

**Financial results for the second quarter
of fiscal year 2011**

< Supplement >

October 31, 2011

 **SHIONOGI & CO., LTD.**

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1. Financial results and forecast

(Billions of yen)

	FY2011 1H actual	FY2011 2H forecast	FY2011 forecast	FY2010 1H actual	FY2010 2H actual	FY2010 actual	Y on Y change		
							1H	2H	full-year
Net Sales	124.0	145.0	269.0	143.3	139.0	282.3	(19.3)	6.0	(13.3)
<i>change %</i>	(13.5)	4.3	(4.7)	8.1	(4.7)	1.4			
Operating Income	18.2	27.8	46.0	19.2	27.6	46.8	(1.0)	0.2	(0.8)
<i>change %</i>	(5.1)	0.3	(1.9)	7.8	(20.0)	(10.6)			
Ordinary Income	18.4	25.6	44.0	17.6	27.5	45.1	0.8	(1.9)	(1.1)
<i>change %</i>	4.1	(7.0)	(2.6)	7.9	(19.5)	(10.6)			
Net Income	8.2	18.8	27.0	6.8	13.2	20.0	1.4	5.6	7.0
<i>change %</i>	19.5	42.8	34.8	(40.8)	(51.3)	(48.2)			

Note: Change % shows changes from the same period of the previous fiscal year

Because of changing fiscal term, FY2010 1H actuals of subsidiaries in the United States include 9-month results from January to September 2010, FY2010 actuals of subsidiaries in the United States include 15-month results from January 2010 to March 2011.

2. Sales of main merchandise and finished goods

(Billions of yen)

	FY2011 1H actual	FY2011 2H forecast	FY2011 forecast	FY2010 1H actual	FY2010 2H actual	FY2010 actual	Y on Y change		
							1H	2H	full-year
Prescription drugs	78.7	87.1	165.8	75.1	83.8	158.9	3.6	3.3	6.9
<i>change %</i>	4.8	4.0	4.4	0.6	7.6	4.2			
CRESTOR	17.2	19.4	36.6	13.7	15.3	29.0	3.5	4.1	7.6
IRBETAN	4.3	5.4	9.7	3.3	4.0	7.3	1.0	1.4	2.4
CYMBALTA	2.8	3.3	6.1	0.9	1.8	2.7	1.9	1.5	3.4
Total of 3 key products	24.3	28.1	52.4	17.9	21.0	38.9	6.4	7.1	13.5
OXYCONTIN	4.5	5.4	9.9	4.8	4.8	9.6	(0.3)	0.6	0.3
FINIBAX	2.2	2.4	4.6	1.8	1.8	3.6	0.4	0.6	1.0
DIFFERIN	1.7	1.9	3.6	1.5	1.7	3.2	0.2	0.2	0.4
PIRESPA	1.6	1.8	3.4	1.3	1.5	2.8	0.3	0.3	0.6
RAPIACTA	0.0	1.4	1.4	0.0	0.3	0.3	0	1.1	1.1
Total of 8 strategic products	34.3	41.0	75.3	27.2	31.1	58.3	7.1	9.9	17.0
Export/Overseas subsidiaries	2.0	13.3	15.3	26.0	11.4	37.4	(24.0)	1.9	(22.1)
<i>change %</i>	(92.0)	15.4	(59.3)	9.0	(54.8)	(23.7)			
Shionogi Inc.	(2.4)	8.2	5.7	*1 21.0	6.0	*2 27.0	(23.4)	2.2	(21.3)
DORIPENEM	1.9	2.9	4.8	2.5	2.2	4.7	(0.6)	0.7	0.1
Contract manufacturing	3.7	4.1	7.8	1.8	3.6	5.4	1.9	0.5	2.4
<i>change %</i>	108.0	11.7	44.2	(46.8)	(10.2)	(27.1)			
OTC and quasi-drugs	2.7	2.6	5.3	2.8	2.4	5.2	(0.1)	0.2	0.1
<i>change %</i>	(4.9)	11.2	2.4	(4.0)	(5.9)	(4.9)			
SEDES	1.3	1.2	2.5	1.3	1.1	2.4	0	0.1	0.1
POPON-S	0.5	0.4	0.9	0.5	0.4	0.9	0	0	0
Diagnostics	1.3	1.5	2.8	1.5	1.4	2.9	(0.2)	0.1	(0.1)
<i>change %</i>	(7.7)	3.8	(2.1)	(6.1)	0.7	(2.9)			
Royalty income	34.3	35.7	70.0	34.8	34.1	68.9	(0.5)	1.6	1.1
<i>change %</i>	(1.6)	4.8	1.6	45.3	3.2	20.9			
CRESTOR	32.3	35.0	67.3	32.8	31.4	64.2	(0.5)	3.6	3.1
Others	0.9	1.1	2.0	1.2	2.4	3.6	(0.3)	(1.3)	(1.6)
<i>change %</i>	(19.5)	(57.7)	(45.3)	(43.7)	24.7	(10.5)			
Total	124.0	145.0	269.0	143.3	139.0	282.3	(19.3)	6.0	(13.3)
<i>change %</i>	(13.5)	4.3	(4.7)	8.1	(4.7)	1.4			

Note: Change % shows changes from the same period of the previous fiscal year

Sales of each product are shown on non-consolidated basis

Because of changing fiscal term *1 Include 9-month actuals from January to September 2010 of subsidiaries in the United States.

*2 Include 15-month actuals from January 2010 to March 2011 of subsidiaries in the United States.

3. Management index

(Management index trend)

		FY2009	FY2010	FY2010 1H	FY2011 1H
Ratio of operating income to net sales	%	18.8	16.6	13.4	14.7
Ratio of ordinary income to net sales	%	18.1	16.0	12.3	14.9
Ratio of net income to net sales	%	13.9	7.1	4.8	6.6
Total asset turnover		0.53	0.53	0.27	0.24
Equity ratio	%	63.2	62.7	63.1	62.6
Return on asset (ROA)	%	9.7	8.5	3.3	3.6
Return on equity (ROE)	%	11.9	6.0	2.1	2.5
Dividend payout ratio	%	31.2	66.9	-	-
Earnings per share	yen	115.33	59.80	20.49	24.50
Earnings per share (diluted)	yen	-	-	-	24.49

4. Capital investments and depreciation cost

(Billions of yen)

	FY2011 1H actual	FY2011 2H forecast	FY2011 forecast	FY2010 1H actual	FY2010 2H actual	FY2010 actual	Y on Y change		
							1H	2H	full-year
Investment in equipments	8.2	7.8	16.0	7.3	10.6	17.9	0.9	(2.8)	(1.9)
Depreciation cost	7.1	8.9	16.0	10.0	7.9	17.9	(2.9)	1.0	(1.9)
Amortization of goodwill	1.6	1.6	3.2	2.7	1.6	4.3	(1.1)	-	(1.1)

5. R&D expenses

(Billions of yen)

	FY2011 1H actual	FY2011 2H forecast	FY2011 forecast	FY2010 1H actual	FY2010 2H actual	FY2010 actual	Y on Y change		
							1H	2H	full-year
R&D expenses	25.7	31.3	57.0	28.0	22.9	50.9	(2.3)	8.4	6.1
<i>change %</i>	(8.5)	37.0	11.9	0.6	(4.5)	(1.7)			
% to net sales	20.7	21.6	21.2	19.6	16.4	18.0			

Note: Change % shows changes from the same period of the previous fiscal year

6. Employees

	End of FY2009	End of 20101H	End of FY2010	End of 20111H	End of FY2011	Y on Y change		
	actual	actual	actual	actual	forecast	1H	2H	full-year
Employees	5,887	5,486	5,277	6,431	6,390	1,154	(41)	1,113

7. Consolidated statement of income

	FY2010 1H actual	FY2011 1H actual	(Millions of yen) Y on Y change	
Net sales	143,366	124,000	(19,366)	Increase in Prescription drugs: 3.6 billion yen Decrease in Shionogi Inc.: 23.4 billion yen
Cost of sales	39,057	37,523	(1,534)	
Gross profit	104,308	86,476	(17,832)	Including 9-month actuals of subsidiaries in the United States in FY2010 1H actual
Selling, general and administrative expenses	85,080	68,237	(16,843)	
Operating income	19,228	18,239	(989)	
Non-operating income	1,205	2,085	880	
Interest income	237	213	(24)	
Dividends income	696	663	(33)	
Foreign exchange gains	-	311	311	
Other	272	896	624	
Non-operating expenses	2,737	1,894	(843)	
Interest expenses	767	667	(100)	
Contribution	568	669	101	
Foreign exchange losses	889	-	(889)	
Other	512	558	46	
Ordinary income	17,696	18,429	733	
Extraordinary income	279	661	382	Land
Gain on sales of noncurrent assets	-	509	509	
Gain on sales of investment securities	-	152	152	
Gain on forgiveness of debts	279	-	(279)	
Extraordinary loss	6,468	4,536	(1,932)	Due to impairment of In-Process R&D in US
Impairment loss	3,145	1,570	(1,575)	
Loss on penalty	-	1,187	1,187	
Loss on disaster	-	1,089	1,089	Due to reorganization of US operations
Business structure improvement expenses	3,323	546	(2,777)	
Loss on valuation of investment securities	-	142	142	
Income before income taxes and minority interests	11,507	14,554	3,047	
Income taxes-current	8,981	9,216	235	
Income taxes-deferred	(4,359)	(2,865)	1,494	
Income before minority interests	6,884	8,203	1,319	
Minority interests in income	22	-	(22)	
Net income	6,862	8,203	1,341	

8-1. Consolidated balance sheets (Assets)

	As of Mar. 31 2011	As of Sep. 30 2011	(Millions of yen) Y on Y change	
(Assets)				
Current assets				
Cash and deposits	27,579	14,137	(13,442)	Decrease by share acquisition of C&O
Notes and accounts receivable-trade	69,498	66,429	(3,069)	
Short-term investment securities	88,914	86,320	(2,594)	
Merchandise and finished goods	24,369	28,568	4,199	
Work in process	13,294	12,758	(536)	
Raw materials and supplies	9,675	10,463	788	
Other	23,618	21,230	(2,388)	
Allowance for doubtful accounts	(12)	(19)	(7)	
Total current assets	256,937	239,889	(17,048)	Increase in construction of SPRC (New research facility): 2.7 billion yen Increase by acquisition of C&O: 2.3 billion yen
Noncurrent assets				
Property, plant and equipment	70,220	74,987	4,767	Decrease by amortization: 1.6 billion yen
Intangible assets				Decrease by exchange rate fluctuations: 4.5 billion yen Increase by acquisition of C&O: 7.9 billion yen
Goodwill	58,830	60,637	1,807	
Other	40,762	46,046	5,284	
Total Intangible assets	99,593	106,684	7,091	Decrease by amortization: 2.0 billion yen Decrease by exchange rate fluctuations: 2.6 billion yen Decrease by impairment: 1.6 billion yen
Investments and other assets				Increase by product acquisition of Victory Pharma, Inc. in US: 10.3 billion yen
Investment securities	60,654	55,859	(4,795)	
Other	35,957	35,640	(317)	
Allowance for doubtful accounts	(121)	(97)	24	
Total investments and other assets	96,491	91,402	(5,089)	Decrease by sales of government bonds: 4.0 billion yen
Total noncurrent assets	266,304	273,074	6,770	
Total assets	523,242	512,963	(10,279)	

8-2. Consolidated balance sheets (Liabilities/Net Assets)

	As of Mar. 31 2011	As of Sep. 30 2011	(Millions of yen) Y on Y change
(Liabilities)			
Current liabilities			
Notes and accounts payable-trade	12,884	14,834	1,950
Current portion of long-term loans payable	14,000	14,000	-
Current portion of bonds	-	10,000	10,000
Income taxes payable	13,510	9,841	(3,669)
Provision for bonuses	7,059	6,886	(173)
Provision for sales returns	1,775	6,234	4,459
Other provision	1,514	374	(1,140)
Other	29,075	27,936	(1,139)
Total Current liabilities	79,819	90,107	10,288
Noncurrent liabilities			
Bonds payable	30,000	20,000	(10,000)
Long-term loans payable	63,000	56,000	(7,000)
Provision for retirement benefits	8,573	8,747	174
Other	13,752	13,377	(375)
Total noncurrent liabilities	115,325	98,125	(17,200)
Total liabilities	195,145	188,232	(6,913)
(Net Assets)			
Shareholders' equity			
Capital stock	21,279	21,279	-
Capital surplus	20,227	20,227	-
Retained earnings	339,970	341,476	1,506
Treasury stock	(19,743)	(19,745)	(2)
Total shareholders' equity	361,733	363,237	1,504
Accumulated other comprehensive income			
Valuation difference on available-for-sale securities	3,732	2,885	(847)
Deferred gains or losses on hedges	(288)	220	508
Foreign currency translation adjustment	(37,081)	(45,000)	(7,919)
Total accumulated other comprehensive income	(33,637)	(41,893)	(8,256)
Subscription rights to shares	-	58	58
Minority interests	-	3,327	3,327
Total net assets	328,096	324,730	(3,366)
Total liabilities and net assets	523,242	512,963	(10,279)

Increase in Shionogi Inc.:
4.4 billion yen

Repayment of syndicate loan:
6.5 billion yen

Due to introducing a stock option
scheme

Due to share acquisition of C&O

9-1 Quarterly trend for FY2010 and FY2011 (Sales of main merchandise and finished goods)

Fiscal year ended March 31, 2011

(Billions of yen)

FY2010	FY2010 1Q actual	Y on Y change %	FY2010 2Q actual	Y on Y change %	FY2010 3Q actual	Y on Y change %	FY2010 4Q actual	Y on Y change %
Prescription drugs	38.0	2.1	37.1	(0.9)	43.9	3.3	39.9	12.7
CRESTOR	6.6	19.9	7.1	17.5	8.4	21.0	6.9	20.4
IRBETAN	1.6	347.9	1.7	95.9	2.2	75.0	1.8	37.9
CYMBALTA	0.4	-	0.5	-	0.9	-	0.9	-
Total of 3 key products	8.5	46.6	9.4	34.8	11.4	40.1	9.6	36.3
OXYCONTIN	2.5	13.7	2.3	13.5	2.7	7.7	2.1	20.2
FINIBAX	0.9	5.2	0.9	0.6	1.0	18.1	0.8	1.0
DIFFERIN	0.6	32.2	0.9	53.5	1.0	54.4	0.7	42.9
PIRESPA	0.7	150.1	0.6	75.3	0.8	79.7	0.7	47.9
RAPIACTA	(0.0)	-	0.0	-	(0.3)	-	0.6	1.6
Total of 8 strategic products	13.2	37.6	14.0	30.1	16.6	32.1	14.5	30.3
FLOMOX	5.3	(8.6)	4.8	(12.6)	6.6	(16.6)	5.2	8.0
RINDERON	2.5	(1.1)	2.5	(2.8)	2.3	(0.5)	2.2	8.0
CLARITIN	1.6	(8.0)	1.5	(13.2)	2.2	9.1	4.7	31.5
FLUMARIN	1.8	(16.5)	2.1	(17.5)	2.1	(9.9)	1.5	(9.0)
VANCOMYCIN	1.2	(29.4)	1.4	(19.1)	1.4	(6.9)	1.0	(13.3)
IMUNACE	0.8	(40.8)	0.8	(32.9)	0.9	(23.1)	0.6	(30.0)
Export/Overseas subsidiaries	17.1	42.6	8.9	(24.9)	8.7	(31.5)	2.7	(78.3)
Shionogi Inc.	* 15.2	58.8	5.8	(33.8)	5.6	(43.5)	0.4	(95.8)
DORIPENEM	0.5	(57.3)	2.0	16.3	1.7	35.8	0.5	(54.7)
Contract manufacturing	1.0	(35.7)	0.8	(55.4)	1.9	0.3	1.7	(19.4)
OTC and quasi-drugs	1.4	(3.9)	1.4	(4.1)	1.3	(3.4)	1.1	(8.9)
SEDES	0.6	(10.5)	0.7	(0.2)	0.7	16.5	0.4	(0.6)
POPON-S	0.3	14.0	0.2	(29.4)	0.2	(38.2)	0.2	(14.7)
Diagnostics	0.7	(9.7)	0.8	(2.2)	0.7	7.5	0.7	(4.9)
Royalty income	16.4	56.6	18.4	36.4	16.7	21.5	17.4	(10.0)
CRESTOR	15.4	53.6	17.4	38.7	15.2	15.1	16.2	14.2
Others	0.6	2.8	0.6	(60.5)	0.7	(28.7)	1.7	83.7
Total	75.2	17.5	68.1	(0.7)	73.9	0.1	65.0	(9.7)

Fiscal year ending March 31, 2012

FY2011	FY2011 1Q actual	Y on Y change %	FY2011 2Q actual	Y on Y change %
Prescription drugs	39.3	3.6	39.4	6.1
CRESTOR	8.3	27.4	8.9	24.1
IRBETAN	2.1	31.0	2.2	27.0
CYMBALTA	1.3	261.0	1.5	190.6
Total of 3 key products	11.8	38.1	12.5	33.9
OXYCONTIN	2.2	(10.5)	2.3	(1.4)
FINIBAX	1.0	11.8	1.2	31.3
DIFFERIN	0.8	27.0	0.9	8.8
PIRESPA	0.8	21.7	0.8	37.8
RAPIACTA	0.0	-	0.0	-
Total of 8 strategic products	16.6	26.1	17.7	26.4
FLOMOX	5.1	(3.9)	4.7	(1.5)
RINDERON	2.4	(6.4)	2.4	(1.1)
CLARITIN	1.8	8.3	1.4	(2.7)
FLUMARIN	1.7	(3.5)	1.8	(16.1)
VANCOMYCIN	1.1	(7.3)	1.2	(16.0)
IMUNACE	0.6	(26.1)	0.6	(31.4)
Export/Overseas subsidiaries	4.3	(74.8)	(2.3)	-
Shionogi Inc.	2.5	(82.9)	(4.9)	-
DORIPENEM	0.5	0.5	1.4	(32.1)
Contract manufacturing	1.6	74.9	2.1	144.6
OTC and quasi-drugs	1.2	(6.9)	1.5	(3.0)
SEDES	0.6	8.9	0.7	(10.5)
POPON-S	0.2	(16.0)	0.3	7.2
Diagnostics	0.7	(2.5)	0.6	(13.1)
Royalty income	15.9	(3.6)	18.4	0.2
CRESTOR	15.2	(0.8)	17.1	(1.9)
Others	0.4	(19.1)	0.5	(19.8)
Total	63.7	(15.3)	60.3	(11.5)

Note: Sales of each product are shown on non-consolidated basis

* Because of changing fiscal term, FY2010 1Q actuals of subsidiaries in the United States include 6-month sales from January to June 2010.

9-2 Quarterly trend for FY2010 and FY2011 (Consolidated statements of income)

Fiscal year ended March 31, 2011

(Billions of yen)

FY2010	FY2010 1Q actual *	Y on Y change %	FY2010 2Q actual	Y on Y change %	FY2010 3Q actual	Y on Y change %	FY2010 4Q actual	Y on Y change %
Net sales	75.2	17.5	68.1	(0.7)	73.9	0.1	65.0	(9.7)
Cost of sales	27.7 20.8	21.2	26.7 18.2	(7.4)	29.6 21.9	8.0	31.9 20.7	8.6
Gross profit	54.3	16.1	49.9	2.0	52.0	(2.9)	44.2	(16.3)
SG & A expenses	61.7 46.4	13.9	56.8 38.6	4.0	48.1 35.5	(2.3)	50.9 33.1	(6.7)
Selling & general expenses	33.3	35.4	23.6	(7.0)	24.5	3.1	21.2	(12.0)
R & D expenses	13.0	(19.1)	15.0	27.5	10.9	(12.5)	11.8	4.4
Operating income	10.6 7.9	31.1	16.5 11.2	(4.3)	22.3 16.4	(4.1)	17.2 11.1	(35.8)
Non-operating income & expenses	(0.7)		(0.7)		(0.4)		0.2	
Ordinary income	9.6 7.2	23.6	15.4 10.4	(0.7)	21.7 16.0	(5.7)	17.6 11.4	(33.2)
Extraordinary income & loss	(2.1)		(4.0)		(5.2)		(0.6)	
Income before income taxes and minority interests	5.0		6.4		10.7		10.8	
Income taxes and minority interests	0.2		4.3		4.1		4.3	
Net income	6.4 4.8	4.9	3.0 2.0	(70.9)	9.0 6.6	(52.2)	10.0 6.4	(50.4)

Fiscal year ending March 31, 2012

FY2011	FY2011 1Q actual	Y on Y change %	FY2011 2Q actual	Y on Y change %
Net sales	63.7	(15.3)	60.2	(11.5)
Cost of sales	28.3 18.0	(13.5)	32.3 19.4	7.0
Gross profit	45.6	(16.0)	40.7	(18.3)
SG & A expenses	53.7 34.2	(26.3)	56.4 34.0	(12.1)
Selling & general expenses	21.1	(36.6)	21.3	(9.5)
R & D expenses	13.0	0.3	12.6	(16.0)
Operating income	18.0 11.4	43.7	11.3 6.7	(39.7)
Non-operating income & expenses	0.2		(0.0)	
Ordinary income	18.3 11.6	62.1	11.2 6.7	(35.7)
Extraordinary income & loss	(6.2)		2.4	
Income before income taxes and minority interests	5.3		9.1	
Income taxes and minority interests	1.6		4.7	
Net income	5.9 3.7	(21.7)	7.3 4.4	117.1

* Because of changing fiscal term, FY2010 1Q actuals of subsidiaries in the United States include 6-month results from January to June 2010.

10. Consolidated affiliated companies and affiliated company accounted for by the equity method

<Consolidated affiliated companies>

No	Company name	Location	Common stock	Business status	Establish	Closing date	Ownership (%)
1	Shionogi Pharma Chemicals Co., Ltd.	Tokushima, Japan	JPY 200 million	Mfg. of pharmaceutical raw materials	August 24, 1976	March 31	100
2	Saishin Igaku Co., Ltd.	Osaka, Japan	JPY 90 million	Publication of medical information	December 21, 1998	March 31	100
3	Shionogi General Service Co., Ltd.	Osaka, Japan	JPY 10 million	Real estate rental, Insurance agency and contract general services	November 2, 1992	March 31	100
4	Shionogi Analysis Center Co., Ltd.	Osaka, Japan	JPY 200 million	Contract testing and analysis on medicine	December 21, 2007	March 31	100
5	Aburahi AgroResearch Co., Ltd.	Shiga, Japan	JPY 10 million	Contract Laboratories for Agro Chemicals	February 26, 2004	March 31	* 100
6	Shionogi Techno Advance Research Co., Ltd.	Osaka, Japan	JPY 9 million	Contract support services for experimental research	September 8, 2010	March 31	100
7	Taiwan Shionogi & Co., Ltd.	Taipei, Taiwan, R.O.C.	TWS 92 million	Mfg. and sale of pharmaceuticals	December 26, 1963	December 31	100
8	Shionogi Inc.	Delaware, U.S.A.	US\$ 6	Mfg. and sale of pharmaceuticals	August 25, 2008	March 31	100
9	SG Holding, Inc.	Delaware, U.S.A.	US\$ 140	Holding company	September 10, 2001	March 31	* 100
10	Ezose Sciences Inc.	Delaware, U.S.A.	US\$ 9	Serum glycan analysis contract services	March 3, 2009	March 31	* 100
11	C&O Pharmaceutical Technology (Holdings) Limited	Bermuda Islands	HK\$ 165,840 thousand	Mfg. and sale of pharmaceuticals	July 28, 2003	June 30	57.84

* Incl. Indirect ownership

<Affiliated company accounted for by the equity method>

No	Company name	Location	Common stock	Business status	Establish	Closing date	Ownership (%)
1	Shionogi-ViiV Healthcare, L.P.	Cayman Islands	-	Holding company	October 19, 2001	December 31	* 50

* Incl. Indirect ownership

Note: Nineteen consolidated affiliated companies and three affiliated companies accounted for by the equity method are not shown on this table as the scale of their business is very small.

11. Pipeline (as of October 2011)

Areas	Code No. (Generic name) 【Product name】	Category (Administration)	Indication	Stage	Origin	Development
Metabolic Syndrome	S-474474 (Irbesartan/trichlormethiazide combination)	Angiotensin receptor blocker/diuretic combination (Oral)	Hypertension	Japan: Phase III	Irbesartan: Sanofi (France) Trichlormethiazide: Shionogi	In-house
	S-2367 (Velneperit)	Neuropeptide Y Y5 receptor antagonist (Oral)	Obesity	Japan: Phase II	In-house	In-house
	S-707106	Insulin sensitizer (Oral)	Type 2 Diabetes	USA: Phase IIa	In-house	In-house
	S-234462	Neuropeptide Y Y5 receptor antagonist (Oral)	Obesity	USA: Phase I	In-house	In-house
Infectious Diseases	S-4661 (Doripenem hydrate) 【Finibax®】	Carbapenem antibiotic (Injection)	Pediatric infection	Japan: NDA submission (August 2011)	In-house	In-house
	S-349572 (Dolutegravir)	Integrase inhibitor (Oral)	HIV infection	Global: Phase III	Shionogi-ViiV Healthcare LLC	Shionogi-ViiV Healthcare LLC
	S-265744 LAP	Integrase inhibitor (Injection; Long acting parenteral formulation)	HIV infection	USA: Phase I	Shionogi-ViiV Healthcare LLC	Shionogi-ViiV Healthcare LLC
Pain	LY248686 (Duloxetine hydrochloride) 【Cymbalta®】	SNRI (Serotonin & noradrenaline reuptake inhibitor) (Oral)	Diabetic peripheral neuropathic pain	Japan: NDA submission (September 2009)	Eli Lilly and Company (USA)	Shionogi/ Eli Lilly Japan K.K.
	S-811717 (Oxycodone hydrochloride)	Natural opium alkaloids (Injection)	For the treatment of moderate to severe pain in patients with cancer pain	Japan: NDA submission (September 2010)	Napp Pharmaceuticals Limited (UK)	In-house
	S-297995	Peripheral opioid receptor antagonist (Oral)	Alleviation of opioid-induced adverse effect	USA: Phase IIb Japan: Phase IIb	In-house	In-house
Women's Health	PSD502 (Lidocaine/prilocaine)	Eutectic mixture of anesthetics (Metered-dose topical aerosol spray)	Premature ejaculation	USA, Europe: Phase III	Plethora Solutions Holdings PLC (UK)	Shionogi/ Plethora Solutions Holdings PLC
	Ospemifene	Selective estrogen receptor modulator (Oral)	Post-menopausal vaginal atrophy	USA: NDA submission (in preparation)	QuatRx Pharmaceuticals Company (USA)	Shionogi/ QuatRx Pharmaceuticals Company
Other	S-555739	Prostaglandin D2 receptor antagonist (Oral)	Allergic disease	Japan: Phase IIb USA: Phase I Europe: POM (Proof of Mechanism)	In-house	In-house
	S-888711	Small molecule TPO mimetic (Oral)	Thrombocytopenia	USA, Europe: Phase II Japan: Phase IIa	In-house	In-house
	S-288310	Cancer peptide vaccine (Injection)	Bladder cancer	Asia: Phase I/II	OncoTherapy Science, Inc. (Japan)	In-house
	S-488410	Cancer peptide vaccine (Injection)	Esophageal cancer	Japan: Phase I/II	OncoTherapy Science, Inc. (Japan)	In-house
	S-222611	HER2/EGFR dual inhibitor (Oral)	Malignant tumor	Europe: Phase Ib	In-house	In-house
	S-524101	Sublingual tablet of house-dust mite allergen extracts for immunotherapy	Allergic rhinitis caused by house-dust mite allergen	Japan: Phase II (in preparation)	Stallergenes SA (France)	In-house

<Out-Licensing Activity>

Code No. (Generic name)	Category (Administration)	Indication	Stage	Origin	Development
S-4661 (Doripenem hydrate)	Carbapenem antibiotic (Injection)	Bacterial infection	USA: Approval (October 2007) Complicated intra-abdominal infections, Complicated urinary tract infections including pyelonephritis NDA submission (June 2007) Hospital-acquired (nosocomial) pneumonia including ventilator-associated pneumonia Europe: Approval (July 2008)	In-house	Johnson & Johnson (USA)
S-3013 (Varespladib methyl)	Secretory PLA2(sPLA2) inhibitor (Oral)	Acute coronary syndromes	USA, Europe: Phase III	Shionogi/Eli Lilly and Company (USA)	Anthera Pharmaceuticals, Inc. (USA)
S-0373	Non-peptide mimetic of TRH (Oral)	Spinocerebellar ataxia	Japan: Phase II	In-house	Kissei Pharmaceutical Co., Ltd. (Japan)

<Since August, 2011>

Change of phase	S-4661 <Japan> : NDA submission (in preparation) → NDA submission (August 2011)
	Ospemifene <USA> : NDA submission (in preparation)
	S-555739 <Japan> : Phase IIb (in preparation) → Phase IIb
	S-555739 <USA> : IND submission (in preparation) → Phase I
	S-288310 <Asia> : Japan: Phase I/II → Asia: Phase I/II
	S-524101 <Japan> : Phase I → Phase II (in preparation)
	Cyclophosphamide hydrate 【Endoxan [®] 】 : delete indication (completed)
	Cyclophosphamide hydrate 【Endoxan [®] 】 : NDA submission (May 2011) → Approval (September 2011)
	Duloxetine hydrochloride 【Cymbalta [®] 】 : To be determined → Clinical trial (in preparation)

<Drugs to acquire new indication requested by the Ministry of Health, Labour and Welfare>

Generic name 【Product name】	Category (Administration)	Indication	Stage	Origin	Development
Cyclophosphamide hydrate 【Endoxan [®] 】	Antineoplastic agent and immunosuppressant (Injection)	Nephrotic syndrome, when the disease fails to respond adequately to appropriate adrenocorticosteroid therapy	Approval (September 2011)	Baxter (USA)	In-house
Metronidazole 【Flagyl [®] 】	Antibacterial and antiprotozoal agent (Oral)	Infections caused by anaerobic bacteria, Amebiasis, Giardiasis	NDA submission (in preparation)	Sanofi (France)	In-house
Metronidazole 【Flagyl [®] 】	Antibacterial and antiprotozoal agent (Oral or Intravaginal)	Bacterial vaginosis	NDA submission (in preparation)	Sanofi (France)	In-house
Lisinopril hydrate 【Longes [®] 】	ACE inhibitor (Oral)	Childhood hypertension	NDA submission (in preparation)	Merck & Co., Inc. (USA)/ AstraZeneca (UK)	Shionogi/AstraZeneca
Ifosfamide 【Ifomide】	Antineoplastic agent (Injection)	Malignant lymphoma in childhood	NDA submission (in preparation)	Baxter (USA)	In-house
Sulfamethoxazole/trimethoprim combination 【Baktar [®] 】	Synthetic folate-antagonist/ anti-infectives combination (Oral)	Prophylaxis and treatment of <i>Pneumocystis carinii</i>	NDA submission (in preparation)	Shionogi/GSK (UK)	In-house
Oxycodone hydrochloride hydrate 【Oxycontin [®] , Oxinorm [®] 】	Natural opium alkaloids (Oral)	For the treatment of moderate to severe chronic pain	To be determined	Napp Pharmaceuticals Limited (UK)	In-house
Duloxetine hydrochloride 【Cymbalta [®] 】	SNRI (Serotonin & noradrenaline reuptake inhibitor) (Oral)	Fibromyalgia	Clinical trial (in preparation)	Eli Lilly (USA)	Shionogi/ Eli Lilly Japan K.K.
Vancomycin hydrochloride 【Vancomycin】	Glycopeptide antibiotic (Drip infusion)	<Spectrum> Methicillin-resistant coagulase-negative staphylococcus, Penicillin-resistant enterococcus <Indication> Gram-positive bacteria-associated bloodstream infection (including intravascular catheter-related infection), Febrile neutropenia, Alternative agent in penicillin-allergic adults and children	To be determined	Eli Lilly (USA)	In-house