

**Financial results for the second quarter  
of fiscal year 2013**

**< Supplement >**

**October 31, 2013**



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## 1. Financial results and forecast

	FY2013 1H actual	FY2013 2H forecast	FY2013 forecast	FY2012 1H actual *	FY2012 2H actual	FY2012 actual	(Billions of yen)		
							Y on Y change		
							1H	2H	full-year
Net Sales	138.7	146.1	284.8	137.3	145.6	282.9	1.4	0.5	1.9
<i>change %</i>	1.0	0.3	0.7	10.7	1.6	5.8			
Operating Income	28.5	33.5	62.0	26.4	33.2	59.6	2.1	0.3	2.4
<i>change %</i>	7.7	1.2	4.1	-	-	-			
Ordinary Income	27.8	33.2	61.0	25.1	33.8	58.9	2.7	(0.6)	2.1
<i>change %</i>	10.9	(1.9)	3.5	36.2	22.3	27.8			
Net Income	21.4	21.6	43.0	14.9	51.8	66.7	6.5	(30.2)	(23.7)
<i>change %</i>	44.0	(58.4)	(35.6)	81.2	174.4	146.2			

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

\* Because of changing fiscal term, FY2012 1H actual of Taiwan Shionogi & Co., Ltd. includes 9-month results from January to September 2012.

The Company has changed its presentation method for litigation expenses from FY2013 1H.  
 Operating income for FY2012 1H, FY2012 2H and FY2012 has been restated to reflect this change.  
 However, the Y on Y change % has been omitted because it has not been calculated.

## 2. Sales of main merchandise and finished goods

	(Billions of yen)					
	Y on Y change					
	1H	2H	full-year			
Prescription drugs	80.9	87.5	168.4	79.7	86.0	165.7
change %	1.5	1.7	1.6	1.2	0.5	0.8
CRESTOR	20.6	21.8	42.4	18.6	19.5	38.1
IRBETAN	6.7	6.3	13.0	4.7	6.0	10.7
CYMBALTA	5.2	5.8	11.0	4.7	5.0	9.7
Total of 3 key products	32.5	33.9	66.4	28.0	30.5	58.5
OXYCONTIN	5.4	5.0	10.4	5.1	5.1	10.2
FINIBAX	2.3	2.5	4.8	2.4	2.6	5.0
DIFFERIN	1.9	2.3	4.2	1.9	2.1	4.0
PIRESPA	2.4	2.2	4.6	2.3	2.2	4.5
RAPIACTA	0.1	2.4	2.5	0.1	1.9	2.0
Total of 8 strategic products	44.4	48.5	92.9	39.8	44.4	84.2
FLOMOX	7.5	9.0	16.5	8.4	9.6	18.0
RINDERON	4.7	4.2	8.9	4.7	4.2	8.9
CLARITIN	1.8	3.6	5.4	2.2	4.1	6.3
FLUMARIN	2.8	2.7	5.5	3.2	2.8	6.0
Export/Overseas subsidiaries	15.4	17.7	33.1	* 14.8	15.8	30.6
change %	3.7	12.2	8.1	607.8	6.1	80.3
Shionogi Inc.	9.5	11.2	20.7	7.5	9.5	17.0
Osphena	0.1	5.4	5.5	-	-	-
C&O	2.9	3.1	6.0	2.9	2.9	5.8
Contract manufacturing	5.0	3.7	8.7	4.5	2.8	7.3
change %	12.4	32.0	20.0	17.3	(26.5)	(4.6)
OTC and quasi-drugs	2.3	2.4	4.7	2.8	2.4	5.2
change %	(17.0)	0.5	(9.0)	3.6	1.9	2.8
Diagnostics	0.8	1.1	1.9	1.1	1.1	2.2
change %	(28.4)	0.4	(14.0)	(18.6)	(18.3)	(18.4)
Royalty income	33.4	32.6	66.0	33.4	36.4	69.8
change %	0.0	(10.6)	(5.5)	(2.7)	6.2	1.7
CRESTOR	31.2	31.8	63.0	30.7	32.3	63.0
Others	0.9	1.1	2.0	1.0	1.1	2.1
change %	(11.7)	5.4	(3.3)	10.5	5.1	7.8
Total	138.7	146.1	284.8	137.3	145.6	282.9
change %	1.0	0.3	0.7	10.7	1.6	5.8
	1.4	0.5	1.9			

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, FY2012 1H actual of Taiwan Shionogi & Co., Ltd. includes 9-month sales from January to September 2012.

### 3. Management index

( Management index trend )

		FY2011	FY2012	FY2012 1H	FY2013 1H
Ratio of operating income to net sales	%	17.6	21.1	19.2	20.5
Ratio of ordinary income to net sales	%	17.2	20.8	18.3	20.1
Ratio of net income to net sales	%	10.1	23.6	10.8	15.4
Total asset turnover		0.51	0.52	0.27	0.24
Equity ratio	%	65.9	73.1	67.9	75.8
Return on asset (ROA)	%	8.8	10.7	4.9	4.8
Return on equity (ROE)	%	8.1	17.5	4.3	4.9
Dividend payout ratio	%	49.4	21.1	-	-
Earnings per share	yen	80.93	199.25	44.38	63.92
Earnings per share (diluted)	yen	80.91	199.17	44.36	63.88

*The Company has changed its presentation method for litigation expenses from FY2013 1H.  
Ratio of operating income to net sales for FY2012 1H and FY2012 has been restated to reflect this change.*

## 4. Capital investments and depreciation cost

(Billions of yen)

	FY2013 1H actual	FY2013 2H forecast	FY2013 forecast	FY2012 1H actual	FY2012 2H actual	FY2012 actual	Y on Y change		
	1H	2H	full-year						
Investment in equipments	2.6	8.4	11.0	6.2	5.2	11.4	(3.6)	3.2	(0.4)
Depreciation cost	6.7	6.0	12.7	6.0	5.9	11.9	0.7	0.1	0.8
Amortization of goodwill	1.3	1.5	2.8	1.9	1.3	3.2	(0.6)	0.2	(0.4)

## 5. R&D expenses

(Billions of yen)

	FY2013 1H actual	FY2013 2H forecast	FY2013 forecast	FY2012 1H actual	FY2012 2H actual	FY2012 actual	Y on Y change		
	1H	2H	full-year						
R&D expenses	25.6	27.4	53.0	25.0	28.0	53.0	0.6	(0.6)	(0.0)
change %	2.4	(2.2)	(0.0)	(2.8)	0.5	(1.1)			

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

## 6. Employees

	End of FY2011 actual	End of 2012 1H actual	End of FY2012 actual	End of 2013 1H actual	End of FY2013 forecast	Y on Y change		
	1H	2H	full-year					
Employees	6,132	6,217	6,082	6,489	6,450	407	(39)	368

## 7. Consolidated statement of income

	FY2012 1H actual	FY2013 1H actual	(Millions of yen)
			Y on Y change
Net sales	137,322	138,715	1,393
Cost of sales	40,213	37,246	(2,967)
Gross profit	97,109	101,468	4,359
Selling, general and administrative expenses	70,688	73,008	2,320
Operating income	26,421	28,460	2,039
Non-operating income	1,112	1,797	685
Interest income	185	171	(14)
Dividends income	622	1,102	480
Other	304	523	219
Non-operating expenses	2,438	2,428	(10)
Interest expenses	605	469	(136)
Contribution	664	744	80
Litigation expenses	314	652	338
Other	853	561	(292)
Ordinary income	25,095	27,828	2,733
Extraordinary income	779	4,757	3,978
Gain on sales of noncurrent assets	228	4,203	3,975
Gain on sales of investment securities	551	554	3
Extraordinary loss	1,091	451	(640)
Loss on valuation of inventories	-	451	451
Loss on valuation of investment securities	1,091	-	(1,091)
Income before income taxes and minority interests	24,783	32,134	7,351
Income taxes-current	10,278	2,705	(7,573)
Income taxes-deferred	(382)	7,987	8,369
Income before minority interests	14,887	21,441	6,554
Minority interests in income	24	36	12
Net income	14,863	21,405	6,542

Increase in:  
Shionogi Inc.: 2.0 billion yen  
Prescription drugs: 1.2 billion yen

Change in classification from Selling,  
general and administrative expenses to  
Non-operating expenses

Sales of land (FY2012 1H)  
Sales of rental properties etc. (FY2013 1H)

In connection with acquisition of global  
rights for Doripenem

Shionogi  
Decrease by loss carried forward

Shionogi  
Reversal of deferred tax assets for loss  
carried forward

*The Company has changed its presentation method for litigation expenses from FY2013 1H.*

*Selling, general and administrative expenses, Operating income and Non-operating expenses for FY2012 1H has been restated to reflect this change.*

## 8-1. Consolidated balance sheets (Assets)

	As of Mar. 31 2013	As of Sep. 30 2013	(Millions of yen)
			Y on Y change
(Assets)			
Current assets			
Cash and deposits	21,575	23,713	2,138
Notes and accounts receivable-trade	67,908	64,867	(3,041)
Short-term investment securities	84,432	100,900	16,468
Merchandise and finished goods	26,531	29,251	2,720
Work in process	14,024	14,746	722
Raw materials and supplies	8,771	10,204	1,433
Other	43,612	29,348	(14,264)
Allowance for doubtful accounts	(12)	(21)	(9)
Total current assets	266,845	273,010	6,165
Noncurrent assets			
Property, plant and equipment	78,473	76,944	(1,529)
Intangible assets			
Goodwill	40,293	41,901	1,608
Other	30,171	27,905	(2,266)
Total Intangible assets	70,464	69,807	(657)
Investments and other assets			
Investment securities	122,628	133,614	10,986
Other	36,560	36,042	(518)
Allowance for doubtful accounts	(90)	(90)	(0)
Total investments and other assets	159,098	169,566	10,468
Total noncurrent assets	308,036	316,318	8,282
Total assets	574,882	589,328	14,446

(Millions of yen)

Y on Y  
change

Increase in Certificate of deposit:  
18.5 billion yen  
Redemption of Governments bonds:  
(2.0) billion yen

Decrease by income tax refund etc.

Increase / (decrease) by:  
Amortization: (1.3) billion yen  
Exchange rate fluctuations etc.:  
3.0 billion yen

Increase / (decrease) by:  
Sales rights  
Amortization: (2.0) billion yen  
Exchange rate fluctuations:  
0.8 billion yen  
Divestiture of pediatric products:  
(Shionogi Inc.) (0.9) billion yen

Increase / (decrease) by:  
Rise in stock markets: 3.4 billion yen  
Purchase of Governments bonds:  
2.0 billion yen  
Exchange rate fluctuations:  
(Shares of ViiV) 5.6 billion yen

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

	As of Mar. 31 2013	As of Sep. 30 2013	(Millions of yen)
			Y on Y change
(Liabilities)			
Current liabilities			
Notes and accounts payable-trade	10,734	11,805	1,071
Short-term loans payable	7,500	7,500	-
Current portion of long-term loans payable	31,500	24,500	(7,000)
Current portion of bonds	-	20,000	20,000
Income taxes payable	1,146	3,528	2,382
Provision for bonuses	7,134	7,193	59
Provision for sales returns	6,459	5,199	(1,260)
Other provision	26	-	(26)
Other	33,706	24,380	(9,326)
Total Current liabilities	98,207	104,107	5,900
Noncurrent liabilities			
Bonds payable	20,000	-	(20,000)
Long-term loans payable	10,027	10,032	5
Provision for retirement benefits	8,995	9,016	21
Other	14,018	15,991	1,973
Total noncurrent liabilities	53,041	35,040	(18,001)
Total liabilities	151,249	139,147	(12,102)
(Net Assets)			
Shareholders' equity			
Capital stock	21,279	21,279	-
Capital surplus	20,227	20,227	-
Retained earnings	407,007	421,045	14,038
Treasury stock	(19,741)	(19,749)	(8)
Total shareholders' equity	428,772	442,802	14,030
Accumulated other comprehensive income			
Valuation difference on available-for-sale securities	16,055	18,261	2,206
Deferred gains or losses on hedges	(450)	(32)	418
Foreign currency translation adjustment	(24,267)	(14,467)	9,800
Total accumulated other comprehensive income	(8,662)	3,761	12,423
Subscription rights to shares	123	207	84
Minority interests	3,399	3,408	9
Total net assets	423,633	450,181	26,548
Total liabilities and net assets	574,882	589,328	14,446

Redemption of 3<sup>rd</sup> Series of Shionogi & Co., Ltd. Unsecured Straight bonds at June 2014.

Decrease in Shionogi Inc.: (1.2) billions yen

Decrease by payment for the development milestones of Osphena etc.

Rising share value

Issuing Stock options FY2013

## 9-1 Quarterly trend for FY2012 and FY2013 (Sales of main merchandise and finished goods)

Fiscal year ended March 31, 2013

(Billions of yen)

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
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)
<b>Total</b>	<b>67.8</b>	<b>6.4</b>	<b>69.5</b>	<b>15.3</b>	<b>74.1</b>	<b>(0.8)</b>	<b>71.5</b>	<b>4.3</b>

Fiscal year ending March 31, 2014

FY2013	FY2013 1Q actual	Y on Y change %	FY2013 2Q actual	Y on Y change %
Prescription drugs	40.4	1.9	40.5	1.1
CRESTOR	10.0	16.7	10.6	5.4
IRBETAN	2.9	23.7	3.8	58.2
CYMBALTA	2.6	19.4	2.6	6.8
Total of 3 key products	15.5	18.4	17.0	14.1
OXYCONTIN	2.7	5.9	2.7	5.4
FINIBAX	1.1	(7.1)	1.2	(3.4)
DIFFERIN	0.9	7.2	1.0	(9.4)
PIRESPA	1.2	15.1	1.2	(10.8)
RAPIACTA	0.1	36.0	0.0	(83.4)
Total of 8 strategic products	21.6	14.4	22.8	9.4
FLOMOX	3.9	(11.9)	3.6	(11.0)
RINDERON	2.4	(0.4)	2.3	(2.3)
CLARITIN	0.9	(26.0)	0.9	(9.4)
FLUMARIN	1.4	(7.9)	1.4	(17.4)
Export/Overseas subsidiaries	8.4	13.3	7.0	(5.8)
Shionogi Inc.	5.4	53.0	4.1	4.9
Osphena	-	-	0.1	-
C&O	1.3	(14.2)	1.6	13.5
Contract manufacturing	2.4	1.4	2.6	24.6
OTC and quasi-drugs	1.0	(25.2)	1.3	(9.6)
Diagnostics	0.4	(22.6)	0.4	(34.7)
Royalty income	14.0	(12.5)	19.4	11.6
CRESTOR	13.1	(10.9)	18.1	13.1
Others	0.6	33.2	0.3	(46.2)
<b>Total</b>	<b>67.3</b>	<b>(0.8)</b>	<b>71.4</b>	<b>2.8</b>

Note: Sales of each product 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 FY2012 and FY2013 (Consolidated statements of income)

Fiscal year ended March 31, 2013

(Billions of yen)

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 %
<b>Net sales</b>	<b>67.8</b>	<b>6.4</b>	<b>69.5</b>	<b>15.3</b>	<b>74.1</b>	<b>(0.8)</b>	<b>71.5</b>	<b>4.3</b>
Cost of sales	30.3		28.3		26.4		26.2	
Gross profit	47.2	3.4	49.9	22.2	54.5	3.6	52.7	4.6
SG & A expenses	51.4		51.5		50.3		51.5	
Selling & general expenses	34.9	—	35.8	—	37.3	—	36.8	—
R & D expenses	23.1	—	22.6	—	22.6	—	23.5	—
	11.8	(10.0)	13.2	4.6	14.7	16.5	13.3	(12.6)
<b>Operating income</b>	<b>18.2</b>		<b>20.2</b>		<b>23.3</b>		<b>22.2</b>	
Non-operating income & expenses	(0.3)		(1.0)		0.2		0.5	
	<b>17.8</b>		<b>18.7</b>		<b>23.6</b>		<b>22.9</b>	
<b>Ordinary income</b>	<b>12.1</b>	<b>3.2</b>	<b>13.0</b>	<b>93.4</b>	<b>17.5</b>	<b>8.4</b>	<b>16.3</b>	<b>41.7</b>
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)	
	<b>10.2</b>		<b>11.4</b>		<b>18.2</b>		<b>53.7</b>	
<b>Net income</b>	<b>6.9</b>	<b>82.8</b>	<b>8.0</b>	<b>79.8</b>	<b>13.5</b>	<b>29.9</b>	<b>38.4</b>	<b>350.2</b>

Fiscal year ending March 31, 2014

FY2013	FY2013 1Q actual	Y on Y change %	FY2013 2Q actual	Y on Y change %
<b>Net sales</b>	<b>67.3</b>	<b>(0.8)</b>	<b>71.4</b>	<b>2.8</b>
Cost of sales	27.3		26.4	
Gross profit	48.9	3.5	52.6	5.4
SG & A expenses	54.6		50.7	
Selling & general expenses	36.8	5.4	36.3	1.3
R & D expenses	23.6	2.2	23.8	5.4
	13.1	11.6	12.5	(5.8)
<b>Operating income</b>	<b>18.1</b>		<b>22.8</b>	
Non-operating income & expenses	0.5		(1.1)	
	<b>18.8</b>		<b>21.3</b>	
<b>Ordinary income</b>	<b>12.2</b>	<b>(1.7)</b>	<b>16.3</b>	<b>16.0</b>
Extraordinary income & loss	0.6		3.8	
Income before income taxes and minority interests	13.2		19.0	
Income taxes and minority interests	2.3		8.4	
	<b>16.1</b>		<b>14.8</b>	
<b>Net income</b>	<b>10.8</b>	<b>56.9</b>	<b>10.6</b>	<b>32.8</b>

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

The Company has changed its presentation method for litigation expenses from the first quarter of the fiscal year ending March 31, 2014.

SG & A expenses, Selling & general expenses, Operating income and Non-operating income & expenses for the fiscal year ended March 31, 2013 has been restated to reflect this change.

However, the Y on Y change % has been omitted because it has not been calculated.

## 10. Consolidated affiliated companies and affiliated company 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\$ 8	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\$ 15	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	71
12	Shionogi Ltd.	London, U.K.	GBP 700 thousand	Contract research for pharmaceuticals	February 10, 2012	March 31	100
13	Beijing Shionogi Pharmaceutical Technology Limited	Beijing, China	JPY 30 million	Support services for development and sales	March 29, 2013	December 31	100

\* Incl. Indirect ownership

Note: Twenty-three 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 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-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 Japan: Phase III	In-house	In-house
	S-117957	Analgesic agent for neuropathic pain (Oral)	Neuropathic pain	USA: POM (Proof of Mechanism)	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
	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-888711 (Lusutrombopag)	Small molecule TPO mimetic (Oral)	Thrombocytopenia	USA, Europe: Phase II Japan: Phase III	In-house	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-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	AnGes MG, Inc. (Japan)	Shionogi/AnGes MG, Inc.

<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) USA: Approval (Aug. 2013)	Shionogi-ViiV Healthcare LLC	ViiV Healthcare Ltd. (UK)
Dolutegravir/Abacavir/Lamivudine	Integrase inhibitor/Nucleoside reverse transcriptase inhibitor (Oral)	HIV infection	USA, Europe: NDA submission (Oct. 2013)	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-0373	Non-peptide mimetic of TRH (Oral)	Spinocerebellar ataxia	Japan: Phase III	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)	<Specification> 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: NDA submission (in preparation)	Eli Lilly (USA)	In-house
Prednisolone 【Prednisone®】	Synthetic corticosteroid (Oral)	Duchenne muscular dystrophy	Japan: Approval (Sep. 2013)	In-house	In-house

<Requested for development by academy>

Generic name 【Product name】	Category (Administration)	Indication	Stage	Origin	Development
Interferon gamma-1a 【Imunomax®-γ】	Interferon gamma-1a (Genetical recombination) (Injection)	Mycosis fungoïdes/Sézary syndrome	Japan: NDA submission (Aug. 2013)	Biogen Idec, Inc. (USA)	In-house
Prednisolone 【Prednisone®】	Synthetic corticosteroid (Injection/Oral)	Kawasaki disease (Acute stage)	Japan: Approval (Sep. 2013)	In-house	In-house

Since August 2013

Change of phase	S-297995 (Naldemedine): Japan: Phase III (in preparation) → Japan: Phase III
	S-888711 (Lusutrombopag): Japan: Phase III (in preparation) → Japan: Phase III
	S/GSK1349572 (Dolutegravir): Global: NDA submission (Dec. 2012) → Global: NDA submission (Dec. 2012), USA: Approval (Aug. 2013)
	Vancomycin hydrochloride【Vancomycin】: Japan: To be determined → Japan: NDA submission (in preparation)
	Prednisolone【Prednisone®】Duchenne muscular dystrophy: Japan: NDA submission (Feb. 2013) → Japan: Approval (Sep. 2013)
	Interferon gamma-1a【Imunomax®-γ】: Japan: Phase II → Japan: NDA submission (Aug. 2013)
Prednisolone【Prednisone®】Kawasaki disease (Acute stage): Japan: NDA submission (Sep. 2012) → Japan: Approval (Sep. 2013)	
Compound added to the list	Dolutegravir/Abacavir/Lamivudine: USA, Europe: NDA submission (Oct. 2013)
Compound erased	S-474474 (Irbesartan/Trichlormethiazide combination): Japan: Approval (Jun. 2013)
	PSD502 (Lidocaine/Prilocaine): Rights return to Plethora Solutions Holdings PLC