4563 Benralizumab Injection	Anti-IL-5 Receptor Humanized Antibody	Asthma	Phase II in JP and KR	In-House	Being Developed by MedImmune as MEDI-563 Worldwide except in Japan and other Asian Countries POTELLIGENT®
		Ⓞ ASKP1240 Injection	Anti-CD40 Fully Human Antibody	Organ Transplant Rejection	Phase I in JP Phase II in US	In-House	Jointly Developed with Astellas KM mouse
		Z-206 Mesalazine Oral	pH Dependent Controlled Release Tablet	Crohn's Disease	Phase II in JP	Licensed from Zeria Pharma	Jointly Developed with Zeria Pharma
		Ⓞ KHK4827 Injection	Anti-IL-17 Receptor Fully Human Antibody	Psoriasis	Phase III in JP	Kirin-Amgen	
Other		Ⓞ KW-3357 Antithrombin Injection	Recombinant Human Antithrombin	Disseminated Intravascular Coagulation, Congenital Antithrombin Deficiency	Phase III in JP Phase I in EU	In-House	

 Updated since July 19th, 2013 (Area, Stage, Filed, Approved, Launched etc.)










Ⓞ New Molecular Entity

VI. R&D Pipeline

Ph I

 antibody  protein  small molecule





As of Oct 18th, 2013

Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Oncology		◎BIW-8962 Injection	Anti-GM2 Humanized Antibody	Cancer	Phase I / IIa in KR	In-House	POTELLIGENT®
		◎KRN951 Tivozanib Oral	VEGF Receptor Inhibitor	Cancer	Phase I in JP	In-House	Being Developed overseas by AVEO as AV-951
		◎CEP-37250/ KHK2804 Injection	Anti-Tumor Specific Glycoprotein Humanized Antibody	Cancer	Phase I in US	Licensed from Teva	Jointly Developed with Teva POTELLIGENT®
		◎KHK2898 Injection	Anti-CD98 Fully Human Antibody	Cancer	Phase I in SG	In-House	POTELLIGENT® KM mouse
		◎ARQ197 Tivantinib Oral	c-Met Inhibitor	Hepatocellular Cancer	Phase I in JP	Licensed from ArQule	
Immunology /Allergy		KW-0761 Mogamulzumab Injection	Anti-CCR4 Humanized Antibody	Asthma	Phase I in JP	In-House	POTELLIGENT®
		◎KHK4083 Injection	Immunomodulator	Autoimmune diseases	Phase I in CA	In-House	POTELLIGENT® KM mouse
		◎KHK4577 Oral	Anti-inflammatory Agent	Inflammatory disease	Phase I in JP	In-House	
Other		◎KRN23 Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemic Rickets/Osteomalacia (XLH)	Phase I / II in US and CA	In-House	Jointly Developed with Ultragenyx KM mouse


 Updated since July 19th, 2013 (Area, Stage, Filed, Approved, Launched etc.)
 ◎ New Molecular Entity

Updated since July 19th, 2013 (Area, Stage, Filed, Approved, Launched etc.)

Filed · Approved

Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Oncology		KW-2246 Fentanyl citrate Sublingual Tablet	μ-Opioid Receptor Agonist	Cancer Pain	Approved in JP September 2013	Licensed from Orexo	
		Granisetron Patch	5-HT ₃ Serotonin Receptor Antagonist	Chemotherapy induced Nausea and Vomiting	Approved in SG August 2013	Licensed from Solasia Pharma (ProStrakan)	
Nephrology		KRN321 Darbepoetin Alfa Injection	Long-Acting Erythropoiesis Stimulating Agent	Pediatric Renal Anemia	Approved in JP September 2013	Kirin-Amgen	
Other		AMG531 Romiplostim Injection	Thrombopoietin Receptor Agonist	Idiopathic (Immune) Thrombocytopenic Purpura	Filed in HK	Kirin-Amgen	

Phase I - III

Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Nephrology		◎KHK7580 Oral	Calcium Receptor Agonist	Secondary Hyperparathyroidism	Phase I / II in JP	Licensed from Mitsubishi Tanabe	

Discontinuation

Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Central Nervous System		◎KHK6188 Oral	Cannabinoid CB2 Receptor Agonist	Neuropathic Pain	Phase II in JP	In-House	

<Appendix> Pipeline of Biosimilar (Fujifilm Kyowa Kirin Biologics)**Phase I**

As of October 18th, 2013

Code Name	Generic Name	Stage	Remarks
FKB327	Adalimumab (fully human anti-TNF- α monoclonal antibody)	Phase I in UK	