TSE:4568

Reference Data

(Consolidated Financial Results for Q2 FY2016)



October 31, 2016

Daiichi Sankyo Co., Ltd.

http://www.daiichisankyo.com

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1. Consolidated Statement of Profit or Loss

	FY2015	Q2 YTD		FY	2016 Q2 YT	D						FY2016			
JPY Bn	to revenue	Results	to revenue	Results (v	s. Forecast (%))	YoY	YoY (%)		to revenue	Forecast as of May.)	to revenue	Forecast as of Oct.)	vs. Forecast (as of May.)	YoY	YoY (%)
Revenue	100.0%	478.8	100.0%	458.0	(49.8%)	-20.8	-4.3% <	Forex impact: -28.7 (USD:-17.8, EUR:-5.3, ASCA:-5.5)	100.0%	920.0	100.0%	920.0	0.0	-66.4	-6.7%
Cost of sales	31.1%	148.9	32.2%	147.3	(48.0%)	-1.7	-1.1% 🗲	Forex impact: -5.3 (USD:-2.7, EUR:-0.7, ASCA:-1.8)	34.8%	320.0	33.4%	307.0	-13.0	-11.6	-3.6%
(excl. Special items)	31.8%	152.4	32.2%	147.3		-5.1	-3.4%	(00D2.7, EUK0.7, AOCA1.0)							
(Special items)	-0.7%	-3.5	-	-		3.5	-								
Gross Profit	68.9%	329.8	67.8%	310.7	(50.7%)	-19.1	-5.8%		65.2%	600.0	66.6%	613.0	13.0	-54.8	-8.2%
SG&A expenses	30.2%	144.5	30.9%	141.7	(45.3%)	-2.8	-1.9% <	Forex impact: -10.2 (USD:-5.2, EUR:-3.1, ASCA:-1.9)	33.7%	310.0	34.0%	313.0	3.0	-15.8	-4.8%
(excl. Special items)	31.9%	152.7	29.6%	135.7		-17.0	-11.2%								
(Special items)	-1.7%	-8.2	1.3%	6.0		14.2	-		_						
R&D expenses	18.5%	88.4	20.9%	95.8	(47.9%)	7.4	+8.4% 4	Forex impact: -6.1 (USD:-5.6, EUR:-0.4)	20.7%	190.0	21.7%	200.0	10.0	-8.7	-4.1%
(excl. Special items)	18.5%	88.4	20.9%	95.8	,	7.4	+8.4%	(0000.0, E0100.4)							
(Special items)	-	-	-	-		-	-		_						
Operating Profit	20.3%	97.0	16.0%	73.3	(73.3%)	-23.7	-24.5%	Forex impact: -7.1 (USD:-4.4, EUR:-1.0, ASCA:-1.7)	10.9%	100.0	10.9%	100.0	0.0	-30.4	-23.3%
(Operating Profit before Special items)	17.8%	85.3	17.3%	79.3		-6.0	-7.1%	, , , , , , , , , , , , , , , , , , , ,							
- · · · ·		5 0				4.7		FY2015: Expenses relating to sale of Sun							
Financial income/expenses Share of profit or loss of investments		-5.9 -0.3		-1.1 -0.2		4.7 0.1		Pharma shares etc.							
accounted for using the equity method		0.0		0.2		0.1		FY2016: Increase in forex loss							
Profit before tax	19.0%	90.8	15.7%	71.9	(71.9%)	-18.9	-20.8%		10.9%	100.0	10.9%	100.0	0.0	-22.4	-18.3%
Income taxes		21.4		24.1		2.7	+12.8%								
Profit for the year	14.5%	69.4	10.4%	47.8		-21.7	-31.2%								
Profit attributable to owners of the Compan	y 14.8%	70.7	10.7%	49.0	(75.4%)	-21.7	-30.7%		7.1%	65.0	7.1%	65.0	0.0	-17.3	-21.0%
								Decrease in R&D tax credit	1						
Tax rate		23.5%		33.5% -					J						
Overseas sales ratio		46.5%		40.0%	Special item	ıs									
Currency Rate (Average)							FY2015	Q2 YTD FY2016 Q2 YTD		Currenc	y Rate (Ave	arage)			
USD/JPY		121.80		105.35	Cost of S		iin on sales of su ain on sales of fi		-	110.00	y Itale (AV	102.67			
EUR/JPY		135.07		118.22	SG&A e	/ G	in on sales of fixe		6.0	125.00		114.11			
					R&D ex			-	-						
					Total			-11.7	6.0						

^{*}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.

Annual impact of one yen change

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		Fore	ecast
		USD	EUR
	Revenue	2.2 JPY Bn	0.6 JPY Bn
	Operating Profit	0.2 JPY Bn	minor

^{*}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	FY2015 Q2 YTD		FY2016 Q2 YTD				FY2016					
JPY Bn	Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of May.)	Forecast (as of Oct.)	vs. Forecast (as of May.)	YoY	YoY (%)		
Olmesartan antihypertensive agent	147.5	115.4	(53.4%)	-32.1	-21.8%	210.0	216.0	6.0	-68.1	-24.0%		
Olmetec (JPN)	36.2	34.9	(51.3%)	-1.3	-3.6%	68.0	68.0	0.0	-5.9	-7.9%		
Rezaltas (JPN)	8.9	8.8	(46.5%)	-0.1	-0.9%	19.0	19.0	0.0	0.8	+4.6%		
Benicar/Benicar HCT incl. AG (US)	40.3	26.2	(48.6%)	-14.1	-35.0%	42.0	54.0	12.0	-25.5	-32.0%		
Azor (US)	10.4	5.8	(73.1%)	-4.6	-44.0%	10.0	8.0	-2.0	-11.7	-59.5%		
Tribenzor (US)	6.3	4.6	(76.5%)	-1.8	-27.7%	6.0	6.0	0.0	-6.4	-51.7%		
Olmetec/Olmetec Plus (EU)	17.1	13.6	(64.9%)	-3.4	-20.2%	24.0	21.0	-3.0	-11.8	-36.0%		
Sevikar (EU)	8.5	6.6	(60.0%)	-1.9	-22.6%	13.0	11.0	-2.0	-5.5	-33.2%		
Sevikar HCT (EU)	4.6	4.5	(55.6%)	-0.2	-4.1%	9.0	8.0	-1.0	-1.6	-16.9%		
Other subsidiaries, export, etc	15.0	10.3	(49.2%)	-4.7	-31.3%	19.0	21.0	2.0	-0.6	-2.7%		
Prasugrel antiplatelet agent	15.3	20.2	· -	5.0	+32.5%	not disclosed	not disclosed	-	-	-		
Effient alliance revenue (US)	10.6	10.8	-	0.2	+2.2%	not disclosed	not disclosed	-	-	-		
Efient (EU)	2.2	4.2	-	2.0	+90.3%	not disclosed	not disclosed	-	-	-		
Efient (JPN)	1.8	4.9	(49.0%)	3.1	+177.5%	8.0	10.0	2.0	5.1	+104.2%		
Other subsidiaries, export, etc	0.7	0.3	-	-0.4	-55.3%	not disclosed	not disclosed	-	-	-		
Edoxaban anticoagulant agent	5.3	16.1	(45.5%)	10.7	+200.1%	36.3	35.3	-1.0	20.3	+135.0%		
Lixiana (JPN)	5.4	11.5	(46.0%)	6.1	+114.4%	25.0	25.0	0.0	12.0	+92.6%		
Savaysa (US)	-0.2	0.9	(57.0%)	1.1	-	2.0	1.6	-0.4	1.2	+255.6%		
Lixiana (EU)	0.2	3.3	(41.2%)	3.1	-	9.0	8.0	-1.0	6.5	+417.6%		
Other subsidiaries	-	0.3	(47.1%)	0.3	-	0.3	0.7	0.4	0.7	-		

3. Revenue by	Business Units and Products (1)	FY2015 Q2 YTD		FY2016 Q2	YTD		FY2016					
JPY Bn		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of May.)	Forecast (as of Oct.)	vs. Forecast (as of May.)	YoY	YoY (%)	
Japan		227.8	239.0	(47.8%)	11.2	+4.9%	496.0	500.0	4.0	5.3	+1.1%	
Nexium	ulcer treatment	38.7	42.0	(50.7%)	3.4	+8.7%	80.0	83.0	3.0	0.6	+0.7%	
Olmetec	antihypertensive agent	36.2	34.9	(51.3%)	-1.3	-3.6%	68.0	68.0	0.0	-5.9	-7.9%	
Memary	Alzheimer's disease treatment	20.5	23.4	(45.9%)	2.9	+14.3%	51.0	51.0	0.0	8.6	+20.2%	
Loxonin	anti-inflammatory analgesic	24.4	18.8	(50.9%)	-5.6	-22.8%	37.0	37.0	0.0	-11.1	-23.1%	
Tenelia	type 2 diabetes mellitus inhibitor	5.3	11.8	(42.0%)	6.4	+121.2%	28.0	28.0	0.0	11.5	+69.3%	
Lixiana	anticoagulant agent	5.4	11.5	(46.0%)	6.1	+114.4%	25.0	25.0	0.0	12.0	+92.6%	
Rezaltas	antihypertensive agent	8.9	8.8	(46.5%)	-0.1	-0.9%	19.0	19.0	0.0	0.8	+4.6%	
Pralia	treatment for osteoporosis	5.4	8.3	(51.8%)	2.9	+54.8%	16.0	16.0	0.0	3.5	+28.5%	
Ranmark	treatment for bone complications caused by bone metastases from tumors	5.9	6.8	(52.2%)	0.9	+15.6%	13.0	13.0	0.0	0.6	+4.9%	
Inavir	anti-influenza treatment	0.0	0.6	(4.3%)	0.5	-	13.0	13.0	0.0	-1.0	-7.3%	
Cravit	synthetic antibacterial agent	9.0	7.3	(56.4%)	-1.7	-18.5%	13.0	13.0	0.0	-5.4	-29.2%	
Omnipaque	contrast medium	8.5	7.2	(59.7%)	-1.3	-15.2%	12.0	12.0	0.0	-4.9	-28.8%	
Urief	treatment for dysuria	5.7	5.8	(52.3%)	0.1	+1.0%	11.0	11.0	0.0	-0.8	-7.0%	
Artist	treatment for hypertension, angina pectoris and chronic heart failure	7.9	5.7	(51.9%)	-2.2	-27.7%	11.0	11.0	0.0	-4.1	-27.0%	
Mevalotin	antihyperlipidemic agent	7.0	5.5	(54.5%)	-1.5	-21.6%	10.0	10.0	0.0	-3.4	-25.6%	
Efient	antiplatelet agent	1.8	4.9	(49.0%)	3.1	+177.5%	8.0	10.0	2.0	5.1	+104.2%	
Daiichi Sankyo	Espha products	8.6	9.9	-	1.3	+15.6%	not disclosed	not disclosed	-	-	-	
Vaccines busine	ess	14.4	14.7	-	0.2	+1.7%	not disclosed	not disclosed	-	-	-	
Daiichi Sankyo H	ealthcare (OTC)	24.6	32.2	(49.5%)	7.6	+30.7%	60.0	65.0	5.0	11.6	+21.8%	

3. Revenue by I	Business Units and Products (2)	FY2015 Q2 YTD		FY2016 Q2	YTD		FY2016					
JPY Bn		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of May.)	Forecast (as of Oct.)	vs. Forecast (as of May.)	YoY	YoY (%)	
Daiichi Sankyo, In	oc. (US)	93.4	70.3	(53.2%)	-23.1	-24.7%	123.0	132.0	9.0	-53.1	-28.7%	
Olmesartan	antihypertensive agent	57.1	36.7	(53.9%)	-20.5	-35.8%	58.0	68.0	10.0	-43.6	-39.1%	
Benicar/Beni	car HCT incl. AG	40.3	26.2	(48.6%)	-14.1	-35.0%	42.0	54.0	12.0	-25.5	-32.0%	
Azor		10.4	5.8	(73.1%)	-4.6	-44.0%	10.0	8.0	-2.0	-11.7	-59.5%	
Tribenzor		6.3	4.6	(76.5%)	-1.8	-27.7%	6.0	6.0	0.0	-6.4	-51.7%	
Welchol	hypercholesterolemia treatment/ type 2 diabetes mellitus inhibitor	24.2	19.5	5 (54.1%)	-4.7	-19.5%	37.0	36.0	-1.0	-12.4	-25.6%	
Effient	antiplatelet agent	10.6	10.8	-	0.2	+2.2%	not disclosed	not disclosed	-	-	-	
Savaysa	anticoagulant agent	-0.2	0.9	(57.0%)	1.1	-	2.0	1.6	-0.4	1.2	+255.6%	
Movantik	opioid-induced constipation treatment	0.6	1.9	-	1.3	+213.5%	not disclosed	not disclosed	-	-	-	
Luitpold Pharmac	euticals, Inc. (US)	46.4	41.7	(50.3%)	-4.7	-10.0%	92.0	83.0	-9.0	-8.0	-8.8%	
Venofer	treatment for iron deficiency anemia	16.0	13.9	(55.5%)	-2.2	-13.4%	25.0	25.0	0.0	-6.2	-19.9%	
Injectafer	treatment for iron deficiency anemia	7.9	11.1	(46.2%)	3.2	+40.7%	27.0	24.0	-3.0	5.4	+28.8%	
Daiichi Sankyo Eu	ırope GmbH	39.2	37.0	(56.0%)	-2.3	-5.8%	74.0	66.0	-8.0	-11.8	-15.1%	
Olmesartan	antihypertensive agent	30.2	24.7	(61.7%)	-5.6	-18.4%	46.0	40.0	-6.0	-18.9	-32.1%	
Olmetec/Olm	netec Plus	17.1	13.6	(64.9%)	-3.4	-20.2%	24.0	21.0	-3.0	-11.8	-36.0%	
Sevikar		8.5	6.6	(60.0%)	-1.9	-22.6%	13.0	11.0	-2.0	-5.5	-33.2%	
Sevikar HCT		4.6	4.5	(55.6%)	-0.2	-4.1%	9.0	8.0	-1.0	-1.6	-16.9%	
Efient	antiplatelet agent	2.2	4.2	-	2.0	+90.3%	not disclosed	not disclosed	-	-	_	
Lixiana	anticoagulant agent	0.2	3.3	3 (41.2%)	3.1	-	9.0	8.0	-1.0	6.5	+417.6%	
Asia, South and C	entral America (ASCA)	42.7	34.0	(48.6%)	-8.7	-20.4%	71.0	70.0	-1.0	-5.3	-7.1%	
Daiichi Sankyo (China	16.4	15.5	; -	-1.0	-5.8%	not disclosed	not disclosed	-	-	-	
Daiichi Sankyo 1	Taiwan	2.7	2.4	-	-0.2	-9.2%	not disclosed	not disclosed	-	-	-	
Daiichi Sankyo k	Korea	4.8	4.1	-	-0.7	-14.5%	not disclosed	not disclosed	-	-	-	
Daiichi Sankyo T	Thailand	1.8	1.1	-	-0.7	-37.7%	not disclosed	not disclosed	-			
Daiichi Sankyo E	Brasil Farmacêutica	4.5	4.1	-	-0.4	-8.7%	not disclosed	not disclosed	-	-		
Daiichi Sankyo \	Venezuela	5.5	0.1	-	-5.5	-99.1%	not disclosed	not disclosed	-	-	-	

3. Revenue by B	Business Units and Products (3)	FY2015 Q2 YTD		FY2016 Q2	YTD		FY2016					
[Reference] Rev	enue in Local Currency	Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of May.)	Forecast (as of Oct.)	vs. Forecast (as of May.)	YoY	YoY (%)	
USD Mn												
Daiichi Sankyo, Inc	c. (US)	766	667	(51.9%)	-99	-13.0%	1,118	1,286	167	-255	-16.5%	
Olmesartan	antihypertensive agent	469	348	(52.5%)	-121	-25.8%	527	662	135	-267	-28.7%	
Benicar/Benic	ar HCT incl. AG	331	249	(47.3%)	-82	-24.9%	382	526	144	-135	-20.5%	
Azor		86	56	(71.3%)	-30	-35.3%	91	78	-13	-86	-52.6%	
Tribenzor		52	44	(74.5%)	-9	-16.4%	55	58	4	-45	-43.4%	
Welchol	hypercholesterolemia treatment/ type 2 diabetes mellitus inhibitor	199	185	(52.7%)	-14	-7.0%	336	351	14	-52	-12.9%	
Effient	antiplatelet agent	87	103	-	16	+18.2%	not disclosed	not disclosed	-	-	-	
Savaysa	anticoagulant agent	-1	9	(55.5%)	10	-	18	16	-3	12	+316.1%	
Movantik	opioid-induced constipation treatment	5	18	-	13	+262.5%	not disclosed	not disclosed	-	-	-	
USD Mn												
Luitpold Pharmace	euticals, Inc. (US)	381	396	(49.0%)	15	+4.0%	836	808	-28	51	+6.7%	
Venofer	treatment for iron deficiency anemia	132	132	(54.1%)	0	+0.1%	227	243	16	-16	-6.3%	
Injectafer	treatment for iron deficiency anemia	65	105	(45.0%)	41	+62.7%	245	234	-12	79	+50.7%	
EUR Mn												
Daiichi Sankyo Eur	rope GmbH	290	313	(54.1%)	22	+7.7%	592	578	-14	-8	-1.4%	
Olmesartan	antihypertensive agent	224	209	(59.5%)	-15	-6.7%	368	351	-17	-94	-21.1%	
Olmetec/Olme	etec Plus	126	115	(62.6%)	-11	-8.8%	192	184	-8	-64	-25.7%	
Sevikar		63	56	(57.9%)	-7	-11.5%	104	96	-8	-28	-22.4%	
Sevikar HCT		34	38	(53.7%)	3	+9.5%	72	70	-2	-2	-3.4%	
Efient	antiplatelet agent	16	35	-	19	+117.4%	not disclosed	not disclosed	-	-	-	
Lixiana	anticoagulant agent	1	28	(39.8%)	27	-	72	70	-2	58	+501.4%	

4. Consolidated Statement of Financial Position

<ass< th=""><th>sets></th><th></th><th></th><th>JPY Bn</th><th></th><th></th></ass<>	sets>			JPY Bn		
		Mar. 2016	Sep. 2016	vs. Mar. 2016		
Asse	ets					
	Current assets					Issuance of bonds +100.0
	Cash and cash equivalents	222.2	300.5	78.3	$ \prec $	Acquisition of own shares -38.4
	Trade and other receivables	248.8	230.2	-18.5	4	Forex loss
	Other financial assets	493.8	476.8	-17.0	4	POTEX IOSS
	Inventories	144.3	157.2	12.9		
	Other current assets	15.2	20.2	4.9		
	Subtotal	1,124.2	1,184.9	60.7		
	Assets held for sale	1.1	2.5	1.5		
	Total current assets	1,125.3	1,187.4	62.2		
'	Non-current assets					Amortization, Forex loss
	Property,plant and equipment	250.2	241.9	-8.3	 - -	
	Goodwill	78.7	72.9	-5.8		Forex loss
	Intangible assets	210.4	205.6	-4.8	7	Acquisition +14.6, Amortization -7.4,
	Investments accounted for using the equity method	1.2	1.0	-0.3		Forex loss -11.8
	Other financial assets	168.2	140.1	-28.1	7	Evaluation loss -24.5
	Deferred tax assets	55.7	63.8	8.0		Evaluation 1033 24.0
	Other non-current assets	10.9	8.9	-2.0		
	Total non-current assets	775.3	734.1	-41.2		
	Total assets	1,900.5	1,921.5	21.0		
*	Liquidity on hand	714.7	776.5	61.8]	
•	Debt with interest	203.6		98.5		
	Net Cash	511.1	474.4			
				3, 5, 1	J	

<liabilities and="" equity=""></liabilities>			JPY Bn
	Mar. 2016	Sep. 2016	vs. Mar. 2016
Liabilities			
Current liabilities			
Trade and other payables	241.8	228.1	-13.7
Bonds and borrowings	20.0	20.0	-
Other financial liabilities	0.8	0.5	-0.3
Income taxes payable	53.9	69.1	15.1
Provisions	28.3	30.3	1.9
Other current liabilities	34.8	33.3	-1.4
Subtotal	379.7	381.3	1.6
Liabilities directly associated with assets held for sale	-	0.2	0.2
Total current liabilities	379.7	381.5	1.8
Non-current liabilities			
Bonds and borrowings	181.0	280.5	99.5
Other financial liabilities	9.1	8.2	-0.9
Post employment benefit liabilities	14.0	14.2	0.2
Provisions	12.3	11.5	-0.8
Deferred tax liabilities	33.7	29.7	-4.0
Other non-current liabilities	37.2	34.6	-2.6
Total non-current liabilities	287.3	378.8	91.5
Total liabilities	667.0	760.3	93.3
quity			
Equity attributable to owners of the Company			
Share capital	50.0	50.0	-
Capital surplus	103.9	103.8	-0.2
Treasury shares	-64.2	-102.5	-38.3
Other components of equity	146.7	82.8	-63.9
Retained earnings	994.9	1,026.8	31.9
Total equity attributable to owners of the Company	1,231.4	1,160.9	-70.5
Non-controlling interests			
Non-controlling interests	2.1	0.3	-1.8
Total equity	1,233.5	1,161.2	-72.4
Fotal liabilities and equity	1,900.5	1,921.5	21.0

Issuance of bonds

Acquisition -38.3 (15 million shares)

Forex loss

Profit for the period +49.0, Dividends -20.5

5. Consolidated Statement of Cash Flows

JPY Bn

	FY2015	FY2016	31 1 101
	Q2 YTD	Q2 YTD	YoY
Cash flows from operating activities			
Profit before tax	90.8	71.9	-18.9
Depreciation and amortization	21.8	21.9	0.
(Increase) decrease in receivables and payables	-16.6	7.9	24.
Others, net	-14.9	-17.4	-2.
Income taxes paid	-20.3	-13.7	6.
Net cash flows from operating activities	60.9	70.6	9.
Cash flows from investing activities			
Net (increase) decrease in time deposits and securities	-281.6	-2.1	279.
(Acquisition of) proceeds from sales of fixed assets	-41.1	-22.0	19.
Proceeds from sale of subsidiary	7.0	-	-7.
Net (increase) decrease in investment securities	374.2	8.0	-366.
Others, net	0.0	2.3	2.
Net cash flows from investing activities	58.5	-13.8	-72.
Cash flows from financing activities			
Net (increase) decrease in borrowings	-0.0	-	0.
Proceeds from bonds and borrowings	-	100.0	100.
Purchase of treasury shares	-50.2	-38.4	11.
Dividends paid	-21.1	-20.5	0.
Others, net	-0.7	-7.5	-6.
Net cash flows from financing activities	-72.0	33.6	105.
Net increase (decrease) in cash and cash equivalents	47.3	90.5	43.
Cash and cash equivalents at the beginning of the period	189.4	222.2	32.
Effect of exchange rate changes on cash and cash equivalents	-1.4	-12.1	-10.
Cash and cash equivalents at the end of the period	235.4	300.5	65.
* Free each flows (Cook flows from an artistic and investing activities)	119.4	56.8	-62.

FY2015: Increase in time deposits and securities

FY2015: Sale of Sun Pharma shares

6. Number of Employees

	Sep. 2015	Mar. 2016	Sep. 2016
	Results	Results	Results
Consolidated	16,377	15,249	15,137
Japan	8,598	8,589	8,735
North America	3,295	2,321	2,461
Europe	2,063	1,997	1,796
Others	2,421	2,342	2,145

7. Capital Expenditure and Depreciation and Amortization

		FY2015 Q2 YTD	FY2015	FY2016 Q2 YTD	FY2016
	JPY Bn	Results	Results	Results	Forecast
Capital expenditure		14.2	23.3	11.1	33.0
Depreciation and amortization		21.8	44.3	21.9	46.0
Property,plant and equipment		13.8	28.0	14.5	-
Intangible assets		8.1	16.3	7.4	-

8. Summary of Product Outlines

Brand Name	Generic Name	Therapeutic Category	<u>Launched</u>	Origin	Marketing Alliance	Type of Alliance
Japan						
Nexium	esomeprazole	ulcer treatment	2011	AstraZeneca	AstraZeneca	Co-promotion (DS: Sales)
Olmetec	olmesartan	antihypertensive agent	2004	Daiichi Sankyo		
Memary	memantine	Alzheimer's disease treatment	2011	Merz		
Loxonin			1986	Daiichi Sankyo		
Loxonin Poultice	loxoprofen	anti-inflammatory analgesic	2006	Lead Chemical		
Loxonin Tape	юхоргоген	and milanimatory analgesic	2008	Lead Chemical		
Loxonin Gel			2010	Daiichi Sankyo		
Tenelia	teneligliptin	type 2 diabetes mellitus inhibitor	2012	Mitsubishi Tanabe	Mitsubishi Tanabe	Co-promotion (DS: Sales)
Lixiana	edoxaban	anticoagulant agent	2011	Daiichi Sankyo		
Rezaltas	olmesartan / azelnidipine	antihypertensive agent	2010	Daiichi Sankyo		
Pralia	denosumab	treatment for osteoporosis	2013	Amgen		
Ranmark	denosumab	treatment for bone complications caused by bone metastases from tumors	2012	Amgen		
Inavir	laninamivir	anti-influenza treatment	2010	Daiichi Sankyo		
Cravit	levofloxacin	synthetic antibacterial agent	1993	Daiichi Sankyo		
Omnipaque	iohexol	contrast medium	1987	GE Healthcare		
Urief	silodosin	treatment for dysuria	2006	Kissei	Kissei	Co-marketing
Artist	carvedilol	treatment for hypertension, angina pectoris and chronic heart failure	1993	Roche		
Mevalotin	pravastatin	antihyperlipidemic agent	1989	Daiichi Sankyo		
Efient	prasugrel	antiplatelet agent	2014	Daiichi Sankyo Ube Industries		
aiichi Sankyo, Inc. (US)						
Olmesartan						
Benicar	olmesartan		2002			
Benicar HCT	olmesartan / hydrochlorothiazide	antihypertensive agent	2003	Daiichi Sankyo		
Azor	olmesartan / amlodipine	anunypertensive agent	2007	Dalichi Sankyo		
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)
uitpold Pharmaceuticals, Inc. (US)						
Venofer	iron sucrose injection	treatment for iron deficiency anemia	2000	Vifor Pharma	Fresenius	Co-marketing
Injectafer	ferric carboxymaltose injection	treatment for iron deficiency anemia	2013	Vifor Pharma		
aiichi Sankyo Europe GmbH						
Olmesartan						
Olmetec	olmesartan		2002			
Olmetec Plus	olmesartan / hydrochlorothiazide	antihypertensive agent	2005	Daiichi Sankyo	Menarini	Co-marketing
Sevikar	olmesartan / amlodipine	, p	2009		Pfizer	22
Sevikar HCT	olmesartan / amlodipine / hydrochlorothiazide		2010			
Efient	prasugrel	antiplatelet agent	2009	Daiichi Sankyo Ube Industries		
Lixiana	edoxaban	anticoagulant agent	2015	Daiichi Sankyo	Merck (MSD)	Co-marketing

<9. Quarterly Data>

1. Consolidated Statement of Profit or Loss FY2016 FY2016 FY2016 FY2015 FY2015 FY2015 FY2016 FY2015 FY2015 FY2016 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Results Results Results to revenue Results YoY YoY (%) Results Results to revenue Results Results Results Results JPY Bn 238.4 240.4 279.8 227.9 986.4 +7.3% 241.0 217.0 100.0% 458.0 Revenue 100.0% 67.1 Cost of sales 74.0 75.0 88.88 80.9 32.3% 318.6 -4.5 -1.49 77.6 69.7 32.2% 147.3 315.6 76.3 76.1 +10.4% 77.6 69.7 147.3 (excl. Special items) 88.8 74.4 32.0% 29.7 32.2% (Special items) -2.4 -1.1 6.5 0.3% 3.0 -34.1 -91.8% **Gross Profit** 164.5 165.4 191.0 147.0 67.7% 667.8 71.5 163.4 147.4 67.8% 310.7 +12.0% 71.6 69.5 SG&A expenses 72.8 87.8 96.5 33.3% 328.8 -2.4 -0.7% 72.2 141.7 30.9% 75.6 (excl. Special items) 77.1 81.7 84.6 32.3% 319.0 0.3 +0.1% 69.5 66.2 29.6% 135.7 (Special items) -3.9 -4.3 6.1 11.9 1.0% 9.8 -2.8 -22.1% 6.0 6.0 1.3% R&D expenses 43.7 44.7 49.8 70.5 21.2% 208.7 18.0 +9.4% 46.6 49.2 20.9% 95.8 (excl. Special items) 43.7 44.7 49.5 65.2 20.6% 203.0 16.8 +9.0% 46.6 49.2 20.9% 95.8 (Special items) 0.3 5.4 0.6% 5.6 1.2 +27.0% **Operating Profit** 49.1 47.9 53.4 -20.0 13.2% 130.4 56.0 +75.2% 47.3 26.0 16.0% 73.3 (Operating Profit before Special items) 42.9 42.5 59.8 3.7 15.1% 148.9 20.3 +15.8% 47.3 32.0 17.3% 79.3 -2.1 -2.9 -1.9 Financial income/expenses -3.7 1.0 -7.7 -14.2 0.7 -1.1 -0.1 0.2 -0.2 Share of profit or loss of investments -0.2 -0.2 -0.3 0.6 -0.0 -0.2 accounted for using the equity method 122.4 **Profit before tax** 45.2 45.6 54.6 -23.0 12.4% 42.5 +53.1% 45.2 26.7 15.7% 71.9 Income taxes 11.1 10.3 14.7 5.9 42.0 5.6 +15.4% 15.1 9.0 24.1 35.3 47.8 Profit for the year 34.1 39.9 -28.9 8.2% 80.4 36.8 +84.5% 30.1 17.7 10.4% 34.9 35.8 40.0 -28.4 8.3% 82.3 35.8 +77.1% 30.6 18.4 10.7% 49.0 Profit attributable to owners of the Company Tax rate 24.6% 22.5% 27.0% -25.5% 34.3% 33.4% 33.7% 33.5% Overseas sales ratio 46.8% 46.2% 40.6% 41.5% 43.7% 42.0% 37.9% 40.0% Currency Rate (Average) USD/JPY 121.37 121.80 121.70 120.14 120.14 108.25 105.35 105.35 **EUR/JPY** 134.16 135.07 134.37 132.57 132.57 122.17 118.22 118.22

<9. Quarterly Data>

2. Revenue of Global Products	FY2015 Q1	FY2015 Q2	FY2015 Q3	FY2015 Q4	F	Y2015		FY2016 Q1	FY2016 Q2	FY2016 Q3	FY2016 Q4	FY2016
JPY Bn	Results	Results	Results	Results	Results	YoY	YoY (%)	Results	Results	Results	Results	Results
Olmesartan	75.6	71.9	80.9	55.7	284.1	-9.4	-3.2%	65.7	49.7			115.4
Olmetec (JPN)	18.5	17.7	24.3	13.4	73.9	-2.5	-3.2%	18.3	16.6			34.9
Rezaltas (JPN)	4.6	4.3	5.2	4.1	18.2	-0.2	-1.3%	4.7	4.2			8.8
Benicar/Benicar HCT incl. AG (US)	19.8	20.5	22.8	16.3	79.5	2.5	+3.2%	17.3	8.9			26.2
Azor (US)	5.8	4.6	5.2	4.1	19.7	1.5	+8.1%	3.3	2.5			5.8
Tribenzor (US)	3.1	3.2	3.3	2.8	12.4	1.1	+9.8%	2.5	2.1			4.6
Olmetec/Olmetec Plus (EU)	8.9	8.2	7.8	7.9	32.8	-4.9	-13.1%	7.7	5.9			13.6
Sevikar (EU)	4.5	4.1	3.5	4.4	16.5	-1.1	-6.3%	3.6	3.0			6.6
Sevikar HCT (EU)	2.5	2.2	2.8	2.2	9.6	-0.3	-2.7%	2.7	1.8			4.5
Other subsidiaries, export, etc	7.9	7.1	6.0	0.5	21.6	-5.4	-20.2%	5.6	4.7			10.3
Prasugrel	7.8	7.4	8.7	8.2	32.2	7.3	+29.4%	10.9	9.3			20.2
Effient alliance revenue (US)	5.2	5.4	5.8	4.3	20.7	3.2	+18.1%	6.0	4.9			10.8
Efient (EU)	1.1	1.1	1.1	2.1	5.4	0.6	+13.0%	2.3	1.9			4.2
Efient (JPN)	1.2	0.6	1.5	1.6	4.9	4.2	+613.5%	2.5	2.4			4.9
Other subsidiaries, export, etc	0.3	0.4	0.3	0.2	1.2	-0.7	-36.5%	0.2	0.2			0.3
Edoxaban	1.8	3.5	5.2	4.5	15.0	10.7	+251.1%	7.3	8.7			16.1
Lixiana (JPN)	2.1	3.2	4.2	3.4	13.0	9.4	+262.6%	5.5	6.0			11.5
Savaysa (US)	-0.3	0.1	0.5	0.2	0.4	-0.2	-35.6%	0.3	0.6			0.9
Lixiana (EU)	0.0	0.1	0.5	0.9	1.5	1.5	-	1.4	1.9			3.3
Other subsidiaries	-	-	-	0.0	0.0	0.0	-	0.1	0.3			0.3

3. Revenue by Business Units and Products (1)	FY2015 Q1	FY2015 Q2	FY2015 Q3	FY2015 Q4	F	Y2015	FY2016 Q1	FY2016 Q2	FY2016 Q3	FY2016 Q4	FY2016
JPY Bn	Results	Results	Results	Results	Results	YoY YoY (%)	Results	Results	Results	Results	Results
Japan	114.2	113.6	149.6	117.2	494.7	14.2 +2.9%	123.4	115.6			239.0
Nexium	19.1	19.6	23.3	20.4	82.4	13.1 +18.8%	21.0	21.0			42.0
Olmetec	18.5	17.7	24.3	13.4	73.9	-2.5 -3.2%	18.3	16.6			34.9
Memary	10.2	10.2	12.2	9.7	42.4	5.6 +15.3%	12.1	11.3			23.4
Loxonin	12.6	11.8	13.9	9.9	48.1	-1.4 -2.8%	10.3	8.5			18.8
Tenelia	2.4	3.0	6.6	4.6	16.5	9.0 +118.9%	6.7	5.1			11.8
Lixiana	2.1	3.2	4.2	3.4	13.0	9.4 +262.6%	5.5	6.0		·	11.5
Rezaltas	4.6	4.3	5.2	4.1	18.2	-0.2 -1.3%	4.7	4.2		·	8.8
Pralia	2.6	2.8	3.7	3.4	12.5	5.1 +70.1%	4.1	4.2			8.3
Ranmark	2.9	3.0	3.5	3.0	12.4	2.2 +22.0%	3.4	3.4			6.8
Inavir	0.0	0.0	2.5	11.5	14.0	-2.6 -15.4%	0.6	0.0		·	0.6
Cravit	4.6	4.4	5.6	3.8	18.4	-9.5 -34.0%	3.8	3.6		·	7.3
Omnipaque	4.2	4.2	4.8	3.6	16.9	-0.3 -1.9%	3.7	3.5			7.2
Urief	2.9	2.8	3.3	2.8	11.8	0.3 +2.8%	3.0	2.7			5.8
Artist	4.1	3.8	4.2	3.0	15.1	-3.0 -16.8%	3.1	2.6			5.7
Mevalotin	3.6	3.4	3.8	2.7	13.4	-2.7 -16.9%	2.9	2.5			5.5
Efient	1.2	0.6	1.5	1.6	4.9	4.2 +613.5%	2.5	2.4			4.9
Daiichi Sankyo Espha products	4.3	4.3	5.6	4.3	18.5	3.6 +23.9%	5.2	4.7			9.9
Vaccines business	6.4	8.0	15.6	6.8	36.8	4.6 +14.2%	6.6	8.0			14.7
Daiichi Sankyo Healthcare (OTC)	10.8	13.8	15.2	13.5	53.4	5.5 +11.6%	14.8	17.4			32.2

3. Revenue by Business Units and Products (2)	FY2015 Q1	FY2015 Q2	FY2015 Q3	FY2015 Q4	F	Y2015		FY2016 Q1	FY2016 Q2	FY2016 Q3	FY2016 Q4	FY2016
JPY Bn	Results	Results	Results	Results	Results	YoY	YoY (%)	Results	Results	Results	Results	Results
Daiichi Sankyo, Inc. (US)	48.0	45.4	52.1	39.6	185.1	12.1	+7.0%	40.7	29.6			70.3
Olmesartan	28.8	28.3	31.3	23.2	111.6	5.1	+4.7%	23.2	13.5			36.7
Benicar/Benicar HCT incl. AG	19.8	20.5	22.8	16.3	79.5	2.5	+3.2%	17.3	8.9			26.2
Azor	5.8	4.6	5.2	4.1	19.7	1.5	+8.1%	3.3	2.5			5.8
Tribenzor	3.1	3.2	3.3	2.8	12.4	1.1	+9.8%	2.5	2.1			4.6
Welchol	13.5	10.6	13.5	10.7	48.4	1.0	+2.1%	10.0	9.5			19.5
Effient	5.2	5.4	5.8	4.3	20.7	3.2	+18.1%	6.0	4.9			10.8
Savaysa	-0.3	0.1	0.5	0.2	0.4	-0.2	-35.6%	0.3	0.6			0.9
Movantik	0.2	0.4	0.7	0.7	2.0	2.0	-	0.9	0.9			1.9
Luitpold Pharmaceuticals, Inc. (US)	21.5	24.9	22.6	22.0	91.0	33.6	+58.6%	22.0	19.8			41.7
Venofer	9.1	6.9	8.4	6.8	31.2	2.6	+9.2%	7.4	6.5			13.9
Injectafer	3.9	4.0	5.0	5.8	18.6	11.0	+143.9%	5.9	5.2			11.1
Daiichi Sankyo Europe GmbH	20.2	19.0	18.8	19.7	77.8	-5.7	-6.9%	20.4	16.5			37.0
Olmesartan	15.8	14.4	14.2	14.5	58.9	-6.3	-9.7%	14.0	10.7			24.7
Olmetec/Olmetec Plus	8.9	8.2	7.8	7.9	32.8	-4.9	-13.1%	7.7	5.9			13.6
Sevikar	4.5	4.1	3.5	4.4	16.5	-1.1	-6.3%	3.6	3.0			6.6
Sevikar HCT	2.5	2.2	2.8	2.2	9.6	-0.3	-2.7%	2.7	1.8			4.5
Efient	1.1	1.1	1.1	2.1	5.4	0.6	+13.0%	2.3	1.9			4.2
Lixiana	0.0	0.1	0.5	0.9	1.5	1.5	-	1.4	1.9			3.3
Asia, South and Central America (ASCA)	21.4	21.3	19.9	12.7	75.3	7.8	+11.6%	17.7	16.3			34.0
Daiichi Sankyo China	7.9	8.6	8.3	9.4	34.2	6.9	+25.1%	8.2	7.3			15.5
Daiichi Sankyo Taiwan	1.4	1.3	1.3	1.4	5.4	0.5	+10.5%	1.3	1.2			2.4
Daiichi Sankyo Korea	2.4	2.4	2.4	2.2	9.3	0.5	+5.2%	2.1	2.0			4.1
Daiichi Sankyo Thailand	0.8	1.0	1.1	1.2	4.1	0.4	+11.5%	0.6	0.5			1.1
Daiichi Sankyo Brasil Farmacêutica	2.6	1.9	2.1	1.4	8.1	-0.3	-3.1%	2.0	2.1			4.1
Daiichi Sankyo Venezuela	3.1	2.4	1.6	-6.9	0.2	-7.9	-98.0%	0.0	0.0			0.1

3. Revenue by Business Units and Products (3)	FY2015 Q1	FY2015 Q2	FY2015 Q3	FY2015 Q4	F	Y2015	FY2016 Q1	FY2016 Q2	FY2016 Q3	FY2016 Q4	FY2016
[Reference] Revenue in Local Currency	Results	Results	Results	Results	Results	YoY YoY (%)	Results	Results	Results	Results	Results
USD Mn											
Daiichi Sankyo, Inc. (US)	396	371	429	345	1,540	-33 -2.1%	376	291			667
Olmesartan	237	232	257	202	929	-40 -4.2%	214	134			348
Benicar/Benicar HCT incl. AG	163	168	187	143	661	-39 -5.6%	160	89			249
Azor	48	38	43	35	164	-2 -1.1%	31	25			56
Tribenzor	26	26	27	24	103	1 +0.5%	23	20			44
Welchol	112	87	111	93	403	-29 -6.6%	92	92			185
Effient	43	44	48	38	173	13 +8.0%	55	48			103
Savaysa	-2	1	4	1	4	-3 -41.1%	3	6			9
Movantik	1	3	6	6	17	17 -	8	9			18
USD Mn											
Luitpold Pharmaceuticals, Inc. (US)	177	204	186	191	758	236 +45.2%	203	193			396
Venofer	75	57	69	59	260	-0 -0.1%	68	63			132
Injectafer	32	33	41	49	155	86 +123.2%	55	51			105
EUR Mn											
Daiichi Sankyo Europe GmbH	151	140	142	155	587	-15 -2.5%	167	145			313
Olmesartan	118	106	106	114	444	-25 -5.4%	114	94			209
Olmetec/Olmetec Plus	66	60	59	62	248	-24 -9.0%	63	52			115
Sevikar	33	30	27	34	124	-2 -1.9%	29	26			56
Sevikar HCT	18	16	21	17	73	1 +1.9%	22	16			38
Efient	8	8	8	16	41	6 +18.3%	19	17			35
Lixiana	0	1	4	7	12	12 -	12	16			28

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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
Efient (EU)	2.9	3.9	4.7	4.8	5.4
Efient (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
Nexium	3.9	21.6	54.2	69.3	82.4
Olmetec	80.9	78.3	79.1	76.3	73.9
Memary	9.8	23.8	33.3	36.8	42.4
Loxonin	61.0	59.6	59.3	49.5	48.1
Tenelia		1.3	1.5	7.6	16.5
Lixiana	0.3	0.3	0.4	3.6	13.0
Rezaltas	13.5	16.9	18.5	18.4	18.2
Pralia		_	3.2	7.3	12.5
Ranmark		4.4	8.1	10.2	12.4
Inavir	10.7	11.1	13.4	16.6	14.0
Cravit	36.3	35.9	33.5	27.8	18.4
Omnipaque	23.5	20.2	19.7	17.2	16.9
Urief	11.0	11.1	11.4	11.5	11.8
Artist	24.5	22.4	22.4	18.1	15.1
Mevalotin	33.1	25.8	21.5	16.2	13.4
Efient				0.7	4.9
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)	FY2011	FY2012	FY2013	FY2014	FY2015
[Reference] Revenue in Local Currency	Results	Results	Results	Results	Results
USD Mn					
Daiichi 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					
Daiichi 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

11. Major R&D Pipeline (Innovative pharmaceuticals)

♦ Filed

Product Code Number/Generic Name	Class	Target indication	Region	Note, Filing year/month
doxaban	Factor Xa inhibitor	Atrial fibrillation (AF)	ASCA etc.	BR (14/6 [*]), TH(15/7), CN(15/8), CA(15/8), TR(15/10) * means June 2014, ditto
doxaban	r actor Ad Illimottor	Venous thromboembolism (VTE)	ASCA etc.	BR (14/6), TH(15/7), CN(15/8), CA(15/8), TR(15/10)
Summary> The once daily oral anti coagulant (FXa inhi	bitor) discovered by Daiichi Sankyo. Edoxa	ban specifically, reversibly and directly inhibits the enzyme, Factor X	(a, a clotting factor in the bl	lood.
CL-108	Opioid mu-receptor agonist combination	Acute pain	US	NDA was submitted in March 2016 by Charleston Laboratories, Inc., licensor and co-development partner
Summary> CL-108 is novel hydrocodone combination peduce the unwanted side effects of opioid-in		b and Daiichi Sankyo for the treatment of moderate to severe pain w	hile preventing or reducing	Opioid-Induced Nausea and Vomiting (OINV). The product expects
•				NDA of oral formulation (extended-release and
łydromorphone	Opioid mu-receptor agonist	Cancer pain	JP	immediate-release formulations) was submitted in Marc
				2016 by Daiichi Sankyo Propharma
Denosumab	Anti-RANKL antibody	pproved Drugs and Indications with High Medical Needs. Daiichi Sar Rheumatoid arthritis	JP	Additional Indication, submitted in Sep 2016
<summary></summary>				
-		nediator of osteoclast formation, in-licensed from Amgen Inc. in 2007. I syringe in June 2013. In addition, from April 2012 Daiichi Sankyo be		
omplications stemming from multiple myelo	oma and bone metastases from solid tumors	s under the product name RANMARK® subcutaneous injection 120 m	ng, and from May 2014, as	a therapeutic agent to treat giant cell tumor of bone under the produ
arne Raniviark® subcutaneous injection	120 mg. Dalichi Sankyo is also participating	in global phase 3 clinical trials of denosumab as adjuvant treatment	Tor women with breast can	<u>icer.</u>
′N-100	Intradermal influenza HA vaccine	Prevention of seasonal Influenza	JP	Submitted by Japan Vaccine in April 2015
	ffers a more easy-to-use, surefire method to	d by four companies [Daiichi Sankyo, Terumo, Japan Vaccine and Ki o administer the vaccine than current methods. The device is also ex	-	-
/N-0107/MEDI3250	Live attenuated influenza vaccine	Prevention of seasonal Influenza	JP	Submitted by Daiichi Sankyo in June 2016
Summary> The US brand name of this vaccine is FluMis	st Quadrivalent that is a live attenuated infl	uenza vaccine which is administered as a nasal spray and contains f	our protective strains.	

Underline: change after FY2016 Q1 Financial Announcement in July 2016. Regarding edoxaban, the filing in Australia was withdrawn considering its business in total.

◆ Under development (Phase1-3)

Generic Name / Project Code Number	Class	Target indication	s	tage a	target FY for approval/launch basically for P3	Remarks
Prasugrel	Anti-platelet agent	Ischemic stroke	JP	P3	2017	Additional indication
Edoxaban	Factor Xa inhibitor	Elderly patients with non-valvular atrial fibrillation	<u>JP</u>	<u>P3</u>	2021	Additional dosage and administration for elderly patients
Denosumab	Anti-RANKL antibody	Breast cancer adjuvant	JP	P3	2020	Additional indication
Tivantinib	MET inhibitor	Hepatocellular cancer	US/EU	P3	2018	
Nimotuzumab	Anti-EGFR antibody	Gastric cancer	JP	P3	2020	
Vemurafenib	BRAF inhibitor	Melanoma adjuvant	US/EU	P3	-	Additional indication. Licensee Roche is conducting the study. Submission in 2016 is planned.
			US/EU/Asia	P3	2018	Relapsed and refractory AML patients
Quizartinib	FLT3-ITD inhibitor	Acute myeloid leukemia	US/ <u>EU/Asia</u>	P3	2021-	Newly diagnosed AML patients
			JP	P1	-	
		Tenosynovial Giant Cell Tumor (TGCT)	US/EU	P3	2019	Including pigmented villonodular synovitis
		Solid tumor	Asia	P1	-	Including TGCT
Pexidartinib/PLX3397	CSF-1R/KIT/FLT3-ITD inhibitor	Glioblastoma	US	P2	-	
		Melanoma	US	P2	-	
		Melanoma, solid tumor	US	P1/2	-	Combination with pembrolizumab in collaboration with Merck
Esaxerenone/CS-3150	MR antagonist	Hypertension	JP	<u>P3</u>	2019	
Lucia Control Control	wirt artagoriist	Diabetic nephropathy	JP	P2b	-	
		Fibromyalgia	US/EU	P3	2019	
Mirogabalin	α2δ ligand	Diabetic peripheral neuropathic pain	JP/Asia	P3	2018	
		Postherpetic neuralgia	JP/Asia	P3	2018	
Hydromorphone	Opioid mu-receptor agonist	Cancer pain	JP	P3	2018	Injection formulation
CHS-0214	TNFlpha inhibitor	Rheumatoid arthritis	JP	P3	2017	Etanercept biosimilar
VN-0105	DPT-IPV/Hib vaccine	Prevention of pertussis, diphtheria, tetanus, poliomyelitis and Hib	JP	P3	2019	Co-develop with Sanofi K.K.and KDSV
Patritumab	Anti-HER3 antibody	Head & neck cancer	EU	P2	-	
DS-1647	G47 ∆ oncolytic virus	Glioblastoma	JP	P2	-	SAKIGAKE Designation granted
DS-8500	GPR119 agonist	Diabetes	JP/US	P2	_	
Laninamivir	Nouraminidaes inhibitar	Influenza	US/EU	P2	-	Out-licensing with Biota
Laninamivir	Neuraminidase inhibitor	Influenza	JP	P1	-	Nebulizer formulation

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Underline: change after FY2016 Q1 Financial Announcement in July 2016

◆ Under development (Phase1-3)

Generic Name / Project code number	Class	Target indication		Stage	target FY for approval/launc basically for P	h Remarks
DS 2022	MDM2 inhibitor	Solid cancer, lymphoma	US/JP	P1	_	
DS-3032		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/ <u>US</u>	P1	-	
U3-1784	Anti-FGFR4 antibody	Solid cancer	EU	P1	-	
DS-1123	Anti-FGFR2 antibody	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	-	
<u>U3-1402</u>	Anti-HER3 antibody drug conjugate	Solid cancer	<u>JP</u>	<u>P1</u>	-	
DS-1040	TAFla inhibitor	Acute ischemic stroke, Acute pulmonary embolism	-	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	US	P1	-	
DS-7080	Angiogenesis inhibitor	Neovascular age-related macular degeneration (AMD)	US	P1	-	
DS-2969	GyrB inhibitor	Clostridium difficile infection (CDI)	-	P1	-	
DS-5141	ENA oligonucleotide	Duchenne muscular dystrophy	JP	P1/2	-	
VN-0102/JVC-001	Measles-Mumps-Rubela vaccine	Prevention of Measles, Mumps and Rubela	JP	P1/2	2022	Japan vaccine company is conducting the phase 1/2 study

♦ Stage-up (major changes from the FY2016 Q1 Financial Announcement in July 2016)

Generic Name / Project code number	Class	Target indication		Current stage	Remarks
Denosumab	Anti-RANKL antibody	Rheumatoid arthritis	JP	Submitted	Additional Indication, submitted in Sep 2016
Edoxaban	FXa inhibitor	Elderly patients with non-valvular atrial fibrillation	JP	P3	Started phase 3 study for new dosage and administration
Quizartinib	FLT3-ITD inhibitor	Acute myeloid leukemia	EU/Asia	P3	Newly diagnosed AML patients. Started phase 3 study in EU and Asia in addition to US
Esaxerenone/CS-3150	MR antagonist	Hypertension	JP	P3	Started phase 3 study
DS-8201	Anti-HER2 antibody drug conjugate	Solid cancer	US	P1	Started phase 1 study in US in addition to Japan
U3-1402	Anti-HER3 antibody drug conjugate	Solid cancer	JP	P1	Started phase 1 study

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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 phase 3 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	InnoCIMAb	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.

Phase 3 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.

ĺ	Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
	Patritumab	U3-1287	Injection	Anti-HER3 antibody	- 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 unrespectable 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.

Pexidartinib PLX339	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.

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
G47 Δ	DS-1647	Injection	Oncolytic Virus	- Glioblastoma	Prof. Todo Institute of Medical Science Univ. of Tokyo	TBD

<Summary>

A triple-mutated, replication-conditional herpes simplex virus type 1 (the third generation oncolytic herpes simplex virus type 1), designed to replicate only in cancer cells. This oncolytic virus therapy is expected better safety and efficacy profile compare to existing oncolytic virus. This product received SAKIGAKE Designation from MHLW on February 10th ,2016. Phase 2 Investigator Initiated Study for Glioblastoma is on-going in Japan.

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, Asia) SAVAYSA (US)

<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.

- Top line results of Hokusai-VTE (VTE) phase 3 study was presented at ESC 2013.
- Top line results of ENGAGE AF-TIMI 48 (AF) phase 3 study was presented at AHA 2013.
- AF/VTE indication: Following the launch in Japan in Sep 2014 (Dec 2014 for 60 mg tablet), edoxaban has already been marketed in more than 10 countries.

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)

<Summary>

The oral antiplatelet agent. Prasugrel helps to keep blood platelets from clumping together and developing a blockage in an artery.

- · 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. Phase 3 studies for ischemic stroke are completed.
- [US] Phase 3 study in pediatric sickle cell disease patients was conducted. The patent exclusivity in US has been extended for 180 days based on the pediatric study completion.

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Esaxerenone	CS-3150	Oral	MR antagonist	- Hypertension - Diabetic nephropathy	Exelixis	TBD

<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.

- On January 2015, phase 2b studies of HTN and DN started.
- On November 2015, phase 2b study in essential hypertension in Japan was completed.
- $\cdot\,$ In September 2016, phase 3 of HTN started.

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
1	DS-8500	Oral	GPR119 agonist	- Diabetes	Daiichi Sankyo	TBD

<Summary>

The agent agonistically acts on GPR119 which is expressed in small intestine and spleen cells, stimulates insulin secretion, and lowers blood sugar concentration.

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

<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.

NDA submission in Apr 2015 by Japan Vaccine

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

<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."

•NDA of oral formulations (extended-release and immediate-release formulations) were submitted in Mar 2016 by Daiichi Saknyo Propharma. Phase 2/3 studies for injection formulation are ongoing.

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)

<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.

- July 2007 In-licensed from Amgen.
- Phase 3 : Breast cancer adjuvant
- September 2016 sNDA submission for rheumatoid arthritis (additional indication)

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
-	CHS-0214	Injection	TNFα inhibitor	- Rheumatoid arthritis	Coherus	TBD

<Summary>

Biosimilar product for etanercept

•Phase 3 study for patients with rheumatoid arthritis in Japan was completed. In preparation for submission.

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

<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

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Mirogabalin	DS-5565	Oral	α2δ ligand	FibromyalgiaDiabetic peripheral neuropathic painPostherpetic neuralgia	Daiichi Sankyo	TBD

<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.

- •Phase 2 studies for diabetic peripheral neuropathic pain were completed.
- •Phase 3 studies for diabetic peripheral neuropathic pain and postherpetic neuralgia are in execution in JP/Asia.
- •Phase 3 studies for fibromyalgia are in execution in US/EU.

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

<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 3 safety and efficacy studies were conducted for FluMist Quadrivalent in Japanese children over the 2014-2015 influenza season and NDA was submitted in Japan in June 2016

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

<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).

Phase 3 study in Japan started in Oct 2014.