



Financial Results for the First Quarter of Fiscal Year 2011(Consolidated)

August 1, 2011

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

Listed Exchanges: Section I of Tokyo and Osaka

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

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Scheduled date of quarterly securities report submission: August 10, 2011

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, 2011 to June 30, 2011

(1) Consolidated operating results (% shows changes from the same period of the previous fiscal year)

	Net sales		Operating income		Ordinary income		Net income	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Three months ended June 30, 2011	63,720	(15.3)	11,454	43.7	11,692	62.1	3,780	(21.7)
Three months ended June 30, 2010	75,230	17.5	7,969	31.1	7,211	23.6	4,825	4.9

Note: Comprehensive income Three months ended June 30, 2011 1,189 million yen (- %)
 Three months ended June 30, 2010 (4,271) million yen (- %)

	Earnings per share	Earnings per share (diluted)
	Yen	Yen
Three months ended June 30, 2011	11.29	—
Three months ended June 30, 2010	14.41	—

(2) Consolidated financial position

	Total assets	Net assets	Shareholders' equity ratio
	Millions of yen	Millions of yen	%
As of June 30, 2011	502,566	322,587	64.2
As of March 31, 2011	523,242	328,096	62.7

Reference: Shareholders' equity As of June 30, 2011: 322,587 million yen As of March 31, 2011: 328,096 million yen

2. Dividends

(Date of record)	Dividends per share				
	End of first quarter	End of second quarter	End of third quarter	Year-end	Annual
Year ended March 31, 2011	Yen —	Yen 20.0	Yen —	Yen 20.0	Yen 40.0
Year ending March 31, 2012	—				
Year ending March 31, 2012 (forecast)		20.0	—	20.0	40.0

Note: Revisions of the most recent dividend forecast: None

3. Consolidated financial forecast for the year ending March 31, 2012

(% 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, 2011	134,500	(6.2)	24,500	27.4	23,500	32.8	15,500	125.9	46.28
Year ending March 31, 2012	286,000	1.3	58,000	23.7	56,000	24.0	37,000	84.8	110.48

Note: Revisions of the most recent consolidated financial forecast: Yes

4. Others

(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, 2011: 351,136,165 shares

As of March 31, 2011: 351,136,165 shares

b) Number of treasury stock

As of June 30, 2011: 16,238,169 shares

As of March 31, 2011: 16,237,775 shares

c) Average number of shares issued during the period

Three months ended June 30, 2011: 334,898,113 shares

Three months ended June 30, 2010: 334,904,414 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 "Qualitative Information on Consolidated Financial Forecast" on page 3 of the supplemental materials for the "Financial Results for the First Quarter of Fiscal Year 2011(Consolidated)"

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1. Qualitative Information on Quarterly Financial Results

(1) Qualitative Information on Consolidated Operating Results

In the first quarter ended June 30, 2011 (April 1, 2011 to June 30, 2011), conditions remained challenging in Japan's pharmaceutical market with an outlook for increasing competition due to factors including the promotion of generic drug use. In these circumstances, the Shionogi Group worked energetically to expand sales, particularly for the anti-hyperlipidemia treatment Crestor, the hypertension treatment Irbetan, and the antidepressant drug Cymbalta.

For the first quarter ended June 30, 2011, net sales were ¥63,720 million, operating income was ¥11,454 million, ordinary income was ¥11,692 million, and net income was ¥3,780 million.

Regarding net sales, overall sales of prescription drugs increased 3.6 percent compared with the same period of the previous fiscal year. Sales of most products including Crestor, Irbetan and Cymbalta were firm, with the exception of some existing antibiotics and other products. On the other hand, sales at U.S. subsidiary Shionogi Inc. decreased because of returns of products past their expiration date. As a result, net sales decreased 15.3 percent overall compared with the same period of the previous fiscal year. Shionogi Inc. changed its fiscal year-end to March 31 during the year ended March 31, 2011, with the result that its first quarter during the previous fiscal year was the six months ended June 30, 2010.

Regarding profit, gross profit decreased 16.0 percent compared with the same period of the previous fiscal year, mainly of the decrease in sales at Shionogi Inc. However, operating income increased 43.7 percent mainly because of the effect of the six-month first quarter for Shionogi Inc. mentioned above and reduced personnel and other selling, general and administrative expenses as a result of the restructuring of operations in North America that has been ongoing since the year ended March 31, 2011. Ordinary income increased 62.1 percent due in part to the impact of foreign currency translation, but net income decreased 21.7 percent because Shionogi recognized loss on valuation of investment securities and other extraordinary losses.

(2) Qualitative Information on Consolidated Financial Position

(1) Assets, Liabilities and Net Assets

As of June 30, 2011, total assets were ¥502,566 million, a decrease of ¥20,676 million compared with the end of the previous fiscal year. Current assets decreased ¥11,424 million from the end of the previous fiscal year to ¥245,512 million due to factors including a decrease in notes and accounts receivable. Non-current assets decreased ¥9,251 million to ¥257,053 million due to factors including a decrease in intangible assets.

Total liabilities decreased ¥15,166 million compared with the end of the previous fiscal year to ¥179,979 million. Current liabilities decreased ¥3,641 million to ¥76,178 million due to factors including a decrease in income taxes payable. Non-current liabilities decreased ¥11,525 million to ¥103,800 million mainly because bonds redeemable within one year shifted to current assets.

Net assets decreased ¥5,509 million compared with the end of the previous fiscal year to ¥322,587 million. Shareholders' equity decreased ¥2,917 million to ¥358,816 million, reflecting factors including an increase from net income and a decrease due to cash dividends paid. Accumulated other comprehensive income decreased ¥2,591 million to negative ¥36,229 million, primarily because foreign currency translation adjustment reduced net assets by an additional ¥3,103 million.

(3) Qualitative Information on Consolidated Financial Forecast

Based on recent performance trends, Shionogi has revised its financial forecast released on May 9, 2011, as follows:

(1) Revisions of financial forecast**a) Revised forecasts for the six months ending September 30, 2011**

	Net sales		Operating income		Ordinary income		Net income		Earnings per share
	<i>Millions of yen</i>	%	<i>Millions of yen</i>	%	<i>Millions of yen</i>	%	<i>Millions of yen</i>	%	<i>Yen</i>
Previous forecast (A)	137,500		24,500		23,500		15,500		46.28
New forecast (B)	134,500		24,500		23,500		15,500		46.28
Change (B-A)	(3,000)		—		—		—		—
Percentage change (%)	(2.2)		—		—		—		—
(reference) For the six month ended March 31, 2011	143,366		19,228		17,696		6,862		20.49

b) Revised forecasts for the year ending March 31, 2012: None**(2) Reason for revision of forecasts**

Sales decreased at consolidated subsidiary Shionogi Inc. in the first quarter ended June 30, 2011 due to returns of products past their expiration date and other factors. Shionogi has therefore revised its forecast for consolidated net sales for the second quarter ending September 30, 2011. However, Shionogi forecasts that products acquired from Victory Pharma, Inc. will contribute to earnings from the second quarter onward, and has therefore not revised its forecast for the full fiscal year.

Regarding profit, Shionogi has not changed its consolidated financial because of the effect of cost reductions at the parent company.

2. Consolidated Financial Statements**(1) Consolidated balance sheets***Millions of yen*

	As of March 31, 2011	As of June 30, 2011
Assets		
Current assets		
Cash and deposits	27,579	22,193
Notes and accounts receivable-trade	69,498	61,216
Short-term investment securities	88,914	94,491
Merchandise and finished goods	24,369	25,279
Work in process	13,294	13,199
Raw materials and supplies	9,675	9,563
Other	23,618	19,581
Allowance for doubtful accounts	(12)	(12)
Total current assets	256,937	245,512
Non-current assets		
Property, plant and equipment	70,220	69,787
Intangible assets		
Goodwill	58,830	56,268
Other	40,762	37,647
Total intangible assets	99,593	93,915
Investments and other assets		
Investment securities	60,654	58,250
Other	35,957	35,221
Allowance for doubtful accounts	(121)	(121)
Total investments and other assets	96,491	93,350
Total non-current assets	266,304	257,053
Total assets	523,242	502,566
Liabilities		
Current liabilities		
Notes and accounts payable-trade	12,884	12,277
Current portion of bonds	—	10,000
Current portion of long-term loans payable	14,000	14,000
Income taxes payable	13,510	5,197
Provision for bonuses	7,059	10,199
Other provision	3,290	1,670
Other	29,075	22,834
Total current liabilities	79,819	76,178
Non-current liabilities		
Bonds payable	30,000	20,000
Long-term loans payable	63,000	62,500
Provision for retirement benefits	8,573	8,692
Other	13,752	12,608
Total non-current liabilities	115,325	103,800
Total liabilities	195,145	179,979

Millions of yen

	As of March 31, 2011	As of June 30, 2011
Net assets		
Shareholders' equity		
Capital stock	21,279	21,279
Capital surplus	20,227	20,227
Retained earnings	339,970	337,053
Treasury stock	(19,743)	(19,743)
Total shareholders' equity	361,733	358,816
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	3,732	4,028
Deferred gains or losses on hedges	(288)	(72)
Foreign currency translation adjustment	(37,081)	(40,184)
Total accumulated other comprehensive income	(33,637)	(36,229)
Total net assets	328,096	322,587
Total liabilities and net assets	523,242	502,566

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

Consolidated statements of income

Millions of yen

	Three month ended June 30, 2010	Three month ended June 30, 2011
Net sales	75,230	63,720
Cost of sales	20,855	18,043
Gross profit	54,375	45,677
Selling, general and administrative expenses	46,406	34,223
Operating income	7,969	11,454
Non-operating income		
Interest income	44	32
Dividends income	561	533
Other	188	515
Total non-operating income	794	1,081
Non-operating expenses		
Interest expenses	394	339
Contribution	166	235
Foreign exchange losses	530	—
Other	460	267
Total non-operating expenses	1,551	842
Ordinary income	7,211	11,692
Extraordinary income		
Gain on sales of noncurrent assets	—	353
Gain on forgiveness of debts	279	—
Total extraordinary income	279	353
Extraordinary loss		
Loss on valuation of investment securities	112	2,705
Impairment loss	127	1,609
Loss on disaster	—	1,089
Loss on penalty	—	969
Business structure improvement expenses	2,177	279
Total extraordinary losses	2,417	6,653
Income before income taxes and minority interests	5,074	5,393
Income taxes-current	1,261	4,581
Income taxes-deferred	(991)	(2,968)
Total income taxes	269	1,612
Income before minority interests	4,804	3,780
Minority interests in loss	(21)	—
Net income	4,825	3,780

Consolidated statements of comprehensive income

Millions of yen

	Three month ended June 30, 2010	Three month ended June 30, 2011
Income before minority interests	4,804	3,780
Other comprehensive income		
Valuation difference on available-for-sale securities	(1,498)	295
Deferred gains or losses on hedges	—	216
Foreign currency translation adjustment	(7,577)	(3,103)
Share of other comprehensive income of associates accounted for using equity method		
Total other comprehensive income	(9,076)	(2,591)
Comprehensive income	(4,271)	1,189
Comprehensive income attributable to		
Comprehensive income attributable to owners of the parent	(4,250)	1,189
Comprehensive income attributable to minority interests	(21)	—

(3) Going concern assumption

None

(4) Significant changes in shareholders' equity

None

Supplemental material for financial results for the 1st quarter of fiscal year 2011

August 1, 2011

Shionogi & Co., Ltd.

1. Sales of main merchandise and finished goods

(Billions of yen)

	FY2011 1H original forecast	FY2011 original forecast	FY2011 1Q actual	FY2010 1Q actual	FY2011 1H revised forecast	FY2011 revised forecast	FY2011 1H change from original	FY2011 change from original
Prescription drugs	80.4	166.8	39.3	38.0	80.4	167.5	-	0.7
<i>change %</i>	7.0	5.0	3.6	2.1	7.0	5.4		
CRESTOR	17.6	37.0	8.3	6.6	17.6	37.0	-	-
IRBETAN	4.8	10.5	2.1	1.6	4.8	10.5	-	-
CYMBALTA	2.5	5.5	1.3	0.4	2.5	5.5	-	-
Total of 3 key products	24.9	53.0	11.8	8.5	24.9	53.0	-	-
OXYCONTIN	5.1	10.5	2.2	2.5	5.1	10.5	-	-
FINIBAX	2.0	4.2	1.0	0.9	2.0	4.2	-	-
DIFFERIN	1.9	4.1	0.8	0.6	1.9	4.1	-	-
PIRESPA	1.6	3.4	0.8	0.7	1.6	3.4	-	-
RAPIACTA	0.1	1.5	0.0	(0.0)	0.1	1.5	-	-
Total of 8 strategic products	35.6	76.7	16.6	13.2	35.6	76.7	-	-
FLOMOX	9.0	19.0	5.1	5.3	9.0	19.0	-	-
RINDERON	4.5	9.2	2.4	2.5	4.5	9.2	-	-
CLARITIN	3.5	7.5	1.8	1.6	3.5	7.5	-	-
FLUMARIN	3.3	6.2	1.7	1.8	3.3	6.2	-	-
VANCOMYCIN	2.0	3.8	1.1	1.2	2.0	3.8	-	-
IMUNACE	1.6	3.0	0.6	0.8	1.6	3.0	-	-
Export/Overseas subsidiaries	15.8	33.5	4.3	17.1	12.3	31.9	(3.5)	(1.6)
<i>change %</i>	(39.3)	(10.5)	(74.8)	42.6	(52.7)	(14.8)		
Shionogi Inc.	10.2	22.4	2.5	* 15.2	7.2	20.8	(3.0)	(1.6)
DORIPENEM	2.4	5.0	0.5	0.5	1.9	5.0	(0.5)	-
Contract manufacturing	2.6	5.9	1.6	1.0	3.1	6.8	0.5	0.9
<i>change %</i>	42.4	9.1	74.9	(35.7)	69.8	25.7		
OTC and quasi-drugs	2.5	5.1	1.2	1.4	2.5	5.1	-	-
<i>change %</i>	(11.9)	(1.5)	(6.9)	(3.9)	(11.9)	(1.5)		
SEDES	1.3	2.5	0.6	0.6	1.3	2.5	-	-
POPON-S	0.4	0.8	0.2	0.3	0.4	0.8	-	-
Diagnostics	1.2	2.7	0.7	0.7	1.2	2.7	-	-
<i>change %</i>	(18.1)	(5.6)	(2.5)	(9.7)	(18.1)	(5.6)		
Royalty income	34.0	70.0	15.9	16.4	34.0	70.0	-	-
<i>change %</i>	(2.5)	1.6	(3.6)	56.6	(2.5)	1.6		
CRESTOR	32.0	67.0	15.2	15.4	32.0	67.0	-	-
Others	1.0	2.0	0.4	0.6	1.0	2.0	-	-
<i>change %</i>	(15.3)	(45.0)	(19.1)	2.8	(15.3)	(45.0)		
Total	137.5	286.0	63.7	75.2	134.5	286.0	(3.0)	-
<i>change %</i>	(4.1)	1.3	(15.3)	17.5	(6.2)	1.3		

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

2-1. 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 1Q actual	Y on Y change %
Prescription drugs	39.3	3.6
CRESTOR	8.3	27.4
IRBETAN	2.1	31.0
CYMBALTA	1.3	261.0
Total of 3 key products	11.8	38.1
OXYCONTIN	2.2	(10.5)
FINIBAX	1.0	11.8
DIFFERIN	0.8	27.0
PIRESPA	0.8	21.7
RAPIACTA	0.0	-
Total of 8 strategic products	16.6	26.1
FLOMOX	5.1	(3.9)
RINDERON	2.4	(6.4)
CLARITIN	1.8	8.3
FLUMARIN	1.7	(3.5)
VANCOMYCIN	1.1	(7.3)
IMUNACE	0.6	(26.1)
Export/Overseas subsidiaries	4.3	(74.8)
Shionogi Inc.	2.5	(82.9)
DORIPENEM	0.5	0.5
Contract manufacturing	1.6	74.9
OTC and quasi-drugs	1.2	(6.9)
SEDES	0.6	8.9
POPON-S	0.2	(16.0)
Diagnostics	0.7	(2.5)
Royalty income	15.9	(3.6)
CRESTOR	15.2	(0.8)
Others	0.4	(19.1)
Total	63.7	(15.3)

Note: Sales of each merchandise and finished goods 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.

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

Fiscal year ended March 31, 2011

(Billions of yen)

	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 1Q actual	Y on Y change %
Net sales	63.7	(15.3)
Cost of sales	28.3 18.0	(13.5)
Gross profit	45.6	(16.0)
SG & A expenses	53.7 34.2	(26.3)
Selling & general expenses	21.1	(36.6)
R & D expenses	13.0	0.3
Operating income	18.0 11.4	43.7
Non-operating income & expenses	0.2	
Ordinary income	18.3 11.6	62.1
Extraordinary income & loss	(6.2)	
Income before income taxes and minority interests	5.3	
Income taxes and minority interests	1.6	
Net income	5.9 3.7	(21.7)

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

3. Pipeline (as of August 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 Aventis (France) Trichlormethiazide: Shionogi	In-house
	S-2367 (Velnepit)	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 (in preparation)	In-house	In-house
	S-349572 (Dolutegravir)	Integrase inhibitor (Oral)	HIV infection	Global: Phase III	Shionogi & GlaxoSmithKline	Shionogi-ViiV Healthcare LLC
	S-265744 LAP	Integrase inhibitor (Injection; Long acting parenteral formulation)	HIV infection	USA: Phase I	Shionogi & GlaxoSmithKline	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: Phase III	QuatRx Pharmaceuticals Company (USA)	Shionogi/ QuatRx Pharmaceuticals Company
Other	S-555739	Prostaglandin D2 receptor antagonist (Oral)	Allergic disease	Japan: Phase IIb (in preparation) Europe: POM (Proof of Mechanism) USA: IND submission (in preparation)	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	Peptide cancer vaccine (Injection)	Bladder cancer	Japan: Phase I/II	OncoTherapy Science, Inc. (Japan)	In-house
	S-488410	Peptide cancer 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 I	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 May, 2011>

Change of phase	S-4661 <Japan> : Phase III → NDA submission (in preparation)
	S-297995 <USA> : Phase IIa → Phase IIb
	S-555739 <Japan> : Phase IIa → Phase IIb (in preparation)
	S-555739 <USA> : IND submission (in preparation)
Compound erased	ADX415 <USA> : Returning development rights to the licensor
	S-4661 <Japan> : (Addition of new dosage regimen) Approved in April 2011
	Glycopyrrolate <USA> : Launched in April 2011

<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)	Refractory rheumatic disease such as systemic lupus erythematosus, Systemic vasculitis, Polymyositis/dermatomyositis complex, Scleroderma, Mixed connective-tissue disease, Refractory rheumatic disease with vasculitis	Approval (February 2011)	Baxter (Germany)	In-house
		Nephrotic syndrome, when the disease fails to respond adequately to appropriate adrenocorticosteroid therapy	NDA submission (May 2011)		
Metronidazole 【Flagyl [®] 】	Antibacterial and antiprotozoal agent (Oral)	Infections caused by anaerobic bacteria, Amebiasis, Giardiasis	NDA submission (in preparation)	Sanofi-aventis (France)	In-house
Metronidazole 【Flagyl [®] 】	Antibacterial and antiprotozoal agent (Oral or Intravaginal)	Bacterial vaginosis	NDA submission (in preparation)	Sanofi-aventis (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 (Germany)	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)	GSK (UK)/Shionogi	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	To be determined	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