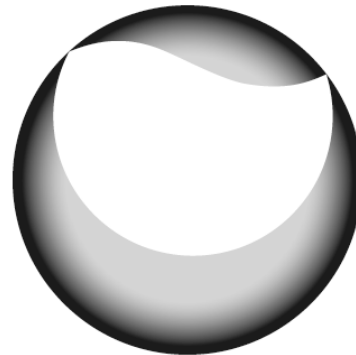


Reference Data

(Consolidated Financial Results for Q4 FY2015)



Daiichi-Sankyo

May 12, 2016

Daiichi Sankyo Co., Ltd.

<http://www.daiichisankyo.com>

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1. Consolidated Statement of Profit or Loss

JPY Bn	FY2014		FY2015					FY2016			
	to revenue	Results	to revenue	Results	(vs. Forecast (%))	YoY	YoY (%)	to revenue	Forecast	YoY	YoY (%)
Revenue	100.0%	919.4	100.0%	986.4	(100.7%)	67.1	+7.3%	100.0%	920.0	-66.4	-6.7%
Cost of sales	35.1%	323.1	32.3%	318.6	(100.8%)	-4.5	-1.4%	34.8%	320.0	1.4	+0.4%
(excl. Special items)	31.1%	285.9	32.0%	315.6		29.7	+10.4%				
(Special items)	4.0%	37.2	0.3%	3.0		-34.1	-91.8%				
Gross Profit	64.9%	596.3	67.7%	667.8	(100.6%)	71.5	+12.0%	65.2%	600.0	-67.8	-10.2%
SG&A expenses	36.0%	331.2	33.3%	328.8	(97.6%)	-2.4	-0.7%	33.7%	310.0	-18.8	-5.7%
(excl. Special items)	34.7%	318.6	32.3%	319.0		0.3	+0.1%				
(Special items)	1.4%	12.6	1.0%	9.8		-2.8	-22.1%				
R&D expenses	20.7%	190.7	21.2%	208.7	(105.9%)	18.0	+9.4%	20.7%	190.0	-18.7	-8.9%
(excl. Special items)	20.3%	186.2	20.6%	203.0		16.8	+9.0%				
(Special items)	0.5%	4.4	0.6%	5.6		1.2	+27.0%				
Operating Profit	8.1%	74.4	13.2%	130.4	(100.3%)	56.0	+75.2%	10.9%	100.0	-30.4	-23.3%
(Operating Profit before Special items)	14.0%	128.6	15.1%	148.9		20.3	+15.8%				
Financial income/expenses		6.4		-7.7		-14.2					
Share of profit or loss of investments accounted for using the equity method		-0.9		-0.3		0.6					
Profit before tax	8.7%	79.9	12.4%	122.4	(102.0%)	42.5	+53.1%	10.9%	100.0	-22.4	-18.3%
Income taxes		36.4		42.0		5.6	+15.4%				
Profit for the year	4.7%	43.6	8.2%	80.4		36.8	+84.5%				
Profit attributable to owners of the Company	5.1%	46.5	8.3%	82.3	(109.7%)	35.8	+77.1%	7.1%	65.0	-17.3	-21.0%
Tax rate		45.5%		34.3%							
Overseas sales ratio		42.7%		43.7%							
Currency Rate (Average)											
USD/JPY		109.94		120.14							
EUR/JPY		138.78		132.57							

Forex impact: +12.9
(USD: +24.1, EUR: -3.5, ASCA: -7.7)

Forex impact: +3.0
(USD: +5.7, EUR: -0.4, ASCA: -2.3)

Forex impact: +4.0
(USD: +10.7, EUR: -2.0, ASCA: -4.7)

Forex impact: +5.7
(USD: +6.1, EUR: -0.3)

Forex impact: +0.2
(USD: +1.6, EUR: -0.8, ASCA: -0.6)

FY2015:
Forex loss, Expenses relating to sale of Sun Pharma shares etc.

Reduction in negative tax rate effect by reversal of deferred tax asset due to change in tax rate etc.

Special items

	FY2014	FY2015
Cost of Sales	Restructuring costs in Japan	2.2
	Gain on sales of subsidiary / Gain on sales of fixed assets	-3.5
	Impairment loss (Intangible)	35.0
SG&A expenses	Restructuring costs in SC	4.6
	Settlement expenses with US DOJ	4.7
	Restructuring costs in US	15.2
	Restructuring costs in EU	2.9
	Gain on sales of fixed assets	-8.2
R&D expenses	Impairment loss (Tangible)	1.8
	Gain on sales of fixed assets	-2.9
Total	Restructuring costs in Japan	4.4
	Total	54.2
		18.5

Currency Rate (Average)

110.00
125.00

Annual impact of one yen change

	Forecast	
	USD	EUR
Revenue	2.0 JPY Bn	0.6 JPY Bn
Operating Profit	minor	minor

*At the time of disclosure of this report, the audit/review procedures for financial statements are in progress in accordance with the Financial Instruments and Exchange Act.

*The figures for FY2014 have been restated and indicated as only the values for continuing operations excluding Ranbaxy.

*Special items : Items having a transitory and material impact on operating profit are defined as "Special items".

Specifically, gains and losses related to: sale of fixed assets, restructuring, impairment, litigation, etc. amounting to 1 billion JPY or more are defined as "Special items".

2. Revenue of Global Products

JPY Bn	FY2014	FY2015				FY2016		
	Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
Olmesartan antihypertensive agent	293.5	284.1	(100.0%)	-9.4	-3.2%	210.0	-74.1	-26.1%
Olmetec (JPN)	76.3	73.9	(93.5%)	-2.5	-3.2%	68.0	-5.9	-7.9%
Rezaltas (JPN)	18.4	18.2	(95.6%)	-0.2	-1.3%	19.0	0.8	+4.6%
Benicar/Benicar HCT (US)	77.0	79.5	(108.9%)	2.5	+3.2%	42.0	-37.5	-47.1%
Azor (US)	18.3	19.7	(116.1%)	1.5	+8.1%	10.0	-9.7	-49.3%
Tribenzor (US)	11.3	12.4	(124.1%)	1.1	+9.8%	6.0	-6.4	-51.7%
Olmetec/Olmetec Plus (EU)	37.8	32.8	(102.6%)	-4.9	-13.1%	24.0	-8.8	-26.9%
Sevikar (EU)	17.6	16.5	(102.9%)	-1.1	-6.3%	13.0	-3.5	-21.0%
Sevikar HCT (EU)	9.9	9.6	(106.9%)	-0.3	-2.7%	9.0	-0.6	-6.5%
Other subsidiaries, export, etc	27.0	21.6	(74.4%)	-5.4	-20.2%	19.0	-2.6	-12.0%
Prasugrel antiplatelet agent	24.9	32.2	-	7.3	+29.4%	not disclosed	-	-
Effient alliance revenue (US)	17.6	20.7	-	3.2	+18.1%	not disclosed	-	-
Efient alliance revenue and others (EU)	4.8	5.4	-	0.6	+13.0%	not disclosed	-	-
Efient (JPN)	0.7	4.9	(98.0%)	4.2	+613.5%	8.0	3.1	+63.3%
Other subsidiaries, export, etc	1.9	1.2	-	-0.7	-36.5%	not disclosed	-	-
Edoxaban anticoagulant agent	4.3	15.0	(102.2%)	10.7	+251.1%	36.3	21.3	+141.6%
Lixiana (JPN)	3.6	13.0	(118.0%)	9.4	+262.6%	25.0	12.0	+92.6%
Savaysa (US)	0.7	0.4	(22.5%)	-0.2	-35.6%	2.0	1.6	+344.5%
Lixiana (EU)	-	1.5	(90.9%)	1.5	-	9.0	7.5	+482.3%
Other subsidiaries	-	0.0	-	0.0	-	0.3	0.3	+550.5%

3. Revenue by Business Units and Products (1)

JPY Bn	FY2014		FY2015				FY2016		
	Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)	
Japan	480.5	494.7	(100.7%)	14.2	+2.9%	496.0	1.3	+0.3%	
Olmetec	antihypertensive agent	76.3	73.9	(93.5%)	-2.5	-3.2%	68.0	-5.9	-7.9%
Nexium	ulcer treatment	69.3	82.4	(107.0%)	13.1	+18.8%	80.0	-2.4	-2.9%
Memary	Alzheimer's disease treatment	36.8	42.4	(90.3%)	5.6	+15.3%	51.0	8.6	+20.2%
Loxonin	anti-inflammatory analgesic	49.5	48.1	(109.4%)	-1.4	-2.8%	37.0	-11.1	-23.1%
Cravit	synthetic antibacterial agent	27.8	18.4	(108.1%)	-9.5	-34.0%	13.0	-5.4	-29.2%
Rezaltas	antihypertensive agent	18.4	18.2	(95.6%)	-0.2	-1.3%	19.0	0.8	+4.6%
Artist	treatment for hypertension, angina pectoris and chronic heart failure	18.1	15.1	(88.6%)	-3.0	-16.8%	11.0	-4.1	-27.0%
Omnipaque	contrast medium	17.2	16.9	(105.4%)	-0.3	-1.9%	12.0	-4.9	-28.8%
Mevalotin	antihyperlipidemic agent	16.2	13.4	(96.0%)	-2.7	-16.9%	10.0	-3.4	-25.6%
Ranmark	treatment for bone complications caused by bone metastases from tumors	10.2	12.4	(95.3%)	2.2	+22.0%	13.0	0.6	+4.9%
Inavir	anti-influenza treatment	16.6	14.0	(116.9%)	-2.6	-15.4%	13.0	-1.0	-7.3%
Urief	treatment for dysuria	11.5	11.8	(107.6%)	0.3	+2.8%	11.0	-0.8	-7.0%
Pralia	treatment for osteoporosis	7.3	12.5	(124.5%)	5.1	+70.1%	16.0	3.5	+28.5%
Lixiana	anticoagulant agent	3.6	13.0	(118.0%)	9.4	+262.6%	25.0	12.0	+92.6%
Efient	antiplatelet agent	0.7	4.9	(98.0%)	4.2	+613.5%	8.0	3.1	+63.3%
Teneria	type 2 diabetes mellitus inhibitor	7.6	16.5	-	9.0	+118.9%	28.0	11.5	+69.3%
Daiichi Sankyo Espha products		14.9	18.5	-	3.6	+23.9%	not disclosed	-	-
Vaccines business		32.2	36.8	-	4.6	+14.2%	not disclosed	-	-
Daiichi Sankyo Healthcare (OTC)	47.8	53.4	(108.9%)	5.5	+11.6%	60.0	6.6	+12.4%	

3. Revenue by Business Units and Products (2)

JPY Bn

	FY2014	FY2015				FY2016		
	Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
Daiichi Sankyo, Inc. (US)	173.0	185.1	(105.2%)	12.1	+7.0%	123.0	-62.1	-33.5%
Olmesartan antihypertensive agent	106.6	111.6	(110.5%)	5.1	+4.7%	58.0	-53.6	-48.0%
Benicar/Benicar HCT	77.0	79.5	(108.9%)	2.5	+3.2%	42.0	-37.5	-47.1%
Azor	18.3	19.7	(116.1%)	1.5	+8.1%	10.0	-9.7	-49.3%
Tribenzor	11.3	12.4	(124.1%)	1.1	+9.8%	6.0	-6.4	-51.7%
Welchol hypercholesterolemia treatment/ type 2 diabetes mellitus inhibitor	47.4	48.4	(102.9%)	1.0	+2.1%	37.0	-11.4	-23.5%
Effient antiplatelet agent	17.6	20.7	-	3.2	+18.1%	not disclosed	-	-
Savaysa anticoagulant agent	0.7	0.4	(22.5%)	-0.2	-35.6%	2.0	1.6	+344.5%
Movantik opioid-induced constipation treatment	-	2.0	-	2.0	-	not disclosed	-	-
Luitpold Pharmaceuticals, Inc. (US)	57.4	91.0	(105.8%)	33.6	+58.6%	92.0	1.0	+1.1%
Venofer iron deficiency anemia	28.6	31.2	(104.1%)	2.6	+9.2%	25.0	-6.2	-19.9%
Injectafer iron deficiency anemia	7.6	18.6	(109.6%)	11.0	+143.9%	27.0	8.4	+44.9%
Daiichi Sankyo Europe GmbH	83.5	77.8	(102.3%)	-5.7	-6.9%	74.0	-3.8	-4.9%
Olmesartan antihypertensive agent	65.2	58.9	(101.6%)	-6.3	-9.7%	46.0	-12.9	-21.9%
Olmetec/Olmetec Plus	37.8	32.8	(102.6%)	-4.9	-13.1%	24.0	-8.8	-26.9%
Sevikar	17.6	16.5	(102.9%)	-1.1	-6.3%	13.0	-3.5	-21.0%
Sevikar HCT	9.9	9.6	(106.9%)	-0.3	-2.7%	9.0	-0.6	-6.5%
Effient antiplatelet agent	4.8	5.4	-	0.6	+13.0%	not disclosed	-	-
Lixiana anticoagulant agent	-	1.5	(90.9%)	1.5	-	9.0	7.5	+482.3%
Asia, South and Central America (ASCA)	67.5	75.3	(85.6%)	7.8	+11.6%	71.0	-4.3	-5.8%
Daiichi Sankyo China	27.4	34.2	-	6.9	+25.1%	not disclosed	-	-
Daiichi Sankyo Taiwan	4.9	5.4	-	0.5	+10.5%	not disclosed	-	-
Daiichi Sankyo Korea	8.9	9.3	-	0.5	+5.2%	not disclosed	-	-
Daiichi Sankyo Thailand	3.7	4.1	-	0.4	+11.5%	not disclosed	-	-
Daiichi Sankyo Brasil Farmacêutica	8.4	8.1	-	-0.3	-3.1%	not disclosed	-	-
Daiichi Sankyo Venezuela	8.1	0.2	-	-7.9	-98.0%	not disclosed	-	-

3. Revenue by Business Units and Products (3)

[Reference] Revenue in Local Currency

USD Mn

	FY2014	FY2015				FY2016		
	Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
Daiichi Sankyo, Inc. (US)	1,574	1,540	(105.4%)	-33	-2.1%	1,118	-422	-27.4%
Olmesartan antihypertensive agent	969	929	(110.4%)	-40	-4.2%	527	-402	-43.2%
Benicar/Benicar HCT	700	661	(108.7%)	-39	-5.6%	382	-280	-42.3%
Azor	166	164	(116.0%)	-2	-1.1%	91	-73	-44.7%
Tribenzor	103	103	(124.0%)	1	+0.5%	55	-49	-47.2%
Welchol hypercholesterolemia treatment/ type 2 diabetes mellitus inhibitor	431	403	(103.2%)	-29	-6.6%	336	-66	-16.5%
Effient antiplatelet agent	160	173	-	13	+8.0%	not disclosed	-	-
Savaysa anticoagulant agent	6	4	(22.5%)	-3	-41.1%	18	14	+385.4%
Movantik opioid-induced constipation treatment	-	17	-	17	-	not disclosed	-	-

USD Mn

Luitpold Pharmaceuticals, Inc. (US)	522	758	(106.1%)	236	+45.2%	836	79	+10.4%
Venofer iron deficiency anemia	260	260	(104.3%)	-0	-0.1%	227	-33	-12.5%
Injectafer iron deficiency anemia	69	155	(109.8%)	86	+123.2%	245	90	+58.2%

EUR Mn

Daiichi Sankyo Europe GmbH	602	587	(100.4%)	-15	-2.5%	592	5	+0.9%
Olmesartan antihypertensive agent	470	444	(99.6%)	-25	-5.4%	368	-76	-17.2%
Olmetec/Olmetec Plus	272	248	(100.6%)	-24	-9.0%	192	-56	-22.4%
Sevikar	127	124	(101.0%)	-2	-1.9%	104	-20	-16.3%
Sevikar HCT	71	73	(104.8%)	1	+1.9%	72	-1	-0.8%
Effient antiplatelet agent	34	41	-	6	+18.3%	not disclosed	-	-
Lixiana anticoagulant agent	-	12	(89.7%)	12	-	72	60	+517.6%

4. Consolidated Statement of Financial Position

<Assets>

JPY Bn

	Mar. 2015	Mar. 2016	vs. Mar. 2015
Assets			
Current assets			
Cash and cash equivalents	189.4	222.2	32.8
Trade and other receivables	241.5	248.8	7.2
Other financial assets	186.5	493.8	307.3
Inventories	150.1	144.3	-5.8
Other current assets	14.7	15.2	0.5
Subtotal	782.2	1,124.2	342.0
Assets held for sale	3.2	1.1	-2.1
Total current assets	785.3	1,125.3	339.9
Non-current assets			
Property, plant and equipment	266.5	250.2	-16.3
Goodwill	71.4	78.7	7.3
Intangible assets	199.4	210.4	11.0
Investments accounted for using the equity method	1.3	1.2	-0.1
Other financial assets	593.9	168.2	-425.8
Deferred tax assets	45.3	55.7	10.4
Other non-current assets	19.1	10.9	-8.2
Total non-current assets	1,197.0	775.3	-421.7
Total assets	1,982.3	1,900.5	-81.8
* Liquidity on hand	374.3	714.7	340.4
Debt with interest	224.6	203.6	-21.0
Net Cash	149.7	511.1	361.4

Increase due to sale of Sun Pharma shares

Increase due to acquisition of Im etc.

Acquisition +35.6, Amortization -16.3

Sale of Sun Pharma shares -424.3
(Sale: -378.5, Evaluation difference -45.8)

<Liabilities and equity>

JPY Bn

	Mar. 2015	Mar. 2016	vs. Mar. 2015
Liabilities			
Current liabilities			
Trade and other payables	235.5	241.8	6.3
Bonds and borrowings	20.0	20.0	-0.0
Other financial liabilities	7.6	0.8	-6.8
Income taxes payable	7.8	53.9	46.2
Provisions	19.4	28.3	8.9
Other current liabilities	6.7	34.8	28.0
Subtotal	297.1	379.7	82.6
Liabilities directly associated with assets held for sale	0.4	-	-0.4
Total current liabilities	297.5	379.7	82.2
Non-current liabilities			
Bonds and borrowings	201.0	181.0	-20.0
Other financial liabilities	8.3	9.1	0.8
Post employment benefit liabilities	11.6	14.0	2.4
Provisions	2.7	12.3	9.6
Deferred tax liabilities	88.4	33.7	-54.7
Other non-current liabilities	65.7	37.2	-28.5
Total non-current liabilities	377.7	287.3	-90.4
Total liabilities	675.2	667.0	-8.2
Equity			
Equity attributable to owners of the Company			
Share capital	50.0	50.0	-
Capital surplus	105.3	103.9	-1.3
Treasury shares	-14.2	-64.2	-50.0
Other components of equity	169.0	146.7	-22.3
Retained earnings	994.0	994.9	1.0
Total equity attributable to owners of the Company	1,304.1	1,231.4	-72.7
Non-controlling interests			
Non-controlling interests	3.0	2.1	-0.9
Total equity	1,307.0	1,233.5	-73.5
Total liabilities and equity	1,982.3	1,900.5	-81.8

Acquisition -50.0 (21 million shares)

Profit for the period +82.3,
Dividends -48.5,
Transfer from comprehensive income -32.8

5. Consolidated Statement of Cash Flows

JPY Bn

	FY2014	FY2015	YoY
Cash flows from operating activities			
Profit before tax from continuing operations	79.9	122.4	42.5
Depreciation and amortization	42.0	44.3	2.3
(Increase) decrease in receivables and payables	2.7	18.0	15.3
Other, net	30.8	27.1	-3.7
Income taxes paid	-21.9	-37.4	-15.6
Cash flows from operating activities of discontinued operations	9.2	-	-9.2
Net cash flows from operating activities	142.8	174.3	31.5
Cash flows from investing activities			
Net (increase) decrease in time deposits and securities	135.7	-316.4	-452.1
(Acquisition of) proceeds from sales of fixed assets	-93.4	-63.9	29.6
Proceeds from sale of subsidiary	-	7.0	7.0
Net (increase) decrease in investment securities	4.6	376.8	372.2
Other, net	-31.4	-9.5	21.8
Cash flows from investing activities of discontinued operations	-36.7	-	36.7
Net cash flows from investing activities	-21.3	-6.0	15.3
Cash flows from financing activities			
Net (increase) decrease in borrowings	-30.0	-23.0	7.0
Repayments of bonds	-60.0	-	60.0
Purchase of treasury shares	-0.0	-50.2	-50.2
Dividends paid	-42.3	-48.5	-6.2
Other, net	-0.9	-1.2	-0.3
Cash flows from financing activities of discontinued operations	1.0	-	-1.0
Net cash flows from financing activities	-132.2	-122.9	9.3
Net increase (decrease) in cash and cash equivalents	-10.7	45.4	56.1
Cash and cash equivalents at the beginning of the period	183.1	189.4	6.3
Effect of exchange rate changes on cash and cash equivalents	17.0	-12.6	-29.6
Cash and cash equivalents at the end of the period	189.4	222.2	32.8
* Free cash flows (Cash flows from operating activities and investing activities)	121.5	168.3	46.8

Increase in time deposits and securities

Sale of Sun Pharma shares +378.5

FY2014: Acquisition of Ambit shares -33.5
FY2015: Acquisition of Im shares -11.8

6. Number of Employees

	Mar. 2015	Mar. 2016
	Results	Results
Consolidated	16,428	15,249
Japan	8,543	8,589
North America	3,322	2,321
Europe	2,094	1,997
Others	2,469	2,342

7. Capital Expenditure and Depreciation and Amortization

		FY2014	FY2015	FY2016
	JPY Bn	Results	Results	Forecast
Capital expenditure		36.3	23.3	33.0
Depreciation and amortization		42.0	44.3	46.0
Property, plant and equipment		27.0	28.0	-
Intangible assets		15.1	16.3	-

8. Other Financial Indicators

	FY2014	FY2015
	Results	Results
Profit attributable to owners of the Company	46.5 JPY Bn	82.3 JPY Bn
Dividends	42.2 JPY Bn	47.8 JPY Bn
Purchase of treasury shares	- JPY Bn	50.0 JPY Bn
Total return ratio	90.9 %	118.9 %
Average equity attributable to owners of the Company for the period	1,142.0 JPY Bn	1,267.7 JPY Bn
Return on Equity	4.1 %	6.5 %

9. Summary of Product Outlines

Brand Name	Generic Name	Therapeutic Category	Launched	Origin	Marketing Alliance	Type of Alliance
Japan						
Olmetec	olmesartan	antihypertensive agent	2004	Daiichi Sankyo		
Nexium	esomeprazole	ulcer treatment	2011	AstraZeneca	AstraZeneca	Co-promotion (DS: Sales)
Memary	memantine	Alzheimer's disease treatment	2011	Merz		
Loxonin			1986	Daiichi Sankyo		
Loxonin Poultice	loxoprofen	anti-inflammatory analgesic	2006	Lead Chemical		
Loxonin Tape			2008	Lead Chemical		
Loxonin Gel			2010	Daiichi Sankyo		
Cravit	levofloxacin	synthetic antibacterial agent	1993	Daiichi Sankyo		
Rezaltas	olmesartan / azelnidipine	antihypertensive agent	2010	Daiichi Sankyo		
Artist	carvedilol	treatment for hypertension, angina pectoris and chronic heart failure	1993	Roche		
Omnipaque	iohexol	contrast medium	1987	GE Healthcare		
Mevalotin	pravastatin	antihyperlipidemic agent	1989	Daiichi Sankyo		
Ranmark	denosumab	treatment for bone complications caused by bone metastases from tumors	2012	Amgen		
Inavir	laninamivir	anti-influenza treatment	2010	Daiichi Sankyo		
Urief	silodosin	treatment for dysuria	2006	Kissei	Kissei	Co-marketing
Pralia	denosumab	treatment for osteoporosis	2013	Amgen		
Lixiana	edoxaban	anticoagulant agent	2011	Daiichi Sankyo		
Efient	prasugrel	antiplatelet agent	2014	Daiichi Sankyo Ube Industries		
Tenelia	teneligliptin	type 2 diabetes mellitus inhibitor	2012	Mitsubishi Tanabe	Mitsubishi Tanabe	Co-promotion (DS: Sales)
Daiichi Sankyo, Inc. (US)						
Olmesartan						
Benicar	olmesartan	antihypertensive agent	2002	Daiichi Sankyo		
Benicar HCT	olmesartan / hydrochlorothiazide		2003			
Azor	olmesartan / amlodipine		2007			
Tribenzor	olmesartan / amlodipine / hydrochlorothiazide		2010			
Welchol	colesevelam	hypercholesterolemia treatment/ type 2 diabetes mellitus inhibitor	2000	Genzyme		
Effient	prasugrel	antiplatelet agent	2009	Daiichi Sankyo Ube Industries	Lilly	Co-promotion (DS: Co-pro revenue)
Savaysa	edoxaban	anticoagulant agent	2015	Daiichi Sankyo		
Movantik	naloxegol	opioid-induced constipation treatment	2015	Nektar AstraZeneca	AstraZeneca	Co-promotion (DS: Co-pro revenue)
Luitpold Pharmaceuticals, Inc. (US)						
Venofer	iron sucrose injection	iron deficiency anemia	2000	Vifor Pharma	Fresenius	Co-marketing
Injectafer	ferric carboxymaltose injection	iron deficiency anemia	2013	Vifor Pharma		
Daiichi Sankyo Europe GmbH						
Olmesartan						
Olmetec	olmesartan	antihypertensive agent	2002	Daiichi Sankyo	Menarini Pfizer	Co-marketing
Olmetec Plus	olmesartan / hydrochlorothiazide		2005			
Sevikar	olmesartan / amlodipine		2009			
Sevikar HCT	olmesartan / amlodipine / hydrochlorothiazide		2010			
Efient	prasugrel	antiplatelet agent	2009	Daiichi Sankyo Ube Industries		
Lixiana	edoxaban	anticoagulant agent	2015	Daiichi Sankyo		

<10. Quarterly Data>

1. Consolidated Statement of Profit or Loss

JPY Bn	FY2014	FY2014	FY2014	FY2014	FY2014		FY2015	FY2015	FY2015	FY2015	FY2015			
	Q1	Q2	Q3	Q4	to revenue	Results	Q1	Q2	Q3	Q4	to revenue	Results	YoY	YoY (%)
	Results	Results	Results	Results			Results	Results	Results	Results				
Revenue	213.7	215.9	264.8	225.0	100.0%	919.4	238.4	240.4	279.8	227.9	100.0%	986.4	67.1	+7.3%
Cost of sales	64.6	66.2	90.1	102.2	35.1%	323.1	74.0	75.0	88.8	80.9	32.3%	318.6	-4.5	-1.4%
(excl. Special items)	64.6	66.2	87.9	67.2	31.1%	285.9	76.3	76.1	88.8	74.4	32.0%	315.6	29.7	+10.4%
(Special items)	-	-	2.2	35.0	4.0%	37.2	-2.4	-1.1	-	6.5	0.3%	3.0	-34.1	-91.8%
Gross Profit	149.1	149.7	174.7	122.8	64.9%	596.3	164.5	165.4	191.0	147.0	67.7%	667.8	71.5	+12.0%
SG&A expenses	74.9	78.7	84.1	93.4	36.0%	331.2	71.6	72.8	87.8	96.5	33.3%	328.8	-2.4	-0.7%
(excl. Special items)	74.9	74.7	79.4	89.6	34.7%	318.6	75.6	77.1	81.7	84.6	32.3%	319.0	0.3	+0.1%
(Special items)	-	4.0	4.7	3.8	1.4%	12.6	-3.9	-4.3	6.1	11.9	1.0%	9.8	-2.8	-22.1%
R&D expenses	41.4	43.5	50.8	55.0	20.7%	190.7	43.7	44.7	49.8	70.5	21.2%	208.7	18.0	+9.4%
(excl. Special items)	41.4	43.5	46.4	54.9	20.3%	186.2	43.7	44.7	49.5	65.2	20.6%	203.0	16.8	+9.0%
(Special items)	-	-	4.4	0.0	0.5%	4.4	-	-	0.3	5.4	0.6%	5.6	1.2	+27.0%
Operating Profit	32.8	27.4	39.7	-25.6	8.1%	74.4	49.1	47.9	53.4	-20.0	13.2%	130.4	56.0	+75.2%
(Operating Profit before Special items)	32.8	31.5	51.1	13.3	14.0%	128.6	42.9	42.5	59.8	3.7	15.1%	148.9	20.3	+15.8%
Financial income/expenses	0.2	2.5	5.5	-1.8		6.4	-3.7	-2.1	1.0	-2.9		-7.7	-14.2	
Share of profit or loss of investments accounted for using the equity method	-0.3	-0.5	0.1	-0.2		-0.9	-0.2	-0.1	0.2	-0.2		-0.3	0.6	
Profit before tax	32.7	29.5	45.3	-27.5	8.7%	79.9	45.2	45.6	54.6	-23.0	12.4%	122.4	42.5	+53.1%
Income taxes	11.8	15.1	14.0	-4.6		36.4	11.1	10.3	14.7	5.9		42.0	5.6	+15.4%
Profit for the year	20.9	14.3	31.3	-22.9	4.7%	43.6	34.1	35.3	39.9	-28.9	8.2%	80.4	36.8	+84.5%
Profit attributable to owners of the Company	21.6	15.1	32.3	-22.5	5.1%	46.5	34.9	35.8	40.0	-28.4	8.3%	82.3	35.8	+77.1%
Tax rate	36.1%	51.3%	31.0%	16.7%		45.5%	24.6%	22.5%	27.0%	-25.5%		34.3%		
Overseas sales ratio	45.2%	41.1%	39.7%	45.3%		42.7%	46.8%	46.2%	40.6%	41.5%		43.7%		
<u>Currency Rate (Average)</u>														
USD/JPY	102.16	103.05	106.88	109.94		109.94	121.37	121.80	121.70	120.14		120.14		
EUR/JPY	140.06	138.91	140.31	138.78		138.78	134.16	135.07	134.37	132.57		132.57		

<10. Quarterly Data>

2. Revenue of Global Products

JPY Bn	FY2014 Q1	FY2014 Q2	FY2014 Q3	FY2014 Q4	FY2014	FY2015 Q1	FY2015 Q2	FY2015 Q3	FY2015 Q4	FY2015		
	Results	Results	Results	Results	Results	Results	Results	Results	Results	Results	YoY	YoY (%)
Olmesartan	75.8	66.5	77.7	73.6	293.5	75.6	71.9	80.9	55.7	284.1	-9.4	-3.2%
Olmetec (JPN)	18.7	19.1	20.6	17.9	76.3	18.5	17.7	24.3	13.4	73.9	-2.5	-3.2%
Rezaltas (JPN)	4.5	4.5	5.0	4.3	18.4	4.6	4.3	5.2	4.1	18.2	-0.2	-1.3%
Benicar/Benicar HCT (US)	18.9	15.1	21.0	22.0	77.0	19.8	20.5	22.8	16.3	79.5	2.5	+3.2%
Azor (US)	4.1	3.9	5.4	4.9	18.3	5.8	4.6	5.2	4.1	19.7	1.5	+8.1%
Tribenzor (US)	2.7	2.5	3.3	2.8	11.3	3.1	3.2	3.3	2.8	12.4	1.1	+9.8%
Olmetec/Olmetec Plus (EU)	11.1	9.3	8.6	8.7	37.8	8.9	8.2	7.8	7.9	32.8	-4.9	-13.1%
Sevikar (EU)	5.3	4.2	3.9	4.1	17.6	4.5	4.1	3.5	4.4	16.5	-1.1	-6.3%
Sevikar HCT (EU)	3.3	2.1	2.2	2.2	9.9	2.5	2.2	2.8	2.2	9.6	-0.3	-2.7%
Other subsidiaries, export, etc	7.1	5.8	7.5	6.7	27.0	7.9	7.1	6.0	0.5	21.6	-5.4	-20.2%
Prasugrel	5.8	5.9	6.7	6.5	24.9	7.8	7.4	8.7	8.2	32.2	7.3	+29.4%
Effient alliance revenue (US)	4.2	4.2	4.6	4.5	17.6	5.2	5.4	5.8	4.3	20.7	3.2	+18.1%
Effient alliance revenue and others (EU)	1.2	1.2	1.3	1.1	4.8	1.1	1.1	1.1	2.1	5.4	0.6	+13.0%
Effient (JPN)	0.2	0.1	0.2	0.2	0.7	1.2	0.6	1.5	1.6	4.9	4.2	+613.5%
Other subsidiaries, export, etc	0.2	0.4	0.5	0.7	1.9	0.3	0.4	0.3	0.2	1.2	-0.7	-36.5%
Edoxaban	0.1	0.1	1.9	2.1	4.3	1.8	3.5	5.2	4.5	15.0	10.7	+251.1%
Lixiana (JPN)	0.1	0.1	1.9	1.4	3.6	2.1	3.2	4.2	3.4	13.0	9.4	+262.6%
Savaysa (US)	-	-	-	0.7	0.7	-0.3	0.1	0.5	0.2	0.4	-0.2	-35.6%
Lixiana (EU)	-	-	-	-	-	0.0	0.1	0.5	0.9	1.5	1.5	-
Other subsidiaries	-	-	-	-	-	-	-	-	0.0	0.0	0.0	-

3. Revenue by Business Units and Products (1)

JPY Bn	FY2014 Q1	FY2014 Q2	FY2014 Q3	FY2014 Q4	FY2014	FY2015 Q1	FY2015 Q2	FY2015 Q3	FY2015 Q4	FY2015		
	Results	Results	Results	Results	Results	Results	Results	Results	Results	Results	YoY	YoY (%)
Japan	108.0	114.6	145.2	112.7	480.5	114.2	113.6	149.6	117.2	494.7	14.2	+2.9%
Olmotec	18.7	19.1	20.6	17.9	76.3	18.5	17.7	24.3	13.4	73.9	-2.5	-3.2%
Nexium	15.3	16.8	23.7	13.6	69.3	19.1	19.6	23.3	20.4	82.4	13.1	+18.8%
Mema	7.9	8.9	10.8	9.3	36.8	10.2	10.2	12.2	9.7	42.4	5.6	+15.3%
Loxonin	12.2	13.2	13.3	10.9	49.5	12.6	11.8	13.9	9.9	48.1	-1.4	-2.8%
Cravit	6.9	7.3	8.8	4.9	27.8	4.6	4.4	5.6	3.8	18.4	-9.5	-34.0%
Rezaltas	4.5	4.5	5.0	4.3	18.4	4.6	4.3	5.2	4.1	18.2	-0.2	-1.3%
Artist	4.8	4.7	4.7	4.0	18.1	4.1	3.8	4.2	3.0	15.1	-3.0	-16.8%
Omnipaque	4.2	4.4	4.7	3.9	17.2	4.2	4.2	4.8	3.6	16.9	-0.3	-1.9%
Mevalotin	4.2	4.1	4.3	3.6	16.2	3.6	3.4	3.8	2.7	13.4	-2.7	-16.9%
Ranmark	2.1	2.6	2.9	2.6	10.2	2.9	3.0	3.5	3.0	12.4	2.2	+22.0%
Inavir	0.3	0.0	7.9	8.4	16.6	0.0	0.0	2.5	11.5	14.0	-2.6	-15.4%
Urief	2.7	2.9	3.1	2.8	11.5	2.9	2.8	3.3	2.8	11.8	0.3	+2.8%
Pralia	1.3	1.7	2.1	2.2	7.3	2.6	2.8	3.7	3.4	12.5	5.1	+70.1%
Lixiana	0.1	0.1	1.9	1.4	3.6	2.1	3.2	4.2	3.4	13.0	9.4	+262.6%
Efient	0.2	0.1	0.2	0.2	0.7	1.2	0.6	1.5	1.6	4.9	4.2	+613.5%
Teneria	1.5	1.8	2.2	2.1	7.6	2.4	3.0	6.6	4.6	16.5	9.0	+118.9%
Daiichi Sankyo Espha products	3.5	3.3	4.8	3.3	14.9	4.3	4.3	5.6	4.3	18.5	3.6	+23.9%
Vaccines business	5.8	6.7	13.1	6.6	32.2	6.4	8.0	15.6	6.8	36.8	4.6	+14.2%
Daiichi Sankyo Healthcare (OTC)	9.4	13.3	14.3	10.8	47.8	10.8	13.8	15.2	13.5	53.4	5.5	+11.6%

3. Revenue by Business Units and Products (2)

JPY Bn	FY2014 Q1	FY2014 Q2	FY2014 Q3	FY2014 Q4	FY2014	FY2015 Q1	FY2015 Q2	FY2015 Q3	FY2015 Q4	FY2015		
	Results	Results	Results	Results	Results	Results	Results	Results	Results	Results	YoY	YoY (%)
Daiichi Sankyo, Inc. (US)	41.6	36.5	48.1	46.8	173.0	48.0	45.4	52.1	39.6	185.1	12.1	+7.0%
Olmesartan	25.7	21.5	29.7	29.6	106.6	28.8	28.3	31.3	23.2	111.6	5.1	+4.7%
Benicar/Benicar HCT	18.9	15.1	21.0	22.0	77.0	19.8	20.5	22.8	16.3	79.5	2.5	+3.2%
Azor	4.1	3.9	5.4	4.9	18.3	5.8	4.6	5.2	4.1	19.7	1.5	+8.1%
Tribenzor	2.7	2.5	3.3	2.8	11.3	3.1	3.2	3.3	2.8	12.4	1.1	+9.8%
Welchol	11.3	10.5	13.4	12.3	47.4	13.5	10.6	13.5	10.7	48.4	1.0	+2.1%
Effient	4.2	4.2	4.6	4.5	17.6	5.2	5.4	5.8	4.3	20.7	3.2	+18.1%
Savaysa	-	-	-	0.7	0.7	-0.3	0.1	0.5	0.2	0.4	-0.2	-35.6%
Movantik	-	-	-	-	-	0.2	0.4	0.7	0.7	2.0	2.0	-
Luitpold Pharmaceuticals, Inc. (US)	12.5	14.3	16.2	14.4	57.4	21.5	24.9	22.6	22.0	91.0	33.6	+58.6%
Venofer	7.2	7.0	8.6	5.8	28.6	9.1	6.9	8.4	6.8	31.2	2.6	+9.2%
Injectafer	1.5	1.5	2.2	2.6	7.6	3.9	4.0	5.0	5.8	18.6	11.0	+143.9%
Daiichi Sankyo Europe GmbH	24.5	20.0	20.1	18.9	83.5	20.2	19.0	18.8	19.7	77.8	-5.7	-6.9%
Olmesartan	19.7	15.7	14.8	15.0	65.2	15.8	14.4	14.2	14.5	58.9	-6.3	-9.7%
Olmetec/Olmetec Plus	11.1	9.3	8.6	8.7	37.8	8.9	8.2	7.8	7.9	32.8	-4.9	-13.1%
Sevikar	5.3	4.2	3.9	4.1	17.6	4.5	4.1	3.5	4.4	16.5	-1.1	-6.3%
Sevikar HCT	3.3	2.1	2.2	2.2	9.9	2.5	2.2	2.8	2.2	9.6	-0.3	-2.7%
Efient	1.2	1.2	1.3	1.1	4.8	1.1	1.1	1.1	2.1	5.4	0.6	+13.0%
Lixiana	-	-	-	-	-	0.0	0.1	0.5	0.9	1.5	1.5	-
Asia, South and Central America (ASCA)	15.1	14.8	18.9	18.6	67.5	21.4	21.3	19.9	12.7	75.3	7.8	+11.6%
Daiichi Sankyo China	5.4	6.1	7.3	8.5	27.4	7.9	8.6	8.3	9.4	34.2	6.9	+25.1%
Daiichi Sankyo Taiwan	1.2	1.1	1.2	1.3	4.9	1.4	1.3	1.3	1.4	5.4	0.5	+10.5%
Daiichi Sankyo Korea	2.7	1.7	2.0	2.5	8.9	2.4	2.4	2.4	2.2	9.3	0.5	+5.2%
Daiichi Sankyo Thailand	0.7	0.9	1.0	1.0	3.7	0.8	1.0	1.1	1.2	4.1	0.4	+11.5%
Daiichi Sankyo Brasil Farmacêutica	2.3	2.0	2.6	1.5	8.4	2.6	1.9	2.1	1.4	8.1	-0.3	-3.1%
Daiichi Sankyo Venezuela	1.2	1.8	2.9	2.1	8.1	3.1	2.4	1.6	-6.9	0.2	-7.9	-98.0%

3. Revenue by Business Units and Products (3)

[Reference] Revenue in Local Currency

	FY2014 Q1	FY2014 Q2	FY2014 Q3	FY2014 Q4	FY2014	FY2015 Q1	FY2015 Q2	FY2015 Q3	FY2015 Q4	FY2015		
	Results	Results	Results	Results	Results	Results	Results	Results	Results	Results	YoY	YoY (%)
USD Mn												
Daichi Sankyo, Inc. (US)	407	351	423	393	1,574	396	371	429	345	1,540	-33	-2.1%
Olmesartan	251	207	262	249	969	237	232	257	202	929	-40	-4.2%
Benicar/Benicar HCT	185	145	185	186	700	163	168	187	143	661	-39	-5.6%
Azor	40	38	48	41	166	48	38	43	35	164	-2	-1.1%
Tribenzor	26	24	30	23	103	26	26	27	24	103	1	+0.5%
Welchol	111	101	117	102	431	112	87	111	93	403	-29	-6.6%
Effient	42	41	40	37	160	43	44	48	38	173	13	+8.0%
Savaysa	-	-	-	6	6	-2	1	4	1	4	-3	-41.1%
Movantik	-	-	-	-	-	1	3	6	6	17	17	-
USD Mn												
Luitpold Pharmaceuticals, Inc. (US)	122	137	142	120	522	177	204	186	191	758	236	+45.2%
Venofer	70	68	75	47	260	75	57	69	59	260	-0	-0.1%
Injectafer	14	14	19	22	69	32	33	41	49	155	86	+123.2%
EUR Mn												
Daichi Sankyo Europe GmbH	175	146	140	141	602	151	140	142	155	587	-15	-2.5%
Olmesartan	141	114	103	112	470	118	106	106	114	444	-25	-5.4%
Olmetec/Olmetec Plus	79	68	60	65	272	66	60	59	62	248	-24	-9.0%
Sevikar	38	31	27	30	127	33	30	27	34	124	-2	-1.9%
Sevikar HCT	24	15	15	17	71	18	16	21	17	73	1	+1.9%
Efient	8	8	9	8	34	8	8	8	16	41	6	+18.3%
Lixiana	-	-	-	-	-	0	1	4	7	12	12	-

<11. Historical Data>

1. Revenue of Global Products

	FY2011	FY2012	FY2013	FY2014	FY2015
JPY Bn	Results	Results	Results	Results	Results
Olmesartan	249.7	258.9	300.2	293.5	284.1
Olmetec (JPN)	80.9	78.3	79.1	76.3	73.9
Rezaltas (JPN)	13.5	16.9	18.5	18.4	18.2
Benicar/Benicar HCT (US)	71.3	73.2	85.9	77.0	79.5
Azor (US)	12.0	14.8	17.4	18.3	19.7
Tribenzor (US)	4.6	6.8	9.0	11.3	12.4
Olmetec/Olmetec Plus (EU)	36.6	32.6	44.5	37.8	32.8
Sevikar (EU)	11.0	10.8	13.5	17.6	16.5
Sevikar HCT (EU)	3.4	4.7	7.6	9.9	9.6
Other subsidiaries, export, etc	16.5	20.7	24.7	27.0	21.6
Prasugrel	10.9	14.4	22.3	24.9	32.2
Effient alliance revenue (US)	7.9	10.5	15.4	17.6	20.7
Effient alliance revenue and others (EU)	2.9	3.9	4.7	4.8	5.4
Effient (JPN)	-	-	-	0.7	4.9
Other subsidiaries, export, etc	-	-	2.2	1.9	1.2
Edoxaban	-	-	0.4	4.3	15.0
Lixiana (JPN)	-	-	0.4	3.6	13.0
Savaysa (US)	-	-	-	0.7	0.4
Lixiana (EU)	-	-	-	-	1.5
Other subsidiaries	-	-	-	-	0.0

2. Revenue by Business Units and Products (1)

	FY2011	FY2012	FY2013	FY2014	FY2015
JPY Bn	Results	Results	Results	Results	Results
Japan	409.8	442.5	486.0	480.5	494.7
Olmotec	80.9	78.3	79.1	76.3	73.9
Nexium	3.9	21.6	54.2	69.3	82.4
Memary	9.8	23.8	33.3	36.8	42.4
Loxonin	61.0	59.6	59.3	49.5	48.1
Cravit	36.3	35.9	33.5	27.8	18.4
Rezaltas	13.5	16.9	18.5	18.4	18.2
Artist	24.5	22.4	22.4	18.1	15.1
Omnipaque	23.5	20.2	19.7	17.2	16.9
Mevalotin	33.1	25.8	21.5	16.2	13.4
Ranmark	-	4.4	8.1	10.2	12.4
Inavir	10.7	11.1	13.4	16.6	14.0
Urief	11.0	11.1	11.4	11.5	11.8
Pralia	-	-	3.2	7.3	12.5
Lixiana	0.3	0.3	0.4	3.6	13.0
Efient	-	-	-	0.7	4.9
Teneria	-	1.3	1.5	7.6	16.5
Daiichi Sankyo Espha products	9.9	11.1	12.5	14.9	18.5
Vaccines business	21.2	39.1	37.5	32.2	36.8
Daiichi Sankyo Healthcare (OTC)	45.9	47.1	48.1	47.8	53.4

2. Revenue by Business Units and Products (2)

	FY2011	FY2012	FY2013	FY2014	FY2015
JPY Bn	Results	Results	Results	Results	Results
Daiichi Sankyo, Inc. (US)	127.1	142.3	171.8	173.0	185.1
Olmesartan	87.9	94.9	112.3	106.6	111.6
Benicar/Benicar HCT	71.3	73.2	85.9	77.0	79.5
Azor	12.0	14.8	17.4	18.3	19.7
Tribenzor	4.6	6.8	9.0	11.3	12.4
Welchol	26.9	33.1	42.3	47.4	48.4
Effient	7.9	10.5	15.4	17.6	20.7
Savaysa	-	-	-	0.7	0.4
Movantik	-	-	-	-	2.0
Luitpold Pharmaceuticals, Inc. (US)	44.7	38.6	39.6	57.4	91.0
Venofer	24.8	23.6	24.9	28.6	31.2
Injectafer	-	-	1.3	7.6	18.6
Daiichi Sankyo Europe GmbH	70.2	64.4	83.9	83.5	77.8
Olmesartan	51.0	48.0	65.6	65.2	58.9
Olmetec/Olmetec Plus	36.6	32.6	44.5	37.8	32.8
Sevikar	11.0	10.8	13.5	17.6	16.5
Sevikar HCT	3.4	4.7	7.6	9.9	9.6
Efient	2.9	3.9	4.7	4.8	5.4
Lixiana	-	-	-	-	1.5
Asia, South and Central America (ASCA)	28.6	45.4	58.8	67.5	75.3
Daiichi Sankyo China	9.7	16.4	21.2	27.4	34.2
Daiichi Sankyo Taiwan	3.1	3.3	4.5	4.9	5.4
Daiichi Sankyo Korea	4.6	5.3	9.1	8.9	9.3
Daiichi Sankyo Thailand	1.2	1.4	2.5	3.7	4.1
Daiichi Sankyo Brasil Farmacêutica	5.5	6.6	7.5	8.4	8.1
Daiichi Sankyo Venezuela	4.2	6.7	6.9	8.1	0.2

2. Revenue by Business Units and Products (3)

[Reference] Revenue in Local Currency

	FY2011	FY2012	FY2013	FY2014	FY2015
	Results	Results	Results	Results	Results
USD Mn					
Daichi Sankyo, Inc. (US)	1,608	1,713	1,714	1,574	1,540
Olmesartan	1,112	1,142	1,120	969	929
Benicar/Benicar HCT	901	881	857	700	661
Azor	152	179	174	166	164
Tribenzor	58	82	90	103	103
Welchol	340	399	422	431	403
Effient	100	127	154	160	173
Savaysa	-	-	-	6	4
Movantik	-	-	-	-	17
USD Mn					
Luitpold Pharmaceuticals, Inc. (US)	566	465	395	522	758
Venofer	314	284	248	260	260
Injectafer	-	-	13	69	155
EUR Mn					
Daichi Sankyo Europe GmbH	644	601	624	602	587
Olmesartan	468	448	488	470	444
Olmetec/Olmetec Plus	336	304	331	272	248
Sevikar	101	100	100	127	124
Sevikar HCT	31	44	57	71	73
Efient	27	36	35	34	41
Lixiana	-	-	-	-	12

12. Major R&D Pipeline (Innovative pharmaceuticals)

As of May 2016

◆ Launched/Approved

Generic Name	Class	Indication	Region	Status	Remarks
Edoxaban	Factor Xa inhibitor	Atrial fibrillation (AF)	ASCA etc.	<u>Launched</u>	<u>S. Korea (16/2)</u> * means Feb 2016, ditto
				<u>Approved</u>	<u>Taiwan (16/2)</u>
		Venous thromboembolism (VTE)	ASCA etc.	<u>Launched</u>	<u>S. Korea (16/2)</u>
				<u>Approved</u>	<u>Taiwan (16/2)</u>
<Summary> The once daily oral anti coagulant (FXa inhibitor) discovered by Daiichi Sankyo. Edoxaban specifically, reversibly and directly inhibits the enzyme, Factor Xa, a clotting factor in the blood. Launched in Japan in July 2011 as the prevention of venous thromboembolism (VTE) in patients with total knee arthroplasty, total hip arthroplasty and hip fracture surgery. Additional indications for AF/VTE was approved in September 2014 and 60 mg tablet was launched in December 2014. Launched in US, Switzerland, UK, Germany, Ireland and Netherlands in February, May, July, August, September and November 2015, respectively. Approved in South Korea in August 2015.					
VN-101	Cell-culture H5N1 flu vaccine	Prevention of H5N1 influenza	JP		Approved in March 2016
<Summary> This vaccine is a cell-culture H5N1 flu vaccine that has developed by Daiichi Sankyo and Kitasato Daiichi Sankyo Vaccine(KDSV). KDSV was submitted a supplemental application for optimization of pediatric use.					

Underline: change after FY2015 Q3 Financial Announcement in Jan 2016

◆ Filed

Product Code Number/Generic Name	Class	Target indication	Region	Note, Filing year/month
Edoxaban	Factor Xa inhibitor	Atrial fibrillation (AF)	ASCA etc.	BR (14/6), TH(15/7) AU(15/8), HK(15/8), CN(15/8), CA(15/8), TR(15/10)
		Venous thromboembolism (VTE)	ASCA etc.	BR (14/6), TH(15/7) AU(15/8), HK(15/8), CN(15/8), CA(15/8), TR(15/10)
<Summary> The once daily oral anti coagulant (FXa inhibitor) discovered by Daiichi Sankyo. Edoxaban specifically, reversibly and directly inhibits the enzyme, Factor Xa, a clotting factor in the blood.				
<u>CL-108</u>	<u>Opioid mu-receptor agonist combination</u>	<u>Acute pain</u>	<u>US</u>	<u>NDA was submitted in March 2016 by Charleston Laboratories, Inc., licensor and co-development partner</u>
<Summary> CL-108 is novel hydrocodone combination products being developed by Charleston Lab and Daiichi Sankyo for the treatment of moderate to severe pain while preventing or reducing Opioid-Induced Nausea and Vomiting (OINV). The product expects to reduce the unwanted side effects of opioid-induced nausea and vomiting.				
<u>Hydromorphone</u>	<u>Opioid mu-receptor agonist</u>	<u>Cancer pain</u>	<u>JP</u>	<u>NDA of oral formulation (extended-release and immediate-release formulations) was submitted in March 2016 by Daiichi Sankyo Propharma</u>
<Summary> Hydromorphone hydrochloride is an opiate, narcotic analgesic that has been available outside of Japan for over 80 years and it is the standard for pain management for cancer pain treatment according to WHO guidelines. Hydromorphone hydrochloride is one of the agents publicly offered for development by the Review Committee on Unapproved Drugs and Indications with High Medical Needs. Daiichi Sankyo decided to develop the drug in 2012.				
VN-100	Intradermal influenza HA vaccine	Prevention of seasonal Influenza	JP	Submitted by Japan Vaccine in April 2015
<Summary> The Vaccine is a pre-filled syringe type, intradermal influenza HA vaccine co-developed by four companies [Daiichi Sankyo, Terumo, Japan Vaccine and Kitasato Daiichi Sankyo Vaccine Co., Ltd.]. The intradermal injection device for this vaccine is developed by Terumo. This device, which offers a more easy-to-use, surefire method to administer the vaccine than current methods. The device is also expected to ease patient hesitation to be injected and lower the risk of damaging peripheral blood vessels and nerves within the subcutaneous tissue.				

Underline: change after FY2015 Q3 Financial Announcement in Jan 2016

◆ Under development (Phase1-3)

Generic Name / Project Code Number	Class	Target indication	Stage		target FY for approval/launch basically for P3	Remarks
Prasugrel	Anti-platelet agent	Ischemic stroke	JP	P3	2017	Additional indication
Denosumab	Anti-RANKL antibody	Breast cancer adjuvant	JP	P3	2020	Additional indication
		Rheumatoid arthritis	JP	P3	2017	Additional indication
Tivantinib	MET inhibitor	Hepatocellular cancer	US/EU	P3	2018	
Nimotuzumab	Anti-EGFR antibody	Gastric cancer	JP	P3	<u>2020</u>	
Vemurafenib	BRAF inhibitor	Melanoma adjuvant	US/EU	P3	-	Additional indication. Licensee Roche is conducting the study. Submission in 2016 is planned.
Quizartinib	FLT3-ITD inhibitor	Acute myeloid leukemia	US/EU/Asia	P3	2018	Relapsed and refractory AML patients
			US	P3	<u>2021-</u>	<u>Newly diagnosed AML patients</u>
			JP	P1	-	
Pexidartinib/PLX3397	CSF-1R/KIT/FLT3-ITD inhibitor	Tenosynovial Giant Cell Tumor (TGCT)	US/EU	P3	2019	Including pigmented villonodular synovitis
		Glioblastoma	US	P2	-	
		Melanoma	US	P2	-	
		Melanoma, solid tumor	US	P1/2	-	Combination with pembrolizumab in collaboration with Merck
Mirogabalin	α2δ ligand	Fibromyalgia	US/EU	P3	2019	
		Diabetic peripheral neuropathic pain	JP/Asia	P3	2018	
		Postherpetic neuralgia	JP/Asia	P3	2018	
Hydromorphone	Opioid mu-receptor agonist	Cancer pain	JP	P3	2018	<u>Injection formulation</u>
CHS-0214	TNFα inhibitor	Rheumatoid arthritis	JP	P3	2017	Etanercept biosimilar
VN-0107/MEDI3250	Live attenuated influenza vaccine	Prevention of seasonal influenza	JP	P3	2017	In-licensed from AZ/MedImmune. US trade name is FluMist Quadrivalent.
VN-0105	DPT-IPV/Hib vaccine	Prevention of pertussis, diphtheria, tetanus, poliomyelitis and Hib	JP	P3	<u>2019</u>	Co-develop with Sanofi K.K.and KDSV
Patritumab	Anti-HER3 antibody	Non small cell lung cancer	US/EU	P2	-	
		Non small cell lung cancer	JP	P1	-	
		Breast cancer	US	P2	-	
		Breast cancer	JP	P1	-	
		Head & neck cancer	EU	<u>P2</u>	-	
CS-3150	MR antagonist	Hypertension	JP	P2b	-	
		Diabetic nephropathy	JP	P2b	-	
DS-8500	GPR119 agonist	Diabetes	JP/US	P2	-	
Laninamivir	Neuraminidase inhibitor	Influenza	US/EU	P2	-	Out-licensing with Biota
			JP	P1	-	Nebulizer formulation

Underline: change after FY2015 Q3 Financial Announcement in Jan 2016

◆ Under development (Phase1-3)

Generic Name / Project code number	Class	Target indication	Stage			Remarks
DS-3032	MDM2 inhibitor	Solid cancer, lymphoma	US/JP	P1	-	
		Leukemia	US	P1	-	
PLX7486	FMS/TRK inhibitor	Solid cancer	US	P1	-	
DS-8895	Anti-EPHA2 antibody	Solid cancer	JP	P1	-	
DS-8273	Anti-DR5 antibody	Solid cancer	US	P1	-	
PLX8394	BRAF inhibitor	Solid cancer, leukemia	US	P1	-	
DS-6051	NTRK/ROS1 inhibitor	Solid cancer	US/JP	P1	-	
DS-5573	Anti-B7-H3 antibody	Solid cancer	JP	P1	-	
PLX9486	KIT inhibitor	Solid cancer	US	P1	-	
DS-8201	Anti-HER2 antibody drug conjugate	Solid cancer	JP	P1	-	
U3-1784	Anti-FGFR4 antibody	Solid cancer	EU	P1	-	
DS-1123	Anti-FGFR2 antibody	Solid cancer	JP	P1	-	
<u>DS-3201</u>	<u>EZH1/2 inhibitor</u>	<u>Non-Hodgkin's lymphoma</u>	<u>JP</u>	<u>P1</u>	-	
<u>PLX73086/AC708</u>	<u>CSF-1R inhibitor</u>	<u>Tenosynovial Giant Cell Tumor (TGCT)</u>	<u>US</u>	<u>P1</u>	-	
<u>PLX51107</u>	<u>BRD4 inhibitor</u>	<u>Hematologic malignancies</u>	<u>US</u>	<u>P1</u>	-	
DS-1040	TAF1a inhibitor	Acute ischemic stroke	-	P1	-	
DS-2330	Hyperphosphatemia treatment	Hyperphosphatemia in chronic kidney disease (CKD)	-	P1	-	
DS-9231/TS23	α2 plasmin inhibitor-inactivating antibody	Thrombosis (cardiovascular diseases, ischemic stroke)	-	P1	-	In-licensed from Translational Sciences Inc.
DS-9001	Anti-PCSK9 Anticalin-Albumod	Dyslipidemia	-	P1	-	
DS-1971	Analgesic agent	Chronic pain	-	P1	-	
DS-1501	Anti-Siglec-15 antibody	Osteoporosis	-	P1	-	
DS-7080	Angiogenesis inhibitor	Neovascular age-related macular degeneration (AMD)	US	P1	-	
DS-2969	GyrB inhibitor	Clostridium difficile infection (CDI)	-	P1	-	
<u>DS-5141</u>	<u>ENA oligonucleotide</u>	<u>Duchenne muscular dystrophy</u>	<u>JP</u>	<u>P1/2</u>	-	
VN-0102/JVC-001	Measles-Mumps-Rubela vaccine	Prevention of Measles, Mumps and Rubela	JP	P1/2	<u>2020</u>	Japan vaccine company is conducting the phase 1/2 study

Underline: change after FY2015 Q3 Financial Announcement in Jan 2016

◆ Stage-up (major changes from the FY2015 Q3 financial announcement in January 2016)

Generic Name / Project code number	Class	Target indication	Current stage		Remarks
Edoxaban	FXa inhibitor	Atrial Fibrillation (AF)	ASCA etc.	Launched	S. Korea (16/2)
		Venous thromboembolism (VTE)		Submitted	Taiwan (16/2)
VN-101	Cell-culture H5N1 flu vaccine	Prevention of H5N1 influenza	JP	Approved	Pediatric use in March 2016
Hydromorphone	Opioid mu-receptor agonist	Cancer pain	JP	Submitted	NDA of oral formulation (extended-release and immediate-release formulations)
CL-108	Opioid mu-receptor agonist combination	Acute pain	US	Submitted	NDA submitted in Mar 2016 by Charleston Laboratories, Inc. licensor and co-development partner
Quizartinib	FLT3-ITD inhibitor	Acute myeloid leukemia	US	P3	Newly diagnosed AML patients
Patritumab	Anti-HER3 antibody	Head & neck cancer	EU	P2	
DS-6051	NTRK/ROS1 inhibitor	Solid cancer	JP	P1	
DS-3201	EZH1/2 inhibitor	Non-Hodgkin's lymphoma	JP	P1	
PLX73086/AC708	CSF-1R inhibitor	Tenosynovial Giant Cell Tumor (TGCT)	US	P1	
PLX51107	BRD4 inhibitor	Hematologic malignancies	US	P1	
DS-5141	ENA oligonucleotide	Duchenne muscular dystrophy	JP	P1/2	

◆ Major R&D Pipeline Table

As of May 2016

Therapeutic Area	Phase 1	Phase 2	Phase 3	Application
Oncology	<p>DS-3032 (US/JP) (MDM2 inhibitor)</p> <p>PLX7486 (US) (FMS/TRK inhibitor)</p> <p>DS-8895 (JP) (Anti-EPHA2 antibody)</p> <p>DS-8273 (US) (Anti-DR5 antibody)</p> <p>PLX8394 (US) (BRAF inhibitor)</p> <p>DS-6051 (US/JP) (NTRK/ROS1 inhibitor)</p> <p>DS-5573 (JP) (Anti-B7-H3 antibody)</p> <p>PLX9486 (US) (KIT inhibitor)</p> <p>DS-8201 (JP) (Anti-HER2 ADC)</p> <p>U3-1784 (EU) (Anti-FGFR4 antibody)</p> <p>DS-1123 (JP) (Anti-FGFR2 antibody)</p> <p>DS-3201 (JP) (EZH1/2 inhibitor)</p> <p>PLX73086/AC708 (US) (CSF-1R inhibitor)</p> <p>PLX51107 (US) (BRD4 inhibitor)</p>	<p>Patritumab (US/EU) (U3-1287 / Anti-HER3 antibody)</p> <p>Pexidartinib (US) (PLX3397 / CSF-1R/KIT/FLT3-ITD inhibitor)</p>	<p>Tivantinib (US/EU) (ARQ 197 / HCC / MET inhibitor)</p> <p>Denosumab (JP) (AMG 162 / Breast cancer adjuvant / Anti-RANKL antibody)</p> <p>Nimotuzumab (JP) (DE-766 / Gastric cancer / Anti-EGFR antibody)</p> <p>Vemurafenib (US/EU) (PLX4032 / Melanoma adjuvant / BRAF inhibitor)</p> <p>Quizartinib (US/EU/Asia) (AC220 / AML-2nd / FLT3-ITD inhibitor)</p> <p>Quizartinib (US) (AC220 / AML-1st / FLT3-ITD inhibitor)</p> <p>Pexidartinib (US/EU) (PLX3397 / TGCT / CSF-1R/KIT/FLT3-ITD inhibitor)</p>	
Cardiovascular - Metabolics	<p>DS-1040 (Acute ischemic stroke / TAFIa inhibitor)</p> <p>DS-2330 (Hyperphosphatemia)</p> <p>DS-9231/TS23 (Thrombosis (cardiovascular diseases, ischemic stroke)/ α 2 plasmin inhibitor-inactivating antibody)</p> <p>DS-9001 (Dyslipidemia / Anti-PCSK9 Anticalin-Albumod)</p>	<p>CS-3150 (JP) (Hypertension / MR antagonist)</p> <p>CS-3150 (JP) (Diabetic nephropathy / MR antagonist)</p> <p>DS-8500 (JP/US) (Diabetes / GPR119 agonist)</p>	<p>Prasugrel (JP) (CS-747 / Ischemic stroke / Anti-platelet agent)</p>	<p>Edoxaban (ASCA etc.) (DU-176b / AF / Oral factor Xa inhibitor)</p> <p>Edoxaban (ASCA etc.) (DU-176b / VTE / Oral factor Xa inhibitor)</p>
Others	<p>DS-1971 (Chronic pain)</p> <p>DS-1501 (Osteoporosis / Anti-Siglec-15 antibody)</p> <p>DS-7080 (US) (AMD / Angiogenesis inhibitor)</p> <p>DS-2969 (CDI / GyrB inhibitor)</p> <p>DS-5141 (JP) (DMD / ENA Oligonucleotide)</p> <p>VN-0102/JVC-001 (JP) (Measles / Mumps / Rubella vaccine)</p>	<p>Laninamivir (US/EU) (CS-8958 / Anti-influenza / Out licensing with Biota)</p>	<p>Mirogabalin (US/EU) (DS-5565 / Fibromyalgia / α 2 δ ligand)</p> <p>Mirogabalin (JP/Asia) (DS-5565 / DPNP / α 2 δ ligand)</p> <p>Mirogabalin (JP/Asia) (DS-5565 / PHN / α 2 δ ligand)</p> <p>Denosumab (JP) (AMG 162 / Rheumatoid arthritis / Anti-RANKL antibody)</p> <p>Hydromorphone (JP) (DS-7113 / Cancer pain/ Opioid mu-receptor agonist <u>injection formulation</u>)</p> <p>CHS-0214 (JP) (Etanercept BS / Rheumatoid arthritis / TNFα inhibitor)</p> <p>VN-0105 (JP) (DPT-IPV/Hib vaccine)</p> <p>VN-0107/MEDI3250 (JP) (Seasonal Flu/Live attenuated influenza vaccine)</p>	<p>Intradermal Seasonal Influenza Vaccine (JP) (VN-100 / prefilled i.d. vaccine for seasonal flu)</p> <p>VN-101 (JP) (Cell-culture H5N1 Influenza vaccine)</p> <p>Hydromorphone (JP) (DS-7113 / Cancer pain/ Opioid mu-receptor agonist oral formulation (extended-release and immediate-release formulations))</p> <p>CL-108 (US) (Acute pain / Opioid mu-receptor agonist combination)</p>

Underline: change after FY2015 Q3 Financial Announcement in January 2016

Oncology

[Project after Phase 2]

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Tivantinib	ARQ 197	Oral	MET inhibitor	- Hepatocellular cancer	ArQule	TBD

<Summary>

The molecular-targeted agent to inhibit HGF(hepatocyte growth factor) receptor, MET which has multiple roles in intracellular signal transductions such as cancer cell proliferation, angiogenesis, invasion, and apoptosis induction.

• A P3 clinical study for HCC with MET high patients was started in Jan 2013.

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Nimotuzumab	DE-766	Injection	Anti-EGFR antibody	- Gastric cancer	InnoCIMAAb	TBD

<Summary>

The humanized monoclonal antibody to target Epidermal Growth Factor Receptor(EGFR). This antibody is expected to be a best in class EGFR, safety against the skin toxicity and the efficacy comparable to the other antibodies.

• P3 in Japan for Gastric cancer started in April 2013.

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Quizartinib	AC220	Oral	FLT3-ITD inhibitor	- Acute myeloid leukemia	Daiichi Sankyo (Ambit)	TBD

<Summary>

Kinase inhibitor against a receptor-type tyrosine kinase, FLT3. Therapeutic effect for patients with acute myeloid leukemia harboring FLT3-ITD mutation is expected.

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Patritumab	U3-1287	Injection	Anti-HER3 antibody	- Non small cell lung cancer - Breast cancer - Head and neck cancer	Daiichi Sankyo (U3 Pharma)	TBD

<Summary>

The fully human monoclonal antibody to target HER3, one of the Epidermal Growth Factor Receptor (EGFR) family of proteins. HER 3 is overexpressed in many tumors of epithelial origin and HER2/HER3 dimers and EGFR/HER3 dimers are more potent to induce tumor cell proliferation than homodimers of HER2 or EGFR.

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Vemurafenib	PLX4032	Oral	BRAF inhibitor	- Melanoma adjuvant	Daiichi Sankyo (Plexxikon)	Zelboraf

<Summary>

The molecular-targeted agent to inhibit BRAF V600E mutation. Launched since 2011 as personalized treatment for patients with unresectable or metastatic melanoma. NDA for combination therapy with MEK inhibitor cobimetinib was approved in US on November 11, 2015. A Phase 1 study of a combination with anti PD-L1 monoclonal antibody atezolizumab and cobimetinib is being investigated by Genentech.

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Pexidartinib	PLX3397	Oral	CSF-1R/KIT/FLT3-ITD inhibitor	- Tenosynovial Giant Cell Tumor - Glioblastoma - Melanoma	Daiichi Sankyo (Plexxikon)	TBD

<Summary>

The molecular-targeted agent to inhibit CSF-1R, KIT and FLT3-ITD. This agent is expected to reduce tumor cell proliferation and expansion of metastases.

Cardiovascular-Metabolics

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Edoxaban	DU-176b	Oral	Factor Xa inhibitor	- Atrial fibrillation (AF) - Venous thromboembolism (VTE)	Daiichi Sankyo	Lixiana (JP) LIXIANA (EU) SAVAYSA (US)
<p><Summary> The once daily oral anti coagulant (FXa inhibitor). Edoxaban specifically, reversibly and directly inhibits the enzyme, Factor Xa, a clotting factor in the blood. Launched in Japan in July 2011 as the prevention of venous thromboembolism (VTE) in patients with total knee arthroplasty, total hip arthroplasty and hip fracture surgery.</p> <ul style="list-style-type: none"> • Top line results of Hokusai-VTE (VTE) P3 study was presented at ESC 2013. • Top line results of ENGAGE AF-TIMI 48 (AF) P3 study was presented at AHA 2013. • AF/VTE indication: Launched (JP: Sep 2014 (Dec 2014 for 60 mg tablet), US: Feb 2015, Switzerland: May 2015, UK: Jul 2015, Germany: Aug 2015, Ireland: Sep 2015, Netherlands: Nov 2015), Approved in South Korea in Aug 2015. 						

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Prasugrel	CS-747	Oral	Anti-platelet agent	- Ischemic stroke	Daiichi Sankyo Ube Industries	Effient (US, Asia) Efient (JPN, EU)
<p><Summary> The oral antiplatelet agent. Prasugrel helps to keep blood platelets from clumping together and developing a blockage in an artery.</p> <ul style="list-style-type: none"> • Co-development with Eli Lilly in the US and EU, development by Daiichi Sankyo in Japan. • [JP] Approved in Mar 2014 for the ischemic heart disease undergoing PCI and launched in May 2014. P3 studies for ischemic stroke are on-going. • [US] P3 study in pediatric sickle cell disease patients was conducted. The study data was provided to US FDA as supplemental NDA (sNDA). 						

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
-	CS-3150	Oral	MR antagonist	- Hypertension - Diabetic nephropathy	Exelixis	TBD
<p><Summary> The agent inhibits aldosterone binding to Mineralocorticoid Receptor(MR) which stimulate the sodium absorption into kidney. This agent is expected antihypertensive and organ-protective effect.</p> <ul style="list-style-type: none"> • On January 2015, Ph2bs of HTN and DN started. • On November 2015, Ph.2b study in essential hypertension in Japan was completed. 						

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
-	DS-8500	Oral	GPR119 agonist	- Diabetes	Daiichi Sankyo	TBD
<p><Summary> The agent agonistically acts on GPR119 which is expressed in small intestine and spleen cells, stimulates insulin secretion, and lowers blood sugar concentration.</p>						

Others

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Intradermal Seasonal Influenza Vaccine	VN-100	Injection (prefilled syringe)	Seasonal flu vaccine	- Prevention of seasonal influenza	Daiichi Sankyo (KDSV) Terumo	TBD
<p><Summary> The Vaccine is a pre-filled syringe type, intradermal influenza HA vaccine co-developed by four companies [Daiichi Sankyo, Terumo, Japan Vaccine and Kitasato Daiichi Sankyo Vaccine Co., Ltd.]. The intradermal injection device for this vaccine is developed by Terumo. This device, which offers a more easy-to-use, surefire method to administer the vaccine than current methods. The device is also expected to ease patient hesitation to be injected and lower the risk of damaging peripheral blood vessels and nerves within the subcutaneous tissue.</p> <p>• NDA submission in Apr 2014 by Japan Vaccine</p>						

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
-	VN-101	Injection	Cell culture H5N1 flu vaccine	- Prophylaxis of H5N1 influenza infection	Daiichi Sankyo (KDSV)	TBD
<p><Summary> Optimization of cell-culture H5N1 flu vaccine approved in Mar. 2014 for pediatric use.</p> <p>• Ph3 study in Japan started in Jul 2014. Submitted sNDA in Aug 2015. Approved in Mar 2016.</p>						

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Hydromorphone	DS-7113	Oral/ Injection	opioid mu-receptor regulator	- Cancer pain	-	TBD
<p><Summary> The opiate, narcotic analgesic that has been available outside of Japan for over 80 years and recommended in WHO guideline as a standard analgesia for cancer pain. It is designated as unapproved drug by "Study Group on Unapproved and Off-label Drugs of High Medical Need."</p> <p>• NDA of oral formulations (extended-release and immediate-release formulations) were submitted in Mar 2016 by Daiichi Sankyo Propharma. Ph2/3 studies for injection formulation are ongoing.</p>						

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Denosumab	AMG 162	Injection	Anti-RANKL antibody	- Breast cancer adjuvant - Rheumatoid arthritis	Amgen	SRE, GCTB: Ranmark(JP) Osteoporosis: Pralia(JP)
<p><Summary> The fully human monoclonal antibody to target RANK Ligand, an essential mediator of osteoclast formation. Launched in Japan in April 2012 as treatment for bone complications stemming from multiple myeloma and bone metastases from solid tumors, in June 2013 as treatment for osteoporosis, and in May 2014 as treatment for giant cell tumor of bone.</p> <p>• July 2007 In-licensed from Amgen. • P3 : Breast cancer adjuvant, Rheumatoid arthritis.</p>						

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
-	CHS-0214	Injection	TNF α inhibitor	- Rheumatoid arthritis	Coherus	TBD
<p><Summary> Biosimilar product for etanercept</p> <p>• Phase 3 study for patients with rheumatoid arthritis in Japan was started in August 2014.</p>						

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
-	CL-108	Oral	opioid mu-receptor regulator	- Acute pain	Charleston Laboratories	TBD
<p><Summary> Combination product of immediate-release promethazine, hydrocodone and acetaminophen. Reduction of Opioid-Induced Nausea and Vomiting is expected. NDA submission in Mar 2016 by Charleston Laboratories</p>						
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Mirogabalin	DS-5565	Oral	$\alpha 2\delta$ ligand	- Fibromyalgia - Diabetic peripheral neuropathic pain - Postherpetic neuralgia	Daiichi Sankyo	TBD
<p><Summary> The pain therapy agent to reduce the neurotransmitter release from nerve terminals. This agent is expected to show the good balanced efficacy and safety profile.</p> <ul style="list-style-type: none"> • Ph2 studies for diabetic peripheral neuropathic pain were completed. • Ph3 studies for diabetic peripheral neuropathic pain and postherpetic neuralgia are in execution . • Ph3 studies for fibromyalgia are in execution . 						
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
-	VN-0107 MEDI3250	Nasal spray	Seasonal flu vaccine	- Prevention of seasonal influenza	AZ/MedImmune	TBD
<p><Summary> The US brand name of this vaccine is FluMist Quadrivalent that is a live attenuated influenza vaccine which is administered as a nasal spray and contains four protective strains. Phase III safety and efficacy studies were conducted for FluMist Quadrivalent in Japanese children over the 2014-2015 influenza season and a regulatory submission is being prepared in Japan.</p> <ul style="list-style-type: none"> • In preparation for NDA submission 						
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
-	VN-0105	Injection	DPT-IPV/Hib vaccine	- Prevention of pertussis, diphtheria, tetanus, poliomyelitis and Hib	Daiichi Sankyo (KDSV) Sanofi Pasteur	TBD
<p><Summary> A combination vaccine reconstituting Hib with precipitated and purified pertussis-diphtheria-tetanus-inactivated polio vaccine (Salk vaccine) vaccine previously licensed and launched in Japan, as 1st in the class of pentavalent vaccine (DPT-IPV/Hib).</p> <ul style="list-style-type: none"> • Ph3 study in Japan started in Oct 2014. 						