



Financial Results for the First Quarter of Fiscal Year 2015(Consolidated)

August 3, 2015

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

Listed Exchanges: Section I of Tokyo

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

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Scheduled date of quarterly securities report submission: August 7, 2015

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, 2015 to June 30, 2015

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

	Net sales		Operating income		Ordinary income		Profit attributable to owners of parent	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Three months ended June 30, 2015	63,863	1.8	12,533	55.7	14,602	7.1	9,657	(6.4)
Three months ended June 30, 2014	62,737	(6.7)	8,049	(33.6)	13,634	8.4	10,322	(4.6)

Note: Comprehensive income Three months ended June 30, 2015: 26,399 million yen (193.6%)
Three months ended June 30, 2014: 8,992 million yen (51.0%)

	Earnings per share	Earnings per share (diluted)
	Yen	Yen
Three months ended June 30, 2015	29.66	29.21
Three months ended June 30, 2014	30.82	30.81

(2) Consolidated financial position

	Total assets	Net assets	Shareholders' equity ratio
	Millions of yen	Millions of yen	%
As of June 30, 2015	614,958	496,159	79.9
As of March 31, 2015	602,900	478,883	78.7

Reference: Shareholders' equity As of June 30, 2015: 491,589 million yen As of March 31, 2015: 474,259 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, 2015	Yen —	Yen 24.0	Yen —	Yen 28.0	Yen 52.0
Year ending March 31, 2016	—				
Year ending March 31, 2016 (forecast)		28.0	—	28.0	56.0

Note: Revisions of the most recent dividend forecast: None

3. Consolidated financial forecast for the year ending March 31, 2016

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

	Net sales		Operating income		Ordinary income		Profit attributable to owners of parent		Earnings per share
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
Six month ending September 30, 2015	138,000	6.3	28,500	25.4	28,000	(10.9)	17,000	75.1	52.22
Year ending March 31, 2016	296,000	8.0	72,500	43.9	79,500	2.1	52,000	18.0	159.72

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

※ 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.: Yes
 - b) Changes in accounting policies other than a) above: None
 - c) Changes in accounting estimates: None
 - d) Restatements: None

Note: For details, please see "2. Summary Data (Notes) (3) Changes in Accounting Policies, Changes/Restatements of Accounting Estimates" on page 3 of the supplemental materials for the Financial Results for the First Quarter of Fiscal Year 2015 (Consolidated).

- (4) Number of shares issued (common stock)
- a) Number of shares issued (including treasury stock)

As of June 30, 2015:	351,136,165 shares
As of March 31, 2015:	351,136,165 shares
 - b) Number of treasury stock

As of June 30, 2015:	25,555,626 shares
As of March 31, 2015:	25,564,239 shares
 - c) Average number of shares issued during the period

Three months ended June 30, 2015:	325,580,930 shares
Three months ended June 30, 2014:	334,907,650 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 Results (3) Description of Consolidated Financial Forecast" on page 2 of the supplemental materials for the Financial Results for the First Quarter of Fiscal Year 2015 (Consolidated).

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1. Qualitative Information on Quarterly Financial Results

(1) Description of Consolidated Operating Results

In the first quarter ended June 30, 2015 (April 1, 2015 to June 30, 2015), net sales were ¥63,863 million, operating income was ¥12,533 million, ordinary income was ¥14,602 million and profit attributable to owners of parent was ¥9,657 million.

Regarding net sales, amid a severe environment due to factors including measures to promote the use of generics, overall domestic sales of prescription drugs increased 2.6 percent compared with the same period of the previous fiscal year, with firm sales of Crestor and Irbetan as well as steady expansion of sales of Cymbalta, for which a change in the agreement with Eli Lilly Japan K.K. took effect during the first quarter. Outside Japan, total overseas sales increased 19.3 percent compared with the same period of the previous fiscal year due to firm sales of Osphena, a treatment for post-menopausal vaginal atrophy, as well as the sale of rights to a product at U.S. subsidiary Shionogi Inc. On the other hand, due to the impact of the abovementioned change in the agreement for Cymbalta, contract manufacturing sales decreased 57.6 percent, but royalty income increased 6.9 percent with steady growth in global sales of the anti-HIV drugs Tivicay and Triumeq, and total net sales increased 1.8 percent compared with the same period of the previous fiscal year.

Regarding profit, gross profit increased 6.8 percent compared with the same period of the previous fiscal year, while selling, general and administrative expenses decreased 4.5 percent, due in part to the effect of more efficient deployment of sales-related expenses inside and outside Japan, and operating income increased 55.7 percent. Despite this increase in operating income and a positive effect from currency translation, the increase in ordinary income was 7.1 percent because of dividends received from ViiV Healthcare in the same period of the previous fiscal year. Profit attributable to owners of parent decreased 6.4 percent because of an increase in tax expenses compared with the same period of the previous fiscal year.

(2) Description of Consolidated Financial Position

As of June 30, 2015, total assets were ¥614,958 million, an increase of ¥12,058 million from the end of the previous fiscal year. Current assets decreased ¥8,422 million from the end of the previous fiscal year to ¥251,525 million, mainly due to decreases in accounts receivable—trade and inventories, collection of accounts receivable recorded in the previous fiscal year (dividends received from ViiV Healthcare) and other factors. Non-current assets increased ¥20,480 million to ¥363,432 million, mainly due to an increase in investment securities as a result of higher stock prices.

Total liabilities decreased ¥5,217 million from the end of the previous fiscal year to ¥118,799 million. Current liabilities decreased ¥9,157 million from the end of the previous fiscal year to ¥58,636 million, mainly due to the payment of income taxes payable. Non-current liabilities increased ¥3,940 million from the end of the previous fiscal year to ¥60,162 million.

Net assets increased ¥17,275 million from the end of the previous fiscal year to ¥496,159 million. Shareholders' equity increased ¥547 million to ¥447,797 million due to factors including an increase from profit attributable to owners of parent and a decrease due to cash dividends paid. Accumulated other comprehensive income increased ¥16,781 million from the end of the previous fiscal year to ¥43,791 million, mainly due to factors including an increase in valuation difference on available-for-sale securities due to higher stock prices and an increase in foreign currency translation adjustment due to the positive effect of currency translation. Subscription rights to shares decreased ¥14 million from the end of the previous fiscal year to ¥256 million and non-controlling interests decreased ¥39 million from the end of the previous fiscal year to ¥4,313 million.

(3) Description of Consolidated Financial Forecast

There are no revisions to the consolidated financial forecast announced on May 11, 2015.

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

Application of Accounting Standard for Business Combinations, etc.

Effective April 1, 2015, the Company has applied “Accounting Standard for Business Combinations” (ASBJ Statement No. 21, issued on September 13, 2013), “Accounting Standard for Consolidated Financial Statements” (ASBJ Statement No. 22, issued on September 13, 2013) and “Accounting Standard for Business Divestitures” (ASBJ Statement No. 7, issued on September 13, 2013). As a result, the method of recording the amount of difference caused by changes in the Company’s ownership interests in subsidiaries in the case of subsidiaries under ongoing control of the Company was changed to record it as capital surplus, and the method of recording acquisition-related costs was changed to recognition as expenses for the fiscal year in which they are incurred. Furthermore, for business combinations carried out on or after April 1, 2015, the accounting method was changed to reflect the reviewed acquisition cost allocation resulting from the finalization of the tentative accounting treatment in the quarterly consolidated financial statements for the quarterly period in which the business combination occurs. In addition, the presentation of net income has been changed, and the presentation of minority interests has been changed to non-controlling interests. The first quarter ended June 30, 2014 and fiscal year ended March 31, 2015 have been reclassified on the quarterly consolidated financial statements and consolidated financial statements to reflect the change in presentation.

The Accounting Standard for Business Combinations, etc. is applied from April 1, 2015 into the future in accordance with the transitional measures provided in Paragraph 58-2 (4) of the Accounting Standard for Business Combinations, Paragraph 44-5 (4) of the Accounting Standard for Consolidated Financial Statements and Paragraph 57-4 (4) of the Accounting Standard for Business Divestitures.

There is no effect on the quarterly consolidated financial statements for the first quarter ended June 30, 2015.

Application of Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for Consolidated Financial Statements

Effective April 1, 2015, the Company has applied “Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for Consolidated Financial Statements” (Practical Issues Task Force (“PITF”) No. 18, issued March 26, 2015). In accordance with the transitional measures provided in PITF No. 18, U.S. subsidiary Shionogi Inc. amortizes goodwill for which it has selected amortization treatment based on Financial Accounting Standards Board (“FASB”) Accounting Standards Codification, Topic 350, “Intangibles—Goodwill and Other” using the remaining amortization period of goodwill on the consolidated financial statements.

There is no effect on the quarterly consolidated financial statements.

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

	As of March 31, 2015	As of June 30, 2015
Assets		
Current assets		
Cash and deposits	50,784	51,863
Notes and accounts receivable-trade	70,584	65,888
Short-term investment securities	58,700	61,300
Merchandise and finished goods	18,943	19,577
Work in process	11,786	9,073
Raw materials and supplies	13,751	14,077
Other	35,425	29,773
Allowance for doubtful accounts	(28)	(28)
Total current assets	259,948	251,525
Non-current assets		
Property, plant and equipment	77,022	77,950
Intangible assets		
Goodwill	46,534	46,323
Other	33,794	33,593
Total intangible assets	80,328	79,916
Investments and other assets		
Investment securities	158,339	176,303
Other	27,323	29,324
Allowance for doubtful accounts	(62)	(62)
Total investments and other assets	185,600	205,565
Total non-current assets	342,951	363,432
Total assets	602,900	614,958
Liabilities		
Current liabilities		
Notes and accounts payable-trade	11,572	11,744
Income taxes payable	16,447	5,950
Provision for bonuses	8,315	10,833
Provision for sales returns	2,873	2,663
Other provision	45	—
Other	28,540	27,444
Total current liabilities	67,794	58,636
Non-current liabilities		
Bonds payable	20,094	20,089
Long-term loans payable	10,000	10,000
Net defined benefit liability	9,901	10,022
Other	16,226	20,050
Total non-current liabilities	56,222	60,162
Total liabilities	124,016	118,799

Millions of yen

	As of March 31, 2015	As of June 30, 2015
Net assets		
Shareholders' equity		
Capital stock	21,279	21,279
Capital surplus	20,227	20,227
Retained earnings	455,497	456,032
Treasury stock	(49,754)	(49,742)
Total shareholders' equity	447,249	447,797
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	28,675	37,759
Deferred gains or losses on hedges	—	(785)
Foreign currency translation adjustment	3,843	11,248
Remeasurements of defined benefit plans	(5,508)	(4,431)
Total accumulated other comprehensive income	27,010	43,791
Subscription rights to shares	270	256
Non-controlling interests	4,353	4,313
Total net assets	478,883	496,159
Total liabilities and net assets	602,900	614,958

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

Consolidated statements of income

Millions of yen

	Three month ended June 30, 2014	Three month ended June 30, 2015
Net sales	62,737	63,863
Cost of sales	19,836	18,048
Gross profit	42,901	45,815
Selling, general and administrative expenses	34,851	33,282
Operating income	8,049	12,533
Non-operating income		
Interest income	52	176
Dividends income	6,898	584
Foreign exchange gains	—	1,626
Other	60	99
Total non-operating income	7,011	2,486
Non-operating expenses		
Interest expenses	95	52
Contribution	123	170
Foreign exchange losses	532	—
Other	674	194
Total non-operating expenses	1,427	417
Ordinary income	13,634	14,602
Income before income taxes	13,634	14,602
Income taxes-current	4,239	5,071
Income taxes-deferred	(973)	(116)
Total income taxes	3,265	4,954
Profit	10,368	9,647
Profit (loss) attributable to non-controlling interests	45	(9)
Profit attributable to owners of parent	10,322	9,657

Consolidated statements of comprehensive income

Millions of yen

	Three month ended June 30, 2014	Three month ended June 30, 2015
Profit	10,368	9,647
Other comprehensive income		
Valuation difference on available-for-sale securities	(908)	9,084
Deferred gains or losses on hedges	—	(785)
Foreign currency translation adjustment	(786)	7,375
Remeasurements of defined benefit plans	319	1,077
Total other comprehensive income	(1,375)	16,751
Comprehensive income	8,992	26,399
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	9,115	26,438
Comprehensive income attributable to non-controlling interests	(122)	(39)

(3) Notes

Going concern assumption

None

Significant changes in shareholders' equity

None

Supplemental material Financial results for the 1st quarter of fiscal year 2015

August 3, 2015

Shionogi & Co., Ltd.

1. Sales by main merchandise and finished goods

(Billions of yen)

	FY2015 1H forecast	FY2015 forecast	FY2015 1Q actual	FY2014 1Q actual	change	Progress % vs. 2015 1H forecast
Prescription drugs	79.2	167.0	39.7	38.7	1.0	50.2
<i>change %</i>	2.9	3.5	2.6	(4.3)		
CRESTOR	21.3	44.4	10.6	10.8	(0.2)	49.9
IRBETAN Franchise	8.2	17.0	4.1	3.7	0.4	49.9
CYMBALTA	7.7	17.4	3.5	2.5	1.0	45.0
Total of 3 key products	37.2	78.8	18.2	17.1	1.1	48.9
OXYCONTIN Franchise	5.3	10.7	2.6	2.7	(0.1)	48.7
FINIBAX	1.9	3.8	1.0	0.9	0.1	51.3
DIFFERIN	1.9	3.8	0.9	0.9	(0.0)	45.2
PIRESPA	3.0	5.4	1.6	1.3	0.3	52.2
RAPIACTA	0.1	2.8	(0.0)	0.1	(0.1)	-
Total of 8 strategic products	49.4	105.3	24.2	22.9	1.3	48.9
FLOMOX	5.4	11.2	2.8	3.1	(0.3)	52.6
RINDERON	3.7	7.4	2.2	2.1	0.1	58.3
CLARITIN	1.6	4.2	0.8	0.9	(0.1)	48.2
FLUMARIN	2.2	4.0	1.1	1.1	0.0	51.3
Export/Overseas subsidiaries	14.8	30.4	7.2	6.0	1.2	48.0
<i>change %</i>	7.3	6.0	19.3	(28.7)		
Shionogi Inc.	9.0	17.4	4.4	2.8	1.6	48.6
Osphena	3.0	7.4	1.3	0.8	0.5	42.1
C&O	3.4	8.0	1.6	1.8	(0.2)	45.8
Contract manufacturing	3.7	7.6	1.5	3.5	(2.0)	40.6
<i>change %</i>	(45.8)	(51.3)	(57.6)	49.0		
OTC and quasi-drugs	2.5	4.7	1.2	1.1	0.1	49.9
<i>change %</i>	1.9	3.0	12.4	11.3		
Royalty income	36.5	83.3	13.5	12.7	0.8	37.1
<i>change %</i>	29.0	37.3	6.9	(9.8)		
CRESTOR *	32.0	74.5	11.2	11.8	(0.6)	39.5
HIV Franchise			1.4	-	1.4	
Others	1.3	3.0	0.7	0.7	(0.0)	56.2
<i>change %</i>	(13.1)	(2.2)	(1.1)	(29.9)		
Total	138.0	296.0	63.9	62.7	1.2	46.3
<i>change %</i>	6.3	8.0	1.8	(6.7)		

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

* FY2015 Forecast and Progress % vs. 2015 1H forecast are indicated in sum total.

2-1. Quarterly trend for FY2014 and FY2015 (Sales of main merchandise and finished goods)

Fiscal year ended March 31, 2015

(Billions of yen)

FY2014	FY2014 1Q actual	Y on Y change %	FY2014 2Q actual	Y on Y change %	FY2014 3Q actual	Y on Y change %	FY2014 4Q actual	Y on Y change %
Prescription drugs	38.7	(4.3)	38.3	(5.5)	43.8	(5.8)	40.6	(0.7)
CRESTOR	10.8	8.2	10.3	(3.2)	11.1	4.4	11.4	15.7
IRBETAN Franchise	3.7	30.4	3.8	(0.1)	3.9	(0.8)	3.7	12.7
CYMBALTA	2.5	(2.5)	3.0	10.9	3.0	(4.2)	2.4	(18.0)
Total of 3 key products	17.1	10.5	16.9	(0.4)	17.9	1.7	17.8	8.9
OXYCONTIN Franchise	2.7	(1.7)	2.6	(1.7)	2.9	(6.6)	2.1	(3.5)
FINIBAX	0.9	(22.0)	1.0	(7.8)	1.1	(18.4)	1.0	(11.9)
DIFFERIN	0.9	(5.8)	0.9	(5.1)	1.1	(13.9)	1.0	(19.7)
PIRESPA	1.3	2.9	1.3	19.4	1.4	3.3	1.4	23.7
RAPIACTA	0.1	(30.7)	(0.0)	-	1.1	172.9	1.4	(2.6)
Total of 8 strategic products	22.9	6.0	22.8	(0.1)	25.5	1.6	24.6	5.2
FLOMOX	3.1	(19.6)	2.7	(25.3)	3.7	(19.2)	3.1	(19.3)
RINDERON	2.1	(13.2)	2.1	(8.8)	2.1	(8.2)	1.7	(8.8)
CLARITIN	0.9	(7.8)	0.7	(16.7)	0.9	(21.0)	1.8	(6.4)
FLUMARIN	1.1	(21.0)	1.3	(6.3)	1.2	(21.8)	1.0	(10.9)
Export/Overseas subsidiaries	6.0	(28.7)	7.8	11.9	7.5	(37.0)	7.4	9.3
Shionogi Inc.	2.8	(47.0)	4.6	9.9	4.6	(44.9)	3.9	11.6
Osphena	0.8	-	0.9	833.0	1.4	227.2	1.5	158.1
C&O	1.8	37.6	1.5	(6.8)	1.7	31.4	1.9	15.8
Contract manufacturing	3.5	49.0	3.4	24.6	3.0	288.7	5.7	123.0
OTC and quasi-drugs	1.1	11.3	1.4	1.4	1.2	7.5	0.9	(15.0)
Royalty income	12.7	(9.8)	15.6	(19.3)	14.0	(22.4)	18.4	(4.4)
CRESTOR	11.8	(10.1)	12.6	(30.2)	10.7	(35.7)	12.3	(30.9)
HIV Franchise	-	-	-	-	1.3	-	4.5	-
Others	0.7	(29.9)	0.8	14.2	0.8	(11.1)	0.8	(36.8)
Total	62.7	(6.7)	67.1	(6.1)	70.4	(11.3)	73.8	2.9

Fiscal year ending March 31, 2016

FY2015	FY2015 1Q actual	Y on Y change %
Prescription drugs	39.7	2.6
CRESTOR	10.6	(1.8)
IRBETAN Franchise	4.1	9.4
CYMBALTA	3.5	36.2
Total of 3 key products	18.2	6.3
OXYCONTIN Franchise	2.6	(4.2)
FINIBAX	1.0	11.7
DIFFERIN	0.9	(2.6)
PIRESPA	1.6	24.1
RAPIACTA	(0.0)	-
Total of 8 strategic products	24.2	5.7
FLOMOX	2.8	(9.4)
RINDERON	2.2	4.3
CLARITIN	0.8	(11.1)
FLUMARIN	1.1	4.3
Export/Overseas subsidiaries	7.2	19.3
Shionogi Inc.	4.4	53.8
Osphena	1.3	66.4
C&O	1.6	(11.9)
Contract manufacturing	1.5	(57.6)
OTC and quasi-drugs	1.2	12.4
Royalty income	13.5	6.9
CRESTOR	11.2	(4.5)
HIV Franchise	1.4	-
Others	0.7	(1.1)
Total	63.9	1.8

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

2-2. Quarterly trend for FY2014 and FY2015 (Consolidated statements of income)

Fiscal year ended March 31, 2015

(Billions of yen)

FY2014	FY2014 1Q actual	Y on Y change %	FY2014 2Q actual	Y on Y change %	FY2014 3Q actual	Y on Y change %	FY2014 4Q actual	Y on Y change %
Net sales	62.7	(6.7)	67.1	(6.1)	70.4	(11.3)	73.7	2.9
Cost of sales	31.6 19.8	8.1	27.3 18.3	(3.1)	29.3 20.6	2.2	31.8 23.4	13.9
Gross profit	42.9	(12.3)	48.8	(7.2)	49.8	(15.9)	50.3	(1.5)
SG & A expenses	55.6 34.9	(5.3)	50.9 34.1	(7.1)	51.8 36.5	(5.0)	48.8 36.0	(5.2)
Selling & general expenses	23.1	(2.2)	22.7	(4.7)	24.1	(2.9)	22.7	(5.5)
R & D expenses	11.7	(10.7)	11.4	(11.5)	12.4	(8.7)	13.3	(4.7)
Operating income	12.8 8.0	(33.6)	21.9 14.7	(7.3)	19.0 13.3	(36.0)	19.4 14.3	9.3
Non-operating income & expenses	5.6		3.1		7.0		11.9	
Ordinary income	21.7 13.6	8.4	26.5 17.8	20.7	28.8 20.3	(10.4)	35.5 26.2	113.6
Extraordinary income & loss	-		0.2		4.3		(0.3)	
Income before income taxes	13.6		18.0		24.6		25.8	
Income taxes and profit attributable to non-controlling interests	3.3		18.6		8.0		8.0	
Profit attributable to owners of parent *	16.5 10.3	(4.6)	(0.9) (0.6)	(4.6)	23.5 16.6	9.8	24.1 17.8	299.3

Fiscal year ending March 31, 2016

FY2015	FY2015 1Q actual	Y on Y change %
Net sales	63.9	1.8
Cost of sales	28.3 18.0	(9.0)
Gross profit	45.8	6.8
SG & A expenses	52.1 33.3	(4.5)
Selling & general expenses	22.7	(1.9)
R & D expenses	10.6	(9.5)
Operating income	19.6 12.5	55.7
Non-operating income & expenses	2.1	
Ordinary income	22.9 14.6	7.1
Extraordinary income & loss	-	
Income before income taxes	14.6	
Income taxes and profit attributable to non-controlling interests	4.9	
Profit attributable to owners of parent *	15.1 9.7	(6.4)

* The Company changed "Profit attributable to owners of parent" from "Net income".

3. Pipeline (as of August 2015)

Areas	Code No. (Generic name) 【Product name】	Category (Administration)	Indication	Stage	Origin	Development
Infectious disease	S-649266	Cephem antibiotic (injection)	Severe gram-negative infections	Global: Phase II	In-house	In-house
	S-033188	Anti-influenza virus infection (oral)	Influenza virus infection	Japan: Phase I	In-house	In-house
Pain/CNS	LY248686 (duloxetine hydrochloride) 【Cymbalta®】	SNRI (serotonin & noradrenaline reuptake inhibitor) (oral)	Pain associated with chronic low back pain	Japan: NDA submission (Dec. 2014)	Eli Lilly (USA)	Shionogi/Eli Lilly Japan K.K.
	S-877503 (guanfacine hydrochloride)	Alpha-2A-adrenergic receptor agonist (oral)	ADHD	Japan: NDA submission (in preparation)	Shire (Ireland)	Shionogi/Shire
	LY248686 (duloxetine hydrochloride) 【Cymbalta®】	SNRI (serotonin & noradrenaline reuptake inhibitor) (oral)	Pain associated with osteoarthritis	Japan: NDA submission (in preparation)	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-877489 (lisdexamfetamine)	DA and NE reuptake inhibitor/releaser of DA, NE (oral)	ADHD	Japan: Phase III	Shire (Ireland)	Shionogi/Shire
	S-120083	Analgesic agent for inflammatory pain (oral)	Inflammatory pain	Japan: Phase I	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-010887	Analgesic agent for neuropathic pain (oral)	Neuropathic pain	Japan: Phase I	In-house	In-house
	S-718632 (hydrocodone)	Abuse-deterrent extended release hydrocodone (oral)	Chronic pain	USA: Phase I	Egalet Limited (UK)	Shionogi/Egalet Corporation (USA)
	S-117957	Agent for insomnia (oral)	Insomnia	USA: Phase I	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
Metabolic disorder	S-237648	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
Frontier	S-888711 (lusutrombopag)	Small molecule TPO receptor agonist (oral)	Thrombocytopenia	Japan: NDA submission (Dec. 2014) Global: Phase III	In-house	In-house
	S-588410	Cancer peptide vaccine (injection)	Esophageal cancer	Japan: Phase III	OncoTherapy Science, Inc. (Japan)	In-house
	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-588410	Cancer peptide vaccine (injection)	Bladder cancer	Japan, Europe: Phase II	OncoTherapy Science, Inc. (Japan)	In-house
	S-525606	Sublingual tablet of Japanese cedar allergen extracts for immunotherapy	Allergic rhinitis caused by Japanese cedar allergen	Japan: Phase II	Stallergenes SA (France)	In-house
	S-646240	Peptide vaccine (injection)	Age-related macular degeneration	Japan: Phase IIa	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-222611	HER2/EGFR dual inhibitor (oral)	Malignant tumor	Europe: Phase I/II	In-house	In-house

<Out-Licensing Activity>

Code No. (Generic name)	Category (Administration)	Indication	Stage	Origin	Development
S/GSK1265744 LAP* (cabotegravir)	Integrase inhibitor (injection)	For the treatment and prevention for 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 IIa	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)	Pain associated with fibromyalgia	Japan: Approval (May 2015)	Eli Lilly (USA)	Shionogi/Eli Lilly Japan K.K.

<Requested for development by academy>

Generic name 【Product name】	Category (Administration)	Indication	Stage	Origin	Development
Cyclophosphamide hydrate 【Endoxan [®] 】	Alkylating agents (injection)	Malignant lymphoma (Hodgkin's disease, lymphosarcomatosis, reticulosarcoma) (Strike-through: scheduled for removal)	Japan: Approval (Jun. 2015)	Baxter (Germany)	In-house
Prednisolone 【Predonine [®] 】	Synthetic corticosteroid (oral)	Malignant lymphoma (lymphosarcomatosis, reticulosarcoma, Hodgkin's disease, cutaneous reticulosis, mycosis fungoides) (Strike-through: scheduled for removal)	Japan: Approval (Jun. 2015)	In-house	In-house

Since May 2015

Change of phase	LY248686: Chronic low back pain → Pain associated with chronic low back pain
	LY248686: Change of Indication, Stage: Osteoarthritis → Pain associated with osteoarthritis, Japan: Phase III → Japan: NDA submission (in preparation)
	S-525606: Japan: Phase I → Japan: Phase II
	S/GSK1265744 LAP (cabotegravir): HIV infection → For the treatment and prevention for HIV infection
	Duloxetine hydrochloride【Cymbalta [®] 】: Change of Indication, Stage: Fibromyalgia → Pain associated with fibromyalgia, Japan: NDA submission (Jun. 2014) → Japan: Approval (May 2015)
	Cyclophosphamide hydrate【Endoxan [®] 】: Japan: NDA submission (Feb. 2015) → Japan: Approval (Jun. 2015)
Compound erased from the list	Prednisolone【Predonine [®] 】: Japan: NDA submission (Feb. 2015) → Japan: Approval (Jun. 2015)
	S-556971: Rights return to Kotobuki Pharmaceutical Co., Ltd.
	S-524101: Approval
	Dolutegravir/abacavir/lamivudine: Approval