

Financial Results for the First Quarter of Fiscal Year 2013(Consolidated)

August 2, 2013

Listed Exchanges: Section I of Tokyo

Name of Listed Company: SHIONOGI & CO., LTD.

Code: 4507 URL: http://www.shionogi.co.jp

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Scheduled date of quarterly securities report submission: August 9, 2013

Scheduled date of dividend payments: -

Preparation of supplemental material for the quarterly financial results: Yes

Holding of presentation for the quarterly financial results: Yes (for investment analysts)

(Note: All amounts are rounded down to the nearest million yen.)

1. Consolidated results for the period from April 1, 2013 to June 30, 2013

(1) Consolidated operating results

(% shows changes from the same period of the previous fiscal year)

	Net sales		Operating income		Ordinary inco	me	Net income	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Three months ended June 30, 2013	67,265	(8.0)	12,159	(1.7)	12,622	4.6	10,846	56.9
Three months ended June 30, 2012	67,823	6.4	12,366	_	12,066	3.2	6,910	82.8

Vote: Comprehensive income Three months ended June 30, 2013 Three months ended June 30, 2012

 Earnings per share
 Earnings per share (diluted)

 Yen
 Yen

 Three months ended June 30, 2013
 32.39
 32.38

Three months ended June 30, 2012 20.64 20.63

Note: The Company has changed its presentation method for litigation expenses from the first quarter of the fiscal year ending March 31, 2014. Operating income for the first quarter of the fiscal year ended March 31, 2013 has been restated to reflect this change. However, the percentage change compared with the same period of the previous fiscal year has been omitted because it has not been calculated.

(2) Consolidated financial position

	Total assets	Net assets	Shareholders' equity ratio
	Millions of yen	Millions of yen	%
As of June 30, 2013	584,232	434,631	73.7
As of March 31, 2013	574,882	423,633	73.1

Reference: Shareholders' equity

As of June 30, 2013: 430,804 million yen

As of March 31, 2013: 420,110 million yen

2. Dividends

		Dividends per share							
(Date of record)	End of first quarter	End of second quarter	End of third quarter	Year-end	Annual				
	Yen	Yen	Yen	Yen	Yen				
Year ended March 31, 2013	_	20.0	_	22.0	42.0				
Year ending March 31, 2014	_								
Year ending March 31, 2014 (forecast)		22.0	_	22.0	44.0				

Note: Revisions of the most recent dividend forecast: None

3. Consolidated financial forecast for the year ending March 31, 2014

(% shows changes from the same period of the previous fiscal year)

	Net sales		Operating income		Ordinary income		Net income		Earnings per share	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen	
Six month ending September 30, 2013	138,000	0.5	24,000	(9.2)	24,000	(4.4)	14,500	(2.4)	43.30	
Year ending March 31, 2014	287,000	1.4	60,000	0.7	59,000	0.1	37,000	(44.6)	110.48	

Note: Revisions of the most recent consolidated financial forecast: None

Note: The Company has changed its presentation method for litigation expenses from the first quarter of the fiscal year ending March 31, 2014. Percentage changes comparing quarterly and annual operating income for the fiscal year ended March 31, 2014 with quarterly and annual operating income for the fiscal year ended March 31, 2013, respectively, have been calculated using restated figures for the fiscal year ended March 31, 2013 that reflect this change.

Notes

- (1) Significant changes in subsidiaries during the period (changes in specified subsidiaries involving changes in scope of consolidation): None
- (2) Adoption of accounting methods specific to the preparation of quarterly consolidated financial statements: None
- (3) Changes in accounting policies, changes/restatements of accounting estimates
 - a) Changes in accounting policies in connection with amendments to accounting standards, etc.: None
 - b) Changes in accounting policies other than a) above: None
 - c) Changes in accounting estimates: None
 - d) Restatements: None
- (4) Number of shares issued (common stock)
 - a) Number of shares issued (including treasury stock)

As of June 30, 2013: 351,136,165 shares
As of March 31, 2013: 351,136,165 shares

b) Number of treasury stock

As of June 30, 2013: 16,237,697 shares As of March 31, 2013: 16,236,003 shares

c) Average number of shares issued during the period

Three months ended June 30, 2013: 334,898,854 shares
Three months ended June 30, 2012: 334,898,101 shares

※ Implementation status of quarterly review procedures

This summary of quarterly results is exempt from the quarterly review procedures based on the Financial Instruments and Exchange Act. Review procedures for the quarterly financial statements based on the Financial Instruments and Exchange Act had not been completed at the time of disclosure of this summary of quarterly results.

Notes to consolidated financial forecasts and other items

The forecasts and other forward-looking statements contained in this document are based on the information currently available and certain assumptions that it judges to be reasonable. Actual results may differ materially due to a variety of factors.

For the assumptions used in forecasts and precautionary statements regarding the use of the forecasts, please refer to "1. Qualitative Information on Quarterly Financial Statements (3) Description of Consolidated Financial Forecast" on page 2 of the supplemental materials for the Financial Results for the First Quarter of Fiscal Year 2013 (Consolidated)

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1. Qualitative Information on Quarterly Financial Results

(1) Description of Consolidated Operating Results

For the first quarter ended June 30, 2013 (April 1, 2013 to June 30, 2013), net sales were ¥67,265 million, operating income was ¥12,159 million, ordinary income was ¥12,622 million and net income was ¥10,846 million.

Regarding net sales, sales of prescription drugs in Japan rose 1.9 percent compared with the same period of the previous fiscal year as the increase in sales of strategic products, centered on Crestor, Irbetan and Cymbalta, compensated for the decrease in sales of existing products. Overseas sales contributed to overall net sales, increasing 13.3 percent with stable performance by Shionogi Inc., our subsidiary in the United States. However, overall net sales decreased a slight 0.8 percent due to lower royalty income resulting from factors such as a decline in sales of Crestor by AstraZeneca.

Regarding profit, gross profit increased 3.5 percent compared with the same period of the previous fiscal year due to an improvement in the cost of sales ratio with the recovery of sales in the United States. Selling, general and administrative (SG&A) expenses increased 5.4 percent, attributable to an increase in marketing-related costs for the U.S. launch of OsphenaTM, a treatment for post-menopausal vaginal atrophy, and an increase in R&D expenses. As a result, operating income decreased 1.7 percent compared with the same period of the previous fiscal year. Ordinary income increased 4.6 because the weak yen resulted in foreign exchange gains. Net income increased 56.9 percent due to a decrease in income tax resulting from revisions to the allowable limit of deductible expenses for the write-down of Shionogi Inc. stock.

(2) Description of Consolidated Financial Position

As of June 30, 2013, total assets were ¥584,232 million, an increase of ¥9,349 million from the end of the previous fiscal year. Current assets increased ¥5,471 million from the end of the previous fiscal year to ¥272,317 million, largely because of increases in both short-term investment securities and inventory. Non-current assets increased ¥3,877 million to ¥311,914 million, mainly because of an increase in foreign-denominated goodwill and investment securities due to changes in foreign currency exchange rates.

Total liabilities decreased ¥1,649 million from the end of the previous fiscal year to ¥149,600 million. Current liabilities increased ¥17,448 million from the end of the previous fiscal year to ¥115,656 million, mainly due to an increase in notes and accounts payable-trade and the transfer of bonds that will mature in one year to current liabilities. Non-current liabilities decreased ¥19,097 million to ¥33,943 million, primarily because of the aforementioned transfer of bonds to current liabilities.

Net assets increased ¥10,998 million from the end of the previous fiscal year to ¥434,631 million. Shareholders' equity increased ¥3,475 million to ¥432,248 million, due to factors including an increase from net income and a decrease due to cash dividends paid. Accumulated other comprehensive income was negative ¥1,444 million, ¥7,218 million higher than at the end of the previous fiscal year, due to an increase in positive foreign currency translation adjustment resulting from exchange rate fluctuations. Minority interests were ¥3,704 million, an increase of ¥305 million compared with the end of the previous fiscal year.

(3) Description of Consolidated Financial Forecast

There are no revisions to the consolidated financial forecast announced on May 9, 2013.

2. Summary Data (Notes)

- (1) Significant changes in subsidiaries during the period (changes in specified subsidiaries involving changes in scope of consolidation)

 None
- (2) Adoption of accounting methods specific to the preparation of quarterly consolidated financial statements

None

(3) Changes in accounting policies, changes/restatements of accounting estimates

Additional Information

Change in Classification of Litigation Expenses

Expenses associated with litigation were formerly recognized under selling, general and administrative expenses together with non-litigation legal expenses on the grounds of materiality. However, from the first quarter of the fiscal year ending March 31, 2014, litigation expenses are recognized separately under non-operating expenses.

This change was made because the number of lawsuits involving foreign corporations has increased as Shionogi's business has expanded overseas, the cost of these lawsuits has become material, and the Company expects these expenses to increase going forward as its business becomes more global in scale. Therefore, after an internal review, Shionogi judged that including expenses associated with litigation in non-operating expenses more accurately presents the Company's position.

The Company has restated its consolidated statements of income for the first quarter of the previous fiscal year to reflect this change.

As a result, ¥155 million of the ¥35,039 million in selling, general and administrative expenses has been reclassified as litigation expenses under non-operating expenses in the consolidated statements of income for the first quarter of the previous fiscal year. As a result of this change, operating income for first quarter of the previous fiscal year increased from ¥12,210 million to ¥12,366 million.

3. Consolidated Financial Statements

(1) Consolidated balance sheets

		Millions or yen
	As of March 31, 2013	As of June 30, 2013
Assets		
Current assets		
Cash and deposits	21,575	21,24
Notes and accounts receivable-trade	67,908	66,71
Short-term investment securities	84,432	87,32
Merchandise and finished goods	26,531	29,90
Work in process	14,024	13,57
Raw materials and supplies	8,771	9,49
Other	43,612	44,06
Allowance for doubtful accounts	(12)	(12
Total current assets	266,845	272,31
Non-current assets		
Property, plant and equipment	78,473	77,64
Intangible assets		
Goodwill	40,293	41,91
Other	30,171	29,21
Total intangible assets	70,464	71,12
Investments and other assets		
Investment securities	122,628	126,11
Other	36,560	37,12
Allowance for doubtful accounts	(90)	(90
Total investments and other assets	159,098	163,14
Total non-current assets	308,036	311,91
Total assets	574,882	584,23
Liabilities		·
Current liabilities		
Notes and accounts payable-trade	10,734	14,07
Short-term loans payable	7,500	7,50
Current portion of long-term loans payable	31,500	31,00
Current portion of bonds	-	20,00
Income taxes payable	1,146	2,01
Provision for bonuses	7,134	9,90
Provision for sales returns	6,459	6,04
Other provision	26	-
Other	33,706	25,11
Total current liabilities	98,207	115,65
Non-current liabilities	70,201	110,000
Bonds payable	20,000	_
Long-term loans payable	10,027	10,03
Provision for retirement benefits	8,995	9,15
Other	14,018	14,75
Total non-current liabilities	53,041	33,94
Total liabilities	151,249	149,600

	As of March 31, 2013	As of June 30, 2013
Net assets		
Shareholders' equity		
Capital stock	21,279	21,279
Capital surplus	20,227	20,227
Retained earnings	407,007	410,486
Treasury stock	(19,741)	(19,745)
Total shareholders' equity	428,772	432,248
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	16,055	16,604
Deferred gains or losses on hedges	(450)	(144)
Foreign currency translation adjustment	(24,267)	(17,904)
Total accumulated other comprehensive income	(8,662)	(1,444)
Subscription rights to shares	123	123
Minority interests	3,399	3,704
Total net assets	423,633	434,631
Total liabilities and net assets	574,882	584,232

(2) Consolidated statements of income and Consolidated statements of comprehensive income Consolidated statements of income

		Willions of yen
	Three month ended June 30, 2012	Three month ended June 30, 2013
Net sales	67,823	67,265
Cost of sales	20,573	18,355
Gross profit	47,249	48,910
Selling, general and administrative expenses	34,883	36,750
Operating income	12,366	12,159
Non-operating income		
Interest income	36	29
Dividends income	486	965
Foreign exchange gains	_	412
Other	210	65
Total non-operating income	733	1,472
Non-operating expenses		
Interest expenses	311	227
Contribution	174	293
Litigation expenses	155	271
Other	391	217
Total non-operating expenses	1,033	1,010
Ordinary income	12,066	12,622
Extraordinary income		
Gain on sales of investment securities	337	554
Total extraordinary income	337	554
Extraordinary loss		
Loss on valuation of investment securities	747	_
Total extraordinary losses	747	_
Income before income taxes and minority interests	11,656	13,177
Income taxes-current	5,541	1,284
Income taxes-deferred	(801)	1,042
Total income taxes	4,740	2,326
Income before minority interests	6,916	10,851
Minority interests in income	5	4
Net income	6,910	10,846

Consolidated statements of comprehensive income

	Three month ended June 30, 2012	Three month ended June 30, 2013	
Income before minority interests	6,916	10,851	
Other comprehensive income			
Valuation difference on available-for-sale securities	739	548	
Deferred gains or losses on hedges	445	306	
Foreign currency translation adjustment	(2,473)	6,663	
Total other comprehensive income	(1,288)	7,518	
Comprehensive income	5,627	18,370	
Comprehensive income attributable to			
Comprehensive income attributable to owners of the parent	5,466	18,064	
Comprehensive income attributable to minority interests	161	305	

(3) Notes

Going concern assumption

None

Significant changes in shareholders' equity

None

Supplemental material Financial results for the 1st quarter of fiscal year 2013

August 2, 2013

Shionogi & Co., Ltd.

1. Sales by main merchandise and finished goods

(Billions of yen) FY2013 1H FY2013 FY2013 1Q FY2012 1Q Progress % vs. 2013 1H forecast forecast actual actual change forecast 48.7 Prescription drugs 83.1 170.6 40.4 39.7 0.7 1.9 0.8 change % 4.3 2.9 CRESTOR 20.8 42.4 10.0 1.4 48.1 8.6 **IRBETAN** 6.0 12.0 2.9 2.3 0.6 47.8 **CYMBALTA** 5.7 11.5 2.6 2.2 0.4 45.8 32.5 65.9 15.5 13.1 2.4 47.6 Total of 3 key products OXYCONTIN 5.3 10.4 2.7 2.6 0.1 51.7 2.5 44.7 **FINIBAX** 5.2 1.1 1.2 (0.1)DIFFERIN 2.2 0.9 42.5 4.5 0.9 0.0 **PIRESPA** 2.4 4.6 1.2 1.1 0.1 51.1 RAPIACTA 0.1 2.5 0.1 0.1 0.0 75.2 45.0 93.1 21.6 18.9 2.7 48.0 Total of 8 strategic products **FLOMOX** 8.4 17.5 3.9 4.4 (0.5)46.5 RINDERON 4.5 8.5 2.4 2.4 (0.0)52.9 2.1 CLARITIN 5.9 0.9 1.3 (0.4)44.8 47.3 **FLUMARIN** 2.9 5.5 1.4 1.5 (0.1)7.4 Export/Overseas subsidiaries 14.4 31.8 8.4 1.0 58.0 change % (2.8)3.9 13.3 71.4 Shionogi Inc. 9.0 20.2 3.5 1.9 59.6 Osphena 0.8 5.5 C&O 2.9 6.0 1.3 1.5 (0.2)44.3 Contract manufacturing 5.2 10.8 2.4 2.3 0.1 45.7 16.7 48.9 39.7 change % 1.4 2.7 5.1 1.0 1.3 (0.3)36.9 OTC and quasi-drugs change % (3.5)(1.2)(25.2)4.9 Diagnostics 0.6 1.7 0.6 (0.2)74.3 0.4 (45.5) (20.6)change % (23.0)(22.6)Royalty income 31.0 65.0 14.0 16.0 (2.0)45.3 (7.2)(6.9)(12.5)0.9 change % CRESTOR 29.5 62.0 13.1 14.7 (1.6)44.4 Others 1.0 2.0 0.6 0.5 0.1 60.8 (4.7)change % (3.3)33.2 (1.3)Total 138.0 287.0 67.3 67.8 (0.5)48.7 0.5 change % 1.4 (0.8)6.4

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

2-1. 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	Y on Y	FY2012 2Q	Y on Y	FY2012 3Q	Y on Y	FY2012 4Q	Y on Y
F 1 2012	actual	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)		(9.6)	4.2	(15.1)
RINDERON	2.4	0.9	2.3	(4.8)		(6.2)	1.9	(3.3)
CLARITIN	1.3	(28.0)	0.9	(32.5)		(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

Fiscal year ending March 31, 2014

FY2013	FY2013 1Q	Y on Y
FY2013	actual	change %
Prescription drugs	40.4	1.9
CRESTOR	10.0	16.7
IRBETAN	2.9	23.7
CYMBALTA	2.6	19.4
Total of 3 key products	15.5	18.4
OXYCONTIN	2.7	5.9
FINIBAX	1.1	(7.1)
DIFFERIN	0.9	7.2
PIRESPA	1.2	15.1
RAPIACTA	0.1	36.0
Total of 8 strategic products	21.6	14.4
FLOMOX	3.9	(11.9)
RINDERON	2.4	(0.4)
CLARITIN	0.9	(26.0)
FLUMARIN	1.4	(7.9)
Export/Overseas subsidiaries	8.4	13.3
Shionogi Inc.	5.4	53.0
Osphena	-	-
C&O	1.3	(14.2)
Contract manufacturing	2.4	1.4
OTC and quasi-drugs	1.0	(25.2)
Diagnostics	0.4	(22.6)
Royalty income	14.0	(12.5)
CRESTOR	13.1	(10.9)
Others	0.6	33.2
Total	67.3	(0.8)

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.

2-2. Quarterly trend for FY2012 and FY2013 (Consolidated statements of income)

Fiscal year ended March 31, 2013

(Billions of yen)

	FY2012 1Q	Y on Y	FY2012 2O	Y on Y	FY2012 3Q	Y on Y	FY2012 4O	Y on Y
FY2012	_		_		`		_	
	actual *	change %	actual	change %		change %		change %
Net sales	67.8	6.4	69.5	15.3	74.1	(0.8)	71.5	4.3
	30.3		28.3		26.4		26.2	
Cost of sales	20.6	14.0	19.6	0.8	19.6	(11.2)	18.8	3.4
Gross profit	47.2	3.4	49.9	22.2	54.5	3.6	52.7	4.6
	51.4		51.5		50.3		51.5	
SG & A expenses	34.9	_	35.8	_	37.3	_	36.8	_
Selling & general expenses	23.1	_	22.6	_	22.6	_	23.5	_
R & D expenses	11.8	(10.0)	13.2	4.6	14.7	16.5	13.3	(12.6)
	18.2		20.2		23.3		22.2	
Operating income	12.4	_	14.1	_	17.3	_	15.9	_
Non-operating income & expenses	(0.3)		(1.0)		0.2		0.5	
	17.8		18.7		23.6		22.9	
Ordinary income	12.1	3.2	13.0	93.4	17.5	8.4	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)	
	10.2		11.4		18.2		53.7	
Net income	6.9	82.8	8.0	79.8	13.5	29.9	38.4	350.2

Fiscal year ending March 31, 2014

Fiscal year ending March 31, 201	4		
FY2013	FY2013 1Q	Y on Y	
1 12013	actual	change %	
Net sales	67.3	(0.8)	
	27.3		
Cost of sales	18.4	(10.8)	
Gross profit	48.9	3.5	
	54.6		
SG & A expenses	36.8	5.4	
Selling & general expenses	23.6	2.2	
R & D expenses	13.1	11.6	
	18.1		
Operating income	12.2	(1.7)	
Non-operating income & expenses	0.5		
	18.8		
Ordinary income	12.6	4.6	
Extraordinary income & loss	0.6		
Income before income taxes and	12.0		
minority interests	13.2		
Income taxes and minority interests	2.3		
	16.1		
Net income	10.8	56.9	

^{*} 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.

3. Pipeline (as of August 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: Approval (Jun. 2013)	Irbesartan: Sanofi (France) Trichlormethiazide: Shionogi	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
	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 preparation)	In-house	In-house
Pain	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.
	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
Other	S-888711 (Lusutrombopag)	Small molecule TPO mimetic (Oral)	Thrombocytopenia	USA, Europe: Phase II Japan: Phase III (in preparation)	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	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		Shionogi-ViiV Healthcare LLC	ViiV Healthcare Ltd. (UK)
S/GSK1265744 LAP*	Integrase inhibitor (Injection)	HIV infection		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>

<drugs acquire="" new<="" p="" to=""></drugs>	indication requested by i	he Ministry of Health, Labou	ir and wellare>	•	
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 Japar 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), Febril neuropenia, Alternative agent in penicillin-allergic adults and children</indication></spectrum>	Japan: To be determined	Eli Lilly (USA)	In-house
Prednisolone 【Predonine [®] 】	Synthetic corticosteroid (Oral)	Duchenne muscular dystrophy	Japan: NDA submission (Feb. 2013)	In-house	In-house

<Requested for development by academy>

Nequested for devel	opinent by academy/				
Generic name 【Product name】	Category (Administration)	Indication	Stage	Origin	Development
Interferon gamma-1a 【Imunomax [®] -γ】	Interferon gamma-1a (Genetical recombination) (Injection)	Mycosis fungoides/Sezary syndrome	Japan: Phase II	Biogen Idec, Inc. (USA)	In-house
Prednisolone [Predonine®]	Synthetic corticosteroid (Injection/Oral)	Kawasaki disease (Acute stage)	Japan: NDA submission (Sep. 2012)	In-house	In-house

Since May 2013

Change of phase	S-474474(Irbesartan/Trichlormethiazide combination): Japan: NDA submission (Jul. 2012) → Japan: Approval (Jun. 2013)
	S-297995(Naldemedine): Global: Phase III (in preparation) → Global: Phase III, Japan: Phase III (in preparation)
	S-117957: USA: Phase I → USA: POM (Proof of Mechanism)
	S-888711(Lusutrombopag): USA, Europe: Phase II, Japan: Phase IIb → USA, Europe: Phase II, Japan: Phase III (in preparation)
	S-414114: Japan: Phase I (in preparation) → Japan: Phase I
	S-0373: Japan: Phase II → Japan: Phase III
	S-2367(Velneperit): Japan: Closed (Aug. 2013)
Compound erased	S-4661(Doripenem hydrate): Global rights return (Jun. 2013)
	Cyclophosphamide hydrate [Endoxan®]: Japan: Approval (Mar. 2013)
	Metreleptin: Japan: Approval (Mar. 2013)
	Metronidazole [Fragyl®]: Japan: Approval (Feb. 2013)