

**Financial results for the year
ended March 31, 2013**

< Supplement >

May 9, 2013

 **SHIONOGI & CO., LTD.**

Contents

- 1 Financial results and forecast
- 2 Sales of main merchandise and finished goods
- 3 Management index
- 4 Capital investments and depreciation cost
- 5 R&D expenses
- 6 Employees
- 7 Consolidated statement of income
- 8 Consolidated balance sheets
- 9 Quarterly trend for FY2011 and FY2012
- 10 Consolidated affiliated companies and affiliated companies accounted for by the equity method
- 11 Pipeline (as of May 2013)

1. Financial results and forecast

(billions of yen)

	FY2011 Results	FY2012 Results *	FY2013 Forecast	Change		FY2013 1H Forecast
				FY2012	FY2013	
Net Sales	267.3	282.9	287.0	15.6	4.1	138.0
<i>change %</i>	(5.3)	5.8	1.4			0.5
Operating Income	47.0	58.8	60.0	11.8	1.2	24.0
<i>change %</i>	0.2	25.2	2.0			(8.1)
Ordinary Income	46.1	58.9	59.0	12.8	0.1	24.0
<i>change %</i>	2.0	27.8	0.1			(4.4)
Net Income	27.1	66.7	37.0	39.6	(29.7)	14.5
<i>change %</i>	35.3	146.2	(44.6)			(2.4)

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

* Because of changing fiscal term, FY2012 results of Taiwan Shionogi & Co., Ltd. includes 15-month results from January 2012 to March 2013.

2. Sales of main merchandise and finished goods

(billions of yen)

	FY2011 Results	FY2012 Results	FY2013 Forecast	Change		FY2013 1H Forecast
				FY2012	FY2013	
Prescription drugs	164.4	165.7	170.6	1.3	4.9	83.1
<i>change %</i>	3.4	0.8	2.9			4.3
CRESTOR	35.7	38.1	42.4	2.4	4.3	20.8
IRBETAN	8.9	10.7	12.0	1.8	1.3	6.0
CYMBALTA	6.6	9.7	11.5	3.1	1.8	5.7
Total of 3 key products	51.3	58.5	65.9	7.2	7.4	32.5
OXYCONTIN	8.9	10.2	10.4	1.3	0.2	5.3
FINIBAX	4.7	5.0	5.2	0.3	0.2	2.5
DIFFERIN	3.7	4.0	4.5	0.3	0.5	2.2
PIRESPA	3.4	4.5	4.6	1.1	0.1	2.4
RAPIACTA	1.4	2.0	2.5	0.6	0.5	0.1
Total of 8 strategic products	73.2	84.2	93.1	11.0	8.9	45.0
FLOMOX	20.7	18.0	17.5	(2.7)	(0.5)	8.4
RINDERON	9.2	8.9	8.5	(0.3)	(0.4)	4.5
CLARITIN	7.8	6.3	5.9	(1.5)	(0.4)	2.1
FLUMARIN	6.9	6.0	5.5	(0.9)	(0.5)	2.9
Export/Overseas subsidiaries	17.0	* 30.6	31.8	13.6	1.2	14.4
<i>change %</i>	(54.6)	80.3	3.9			(2.8)
Shionogi Inc.	5.8	17.0	20.2	11.2	3.2	9.0
Osphena	-	-	5.5	-	5.5	0.8
C&O	1.9	5.8	6.0	3.9	0.2	2.9
Contract manufacturing	7.6	7.3	10.8	(0.3)	3.5	5.2
<i>change %</i>	40.5	(4.6)	48.9			16.7
OTC and quasi-drugs	5.0	5.2	5.1	0.2	(0.1)	2.7
<i>change %</i>	(3.0)	2.8	(1.2)			(3.5)
Diagnostics	2.7	2.2	1.7	(0.5)	(0.5)	0.6
<i>change %</i>	(5.3)	(18.4)	(23.0)			(45.5)
Royalty income	68.7	69.8	65.0	1.1	(4.8)	31.0
<i>change %</i>	(0.4)	1.7	(6.9)			(7.2)
CRESTOR	64.7	63.0	62.0	(1.7)	(1.0)	29.5
Others	1.9	2.1	2.0	0.2	(0.1)	1.0
<i>change %</i>	(47.3)	7.8	(3.3)			(4.7)
Total	267.3	282.9	287.0	15.6	4.1	138.0
<i>change %</i>	(5.3)	5.8	1.4			0.5

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

Sales of each main merchandise and finished goods are shown on non-consolidated basis

* Because of changing fiscal term, FY2012 results of Taiwan Shionogi & Co., Ltd. includes 15-month sales from January 2012 to March 2013.

3. Management index

(Management index trend)

		FY2010	FY2011	FY2012
Ratio of operating income to net sales	%	16.6	17.6	20.8
Ratio of ordinary income to net sales	%	16.0	17.2	20.8
Ratio of net income to net sales	%	7.1	10.1	23.6
Total asset turnover		0.53	0.51	0.52
Equity ratio	%	62.7	65.9	73.1
Return on asset (ROA)	%	8.5	8.8	10.7
Return on equity (ROE)	%	6.0	8.1	17.5
Dividend payout ratio	%	66.9	49.4	21.1
Earnings per share	yen	59.80	80.93	199.25
Earnings per share (diluted)	yen	—	80.91	199.17

4. Capital investments and depreciation cost

(billions of yen)

	FY2011 Results	FY2012 Results	FY2013 Forecast	Change		FY2013 1H Forecast
				FY2012	FY2013	
Investment in equipments	13.2	11.4	11.0	(1.8)	(0.4)	4.5
Depreciation cost	16.3	11.9	11.8	(4.4)	(0.1)	5.9
Amortization of goodwill	3.4	3.2	2.8	(0.2)	(0.4)	1.4

5. R&D expenses

(billions of yen)

	FY2011 Results	FY2012 Results	FY2013 Forecast	Change		FY2013 1H Forecast
				FY2012	FY2013	
R&D expenses	53.6	53.0	53.0	(0.6)	(0.0)	27.0
<i>change %</i>	5.3	(1.1)	(0.0)			8.1
% to net sales	20.1	18.7	18.5			19.6

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

6. Employees

	FY2011 Results	FY2012 Results	FY2013 Forecast	Change		FY2013 1H Forecast
				FY2012	FY2013	
Employees	6,132	6,082	6,540	(50)	458	6,570

7. Consolidated statement of income

(Unites: Million yen)

	FY2011 Results	FY2012 Results	Change	
Net sales	267,275	282,903	15,628	Increase in Shionogi Inc.: 11.2 billion yen Increase in C&O: 3.9 billion yen
Cost of sales	77,753	78,574	821	
Gross profit	189,521	204,329	14,808	
Selling, general and administrative expenses	142,518	145,480	2,962	
Operating income	47,003	58,848	11,845	
Non-operating income	2,925	4,220	1,295	
Interest income	384	381	(3)	
Dividends income	1,249	1,691	442	
Foreign exchange gains	1	1,377	1,376	
Other	1,289	770	(519)	
Non-operating expenses	3,834	4,147	313	
Interest expenses	1,330	1,123	(207)	
Contribution	1,374	1,363	(11)	
Loss on disposal of non-current assets	330	556	226	
Other	799	1,104	305	
Ordinary income	46,093	58,922	12,829	
Extraordinary income	739	41,680	40,941	Land (FY2012, FY2011)
Gain on sales of non-current assets	587	228	(359)	The difference between the carrying value of the its equity position in the JV and the market value (fair value) of equity position in ViiV
Gain on exchange of investment securities	-	40,433	40,433	
Gain on sales of investment securities	152	1,018	866	Buildings and Land
Extraordinary loss	5,338	42,296	36,958	FY2012: Due to impairment of Shionogi Inc.'s goodwill and sales rights etc. FY2011: Due to impairment of Shionogi Inc.'s In-Process R&D
Loss on sales of non-current assets	-	329	329	
Impairment loss	1,557	40,835	39,278	
Loss on disaster	1,165	269	(896)	
Settlement package	-	489	489	
Loss on penalty	1,345	158	(1,187)	
Loss on valuation of investment securities	426	124	(302)	
Special retirement expenses	-	89	89	
Business structure improvement expenses	843	-	(843)	
Income before income taxes and minority interests	41,494	58,306	16,812	
Income taxes-current	20,339	763	(19,576)	FY2012: Due to decrease in Shionogi's income taxes because of loss on valuation of Shionogi Inc.'s stocks (The loss is eliminated upon consolidation.)
Income taxes-deferred	(5,947)	(9,295)	(3,348)	
Income before minority interests	27,103	66,838	39,735	
Minority interests in income	1	110	109	
Net income	27,101	66,727	39,626	

8-1. Consolidated balance sheets (Assets)

(Unites: Million yen)

	As of Mar. 31 2012	As of Mar. 31 2013	Change	
(Assets)				
Current assets				
Cash and deposits	18,427	21,575	3,148	
Notes and accounts receivable-trade	65,568	67,908	2,340	
Short-term investment securities	86,556	84,432	(2,124)	
Merchandise and finished goods	26,040	26,531	491	
Work in process	12,662	14,024	1,362	
Raw materials and supplies	11,418	8,771	(2,647)	
Other	20,275	43,612	23,337	
Allowance for doubtful accounts	(17)	(12)	5	
Total current assets	240,931	266,845	25,914	
Noncurrent assets				
Property, plant and equipment	74,282	78,473	4,191	Increase in construction of a beta lactam injectable drug facility and a new production facility for high-potency active pharmaceutical ingredients.
Intangible assets				
Goodwill	63,572	40,293	(23,279)	Increase / (decrease) by: Amortization (3.2) billion yen Exchange rate fluctuations 5.0 billion yen
Sales rights	36,663	24,048	(12,615)	Impairment loss of Shionogi Inc, (26.4) billion yen
Other	6,457	6,123	(334)	
Total Intangible assets	106,694	70,464	(36,230)	Increase / (decrease) by: Amortization (3.7) billion yen Exchange rate fluctuations 2.6 billion yen
Investments and other assets				
Investment securities	63,568	122,628	59,060	Impairment loss of Shionogi Inc, (14.5) billion yen
Other	36,783	36,560	(223)	
Allowance for doubtful accounts	(97)	(90)	7	Increase / (decrease) by: Rise in stock markets 13.0 billion yen Sales (2.8) billion yen Received shares of ViiV in return for equity ownership in the JV 46.4 billion yen
Total investments and other assets	100,253	159,098	58,845	
Total noncurrent assets	281,230	308,036	26,806	
Total assets	522,161	574,882	52,721	

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

(Unites: Million yen)

	As of Mar. 31 2012	As of Mar. 31 2013	Change	
(Liabilities)				
Current liabilities				
Notes and accounts payable-trade	8,613	10,734	2,121	Refinancing from long-term loans payable
Short-term loans payable	-	7,500	7,500	
Current portion of long-term loans payable	14,000	31,500	17,500	Redemption of 2nd Series of Shionogi & Co., Ltd. Unsecured Straight bonds
Current portion of bonds	10,000	-	(10,000)	
Income taxes payable	9,891	1,146	(8,745)	
Provision for bonuses	6,745	7,134	389	
Provision for sales returns	5,356	6,459	1,103	
Other provision	25	26	1	
Other	27,430	33,706	6,276	
Total current liabilities	82,063	98,207	16,144	
Noncurrent liabilities				
Bonds payable	20,000	20,000	-	Repayment of syndicate loan and others 21.5 billion yen
Long-term loans payable	49,000	10,027	(38,973)	Transfer to Current portion of long-term loans payable 17.5 billion yen
Provision for retirement benefits	8,793	8,995	202	
Other	15,106	14,018	(1,088)	
Total noncurrent liabilities	92,899	53,041	(39,858)	
Total liabilities	174,963	151,249	(23,714)	
(Net Assets)				
Shareholders' equity				
Capital stock	21,279	21,279	-	
Capital surplus	20,227	20,227	-	
Retained earnings	353,676	407,007	53,331	
Treasury stock	(19,746)	(19,741)	5	
Total shareholders' equity	375,436	428,772	53,336	Rising share value
Valuation and translation adjustments				
Valuation difference on available-for-sale securities	7,729	16,055	8,326	
Deferred gains or losses on hedges	(141)	(450)	(309)	
Foreign currency translation adjustment	(38,809)	(24,267)	14,542	
Total valuation and translation adjustments	(31,220)	(8,662)	22,558	
Subscription rights to shares	58	123	65	
Minority interests	2,923	3,399	476	
Total net assets	347,198	423,633	76,435	
Total liabilities and net assets	522,161	574,882	52,721	

9-1. Quarterly trend for FY2011 and FY2012 (Sales of main merchandise and finished goods)

Fiscal year ended March 31, 2012

(Billions of yen)

FY2011	FY2011 1Q actual	Y on Y change %	FY2011 2Q actual	Y on Y change %	FY2011 3Q actual	Y on Y change %	FY2011 4Q actual	Y on Y change %
Prescription drugs	39.3	3.6	39.4	6.1	45.9	4.5	39.8	(0.3)
CRESTOR	8.3	27.4	8.9	24.1	9.5	13.1	9.1	31.3
IRBETAN	2.1	31.0	2.2	27.0	2.5	15.1	2.2	21.1
CYMBALTA	1.3	261.0	1.5	190.6	1.9	113.0	1.9	113.3
Total of 3 key products	11.8	38.1	12.5	33.9	13.8	21.2	13.1	37.0
OXYCONTIN	2.2	(10.5)	2.3	(1.4)	2.6	(4.6)	1.8	(16.4)
FINIBAX	1.0	11.8	1.2	31.3	1.4	50.7	1.1	32.4
DIFFERIN	0.8	27.0	0.9	8.8	1.0	5.9	0.9	21.4
PIRESPA	0.8	21.7	0.8	37.8	1.0	21.1	0.8	10.9
RAPIACTA	0.0	-	0.0	-	0.3	-	1.1	98.5
Total of 8 strategic products	16.6	26.1	17.7	26.4	20.1	21.3	18.8	29.2
FLOMOX	5.1	(3.9)	4.7	(1.5)	6.0	(9.5)	5.0	(5.0)
RINDERON	2.4	(6.4)	2.4	(1.1)	2.5	4.5	1.9	(9.9)
CLARITIN	1.8	8.3	1.4	(2.7)	2.3	2.8	2.4	(49.4)
FLUMARIN	1.7	(3.5)	1.8	(16.1)	1.6	(19.8)	1.8	13.4
Export/Overseas subsidiaries	4.3	(74.8)	(2.3)	-	7.8	(11.1)	7.2	164.4
Shionogi Inc.	2.5	(82.9)	(4.9)	-	4.1	(26.2)	4.2	850.3
C&O	-	-	-	-	0.9	-	1.0	-
Contract manufacturing	1.6	74.9	2.1	144.6	2.1	9.3	1.8	2.6
OTC and quasi-drugs	1.2	(6.9)	1.5	(3.0)	1.3	(4.1)	1.1	3.6
Diagnostics	0.7	(2.5)	0.6	(13.1)	0.7	0.4	0.7	(5.8)
Royalty income	15.9	(3.6)	18.4	0.2	16.7	(0.3)	17.6	1.9
CRESTOR	15.2	(0.8)	17.1	(1.9)	16.0	5.7	16.4	0.6
Others	0.4	(19.1)	0.5	(19.8)	0.5	(33.2)	0.5	(72.3)
Total	63.7	(15.3)	60.3	(11.5)	74.7	1.1	68.5	5.3

Fiscal year ended March 31, 2013

FY2012	FY2012 1Q actual	Y on Y change %	FY2012 2Q actual	Y on Y change %	FY2012 3Q actual	Y on Y change %	FY2012 4Q actual	Y on Y change %
Prescription drugs	39.7	0.8	40.0	1.6	45.2	(1.3)	40.8	2.6
CRESTOR	8.6	2.7	10.0	13.3	9.8	4.1	9.7	6.4
IRBETAN	2.3	9.3	2.4	12.2	3.6	42.4	2.4	12.7
CYMBALTA	2.2	65.5	2.5	62.8	2.4	29.2	2.6	36.4
Total of 3 key products	13.1	11.0	14.9	19.1	15.8	14.4	14.7	11.8
OXYCONTIN	2.6	16.6	2.5	9.3	2.9	14.2	2.2	19.9
FINIBAX	1.2	23.4	1.2	(2.6)	1.5	6.3	1.1	3.5
DIFFERIN	0.9	8.4	1.0	18.4	1.1	10.0	1.0	3.0
PIRESPA	1.1	34.6	1.2	51.9	1.1	9.5	1.1	43.9
RAPIACTA	0.1	76.2	0.0	-	0.3	49.9	1.6	42.7
Total of 8 strategic products	18.9	13.6	20.9	18.1	22.8	13.8	21.6	14.8
FLOMOX	4.4	(13.7)	4.0	(14.6)	5.4	(9.6)	4.2	(15.1)
RINDERON	2.4	0.9	2.3	(4.8)	2.3	(6.2)	1.9	(3.3)
CLARITIN	1.3	(28.0)	0.9	(32.5)	1.3	(43.0)	2.8	17.0
FLUMARIN	1.5	(14.8)	1.7	(2.7)	1.5	(7.2)	1.3	(29.7)
Export/Overseas subsidiaries	* 7.4	71.4	7.4	-	6.6	(15.1)	9.2	29.0
Shionogi Inc.	3.5	35.4	4.0	-	4.2	2.5	5.3	26.1
C&O	1.5	-	1.4	-	1.3	40.1	1.6	58.4
Contract manufacturing	2.3	39.7	2.2	(0.4)	1.3	(35.2)	1.5	(16.3)
OTC and quasi-drugs	1.3	4.9	1.5	2.4	1.2	(4.8)	1.2	9.9
Diagnostics	0.6	(20.6)	0.5	(16.2)	0.5	(23.8)	0.6	(12.7)
Royalty income	16.0	0.9	17.4	(5.8)	18.8	12.2	17.6	0.4
CRESTOR	14.7	(3.5)	16.0	(6.4)	15.7	(2.0)	16.6	1.0
Others	0.5	(1.3)	0.5	21.6	0.6	10.4	0.6	(0.3)
Total	67.8	6.4	69.5	15.3	74.1	(0.8)	71.5	4.3

Note: Sales of each main merchandise and finished goods are shown on non-consolidated basis

* Because of changing fiscal term, FY2012 1Q actual of Taiwan Shionogi & Co., Ltd. includes 6-month sales from January to June 2012.

9-2. Quarterly trend for FY2011 and FY2012 (Consolidated statements of income)

Fiscal year ended March 31, 2012

(Billions of yen)

FY2011	FY2011 1Q actual	Y on Y change %	FY2011 2Q actual	Y on Y change %	FY2011 3Q actual	Y on Y change %	FY2011 4Q actual	Y on Y change %
Net sales	63.7	(15.3)	60.3	(11.5)	74.7	1.1	68.5	5.3
Cost of sales	28.3 18.0	(13.5)	32.3 19.5	7.0	29.6 22.1	0.9	26.5 18.1	(12.7)
Gross profit	45.7	(16.0)	40.8	(18.3)	52.6	1.2	50.4	13.8
SG & A expenses	53.7 34.2	(26.3)	56.4 34.0	(12.1)	48.4 36.2	1.9	55.6 38.1	15.0
Selling & general expenses	21.2	(36.6)	21.4	(9.5)	23.6	(4.0)	22.8	7.3
R & D expenses	13.1	0.3	12.6	(16.0)	12.6	15.0	15.3	28.8
Operating income	18.0 11.5	43.7	11.3 6.8	(39.7)	22.0 16.4	(0.2)	18.0 12.3	10.1
Non-operating income & expenses	0.2		(0.0)		(0.3)		(0.8)	
Ordinary income	18.3 11.7	62.1	11.2 6.7	(35.7)	21.6 16.1	0.7	16.8 11.5	0.6
Extraordinary income & loss	(6.3)		2.4		(0.8)		0.0	
Income before income taxes and minority interests	5.4		9.2		15.4		11.6	
Income taxes and minority interests	1.6		4.7		5.0		3.0	
Net income	5.9 3.8	(21.7)	7.3 4.4	117.1	13.9 10.4	55.6	12.4 8.5	31.2

Fiscal year ended March 31, 2013

FY2012	FY2012 1Q actual *	Y on Y change %	FY2012 2Q actual	Y on Y change %	FY2012 3Q actual	Y on Y change %	FY2012 4Q actual	Y on Y change %
Net sales	67.8	6.4	69.5	15.3	74.1	(0.8)	71.5	4.3
Cost of sales	30.3 20.6	14.0	28.3 19.6	0.8	26.4 19.6	(11.2)	26.2 18.8	3.4
Gross profit	47.2	3.4	49.9	22.2	54.5	3.6	52.7	4.6
SG & A expenses	51.7 35.0	2.4	51.7 36.0	5.7	50.5 37.4	3.4	51.9 37.1	(2.7)
Selling & general expenses	23.3	10.1	22.7	6.4	22.7	(3.6)	23.7	4.0
R & D expenses	11.8	(10.0)	13.2	4.6	14.7	16.5	13.3	(12.6)
Operating income	18.0 12.2	6.6	20.0 13.9	104.8	23.1 17.1	4.0	21.9 15.6	27.0
Non-operating income & expenses	(0.1)		(0.9)		0.4		0.7	
Ordinary income	17.8 12.1	3.2	18.7 13.0	93.4	23.6 17.5	8.4	22.9 16.3	41.7
Extraordinary income & loss	(0.4)		0.1		2.6		(2.9)	
Income before income taxes and minority interests	11.7		13.1		20.1		13.4	
Income taxes and minority interests	4.7		5.2		6.6		(25.0)	
Net income	10.2 6.9	82.8	11.4 8.0	79.8	18.2 13.5	29.9	53.7 38.4	350.2

* Because of changing fiscal term, FY2012 1Q actual of Taiwan Shionogi & Co., Ltd. includes 6-month results from January to June 2012.

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

<Consolidated affiliated companies and affiliated companies accounted for by the equity method>

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.	TW\$ 92 million	Mfg. and sale of pharmaceuticals	December 26, 1963	March 31	100
8	Shionogi Inc.	Delaware, U.S.A.	US\$ 7	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\$ 13.5	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	December 31	66
12	Shionogi Ltd.	London, U.K.	GBP 700 thousand	Contract research for pharmaceuticals	February 10, 2012	March 31	100

* Incl. Indirect ownership

Note: Twenty 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 May 2013)

Areas	Code No. (Generic name) 【Product name】	Category (Administration)	Indication	Stage	Origin	Development
Infectious Diseases	S-649266	Cephem antibiotic (Injection)	Infection	Japan: Phase I USA: Phase I	In-house	Shionogi/ GlaxoSmithKline (UK)
Metabolic Syndrome	S-474474 (Irbesartan/ Trichlormethiazide combination)	Angiotensin receptor antagonist/Diuretic combination (Oral)	Hypertension	Japan: NDA submission (Jul. 2012)	Irbesartan: Sanofi (France) Trichlormethiazide: Shionogi	In-house
	S-2367 (Velneperit)	Neuropeptide Y Y5 receptor antagonist (Oral)	Obesity	Japan: Phase IIb	In-house	In-house
	S-556971	Cholesterol absorption inhibitor (Oral)	Dyslipidemia	Japan: Phase IIb	Kotobuki Pharmaceutical Co., Ltd. (Japan)	Shionogi/Kotobuki Pharmaceutical Co., Ltd.
	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
Pain	LY248686 Duloxetine hydrochloride 【Cymbalta®】	SNRI (Serotonin & noradrenaline reuptake inhibitor) (Oral)	Chronic low back pain	Japan: Phase III	Eli Lilly (USA)	Shionogi/Eli Lilly Japan K.K.
	S-297995 (Naldemedine)	Peripheral opioid receptor antagonist (Oral)	Alleviation of opioid- induced adverse effects	Global: Phase III (in preparation)	In-house	In-house
	S-117957	Analgesic agent for neuropathic pain (Oral)	Neuropathic pain	USA: Phase I	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-120083	Analgesic agent for inflammatory pain (Oral)	Inflammatory pain	Japan: Phase I	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
Other	Ospemifene	Selective estrogen receptor modulator (Oral)	Post-menopausal vaginal atrophy	USA: Approval (Feb. 2013) Europe: NDA submission (Mar. 2013)	QuatRx Pharmaceuticals Company (USA)	Shionogi/QuatRx Pharmaceuticals Company
	PSD502 (Lidocaine/Prilocaine)	Eutectic mixture of anesthetics (Metered-dose topical aerosol spray)	Premature ejaculation	USA: Phase III	Plethora Solutions Holdings PLC (UK)	Shionogi/Plethora Solutions Holdings PLC
	S-555739	Prostaglandin D2 receptor antagonist (Oral)	Allergic rhinitis	Japan: Phase III USA: Phase IIa Europe: POM (Proof of Mechanism)	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/III	Stallergenes SA (France)	In-house
	S-877503 (Guanfacine hydrochloride)	Alpha-2A-adrenergic receptor agonist (Oral)	ADHD	Japan: Phase II/III	Shire (Ireland)	Shionogi/Shire
	S-877489 (Lisdexamfetamine)	DA and NE reuptake inhibitor/Releaser of DA, NE (Oral)	ADHD	Japan: Phase II	Shire (Ireland)	Shionogi/Shire
	S-888711 (Lusutrombopag)	Small molecule TPO mimetic (Oral)	Thrombocytopenia	USA, Europe: Phase II Japan: Phase IIb	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-488210	Cancer peptide vaccine (Injection)	Head and neck squamous cell carcinoma	Europe: Phase I/II	OncoTherapy Science, Inc. (Japan)	In-house
	S-646240	Peptide vaccine (Injection)	Age-related macular degeneration	Japan: Phase IIa	OncoTherapy Science, Inc. (Japan)	In-house
	S-222611	HER2/EGFR dual inhibitor (Oral)	Malignant tumor	Europe: Phase Ib	In-house	In-house
	S-414114	NF-κB decoy oligodeoxynucleotide (Topical)	Atopic dermatitis	Japan: Phase I (in preparation)	AnGes MG, Inc. (Japan)	Shionogi/AnGes MG

<Out-Licensing Activity>

Code No. (Generic name)	Category (Administration)	Indication	Stage	Origin	Development
S/GSK1349572 (Dolutegravir)	Integrase inhibitor (Oral)	HIV infection	Global: NDA submission (Dec. 2012)	Shionogi-ViiV Healthcare LLC	ViiV Healthcare Ltd. (UK)
S/GSK1265744 LAP*	Integrase inhibitor (Injection)	HIV infection	USA: Phase II	Shionogi-ViiV Healthcare LLC	ViiV Healthcare Ltd. (UK)
S-4661 (Doripenem hydrate)	Carbapenem antibiotic (Injection)	Bacterial infection	USA: Approval (Oct. 2007) Complicated intra-abdominal infections, Complicated urinary tract infections including pyelonephritis NDA submission (Jun. 2007) Hospital-acquired (nosocomial) pneumonia including ventilator- associated pneumonia Europe: Approval (Jul. 2008)	In-house	Janssen Pharmaceuticals, Inc. (USA)
S-0373	Non-peptide mimetic of TRH (Oral)	Spinocerebellar ataxia	Japan: Phase II	In-house	Kissei Pharmaceutical Co., Ltd. (Japan)
Janssen/Shionogi BACE inhibitor	BACE inhibitor (Oral)	Alzheimer's disease	Europe: Phase I	In-house	Janssen Pharmaceuticals, Inc. (USA)

*: Long acting parenteral formulation

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

Generic name 【Product name】	Category (Administration)	Indication	Stage	Origin	Development
Oxycodone hydrochloride hydrate 【OxyContin®】	Natural opium alkaloids (Oral)	For the treatment of moderate to severe chronic pain	Japan: Phase III	Napp Pharmaceuticals Limited (UK)	In-house
Duloxetine hydrochloride 【Cymbalta®】	SNRI (Serotonin & noradrenaline reuptake inhibitor) (Oral)	Fibromyalgia	Japan: Phase III	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	Japan: To be determined	Eli Lilly (USA)	In-house
Cyclophosphamide hydrate 【Endoxan®】	Alkylating agent (Injection)	Pheochromocytoma	Japan: Approval (Mar. 2013)	Baxter (Germany)	In-house
Prednisolone 【Predonine®】	Synthetic corticosteroid (Oral)	Duchenne muscular dystrophy	Japan: NDA submission (Feb. 2013)	In-house	In-house

<Requested for development by academy>

Generic name 【Product name】	Category (Administration)	Indication	Stage	Origin	Development
Metreleptin	Human leptin (Genetical recombination) (Injection)	Lipodystrophy	Japan: Approval (Mar. 2013)	Amylin Pharmaceuticals Inc. (USA)	In-house
Interferon gamma-1a 【Imunomax®-γ】	Interferon gamma-1a (Genetical recombination) (Injection)	Mycosis fungoides/Sezary syndrome	Japan: Phase II	Biogen Idec, Inc. (USA)	In-house
Metronidazole 【Fragyl®】	Antiprotozoal agent (Oral)	<i>Helicobacter pylori</i> gastritis	Japan: Approval (Feb. 2013)	Sanofi (France)	Co-development with 9 companies
Prednisolone 【Predonine®】	Synthetic corticosteroid (Injection/Oral)	Kawasaki disease (Acute stage)	Japan: NDA submission (Sep. 2012)	In-house	In-house

Since February 2013

Change of phase	S-649266: USA: Phase I
	Ospemifene: USA: NDA submission (Apr. 2012) → USA: Approval (Feb. 2013), Europe: NDA submission (in preparation) → Europe: NDA submission (Mar. 2013)
	S-877489: Japan: Phase II (in preparation) → Japan: Phase II
	S-877503: Japan: Phase II/III (in preparation) → Japan: Phase II/III
	Oxycodone hydrochloride hydrate 【OxyContin®】 For the treatment of moderate to severe chronic pain: Japan: Clinical trial (in preparation) → Japan: Phase III
	Cyclophosphamide hydrate 【Endoxan®】 Pheochromocytoma: Japan: NDA submission (Nov. 2012) → Japan: Approval (Mar. 2013)
	Prednisolone 【Predonine®】 Duchenne muscular dystrophy: Japan: NDA submission (in preparation) → Japan: NDA submission (Feb. 2013)
	Metreleptin: Japan: NDA submission (Jul. 2012) → Japan: Approval (Mar. 2013)
Compound added to the list	LY248686 (Duloxetine hydrochloride) 【Cymbalta®】 Chronic low back pain: Japan: Phase III
	S-414114: Japan: Phase I (in preparation)
	Janssen/Shionogi BACE inhibitor: Europe: Phase I