



# Financial Results for the First Quarter of Fiscal Year 2016(Consolidated)

August 1, 2016

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 10, 2016

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, 2016 to June 30, 2016

(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, 2016	73,158	14.6	18,036	43.9	16,685	14.3	12,536	29.8
Three months ended June 30, 2015	63,863	1.8	12,533	55.7	14,602	7.1	9,657	(6.4)

Note: Comprehensive income Three months ended June 30, 2016: (6,375) million yen (-%)  
Three months ended June 30, 2015: 26,399 million yen (193.6%)

	Earnings per share	Earnings per share (diluted)
	Yen	Yen
Three months ended June 30, 2016	38.50	37.91
Three months ended June 30, 2015	29.66	29.21

(2) Consolidated financial position

	Total assets	Net assets	Shareholders' equity ratio
	Millions of yen	Millions of yen	%
As of June 30, 2016	605,389	496,427	81.3
As of March 31, 2016	639,638	513,877	79.6

Reference: Shareholders' equity As of June 30, 2016: 492,303 million yen As of March 31, 2016: 509,439 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
	Yen	Yen	Yen	Yen	Yen
Year ended March 31, 2016	—	28.00	—	34.00	62.00
Year ending March 31, 2017	—				
Year ending March 31, 2017 (forecast)		34.00	—	34.00	68.00

Note: Revisions of the most recent dividend forecast: None

## 3. Consolidated financial forecast for the year ending March 31, 2017

(% 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 months ending September 30, 2016	145,000	4.9	33,000	(2.8)	33,000	(5.1)	21,000	(1.8)	64.50
Year ending March 31, 2017	318,000	2.6	91,500	0.1	101,500	0.6	71,000	6.5	218.07

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.: 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, 2016:	351,136,165 shares
As of March 31, 2016:	351,136,165 shares
  - b) Number of treasury stock

As of June 30, 2016:	25,543,706 shares
As of March 31, 2016:	25,559,022 shares
  - c) Average number of shares issued during the period

Three months ended June 30, 2016:	325,592,633 shares
Three months ended June 30, 2015:	325,580,930 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 2016 (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, 2016 (April 1, 2016 to June 30, 2016), net sales were ¥73,158 million, operating income was ¥18,036 million, ordinary income was ¥16,685 million, and profit attributable to owners of parent was ¥12,536 million.

Overall domestic sales of prescription drugs increased 0.5 percent compared with the same period of the previous fiscal year, as sales of the three strategic products Crestor, Cymbalta and Irbetan expanded steadily in the domestic prescription drug market, more than offsetting the decline in sales of existing products. Exports and overseas subsidiary sales decreased 8.1 percent due to the impact from the sale of rights to a product at U.S. subsidiary Shionogi Inc. in the previous fiscal year. On the other hand, contract manufacturing sales increased 71.9 percent with the expansion in contract manufacturing of the dolutegravir active pharmaceutical ingredient (API), and royalty income increased 60.8 percent due to steady growth in global sales of anti-HIV drugs Tivicay and Triumeq. As a result, overall net sales increased 14.6 percent compared with the same period of the previous fiscal year.

Gross profit increased 16.4 percent compared with the same period of the previous fiscal year. Selling, general and administrative expenses increased 6.1 percent, mainly due to the progress of research and development activities, but operating income increased 43.9 percent, reflecting the increase in gross profit. Despite the increase in operating income, ordinary income increased only 14.3 percent due to the effect of currency translation. Profit attributable to owners of parent increased 29.8 percent.

### (2) Description of Consolidated Financial Position

As of June 30, 2016, total assets were ¥605,389 million, a decrease of ¥34,249 million from the end of the previous fiscal year. Current assets decreased ¥12,598 million to ¥303,012 million due to redemption of short-term investment securities for surplus fund management and collection of accounts receivable recorded in the previous fiscal year (dividends received from ViiV Healthcare, included in "Other" in current assets). Non-current assets decreased ¥12,598 million to ¥303,012 million, largely because of a decrease in investment securities reflecting lower stock prices and the effect of currency translation and a decrease in foreign currency-denominated intangible assets due to the effect of currency translation.

Total liabilities decreased ¥16,799 million from the end of the previous fiscal year to ¥108,961 million. Current liabilities decreased ¥15,609 million to ¥56,372 million, mainly because of a decrease in income taxes payable. Non-current liabilities decreased ¥1,190 million to ¥52,588 million.

Net assets decreased ¥17,449 million from the end of the previous fiscal year to ¥496,427 million. Shareholders' equity increased ¥1,489 million to ¥497,183 million as a result of factors including an increase from profit attributable to owners of parent and a decrease due to cash dividends paid. Accumulated other comprehensive income decreased ¥18,625 million to a loss of ¥4,880 million, mainly due to a decrease in valuation difference on available-for-sale securities due to lower stock prices and a decrease in foreign currency translation adjustment due to the effect of currency translation. Subscription rights to shares decreased ¥26 million to ¥325 million and non-controlling interests decreased ¥286 million to ¥3,799 million.

### (3) Description of Consolidated Financial Forecast

There are no revisions to the consolidated financial forecast announced on May 11, 2016.

## 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

None

(4) Additional Information

### Application of Implementation Guidance on Recoverability of Deferred Tax Assets

The Company is applying the Implementation Guidance on Recoverability of Deferred Tax Assets (Accounting Standards Board of Japan, Guidance No. 26, issued on March 28, 2016) from the start of the fiscal year beginning on April 1, 2016.

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

	As of March 31, 2016	As of June 30, 2016
<b>Assets</b>		
Current assets		
Cash and deposits	80,230	86,136
Notes and accounts receivable-trade	65,207	65,570
Short-term investment securities	97,200	79,387
Merchandise and finished goods	21,263	23,304
Work in process	8,839	7,368
Raw materials and supplies	12,080	12,796
Other	30,834	28,490
Allowance for doubtful accounts	(45)	(43)
Total current assets	315,611	303,012
Non-current assets		
Property, plant and equipment	78,673	78,395
Intangible assets		
Goodwill	41,208	37,174
Other	30,417	29,359
Total intangible assets	71,626	66,534
Investments and other assets		
Investment securities	146,451	130,249
Other	27,319	27,240
Allowance for doubtful accounts	(44)	(42)
Total investments and other assets	173,727	157,446
Total non-current assets	324,027	302,377
Total assets	639,638	605,389
<b>Liabilities</b>		
Current liabilities		
Notes and accounts payable-trade	11,050	11,909
Income taxes payable	20,294	5,513
Provision for bonuses	10,118	12,756
Provision for sales returns	2,414	2,005
Other provision	88	—
Other	28,016	24,188
Total current liabilities	71,982	56,372
Non-current liabilities		
Bonds payable	20,074	20,069
Long-term loans payable	10,000	10,000
Net defined benefit liability	9,447	9,588
Other	14,256	12,930
Total non-current liabilities	53,778	52,588
Total liabilities	125,761	108,961

Millions of yen

	As of March 31, 2016	As of June 30, 2016
Net assets		
Shareholders' equity		
Capital stock	21,279	21,279
Capital surplus	20,227	20,227
Retained earnings	503,946	505,408
Treasury stock	(49,759)	(49,732)
Total shareholders' equity	495,693	497,183
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	26,748	20,879
Deferred gains or losses on hedges	—	2,710
Foreign currency translation adjustment	(7,333)	(23,466)
Remeasurements of defined benefit plans	(5,669)	(5,003)
Total accumulated other comprehensive income	13,745	(4,880)
Subscription rights to shares	352	325
Non-controlling interests	4,085	3,799
Total net assets	513,877	496,427
Total liabilities and net assets	639,638	605,389

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

## Consolidated statements of income

*Millions of yen*

	Three months ended June 30, 2015	Three months ended June 30, 2016
Net sales	63,863	73,158
Cost of sales	18,048	19,813
Gross profit	45,815	53,345
Selling, general and administrative expenses	33,282	35,308
Operating income	12,533	18,036
Non-operating income		
Interest income	176	172
Dividends income	584	595
Foreign exchange gains	1,626	—
Other	99	155
Total non-operating income	2,486	923
Non-operating expenses		
Interest expenses	52	48
Contribution	170	225
Foreign exchange losses	—	1,682
Other	194	317
Total non-operating expenses	417	2,274
Ordinary income	14,602	16,685
Income before income taxes	14,602	16,685
Income taxes-current	5,071	4,767
Income taxes-deferred	(116)	(573)
Total income taxes	4,954	4,193
Profit	9,647	12,491
Loss attributable to non-controlling interests	(9)	(44)
Profit attributable to owners of parent	9,657	12,536



## Consolidated statements of comprehensive income

*Millions of yen*

	Three months ended June 30, 2015	Three months ended June 30, 2016
Profit	9,647	12,491
Other comprehensive income		
Valuation difference on available-for-sale securities	9,084	(5,868)
Deferred gains or losses on hedges	(785)	2,710
Foreign currency translation adjustment	7,375	(16,375)
Remeasurements of defined benefit plans	1,077	665
Total other comprehensive income	16,751	(18,867)
Comprehensive income	26,399	(6,375)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	26,438	(6,089)
Comprehensive income attributable to non-controlling interests	(39)	(286)

(3) Notes

Going concern assumption

None

Significant changes in shareholders' equity

None

# Supplemental material Financial results for the 1st quarter of fiscal year 2016

August 1, 2016

Shionogi & Co., Ltd.

## 1. Sales by main merchandise and finished goods

(Billions of yen)

	FY2016 1H forecast	FY2016 forecast	FY2016 1Q actual	FY2015 1Q actual	change	Progress % vs. 2016 1H forecast
Prescription drugs	76.3	158.2	39.9	39.7	0.2	52.3
<i>change %</i>	(2.7)	(2.4)	0.5	2.6		
CRESTOR	20.9	41.5	11.4	10.6	0.8	54.7
CYMBALTA	8.9	19.3	4.4	3.5	0.9	49.6
IRBETAN Franchise	7.4	15.1	4.2	4.1	0.1	56.7
<b>Total of 3 key products</b>	<b>37.2</b>	<b>75.9</b>	<b>20.0</b>	<b>18.2</b>	<b>1.8</b>	<b>53.9</b>
OXYCONTIN Franchise	5.5	10.5	2.6	2.6	(0.0)	46.8
FINIBAX	2.0	3.9	0.9	1.0	(0.1)	46.0
PIRESPA	3.3	6.3	1.6	1.6	0.0	49.6
RAPIACTA	0.1	2.3	0.1	(0.0)	0.1	124.2
<b>Total of 7 strategic products*</b>	<b>48.1</b>	<b>99.0</b>	<b>25.3</b>	<b>23.3</b>	<b>2.0</b>	<b>52.6</b>
FLOMOX	4.5	9.0	2.2	2.8	(0.6)	48.9
RINDERON	3.7	7.4	2.0	2.2	(0.2)	53.5
CLARITIN	1.5	3.5	0.8	0.8	0.0	54.1
FLUMARIN	2.1	3.7	0.9	1.1	(0.2)	45.8
Export/Overseas subsidiaries	12.4	24.7	6.5	7.2	(0.7)	52.8
<i>change %</i>	(16.0)	(16.8)	(8.1)	19.3		
Shionogi Inc.	6.0	12.4	3.6	4.4	(0.8)	60.4
Osphena	2.6	5.3	1.2	1.3	(0.1)	46.4
C&O	3.1	6.4	1.5	1.6	(0.1)	48.3
Contract manufacturing	5.3	10.9	2.6	1.5	1.1	48.7
<i>change %</i>	44.2	28.8	71.9	(57.6)		
OTC and quasi-drugs	3.5	7.0	1.7	1.2	0.5	48.6
<i>change %</i>	36.6	42.9	37.0	12.4		
Royalty income	46.3	114.9	21.8	13.5	8.3	47.0
<i>change %</i>	23.7	12.8	60.8	6.9		
CRESTOR	16.5	33.0	10.5	11.2	(0.7)	63.9
HIV Franchise	26.0	62.0	10.2	1.4	8.8	39.3
Others	1.2	2.4	0.6	0.7	(0.1)	52.8
<i>change %</i>	(17.1)	(20.8)	(15.7)	(1.1)		
<b>Total</b>	<b>145.0</b>	<b>318.0</b>	<b>73.2</b>	<b>63.9</b>	<b>9.3</b>	<b>50.5</b>
<i>change %</i>	4.9	2.6	14.6	1.8		

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

\* Strategic products were changed from eight to seven because Differin sales right was returned in July 2016.

## 2-1. Quarterly trend for FY2015 and FY2016 (Sales of main merchandise and finished goods)

Fiscal year ended March 31, 2016

(Billions of yen)

FY2015	FY2015 1Q actual	Y on Y change %	FY2015 2Q actual	Y on Y change %	FY2015 3Q actual	Y on Y change %	FY2015 4Q actual	Y on Y change %
Prescription drugs	39.7	2.6	38.7	1.2	45.0	2.7	38.7	(4.7)
CRESTOR	10.6	(1.8)	9.8	(4.4)	13.2	18.8	10.1	(11.5)
CYMBALTA	3.5	36.2	3.7	27.5	4.3	44.0	3.7	49.6
IRBETAN Franchise	4.1	9.4	4.2	11.6	3.7	(4.0)	3.6	(2.2)
<b>Total of 3 key products</b>	<b>18.2</b>	<b>6.3</b>	<b>17.7</b>	<b>4.7</b>	<b>21.2</b>	<b>18.1</b>	<b>17.5</b>	<b>(0.9)</b>
OXYCONTIN Franchise	2.6	(4.2)	2.6	(0.5)	2.8	(2.7)	2.0	(1.4)
FINIBAX	1.0	11.7	1.1	6.6	0.9	(17.5)	0.8	(18.1)
DIFFERIN	0.9	(2.6)	0.7	(24.0)	0.7	(33.3)	0.7	(32.0)
PIRESPA	1.6	24.1	1.2	(11.2)	1.9	35.1	1.4	(0.4)
RAPIACTA	(0.0)	-	(0.0)	-	0.5	(58.3)	1.6	4.3
<b>Total of 8 strategic products</b>	<b>24.2</b>	<b>5.7</b>	<b>23.3</b>	<b>2.1</b>	<b>28.0</b>	<b>9.7</b>	<b>23.9</b>	<b>(2.6)</b>
FLOMOX	2.8	(9.4)	2.9	9.9	3.1	(17.3)	2.4	(19.3)
RINDERON	2.2	4.3	2.1	0.5	2.1	1.4	1.7	(4.2)
CLARITIN	0.8	(11.1)	0.8	15.9	1.0	13.3	1.7	(2.2)
FLUMARIN	1.1	4.3	1.2	(5.3)	1.0	(14.1)	0.8	(15.9)
Export/Overseas subsidiaries	7.2	19.3	7.6	(2.9)	8.0	6.5	7.0	(5.0)
Shionogi Inc.	4.4	53.8	4.0	(11.6)	4.8	5.1	3.4	(13.8)
Osphena	1.3	66.4	1.3	41.8	1.2	(16.8)	1.0	(27.7)
C&O	1.6	(11.9)	1.8	18.2	1.3	(24.1)	2.0	7.0
Contract manufacturing	1.5	(57.6)	2.2	(33.7)	1.6	(45.4)	3.1	(46.0)
OTC and quasi-drugs	1.2	12.4	1.3	(1.4)	1.2	5.2	1.1	13.3
Royalty income	13.5	6.9	23.9	53.0	30.9	120.0	33.5	82.6
CRESTOR	11.2	(4.5)	12.4	(1.6)	12.0	12.0	11.9	(3.0)
HIV Franchise	1.4	-	10.0	-	13.7	945.2	15.5	241.5
Others	0.7	(1.1)	0.7	(10.5)	0.9	1.9	0.7	0.7
<b>Total</b>	<b>63.9</b>	<b>1.8</b>	<b>74.4</b>	<b>10.9</b>	<b>87.6</b>	<b>24.4</b>	<b>84.0</b>	<b>14.0</b>

Fiscal year ending March 31, 2017

FY2016	FY2016 1Q actual	Y on Y change %
Prescription drugs	39.9	0.5
CRESTOR	11.4	7.5
CYMBALTA	4.4	27.0
IRBETAN Franchise	4.2	3.1
<b>Total of 3 key products</b>	<b>20.0</b>	<b>10.2</b>
OXYCONTIN Franchise	2.6	(0.1)
FINIBAX	0.9	(5.6)
PIRESPA	1.6	3.9
RAPIACTA	0.1	-
<b>Total of 7 strategic products *</b>	<b>25.3</b>	<b>8.5</b>
FLOMOX	2.2	(22.9)
RINDERON	2.0	(8.3)
CLARITIN	0.8	5.9
FLUMARIN	0.9	(16.3)
Export/Overseas subsidiaries	6.5	(8.1)
Shionogi Inc.	3.6	(17.4)
Osphena	1.2	(5.4)
C&O	1.5	(4.8)
Contract manufacturing	2.6	71.9
OTC and quasi-drugs	1.7	37.0
Royalty income	21.8	60.8
CRESTOR	10.5	(6.2)
HIV Franchise	10.2	637.5
Others	0.6	(15.7)
<b>Total</b>	<b>73.2</b>	<b>14.6</b>

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

\* Strategic products were changed from eight to seven because Differin sales right was returned in July 2016.

## 2-2. Quarterly trend for FY2015 and FY2016 (Consolidated statements of income)

Fiscal year ended March 31, 2016

(Billions of yen)

FY2015	FY2015 1Q actual	Y on Y change %	FY2015 2Q actual	Y on Y change %	FY2015 3Q actual	Y on Y change %	FY2015 4Q actual	Y on Y change %
<b>Net sales</b>	<b>63.9</b>	<b>1.8</b>	<b>74.4</b>	<b>10.9</b>	<b>87.6</b>	<b>24.4</b>	<b>84.0</b>	<b>14.0</b>
Cost of sales	28.3 18.0	(9.0)	24.7 18.4	0.5	21.4 18.7	(9.2)	23.3 19.6	(16.4)
Gross profit	45.8	6.8	56.0	14.8	68.9	38.4	64.5	28.2
SG & A expenses	52.1 33.3	(4.5)	46.5 34.6	1.4	42.7 37.4	2.6	45.8 38.5	7.0
Selling & general expenses	22.7	(1.9)	23.4	3.2	23.9	(0.5)	24.0	5.7
R & D expenses	10.6	(9.5)	11.2	(2.1)	13.5	8.6	14.5	9.1
<b>Operating income</b>	19.6 <b>12.5</b>	<b>55.7</b>	28.8 <b>21.4</b>	<b>45.9</b>	36.0 <b>31.5</b>	<b>136.2</b>	30.9 <b>25.9</b>	<b>81.5</b>
Non-operating income & expenses	2.1		(1.2)		0.2		8.4	
<b>Ordinary income</b>	22.9 <b>14.6</b>	<b>7.1</b>	27.1 <b>20.2</b>	<b>13.5</b>	36.2 <b>31.8</b>	<b>56.4</b>	40.8 <b>34.3</b>	<b>31.2</b>
Extraordinary income & loss	-		(0.1)		(1.1)		(2.1)	
Income before income taxes	14.6		20.0		30.6		32.2	
Income taxes and profit attributable to non-controlling interests	4.9		8.3		10.3		7.2	
<b>Profit attributable to owners of parent</b>	15.1 <b>9.7</b>	<b>(6.4)</b>	15.8 <b>11.7</b>	-	23.1 <b>20.3</b>	<b>22.5</b>	29.8 <b>25.0</b>	<b>40.6</b>

Fiscal year ending March 31, 2017

FY2016	FY2016 1Q actual	Y on Y change %
<b>Net sales</b>	<b>73.2</b>	<b>14.6</b>
Cost of sales	27.1 19.8	9.8
Gross profit	53.3	16.4
SG & A expenses	48.3 35.3	6.1
Selling & general expenses	22.7	0.2
R & D expenses	12.6	18.7
<b>Operating income</b>	24.7 <b>18.0</b>	<b>43.9</b>
Non-operating income & expenses	(1.4)	
<b>Ordinary income</b>	22.8 <b>16.7</b>	<b>14.3</b>
Extraordinary income & loss	-	
Income before income taxes	16.7	
Income taxes and profit attributable to non-controlling interests	4.1	
<b>Profit attributable to owners of parent</b>	17.1 <b>12.5</b>	<b>29.8</b>

### 3. Pipeline (as of August 2016)

Areas	Code No. (Generic name) 【Product name】	Category (Administration)	Indication	Stage	Origin	Development
Infectious disease	S-649266	Cephem antibiotic (injection)	Multidrug-resistant Gram-negative bacterial infections	Global: Phase II & III	In-house	In-house
	S-033188	Anti-influenza virus infection (oral)	Influenza virus infection	Japan: Phase II US: Phase I	In-house	Shionogi/Roche (Switzerland)
Pain/CNS	S-877503 (guanfacine hydrochloride)	Alpha-2A-adrenergic receptor agonist (oral)	ADHD (pediatric)	Japan: NDA submission (Jan. 2016)	Shire (Ireland)	Shionogi/Shire
	LY248686 (duloxetine hydrochloride) 【Cymbalta®】	SNRI (serotonin & noradrenaline reuptake inhibitor) (oral)	Pain associated with osteoarthritis	Japan: NDA submission (Feb. 2016)	Eli Lilly (USA)	Shionogi/Eli Lilly Japan K.K.
	S-297995 (naldemedine tosilate)	Peripheral opioid receptor antagonist (oral)	Opioid-induced constipation	US, Japan: NDA submission (Mar. 2016)	In-house	In-house
	S-877489 (lisdexamfetamine)	DA and NE reuptake inhibitor/releaser of DA, NE (oral)	ADHD (pediatric)	Japan: Phase III	Shire (Ireland)	Shionogi/Shire
	S-877503 (guanfacine hydrochloride)	Alpha-2A-adrenergic receptor agonist (oral)	ADHD (adult)	Japan: Phase III	Shire (Ireland)	Shionogi/Shire
	S-120083	Analgesic agent for inflammatory pain (oral)	Inflammatory pain	Japan: Phase I US: 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-117957	Agent for insomnia (oral)	Insomnia	USA: Phase I	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-600918	Analgesic agent for neuropathic pain (oral)	Neuropathic pain	Japan: Phase I	In-house	In-house
Metabolic disorder	S-237648	Neuropeptide Y Y5 receptor antagonist (oral)	Obesity	Japan: Phase II USA: Phase I	In-house	In-house
	S-707106	Insulin sensitizer (oral)	Type 2 diabetes	USA: Phase IIa	In-house	In-house
Frontier	S-888711 (lusutrombopag) 【Japan: Mulpleta®】	Thrombopoietin (TPO) receptor agonist (oral)	Thrombocytopenia associated with chronic liver disease	Japan: Approval (Sep. 2015) Global: Phase III	In-house	In-house
	Ospemifene 【USA: Osphena®】 【Europe: Senshio®】	Selective estrogen receptor modulator (oral)	Vaginal dryness associated with postmenopausal VVA	USA: Phase III	QuatRx (USA)	In-house
	S-524101 【Actair®】	Sublingual tablet of house-dust mite allergen extracts for immunotherapy (sublingual)	Pediatric patients with perennial allergic rhinitis caused by HDM	Japan: Phase III	Stallergenes (France)	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 (sublingual)	Allergic rhinitis caused by Japanese cedar allergen	Japan: Phase II	Stallergenes (France)	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	Global: Phase II/III	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

Since May 2016

Compound added to the list	S-600918: Japan: Phase I
Compound erased from the list	LY248686 (pain associated with chronic low back pain) : Japan: Approval (Mar. 2016)
Change of phase	S-237648: Japan: Phase II → Japan: Phase II, US: Phase I